6802905EN

Reference Guide

VITROS® 5600 Integrated System

Ortho Clinical Diagnostics
a Johnson & Johnson company

VITROS®

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IMPORTANT

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Revision History: Reference Guide

Title	Location	Change
All	Throughout	Edited text, capitalization, and punctuation for clarity.
Sample Programming Overview	• On the system: Sample Programming Overview (page 9-1) • On the CD-ROM: Chapter 9, Sample Programming Overview, "Sample Programming Screen"	Updated the note to state "When a restricted assay is processed, Sample Indices are automatically enabled and cannot be overridden."
Manually Program Sample IDs with Tray and Cup Assignments	• On the system: Manually Program Sample IDs with Tray and Cup Assignments (page 9-15) Manually Program Sample IDs with Tray and Cup Assignments • On the CD-ROM: Chapter 9, Sample Programming Overview, "Sample Programming Procedures"	Clarified information in this procedure by adding notes about keeping samples in their tray positions once the sample bar codes are read, unique Sample IDs, tray IDs matching the bar code number, and placing samples in the STAT lane for STAT processing.

(Continued)

Title	Location	Change
Sample Programming Overview, Sample Program IDs, Manual Batch Processing, and Edit Sample Programs	• On the system: Sample Programming Overview (page 9-1) and Sample Programming IDs (page 9-7) • On the system: Manual Batch Processing (page 9-14) and Edit Sample Programs (page 9-16) • On the CD-ROM: Chapter 9, Sample Programming Overview, "Sample Programming Methods" and "Sample Program IDs" • On the CD-ROM: Chapter 9, Sample Programming Overview, "Sample Programming Procedures."	Added this Important statement: Ortho Clinical Diagnostics (OCD) does not recommend the use of confidential, patient-identifying information such as patient name or government identifier as part of the sample ID. OCD occasionally requests files from your system that contain sample IDs to assist in troubleshooting or performing routine maintenance of the system. Avoid the use of patient-identifying information as part of the sample ID.
Reagents	• On the system: Reagents (page 8-3) • On the CD-ROM: Chapter 8, Supply Categories, "Reagents"	Updated the image of the MicroSlide Cartridge.
Dilutions	• On the system: Dilutions (page 9-10) • On the CD-ROM: Chapter 9, Sample Programming Overview, "Dilutions"	• Under Manual Dilution: Removed the note that stated "When you touch Manual Dilution on the Sample Programming screen, Sample Indices may become enabled for that sample." • Edited this sentence to state "With manual dilution, you must enter the manual dilution factor on the Sample Programming screen, and the Sample Indices check will be disabled for the sample."
Sample Indices Flags and Sample Indices Codes	• On the system: Sample Indices Flags (page 13-18) and Sample Indices Codes (page 13-19) • On the CD-ROM: Chapter 13, Flags and Codes, "Sample Indices Flags" and "Sample Indices Codes"	Updated the ES code to state "The system was unable to evaluate the SI index, possibly due to Setting a Manual Dilution Factor for a restricted assay."
Daily Maintenance	• On the system: Daily Maintenance (page 16-15) • On the CD-ROM: Chapter 16, Diagnostics Overview, "Periodic Maintenance"	Added the task Clean Cap Retainers to the Daily Maintenance list.

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Title	Location	Change
Weekly Maintenance	• On the system: Weekly Maintenance (page 16-17) • On the CD-ROM: Chapter 16, Diagnostics Overview, "Periodic Maintenance"	Removed the task Clean Cap Retainers from the Weekly Maintenance list.
How to Clean the System	• On the system: How to Clean the System (page 3-10) • On the CD-ROM: Chapter 3, Safeguards and Precautions Overview, "How to Clean the System"	Removed the Caution that stated "Wipe all components thoroughly with warm distilled or deionized water to remove all traces of isopropyl alcohol."
Configure Assays	• On the system: Configure Assays (page 17-3) • On the CD-ROM: Chapter 17, Options and Configuration Overview, "Configure Assays"	• Updated the note to state "For restricted assays, you cannot change the values of the three thresholds to be above the default limit, as defined on the ADD." • Added a new note under Sample Indices that states "You cannot disable the Threshold Limits for restricted assays."
Configure System	• On the system: Configure System (page 17-21) • On the CD-ROM: Chapter 17, Options and Configuration Overview, "Configure System"	Updated the note to state "For restricted assays, the system overrides the global setting for Sample Indices in Options & Configuration and enables Sample Indices."
Configure Subsystems	• On the system: Configure Subsystems (page 17-25) • On the CD-ROM: Chapter 17, Options and Configuration Overview, "Configure Subsystems"	Updated the note in MicroSensor Processing to state"Restricted assays cannot be processed if the Microsensor subsystem is disabled."

Note: Refer to V-Docs for Revision Histories of previous versions.

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Chapter 1 Introduction Overview

This introduction summarizes some of the main features of the VITROS ®5600 Integrated System. It includes the following information:

Intended Use

For *in vitro* diagnostic use only. The VITROS 5600 Integrated System is intended for use in the *in vitro* quantitative, semi-quantitative, and qualitative measurement of a variety of analytes of clinical interest, using VITROS Chemistry Products MicroSlides, VITROS Chemistry Products MicroTip Reagents and VITROS Immunodiagnostic Products Reagents.

Installation and Site Specifications

Although trained service personnel uncrate and install the VITROS 5600 Integrated System at the laboratory site, the site needs to be prepared according to specifications.

This section describes general requirements for installing the VITROS 5600 Integrated System at your laboratory, including physical and environmental requirements.

Safety Requirements

The system meets all safety requirements for bearing the CE marking, and complies with safety standards UL 61010-1, CSA C22.2 No. 61010-1, IEC 61010-1, and IEC 61010-2-101.

Refer to Safeguards and Precautions Overview (page 3-1) for more information.

Power Requirements

System

The system requires two dedicated, single phase, AC power lines:

Description	AC1 (Line Cord 1)	AC2 (Line Cord 2)	Total
Input Voltage (nominal)	200 to 240 volt AC	200 to 240 volt AC	
Input Voltage (min/max)	180 to 264 volt AC	180 to 264 volt AC	

(Continued)

Input Frequency Limits	47 to 63 HZ	47 to 63 HZ	
Maximum Power	1600 W	1400 W	3000 W
Circuit Type	Dedicated with isolated ground	Dedicated with isolated ground	
Receptacle Type (No UPS) Continental Europe North America	NEMA L6-20R **OR** CEE 7/7 “Schuko”	NEMA L6-20R **OR** CEE 7/7 “Schuko”	2 Required
System tolerance to voltage interruptions	Tolerant of missing one full cycle at 50 Hz (20 ms). Complies with EN61326-2-2 requirements.	Tolerant of missing one full cycle at 50 Hz (20 ms). Complies with EN61326-2-2 requirements.	
Power cords (included with system) Continental Europe North America	IEC 60320-C19 to NEMA L6-20P IEC 60320-C19 to NEMA L6-20P	IEC 60320-C19 to NEMA L6-20P IEC 60320-C19 to NEMA L6-20P	2 Power cords provided with each system

Printer

Line Voltage and Frequency for printers used in North America:

Lexmark T642*	
Line Voltage	102 -132 volt AC
Frequency	50/60 Hz
Receptacle Type	NEMA 5-15R

*Standard printer for the system. Printers are ordered in accordance with regional specifications.

e-Connectivity®

A Virtual Private Network (VPN) device establishes a secure connection between your System and Ortho Clinical Diagnostics. The VPN is internal to the system computer and does not require any additional hardware or power.

e-Connectivity® Network Connection

The following sections provide network connection specifications for e-Connectivity® Interactive System Management.

Refer to Configure e-Connectivity Screen (page 17-34) for detailed information on e-Connectivity®

Network Connection

The following are required for e-Connectivity® network connection:

IMPORTANT: An auxiliary means of establishing a connection must not be used for the network connection. For example, a dialup PPP connection to establish connectivity to the broadband connection must not be used.

Note: Category 5e or better cabling should be utilized for the network connection.

Note: A Category 5e cable with a male RJ45 connector is provided with the equipment.

Note: Ortho Clinical Diagnostics is not responsible for any other equipment necessary to support the network connection.

- Continuous broadband connection or direct connection to the customer LAN with access to the Internet at a speed greater than or equal to 128 kbps.
- Support local area network port speeds of automatic, 100 and 10 Mbps with full duplex, half duplex, and automatic detection of duplex.

  IMPORTANT: If you are using Cisco equipment, Portfast is disabled.
- IP Address either supplied automatically via DHCP (Dynamic Host Configuration Protocol) or statically assigned by the Information Technology (IT) department and provided to Ortho Clinical Diagnostics Technical Support.
- Support IPSec pass through to the Internet IP Address of 148.177.0.108.

  Note: IPSec utilizes port 500 outbound and inbound, port 4500 outbound and inbound. These ports must be open in the local area network's firewall and allow the specified protocol.
- Female RJ45 connector on the network port within 20 feet of the center of the system.

Uninterruptible Power Supply

If you experience frequent power fluctuations, you may want to use an uninterruptible power supply.

Contact your sales representative for more information.

Telephone and Broadband Internet Recommendations

You may also find it convenient to have a telephone near the system to communicate with Customer Technical Support during troubleshooting sessions.

A broadband Internet connection is required for e-Connectivity® which provides a secure connection between your system and Ortho Clinical Diagnostics. The Virtual Private Network (VPN) router installed on your system for e-Connectivity® is connected to the broadband Internet connection.

Refer to Configure e-Connectivity Screen (page 17-34) for detailed information on e-Connectivity®

Environmental Specifications

The environmental limits for normal operation of the system are defined and shown below.

- BTU Output: 8755 BTUs per hour
- Operating Temperature: 15–30 °C (59–86 °F)
- Site Relative Humidity: 15–75% RH noncondensing
- Altitude: up to 2.439 km (up to 8000 ft.)

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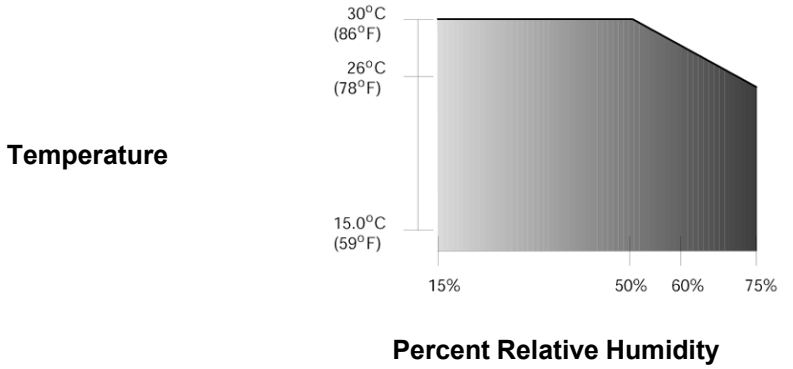


System Relocation

The system is mounted on casters to facilitate its relocation within the laboratory. The new site must meet the same space, electrical, and environmental requirements as specified for the original site.

Physical Dimensions

The following sections provide general component dimensions and a site drawing that illustrates setup and space requirements.

Dimensions

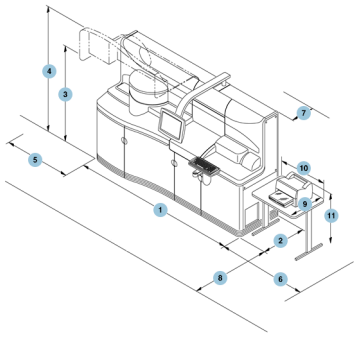
The following table provides the physical dimensions of the system, the printer, and the printer stand.

Dimension	System	Printer: Lexmark T642*	Printer Stand
Width	279.4 cm (110 in.)	43.2 cm (17 in.)	64.8 cm (25.5 in.)
Depth	88.7 cm (34.9 in.)	51.3 cm (20 in.)	57.1 cm (22.5 in.)
Height	172.7 cm (68 in.), top cover down 213.4 cm (84 in.), top cover up	40.6 cm (16 in.)	80.0 kcm (31.5 in.)
Weight	1070.5 kg (2360 lbs.)	4.4 kg (9.8 lbs.)	10.9 kg (24 lbs.)

*Standard printer for the system. Printers are ordered in accordance with regional specifications.

Site Drawing

The following site drawing provides the physical dimensions of the system. The system weighs approximately 1062 kilograms (2360 pounds).



The system and printer dimensions are described below:

Reference	Dimension
1	279.4 cm (110 in.)
2	88.7 cm (34.9 in.)
3	172.7 cm (68 in.), top cover down
4	213.4 cm (84 in.), top cover up
5	76.2 cm (30 in.) - Left side door clearance
6	76.2 cm (30 in.) - Right side door clearance
7	45.7cm (18 in.) - Distance from wall
8	76.2 cm (30 in.) - Area in front of system
Printer Stand with Lexmark T642* Printer Dimensions	
9	57.1 cm (22.5 in.)
10	64.8 cm (25.5 in.)
11	119.4 cm (47 in.)

*Standard printer for the system. Printers are ordered in accordance with regional specifications.

Entrance to Room

The entrance door opening should be a minimum of 81.3 cm (32 in.) wide.

Summary of System Performance Characteristics and Specifications

The following tables summarize system performance characteristics, capacities, and computer and interface specifications. Consult the assay Instructions for Use for individual assay performance characteristics.

Sample and Assay Performance Characteristics

Characteristic	Description

(Continued)

Intellicheck® Technology	Proprietary Ortho Clinical Diagnostics technology designed to significantly reduce errors. Intellicheck® is a series of patented and unique technologies that perform, monitor and verify diagnostic checks throughout sample processing and results reporting. When exceptions are detected, Intellicheck® Technology provides immediate operator notifications and prevents results that may be affected from being reported. Refer to Intellicheck Technology (page 14-39) for more information.
MicroSensor™ Technology	The MicroSensor feature is intended to assist laboratory personnel in assessing the suitability of a patient sample for use on the system. Refer to VITROS MicroSensor Overview (page 14-31) for more information.
Assays and Derived Tests	Refer to Summary of Assays and Derived Tests (page 1-9) for more information.
Technology	MicroWell, MicroTip, and MicroSlide.
Sample Types	Serum, plasma, urine, whole blood, cerebrospinal fluid (CSF), and amniotic fluid.
Reagents and Capacity	MicroTip Reagents — 30 packs MicroSlide Reagents — 89 cartridges MicroWell Reagents — 31 packs Signal Reagent — 3 packs Universal Wash Reagent — approximately 5 L Electrolyte Reference Fluid (ERF) — 800 tests per reservoir Immuno-rate Wash Fluid (IWF) — 300 tests per reservoir
Sample and Assay Processing	Continuous, random, STAT access and batch (STAT samples can be processed with STAT priority processing at any time).
Random Access Calibration	For calibrators with bar codes, process calibrators in any tray position, in non-sequential order, and across trays, including quality control and patient samples.

(Continued)

Disposable Tip Metering	Disposable tip metering with automated sample status checks for clot detection, with Save-the-Sample Clot Detection Management, bubble detection, high and low-viscosity detection, thin layer fluid detection, level sensing and short-sample detection.
Automatic Dilution and Repeat Testing	Samples can be automatically diluted and automatically repeated for: • Reflex and operator requested dilutions • Protocol and pre-treatment dilutions • Automatic reflex processing to the same assay and to different assays • Sample programs retained in the system memory containing assays without a result reported after the sample was initially processed
Sample Capacity	Up to 90 samples can be loaded, 10 on each tray
Sample Volume	2 to 80 microliters, depending on the assay
Sample Containers and Minimum Fill Volumes	Universal Sample Trays accommodate primary and secondary tubes, Micro-collection containers, and sample cups. Refer to Containers (page 8-7) for more information.

System Capacities

Characteristic	Description
Liquid and Solid Waste Capacity	Refer to Waste Containers (page 8-23) for more information. The system includes three solid waste containers and one liquid waste bottle.
Plumbing	Self-contained, on-board liquid waste management eliminates the need for off-board plumbing.
Sample Program Capacity	Up to 10,000 programs can be downloaded to the system.
Result Record Capacity	25,000 result records can be saved in the system memory.
Quality Control Result Record Capacity	Up to 2190 results for each analyte

e-Connectivity®

Characteristic	Description
Interactive System Management	Provides real-time, secure, two-way interactive connection between your system and Ortho Clinical Diagnostics.
Automatic Two-Way Data Exchange	Automatically send and retrieve data with Customer Technical Support. Data regarding multiple aspects of system performance can be automatically transferred to Customer Technical Support for real-time analysis. Includes automatic download of system software updates.
Remote Connectivity	Provides the ability to connect your system to Ortho Clinical Diagnostics in a way that enables remote diagnostics. Remote connectivity includes the ability for Customer Technical Support to perform remote control operation of the system, as well as, monitor and review system configuration, data, and performance information.

System Computer and Interface Specifications

Characteristic	Description
Operator Interface	**Monitor** — 17 inch, ergonomically designed flat, low-glare, LCD monitor with an integrated resistive touchscreen including a keyboard. All provide for flexible positioning for customized operator interaction. **Keyboard** — 102-key, AT-Style **Assay Data Disk (ADD)** — CD/ROM containing assay protocol definitions as well as reagent lot specific calibration parameters. Refer to Assay Data Disk (ADD) (page 10-2) for more information.
Minimum Computer Specifications	**Processor —** Intel Pentium 4, 3 GHz, 2 GBytes ECC RAM **Hard Drive —** 80 GBytes DVD-RW Drive, 2 USB Ports
Interface Specifications	Bidirectional protocols for a Laboratory Information System (LIS). Refer to Configure LIS Screen (page 17-30) for more information.
PCI to CAN Interface	Laboratory Automation System (LAS)

(Continued)

Universal Sample Bar Code Reader	Reads, with auto-discrimination capability, all standard bar code symbologies including Code 128, ISBT 128, Code 39, Codabar and Interleaved 2 of 5. Also recognizes UPC. Only the 5 standard symbologies are approved for use on patient sample containers. Calibrators, Universal Sample Trays and the Micro-collection Container Adapters use Code 128.
Reagent Bar Code Readers	Reads internal proprietary labels to identify reagent packs, slide cartridges and signal reagent packs.
Communication Ports	Two USB ports for printers, three RS232 ports: two for Laboratory Automation Systems and one for a Laboratory Information System. An Ethernet port is also available for a VPN.

Printer Specifications

Characteristic	Description
Printer — Lexmark T642* *Standard printer for the system. Printers are ordered in accordance with regional specifications.	Serves as an output device for patient, quality control, and calibration results. Patient and quality control results can be printed in a laboratory report format; patient results can also be printed in a patient report format for distribution outside the laboratory. Calibration, quality control, and other miscellaneous reports are also available. The printer has the capability to print single forms. Provides top paper delivery, including single sheet delivery.

Summary of Assays and Derived Tests

The following tables list the assays that can be processed on the system. The abbreviation appears on the assay selection menus and the Laboratory Report, and the assay name appears on the Patient Report.

Note: The availability of these assays in certain markets is subject to regulatory clearance or approval.

MicroWell Assays

Full Assay Name	Abbreviation
AFP*	AFP

(Continued)

Anti-HAV IgM* †	HAV M
Anti-HAV Total* †	HAVT
Anti-HBc* †	aHBc
Anti-HBc IgM* †	HBc M
Anti-HBe** †	aHBe
Anti-HBs* †	aHBs
Anti-HCV* †	aHCV
Anti-HIV 1+2* †	aHIV
CA 125 II	CA125
CA 15-3	CA153
CA 19-9	CA199
CEA	CEA
CK-MB	CK-MB
CMV IgM**	CMV M
CMV IgG**	CMV G
Cortisol	Cort
Estradiol	E2
Ferritin	Ferr
Folate	Fol
Free T3	FT3
Free T4	FT4
FSH	FSH
HBeAg** †	HBeAg
HBsAg* †	HBsAg
LH	LH
Myoglobin	Myog
NTx	NTx
NTBNP	NTBNP
Progesterone	Prog
Prolactin	Prol
PSA	PSA
Rubella IgG	Rub G

(Continued)

Rubella IgM**	Rub M
T3 Uptake	T3U
Testosterone	Testo
Toxoplasma IgG**	Tox G
Toxoplasma IgM**	Tox M
Troponin I	TropI
Troponin I ES	TropI ES
Total ß-hCG	ß-hCG
Total T3	TT3
Total T4	TT4
Total B-hCG II	B-hCG
TSH	TSH
Vitamin B12	B12

* Some or all types of specimens or suggested reference interval or cutoff for these analytes are not approved or cleared for market in the United States.

** International only – not sold in U.S.

† Co-developed with Novartis Corporation.

CA 125 II, CA 15-3, CA 19-9 are trademarks of Fujirebio Diagnostics, Inc.

MicroSlide Assays

Full Assay Name	Abbreviation
Acetaminophen	ACET
Acid Phosphatase	AcP
Albumin	ALB
Alcohol	ALC
Alkaline Phosphatase	ALKP
Alanine Aminotransferase	ALT
Ammonia	AMON
Amylase	AMYL
Aspartate Aminotransferase	AST
Bilirubin, unconjugated and conjugated	BuBc
Blood Urea Nitrogen	BUN/UREA
Calcium	Ca

(Continued)

Cholinesterase	CHE
Cholesterol	CHOL
Creatine Kinase	CK
Creatine Kinase - MB	CKMB
Chloride	Cl^-
Carbamazepine	CRBM
Creatinine	CREA
C-Reactive Protein	CRP
Digoxin	DGXN
Direct HDL Cholesterol	dHDL
Carbon Dioxide	ECO_2
Iron	Fe
Gamma Glutamyltransferase	GGT
Glucose	GLU
Potassium	K^+
Lactate	LAC
Lactate Dehydrogenase	LDH
Lithium	Li
Lipase	LIPA
Magnesium	Mg
Sodium	Na+
Phenobarbital	PHBR
Phosphorus	PHOS
Phenytoin	PHYT
Cerebral Spinal Fluid Protein	PROT
Salicylate	SALI
Total Bilirubin	TBIL
Theophylline	THEO
Total Iron Binding Capacity	TIBC
Total Protein	TP
Triglyceride	TRIG
Urine Protein	UPRO

(Continued)

Uric Acid	URIC

MicroTip Assays

Full Assay Name	Abbreviation
a1-Antitrypsin	AAT
Amphetamine	AMPH
Apolipoprotein A1	ApoA1
Apolipoprotein B	ApoB
Antistreptolysin O	ASO
Barbiturates	BARB
Benzodiazepines	BENZ
Complement C3	C3
Complement C4	C4
Caffeine	CAFFN
Cocaine metabolite	COCM
Direct % Glycated Hemoglobin	d%A1c
Direct LDL	dLDL
Direct Total Iron-Binding Capacity	dTIBC
Gentamicin	GENT
Homocysteine	HCY
Haptoglobin	HPT
High-Sensitivity C-Reactive Protein	hsCRP
Immunoglobulin A	IgA
Immunoglobulin G	IgG
Immunoglobulin M	IgM
Microalbumin	mALB
Methadone	METD
Opiates	OP
Prealbumin	PALB
Phencyclidine	PCP
Rheumatoid Factor	RF
Cannabinoids	THC

(Continued)

Tobramycin	TOBRA
Transferrin	TRFRN
Valproic Acid	VALP
Vancomycin	VANC

Derived Tests

The following table lists the derived tests calculated by the system. The abbreviation appears on assay selection menus and the Laboratory Report, and the derived test name appears on the Patient Report.

MicroWell Assays

Full Assay Name	Abbreviation
FT3 Index	FT3I
FT4 Index	FT4I
LH/FSH Ratio	L/F
TT3/TT4 Ratio	T3/T4

MicroSlide Assays

Full Assay Name	Abbreviation
Albumin/Globulin Ratio	A/G
Anion Gap (without K+)	AGp
Anion Gap (with K+)	AGpK
Bilirubin Supplement	-
BUN/Creatinine Ratio	B/CR
Cholesterol/HDLC Ratio	C/H
Delta Bilirubin^	DELB
Direct Bilirubin^	DBIL
Globulin	GLOB
Low Density Lipoprotein	LDL
Neonatal Bilirubin^	NBil
Osmolality	OSMO
CKMB/CK Ratio	% MB
Percent Iron Saturation	% Sat
Very Low Density Lipoprotein	VLDL

^ Refer to the Bilirubin Supplement.

Chapter 2 V-Docs Overview

V-Docs is short for **V**ITROS System **Doc**umentation. V-Docs provides you with information about your system at the touch of a button. V-Docs explains how to perform specific tasks on the system. It describes the various system modules, equipment maintenance procedures, and diagnostics and troubleshooting actions. V-Docs helps you understand the software that controls the system and enables you to interact with it. It also provides important information about calibration, the assays that the system performs, and the materials required to perform those assays.

The V-Docs main screen is split into tabbed sections, and a search feature. The tabbed sections are used for general system information, operation, and maintenance, while the search feature allows you to locate information quickly from anywhere within V-Docs. Refer to Available Documentation (page 2-1) for more information about each tab.

Ortho Clinical Diagnostics also provides V-Docs in printed form, on demand, for use away from your system. The printed version contains the same content as the material provided on-board your system.

Audience

Ortho Clinical Diagnostics (OCD) provides V-Docs for clinical laboratory personnel responsible for using the system, OCD Laboratory Specialists, OCD trained service personnel, and other support groups who maintain and troubleshoot the system.

The system has different access levels for general users, Key Operators, and Service Personnel. General users and Key Operators will not have access to certain service related system features and documentation.

Available Documentation

V-Docs includes the following types of documentation:

Operations and Maintenance

The Operations and Maintenance tab lists System Operation and System Maintenance procedures. Touch a topic to read about it.

Operational procedures are on the left side of screen. This area contains procedures that keep the system running, or are frequently used. For example, you can find procedures for loading consumables, loading reagents, programming samples, and many more.

Periodic Maintenance procedures are on the right side of screen. This area contains procedures for system maintenance, and reflects the default tasks listed on the Periodic Maintenance Daily, Weekly, Monthly and As-required screens.

These procedures are step-by-step instructions that help you perform an action on the system. For example, there are procedures that explain how to load samples or how to perform maintenance activities. Many procedures include illustrations that show you how to do the task. Some illustrations are animated to show you exactly how the action looks. You can replay the animation as often

as you need to in order to understand the task. Often, there are links to other related procedures that you need to perform as part of a major activity.

Note: Any procedure that is not listed under the Operations and Maintenance tab can be found using the Search feature (page 2-4).

Help

Help screens assist you in understanding the various software screens you use to interact with the system. When you touch the Help button (located at the bottom right corner of any screen), the system displays a Help screen containing information specific to the screen you are viewing.

The Help screen may describe the following:

- the access level required for certain functions on the screen to be enabled
- the purpose of the system screen
- links to tell you more about a specific topic
- screen information descriptions of the fields or other data on the screen
- instructions to help you use the screen
- process buttons listed on the system screen

Any of the following topics listed below may appear as links at the top of the Help file, and link to information further down in the Help screen:

Topic Link	Result
Tell me more...	Links to tell you more about a specific topic
Screen Information	Descriptions of the fields or other data on the screen, and instructions to help you use the screen
Process Buttons	Descriptions of the process buttons listed on the system screen

Tell Me More

Many Reference Guide topics and Help screens include Tell Me More links. These links take you beyond what is provided in the current file and goes into additional information about a concept or topic. Use the Tell Me More links to gain more in-depth understanding of key system functionality and design.

System Centers and Modules

System Centers and Modules shows you a graphical depiction of the location of a system component. This information is helpful if you are performing diagnostics or maintenance on the system. You can quickly identify where a component is located and how to access it.

Condition code descriptions

Condition codes keep you informed about the system status and alert you to situations that require attention. Short condition code descriptions summarize the situation. Longer condition code descriptions offer more detailed information about the condition and how to resolve it. If you need to perform a procedure (for example, clean or replace a component), links in the condition code description take you to instructions for the procedure.

Reference Guides

The Reference Guides tab in V-Docs contains both the Reference Guide and the User Defined Assay (UDA) Guide. Touch the button that matches the guide you want to read. Each guide, and how it is structured is briefly described below.

The Reference Guide summarizes concepts and procedures that you might encounter while using the system. It explains how the system works including safeguards and precautions, system components, status messages, functional theory, and other operational topics.

For your convenience, this Reference Guide is designed to correspond with the user interface on the system. It is organized by the navigation buttons that are displayed in the Status Console, beginning with the Status button, and ending with the Conditions button.

Tell me more about the Status Console (page 6-2)

For example, if you need to know how to program a sample tray, touch the V-DOCS navigation button and then touch Samples and then Sample Programming and Handling from the main Reference Guide menu.

If you want to find Reference Guide information without using the buttons, you can perform a search at anytime using the Search feature (page 2-4).

Click on the Reference Guides tab to view the different topics about the system and its operation. Once on the Reference Guides tab, choose a topic from the list provided and touch the appropriate sequence of buttons until you find the topic you want to read about. The topic buttons will appear on the left side of the screen, and the content displays on the right. Most topics will be discussed within one screen, but sometimes the content goes over one page and a scroll bar appears. Refer to Move Up and Down within a V-Docs screen (page 2-4) for instructions on how see more of the page.

The User Defined Assay (UDA) Guide provides conceptual and practical information about User Defined Assays. The UDA feature of the system allows you to expand the assay menu beyond those assays currently available from Ortho Clinical Diagnostics. Using the UDA feature, you can program assay protocols using pre-formatted assay templates and reagents from other vendors, or you can define your own protocols.

Click on the topic buttons to find the information you are looking for, similar to navigating through the Reference Guide. The UDA Guide discusses working with UDAs, Antigen Excess, Triple Read Algorithms, and Molar Extinction Coefficient. There are also additional reference materials like the UDA Worksheet and Quick Reference Table.

WARNING: ORTHO CLINICAL DIAGNOSTICS EXPRESSLY DISCLAIMS ALL WARRANTIES WITH RESPECT TO USER-DEFINED METHODS WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

WARNING: Since Ortho Clinical Diagnostics does not manufacture or otherwise control the reagents that may be used in the VITROS UD Pack, the warranty for the system does not extend to the performance of user-defined reagents (including user-defined test results or standard system test results that are affected by user-defined testing), their effect on the system operation and types and frequency of maintenance, or their effect on operator safety. The user assumes full responsibility for the selection of the proper reagents and entering the proper test parameters, use of the proper test protocol, correctness of the test results, and any associated errors or omissions. Each laboratory must establish its own performance characteristics in compliance with applicable laws and regulations before performing tests and reporting patient results for diagnostic purposes. The user assumes full responsibility for any local or regional regulatory requirements resulting from the use of user-defined reagents on the system .

WARNING: All fluids used on the system are disposed of in an on-board waste container. Use of reactive chemicals may create a hazard to the operator.

Ortho Clinical Diagnostics provides the Reference Guide and User Defined Assay (UDA) Guide in printed form for use away from your system. The printed guides contain the same content as the guides provided on-board your system.

Note: If you need to replace one of your printed Guides, please contact your Ortho Clinical Diagnostics Account Manager, or Ortho Clinical Diagnostics Laboratory Specialist.

About

The About tab in V-Docs includes information regarding other properties of your system. The About tab displays:Touch a link to display the information.

- the current V-Docs version number
- a link to the latest software release notes
- a link to the latest ADD History chart
- a link to the current and previous V-Docs revision histories

Glossary

The Glossary provides definitions of terms used throughout V-Docs. Access the Glossary in any of the following ways:

- From the Reference Guide menu, touch Glossary. The system opens the Glossary. You can scroll through the list to find the term you want.
- Within V-Docs screens, touch any term shown as a blue link with a green underscore (for example, MicroWell (V-Docs)). The system opens the Glossary to that term. Touch Back to return to the V-Docs screen you were reading.
- Use the Search feature (page 2-4) to search for the term you want. If the term is found in the Glossary, the system returns a link to the Glossary.

V-Docs Access

You can access V-Docs in one of three ways.

Touch the V-Docs button in the upper right corner of any system screen. If this is the first time you've accessed V-Docs since energizing the system, the Operations and Maintenance tab opens. If you've already been using V-Docs since energizing the system, the system opens the last V-Docs screen you viewed.

(Continued)

Touch the Conditions button in the upper right corner of certain system screens. For example, if you are performing daily Metering Maintenance and a dialog box opens, you will not be able to access the Conditions button. When you touch the Conditions button the system opens a screen listing condition codes that currently apply to your system. Select a condition code and touch the View Description button to open a V-Docs screen providing more information about the condition and what to do to resolve it.

Touch the Help button in the lower right corner of any system screen. The system displays the Help screen for the screen you currently are using. The Help information may contain links to related V-Docs procedures, or links to related information in the Reference Guide.

How to Find Information

You can quickly find information within V-Docs using the Search feature. There are two ways to perform a search within V-Docs:

- Basic search
- Advanced search

Both search features take your keyword or phrase, and look for a match within V-Docs.

A basic search allows you to enter a keyword or phrase to look for within V-Docs but it will only return results that match exactly to the keyword or phrase entered. To perform a basic search, type a keyword or phrase you are looking for into the Search field provided and either touch Search or press [Enter]. The system displays a highlighted list of V-Docs screens or topics that match the keyword or phrase. Touch the result link to select the page you want to access.

If you are having difficulty finding the information with a basic search, try an advanced search. An advanced search allows you to choose more options, and can improve the results that are returned from a basic search. To perform an advanced search, touch Search without entering any keywords. The system displays the Advanced search screen. Set the keyword or phrase match type: any search words, or all search words, and touch Search or press [Enter].

The system displays a highlighted list of V-Docs screens or topics that matches *some* of the keywords or phrases, or matches *all* of the keywords or phrases; depending on the match type you selected. Touch the result link to select the page you want to access.

The asterisk (*) and question mark (?) wildcards are available for use in your search. The asterisk should be used for replacing or representing a zero or several missing characters. For instance, if you are looking for information about the LUMINOMETER, but only know the first few letters, you can type “LUMIN*” into the search field provided and the Search function returns results for LUMINOMETER.

The question mark should be used for replacing a single character. For instance, if you are looking for information about samples and want to return all the information contained in V-Docs relating to samples, you should use the question mark so that the singular, “sample,” or plural, “samples” is returned.

The asterisk and the question mark can be used within the same search query.

The V-Docs Search feature looks and functions much like your favorite web browser search engine. After all of the keywords or phrases have been found, the system returns the results on the page. The title of the page, excerpt from the screen, and number of keyword or phrases (terms) matched are displayed for you to review.

Navigation

When you finish reviewing a V-Docs, Help, or Condition Code screen, touch Return to display the System Status screen or touch any of the Status Console navigation buttons.

To return to the screen you were viewing, touch the Status Console navigation button for the function you were performing.

For example, if you were programming a sample, touch  for Samples.

If you touch the V-Docs button again, the system returns you to the last V-Docs screen you were viewing.

You can page forward and backward through V-Docs screens that you have already viewed by touching the Back and Forward buttons on the screen. They work like forward and back buttons in a web browser. If you want to move from page to page within a procedure use the navigation on V-Docs screens. To replay an animation, touch the replay button.

V-Docs navigation and replay buttons include:

	Move forward one page in the procedure
	Move back one page in the procedure
	Go to the beginning of the procedure
	Replay the animation

Move Up and Down Within a V-Docs Screen

Within a V-Docs screen, you can scroll down to view all text using either the scroll bar to the right of the screen, or the [Page Down] key. Scroll up using the scroll bar, or the [Page Up] key. You can use the up arrow and down arrow keys to move up or down one line at a time.

V-Docs Conventions

V-Docs uses the following style conventions for notations and user interface features.

Notations

Notations call attention to important details. All notations should be read and understood to make sure you are prepared to properly operate the system.

Note: To emphasize or clarify information or instructions.

IMPORTANT: To emphasize information or instructions that are essential to read and follow.

Caution: To prevent damage to the equipment.

WARNING: To prevent actions that can cause personal injury.

DANGER: TO INFORM THE USER THAT A SAFETY RISK EXISTS.

Targets, Keys, and Buttons

As you move through V-Docs you may see boxes around words, or different text used within a screen. Refer to the table below for the different styles used to recognize targets, keys, system prompts, or buttons encountered while operating the system.

Screen Conventions	Example
Names of targets and buttons appear in boxes with initial capitals.	Touch Move/Cycle
Names of keys on the keyboard appear in square brackets.	Press [Enter] to continue
System prompts or status messages displayed on the screen are shown in a different typeface.	Assays complete
Names of system components appear in upper-case.	LUMINOMETER

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Chapter 3 Safeguards and Precautions Overview

This section includes the following topics:

Proper Equipment Use

If this equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired. Only authorized Ortho Clinical Diagnostics service personnel are allowed to move the unit from one power supply receptacle to another.

The system processes potentially biohazardous materials. Operate the system in compliance with your laboratory procedures for handling biohazardous materials, and in accordance with the procedures defined by the appropriate national biohazard safety guidelines or regulations. Equipment operators should wear safety glasses, gloves, and follow OSHA/CDC/NIH/WHO safety guidelines.

FCC (United States)

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

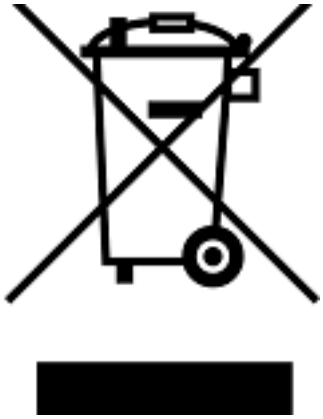
Labeling of RoHs

The labeling of Ortho Clinical Diagnostics instruments complies with Chinese regulations on Management Methods of the Control of Pollution from Electronic Information Products (EIP) - Ministry of Information Industry, February 28, 2006, Order No. 39 (China RoHS). This labeling applies to the Chinese market; however, customers outside of China will also see this labeling on their equipment.

The label will be placed on the instrument and on the packaging for the instrument. The number in the symbol indicates the Environmental Protection Use Period (EPUP). The EPUP is the period of time (in years) during which, with normal use, no hazardous substances or elements will leach from the EIP or mutate into other forms that could result in severe environmental pollution, bodily damage or material damage.

Labeling of Electrical and Electronic Equipment

In compliance with the European Directive 2002/96/EC on waste electrical and electronic equipment (WEEE), this device must not be disposed of as unsorted municipal waste. Instead, this device must be collected separately in accordance with local recycling regulations. Presence of the symbol below indicates that compliance must be adhered to for this device.



Moving the Equipment

Only authorized service personnel are permitted to move equipment from one location to another. If the equipment is moved, it should be checked by authorized personnel. The equipment should also be checked if any unusual vibration has occurred that may affect it (for example, heavy construction nearby or earthquake). The packaged system can withstand the following non-operational conditions without degrading performance:

- Cold: -23.3 °C (-10 °F) at 5 - 15% RH for 12 hours
- Heat: 65.5 °C (150 °F) at 5 - 15% RH for 12 hours
- Humidity: 86% +5% RH at 35.5 °C (96 °F) for 12 hours

Environmental Conditions

The system is designed to run within a specified range of environmental conditions. For example, altitude, temperature, or humidity can affect system performance. Use Environmental Monitoring to make sure the system is within its specified range.

Tell me more about Environmental Monitoring (page 16-5)

Electrical Hazards

The system complies with applicable domestic and international *in vitro* Diagnostic medical equipment safety standards. See the "Declaration of Conformity" for more information.

Potential electrical hazards exist behind the side, front, and back panels of the system. Keep doors, covers, safety shields, and panels closed during normal operation for your own protection and to maintain system temperature. Do not

operate the system if any of the assemblies or subassemblies have been removed. Removing assemblies or subassemblies from their normal positions may create electrical hazards. This includes components of the MicroSlide Center, Sampling Center, MicroImmunoassay Center, and the Command Center.

Two power cords supply power to the system. If at any time power needs to be removed for maintenance purposes, both power cords must be disconnected. The main disconnect for the system is the main power switch, and is located behind the right-middle door. Do not block access to this door.

System Labels

This topic describes the agency-approved safety and service labels found on the system. It includes images that represent the details of each label and where it is located on the system.

Safety Labels

Safety labels indicate areas on the machine where operators should be aware of biohazards, high voltage, hot surfaces or places where operators could pinch or injure their hands in normal operating modes.

Label	Description
	High Voltage
	Electrostatic Sensitive
	Caution, Hot Surface
	Biohazard

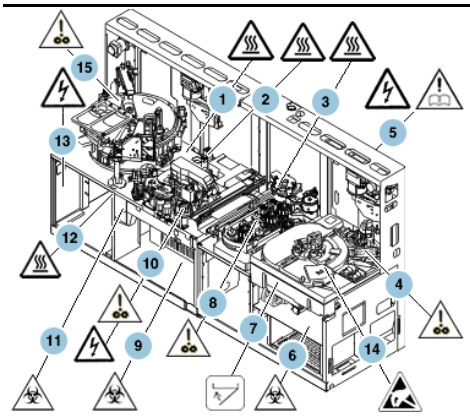
(Continued)

Caution, Risk of Danger, Refer to Manual

Pinch Hazard

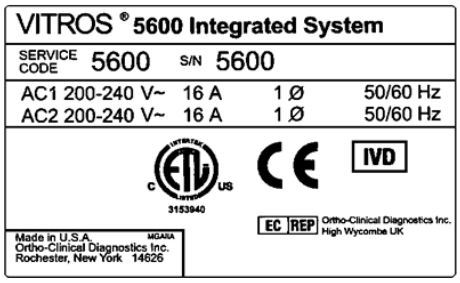
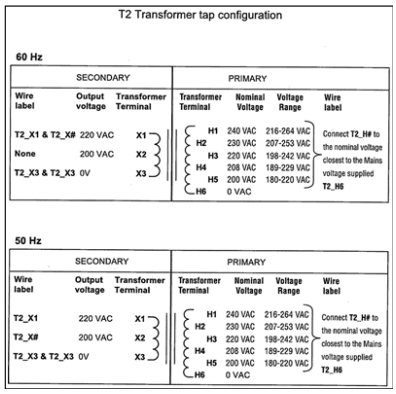
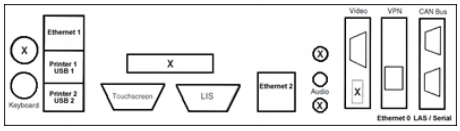
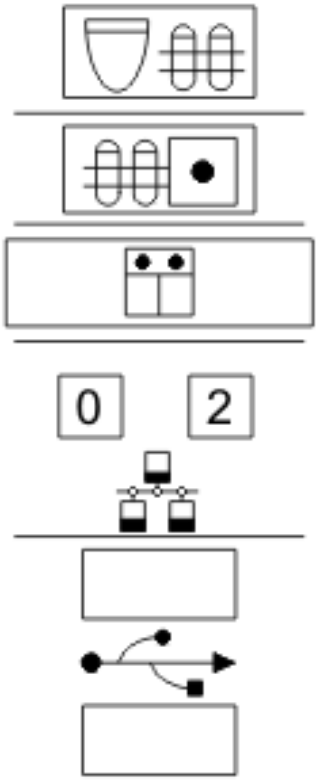
Safety Label Locations

The following image identifies the location of the safety labels placed on the system.

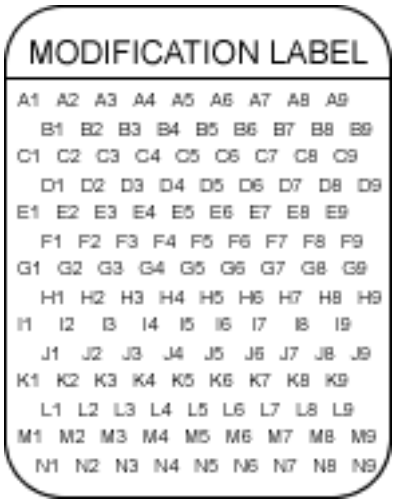


1. Photometer
2. Secondary Tip Sealer
3. Primary Tip Sealer
4. Slide Dispenser
5. Behind left back panel
6. Waste Container C
7. Behind right door
8. Sampling Center
9. Waste Container B
10. Signal Reagent Metering
11. Waste Container A
12. Cooler
13. Compressor Relay Box
14. Electrometer (MicroSlide Center)
15. MicroTip Pack Opener

Service Labels

Label	Description
	System Dataplate
	Transformer Cover
	Master Computer Connections
	Communication Port Panel

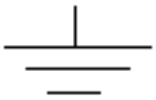
(Continued)



Modification Label

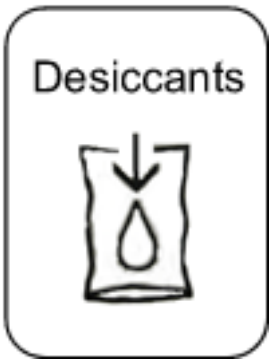
Primary Protective Main Power Ground

(AC1 and AC2)



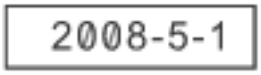
Ground, Service and Frame Stud

Humidity Control Pad



Desiccant Packs

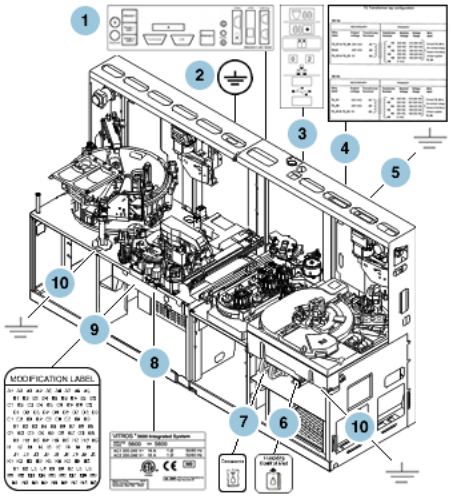
(Continued)

	Close Door
	RoHS EPUP
	Date of Manufacturing
This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.	FCC (United States)
	IVD
Le présent apparell numérique n'émet pas de brulis radio-électriques dépassant les limites applicables aux apparells numériques de la classe B prescrites dans le Réglement sur le brouillage ra- dioélectrique édicté par le ministére des Communications du Canada. This digital apparatus does not exceed the Class B limits for radio noise emissions from digital apparatus set out in the Radio Interference Regulations of the Canadian Department of Communications.	CDOC (Canada)

Service Label Locations

The following illustration identifies the location of service labels on the system.

(Continued)



1 Master Computer Connections
(behind bottom left middle back panel)

2 Primary Protective Main Power Ground - AC1 and AC2
(behind bottom left middle back panel)

3 Communication Port Panel
(bottom left middle back panel)

4 Transformer Cover
(behind left back panel)

5 Service Ground
(behind left back panel and bottom right middle back panel)

6 Humidity Control Pad

7 Desiccant Packs

8 System Dataplate

9 Modification Label

10 Service Ground

General Precautions

The following precautions should be considered when operating the system. The key operator should perform all periodic maintenance procedures.

Bloodborne Pathogens

Observe Universal Precautions following the OSHA Bloodborne Pathogens Standard and the CDC/NIH and WHO (World Health Organization) guidelines at all times when dealing with blood or body fluid and contaminated equipment.

Product Disposal

Customers within the European Union should dispose of labeled products (including associated cables, cords, and accessories) at the end of life by returning them to a collection system or treatment and recycling facilities. Follow your local decontamination procedures before returning electrical and electronic equipment. Contact local waste management authorities for additional information on the disposal of electrical and electronic equipment.

For customers outside the European Union, no action is required unless specified otherwise by local or national regulations.

Initial Use

It is recommended that, before initial use, appropriate performance characteristics specific to each VITROS Chemistry Product and each VITROS Immunodiagnostic Product be verified by the operator or the laboratory.

Moving Parts

During normal operations, the system top cover is interlocked to prevent exposure to any dangerous movements. However, during maintenance or troubleshooting there are several areas in the system where the operator may be exposed to components that move suddenly. Use caution when working on and around the following system components:

- DISPENSE BLADE
- SLIDE SUPPLY RINGS
- INCUBATOR
- SAMPLE TRAY CONVEYOR
- WELL WASH ARMS
- SIGNAL REAGENT DISPENSE ARMS
- SIGNAL REAGENT CAROUSEL
- METERING ARMS

  Note: The METERING ARMS are safety interlocked; they do not move when the top cover is open. They are not a hazard to the operator under normal circumstances.

Always exercise appropriate caution when operating the system and correcting any conditions.

Lamps

The REFLECTOMETER and PHOTOMETER LAMPS are hot. Exercise appropriate caution when working near these areas.

WARNING: Let the LAMP and base cool for at least 15 minutes so that you do not burn your hands.

Maintenance while Sampling

You may leave the system on unless specified otherwise; but do not process samples while you perform maintenance procedures. Refer to instructions for the individual maintenance procedures for more information on proper maintenance procedures.

Touch the Operations and Maintenance tab on the V-DOCS screen to access the periodic maintenance procedures.

Interference from Radio Frequencies

This system has been tested for Radio Frequency Immunity compliance to the requirements of EN 61000-4-3 to a signal strength of 3V/m. Cellular phones and two-way radios when used in close proximity to the system exceed this signal strength and can cause some assay results to be suppressed with an error reported instead. Prohibit the use of these devices at least one meter from the system for optimum performance.

Electromagnetic Compatibility (EMC)

This system complies with the emission and immunity requirements described in IEC 61326-1 and IEC 61326-2-6 for *in vitro* diagnostic equipment. This equipment has been designed and tested to CISPR 11 Class A. In a domestic

environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.

The electromagnetic environment in the area where the system is to be placed should be evaluated prior to operation of this device. Do not operate in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these may interfere with the proper system operation.

Assay Data Disk and Software Disk Storage

Save and properly store Assay Data Disks or software disks. You may need the previous Assay Data Disk (ADD) if the data does not successfully transfer to the system during an ADD load.

To store an Assay Data Disk or software disk properly:

- Do not store the disk in the system.
- Store the disk in its case for protection.
- Store the disk at room temperature 18–28 °C (64–82 °F). Do not expose the disk(s) to a humidity above 50%.
- Keep the disk away from extreme heat or cold. Rapid changes in temperature or humidity may damage the disk(s).
- Keep the disk away from magnetic fields, your computer printer, telephones, and other electromagnetic devices.
- Keep the disk away from direct sunlight, ultra-violet light, and infrared light.
- Do not write on the surface of the disk with a felt-tip pen or any other instrument.

If necessary, the surface of the disk(s) may be cleaned by gently wiping straight from the center to the edge of the disk (not in a spiral), using a lint-free cloth.

USB Flash Drives

System backups have the option of saving the data to a USB Flash drive, located next to the MASTER COMPUTER (page 4-7). USB Flash drive backups usually only take seconds to complete. During data backup:

- Do not remove the USB Flash drive before Writing to the USB appears in the status dialog, after touching Backup on the Start Backup dialog box.
- Do not remove the USB Flash drive while Writing to the USB appears in the status dialog.
- Do not remove the USB Flash drive before the Backup Successful dialog box is displayed.

IMPORTANT: The USB Flash drive should not be removed before the system completes saving the data. Removal of the USB Flash drive may result in only part of the backup transferring to the USB Flash drive or corruption of the file system on the USB Flash drive.

If the system cannot detect a USB Flash drive when the data is being saved, the backup will fail, no data is transferred to the USB Flash drive, and a system condition code posts.

How to Clean the System

This section contains general information about cleaning the system. Please refer to the individual maintenance procedures for instructions on cleaning specific system components.

Precautions

Assume that all used equipment is contaminated with potentially infectious biological material. In the United Sates, OSHA, CDC, and NIH recommend Universal Precautions described in the Bloodborne Pathogen Standard 29CFR1910.1030 when handling, cleaning, and packing the equipment.

- Wear gloves, closed shoes, buttoned lab coats, and safety glasses throughout the cleaning process (and packing, if the system is being shipped or relocated).
- Handle all equipment with care. Mechanical parts may have edges, pinch points, and corners that could potentially cause injury.
- Treat materials used in the cleaning process as contaminated. Follow the site procedures for your laboratory to dispose of these materials.
- Soak up any fluid dripping from the tubes with an absorbent material. Disconnecting tubing may result in fluid dripping from the tubes.

Outside the United States, follow WHO (World Health Organization) and your country's regulations for handling and cleaning bloodborne pathogens.

Cleaning Solutions

Do not use any solvents or cleaning solutions on the equipment other than distilled or deionized water. Never use ammonia cleaners on or near the system. If necessary, clean contaminated system components using a 70% Isopropyl alcohol-in-water solution when suggested in the maintenance procedures.

Note: Sodium hypochlorite solution, bleach, ammonia, any ammonia-containing compound, and any other oxidizing agents will corrode unprotected metal parts and may cause erroneous results. Therefore, 70% isopropyl alcohol-in-water is recommended.

Note: Do not autoclave any component unless autoclaving is specifically indicated to be an acceptable alternative.

WARNING: Sodium hypochlorite, bleach, and other oxidizing agents may be hazardous, may cause erroneous results, and may also corrode metal parts. Observe all precautionary handling instructions on the manufacturer's package.

Caution: Do not use solvents, isopropyl alcohol, glass cleaners, ammonia, or cleaning agents containing abrasives to clean the touchscreen MONITOR. These items will damage the touch screen and impair your ability to interact with the system computer. Use only non-ammonia glass cleaner.

Caution: Do not use solvents, alcohol, ammonia, glass cleaners, or cleaning agents containing abrasives to clean the INCUBATOR EVAPORATION CAPS. These items will damage the caps and affect system performance.

Caution: Dispose of paper towels and cotton swabs used to clean the system following Universal Precaution procedures. These items may be contaminated with serum or other body fluids.

Caution: Be sure to use no more than a 70% concentrated solution of isopropyl alcohol-in-water. It is critical that enough water be present to solubilize proteins. Do not use 10% bleach for general cleaning; it can corrode metal parts.

How to Clean the System Exterior

If any spills occur and the system exterior requires cleaning, refer to the procedure for How to Clean the System Exterior (page 3-12).

Extended Shutdown

If the system needs to be shutdown for an extended period of time the reagents must be removed and the system needs to be cleaned. Certain maintenance procedures should also be performed prior to starting the system after an extended shutdown.

Touch the Operations and Maintenance tab on the V-DOCS screen to access the periodic maintenance procedures.

Storage Environment

The system can withstand the following non-operational conditions without degrading performance:

- Cold: -23.3 °C (-10 °F) at 5 - 15% RH for 12 hours
- Heat: 65.5 °C (150 °F) at 5 - 15% RH for 12 hours
- Humidity: 86% +5% RH at 35.5 °C (96 °F) for 12 hours

Clean System Exterior

1. Empty all WASTE containers.
2. Clean all obvious materials from the outside of the system with a cloth moistened with soapy water. Avoid excessive use of water. Remove soap residue with a cloth moistened with clean water.
3. Clean the system COVERS with distilled water.
4. Clean the MONITOR screen with non-ammonia glass cleaner.
5. Clean potentially contaminated areas of the system with soapy water and then with a 70% isopropyl alcohol-in-water solution.

   Note: Do not scrub excessively. Excessive scrubbing of the surfaces with the 70% isopropyl alcohol-in-water solution may remove the paint.

   Caution: Be sure to use 70% isopropyl alcohol and not more-concentrated solutions. It is critical that enough water be present to solubilize proteins. Do not use 10% bleach for general cleaning; it can corrode metal parts.
6. Allow the surfaces to air dry completely.

Chapter 4 System Centers Overview

This section includes the following topics:

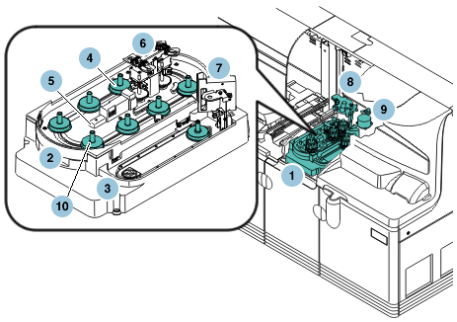
Sampling Center

The Sampling Center identifies, manages, and analyzes patient samples. In addition, the Sampling Center is where patient samples are aspirated and dispensed for processing.

TRAYS of patient samples are loaded into the SAMPLE SUPPLY (V-Docs) Load/Unload Area, where the system identifies each sample. BAR CODE READERS at the Metering Area, and STAT Metering Position read the bar codes affixed to the UNIVERSAL SAMPLE TRAYS and the individual sample tubes to identify samples and their location. The ROUTINE BAR CODE READER scans TRAYS and samples on the Routine Lane. The STAT BAR CODE READER only scans the TRAY and samples in the STAT Lane. The Routine Lane holds 8 UNIVERSAL SAMPLE TRAYS holding up to 10 samples per TRAY and moves samples of normal and designated STAT priority into position. The STAT Lane holds 1 TRAY, and positions samples of immediate priority, before any other samples in the Routine Lane. Once the samples are in position, MICROSLIDE METERING and MICROIMMUNOASSAY METERING PROBOSCISES aspirate the sample using VITROS VersaTips™ and dispense it as required to process the assays. CAP RETAINERS at the Metering positions help prevent the PROBOSCIS from removing pierceable caps after the sample is aspirated. The system reports the results on the Results Review screen, the laboratory report, and the patient report (if configured). The system also sends the results to the Laboratory Information System (LIS), if configured. If assay results are out-of-range for the initial test, the sample is re-aspirated and retested if the system is configured for reflex dilution.

If sample indices are enabled for the sample, the system aspirates the sample as described above and then analyzes the sample indices while the assay is processing. To perform the sample indices check, the system seals the VersaTip™ used to aspirate the sample fluid using the PRIMARY TIP SEALER. This creates a CuveTip™. The CuveTip™ moves into position within the MICROSENSOR SUBSYSTEM, where it checks for hemolysis, icterus, and turbidity. If the MICROSENSOR SUBSYSTEM detects an interferent value in a sample that exceeds the threshold for the assay, the system flags the result accordingly with a “H,” “I,” or “T.”

(Continued)



1 SAMPLE SUPPLY

2 Routine Lane

3 STAT Lane

4 TRAY TRANSPORT

5 TRAY MOTION INDICATOR

6 Metering Area

7 STAT Metering Position

8 MICROSENSOR SUBSYSTEM

9 SAMPLING CENTER VERSATIP RING

10 Load/Unload Area

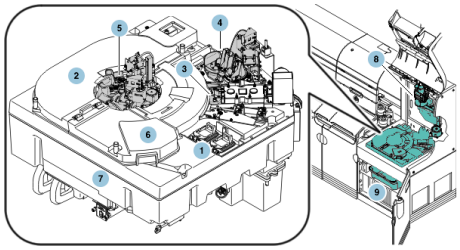
MicroSlide Center

The MicroSlide Center processes, incubates, and reads all MicroSlide assays.

A MicroSlide is dispensed from a bar-coded cartridge in the SLIDE SUPPLY to the TIP LOCATOR. At the TIP LOCATOR, MICROSLIDE METERING dispenses sample fluid onto the MicroSlide. For Potentiometric assays, ERF METERING dispenses Electrolyte Reference Fluid at the same time the sample fluid is dispensed. The MicroSlide is then delivered to the MICROSLIDE INCUBATOR. The MicroSlide incubates as it revolves to either the ELECTROMETER or REFLECTOMETER for a reading, depending on the assay type. For an Immuno-rate assay, WF METERING dispenses Immuno-Wash Fluid onto the MicroSlide at the appropriate time during incubation, before the reading. After the reading, the MicroSlide is discarded to WASTE CONTAINER C.

Tell me more about the MicroSlide Incubator (page 4-3)

(Continued)



1 SLIDE SUPPLIES
2 MICROSLIDE INCUBATOR
3 TIP LOCATOR
4 ERF METERING
5 WF METERING
6 ELECTROMETER
7 REFLECTOMETER
8 MICROSLIDE METERING
9 WASTE CONTAINER C

MicroSlide Incubator

Theory

The MICROSLIDE INCUBATOR consists of three concentric positions of two rings that keep metered MicroSlides incubated at 37 °C until they are read. The rings rotate independently to optimize MicroSlide assay processing. The outer PM RING incubates potentiometric slides and has 36 slots. The inner CM/RT RING has two positions that incubate CM, Rate, and IR MicroSlides: An outer CM Position and an inner Rate Position. Both positions of the CM/RT RING have 34 available slots.

- The ELECTROMETER reads PM slides.
- The REFLECTOMETER reads CM, Rate, and IR slides.

Events

1 The DISPENSE BLADE of the SLIDE SUPPLY pushes MicroSlides from the TIP LOCATOR into the PM RING, where all MicroSlides enter the MICROSLIDE INCUBATOR.

2 From the PM RING, one of the two INSERT BLADES pushes CM, Rate, and IR MicroSlides into the CM/RT RING for their incubation.

3 During incubation, one of the two INSERT BLADES pushes CM and Rate MicroSlides into the Rate Position to be read.

4 The RT DISCARD BLADE

- pushes IR MicroSlides from the CM Position to the Immuno-Wash location in the WF METERING ASSEMBLY
- pushes CM MicroSlides from the CM Position to the Rate Position for further incubation

The RE-INSERT BLADE moves IR MicroSlides from the Immuno-Wash location back into the Rate Position for further incubation.

5 Once MicroSlides are read

- the CM DISCARD BLADE pushes MicroSlides in the CM/RT RING into the CM DISCARD CHUTE or RT DISCARD CHUTE
- MicroSlides in the PM RING rotate to the Discard location of the ring and fall into the PM DISCARD CHUTE

MicroImmunoassay Center

The MicroImmunoassay Center processes, incubates, and reads all MicroTip and MicroWell assays. It is the complement to the MicroSlide Center (page 4-2) of the system.

The MICROIMMUNOASSAY REAGENT SUPPLY is environmentally controlled and automatically opens and closes reagent packs as needed. BAR CODE READERS in the SUPPLY identify packs after they are loaded.

MicroWellAssay Processing

MICROIMMUNOASSAY METERING picks up a tip from the MICROIMMUNOASSAY VERSATIP RING and aspirates sample fluid from the SAMPLE SUPPLY. It dispenses the fluid into a MicroWell that was shuttled from the MICROIMMUNOASSAY REAGENT SUPPLY to the OUTER RING of the MICROWELL INCUBATOR. (MicroWells used for pretreatment or dilution are shuttled to the MIDDLE RING.) MICROWELL REAGENT METERING picks up a VersaTip and dispenses reagent fluid into the MicroWell. The MicroWell with the sample and reagent revolves in the OUTER RING as it incubates. The INCUBATOR MICROWELL SHUTTLE moves the MicroWell to the INNER RING where one of the MICROWELL WASH STATIONS dispense Universal Wash Reagent, and SIGNAL REAGENT METERING dispenses Signal Reagent. The solution in the MicroWell then incubates in the INNER RING. The SHUTTLE moves the MicroWell to a position where the LUMINOMETER reads the chemiluminescence of the solution. After the reading, the MicroWell is discarded to WASTE CONTAINER B.

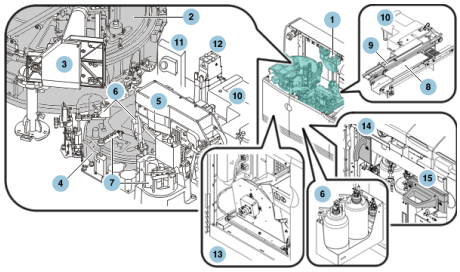
MicroTip Assay Processing

The following describes a typical example of MicroTip assay processing.

MICROIMMUNOASSAY METERING picks up a VersaTip and aspirates reagent. It dispenses the fluid into a cuvette in the CUVETTE INCUBATOR, and then seals and disposes the tip at the SECONDARY TIP SEALER. MICROIMMUNOASSAY METERING then picks up a MicroTip and aspirates sample fluid from a CuveTip at the MICROSENSOR SUBSYSTEM. It dispenses the sample into the cuvette with the reagent. As MICROIMMUNOASSAY METERING dispenses the sample fluid, it swishes it with the reagent to mix the solution. The solution incubates for a period, and then the PHOTOMETER measures the light absorption. After the read, the cuvette is discarded to WASTE CONTAINER B.

Note: In pre-diluted MicroTip assays, diluent is first aspirated into the cuvette, followed by the sample. MICROIMMUNOASSAY METERING mixes the sample and diluent together to use as the sample fluid that is added to the reagent.

(Continued)



1 MICROIMMUNOASSAY METERING

2 MICROIMMUNOASSAY REAGENT SUPPLY

- Supply 3 (MicroTip)
- Supply 4 (MicroWell)
- MICROIMMUNOASSAY VERSATIP RING

3 MICROWELL REAGENT METERING

4 MICROWELL INCUBATOR

5 LUMINOMETER

6 DUAL MICROWELL WASH SUBSYSTEM

7 SIGNAL REAGENT METERING SUBSYSTEM

8 MICROTIP SUPPLY

9 CUVETTE SUPPLY

10 CUVETTE INCUBATOR

11 PHOTOMETER

12 SECONDARY TIP SEAL/EJECT ASSEMBLY

13 VERSATIP SUPPLY

14 WASTE CONTAINER A

15 WASTE CONTAINER B

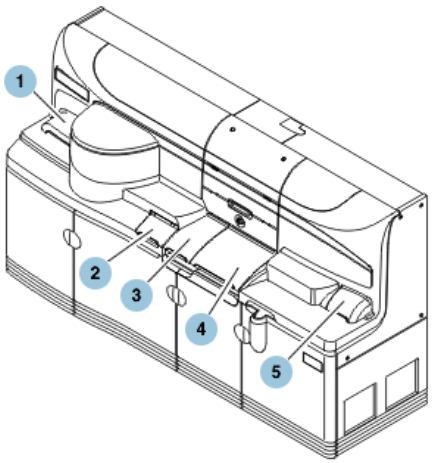
System Frame and Cabinetry

The System Frame and Cabinetry Center includes the following:

- Access Covers

- Doors
- Main Covers and Panels

Access Covers



1 MICROIMMUNOASSAY SUPPLY COVER

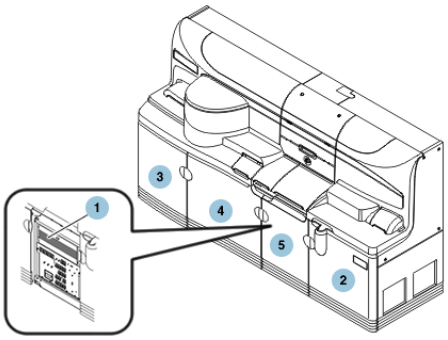
2 SIGNAL REAGENT SUPPLY COVER

3 MICROTIP/CUVETTE SUPPLYCOVER

4 SAMPLE SUPPLY COVER

5 MICROSLIDE SUPPLY COVER

Doors



1 MASTER COMPUTER ACCESS DOOR

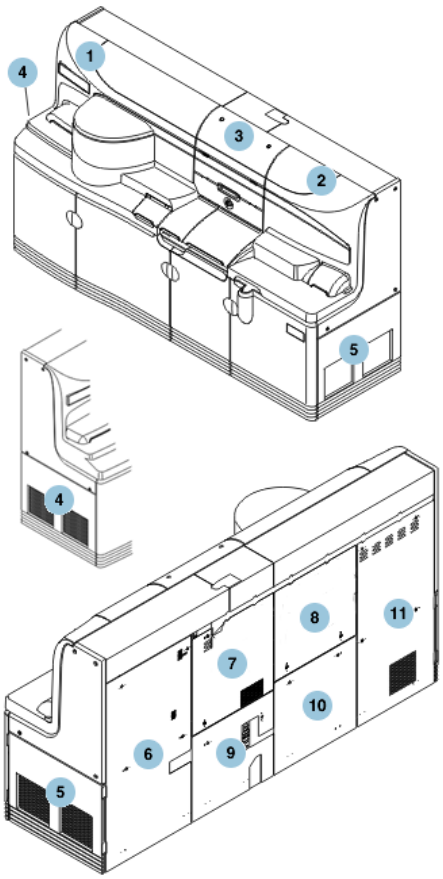
2 right door

3 left door

4 left-middle door

5 right-middle door

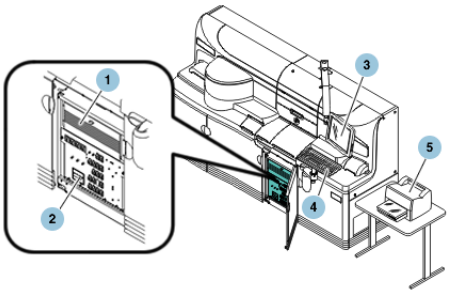
Main Covers and Panels



1. top left cover
2. top right cover
3. top center cover
4. left side bottom panel
5. right side bottom panel
6. right back panel
7. top right middle back panel
8. top left middle back panel
9. bottom right middle back panel
10. bottom left middle back panel
11. left back panel

Command Center

The Command Center consists of the input, output, and processing components of the system.



1. MASTER COMPUTER
2. SYSTEM POWER
3. TOUCHSCREEN MONITOR
4. KEYBOARD
5. PRINTER

COMMUNICATION PORT PANEL:
See description below (page 4-8)

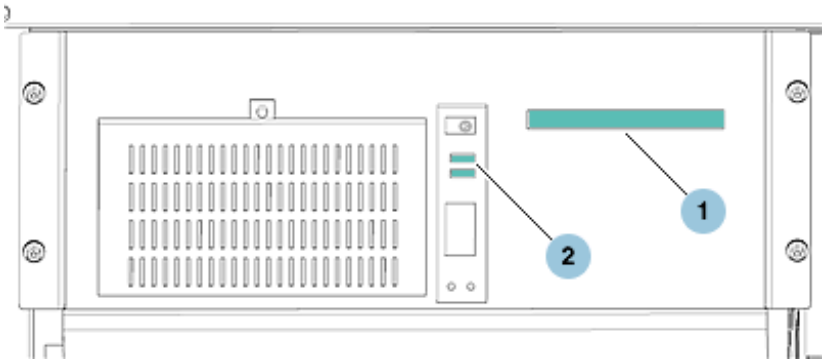
MASTER COMPUTER

The MASTER COMPUTERis a dedicated computer that stores data, provides software execution, and user interface facilities for the operator to interact with

the System. The MASTER COMPUTERinterfaces with all the subsystem driver boards, external and internal communication ports, and all peripherals.

The MASTER COMPUTER also contains a 1 DVD-RW DRIVE for loading software updates, loading Assay Data Disks, saving system information as log files, and data backup.

2 USB Ports are also available for data backup using a USB Flash drive.



Tell me more about loading software (page 17-41)

Tell me more about saving system information (page 17-39)

SYSTEM POWER

SYSTEM POWERis controlled by rows of CIRCUIT BREAKERS and a main power switch located below the MASTER COMPUTER. Some maintenance procedures require you to de-energize a circuit breaker(s) to cut off power to a system module.

Tell me more about system startup and shutdown (page 5-1)

TOUCHSCREEN MONITOR and KEYBOARD

The TOUCHSCREEN MONITOR and KEYBOARD serve as the point of operator input. User interface and V-Docs navigation is done by touching on-screen targets, such as buttons and links. The KEYBOARD is used to enter alphanumeric information within screens. The TOUCHSCREEN MONITOR and KEYBOARD are mounted on separate ergonomic articulating arms that can be positioned to access the system covers.

Tell me more about the User Interface (page 6-1)

COMMUNICATION PORT PANEL

The COMMUNICATION PORT PANELprovides access to the Serial, Ethernet, and USB ports and connectors.

These connections facilitate the following communication features:

- Laboratory Information System (LIS) (V-Docs)
- Laboratory Automation System (LAS) (V-Docs)
- e-Connectivity® (V-Docs)

Communication settings can be configured on the Options & Configuration – Configure Communication screen. See Configure Communication (page 17-29) for more information.

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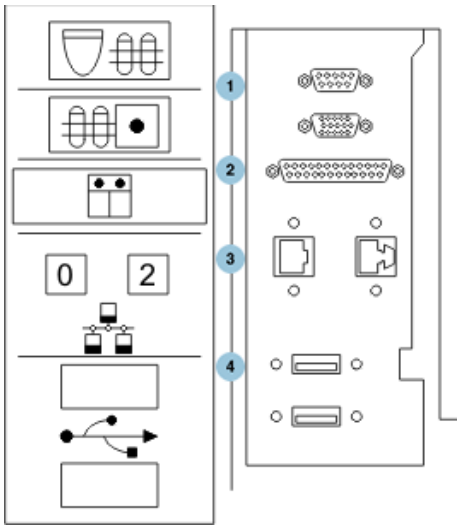

1 PCI to CAN interface connection for the LAS

2 RS-232 Serial Port for the LIS

3 Ethernet Ports — Port 0 is for the LIS and remote diagnostics (V-Docs) connectivity. Port 1 (not pictured) is for the metering arm. Port 2 is for internal system use only.

4 USB Ports for printers

Printer

The PRINTER connected to the system is used to print reports and logs.

Tell me more about Reports (page 12-1)

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Chapter 5 Startup and Shutdown

Refer to the following topics and procedures when starting up or shutting down the system.

- See System Setup (page 5-1) when you are starting the system for the first time or after the system has been shutdown for an extended period of time.
- See System Shutdown (page 5-2) to shutdown the system normally or to perform an emergency shutdown. When shutting down for extended periods of time, you should remove reagents from the system.

After the system is started up, you do not need to shut it down; it is intended to remain in operation 24 hours a day. When not in use, the system continues to control the temperatures of the reagent cooler and incubator; also, the motors operate in a reduced power state to conserve energy.

System Setup

This information should be reviewed before starting the system for the first time, or after the system has been shutdown for an extended period of time.

Note: Qualified Ortho Clinical Diagnostics Service Personnel perform initial system setup in your location.

Before starting the system:

- Close the system covers.
- Make sure the system is plugged into a grounded receptacle.
- Ensure the printer USB cable is plugged into the USB port located on the back of the system and the printer power cord is plugged into a receptacle.
- Examine the printer paper supply to ensure that paper is loaded properly and that a sufficient supply of paper is available for operation; add paper if necessary.

System Startup

Startup begins when you energize the system. It is completed when Ready is displayed on the Status Line (page 6-1) of the System Status screen.

Tell me how to Start the System (page 5-3)

Once startup is complete, you can:

- Set the Access Level (page 7-2)
- Select a Process Button (page 6-8) from the bottom of the screen
- Navigate through the User Interface (page 6-9)
- Use the System Status (page 7-1) screen to check the status of system components

Lab Computer and Printer Status

After initial startup, use the Options & Configuration – Configure Report Control screen to set up or verify the status of the lab computer and printer(s) used for reporting during system operation. The Options & Configuration – Configure Report Control screen provides the status of these devices at any time during system operation.

Tell me more about configuring report control (page 17-27)

System Shutdown

The system is intended to remain in operation 24 hours a day. If you need to shut down the system, follow normal shutdown procedures.

If sample metering is underway or assays are processing when you shut down, you can select one of the following options:

- Cancel metering or processing and continue with shutdown
- Cancel shutdown and continue with metering or processing
- Wait for metering or processing to complete and automatically continue with shutdown

Normal Shutdown

Shutdown consists of two states:

- Shutdown state — The system remains operational. Reagents may remain loaded when the system is in the shutdown state.
- Final shutdown state — You can de-energize the system or reset it from the final shutdown state.

Note: See Electrical Hazards (page 3-2) for more information about the main power switch and how to disconnect the main electrical source.

Tell me how to Shutdown the System (page 5-4)

Emergency Shutdown

An emergency shutdown should only be performed if normal shutdown procedures are not available.

Caution: Emergency shutdown may cause loss of data from the fixed disk or damage to the fixed disk.

- To perform an emergency shutdown, move the main power switch to the Off position. Wait 10 seconds before attempting to restart the system.
- To restart after an emergency shutdown, wait 10 seconds after moving the main power switch to the Off position. Then, move the main power switch to the On position. Follow the steps outlined in System Startup (page 5-1).

If system power is interrupted (for example, due to an unintentional power loss), current assay processing is lost; however, configuration information may be saved. To energize the system, move the main power switch to the On position. See System Startup (page 5-1) for more information.

Extended Shutdown

If the system needs to be shutdown for an extended period of time the reagents must be removed and the system needs to be cleaned. Certain maintenance procedures should also be performed prior to starting the system after an extended shutdown.

Touch the Operations and Maintenance tab on the V-DOCS screen to access the periodic maintenance procedures.

Startup and Shutdown Procedures

The following table lists the Startup and Shutdown topics that reference the procedures included in this section.

Topic Title	Procedure Title
System Startup (page 5-1)	Start the System (page 5-3)
System Shutdown (page 5-2)	Shut Down the System (Normal Shutdown) (page 5-4)

Energize the System

Special requirements: Close all covers and make sure the system is plugged into a grounded receptacle.

1 Open the RIGHT MIDDLE DOOR of the system.

2 Energize the system by moving its main power switch to the On position.

A set of internal computer commands verifies that the system's computers and memory are operating correctly. After this verification, the system initializes its subsystems and components. The system sends all subsystems to their startup positions and powers on environmental controls.

A blank screen is displayed briefly as the system energizes, followed by the Startup/Shutdown screen. The system displays the following status information, one line at a time, on the status line:

Startup in _ seconds

(The status line replaces _ with the number of seconds until startup)

Verifying databases.

The system is proceeding to Operational State.

The system first counts down for 10 seconds before beginning to verify databases. During this 10 seconds, you can touch the following process buttons:

- Final Shutdown — Used to halt the startup process
- System Menu — Used to configure languages, restore or optimize databases, and install new software
- View Patents — Used to review all United States patents that apply to the system.

Once the startup process begins, the process buttons are disabled.

The System Status screen is displayed when the system is in operational state. The Status Console contains the message:

Initializing. . .

When startup is complete, the status console contains the message:

Ready

The system is now ready for operation.

3 Energize the PRINTER by moving its main power switch to the On position.

Shut Down the System (Normal Shutdown)

1 Unload reagents from the system if it will be shut down for an extended period of time. Touch  to display the Reagent Management screen and unload reagents. Store unloaded reagents according to their Instructions for Use.

- Unload VITROS Chemistry Products MicroSlide reagents if the system will be shut down for two hours or longer
- Unload VITROS Chemistry Products MicroTip reagents if the system will be shut down for 30 minutes or longer.
- Unload VITROS Immunodiagnostic Products reagents (reagent packs, Signal Reagent and Universal Wash Reagent) if the system will be shut down for an extended period of time.

2 Check the status console for condition messages. If conditions are reported, touch the  button and perform the recommended actions to resolve all reported conditions.

3 Touch  to display the System Status screen.

4 Touch Shutdown.

The system displays one of two Confirm Shutdown dialogs, depending on system activity.

System Activity	Confirm Shutdown Dialog	Action
Metering and assay processing are not in progress	Shut down the system?	• Touch Yes to continue with shutdown. • Touch No to cancel the shutdown.
System is processing samples	There are assays currently in progress. Shutting down now will cancel those assays. Shutdown the system?	• Touch Yes to continue with shutdown. • Touch No to cancel the shutdown.

Once the Confirm Shutdown dialog box is no longer displayed, the system displays the Startup/Shutdown screen. The following shutdown messages are displayed on the status line:

Shutting down operational tasks. . .

Select a process below to continue.

5 Touch Final Shutdown to begin the final shutdown procedure.

The status line displays the following messages:

The system is proceeding to Final Shutdown.

Final shutdown complete; it is now safe to power off the system.

6 De-energize the system by moving the main power switch to the Off position.

7 De-energize the printer. Refer to the printer documentation for specific instructions.

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Chapter 6 User Interface Overview

Master Computer System Electronics

The user interface for the Master Computer consists of a flat panel monitor with an integrated touch screen, and a keyboard on articulating arms.

Tell me how to Set Volume and Lock Monitor (page 6-11)

Tell me more about the MASTER COMPUTER and the COMMAND CENTER (page 4-7)

System Screens

The System Status screen is the first user interface screen that displays when system startup completes. From this screen, you can access all major system functions and shut down the system. The system functions are represented by navigation buttons at the top of the screen. Each function is color coded; the same color is used for all screens within a function.

Tell me more about System Status (page 7-1)

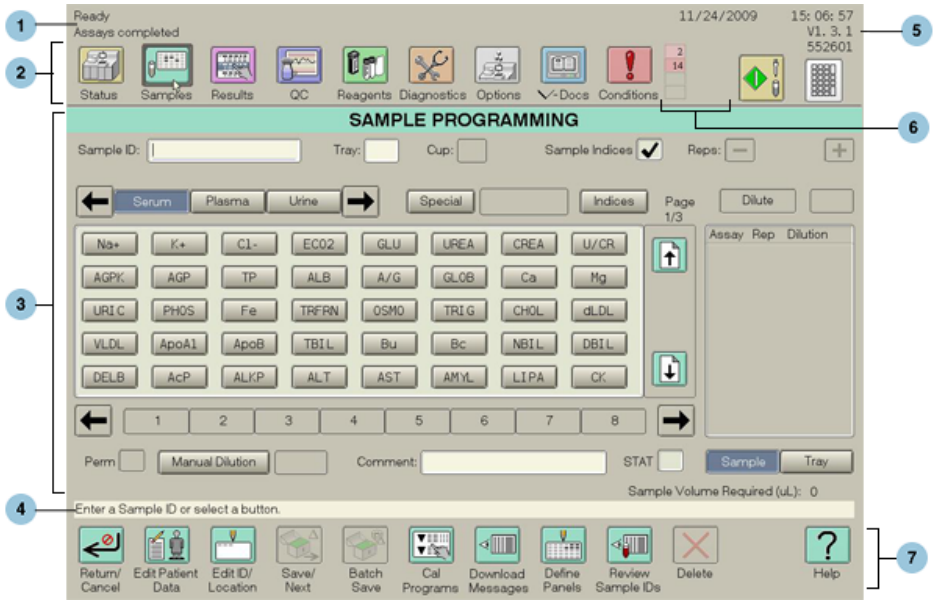
The user interface consists of three main areas:

- Status Console (page 6-2)
- Function Screen (page 6-8)
- Process Buttons (page 6-8)

These areas are shown in the Interface Layout (page 6-1).

Interface Layout

Refer to the table below for information about the user interface areas.



(Continued)

1. Status Line	Displays the status of the system (top line) and the status of assay processing (bottom line)
2. Status Console	Contains navigation buttons to access the system function screens, the Start Sampling and End Sampling buttons, and status indicators. Tell me more about the Status Console (page 6-2)
3. Function Screen	Performs system functions. The screen title displays the name of the currently active screen. Use the navigation buttons in the Status Console to change the active function screen. Tell me more about the Function Screen (page 6-8)
4. Prompt Line	Displays instructions and feedback needed to perform tasks within the function screen.
5. Time, Date, and Version Display	Shows the current date and time, installed system software version, and installed Assay Data Disk version.
6. Status Indicators	Displays a count of unreviewed condition codes, LIS and LAS configuration information, e-Connectivity status, and the current user access level. For more information, see: • System Status Overview (page 7-1) • Sample Programming Overview (page 9-1)
7. Process Buttons	Executes operations within the current function screen. These buttons change according to the function screen displayed. Tell me more about the Process Buttons (page 6-8)

Status Console

The Status Console is located near the top of the user interface screen and remains in place to be accessible from every function screen. The Status Console displays the current state of the system and contains the navigation buttons used to access the different function screens. The Status Console also contains the Start Sampling and End Sampling buttons.

Navigation Buttons

The different system function screens can be displayed by touching one of the navigation buttons in the Status Console.

Navigation Button	Result
 Status	Displays the System Status screen used to quickly identify the status of several subsystems and supply levels Tell me more about System Status (page 7-1)
 Samples	Displays the Sample Programming screen used to select assays and program samples. Tell me more about Samples (page 9-1)
 Results	Displays the Results Review screen used to evaluate and manage assay results Tell me more about Results (page 11-1)
 QC	Displays the Quality Control (QC) screen used to edit QC parameters and review QC results Tell me more about Quality Control (page 14-1)
 Reagents	Displays the Reagent Management screen used to review and manage the reagent supply Tell me more about Reagents (page 15-1)
 Diagnostics	Displays the Diagnostics screen used to evaluate system operation and perform periodic maintenance Tell me more about Diagnostics (page 16-1)
 Options	Displays the Options & Configuration screen used to set system defaults, customize system features, and perform system services Tell me more about Options (page 17-1)

(Continued)

 V-Docs	Displays the V-Docs screen used to view online documentation for system operation and maintenance Tell me more about V-Docs (page 2-1)
 Conditions	Displays the Condition Review screen used to view system condition codes Tell me more about Conditions (page 18-1)

Status Line

The Status Line displays system and sampling status messages on the top left corner of the Status Console.

Ready Sampling in progress	Displays the status of the system (top line) and the status of assay processing (bottom line) System Status Messages: • The system is currently Initializing • The system is currently Equilibrating its environment(s) • The system is currently Ready for sample processing • The system is currently in Diagnostics Mode • The system is currently Not Ready for sample processing Sampling Status Messages: • Sampling In Progress - the system is performing primary metering or searching for samples to meter in the sample handler • Assays In Progress - sampling is complete but processing is continuing • Assays Completed - no samples are currently being processed • External Sampling in Progress - the system is metering samples from the Automation Track. • Internal External Sampling in progress - the system is performing primary metering or searching for samples to meter in the sample handler and metering samples from the Automation Track.

Subsystem Status

The Subsystem status area of the Status Console may display one or more of the following icons to indicate that a subsystem is not operating, or is operating outside of a normal state.

	A subsystem is inoperative.
	A subsystem is out of range.
	A subsystem is disabled.
	Environmental monitoring is disabled.

Touch the View Subsystems process button on the System Status screen to identify the subsystems that are disabled, out of range, or inoperative. Subsystems operating normally will not be listed.

Condition Codes

	Shows the number and type of condition codes that have not been reviewed; from top to bottom: Attention codes, Action codes, Malfunction codes, and Shutdown codes.

Tell me more about Condition Codes (page 18-3)

LIS Status

The status console displays icons that indicate communication activity between the system and the Laboratory Information System (LIS).

Icon	Description
	LIS configured and enabled
	LIS configured, but not enabled
	LIS downloading
	LIS uploading
	LIS in Query mode
	LIS download messages are present

LAS Status

The LAS status icons identify the status and activity of the Laboratory Automation System (LAS).

	MicroSlide LAS configured and enabled
	MicroSlide LAS configured, but not enabled
	MicroImmunoassay LAS configured and enabled
	MicroImmunoassay LAS configured, but not enabled

E-Connectivity

The e-Connectivity area of the Status Console Indicates the level and state of e-Connectivity.

	e-Connectivity Level 1 is active
	e-Connectivity Level 1 is configured but not active
	e-Connectivity Level 2 (remote control) is active

Access Levels

The access level icons indicate if Key Operator or Service level access is enabled.

	Service level access
	Key Operator level access

Tell me more about System Access (page 7-2)

Sampling Button

The Sampling button has two states depending on the sampling status. Touch the Start Sampling button to initiate sampling. Touch the End Sampling button to stop the metering process. Metering is halted after the sample currently being metered is complete.

(Continued)

	Ready to Sample
	Sampling in Progress

Date and Time – Software Version

5/29/2008 10:21:30 3.5 1510	Displays the system date and time, the system software version (second line) and assay data version (bottom line)

Input Mode

The input mode selection provides a means of converting keystrokes from the keyboard into specific Asian language text.

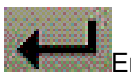
	Input mode selections for Asian language input processor

Virtual Keypad Features

When the monitor is not close to the keyboard, the Virtual Keypad can be used for data entry (values or dates) and value adjustment (increase/decrease values via adjustment keys).

The Virtual Keypad helps to facilitate the following system functionality, but it may also be used with any field that accepts data entry or value adjustment.

- Reagents – Manual Load
- Diagnostics – Adjustments
- Diagnostics – MEDs
- Diagnostics – Performance Tests

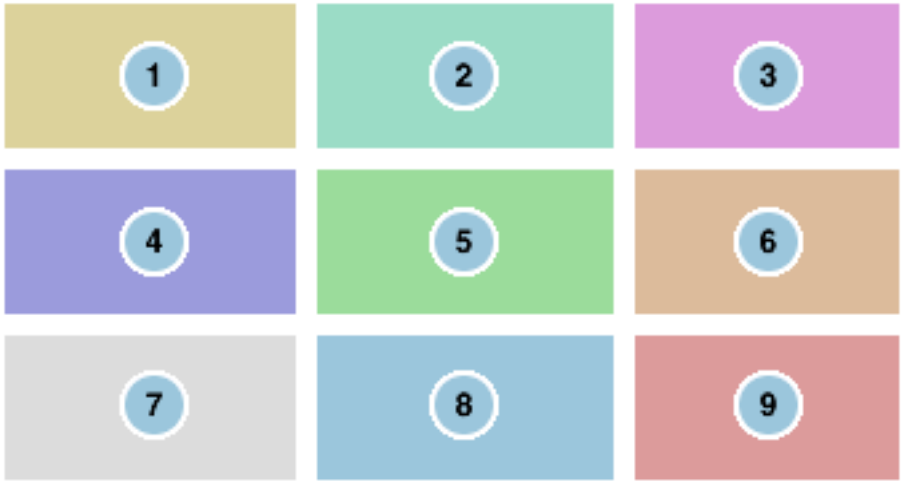
	Launches the Virtual Keypad
Numeric keys 0…9	Used to enter required values
 Enter key	Used to transfer values from the Virtual Keyboard to the focus field of concern
←Backspace key	Used to backspace one digit
Decimal key	Used to enter a decimal place or a European date separator
Arrow/adjustment keys, <, >, \/, /\	Adjustment functionality keys

(Continued)

Page Up Page Down	Adjustment keys
Multiplier key	Toggle key used in conjunction with adjustment keys to increase the adjustment by a multiple amount
"/", "-"	Date and numeral separator keys, respectively

Function Screen

The function screen area, located below the Status Console, occupies the majority of the user interface. This part of the screen changes as you switch between the system screens. The function screen title bars are color coded so that their main screen, sub-screens, and buttons match.



Function Screen	Color Code
1. Status	Gold
2. Sample Programming	Teal
3. Results Review	Fuchsia
4. Quality Control	Purple
5. Reagent Management	Green
6. Diagnostics	Peach
7. Options & Configuration	Grey
8. V-Docs	Blue
9. Condition Review	Pink/Red

Process Buttons

The process buttons are located at the bottom of the user interface screens. Touch these buttons to display additional function screens or to perform actions

on the current screen. These buttons change according to the function screen that is currently displayed.

The following process buttons are available on the Sample Programming screen.

The Help button and the Return/Cancel button are always available as process buttons.

Process Button	Result
 Help	Information about using the current function screen is displayed
 Return/Cancel	Cancels an operation or returns to the previous function screen

User Interface Navigation

The navigation and process buttons on the user interface enable operators to access various function screens, sub-screens and dialog boxes.

Tell me more about Navigation Buttons (page 6-3)

Tell me more about Process Buttons (page 6-8)

How to Move Between Function Screens

If an operator is actively working on a function screen or sub-screen, it is possible to navigate to a different function and then easily return to the previously active screen. When a navigation button is touched on the Status Console, the user interface will display the screen that was previously active within that function the last time it was used.

For example, an operator that is actively working on the Sample Programming – Edit Patient Data sub-screen, can touch the Options navigation button to configure system options. When the Samples navigation button is touched again, the user interface will display the previously active Sample Programming – Edit Patient Data sub-screen. This prevents operators from having to navigate back to a previously active screen when switching between functions.

How to Move through Sub-screens

If a function sub-screen is active, touch the Return button to display the previous screen. Touch the Return/Cancel button on screens that facilitate operator input to display the previous screen without saving any changes. Touch the Save button to keep any entered values, selections, or changes before touching the Return/Cancel button.

Touch the Return button from any of the top level function screens to display the System Status screen.

To return immediately to the top level function screen from any sub-screen, touch the navigation button again in the Status Console.

Dialog Boxes

Dialogs boxes are pop-up windows that display over the active function screen. All areas of the function screen are inactive until the dialog is dismissed. If data has been entered, be sure to touch Save first. Once a dialog box is launched, it is not possible to navigate to other screens until it is dismissed.

Button Behavior

Button	Result
Return	Moves back a screen from within a system function
Return/Cancel	Cancels any configurations appearing on the screen and returns to the previous screen
Save	Saves the configurations appearing on the screen
Cancel in a dialog box	Dismisses a dialog box without saving any new selections
Save in a dialog box	Saves the selections and changes made
The navigation button for the active function screen	Returns to the top level function screen, from within a sub-screen
A navigation button for a different function screen	Switches between function screens

Hot Keys

Certain key combinations enable you to perform actions without touching the screen. These hot keys can be helpful if your touchscreen has become uncalibrated.

For instance, to calibrate the touchscreen, touch [F6] to activate the Diagnostics button, and [Home] to activate the Calibrate Touchscreen process button.

Key Combination	Result
[F12]	Activates Stop Sampling button
[F11]	Activates the Start Sampling button
[F9]	Activates the Conditions button
[F8]	Activates the V-Docs button
[F7]	Activates the Options button
[F6]	Activates the Diagnostics button
[Home]	Activates the Calibrate Touchscreen button
[F5]	Activates the Reagents button
[F4]	Activates the QC button
[F3]	Activates the Results button

(Continued)

[F2]	Activates the Samples button
[F1]	Activates the Status button
[Ctrl + C]	Copy
[Ctrl + X]	Cut
[Ctrl + V]	Paste
[Delete]	Deletes the character appearing after the cursor
[Left Arrow]	Moves left one character in an input field when text is present
[Right Arrow]	Moves right one character in an input field when text is present
[End]	Scrolls to the end of a list or moves to the end of an input field
[Home]	Scrolls to the top of a list or moves to the beginning of an input field
[Space]	Selects an item in a list
[Up Arrow]	Scrolls up one line in a list
[Down Arrow]	Scrolls down one line in a list
[Page Down]	Scrolls down one screen in a list
[Page Up]	Scrolls up one screen in a list
[Shift + Tab]	Confirms a text entry and moves to the previous field
[Tab], [Enter]	Moves to the next field, and Confirms a text entry

User Interface Procedures

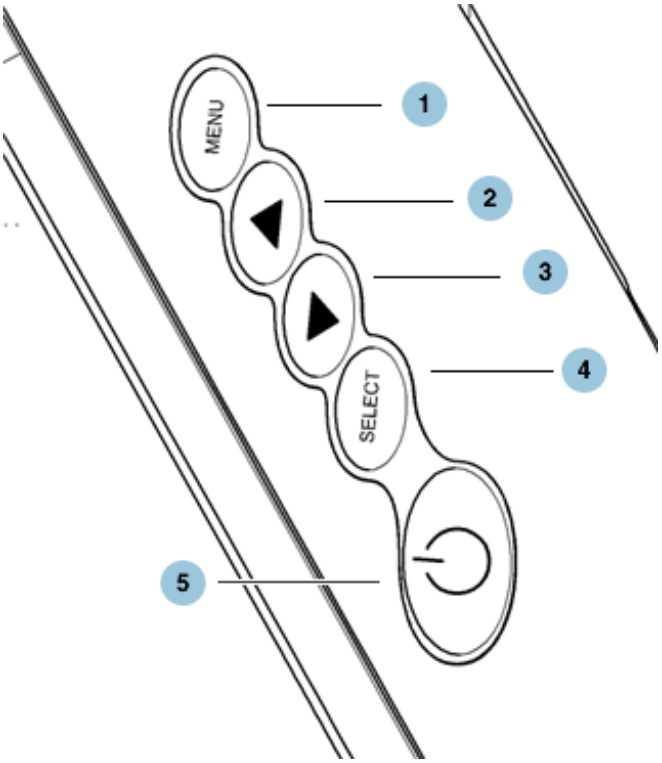
The following table identifies the User Interface topic that references the procedure included in this section.

Topic Title	Procedure Title
User Interface Overview (page 6-1)	Set Volume and Lock Monitor (page 6-11)

Set Volume and Lock Monitor

Adjust the volume (or disable mute) of the system using the monitor buttons. Steps 4 and 5 describe how to lock the monitor.

1 Enable the On Screen Display (OSD) on the monitor.



1	Menu	Display on exit the OSD menus.
2	Up Toggle	• Shortcut to Contrast adjustment • Increase value of adjustment items • With menu on, toggles OSD options
3	Down Toggle	• Shortcut to Volume adjustment • decrease value of adjustment items • With menu on, toggles OSD options
4	Enter Select Item	• Shortcut to Auto Adjust • Select — To select the adjustment items from the OSD menus • Auto — To activate the “Auto Adjustment” function to obtain an optimum image
5	Power	Switches the power on/off to the touchscreen monitor

a Press and hold at the same time the top button (Menu) and second button (Up).

A window is displayed that toggles between “OSD Lock” and “OSD Unlock.”

b When the “OSD Unlock” is displayed, release the buttons.

2 Once the OSD is unlocked, touch the third button to enable the volume control.

3 Use the top two buttons (Up and Down) to adjust the volume.

4 When done, press and hold the top and second buttons until “OSD Lock” is displayed.

5 Release the buttons.

This locks the monitor.

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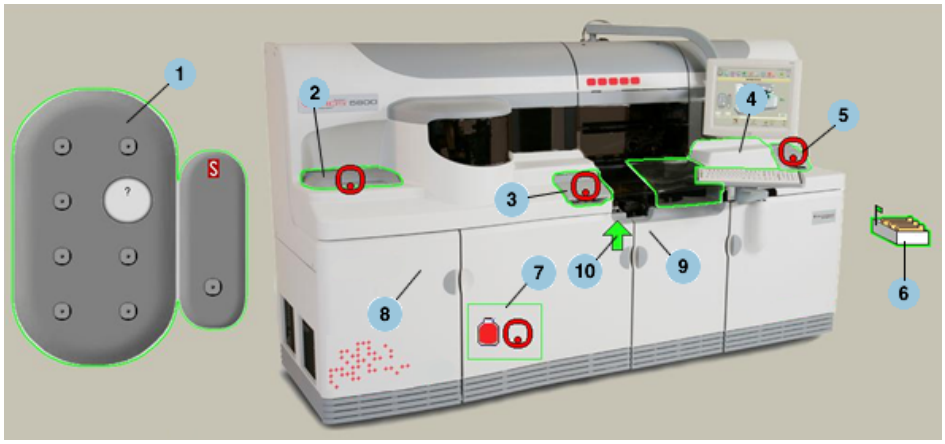
Chapter 7 System Status Overview

Use the System Status screen to check the current status of system components.

The System Status screen appears when the Status navigation button is touched on the Status Console, or when Return is touched on any V-Docs or top-level function screen.

The System Status Screen

The System Status screen contains a picture of the system with certain areas outlined in color. When the outlined areas are touched, the status of that system component is displayed. Some areas contain icons that identify the component's status. See Supplies (page 7-4) for more information.

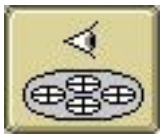


1	View Tray Status (Sample Supply) (page 7-7)
2	MicroImmunoassay Reagent Supply (page 7-6)
3	Signal Reagent Carousel Supply (page 7-6)
4	Fluid Supplies (page 7-6) — Includes Electrolyte Reference Fluid (ERF) and Immuno-Rate Wash Fluid (IWF)
5	MicroSlide Supplies 1 and 2 (page 7-5)
6	Delivered Files (page 7-3) (when software or ADD files have been delivered)
7	Universal Wash Reagent (page 7-7) and Liquid Waste (page 7-8)

(Continued)

8	VITROS VersaTip Supply (page 7-6)
9	MicroTip Supply (page 7-6)
10	CUVETTE SUPPLY (page 7-6)

The following functions can also be performed on the System Status screen.

Process Button	Description
	**Shutdown**: Initiate system shutdown Tell me more about System Shutdown (page 5-2)
	**Set Access Level**: Change or set the system access level Tell me more about System Access and Login (page 7-2)
	**View Subsystems**: Display the View Subsystem Status dialog box. Tell me more about Subsystem Status (page 6-5)
	**Login**: Login or logout using an Operator ID Tell me more about System Access and Login (page 7-2)

J Number

The system J Number is displayed on the lower-right corner of the System Status screen. This number is entered during the manufacturing process and/or during system installation. It is used to used to uniquely identify each system. Operators should not edit or modify this value.

System Status Sounds

Tones can be enabled for certain system status events such as low supply levels or full waste containers.

The Options & Configuration – Configure System (page 17-21) screen includes a Sound function that can be used to configure sound settings.

System Access and Login

The Set Access Level and Login process buttons on the System Status screen launch two separate functions that specify operator system access and operator identification. Both of these functions are optional and not required for general operator activities.

System Access

A code issued by Ortho Clinical Diagnostics can be used to set the level of system access for different types of operators. This enables higher level operators to access secure functions without having to re-enter a password. User level access is the default setting that is available to operators if no access

code is entered. Any operator at this level can perform general operator activities such as sample processing and daily maintenance.

The system provides three levels of access security as described in the following table. An icon will appear in the Status Console to indicate if Key Operator or Service level access is enabled.

Caution: Do not attempt to access and perform functions for which you are not trained. Damage to the system or bodily injury could result.

Icon	Description	Functionality
No Icon	User level access	Enables access for general operator activities such sample processing and daily maintenance.
	Key Operator level access	Enables user level access plus additional maintenance and diagnostic activities. Allows editing and modifying of system configuration data.
	Service level access	Enables access for trained service personnel only.

Tell me how Set System Access (page 7-9)

Operator Login

The login/logout function does not affect system access. It is used by the system to associate a unique Operator ID with result records that are generated while that operator is logged on. The login Operator ID can be 1 to 15 characters long. The login function is optional and it is not required to startup and run the system.

- The system stores only the ID of the operator who is currently logged on.
- The Operator ID prints on Lab, Calibration, and Lot Switch reports. It currently does not print on the Patient Report.
- The Operator ID is stored with every result record on the data log file.
- Calibration reports store the Operator ID in the cal curve record.
- The Operator ID is sent to the LIS. The data log file captures the Operator ID, the access level (Key Operator or Service), and the time.
- On shutdown, the operator is automatically logged off and will need to login after startup.

Tell me how to Login and Logout (page 7-9)

Note: The login Operator ID that is saved with result records is different than the maintenance Operator ID used to record maintenance activities.

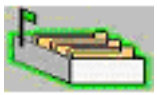
Tell me more about Periodic Maintenance (page 16-2)

Delivered Files

Ortho Clinical Diagnostics can remotely deliver files to your system electronically using e-Connectivity®. The files may include:

- Assay data (includes calibration protocols)
- New software releases (includes V-Docs updates)

One of the following icons is displayed on the System Status screen to indicate the status of delivered files.

Icon	Description
	No new files were delivered.
	New files have been delivered; can also provide access to the ADD History Chart, Release Notes, and Installation Instructions.

When you touch the Delivered Files icon, the system displays a dialog summarizing the files that are available. You can choose to display:

- ADD History Chart – Provides information about data delivered via the Assay Data Disk
- Release Notes – Provides information about a new release of software
- Installation Instructions – Provides step by step instructions for installing a new release of software

Touch the button for the information you want to display.

Tell me how to Load System Data (page 17-40)

Supplies

The following supply levels can be monitored on the System Status screen:

- MicroSlide (page 7-5)
- Fluid (ERF and IWF) (page 7-6)
- Signal Reagent (page 7-6)
- MicroImmunoassay Reagent (page 7-6)
- VITROS VersaTip (page 7-6)
- VITROS FS MicroTip (page 7-6)
- VITROS FS Cuvette (page 7-6)
- Universal Wash Reagent (page 7-7)

The System Status screen will display icons over various outlined supply areas to indicate when the threshold level has been reached, or when there are no supplies available.

Icon	Description
	The number of calibrated tests, reagents, or diluents for at least one type is at low level threshold. (Other Supplies) Available supplies are at low level.

(Continued)

	The number of calibrated tests, reagents, or diluents for at least one type is at zero. (Other Supplies) Available supplies are at zero.
	The MICROTIP SUPPLY contains less than three trays of tips; another tray may be loaded. The CUVETTE SUPPLY contains less than two blocks of cuvettes; another block may be loaded.

Tell me more about the System Status Screen (page 7-1)

Tell me How to Configure Thresholds for supplies (page 17-23)

When the MicroImmunoassay Reagent or the MicroSlide supply area is selected, a dialog box displays inventory information using the following color codes:

Text Color	Indication
Black	MicroSlide reagents have a total calibrated slide count above the low level slide threshold limit MicroImmunoassay Reagent levels are above the low level threshold
Yellow	MicroSlide reagents have a total calibrated slide count equal to or below the low level slide threshold limit MicroImmunoassay Reagent levels are equal to or below the low level threshold
Red	MicroSlide reagents have zero calibrated slides. This includes slide types that are on board and slide types that are not on board but have a current calibration. MicroImmunoassay Reagents that have zero calibrated tests or a zero volume/test count remaining.

MicroSlide Supplies

The icon in this area of the System Status screen shows the current status of MicroSlide Supplies 1 and 2.

Tell me how to configure threshold limits for MicroSlide Supplies (page 17-23)

When the outlined MicroSlide Supplies area on the System Status screen is touched, a dialog box displays inventory information for the MicroSlide reagents, indicating the quantity of slides available for each assay.

Touch Print to print an Inventory Report.

Where Is It? — Slide Supply 1 and 2 (page 4-2)

Fluid Supplies

The Fluid Supplies area of the System Status screen indicates the current supply status of the VITROS 950/FS Electrolyte Reference Fluid (ERF) and VITROS Immuno-Wash Fluid (IWF).

Tell me how to configure threshold limits for Fluid Supplies (page 17-23)

When the outlined Fluid Supplies area on the System Status screen is touched, a dialog box displays a level indicator for ERF and IWF, and the number of tests that the current fluid level can accommodate.

Tell me more about ERF/IWF (page 15-6)

Where Is It? — ERF and WASH FLUID (WF) METERING (page 4-4)

Signal Reagent Carousel

The Signal Reagent Carousel area of the System Status screen indicates the current status of at least one of the three Signal Reagent supplies.

When the outlined Signal Reagent Carousel area is touched on the System Status screen, a dialog box displays a bar graph for each of the containers showing the total number of tests remaining and the lot number of the container that is in the metering position.

Where Is It? — Signal Reagent Carousel (page 4-4) (part of the SIGNAL REAGENT METERING SUBSYSTEM)

MicroImmunoassay Reagent Supply

The MicroImmunoassay Reagent Supply area is where MicroTip and MicroWell reagents, diluents, and ancillary packs are loaded and stored.

Tell me how to configure threshold limits for MicroImmunoassay Reagent Supplies (page 17-23)

When the outlined MicroImmunoassay Reagent area on the System Status screen is touched a dialog box displays inventory information for the MicroImmunoassay Reagents.

Where Is It? — MicroImmunoassay Reagent Supply (page 4-4)

VITROS VersaTip Supply

The VITROS VersaTip Supply holds approximately 2000 VITROS VersaTips when full.

An icon will appear in the VersaTip supply area on the System Status screen to indicate a low or zero level.

Where Is It? — VITROS VERSATIP SUPPLY (page 4-4)

VITROS FS MicroTip Supply

The VITROS FS MicroTip Supply holds three trays containing 128 VITROS FS MicroTips each, a total of 384 VITROS FS MicroTips.

An Icon will appear in the MicroTip supply area on the System Status screen to indicate the current level.

Where Is It? — MICROTIP SUPPLY (page 4-4)

VITROS FS Cuvette Supply

The VITROS FS Cuvette Supply holds two blocks of 150 VITROS FS Cuvettes, a total of 300 VITROS FS Cuvettes.

An icon will appear in the Cuvette supply area on the System Status screen to indicate the current level.

Where Is It? — CUVETTE SUPPLY (page 4-4)

Universal Wash Reagent

An icon will appear in the Universal Wash Reagent (UWR) supply area on the System Status screen to indicate a low or zero level.

When the outlined UWR area on the System Status screen is touched a dialog box displays UWR inventory information.

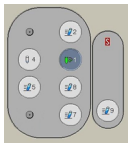
Where Is It? — UWR (page 4-4) (part of DUAL MICROWELL WASH SUBSYSTEM)

Sample Supply

The Sample Supply area of the System Status screen indicates where TRAYS, or samples are located in the system SAMPLE SUPPLY.

Tell me more about the SAMPLING CENTER (page 4-1)

Touch the outlined Sample Supply area to display the System Status – View Tray Status screen.

	The System Status – View Tray Status screen displays a graphical representation of the samples currently in the system SAMPLE SUPPLY. Each tray is represented by a circle with an icon that indicates the sampling status.

The following icons represent the sampling status for each given TRAY:

Icon	Description
	No sample tray is in this position.
?	A tray exists in this Sample Supply position but the tray number is unknown.
	At least one sample on a tray has the status of retest.
	At least one sample has a status of sample metering in progress.
	No metering is occurring on this tray, no samples have a status of retest and at least one sample has a status of tests in progress.
	The results for all samples on this tray are complete.
	No work has been programmed for any samples on this tray.

Tray Selection and Sample ID

Touch one of the TRAY icons to display a list of samples in that TRAY. A status icon will be displayed for each sample (as described above) along with the

sample cup position and Sample ID.You can also type a **Sample ID** to locate that sample in the system SAMPLE SUPPLY.

Tell me more about Sample Program IDs (page 9-7)

Process Buttons

The following process buttons are available in the View Tray Status screen.

Process Button	Description
 Update Status	Updates the contents of the Sampling Center graphic that displays the location of the trays in the Sample Supply at the time the button is selected. This graphic depicts a snapshot in time.
 Retrieve Tray	Retrieves the selected tray. If sampling is in process, metering of the current sample will complete before retrieval will begin. When retrieval ends, sampling will resume unless it was otherwise stopped.
 View Log	Displays a list of the last 50 samples that left the Sampling Center before reprocessing could occur.

Tell me how to Retrieve a TRAY (V-Docs)

Tell me how to Retrieve a Sample (V-Docs)

Waste Container Status

There are several waste container areas on the system that require attention. A status of each is available on the System Status screen. Icons indicate which waste container is approaching, or at a full level. Both solid and liquid waste containers can be emptied at any time. A full waste container shuts down metering capabilities.

Note: To avoid overflow conditions, waste containers must be emptied when removed. The user interface assumes that waste containers are empty when they are put back in the system.

Tell me more about waste containers (page 8-23)

Waste Container Capacity

Icon	Description
	The waste container is reaching the full level.
	The waste container is full, or has been removed.

Tell me how to empty WASTE CONTAINER A (V-Docs)

Tell me how to empty WASTE CONTAINER B (V-Docs)

Tell me how to empty WASTE CONTAINER C (V-Docs)

Liquid Waste Capacity

Icon	Description
	The liquid waste container is reaching the full level.
	The liquid waste is full, or the primary liquid waste bottle has been removed.

Tell me how to Remove and Empty Liquid Waste (V-Docs)

System Status Procedures

The following table lists the System Status topics that reference the procedures included in this section.

Topic Title	Procedure Title
System Access and Login (page 7-2)	• Log In and Log Out (page 7-9) • Set System Access (page 7-9)

Log In and Log Out

1. On the System Status screen, touch Login.
2. Type your operator ID in the Login dialog.
3. Touch OK.

   The screen displays your operator ID and name on the System Status screen while you are logged on. The Login button changes to Logout.
4. To log out, touch Logout.

   The button changes to Login, enabling another operator to log into the system.

Set System Access

1. On the System Status screen, touch Set Access Level.
2. Type in the access code and press [Enter].

   The access code determines the level of activities available to you.

Description	Functionality	Icon

(Continued)

User level access	Enables access for general operator activities such sample processing and daily maintenance.	(none)
Key Operator level access	Enables user level access plus additional maintenance and diagnostic activities. Allows editing and modifying of system configuration data.	
Service level access	Enables access for trained service personnel only.	

3 Touch OK to complete the setting and close the Set Access Level dialog.

Chapter 8 Supply Categories

The system includes supplies that require regular loading, unloading, replacement, and maintenance. Supplies are grouped in the following categories:

Reagents:

- VITROS Chemistry Products MicroSlides
- VITROS Chemistry Products MicroTip Reagents
- VITROS Immunodiagnostic Products Reagent Pack
- VITROS Immunodiagnostic Products Signal Reagent
- VITROS Immunodiagnostic Products Universal Wash Reagent
- VITROS Immunodiagnostic Products High Sample Diluent A Reagent Pack
- VITROS Immunodiagnostic Products High Sample Diluent A
- VITROS Immunodiagnostic Products High Sample Diluent B Reagent Pack
- VITROS Immunodiagnostic Products High Sample Diluent B

Tell me more about Reagents (page 8-3)

Containers:

- Primary sample containers
- VITROS Chemistry Products MicroSample Cups
- VITROS Chemistry Products FS Cuvettes
- Micro-collection Container Adapters
- FS MicroCollection Tube Adapters
- VITROS FS Adapter - Microsample Cup Adapter (16mm tube, plastic)
- VITROS Chemistry Products Pierceable Caps

Tell me more about Containers (page 8-7)

Universal Sample Trays:

- UNIVERSAL SAMPLE TRAY
- UNIVERSAL SAMPLE TRAY Labels

Tell me more about Universal Sample Trays (page 8-10)

Tips:

- VITROS Chemistry Products VersaTips
- VITROS Chemistry Products FS MicroTips

Tell me more about Tips (page 8-16)

Calibrators:

- VITROS Chemistry Products Calibrator Kits
- VITROS Immunodiagnostic Products Calibrators

Tell me more about Calibrators (page 8-18)

Quality Control Fluids:

- VITROS Chemistry Products Performance Verifiers
- VITROS Immunodiagnostic Products Controls

Tell me more about Quality Control Fluids (page 8-18)

Fluids:

- VITROS Chemistry Products FS Diluent Pack 1 (Apo Diluent/UED)
- VITROS Chemistry Products FS Diluent Pack 2 (BSA/Saline)
- VITROS Chemistry Products FS Diluent Pack 3 (Specialty Diluent/Water)
- VITROS Chemistry Products FS Diluent Pack 4 (DAT Dil/DAT Dil 2)
- VITROS Chemistry Products Chemistry Products 950/FS Reference Fluid
- VITROS Chemistry Products Immuno-Wash Fluid
- VITROS Immunodiagnostic Products Maintenance Pack

Tell me more about Fluids (page 8-18)

MicroSensor™ Check Fluids:

VITROS Chemistry Products MicroSensor™ Check Fluids

Tell me more about Microsensor™ Check Fluids (page 8-19)

Range Verifiers:

VITROS Immunodiagnostic Products Range Verifiers

Tell me more about Range Verifiers (page 8-19)

Bar Code Labels:

- PSID Bar Code Labels (supported only)
- Pre-printed Tray Bar Code Labels

Tell me more about Bar Code Labels (page 8-20)

Environmental Supplies:

- VITROS Chemistry Products FS Humidification Pack
- VITROS Chemistry Products Desiccant Pack
- VITROS Immunodiagnostic Products Reagent Pack Storage Box
- Desiccant Pack with Humidity Control Card for Reagent Pack Storage Box

Tell me more about Environmental Supplies (page 8-23)

Waste Containers:

- Waste Container A
- Waste Container A Liners

- Waste Container B
- Waste Container B Liners
- Waste Container C
- Waste Container C Liners
- Liquid Waste Bottle
- Auxiliary Waste Bottle (unloaded by trained service personnel only)

Tell me more about Waste Containers (page 8-23)

Reagents

Reagents used by the system include:

- VITROS Chemistry Products MicroSlides
- VITROS Chemistry Products MicroTip Reagents
- VITROS Immunodiagnostic Products Reagent Packs
- VITROS Immunodiagnostic Products Signal Reagent
- VITROS Immunodiagnostic Products Universal Wash Reagent

Note: The reagent expiration occurs at midnight on the specified expiration date.

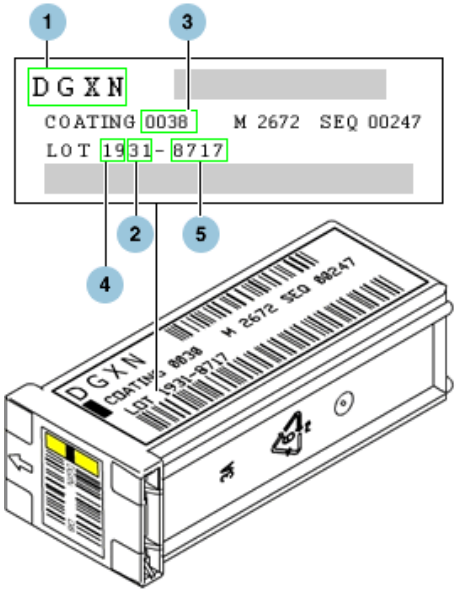
VITROS Chemistry Products MicroSlides

VITROS Chemistry Products MicroSlides contain reagents in a dry, multi-layered form. VITROS MicroSlides are supplied in opaque black cartridges containing 18, 50, or 60 slides for one specific type of assay.

Cartridges are packaged in polyethylene-coated aluminum foil wrappers within a cardboard carton. Both the carton and the cartridge are labeled with the assay identification and manufacturing lot number. The cartons are color-coded to indicate required storage conditions. Use the slides before the date indicated on the carton.

A color-coded stripe on the top bar code label directs the operator into which SLIDE SUPPLY the cartridge must be loaded. A yellow stripe indicates that the cartridge must be loaded into SLIDE SUPPLY 1. A white top bar code label indicates SLIDE SUPPLY 2.

(Continued)



1 Test Name

2 Generation Number

3 Coating Number

4 Chemistry ID Number

5 Lot Number Identifier

The Generation number uniquely defines the chemical formulation and manufacturing process for each assay. It refers to the mathematical formula the system uses to correctly calculate analyte concentration.

The Coating number defines each separate production of a slide generation. A coating may be thought of as a manufacturing event when a certain chemistry is produced.

Within each coating, separate lots are identified during the manufacturing process. Slide cartridges with the same lot number will have the same chemical characteristics. Conversely, when lot numbers change, the slides chemical characteristics change and the analyzer must be recalibrated before use.

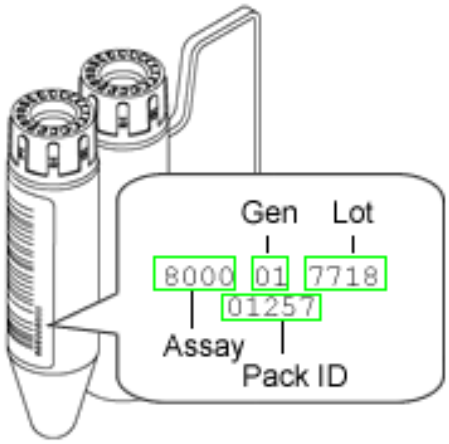
Prior to use, storage-condition requirements for slide cartridges vary. Refer to the Instructions for Use for the assay for specific requirements.

Note: Discard any slide that becomes separated from the cartridge. Do not re-insert it into the cartridge.

VITROS Chemistry Products MicroTip Reagents

VITROS Chemistry Products MicroTip Reagents are provided in reagent packs. The reagent pack contains two chambers containing liquid reagents. These chambers may contain antigen, antibody, or conjugate reagents. The system is able to store at least 30 MicroTip reagent packs on-board.

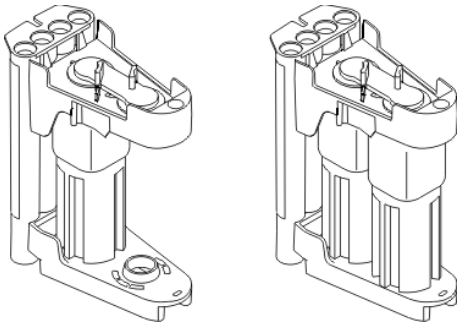
(Continued)



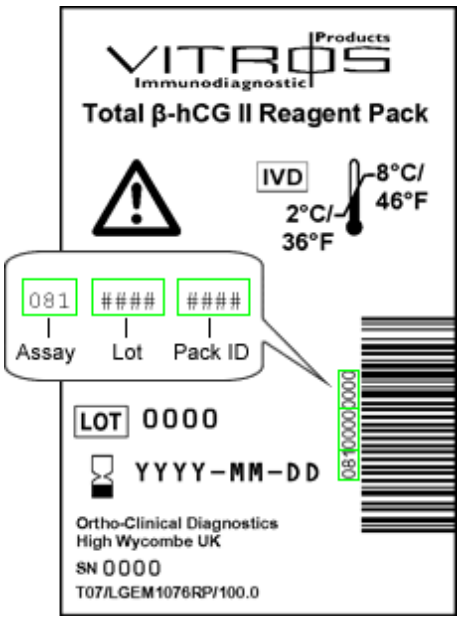
Each reagent pack has a bar-coded pack label containing the following information:

- 4 digit Pack code that identifies the assay or reagent
- 2 digit Generation number that identifies the version of the calibration data assigned to a reagent lot.
- 4 digit Lot number that identifies the lot for an assay or reagent
- Pack ID, or sequence number that identifies each individual pack within a lot number

VITROS Immunodiagnostic Products Reagent Packs



VITROS Immunodiagnostic Products Reagents are provided in reagent packs. The reagent pack contains one or two bottles of liquid reagent which may contain antigen, antibody, or conjugate reagents, and tubes of MicroWells.



The 11 digit Reagent Pack Lot Number is found next to the bar code on the reagent pack label. The first 3 digits identify the assay and remain the same from lot to lot within the assay. The middle 4 digits are called the Lot Number and signify that all reagent packs of the assay with this lot number should perform the same. The last 4 digits are the Pack ID which allows the system to track the open expiration of the pack and pack loading/unloading.

The MicroWell Reagent Pack is supplied ready for use with no warm up required before loading. No reconstitution is necessary. Do not mix; avoid agitation which could cause bubbles in the reagent bottles. If agitation occurs do not use the reagent pack for a minimum of 24 hours. Stability may vary by

assay. Refer to the Instructions for Use for assay specific requirements. The system is able to store at least 31 MicroWell reagent packs on-board.

When reagents are being stored off the system, store the opened reagent pack in a sealed Reagent Pack Storage Box that contains an active Desiccant Pack and a Humidity Card placed in the bottom of the box.

Note: Store unopened and opened reagents according to the Instructions for Use for each assay or reagent.

VITROS Immunodiagnostic Products Signal Reagent

VITROS Immunodiagnostic Products Signal Reagent (SR) is used for immunoassays. It is added to the MicroWell to generate the chemiluminescence reaction that allows the LUMINOMETER to read the light emission from the coated well after it has been washed with Universal Wash Reagent.

Signal Reagent usage is dependent on work flow. The maximum number of tests from each Signal Reagent pack is 210.

The Signal Reagent pack is supplied ready for use. No reconstitution is necessary, do not mix the reagent. Load Signal Reagent Packs onto the System at least 45 minutes before the pack is rotated into the in-use position. The two bottle configuration of the SR pack keeps the reagents separate until it is dispensed to prolong the stability of the reagent. Use within 7 days of loading onto the System; do not use beyond the expiration date. Store Signal Reagent packs at 2 to 8 °C in the box, protected from light, until required. Do not freeze.

Caution: Do not reload used SR packs. Verify that SR packs are new and have never been used before loading them onto the system. A SR pack can only be unloaded and stored for future use if it has never been used, pierced, or placed in the in-use position on the SR carousel.

Note: Do not move or reposition Signal Reagent packs after they have been loaded onto the system.

VITROS Immunodiagnostic Products Universal Wash Reagent

VITROS Immunodiagnostic Products Universal Wash Reagent (UWR) is used in washing MicroWells in the MicroImmunoassay Center, and is used in the automatic cleaning of the associated tubing. Universal Wash Reagent is provided ready for use. The on-board stability is 12 weeks. Stability may vary; refer to the Universal Wash Reagent label. Store at room temperature (15–30° C). Do not freeze. Protect from light and heat.

VITROS Immunodiagnostic Products High Sample Diluents

VITROS Immunodiagnostic Products High Sample Diluent Reagents hold diluents for use on-board the system. VITROS Immunodiagnostic Products High Sample Diluent Manuals hold diluents for use off-board the system. Four types of High Sample Diluents are available:

- VITROS Immunodiagnostic Products High Sample Diluent A Reagent Pack
- VITROS Immunodiagnostic Products High Sample Diluent B Reagent Pack
- VITROS Immunodiagnostic Products High Sample Diluent A
- VITROS Immunodiagnostic Products High Sample Diluent B

VITROS Immunodiagnostic High Sample Diluent A is used for sample dilution of immunoassays; to allow the assay of samples with values greater than the measuring (reportable) range of the system when used for the measurement of selected analytes. The High Sample Diluent pack is supplied ready for use. Store unopened at 2–8 °C, do not freeze. Use opened packs within 8 weeks of first loading onto a System; do not use beyond the expiration date. Store opened packs on-board the System, or at 2–8 °C in a sealed reagent pack storage box containing dry desiccant.

VITROS Immunodiagnostic High Sample Diluent B is used for sample dilution of immunoassays; to allow the assay of samples with values greater than the measuring (reportable) range of the system when used for the measurement of selected analytes. The High Sample Diluent pack is supplied ready for use. Store unopened at 2–8 °C, do not freeze. Use opened packs within 8 weeks of first loading onto a System; do not use beyond the expiration date. Store opened packs on-board the System, or at 2–8 °C in a sealed reagent pack storage box containing dry desiccant.

Tell me more about reagent management (page 15-1)

Refer to the Instructions for Use for more information.

Containers

Containers hold samples, fluids, or other containers.

Primary Sample Containers

Primary sample containers are standard blood collection tubes which are available in the following sizes:

- 12×75 mm
- 12×100 mm
- 13×75 mm (5 mL)
- 13×100 mm (7 mL)
- 16×75 mm (7 mL)
- 16×100 mm (10 mL)
- Selected Micro-collection Containers (requires either a Micro-collection Container Adapter (page 8-8), or a VITROS FS MicroCollection Tube Adapter (page 8-9))

The volume of fluid in the container must be within a prescribed range in order for the system to accurately meter the fluid.

Tell me more about fill requirements (page 8-10)

VITROS Chemistry Products MicroSample Cups

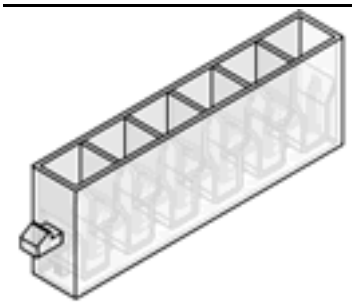
VITROS Chemistry Products Microsample Cups can be used in place of a primary sample container when the sample volume is less than 500 µL. The cup's design causes sample fluid to flow into a small well in the bottom of the cup. The shape of the cup controls the way the proboscis travels, positioning the sample tip at the cup depth necessary to aspirate a limited fluid volume. A FS Microsample Cup Adapter is used to hold the sample cup.

Other acceptable Micro-collection containers are:

- 2.0 mL sample cup with VITROS Pierceable Cap, supported by a FS Microsample Cup Adapter or 16 x 100 mm plastic tube

- 0.5 mL VITROS Microsample Cup with VITROS Pierceable Cap (or equivalent), supported by a FS Microsample Cup Adapter or 16 x 100 mm plastic tube

VITROS Chemistry Products FS Cuvettes



Use VITROS Chemistry Products FS Cuvettes with VITROS MicroTip assays and diluted assays. The cuvettes are small plastic vessels designed to hold a small amount of fluid. Ortho Clinical Diagnostics supplies cuvettes in blocks of 150 (25 rows of 6 cuvettes).

A VITROS FS MicroTip aspirates either sample fluid from a VITROS CuveTip, or liquid reagent and dispenses it into a cuvette. For larger volumes, a VITROS VersaTip is used. The system mixes the reagent and sample, or diluent and sample, within the cuvette. The system analyzes and reports the results.

Polypropylene Tubes

Ensure that the sample containers in use are appropriate for the assays being run. Refer to assay specific Instructions for Use (IFU) for additional information.

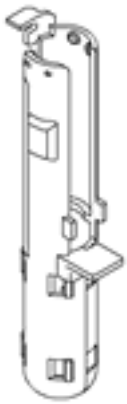
Note: Polypropylene sample tubes are recommended for the VITROS THC assay in order to minimize interaction with the sample that can cause lower than expected recovery of THC.

Micro-collection Container Adapters

Micro-collection Container Adapters are reusable hollow plastic holders used to position micro-collection containers at the proper height for sample metering. A bar code on the adapter indicates to the system that the adapter is in use. Refer to Sample Programming (page 9-1) for more information.

Only the Eppendorf® Micro-centrifuge tube (1.5 mL or equivalent diameter and length) can be used with the adapter.

VITROS FS MicroCollection Tube Adapters



VITROS FS MicroCollection Tube Adapters are plastic adapters that are inserted into the Universal Sample Tray in order to allow the use of various micro-collection containers. A flag on the adapter indicates to the system that the adapter is in use. There is a 50 mm opening that supports the use of barcodes on the containers.

Note: The entire barcode, including the quiet zone, must fit within the opening for a successful barcode read. See document C-20 (PSID Requirements) for more information.

The following micro-collection products can be used with the adapter:

- Eppendorf® Micro-centrifuge tube (1.5 mL or equivalent diameter and length)
- Becton-Dickinson (B-D) MICROTAINER® (with or without optional extender)
- Terumo CapiJect® Capillary Blood Collection Tubes
- Greiner MiniCollect® Capillary Blood Collection Tubes (0.5 mL and 1.0 mL)
- RAM Scientific Safe-T-Fill® Capillary Blood Collection Tubes (125 µL, 150 µL, 200 µL and 300 µL, all without optional Tube Extender.)
- Sarstedt Microvette® 200 µL and 500 µL with Cylindrical Inner Vessel
- TEKLAB 2 mL
- 10.25 mm diameter evacuated glass tubes (maximum 64 mm length)

FS MicroSample Cup Adapter

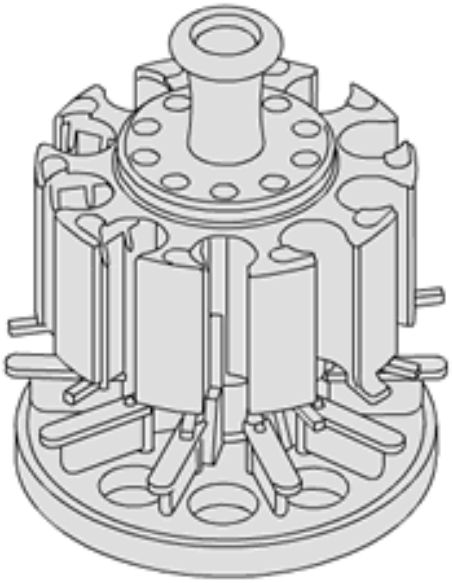
This is a plastic 16×100 mm tube that is designed to hold the VITROS MicroSample cup. It is used to make sure the cup is consistently at the correct height in the Universal Sample Tray. It is designed to make sure the cup is consistently at the correct height in the Universal Sample Tray.

VITROS Chemistry Products Pierceable Caps

Use VITROS Chemistry Products Pierceable Caps on VITROS Microsample Cups, 0.5 mL cups, or 2.0 mL cups only. The caps allow a VITROS Chemistry Products VersaTip to aspirate the sample while minimizing sample evaporation.

Note: Use VITROS Chemistry Products Pierceable Caps only while containers are on the system. For extended off-system storage, use standard non-pierceable caps.

Universal Sample Trays



Universal Sample Trays are used for both routine and STAT sampling. Universal Sample Trays are carousel-shaped and fit onto a carrier in the sample supply. A TRAY contains 10 numbered positions for sample containers of various sizes and diameters.

Each tray position includes a height adapter to hold shorter tubes and a spring clip to accommodate different tube widths.

Each TRAY contains an identification and bar code label.

Fill Requirements for Sample Containers

The volume of fluid in the containers must be within a prescribed range in order for the system to accurately meter the fluid. Review the following sample container fill requirements for the specific ranges.

16 × 100 mm (10 mL) (page 8-11)

16 × 75 mm (7 mL) (page 8-11)

12-13 × 100 mm (page 8-11)

12-13 × 75 mm (page 8-12)

0.5 mL Sample Cup (page 8-13)

2.0 mL Sample Cup (page 8-13)

0.5 mL VITROS Microsample Cup (page 8-12)

1.0 mL Sample Cup (13 mm Tube) (page 8-13)

Micro-collection Containers (page 8-14)

Fill Requirements: 16 × 100 mm (10 mL)

Caution: Remove stoppers from the collection tubes before loading them in the SAMPLE SUPPLY.

Adapters needed	None
Types	• Plain tube • SST tube and collection tubes with clots
Minimum fill volume	• Plain: 4470 µL plus the volume required for the assays • SST: 0.5 mL plus the volume required for the assays. The gel or clot layer must be at the minimum fill volume for the plain tube.
Maximum initial fill volume (includes any clot or gel layer)	18 mm (0.71 inches) from top of tube (for either tube type)

Return to Fill Requirements for Sample Containers (page 8-10)

Fill Requirements: 16 × 75 mm (7 mL)

Caution: Remove stoppers from the collection tubes before loading them in the SAMPLE SUPPLY.

Adapters needed	None
Types	• Plain tube • SST tube and collection tubes with clots
Minimum fill volume	• Plain: 450 µL plus the volume required for the assays • SST: 0.5 mL plus the volume required for the assays. The gel or clot layer must be at the minimum fill volume for the plain tube.
Maximum initial fill volume (includes any clot or gel layer)	18 mm (0.71 inches) from top of tube (for either tube type)

Return to Fill Requirements for Sample Containers (page 8-10)

Fill Requirements: 12-13 × 100 mm

Caution: Remove stoppers from the collection tubes before loading them in the SAMPLE SUPPLY.

Adapters needed	None
Types	• Plain tube • SST tube and collection tubes with clots

(Continued)

Minimum fill volume	• Plain: 3000 µL plus the volume required for the assays • SST: 0.3 mL plus the volume required for the assays. The gel or clot layer must be at the minimum fill volume for the plain tube.
Maximum initial fill volume (includes any clot or gel layer)	18 mm (0.71 inches) from top of tube (for either tube type)

Return to Fill Requirements for Sample Containers (page 8-10)

Fill Requirements: 12-13 × 75 mm

Caution: Remove stoppers from the collection tubes before loading them in the SAMPLE SUPPLY.

Adapters needed	None
Types	• Plain tube • SST tube and collection tubes with clots
Minimum fill volume	• Plain: 300 µL plus the volume required for the assays • SST: 0.3 mL plus the volume required for the assays.
Maximum initial fill volume (includes any clot or gel layer)	18 mm (0.71 inches) from top of tube (for either tube type)

Return to Fill Requirements for Sample Containers (page 8-10)

Fill Requirements: 0.5 mL VITROS Microsample Cup

IMPORTANT: Use a pierceable cap to minimize sample evaporation from this container.

Adapters needed	• FS MicroSample Cup Adapter (Cat. No. 6802095) • Processed in 16 mm tubes; make sure the cup fits loosely within the tube
Types	N/A
Minimum fill volume	• Test volume less than or equal to 66 µL: 35 µL plus volume required for assays • Test volume greater than 66 µL: 100 µL plus volume required for assays **Note:** For MicroWell assays, add 30 µL for each dilution replicate.

(Continued)

Maximum initial fill volume (includes any clot or gel layer)	500 µL (Meniscus [at cup center] is at lower edge of cup rim)

Return to Fill Requirements for Sample Containers (page 8-10)

Fill Requirements: 2 mL Sample Cup

IMPORTANT: Use a pierceable cap to minimize sample evaporation from this container.

Adapters Needed	Processed in 16 mm tubes
Types	• Fisher Cat. No. 02-544-19 • VWR Cat. No. 15070-290 / Pierceable cap 15070-089 (cup must fit loosely in support tube)
Minimum fill volume	100 µL plus the volume required for the assays
Maximum initial fill volume (includes any clot or gel layer)	1500 µL (Meniscus [at cup center] is at lower edge of cup rim)

Return to Fill Requirements for Sample Containers (page 8-10)

Fill Requirements: 0.5 mL Sample Cup

IMPORTANT: Use a pierceable cap to minimize sample evaporation from this container.

Adapters Needed	Processed in 16 mm tubes
Types	• Fisher Cat. No. 02-544-2 • VWR Cat. No. 15070-167 (cup must fit loosely in support tube)
Minimum fill volume	100 µL plus the volume required for the assays
Maximum initial fill volume (includes any clot or gel layer)	500 µL (Meniscus [at cup center] is at lower edge of cup rim)

Return to Fill Requirements for Sample Containers (page 8-10)

Fill Requirements: 1 mL Sample Cup (13 mm Tube)

Adapters Needed	13 mm tube
Types	N/A
Minimum fill volume	• 300 µL (Whole Blood) • 100 µL plus the volume required for the assays (Non-Whole Blood)

(Continued)

Maximum initial fill volume (includes any clot or gel layer)	• 400 µL (Whole Blood) • 1.0 mL or refer to the manufacturer's specifications (Non-Whole Blood)

Return to Fill Requirements for Sample Containers (page 8-10)

Fill Requirements for Micro-collection Containers

Micro-collection containers are used with the VITROS® FS MicroCollection Tube Adapter. The FS MicroCollection Tube Adapter is a device that is inserted into the Universal Sample Tray to support the primary blood Micro-collection containers for sample aspiration onboard the system. The volume of fluid in the containers must be within a prescribed range in order for the system to accurately meter the fluid. Review the following sample container fill requirements for the specific ranges when using Micro-collection containers.

Fill Requirements: Becton-Dickinson (B-D) MICROTAINER (page 8-14)

Fill Requirements: Becton-Dickinson (B-D) 10.25 (page 8-14)

Fill Requirements: Terumo CapiJect (page 8-15)

Fill Requirements: Greiner MiniCollect (page 8-15)

Fill Requirements: RAM Scientific Safe-T-Fill (page 8-15)

Fill Requirements: Sarstedt Microvette (page 8-15)

Fill Requirements: TEKLAB (page 8-16)

Fill Requirements: 1.5 Eppendorf (or equivalent) (page 8-16)

Return to Fill Requirements for Sample Containers (page 8-10)

Fill Requirements: Becton-Dickinson (B-D) 10.25®

Adapters Needed	VITROS FS MicroCollection Adapter
Types	10.25 × 64 mm or exact equivalent
Minimum fill volume	2.6 mL plus the volume required for the assays
Maximum initial fill volume (includes any clot or gel layer)	Refer to the manufacturer's specifications

Return to Fill Requirements for Micro-collection Containers (page 8-14)

Fill Requirements: Becton-Dickinson (B-D) MICROTAINER®

Adapters Needed	VITROS FS MicroCollection Adapter
Types	All types with or without optional extender
Minimum fill volume	250 µL plus the volume required for the assays
Maximum initial fill volume (includes any clot or gel layer)	Refer to the manufacturer's specifications

Return to Fill Requirements for Micro-collection Containers (page 8-14)

Fill Requirements: Terumo CapiJect®

Adapters Needed	VITROS FS MicroCollection Adapter
Types	All types
Minimum fill volume	Bottom fill line
Maximum initial fill volume (includes any clot or gel layer)	Refer to the manufacturer's specifications

Return to Fill Requirements for Micro-collection Containers (page 8-14)

Fill Requirements: Greiner MiniCollect®

Adapters Needed	VITROS FS MicroCollection Adapter
Types	0.5 mL and 1.0 mL
Minimum fill volume	• 0.5 mL: 210 µL plus the volume required for the assays • 1.0 mL: 250 µL plus the volume required for the assays
Maximum initial fill volume (includes any clot or gel layer)	Refer to the manufacturer's specifications

Return to Fill Requirements for Micro-collection Containers (page 8-14)

Fill Requirements: RAM Scientific Safe-T-Fill®

Adapters Needed	VITROS FS MicroCollection Adapter
Types	125 µL, 150 µL, 200 µL, and 300 µL without optional Tube Extender
Minimum fill volume	• 125 µL: 200 µL plus the volume required for the assays • 150 µL: 200 µL plus the volume required for the assays • 200 µL: 200 µL plus the volume required for the assays • 300 µL: 250 µL plus the volume required for the assays
Maximum initial fill volume (includes any clot or gel layer)	Refer to the manufacturer's specifications

Return to Fill Requirements for Micro-collection Containers (page 8-14)

Fill Requirements: Sarstedt Microvette®

Adapters Needed	VITROS FS MicroCollection Adapter

(Continued)

Types	200 µL and 500 µL with Cylindrical Inner Vessel
Minimum fill volume	185 µL plus the volume required for the assays
Maximum initial fill volume (includes any clot or gel layer)	Refer to the manufacturer's specifications

Return to Fill Requirements for Micro-collection Containers (page 8-14)

Fill Requirements: TEKLAB®

Adapters Needed	VITROS FS MicroCollection Adapter
Types	2 mL
Minimum fill volume	1.2 mL plus the volume required for the assays
Maximum initial fill volume (includes any clot or gel layer)	Refer to the manufacturer's specifications

Return to Fill Requirements for Micro-collection Containers (page 8-14)

Fill Requirements: 1.5 Eppendorf® (or equivalent)

IMPORTANT: Use a pierceable cap to minimize sample evaporation from this container.

Adapters Needed	Micro-collection container adapter or VITROS FS MicroCollection Adapter
Types	1.5 mL Eppendorf or exact equivalent Micro-centrifuge tube (rim must touch the adapter)
Minimum fill volume	150 µL plus the volume required for the assays
Maximum initial fill volume (includes any clot or gel layer)	Refer to the manufacturer's specifications

Return to Fill Requirements for Micro-collection Containers (page 8-14)

Tips

Disposable sample tips eliminate sample and reagent carryover. The system uses the following tips to process samples. The system selects which tip to use based on the sample requirements and assays programmed.

Note: Tips must be periodically removed from the solid waste container.

VITROS Chemistry Products VersaTips

VITROS Chemistry Products VersaTips are placed in the MICROIMMUNOASSAY VERSATIP RING and SAMPLING CENTER VERSATIP RING. A new tip is used for each sample, delivered by a pneumatic tube to the VERSATIP RING. Once the samples are in position, MICROIMMUNOASSAY METERING aspirates the sample using VITROS VersaTips and dispenses it as required to process the assays.

After dispensing the sample fluid onto a slide, or into a MicroWell, the PROBOSCIS ejects the tip to WASTE CONTAINER B, or seals the tip so that it can contain fluid. If sample indices are enabled for the sample, the system seals the VersaTip used to aspirate the sample fluid using the PRIMARY TIP SEALER. This creates a CuveTip. The heat-sealed VITROS CuveTip uses the contained sample fluid for MICROSENSOR measurement, MicroTip assays, and MicroSlide dilutions.

Tell me more about MICROSLIDE METERING (page 4-2)

Tell me more about MICROIMMUNOASSAY METERING (page 4-4)

VITROS Chemistry Products FS MicroTips

VITROS FS MicroTips are smaller versions of the VITROS VersaTip. MICROIMMUNOASSAY METERING uses them to:

- aspirate sample from an FS CuveTip for MicroTip assays or to make MicroSlide or MicroTip on-board dilutions
- aspirate MicroTip reagent volumes of less than 100µL
- dispense sample fluid into a VITROS FS Cuvette

After use, the SECONDARY TIP SEAL/EJECT ASSEMBLY seals the tip and ejects it into WASTE CONTAINER B.

Tell me more about MICROIMMUNOASSAY METERING (page 4-4)

Calibrators

VITROS Chemistry Products Calibrator Kits

VITROS Chemistry Products Calibrator Kits are required to calibrate MicroSlide and MicroTip assays on the system. For calibration, the system requires two or more levels of calibrator fluids containing different concentrations or activities of an analyte. The calibrators may be lyophilized or liquid and are supplied in numbered kits. The lyophilized calibrators must be reconstituted with the diluent provided in the kit, or a separate product such as FS ReconDiluent. The kit numbers required for calibration depend on the assays being calibrated. All calibration information is obtained from the Assay Data Disk (ADD).

VITROS Chemistry Products MicroSlide Calibrator Kits 1-10 and 25 are packaged with bar code labels (one for each level) to be affixed to tubes that hold the sample cup during the calibration process.

Tell me more about calibration (page 10-1)

VITROS Immunodiagnostic Products Calibrators

The calibration process uses a calibrator package that includes one to three calibrators with bar code labels. The calibrators contain known concentrations. The package can contain liquid calibrators or lyophilized calibrators. The liquid calibrators come ready for use in bar coded tubes, one for each level, with additional bar code labels provided in the package. The packages for lyophilized calibrators have the bar code provided, but the calibrators must be reconstituted for use. Reconstitute calibrators according to the Instruction for Use.

VITROS Immunodiagnostic Products Reagents and Calibrators are lot-linked. If a TSH Reagent is purchased with a lot number of 0900 then the associated calibrator must also have a lot number of 0900. All calibration information is obtained from the Assay Data Disk (ADD).

Tell me more about calibration (page 10-1)

Fluids

This topic covers most of the Fluids that are used on the system. Refer to Reagents (page 8-3) for information regarding Signal Reagent and Universal Wash Reagent.

VITROS Chemistry Products Diluent Packs (1 – 4)

VITROS Chemistry Products Diluent Packs hold diluents for use on the system. Four types of diluent packs, each containing two bottles, are available:

- VITROS Chemistry Products FS Diluent Pack 1 (APO Diluent/Urine Electrolyte Diluent)
- VITROS Chemistry Products FS Diluent Pack 2 (BSA/Saline)
- VITROS Chemistry Products FS Diluent Pack 3 (Specialty Diluent/Water)
- VITROS Chemistry Products FS Diluent Pack 4 (DAT Dil/DAT Dil 2)

VITROS Chemistry Products 950/FS Reference Fluid (ERF)

VITROS Chemistry Products 950/FS Reference Fluid (ERF) is used in potentiometric assays to measure the concentration of certain ions (such as potassium, chloride, and sodium) in a sample fluid. During operation, the system deposits 10 µL of ERF on one side of a potentiometric slide and deposits 10 µL of sample fluid on the other side of the slide.

VITROS Chemistry Products 950/FS Reference Fluid is delivered in reservoirs containing fluid for 800 potentiometric tests. The label on the ERF reservoir identifies the fluid's lot number and the use-before date.

Tell me more about ERF Metering in the MicroSlide Center (page 4-2)

VITROS Chemistry Products Immuno-Wash Fluid (IWF)

VITROS Immuno-Wash Fluid (IWF) is used for immuno-rate assays. After initial incubation, the WASH FLUID METERING ASSEMBLY deposits 12 µL of IWF on the slide, and the slide returns to the INCUBATOR.

VITROS Immuno-Wash Fluid is delivered in reservoirs containing fluid for 300 immuno-rate tests. The label on the IWF reservoir identifies the fluid's lot number and the expiration date.

Tell me more about WF METERING in the MicroSlide Center (page 4-2)

VITROS Chemistry Products MicroSensor™ Check Fluids

VITROS Chemistry Products MicroSensor™ Check Fluids are used specifically for performance checking of the VITROS MICROSENSOR. There are two levels of VITROS Chemistry Products MicroSensor™ Check Fluids. Each level verifies the system's performance in detecting hemolysis, icterus, and turbidity in samples.

Tell me more about VITROS MICROSENSOR and Check Fluids and Sample Indices (page 14-31)

Tell me how to process VITROS MicroSensor Check Fluids (page 14-32)

VITROS Chemistry Products Performance Verifiers

VITROS Chemistry Products Performance Verifiers (PVs) are assayed controls designed for use as a daily quality control for MicroSlide and MicroTip assays. PVs provide a way to assess the calibration of the system, monitor the daily performance of the system, and assist in troubleshooting out-of-control conditions indicated by daily quality control results.

Tell me more about Performance Verifiers (page 14-5)

The assay sheet which accompanies these fluids includes the following information for each analyte:

- A Generation (Gen) (V-Docs) specific Range of Means (ROM) (V-Docs).
- A recommended within-lab Standard Deviation (SD).

Tell me more about Quality Control (page 14-1)

VITROS Immunodiagnostic Products Controls

VITROS Immunodiagnostic Products Controls are control materials formulated for quality control on the system.The recommended frequency for processing quality control is once every 24 hours. However the frequency with which you perform quality control procedures may vary depending on the requirements and regulations for processing control fluids by your national, state, provincial, and local governments. Quality control procedures within your own laboratory may also require a different frequency. You should also perform quality control procedures following calibration and after certain maintenance and service procedures are performed. The quality control results should fall within the acceptable range found on the assay sheet.

Tell me more about Quality Control (page 14-1)

VITROS Immunodiagnostic Products Range Verifiers

The VITROS Range Verifiers have been validated for use on the VITROS System for VITROS Immunodiagnostic Products Reagent Packs and VITROS

Immunodiagnostic Products Calibrators. The range verifiers contain low and high concentrations of the analyte, close to the limits of the calibration range, and can be used to verify measurement of the analyte at the limits of that range.

Bar Code Labels

Bar code labels automate identification of a sample and its corresponding sample program. The sample identification number is printed in bar code form on a label that is affixed to the original sample container or other specimen container. The bar code label represents the sample identification number in both bar code symbology and human-readable characters. The bar code appears with its bars perpendicular to the label length.

When using bar code labels, it is not necessary to assign the program to a tray using the Sample Programming screen. Place the bar-coded sample container in any position on any tray with the label facing out. A scanner reads and decodes the bar code, then transmits the sample ID to the system. The system searches its database to find the corresponding sample program, or if the system is configured for Host Query, it will request the sample program from the Laboratory Information System (LIS).

You can place human-readable information or graphics on the label in any orientation, as long as it does not interfere with the bar code, the bar code quiet zone, or the human-readable interpretation of the bar code.

PSID Bar Code Labels

Positive Sample Identification (PSID) identifies a sample and its corresponding sample program through an alphanumeric identification number. This identification number is printed in bar code form on a label affixed to the primary sample container. Ortho Clinical Diagnostics supports but does not provide PSID Bar code labels.

Refer to *Bar Code Specifications for Positive Sample Identification (PSID)*, Part No. C-20 for more information.

Tell me more about PSID (page 8-22)

Pre-printed Tray Bar Code Labels

Ortho Clinical Diagnostics provides pre-printed TRAY bar code labels for UNIVERSAL SAMPLE TRAYS and corresponding tray identification labels in the Maintenance Kit. Use these labels as new or replacement labels for Universal Sample Trays.

Bar Code Types

Refer to the following table for supported bar code types. The table identifies the character length of the sample ID and type of characters used for each bar code.

Bar Code Type	Sample ID Length	Alphanumeric/Numeric
Code 39	4 to 15	Alphanumeric
Codabar	4 to 15	10 numeric and 6 additional characters
Interleaved 2 of 5	4 to 14	Numeric
Code 128	4 to 15	Alphanumeric
ISBT 128	13	Alphanumeric

Code 39 (also called Code 3 of 9) is an alphanumeric bar code symbology consisting of 43 data characters.

Codabar symbology uses characters 0 to 9, A to D, and 6 additional characters (/ . : + - $). It also designates four different start and stop characters. The system does not differentiate the various start/stop combinations.

Interleaved 2 of 5 uses numeric bar code symbology only. The characters interleave together to represent data characters in the odd positions, and spaces represent data characters in the even positions. The total number of characters you place on the label must be even, since the characters are interleaved in pairs. If you encode an odd number of characters, add a leading zero to change to an even number of characters.

Code 128 uses 103 encodable characters, including the full 128 ASCII character set. This code contains an encodable character set, four non-data function characters, four code-set selection function characters, three start characters, and one stop character. The check digit is encoded into this character set.

ISBT 128 bar code symbology uses a specific format for labels that contain the Donation Identification Number. ISBT 128 bar codes uses a 16 character format: P apppp yy nnnnnn ff.

- P is the primary data identifier (’=’ or ’&’)
- apppp designates the country/collection facility
- yy designates the year in which the donation was made
- nnnnnn is the serial number associated with the donation
- ff represent special flag characters

Since the sample ID field has a maximum of 15 characters, the ISBT 128 primary data identifier and special flag character fields will be removed after the Bar Code Reader scans the bar code. The sample ID contains 13 characters representing the country and collection facility, the year in which the donation was made, and the serial number associated with the donation. The following 13 character format used by the system for the ISBT 128 bar code is: **appppyynnnnnn**

- apppp designates the country/collection facility
- yy designates the year in which the donation was made
- nnnnnn designates the serial number associated with the donation

Since the system interprets the ISBT 128 bar codes as 13 characters, sample IDs manually programmed in the Sample Programming screen, or downloaded from a Laboratory Information System (LIS), must contain 13 characters to match the ISBT 128 bar code read by the Bar Code Reader.

IMPORTANT: If the donation serial number described above (nnnnnn) is less than six digits, leading zeros must be added to retain the 13 character sample ID required by the system.

Check Digits

A check digit is a character included within a bar code whose value is used to perform a mathematical check that ensures the accuracy of the read. Ortho Clinical Diagnostics highly recommends check digit use. The probability of misreads with the check digit enabled is significantly reduced.

To enable or disable check digit use, touch Options & Configuration > Configure System > PSID.

How to Place the Bar Code Label on the Sample Container

Tell me how to place the bar code label on the sample container (page 8-24)

Bar Code Accommodation

The minimum height of the bar code is 9.5 mm (0.375 inch).

The minimum narrow element width is 0.19 mm (0.0075 inch).

The maximum narrow element width is 0.51 mm (0.020 inch). The ratio of the widths of the wide elements to the narrow elements must be within 2:2:1 to 3:1.

Refer to the following table for additional specifications.

Container Size	Maximum Symbol Length
16 mm diameter	2.125 inches
13 mm diameter	2.125 inches
10.25 mm diameter	2.125 inches
7 mm diameter (Micro-collection)	See below

For Micro-collection containers, the symbol length must not exceed the actual cylindrical container length. The bar code must be entirely visible through the adaptor window, as appropriate. Refer to Fill Requirements for Micro-collection Containers (page 8-14) for details on using adaptors with Micro-collection containers.

Positive Sample Identification

Positive Sample Identification (PSID) uses bar code labels on the sample container to automate the process of identifying samples. When using PSID, you do not have to assign tray positions in Sample Programming. The PSID scanner reads and decodes the bar code, then transmits the sample ID number to the system. Sample processing continues normally.

For maximum efficiency:

- Print the bar code labels containing the sample ID number while printing the draw list during sample collection
- Download sample information such as the sample ID number and test request from the LIS to the system using the bidirectional interface.
- If you are not using the bidirectional interface, use the system keyboard to manually enter the sample ID and tests requested using the sample ID programming method.
- Make sure the pre-printed bar code labels containing matching sample ID numbers (or labels generated by your laboratory printer) are on the sample containers.

Caution: Do not move samples from one position to another in the tray until sample processing is completed.

Tell me how to use PSID (page 8-25)

Tell me more about sample programming (page 9-1)

Tell me how to place bar code labels on containers (page 8-24)

Tell me more about bar codes and bar code symbologies (page 8-20)

Environmental Supplies

The system controls relative humidity inside SLIDE SUPPLY 1 and SLIDE SUPPLY 2 to meet on-board slide storage requirements. The system also has the ability to control the temperature and relative humidity in the REAGENT SUPPLY to meet on-board reagent storage requirements. Environmental supplies are required to maintain relative humidity at the proper level.

VITROS Chemistry Products FS Humidification Pack

The VITROS Chemistry Products FS Humidification Pack is a gel suspension in a cotton-fiber bag that is inserted in the RH CONTROL BOX located below SLIDE SUPPLY 1. The pack supplies the moisture needed to maintain a relative humidity between 29 and 38%.

VITROS Chemistry Products Desiccant Pack

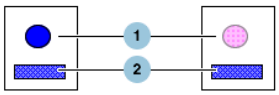
VITROS Chemistry Products Desiccant Packs are used in each of the removable Humidity Boxes. For SLIDE SUPPLY 1 it is used to help remove moisture and maintain a 29 to 38% relative humidity. In SLIDE SUPPLY 2 the pack removes moisture to maintain a relative humidity below 18% for slides that require a drier environment.

Reagent Pack Storage Box

The Reagent Pack Storage Box is a lidded plastic container used to store open VITROS Immunodiagnostic Products Reagent Packs when they are being stored off the system. When storing reagent packs, the Reagent Pack Storage Box should contain a Desiccant Pack with Humidity Control Card placed in the bottom of the box to reduce humidity in the box. The boxes should be used according to the Instruction for Use provided with each reagent pack.

Desiccant Pack with Humidity Control Card

The Desiccant Pack contains silica gel for reducing humidity in the Reagent Storage Box. The Humidity Cards, as shown below, indicate the condition of the Desiccant Pack.

Active Desiccant Pack: Circle (1) color *matches* or appears *darker* than the panel (2) color		Exhausted Desiccant Pack: Circle (1) color appears lighter than the panel (2) color

The Desiccant Pack remains active when the Humidity Card displays the following:

- The circle color (blue) matches the panel color (blue), OR
- The circle color appears darker (blue) then the panel color (blue)

Discard the Desiccant Pack when the spot color appears lighter in color (pink) then the panel color (blue).

Tell me more about environmental control (page 17-26)

Waste Containers

The system includes three solid waste containers and one liquid waste bottle.

Empty the waste containers as part of daily maintenance. The waste containers can be emptied at any time during system operation.

DANGER: HANDLE WASTE AS BIOHAZARDOUS MATERIAL. DISPOSE OF WASTE ACCORDING TO INSTRUCTIONS AND ACCEPTED LABORATORY PROCEDURES.

Tell me more about Waste Container Status (page 7-8)

WASTE CONTAINER A

WASTE CONTAINER A collects used Versa Tips and MicroWells. After delivering the reagent, the PROBOSCIS discharges used VITROS VersaTips or rejected MicroWells, and sends them down a metal chute, depositing them into the waste container.

WASTE CONTAINER B

WASTE CONTAINER B collects used tips (both VITROS VersaTips and VITROS FS MicroTips), cuvettes, and MicroWells. The PROBOSCIS discharges used tips after sampling and sends them down a metal chute to Waste Container B. VITROS CuveTips are disposed through the CUVETIP RING to the WASTE CONTAINER B.

WASTE CONTAINER C

WASTE CONTAINER C collects processed VITROS MicroSlides. After analysis, the system pushes used slides into a chute leading to WASTE CONTAINER C. The container will hold approximately 2500 processed MicroSlides.

Liquid Waste Bottle

Liquid waste refers to used Universal Wash Reagent, sample fluid, Signal Reagent, and all reagents used for processing MicroWell assays. The primary liquid waste bottle has the capacity to hold 5000 mL, and the auxiliary bottle can hold up to 250 mL of liquid waste.

Supply Procedures

The following table lists the Supply topics that reference the procedures included in this section.

Topic Title	Procedure Title
Bar Codes (page 8-20)	Place a Bar Code Label on a Sample Tube (page 8-24)
Positive Sample Identification (page 8-22)	Use Positive Sample Identification (PSID) (page 8-25)

Place a Bar Code Label on a Sample Tube

1. Place the label on the sample tube or other sample container so it is oriented lengthwise along the tube. The top of the label should be within 3.2 mm (1/8 in) of the rim of the tube.
2. Make sure that the label does not overhang the rim. This overhang interferes with the placement of the stopper.
3. Make sure that the label is straight with the bar code lines as perpendicular as possible to the tube's length.
4. Turn the tube to view the fluid level. The label width should not exceed 60 to 70 percent of the tube's circumference. You should be able to see the fluid.

Note: The laboratory determines the minimum label width depending on the additional human-readable data printed on the label.

5 Make sure that the length of the label does not extend into the taper of the tube.

Note: The label length may vary depending on the bar code type, bar code density, and the amount of information that is encoded.

Use Positive Sample Identification (PSID)

1 Place a bar code label on the sample tube or sample container. Make sure that the label is not skewed, offset, or extended beyond the length of the tube.

2 Insert the tube into the UNIVERSAL SAMPLE TRAY. Make sure that the bar code label is visible through the slot in the TRAY.

3 Load the TRAY onto the system.

4 Download the program from the Laboratory Information System (LIS).

5 Touch Start Sampling  if sampling is not already in progress.

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Chapter 9 Sample Programming Overview

Sample programming is the process of selecting assays and programming characteristics for samples. The system uses the sample program to meter the appropriate sample and select the right reagent for the assay, then report the results with the correct identification.

Sample Programming Methods

You can program samples through one of the following methods:

- By Sample ID — An alphanumeric name identifies the sample. Use this name to program samples not immediately assigned to trays. This method is useful when the samples are not available or you need to program multiple samples prior to tray setup. If you are not using bar code labels on the sample containers, you must assign the programs to trays. If you are using bar code labels, tray assignment is not necessary.

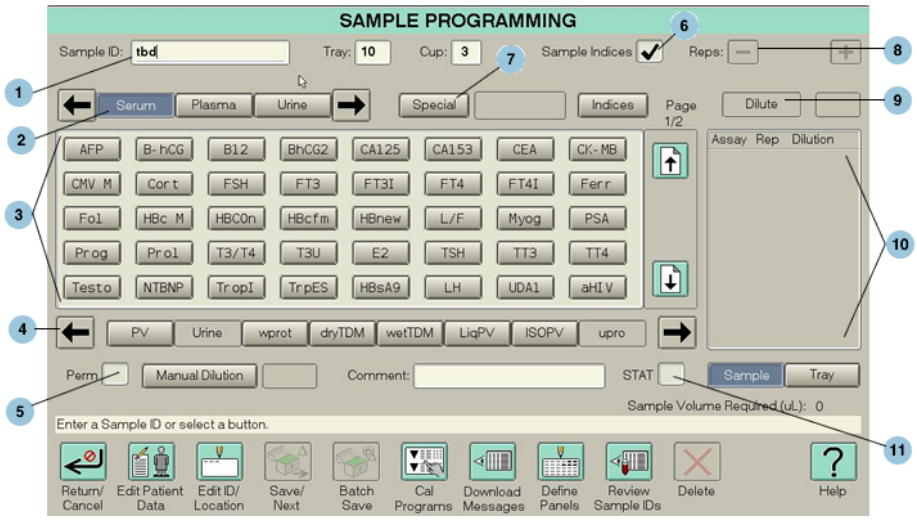
  IMPORTANT: Ortho Clinical Diagnostics (OCD) does not recommend the use of confidential, patient-identifying information such as patient name or government identifier as part of the sample ID. OCD occasionally requests files from your system that contain sample IDs to assist in troubleshooting or performing routine maintenance of the system. Avoid the use of patient-identifying information as part of the sample ID.
- By Tray/Cup ID — The sample is identified by its location on a tray. Use this method to program samples assigned to trays at the time of programming. This method is useful when you are programming samples at the time of tray setup or if you want to program multiple trays before loading them onto the system.
- By Laboratory Information System (LIS) Download — Use this method to transmit sample programs from a LIS to the system.
- By Batch Save — Batch programming allows you to define multiple identical sample programs quickly and easily. Use this method to program a group of samples that have the same assays, program characteristics, patient data, and report status.

Tell me how to program batch processing for samples without bar codes (page 9-14)

You can use bar code labels with any of these methods. When sample containers have bar code labels on them, the system scans the sample ID and associated information from the label. If the Host Query LIS option is enabled, the LIS will be queried for sample programs. You do not need to assign the sample to a tray.

Sample Programming Screen

Touch the Samples navigation button to display the Sample Programming screen. Use this screen to identify the body fluid, assays, and other information for the sample. Refer to the illustration and table below for more information about this screen.



Callout	Description
1. Sample ID	Identifies the sample with 1 - 15 alphanumeric characters; must be unique.  **Note:** An icon appears next to a Sample ID when the ID matches the first six characters of a control fluid.
2. Body Fluid	Identifies one of the nine specimen types (serum, plasma, urine, etc.).
3. Assays	Identifies the assays to be processed for this sample. The assay buttons vary, depending on the body fluid selected. **Note:** The availability of these assays is subject to regulatory clearance or approval.
4. Panels	Previously-defined groups of assays to be processed for the sample. Touch the horizontal arrows to display additional panel buttons. Tell me more about Panels (page 9-9)
5. Perm	Indicates that sample program is saved permanently on the fixed disk.
6. Sample Indices	Indicates if Sample Indices is enabled or disabled for this sample. **Note:** This check box can be used to override the system configuration for Sample Indices on the Options and Configuration — Sample/Result Options screen. **Note:** When a restricted assay is processed, Sample Indices are automatically enabled and cannot be overridden.

(Continued)

7. Special	Indicates if the sample is a Special Body Fluid. Enter up to nine characters to indicate the fluid type. **Note:** The sample is still processed using one of the standard body fluid selection buttons.
8. Reps	Replicates an assay or panel for a program by increasing or decreasing its default replication count. Touch + to increase the replication count; touch - to decrease the replication count. Tell me more about Replicates (page 9-12)
9. Dilute	Indicates that the sample will be diluted using the associated dilution factor. Tell me more about Dilutions (page 9-10)
10. Current Programs	Shows the current samples that are programmed. Touch Tray to list programs by tray. Touch Sample to list programs by sample.
11. STAT	Indicates the processing priority for a sample in the SAMPLE SUPPLY. Samples in the STAT Lane have the highest priority. Samples designated as STAT, but located in the Routine Lane, have a higher priority than Routine samples. Tell me more about STAT Samples (page 9-10)

Sample Programming Process Buttons

Tell me more about the process buttons on the Sample Programming screen (page 9-3)

Sample Programming Process Buttons

The Sample Programming screen offers the following features:

Process Button	Description
	**Edit Patient Data**: Allows for patient demographic information to be entered and changed. This information is optional. Tell me how to Edit Patient Data (page 9-9)
	**Edit ID/Location**: Allows for the name or location of an existing sample program to be changed. **Note:** You must touch Save/Next on the Sample Programming screen after touching Edit on the Edit ID/Location screen in order to save your changes.
	**Save/Next**: Saves the current entries on the screen and resets the fields so the next sample program can be entered.

(Continued)

Batch Save: Allows for the creation of multiple sample programs with the same assay or group of assays. For example, if several samples require a Folate assay, you can select that assay and enter multiple Sample IDs.

Note: Make sure to touch Save before dismissing the Batch Save screen.

Note: An icon appears next to a Sample ID on the Batch Save screen when the ID matches the first six characters of a control fluid.

Note: Sample programs can be created and assigned to a specific Tray ID but the system will recall any sample programs on that tray and will not allow them to be overwritten. The operator must choose a position on the tray that does not contain an existing sample program.

Cal Programs: Defines, cancels, or deletes a calibration program.

Download Messages: Displays any messages that have been downloaded from the Laboratory Information System. Touch Update Messages to refresh the Sample Programming - Review Download Messages screen.

Define Panels: Defines a group of assays for a program.

Tell me more about Panels (page 9-9)

Review Sample IDs: Lists the programmed Sample IDs.

Tell me more about Sample Program IDs (page 9-7)

Delete: Deletes the current sample program, if confirmed by the operator.

Sample Programs

How to Program Tray/Cup IDs

Use this method to assign sample programs to trays at the time of programming (for example, when samples are not bar coded and you want to program samples during tray setup, or when you want to program multiple trays before loading them).

Note: Do not reassign samples to a different TRAY position once the sample bar codes are read.

Tell me how to Program Sample IDs with Tray and Cup Assignments (page 9-15)

Tray IDs must match the bar code number of the tray used for processing the samples.

Sample IDs must be unique. Once all results are complete for a given sample ID or the sample program has been deleted, you can reuse the sample ID.

How to Modify Sample Programs

A saved sample program can be modified at anytime via the Sample Programming screen if all of the following are true:

- The sample is still in the STAT Lane or SAMPLING CENTER.
- The sample has not expired.
- All initial sample metering has been performed on that sample.
- All current tests of the same type (MicroWell or non-Microwell) have completed.

Note: You must touch Save/Next on the Sample Programming screen in order to save your changes.

In-process sample program modification has the following restrictions:

- Existing sample program assays cannot be deleted, and will remain as originally programmed. It is only possible to add assays.

  Note: Make sure that the system inventory completes prior to processing samples, if loading reagents on the system. Some assays may not be run because the system has not had enough time to record the new inventory.
- Tray/Cup program modifications only affect added or reprocessed tests which are scheduled after the change is made.
- Tray/Cup IDs can only be changed when the sample tray is in the SAMPLING CENTER.
- Derived tests will only be added to the in-process sample program if all components are being added, or if all components already exist and are either ready to run or are waiting for retest.

How to Edit and Delete Sample Programs

Delete individual sample programs using the Sample Programming screen.

Tell me how to edit programs (page 9-16)

Tell me how to delete programs (page 9-16)

Downloaded Programs

You can download up to 10,000 programs from a Laboratory Information System (LIS). The system saves the programs on its fixed disk until the program is recalled for editing, the sample is loaded onto the system, or the program has been deleted if the auto delete feature is enabled. View downloaded programs via the SAMPLE PROGRAMMING — Review Sample IDs screen.

The LIS downloads the following information for each sample program:

(Continued)

• Assay requests	• Birth date
• Sample ID	• Gender
• Body fluid	• Room
• STAT or routine status	• Collection date and time
• Dilution factor	• Physician ID
• Tray ID and position	• Physician name
• Patient name	• Physician address
• Patient ID	• Comments

The LIS also handles extended sample program information, including:

- Reagent lot number
- Reagent shelf expiration date
- Reagent load date
- ERF lot number
- IWF lot number
- Calibration date
- Calibration status
- Operator ID

Note: If a program with the same sample ID or tray ID and position already exists on the system, the downloaded program replaces it. If the system is currently using the sample program, the system displays a message on the prompt line.

If the downloaded program specifies a tray ID, you must assign tray positions to each sample program assigned to that tray. If a tray ID is not specified, you cannot assign tray positions.

How to Edit Downloaded Programs

You can edit previously-downloaded sample programs on the LIS, then download them again to the system. However, once you change a downloaded sample program using the Sample Programming screen, you can no longer change it through the LIS.

Edit individual sample programs using the Sample Programming screen.

Tell me how to edit programs (page 9-16)

Sample Program Auto Deletion

You can configure the system to automatically delete sample programs that have not been processed. For example, the system can automatically delete sample programs that are broadcast downloaded from the LIS if they are not processed within a configured time interval.

Note: The system does not automatically delete permanent sample programs and programs in progress.

Configure Sample Program Auto Deletion using Options & Configuration - Sample/Result Options.

How to Save Programs for Later Use

After reporting all results for a sample or tray program, the system normally deletes the program. However, you may want to save a program for certain samples, such as control samples, to avoid programming the sample each day. Use the Perm field to save the sample program on the fixed disk.

To save a sample program permanently on the fixed disk, touch the Perm field. A check mark appears in the field.

To remove the permanent status, touch the Perm field again. The check mark disappears and the program will be deleted.

LIS Status

The status console displays icons that indicate communication activity between the system and the Laboratory Information System (LIS).

Icon	Description
	LIS configured and enabled
	LIS configured, but not enabled
	LIS downloading
	LIS uploading
	LIS in Query mode
	LIS download messages are present

Sample Program IDs

Sample ID Programming

Use this method to program samples without assigning them to trays (for example, when samples have bar code labels but the system does not receive downloaded programming from a LIS, or when you receive test requests prior to receiving the samples).

IMPORTANT: Do not reassign samples to a different TRAY position once the sample bar codes are read.

Tell me how to program samples without assigning them to trays (page 9-17)

If you are not using bar code labels on the containers, be sure to assign the samples to a tray before processing.

IMPORTANT: Ortho Clinical Diagnostics (OCD) does not recommend the use of confidential, patient-identifying information such as patient name or government identifier as part of the sample ID. OCD occasionally requests files from your system that contain sample IDs to assist in troubleshooting or performing routine maintenance of the system. Avoid the use of patient-identifying information as part of the sample ID.

If you are using bar code labels, the sample ID must match the number on the bar code label. Include all leading zeros.

Note: If you touch the Return/Cancel button before saving the program, the system cancels information entered on the screen and restores entries and selections set during the last save.

How to Modify Sample Programs

A saved sample program can be modified at anytime it is not being metered via the Sample Programming screen. Tell me more about How to Modify Sample Programs (page 9-5)

How to Review and Delete Pending Sample IDs

Review and delete Sample IDs, before processing, using the Sample Programming screen.

Tell me how to review IDs (page 9-17)

Tell me how to review IDs and delete IDs by age (page 9-17)

Note: The system will delete permanent sample programs using this method of deletion.

Sample ID Reuse

All versions of VITROS System Software contain a feature that retains in memory any sample programs that do not complete processing. This enables the repeat analysis of a sample, without re-programming. If a retained sample ID is processed again, the remaining tests in the program for the original sample ID will be processed.

If a retained sample ID is not processed to completion, the sample ID and its associated program including tests and demographics, is retained in system memory indefinitely, unless auto deletion is configured. If a new sample is processed in the future using the same retained sample ID, the tests and demographics associated with the new sample program will not be stored in the system memory. After processing the new sample, the results for the previous incomplete tests and associated patient demographics will be reported for the retained sample program for the original sample ID.

VITROS Systems will retain a sample program in the system memory when all sample and assay processing steps are not complete for that sample program including the following:

- The system detects exceptions from normal operation resulting in incomplete processing. Exceptions may include detection of clots and bubbles and out of range subsystem temperature.
- Reflex processing of a sample program for different assays.
- Automatic dilutions

When processing a new sample programmed with a sample ID retained in the system memory, the patient data for the retained sample program will be reported with the newly processed sample for the following reports:

- The Results Review - Edit Patient Data screen
- Printed as Laboratory and Patient reports
- Uploaded to a Laboratory Information System (LIS) as a Laboratory Computer report.

Patient data is uploaded to the LIS only when using the HL7 or ASTM communication protocol.

Note: When downloading a sample ID previously used for a sample program, the system will provide a notification via a sample/patient mismatch message on the Sample Programming - Review Download Messages screen.

Note: Refer to the Specifications for Laboratory Computer Interface document for detailed information on laboratory computer interface protocols for VITROS Systems.

How To Load/Unload Samples

You can load a maximum of 8 UNIVERSAL SAMPLE TRAYS (plus one STAT sample tray) in the SAMPLE SUPPLY.

How to Load Samples

Tell me how to load samples into the sample supply (V-Docs)

How to Unload Samples During Sample Metering

Tell me how to unload samples during sample metering (V-Docs)

How to Start and Stop Sample Metering

Touch the appropriate button on the System Status screen to activate or stop metering:

- Touch  to activate sample metering.
- Touch  to stop sample metering.

How to Retrieve a Tray or Sample

Use the Retrieve Tray process button on the System Status — View Tray Status screen to request the system return a TRAY or a sample from the Metering Area to the Load/Unload Area of the SAMPLE SUPPLY. Retrieve Tray is available only if TRAYS or samples are in the SAMPLING CENTER.

Tell me how to Retrieve a Sample (V-Docs)

Tell me how to Retrieve a UNIVERSAL SAMPLE TRAY (V-Docs)

Tell me more about the Sampling Center (page 4-1)

Panels

A panel is a predefined group of assays that are routinely processed together for a single sample. Assays programmed within a panel do not need to be individually selected each time you want to process a particular group. The system allows for up to 32 panels to be defined.

Tell me how to define a panel (page 9-17)

Tell me how to edit a panel (page 9-18)

Tell me how to delete a panel (page 9-19)

Patient Data

The Edit Patient Data screen under Sample Programming enables you to add optional patient demographic information prior to processing a sample.

The Edit Patient Data screen can be launched from both the Sample Programming screen and the Results Review screen. It is included in Results Review so that information not entered at the time of programming can be

entered after the sample has been processed. Edits result in an "EP" code on the Patient Report. See Patient Data (page 11-6) for more information.

Tell me how to Add or Edit Patient Data (page 9-19)

Tell me how to Set Report Status (page 9-21)

STAT Samples

STAT indicates priority processing status for a sample. There are two kinds of STAT on the system:

- Designated STAT — STAT samples that are placed in the Routine Lane. The system processes these samples after samples in the STAT Lane, but before any other routine patient samples in the Routine Lane.
- STAT — STAT samples that are placed in the STAT Lane. The system immediately processes the STAT samples in the STAT Lane before all other samples in the Routine Lane.

How to Load a STAT Sample

Tell me how to load a STAT sample (V-Docs)

STAT Priority

Once alerted to the presence of a STAT sample, the system completes the sample it is metering, then draws the STAT sample into the SAMPLE SUPPLY metering position. STAT samples in the Routine Lane move into the Metering Area, while STAT samples in the STAT Lane move into the STAT Metering Position.

Tell me more about the SAMPLE SUPPLY metering positions (page 4-1)

After metering the STAT sample, the system returns to the tray that it was processing when the STAT sample was loaded. The system completes metering of samples in that tray, then continues processing as usual.

How to Set the STAT Indicator

Touch the STAT field on the Sample Processing screen to mark the sample as STAT for recordkeeping purposes. The STAT indicator appears on the Laboratory Report and Patient Report for that sample. If a STAT indicator is downloaded from the LIS for the sample, the Sample Programming screen for that sample ID includes a check mark in the STAT field.

To deselect the STAT field and remove the indicator, touch STAT again. The check mark disappears. Reports for the sample will not include a STAT indicator.

Dilutions

The system can dilute samples on-board, or you can choose to dilute them manually.

Refer to Lower Dilution Ratio = More Sample Taken (page 9-11) and Maximum Volume Allowed by System (page 9-12) to read more about dilution ratios, and maximum volume.

On-board Dilutions

On-board dilution is performed by the system using diluents stored onboard the system (in the Reagent Supply). There are three types of onboard dilution: standard dilution, reflex dilution, and dilutions requested by the operator.

- Standard dilution is the dilution performed automatically on a sample for any assays. The standard dilution factor for most assays is 1.0, indicating no dilution is necessary for normal processing. Some serum/plasma tests (Hepatitis) require a standard dilution greater than 1.0 for normal processing. For example, the system automatically dilutes a sample for serum/plasma Anti-HBc IgM by a factor of 1:20, before using the 10 µL to perform the assay.

  The standard dilution factors and out-of-range dilution factors recommended by Ortho Clinical Diagnostics are loaded on the system when you load the Assay Data Disk. No operator intervention is required for programming tests for standard dilutions.
- Reflex dilution refers to the dilution used to repeat a test when the standard dilution yields a result that is outside the measuring (reportable) range for the test. To use reflex dilution, it must be configured through Options & Configuration for both the system (under Configure System, select Sample/Result Options, then touch On for Reflex Dilution) and the assay (under Configure Assays, select the body fluid/assay combination, touch Review/Edit Configuration, then touch On for Reflex Dilution).
- On-board dilutions requested by the operator are operator-defined dilutions performed automatically by the system on a sample for a specified assay. Request an on-board dilution while entering a sample program on the main Sample Programming screen.

  To cancel the dilution factor, touch Dilute again.

Tell me how to program an assay for an operator requested dilution (page 9-21)

Manual Dilution

Manual dilution is required if the necessary diluent is not currently stored on the system, or when the sample result still exceeds the highest out of range dilution factor for the assay. You dilute the sample using a pipette or automatic pipetting device. With manual dilution, you must enter the manual dilution factor on the Sample Programming screen, and the Sample Indices check will be disabled for the sample.

Tell me how to Set a Manual Dilution Factor (page 9-22)

Tell me how to Cancel a Manual Dilution Factor (page 9-22)

Lower Dilution Ratio = More Sample Taken

IMPORTANT: The smaller the dilution factor, the more sample is required.

For example purposes, the dilution is based on 100 µL of total volume (sample plus diluent). The equation is:

100/dilution factor = volume required

Sample required = 1 × volume required

Diluent required = dilution factor - 1 × volume required

100/dilution factor is initially determined.

If the dilution is 1:2 (one part to one part), the volume required is 50 µL.

(100/2 = 50 µL where 50 µL is the volume required)

Sample volume required = 1 × 50 = 50 µL

Diluent volume required = (2-1) × 50 = 50 µL

Thus, sample volume required is 50 µL, diluent volume required is 50 µL.

If the dilution factor is 21, the sample volume required is 4.76 µL.

(100/21 = 4.76 µL where 4.76 µL is the volume required)

Sample = 1 × 4.76 = 4.76 µL

Diluent = (21-1) × 4.76 = 95.24 µL

Thus, sample volume required is 4.76 µL, diluent volume required is 95.24 µL.

Note: The above does not take into account dead volume in the sample container. See Fill Requirements for Sample Containers (page 8-10) for more information.

Maximum Volume Allowed by the System

Note: The higher the dilution factor, the smaller the sample volume is required.

Replications

Replication is when an assay is repeated multiple times within a sample program. The system calculates the mean result of the replications and reports it as the result for the assay. The system permits a total of 40 measured and 10 derived tests for a sample program.

Tell me how to replicate an assay (page 9-22)

Bar Code Label Use

You can use bar code labels with any sample programming method. Bar code labels automate identification of a sample and its corresponding sample program. The sample identification number is printed in bar code form and in human-readable characters on a label that is affixed to the original sample container or other specimen container. The bar code appears with its bars perpendicular to the label length.

When using bar code labels, it is not necessary to assign the program to a tray using the Sample Programming Screen (page 9-1). Place the bar-coded sample container in any position on any tray with the label facing out. A scanner reads and decodes the bar code, then transmits the sample ID to the system. The system searches its database to find the corresponding sample program.

You can place human-readable information or graphics on the label in any orientation, as long as they do not interfere with the bar code.

Tell me more about bar codes (page 8-20)

Auto-Recovery

If a mechanical condition occurs during sample processing, the system automatically attempts to correct the condition and attempts to repeat any samples that did not report results.

If the auto-recovery is successful, the system posts a Transient-level condition code. Operator intervention is not required to resolve the condition. If the condition causes any assay result(s) to be lost, an Action-level condition code (PER-250) is posted. The system will automatically repeat any samples that did not report results (displaying an ME or other code) on the Laboratory Report (page 12-2).

If the auto-recovery is unsuccessful or the number of consecutive occurrences exceeds the limit, the system posts a Malfunction-level code and reduces the affected module(s). Perform any additional procedures outlined in the condition code description, then review the Laboratory Report and repeat any samples that did not report results.

The system posts a Transient-level condition code (PER-152) when the limit of consecutive occurrences is reached for a specific code.

External Sampling (AT Feature Only)

External sampling can accommodate 13 mm, and 16 mm tubes for use with sample containers. The lab automation system delivers the external sample and its associated ID to the system. The system aspirates the sample fluid directly from the containers on the automation track using adapters. These adapters hold the sample containers at the proper height so the PROBOSCIS can enter the tube and aspirate the correct amount of fluid for the number of sample tests required.

The sample container fill level is extremely important because the PROBOSCIS has a predetermined travel limit. An insufficient fluid level cancels metering for that sample.

Tell me more about sample containers (page 8-7)

Tell me more about fill requirements (page 8-10)

IMPORTANT: Loss of volatile analytes — such as alcohol, ammonia, or CO_2 can occur due to evaporation or outgassing while the sample awaits testing on the automation track. To minimize loss, these sample types should be assayed from a sample tray on-board the system.

Containers Not Supported

External sampling cannot accommodate sample cups and pediatric capillary draw tubes. These containers should be used in sample trays on-board the system.

Minimum Fill Requirements

The following table shows fill volumes for sample tubes used with the external track.

Tube size	Minimum fluid volume
13 × 100 mm	200 µL
16 × 100 mm	
13 × 75 mm	
16 × 75 mm	

Assay Processing Order

Testing order is not necessarily based on the cup position on the tray. The system will select tests to process in an order that will maximize workflow. This means that tests from cup 5 may process prior to cup 2 based on the assays requested.

Sample Programing Procedures

The following table lists the Sample Programming topics that reference the procedures included in this section.

Topic Title	Procedure Title
Sample Programming Overview (page 9-1)	• Manual Batch Processing (page 9-14)

(Continued)

Sample Programs (page 9-4)	• Manually Program Sample IDs with Tray and Cup Assignments (page 9-15) • Edit Sample Programs (page 9-16) • Delete a Sample Program (page 9-16)
Sample Program IDs (page 9-7)	• Program Sample IDs Manually (page 9-17) • Review Sample IDs (page 9-17) • Delete Sample IDs by Age (page 9-17)
Panels (page 9-9)	• Define a Panel (page 9-17) • Edit a Panel (page 9-18) • Delete a Panel (page 9-19)
Patient Data (page 9-9)	• Add or Edit Patient Data (page 9-19) • Set Report Status (page 9-21)
Dilutions (page 9-10)	• Program an Assay for an Operator-Requested Dilution (page 9-21) • Set a Manual Dilution Factor (page 9-22) • Cancel a Manual Dilution Factor (page 9-22)
Replications (page 9-12)	• Replicate an Assay (page 9-22)

Manual Batch Processing

Use this procedure to program batch processing for samples without bar codes.

1 Touch  to display the Sample Programming screen.

2 Determine the assays to run for all samples. Choose one of the following methods:

a Touch the body fluid and then the assays. (Optional: If needed, enter Reps and Dilutions for each assay.)

b Touch the body fluid and then a panel of assays.

3 Touch Batch Save to display the Batch Save dialog.

4 Enter a tray number for the samples and press [Enter].

Note: Cup numbers are checked by default. Touch the check box to deselect the cup.

5 Enter the Sample ID and press [Enter] after each entry.

IMPORTANT: Ortho Clinical Diagnostics (OCD) does not recommend the use of confidential, patient-identifying information such as patient name or government identifier as part of the sample ID. OCD occasionally requests files from your system that contain sample IDs to assist in troubleshooting or performing routine maintenance of the system. Avoid the use of patient-identifying information as part of the sample ID.

The cursor moves to the next Sample ID field automatically.

Note: A QC control fluid is marked with a bottle icon shown next to the ID if QC software is being used and the QC ID has been configured.

6 When the tray is complete, touch Save.

7 Repeat Steps 4 (page 9-14) through 6 (page 9-15) to program more trays.

8 When all samples have been programmed, touch Done.

9 Place the samples in the assigned cup positions and load the trays onto the system.

10 Touch  to begin processing.

Manually Program Sample IDs with Tray and Cup Assignments

Note: Do not reassign samples to a different TRAY position once the sample bar codes are read.

1 Touch  to display the Sample Programming screen.

2 Touch the Sample ID field.

3 Type the sample ID (1–15 alphanumeric characters).

IMPORTANT: Sample IDs must be unique. Once all results are complete for a given sample ID or the sample program has been deleted, you can reuse the sample ID.

4 Press [Enter].

The cursor moves to the Tray field.

5 Type a tray ID (1 or 2 alphanumeric characters).

Note: The tray ID must match the bar code number of the tray used for processing the samples.

The system enters the next available cup ID for the tray.

6 To change the cup ID, type another cup position (1 - 10).

7 Press [Enter].

8 Touch a body fluid choice. Touch the left or right arrows to display additional body fluid choices.

9 Touch the buttons for the assays or panels you want to process for the sample. (Touch Page Down to display additional assays; touch Page Horizontal to display additional panel buttons.)

10 (Optional) Touch additional characteristics you want (Reps, Dilute, Perm, Manual Dilution, STAT).

Note: STAT is provided for documentation only. You must load a sample in the STAT LANE of the Sampling Center in order for it to receive STAT processing.

11 (Optional) Touch the Edit Patient Data button to edit or add patient demographics.

12 Touch the Save/Next button.

13 Repeat Steps 2 (page 9-15) through 12 (page 9-16) to program additional samples.

Edit Sample Programs

1 Touch  to display the Sample Programming screen.

2 Touch the Sample ID entry field.

3 Type the sample ID (1 - 15 alphanumeric characters).

4 Press [Enter].

5 Change the appropriate information for the program.

- Touch Edit ID/Location to change the Sample ID, the Tray ID or the Cup ID.

  IMPORTANT: Ortho Clinical Diagnostics (OCD) does not recommend the use of confidential, patient-identifying information such as patient name or government identifier as part of the sample ID. OCD occasionally requests files from your system that contain sample IDs to assist in troubleshooting or performing routine maintenance of the system. Avoid the use of patient-identifying information as part of the sample ID.

- Touch Define Panels to edit panels.
- Touch Set Report Status to change the report status for the record.
- Touch Edit Patient Data to edit patient demographic information, edit results, or send reports.

  Note: Results for restricted assays cannot be edited.

6 Touch Save/Next to save your changes.

7 Touch  to clear the Sample Programming screen.

Delete a Sample Program

1 Touch  to display the Sample Programming screen.

2 Type the sample ID (1 - 15 alphanumeric characters) of the sample you want to delete.

3 Press [Enter].

The system displays the sample program.

4 Touch Delete to display the Delete dialog.

5 Touch Yes to delete the sample program.

The sample program is deleted, the Delete dialog is dismissed, and the Sample Programming screen is cleared.

Program Sample IDs Manually

1 Touch  to display the Sample Programming screen.

2 Touch Sample ID and type the sample ID (1–15 alphanumeric characters).

3 Press [Enter].

4 Touch a Body Fluid button.

5 Touch the buttons for the assays or panels you want to process for the sample. (Touch Page Down to display additional assays; touch Page Horizontal to display additional panel buttons.)

6 (Optional) Touch additional characteristics you want to define for the Sample ID. These can be Reps, Dilute, Perm, Manual Dilution, STAT, and Lab Report Comments.

7 (Optional) Touch the Edit Patient Data button to edit or add patient demographics.

8 Touch the Save/Next button.

9 Repeat Steps 2 (page 9-17) through 8 (page 9-17) to program additional samples.

Note: If you are not using bar code labels on the containers, you must assign the programs to a tray using the Sample Programming screen before the samples can be processed.

Review Sample IDs

1 Touch  to display the Sample Programming screen.

2 Touch Review Sample IDs to access the Review Sample IDs screen.

3 View the alphanumeric list of all pending Sample IDs.

Delete Sample IDs by Time

This deletion method will delete permanent sample programs – STAT, Downloaded, and Control – that have been programmed and have not been processed during the defined time.

1 Touch Sample Programming > Review Sample IDs > Display by Time.

2 Enter the minimum time (in hours) of the Sample IDs you wish to review/delete and press [Enter].

3 Touch OK.

4 Touch Delete to delete all the Sample IDs displayed on the screen.

A confirmation dialog is displayed.

5 Touch Yes.

Define a Panel

Define a panel to group assays that are frequently processed together.

Note: Touch Define Program at any point to return to the Sample Programming screen and cancel any information not yet saved on the Define Panels screen. The system restores any entries or selections that were last saved.

1 Touch  to display the Sample Programming screen.

2 Touch Define Panels to access the Define Panels screen.

3 Touch the appropriate Body Fluid button. By default, the Body Fluid button that is selected on the Sample Programming screen is selected on the Define Panels screen.

The assays available for the selected Body Fluid are displayed in the assay area.

4 Touch a blank Panel button under the assay area.

5 Type the name of the panel in the Panel field. The name can be up to 6 characters in length.

6 Press [Enter].

7 Touch the button of an assay that you want to include in the panel.

8 (Optional) Touch Dilute and type a dilution factor for sample dilution or accept the default dilution factor that is displayed. Press [Enter] if you typed in a new dilution factor.

The assay name and its dilution factor, if defined, is displayed on the list on the right side of the screen.

9 Continue selecting assays to include in the panel. Define a dilution factor for the assay if needed.

The assay names and their dilution factors, if defined, are added to the list on the right side of the screen.

10 Touch Save/Next to save the panel. The panel button displays the new panel name.

11 If desired, repeat steps 3 (page 9-18) through 10 (page 9-18) to define additional panels.

12 Touch Define Program to return to the Sample Programming screen.

Edit a Panel

Edit a panel to change its name or the assays associated with it.

Note: Touch Define Program at any point to return to the Sample Programming screen and cancel any information not yet saved on the Define Panels screen. The system restores any entries or selections that were last saved.

1 Touch  to display the Sample Programming screen.

2 Touch Define Panels to access the Define Panels screen.

3 Touch the name of the panel you want to edit.

4 To change the Body Fluid, touch a different Body Fluid button.

The assays available for the selected Body Fluid are displayed in the assay area. All assays that are associated with original Body Fluid are cleared from the assay area and from the list on the right side of the screen

5 To change the name of the panel, type the new name in the Panel field and press [Enter]. The name can be up to 6 characters in length.

6 To delete an assay from the panel, touch the (selected) button of the assay.

7 To add an assay to the panel, touch the button of the assay.

8 (Optional) For the added assay, touch Dilute and type a dilution factor for sample dilution or accept the default dilution factor that is displayed. Press [Enter] if you typed in a new dilution factor.

The assay name and its dilution factor, if defined, is displayed on the list on the right side of the screen.

9 Continue deleting assays from the panel or selecting assays to include in the panel. Choose a dilution factor for the assay if needed.

The assay names and their dilution factors, if defined, are added to the list on the right side of the screen.

10 Touch Save/Next to save the panel. If you changed the panel name, the new name is displayed for the panel.

11 If desired, repeat Steps 3 (page 9-18) through 10 (page 9-19) to edit additional panels.

12 Touch Define Program to return to the Sample Programming screen.

Delete a Panel

Deleting a panel deletes only the named group of assays; the assays themselves are not deleted.

Note: Touch Define Program at any point to return to the Sample Programming screen and cancel any information not yet saved on the Define Panels screen. The system restores any entries or selections that were last saved.

1 Touch  to display the Sample Programming screen.

2 Touch Define Panels to access the Define Panels screen.

3 Touch the name of the panel you want to delete.

4 Touch the Delete button.

The system displays a confirmation dialog.

5 Touch Yes to delete the panel.

The panel is deleted and the name of the panel button reverts to the default name.

6 If desired, repeat steps 3 (page 9-19) through 5 (page 9-19) to delete other panels.

7 Touch Define Program to return to the Sample Programming screen.

Add or Edit Patient Data

Add or edit patient information to be printed on the Patient Report.

1 Touch  to display the Sample Programming screen.

2 Type the sample ID (1–15 alphanumeric characters) and press [Enter].

3 Touch Edit Patient Data. The system displays the Edit Patient Data screen.

4 Type or edit any of the following patient information. Press [Enter] to confirm each entry and move to the next field or touch the next field in which you want to type.

Note: For Birth Date, Collection Date, and Time, use the formats defined through Options & Configuration - Date/Time. Always use four digits for the year.

Patient ID	Patient identification (1–20 alphanumeric characters).
Last Name	Patient's last name (1–20 alphanumeric characters).
First Name	Patient's first name (1–15 alphanumeric characters).
MI	Patient's middle initial (1 alphanumeric character).
Address	Patient address (1–20 alphanumeric characters per line). Press [Tab] or [Enter] to move from one line to the next.
Range Attribute	A defined patient demographic other than sex that has been configured in Options & Configuration - Configure Demographics screen. Some examples include race, smoker, or disease states.
Birth Date	Patient date of birth. Always use four digits for the year.
Age	Patient's age (1–3 alphanumeric characters).
Room	The patient's room identification (10 alphanumeric characters).
Sex	Patient's gender (1 alphanumeric character).
Collection Date	Date that the sample was collected. Always use four digits for the year.
Collection Time	Time that the sample was collected.

5 Type or edit any of the following physician information. Press [Enter] to confirm each entry and move to the next field or touch the next field in which you want to type.

Physician ID	Physician identification (1 - 15 alphanumeric characters).
Last Name	Physician last name (1 - 20 alphanumeric characters).
First Name	Physician first name (1 - 15 alphanumeric characters).
MI	Physician middle initial (1 alphanumeric character).

(Continued)

Address	Physician address (1 - 20 alphanumeric characters).

6 If desired, type notes (such as hemolyzed) in the Comments fields (1 - 20 alphanumeric characters on each line). Text on a line does not wrap from one line to the next. Press [Tab] or [Enter] to move to the next line.

7 Touch Save or Save/Next to save your entries.

Set Report Status

The default Report Status settings in Sample Programming reflect the settings defined on the Options & Configuration — Configure Report Control screen. Use this procedure to override the default setting for a specific sample.

1 Touch  to display the Sample Programming screen.

2 Type the Sample ID to identify the report information and press [Enter].

3 Touch Edit Patient Data to display the Edit Patient Data screen.

4 Touch Set Report Status to display the Set Report Status dialog.

5 For Patient, Laboratory, or Laboratory Computer (LIS),

- Touch Off if you do not want to generate the report.
- Touch Send to send the report when the sample has completed processing.

6 Touch OK to save your choices and return to the Sample Programming– Edit Patient Data screen.

Program an Assay for an Operator-Requested Dilution

1 Touch  to display the Sample Programming screen.

2 Touch the button for the desired fluid.

3 Touch the button for the desired assay.

4 Touch Dilute.

The system displays the default out-of-range dilution factor.

5 Choose one of these steps:

a To change the default out-of-range dilution factor, type a new dilution factor and press [Enter].

MicroSlide: 1.3-101.0

MicroTip: 1.3-101.0

MicroWell: 1.3-400

b To use the default out-of-range dilution factor, press [Enter] without changing the dilution factor.

Set a Manual Dilution Factor

1 Touch  to display the Sample Programming screen.

2 Type the Sample ID (1 - 15 alphanumeric characters) and press [Enter].

3 Touch the Manual Dilution button.

4 Type the dilution factor (1 - 9999 with a floating decimal point) for the sample.

5 Press [Enter].

6 Touch Save.

Cancel a Manual Dilution Factor

1 Touch  to display the Sample Programming screen.

2 Type the Sample ID (1 - 15 alphanumeric characters) and press [Enter].

3 Touch the Manual Dilution button.

4 Change the dilution factor to 1.000 for the sample.

The value 1.0000 indicates no dilution is necessary for normal processing

5 Press [Enter].

6 Touch Save.

Replicate an Assay

1 Touch  to display the Sample Programming screen.

2 Touch the assay you want to replicate.

3 Touch Reps + the number of times you want to replicate the assay. (Touch Reps - to decrease the number of replicates.)

The system displays the name of the last selected assay or panel between the - and + buttons.

4 Touch Save/Next.

Chapter 10 Assay Calibration Overview

Assay calibration is a process that relates the response of the system to analyte concentration or activities. Calibration is performed periodically to adjust for changes in the system, assay protocols, or assay reagent lots.

Calibration is an automatic process: bar-coded calibrators (when available) or manually programmed TRAYS are placed on the system for assay calibration, the calibrators are processed in a random access format (bar-coded) or in the order they were defined (manual), and a new calibration curve is calculated. The new curve is saved on the system and used for subsequent assays to determine the analyte concentrations in the patient and control samples.

Calibrators with bar codes can be placed in any tray, across different trays, and in any position and sequence. Quality control and patient samples can be processed with the calibrators. The system distinguishes between patient and calibrator samples, recognizes the calibrators that are part of a set, and processes the samples accordingly.

The calibration procedure involves loading reagents for each assay to be calibrated, preparing and loading the calibrators, programming and running the calibration, and verifying the calibration by running controls.

Each VITROS Calibrator Kit has certain VITROS MicroTip or MicroSlide assays it can calibrate. Each VITROS Immunodiagnostic Products Calibrator is lot-linked to its associated reagent lot. The lot numbers required for calibration depend on the assays being calibrated. So, if a MicroWell TSH Reagent is purchased with a lot number of 0900 then the associated calibrator must also have a lot number of 0900. You must calibrate an assay reagent lot in order to use that lot for assay processing. Other reagents (ancillary reagents, signal reagent, universal wash reagent, and diluents) do not require calibration when lots are changed. The system stores the last 25 calibrations per analyte/body fluid/slide or reagent lot combination.

Tell me more about VITROS Chemistry Products Calibrator Kit Contents (page 10-4)

When to Calibrate

Always refer to the specific Instructions for Use for when to calibrate the system. However, the system can also require calibration for individual assays when:

- A calibration expires
- A reagent lot number changes
- The Electrolyte Reference Fluid (ERF) lot changes for the affected assays (sodium, potassium, chloride)
- The Immuno-Wash fluid (IWF) lot changes for the affected Immuno-Rate chemistries
- System maintenance or service results in replacement of critical parts (for example, LUMINOMETER)
- Required by government regulations. In the United States, the system must be calibrated or calibration verified at least every six months.
- Quality Control performance is out of range

Recalibration for some assays may be required under certain conditions. In the following situations, process control fluids and use the results to determine the need for recalibration:

- Following the update of the white reference correction factors
- When the quality control limits specified by the laboratory are exceeded

For user-defined assays, recalibrate when any parameter on the Edit Protocol Parameters screen is changed (for example, reagent volume, reagent pack name/bottle, sample volume, incubation time). It is recommended that user-defined assays be recalibrated after changes to:

- Reagent lot number
- Diluent type
- Diluent volume
- Units

Manual Calibration Programs

A reagent lot calibration can be manually programmed if bar code labels are not present on the calibrators. Touch Samples > Cal Programs > Define New Cal to manually program a reagent lot. In order to process a calibration without bar codes, the system requires a Calibration ID, Tray, Cup, and assay(s) to be assigned for a calibration to occur.

Note: Make sure the calibrators appear on the sample tray in the cup order that is displayed on the Sample Programming – Cal Program screen.

Bar-Coded Calibrator Rules

Calibrator rules are set manually on the system. Touch Options > Configure System > Calibration Rules to configure the calibration rules. The rules are used to establish protocols for 3 different circumstances:

- When there is a new lot introduced to the system, or a lot has been uncalibrated by an ADD load
- When a calibration has a current/failed Status.
- When a current calibration is reaching its user defined calibration expiration date

  Note: The default expiration date for MicroSlide, MicroTip, and MicroWell assays is 3 days.

Tell me how to select Bar-Coded Calibrator Rules (page 17-23)

Tell me more about calibration (page 10-1)

Assay Data Disk (ADD)

The Assay Data Disk (ADD) contains data required to calibrate the system. Each disk has a Data Release Version number identifying its data. The disk with the highest Data Release Version number contains the latest data.

ADD information can also be viewed on the system. Touch V-Docs > About, and then touch the Assay Data Disk History Chart button, under Currently Loaded Software.

Calibration Data

The Assay Data Disk contains three types of calibration data:

- Calibrator Kit Definitions — Identify the specific calibrators required to calibrate the system for each assay/body fluid combination.
- Coefficients/Limits — Mathematical information specific to each lot/generation of reagent/slide. A set of coefficients/limits is defined for each assay and body fluid generation combination.
- Calibrator Values — Calibrator bottle values that are determined for VITROS calibrators under controlled laboratory conditions, used to maintain calibration traceability.
- Manufacturers Generated Calibration Curve (MGCC) — (MicroWells only) A master calibration based on 1 to 10 master calibrators, established for each reagent lot by the manufacturer.

The Assay Data Disk also includes updated VITROS MicroTip™ and VITROS MicroSlide™ Assay Sheets, and contains history for the currently loaded Assay Data Disk. The Assay Sheets can be printed, or viewed on an off-board computer (PC).

How to Load the Assay Data Disk (ADD)

If a new shipment of reagents or calibrators contains a lot number never processed on the system before, an Assay Data Disk will be included with the order. Load the new disk before using the new materials.

If a new Assay Data Disk (ADD) becomes available through e-Connectivity®, the system indicates a file is ready for download on the System Status screen. The ADD stays in the Inbox until another ADD is downloaded. The most recent ADD download replaces any previous version.

Tell me how to load a downloaded file (page 17-40)

There are two types of ADD loads:

- All Assay Data
- New Lots

An All Assay Data load will take about five minutes to complete, and needs to be done while the system is not processing samples. During All Assay Data loading, all of the data on the Assay Data Disk is copied to the system. An Alternative Assays dialog box will prompt the operator to decide how to handle duplicate assays.

Tell me more about the Load System Data process (page 17-40)

A New Lots load copies only new lot information to the system, and can be completed while the system is processing samples.

Note: Refer to the History Chart to verify that no performance changes have occurred. If there are performance changes, an All Assay Data load is required when convenient.

The information remains on the fixed disk until you load a new ADD, regardless of the load type.

Note: Schedule disk loading at a convenient time for calibration, since loading a new disk may cause assays to become uncalibrated. Read the Assay Data Disk communication prior to loading the disk to determine which assays may become uncalibrated.

Retain the latest version of the Assay Data Disk for reloading if necessary.

See Load System Data (page 17-40) for more information on loading the delivered files.

How to Replace or Save Modified Parameters

There are two classifications of assay data parameters that the user can modify: M1 and M2. When you load the Assay Data Disk, you can replace your current M1 parameters with the data on the Assay Data disk, or you can retain any M1 parameters that have changed. Default values from the Assay Data Disk always replace the M2 parameters. Loading the Assay Data Disk always causes assays with modified M2 values to become uncalibrated.

Tell me more about How to Replace or Save Modified Parameters (page 10-9)

Tell me more about M1 parameters (page 10-9)

Tell me more about M2 parameters (page 10-10)

Assay Data Disk Storage

Save and properly store the Assay Data Disk (ADD). You may need the previous disk if the data does not successfully transfer to the system's fixed disk.

Tell me how to properly store the Assay Data Disk (ADD) (page 3-10)

Calibration Fluids

For calibration, the system requires one or more calibrator fluids containing different concentration or activities of an analyte. VITROS calibrators may be lyophilized or liquid and are lot-linked to their associated reagent lot, or supplied in numbered calibrator kits (page 10-4). The lots and kit numbers required for calibration depend on the assays being calibrated.

Quality Control (QC) should be performed after calibration, to verify a successful calibration has occurred.

Calibrator Values

Calibrator values are determined under controlled laboratory conditions. Using calibrator values enables the system to report analyte concentrations for specimens which are traceable to the values that would be obtained using the manufacturer selected method.

A master calibration is established for each MicroWell reagent lot by the manufacturer. The master calibration process establishes a curve based on the generated light signals versus the concentrations of six to ten master calibrators, depending on the assay. Multiple measurements of each master calibrator are made for each reagent lot. The mean light signals for each master calibrator concentration are calculated to determine the master calibration. This information is transferred to the Assay Data Disk for each reagent lot.

When an All Assay Data load is selected on the system, calibrator values from the Assay Data Disk or downloaded via e-Connectivity® are transferred to the system, where they are stored for use during calibration. Calibrator values are specific for each reagent and calibrator. To view a calibrator value, touch Options > Review/Edit Calibrations. Select a body fluid/assay combination, then touch Review Cal Definition. Refer to the analyte-specific Instructions for Use for additional calibration information.

Calibrator Kit Contents

The following tables identify the calibrators included in VITROS Chemistry Products MicroSlide and MicroTip Calibrator Kits. VITROS Immunodiagnostic Products Reagents and Calibrators are lot-linked. Refer to the Instructions for Use for the assay for more information.

VITROS Chemistry Products MicroSlide Calibrator Kits

Kit	Tests
1	BUN, Ca, CREA, GLU, LAC, Li, Mg, PHOS , SALI, THEO, URIC
2	Na+, K+, Cl-, ECO_2, CHOL, TRIG
3	AcP, ALT, ALKP, AMYL, LIPA, AST, CK, GGT, LDH
4	ALB, TP, BuBc, TBIL, Fe, TIBC
5	AMON, PROT
6	CHE, CKMB
7	CRP
8	ALC
9	ACET, CRBM, DGXN, PHBR, PHYT
10	UPRO
25	dHDL (MicroSlide)

VITROS Chemistry Products MicroTip Calibrator Kits

Kit	Tests
11	VANC
12	VALP
13	GENT
14	TOBRA
16	RF*
17	hsCRP*
18	d%A1c*
19	dLDL*
20	TRFRN, C3, C4, IgA, IgG, IgM
21	Apo A1
22	Apo B
23	PALB
24	mALB
26	AMPH, BARB, BENZ, COCM, METD, OP, PCP*
27	HCY

(Continued)

28	ASO*
29	dTIBC
30	THC*
99	AAT, HPT

*Also requires use of VITROS Chemistry Products FS Calibrator 1.

Calibrator Use and Storage

Calibrator Use

Remove the appropriate kit or lot numbers of calibrators (and any associated diluents) from storage. The calibrators that are required depend upon the assays to be calibrated.

Refer to Calibrator Kit Contents (page 10-4) to determine which assays are calibrated through each VITROS® Chemistry Products Calibrator Kits.

Reconstituted Lyophilized Calibrators

IMPORTANT: Refer to the Instructions for Use for special calibration preparation, such as Hepatitis.

Tell me how reconstitute lyophilized calibrators (page 10-19)

Use of Liquid Calibrators

IMPORTANT: Refer to the calibrator Instructions for Use for specific preparation instructions.

Tell me how to prepare liquid calibrators (page 10-19)

Calibration Tray Preparation

If manually programming the calibrators, prepare the TRAY containing the calibrators after creating the calibration program. This sequence minimizes the time the calibrators are allowed to stand in the sample cups prior to use, and makes sure that the manually programmed TRAY is not scanned before they are assigned. If a manually programmed calibration is scanned by the system prior to assigning a TRAY, it cannot be sampled.

If using bar codes, simply place the calibrators in any position or order on the TRAY. Load the TRAY on the system. The system assigns the cup position for each calibrator. The assignments are displayed on the SAMPLE PROGRAMMING — Calibration Programs screen for reference.

Note: Not all VITROS® Chemistry Products Calibrators use bar codes. Manually program the calibrators that do not have bar codes.

Different system rules can be configured for which assay lots to calibrate when using bar-coded calibrators.

Tell me how to Configure Bar-Coded Calibrator Rules (page 17-46)

Tell me how to Process Calibrators without Bar Codes (page 10-20)

Refer to the calibrator Instructions for Use for information about storing any remaining calibration fluid.

Calibrator Storage

Store calibrators according to their Instructions for Use. Under these storage conditions, calibrators are stable to the date appearing on the calibrator package.

IMPORTANT: Refer to the Instructions for Use and procedures for special calibration precautions.

Calibration Programs

Calibration Program Definition

A calibration program defines a set of assays that are calibrated together. You can fully automate the calibration process by using bar code labels (when available), or you can create the program manually by selecting the assays for calibration. You can choose to save the calibration permanently for reuse, eliminating the need for reprogramming.

A calibration program automatically includes all body fluids appropriate for its component assays. For example, if a calibration program includes the serum Cortisol assay, serum Cortisol, plasma Cortisol, and urine Cortisol are all calibrated.

Tell me how to define a calibration program (page 10-20)

Manual Calibration Lot Number Assignment

Note: Manual calibration lot number assignment is not necessary when using bar-coded calibrators (when available). Simply place the bar-coded calibrators on the TRAY, and load the TRAY onto the system. The system automatically processes the calibrators.

Touch the Assign Cal button on the SAMPLE PROGRAMMING – Calibration Programs screen to manually assign calibrator lot numbers. The Select Lot Numbers dialog box appears for you to identify the assay lot numbers to be calibrated for a specific calibration program.

Tell me how to assign lot numbers for calibrations (page 10-21)

The Work List dialog box enables you to assign trays for the calibration, and appears after you have assigned the lot numbers in the Select Lot Numbers dialog box. A calibration program can be assigned to one or two trays. If the program is assigned to two trays, one calibrator kit/lot can span the trays. In such cases, if the system cannot locate the second tray, the calibrator kit/lot that spans the trays will fail.

The Work List dialog box displays the assays and lot numbers of the assays to be calibrated.

Tell me how to assign a tray for the calibration (page 10-21)

The system assigns the cup position for each calibrator, and displays the cup, kit, lot, and bottle numbers on the Work List dialog box. The system also displays this information on the SAMPLE PROGRAMMING – Calibration Programs screen after you close the Work List dialog box.

Calibration Program Review and Edits

Use the Review/Edit Cal button on the SAMPLE PROGRAMMING – Calibration Programs screen to review or edit programmed calibrations.

Tell me how to review and edit calibration programs (page 10-22)

Select Bar-Coded Calibrator Rules

Different system rules can be configured for which assay lots to calibrate when using bar-coded calibrators.

Tell me more about Bar-Coded Calibrator Rules (page 17-23)

Tell me how to Configure Bar-Coded Calibrator Rules (page 17-46)

Calibration Process

Assay Calibration

On-board reagents must be calibrated before they are used for patient or control sample processing.

The actual process of calibration is similar to running tests except that calibration fluids are run, and the results are stored for use in calculating subsequent results for patient and control samples. Calibration fluids are processed automatically using bar codes, or they are manually programmed. The system keeps track of how long a calibration for an individual assay is usable before it expires (as specified on the Assay Data Disk).

Tell me how to perform assay calibration (page 10-22)

If you manually program the calibration, the system identifies the TRAY as a calibration TRAY based on TRAY ID, meters the set, calculates new calibration parameters, and assigns the calibration a **current** status.

If you use bar-coded calibrators, the system automatically identifies the TRAY, meters the set, calculates new calibration parameters, and assigns the calibration a **current** status.

The system applies the most recently processed calibration to subsequent assays to determine analyte concentrations in patient and control samples. The system must complete a calibration for a reagent lot before another lot of the same assay can be calibrated. It is possible to calibrate several assays at the same time but you can only calibrate one lot of a given assay at a time. The most recent calibration completed becomes the current calibration. All calibrators (levels) within a set must be metered within two hours of metering the initial calibrator.

- If a condition occurs (for example, if no inventory exists for the reagents) prior to metering the initial calibrator, the system cannot process the calibration. The previous calibration remains current. If conditions occur for any subsequent calibrators of a set, the calibration will fail.
- Following each calibration, perform quality control procedures.

How to Cancel or Delete a Calibration Program

Use the Cancel Cal or Delete Cal buttons on the SAMPLE PROGRAMMING – Calibration Programs screen to cancel or delete any calibration programs, respectively.

Tell me how to Cancel a Calibration Program During Metering (page 10-22)

Tell me how to Delete a Calibration Program Before Metering (page 10-22)

Calibration Reports

Following calibration, the system prints a Calibration Report. The report destination is defined on the Options & Configuration - Configure Report Control screen. Review the printed report to ensure that the calibration was successful. Also verify calibrations by performing quality control procedures. A calibration is successful if the system did not report any calibration failure conditions and QC results are within acceptable limits.

If a calibration did not succeed, review the corresponding calibration record to determine the reason. Also refer to the section below about Calibration Troubleshooting (page 10-9).

Tell me more about Calibration Reports (page 12-3)

Calibration Troubleshooting

Consider the following if you are experiencing problems with calibration:

1. Is the calibrator material fresh and fully reconstituted?
2. Are you using a fresh cartridge of slides or reagent pack?
3. Are you using the correct calibrators?
4. Are any condition codes or calibrator codes associated with the status, or were any condition codes generated during the calibration? Review the possible causes and perform recommended actions.
5. Are calibrator responses similar to previous responses?

To Replace or Save Modified Parameters

As you configure assays, and enter assay data, you can modify certain parameters (data) for each assay. There are two classifications for modifiable parameters: M1 and M2. If you select All Assay Data as the Assay Data Disk (ADD) load method, you can choose Retain Configuration for any M1/M2 parameters that you have changed, or Restore Defaults from the ADD.

Note: If you choose Restore Defaults, any assays with modified M1/M2 parameters become uncalibrated after the Assay Data Disk loading completes.

Tell me more about the Load System Data process (page 17-40)

Identifying M1 and M2 Parameters

M1 and M2 parameters that have been modified appear on the Laboratory Report with the code "M1" or "M2". The codes also appear on the Options and Configuration - Review Assay Data screen and the Review Results screen.

Tell me more about M1 Parameters (page 10-9)

Tell me more about M2 Parameters (page 10-10)

Tell me more about the Parameter/Screen/Assay Type Chart (page 10-11)

M1 Parameters

The following parameters are classified as M1. For more detailed information about these parameters, refer to the Parameter/Screen/Assay Type Chart (page 10-11).

(Continued)

- Diluent
- Standard Dilution Factor
- Reflex Dilution — Dilution Factor
- Reflex Dilution — Reduction Factor
- Descriptive Text (Positive, Negative, Borderline, Trace)
- Cutoff Values
- Measuring (Reportable) Range
- HIT Flagging Limits
- Calibrator Replicate Response Range (Bottle One to Bottle Six)
- Measuring (Reportable) Range Lower Limit
- Measuring (Reportable) Range Upper Limit
- Calibrator Replicate Response Range (Level One to Level Four)
- Calibrator Millivolt Response Range (Level One to Level Four)
- Calibrator Validation Response Range (Level One to Level Four)
- Calibrator Replicate Response Range - 1st Reading (Level One to Level Four)
- Calibrator Replicate Response Range - 2nd Reading (Level One to Level Four)
- Slide Impedance Limit
- Calibration Interval
- Minimum Points in Window
- Spike Derivative Tolerance
- SD-T
- Critical Activity

M2 Parameters

The following parameters are classified as M2.

(Continued)

- Calibrator Value (Bottle One to Bottle Six)
- Substrate Depletion Multiplier
- First Point Reference Multiplier
- Wash Detection Tolerance
- Extrema Check — Slope One
- Extrema Check — Slope Two
- K Exponent
- Drop Volume (µL)
- Initial Value for Blank
- Convergence Tolerance Factor
- Initial Absorbance Limits - Lower Limit
- Initial Absorbance Limits - Upper Limit
- Blank Absorbance Limits - Lower Limit
- Blank Absorbance Limits - Upper Limit
- Second Absorbance Limits - Lower Limit
- Second Absorbance Limits - Upper Limit
- Antigen Excess Factor
- Antigen Excess Limit
- Nonlinearity Limit
- Minimum Read Points Allowed
- Max SD of Regression Line
- Max Relative SD of Regression Line
- Linear Kinetics Only (Yes/No)
- Increasing Rate (Yes/No)
- Substrate Depletion Delta Density Method (Yes/No)
- First Derivative Tolerance
- Inside Out Threshold
- Regression Method: Maximum Rate or Linear Inside Out
- Substrate Depletion Time 1
- Substrate Depletion Time 2
- Induction Time
- Window Modulator
- Lo Rate Long Window
- Hi Rate Short Window
- Minimum Window Length
- Maximum Window Length
- Algorithm Method: Endpoint or Rate Model
- Substrate Depletion Time
- Induction Time

Parameter/Screen/Assay Type Chart: Review/Edit Configuration

The following chart lists M1 and M2 parameters as they are found on system screens. For each screen:

- The Screen Field column below shows the name of the field containing the parameter.
- The Assay Types column below indicates the type of assay affected by the parameter. A parameter may apply to all types of assays, or only to one or more specific assay types.
- The M1/M2 column below indicates whether the parameter is M1 or M2.

To access the OPTIONS & CONFIGURATION — Review/Edit Configuration screen, touch Options > Configure Assays, select the body fluid/assay combination, and touch the Review/Edit Configuration button.

For additional Parameter/Screen/Assay Type Charts refer to:

- Parameter/Screen/Assay Type Chart — Review Assay Data (page 10-14)
- Parameter/Screen/Assay Type Chart — Review Cal Definition (page 10-13)

OPTIONS & CONFIGURATION - Review/Edit Configuration (MicroSlide, MicroTip)

Screen Field	Assay Types	M1/M2
Diluent	• Quantitative MicroSlide • Quantitative MicroTip • Semi-Quantitative/Qualitative MicroTip	M1
Standard Dilution Factor	• Quantitative MicroSlide • Quantitative MicroTip • Semi-Quantitative/Qualitative MicroTip	M1
REFLEX DILUTION — Reflex Dilution	• Quantitative MicroSlide • Quantitative MicroTip • Semi-Quantitative/Qualitative MicroTip	M1
REFLEX DILUTION — Dilution Factor	• Quantitative MicroSlide • Quantitative MicroTip • Semi-Quantitative/Qualitative MicroTip	M1
REFLEX DILUTION — Reduction Factor	• Quantitative MicroSlide • Quantitative MicroTip • Semi-Quantitative/Qualitative MicroTip	M1

OPTIONS & CONFIGURATION - Review/Edit Configuration (MicroWell)

Screen Field	Assay Types	M1/M2
Diluent	All	M1
REFLEX DILUTION — Reflex Dilution	All	M1
REFLEX DILUTION — Dilution Factor	All	M1

Parameter/Screen/Assay Type Chart: Review Cal Definition

The following chart lists M1 and M2 parameters as they are found on system screens. For each screen:

- The Screen Field column below shows the name of the field containing the parameter.
- The Assay Types column below indicates the type of assay affected by the parameter. A parameter may apply to all types of assays, or only to one or more specific assay types.
- The M1/M2 column below indicates whether the parameter is M1 or M2.

To access the OPTIONS & CONFIGURATION — Review Cal Definition screen, touch Options > Review/Edit Calibrations, select the body fluid/assay combination, and touch the Review Cal Definition button.

OPTIONS & CONFIGURATION - Review Cal Definition (MicroSlide)

Screen Field	Assay Types	M1/M2
Calibrator Value - Bottle One to Bottle Six (number of bottles is assay-dependent)	All	M2
Substrate Dep Multiplier	• MicroSlide 2-Point Rate • MicroSlide Multiple-Point Rate • MicroSlide Immuno-Rate	M2
Wash Detection Tolerance	MicroSlide Immuno-Rate	M2
First Point Ref Multiplier	MicroSlide Multiple-Point Rate	M2

OPTIONS & CONFIGURATION - Review Cal Definition (MicroTip)

Screen Field	Assay Types	M1/M2
Dilution Factor	All	M1
Calibrator Value - Bottle One to Bottle Six (number of bottles is assay-dependent)	All	M2
Calibrator Replicate Response Range	All	M1

OPTIONS & CONFIGURATION - Review Cal Definition (MicroWell)

Screen Field	Assay Types	M1/M2

(Continued)

Calibrator Value - Bottle One to Bottle Six (number of bottles is assay-dependent)	All	M2

Parameter/Screen/Assay Type Chart: Review Assay Data

The following chart lists M1 and M2 parameters as they are found on system screens. For each screen:

- The Screen Field column below shows the name of the field containing the parameter.
- The Assay Types column below indicates the type of assay affected by the parameter. A parameter may apply to all types of assays, or only to one or more specific assay types.
- The M1/M2 column below indicates whether the parameter is M1 or M2.

To access the OPTIONS & CONFIGURATION — Review Assay Data screen, touch Options > Review/Edit Calibrations, select the body fluid/assay combination, and touch the Review Assay Data button.

OPTIONS & CONFIGURATION — Review Assay Data (MicroSlide)

Screen Field	Assay Types	M1/M2
Measuring (Reportable) Range Lower Limit	All	M1
Measuring (Reportable) Range Upper Limit		
Calibration Interval	All	M1
Extrema Check - Slope One	All	M2
Extrema Check - Slope Two		
K Exponent	All	M2
Drop Volume (µL)	• MicroSlide Dual Measurement • MicroSlide Dual Measurement, Blank Wavelength Corrected • MicroSlide Colorimetric • MicroSlide 2-Point Rate • MicroSlide Multiple-Point Rate • MicroSlide Immuno-Rate	M2

(Continued)

Calibrator Rep Resp Range	• MicroSlide Colorimetric • MicroSlide 2-Point Rate • MicroSlide Multiple-Point Rate • MicroSlide Immuno-Rate	M1
Calibrator MV Resp Range	• MicroSlide Potentiometric • MicroSlide Potentiometric with Blank	M1
Calibrator Val Resp Range	• MicroSlide Potentiometric • MicroSlide Potentiometric with Blank	M1
Cal Rep Range - First Read	• MicroSlide Dual Measurement • MicroSlide Dual Measurement, Blank Wavelength Corrected	M1
Cal Rep Range - Second Read	• MicroSlide Dual Measurement • MicroSlide Dual Measurement, Blank Wavelength Corrected	M1
Slide Impedance Limit	• MicroSlide Potentiometric • MicroSlide Potentiometric with Blank	M1
Initial Value For Blank	MicroSlide Potentiometric with Blank	M2
Convergence Tolerance Factor	MicroSlide Potentiometric with Blank	M2

OPTIONS & CONFIGURATION — Review Assay Data (MicroTip)

Screen Field	Assay Types	M1/M2

(Continued)

Measuring (Reportable) Range Lower Limit Measuring (Reportable) Range Upper Limit	All	M1
Calibration Interval	All	M1
Initial Absorbance Limits - Lower Limit Initial Absorbance Limits - Upper Limit	• MicroTip Endpoint • MicroTip 2-Point Rate • MicroTip 2–Point Rate with Blank • MicroTip Multiple-Point Rate	M2
Blank Absorbance Limits - Lower Limit Blank Absorbance Limits - Upper Limit	MicroTip Endpoint	M2
Second Absorbance Limits - Lower Limit Second Absorbance Limits - Upper Limit	• MicroTip 2-Point Rate • MicroTip 2–Point Rate with Blank	M2
Antigen Excess Limit	MicroTip Multiple-Point Rate	M2
Antigen Excess Factor	• MicroTip 2-Point Rate • MicroTip 2–Point Rate with Blank	M2
Nonlinearity Limit	MicroTip Multiple-Point Rate	M2
Minimum Read Points Allowed	MicroTip Multiple-Point Rate	M2
Max SD of Regression Line	MicroTip Multiple-Point Rate	M2
Max Relative SD of Regression Line	MicroTip Multiple-Point Rate	M2
Linear Kinetics Only (Yes/No)	MicroTip Multiple-Point Rate	M2

OPTIONS & CONFIGURATION — Review Assay Data (MicroWell)

Screen Field	Assay Types	M1/M2
Measuring (Reportable) Range Lower Limit	All	M1
Measuring (Reportable) Range Upper Limit	All	M1

(Continued)

Calibration Interval	All	M1

Multiple-Point Rate Additional Parameters

To access the Multiple-Point Rate Additional Parameters screen, touch Options > Review/Edit Calibrations, select the body fluid/assay combination, and touch Review Assay Data > View More Parameters.

Screen Field	Assay Types	M1/M2
Increasing Rate (Yes/No)	MicroSlide Multiple-Point Rate	M2
Substrate Depletion Delta Density Method (Yes/No)	MicroSlide Multiple-Point Rate	M2
Minimum Points in Window	MicroSlide Multiple-Point Rate	M2
First Derivative Tolerance	MicroSlide Multiple-Point Rate	M2
Inside Out Threshold	MicroSlide Multiple-Point Rate	M2
Spike Derivative Tolerance	MicroSlide Multiple-Point Rate	M1
SD-T	MicroSlide Multiple-Point Rate	M1
Regression Method: Maximum Rate or Linear Inside/Out	MicroSlide Multiple-Point Rate	M2
Substrate Depletion Time 1	MicroSlide Multiple-Point Rate	M2
Substrate Depletion Time 2		
Critical Activity	MicroSlide Multiple-Point Rate	M1
Induction Time	MicroSlide Multiple-Point Rate	M2

Immuno-Rate Additional Parameters

To access the Immno-Rate Additional Parameters screen, touch Options > Review/Edit Calibrations, select the body fluid/assay combination, and touch Review Assay Data > View More Parameters.

Screen Field	Assay Types	M1/M2
Increasing Rate (Yes/No)	MicroSlide Immuno-Rate	M2
Log K-Model (Yes/No)	MicroSlide Immuno-Rate	M2

(Continued)

Window Modulator	MicroSlide Immuno-Rate	M2
Lo Rate Long Window	MicroSlide Immuno-Rate	M2
Hi Rate Short Window	MicroSlide Immuno-Rate	M2
Minimum Window Length	MicroSlide Immuno-Rate	M2
Maximum Window Length	MicroSlide Immuno-Rate	M2
Regression Method: Maximum Rate or Linear Inside/Out	MicroSlide Immuno-Rate	M2
Algorithm Method: Endpoint or Rate Model	MicroSlide Immuno-Rate	M2
Spike Derivative Tolerance	MicroSlide Immuno-Rate	M1
Substrate Depletion Time	MicroSlide Immuno-Rate	M2
Critical Activity	MicroSlide Immuno-Rate	M1
Induction Time	MicroSlide Immuno-Rate	M2

Assay Calibration Procedures

The following table lists the Assay Calibration topics that reference the procedures included in this section.

Topic Title	Procedure Title
Calibrator Preparation and Storage (page 10-6)	• Reconstitute Lyophilized Calibrators (page 10-19) • Use Liquid Calibrators (page 10-19) • Process Calibrators without Bar Codes (page 10-20)
Calibration Programs (page 10-7)	• Manually Define a Calibration Program (page 10-20) • Assign Lot Numbers for Calibrations (page 10-21) • Manually Assign a Tray for Calibration (page 10-21)

(Continued)

Calibration Process (page 10-8)	• Perform an Assay Calibration (page 10-22) • Cancel a Calibration Program During Metering (page 10-22) • Delete a Calibration Program Before Metering (page 10-22) • Review and Manually Edit Calibration Programs (page 10-22)

Reconstitute Lyophilized Calibrators

IMPORTANT: Refer to the Instructions for Use for the specific calibrator for exact preparation instructions.

1. Slowly invert the diluent bottle several times to mix the contents thoroughly. DO NOT SHAKE.
2. Gently tap the lyophilate vial on the counter several times to dislodge any material adhering to the stopper.
3. Remove the seal and stopper from each bottle just before adding the diluent. Do not leave vials unstoppered.
4. Add diluent for the appropriate type of assay. Use a clean, dry pipette for each vial. A Class A volumetric pipette or an automated pipette of equivalent accuracy is recommended because this reconstitution procedure is important for the accuracy of the results. Discard any remaining diluent.
   - For MicroSlide assays, add the appropriate amount of the corresponding supplied diluent to each vial.
   - For MicroTip assays, add the appropriate amount of FS Reconstituted Diluent to each vial.
   - For MicroWell assays, add the appropriate amount of distilled water.
5. Replace the stopper and hold it firmly in place. Invert the vial gently. DO NOT SHAKE.
6. Visually verify that all freeze-dried material is dissolved prior to use. Reconstitution, with occasional inversion, may take up to 30 minutes.
7. Keep all fluids tightly stoppered when not in use. At the time of reconstitution, it is recommended the operator date and initial the vial.
8. Use reconstituted product immediately or store them in their appropriate storage area.

Use Liquid Calibrators

IMPORTANT: Refer to the Instructions for Use for the specific calibrator for exact preparation instructions.

1. Mix each bottle thoroughly by gently inverting several times. DO NOT SHAKE.
2. Choose one of the following methods to prepare the container for the calibrator:
   - Apply a calibrator bar code label to each container, place each level of calibrator in a separate cup, cover each cup with a pierceable cap, place each cup on a calibrator container, and place the container in the tray.

- If the calibrator is in a bar-coded container, place the bar-coded container in the tray.
- For containers without a bar code, place the calibrator in a cup, place it in the container, and manually program it.

3 Recap the bottles and immediately return them to their appropriate storage.

4 Place each calibrator on the system for analysis.

5 Discard any unused portions in the containers following calibration.

Process Calibrators without Bar Codes

Use this method to prepare calibrator trays when there is no bar code label on the calibrator.

1 Allow the calibrators to reach room temperature. Reconstitute lyophilized calibrators if necessary. Refer to the appropriate Instructions for Use for exact preparation information for each calibrator.

2 Mix calibrators thoroughly by gentle inversion several times. DO NOT SHAKE.

3 Place sample cups into the tray cup positions specified on the Work List screen.

4 Pipette the correct amount of calibrator into each cup from the appropriate bottle.

Note: When calibrating DAT (Drugs of Abuse Testing) assays, refer to the Instructions for Use, Calibration Procedure, for instructions on loading the calibration tray.

5 Immediately place a pierceable cap on each sample cup and place the stopper on each calibrator bottle.

6 If calibrators have been refrigerated, make sure that the calibrator in the sample cups reach room temperature before sampling (approximately 10 minutes).

Note: Do not leave calibrators on the system longer than 30 minutes before beginning sampling.

7 Place the tray(s) in the appropriate position in the SAMPLE SUPPLY.

Note: The calibration tray can be placed in the STAT Lane.

Manually Define a Calibration Program

Use this method to define a calibration program for calibrators without bar codes.

1 Touch Sample Programming > Cal Programs > Define New Cal to display the Calibration dialog.

2 Type the name of the calibration program in the Calibration ID field and press [Enter].

The name can be up to 15 characters long.

3 Touch the buttons for assays you want to include in the calibration program. Touch the Up and Down arrow buttons to display additional assays.

When you select a MicroSlide or MicroTip assay, the number of the kit used to calibrate that assay is displayed by the assay name. The number also appears beside the buttons for other assays calibrated by the kit. The system provides this number for your information; you are not required to calibrate all highlighted assays.

For MicroWell assays, each assay has its own calibrator.

Note: Some calibrator kits require the use of an additional calibrator. Be sure to assign the additional calibrator to the program.

4 Touch Save to save your selections.

5 Touch Assign to assign calibrator and lot numbers for the calibration program.

The Select Lot Numbers dialog is displayed.

6 Assign lot numbers for the calibrator and also the assay(s). Choose these from the drop down lists.

7 Touch Next when you are finished.

The Worklist dialog is displayed.

8 Place the calibrators in the appropriate position tray(s). You can assign up to 2 trays per calibration group.

9 Touch Finish when you have completed the calibration programs.

The system displays the Calibration Program screen.

Assign Lot Numbers for Calibrations

Note: This procedure is for any assay using calibrators without bar codes.

1 Touch  to display the Sample Programming screen.

2 Touch Cal Programs to access the Calibration Programs screen.

3 Find the calibration program you require in the list in the Cal Programs area of the screen.

4 Touch the calibration program name to select it.

5 Touch Assign Cal.

The system displays the Select Lot Numbers screen.

6 For MicroSlide and MicroTip assays, touch the Kit Lot field to select the calibrator lot number. Use the down arrow to scroll through the list and review all available calibrator lots.

7 For MicroSlide and MicroTip assays, when you locate the appropriate calibrator lot number, touch the lot number to select it.

8 Touch the Lot field for each assay calibrated by the kit or calibrator lot and select the lot number from the drop down list to be calibrated with this program.

9 When you finish assigning lots, touch Next.

The system displays the Work List screen that allows you to assign a tray for calibration.

Manually Assign a Tray for Calibration

Use this method to assign a tray for calibration when there is no bar code label on the calibrator.

1 On the Work List screen, touch Tray and type the tray number. If the calibration program spans two trays, touch the second Tray field and type the number of the second tray.

Note: If you enter the ID of a tray that is already programmed, the system sounds an alert tone. Type another tray ID.

2 Touch Finish.

Perform an Assay Calibration

Special requirements: Make sure calibration programs have been defined.

Note: This procedure is for any assay using calibrators without bar codes.

1 Place the sample cups onto a tray in the positions defined through the Work List screen.

2 Load the tray into the SAMPLE SUPPLY.

3 Touch  on the status console.

Cancel a Calibration Program During Metering

1 Touch  to display the Sample Programming screen.

2 Touch Cal Programs to access the Calibration Programs screen.

3 Find the calibration program you require in the list in the Cal Programs area of the screen. The calibration program should have a status of "In-Progress."

4 Touch the name of the calibration program to select it.

5 Touch Cancel Cal.

Note: Replicates that were successfully metered will be completed.

6 Remove the UNIVERSAL SAMPLE TRAY from the SAMPLE SUPPLY after it has moved out of the Metering Area.

Delete a Calibration Program Before Metering

1 Touch  to display the Sample Programming screen.

2 Touch Cal Programs to access the Calibration Programs screen.

3 Find the calibration program you require in the list in the Cal Programs area of the screen. The calibration program should have a status of "Assigned."

4 Touch the calibration program name to select it.

5 Touch Delete Cal.

A confirmation dialog is displayed.

6 Touch Yes to delete the calibration program.

7 Remove the tray from the SAMPLE SUPPLY if you have already loaded it.

Review and Manually Edit Calibration Programs

Use this method to manually edit a calibration program for calibrators without bar codes.

Note: Calibrations for restricted assays cannot be edited.

1 Touch  to display the Sample Programming screen.

2 Touch the Cal Programs button to access the Calibration Programs screen.

3 Find the calibration program you require in the list in the Cal Programs area of the screen.

4 Touch the calibration program name to select it.

5 Touch the Review/Edit Cal button.

The system displays the Calibration screen.

6 Review the information for the selected calibration program.

7 Change this information as follows:

Note: Editing groups by either selecting new assays or de-selecting assays causes an assigned calibration group to become unassigned.

- To select additional assays for the calibration program, touch the assay button.
- To remove programmed assays, touch the button for a selected assay.
- To change lot number assignments, touch Assign.
- To change tray assignments, touch Assign and then touch Next.

8 Touch Save to save your changes and then touch Done.

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Chapter 11 Result Records

Result records contain the data generated by the system when assays are processed. The system can store up to 25,000 result records. When this limit is reached, new result records overwrite the oldest records. The system permanently deletes the overwritten records from computer memory. The system does not overwrite a record if:

- A Patient Report or Laboratory Report has been requested and the requested printing has not occurred
- Transmission of results to the Laboratory Computer has been requested and results have not been sent
- It is designated for archiving, but has not been archived.

Once the result record file contains 25,000 records and cannot overwrite any more records, sample metering becomes unavailable. To process more samples, print any flagged Patient or Laboratory Reports, transmit results to the Laboratory Computer, archive results to a disk or USB Flash Drive, or touch Set Report Status on the Results Review screen to clear the flags.

Tell me more about Set Report Status (page 11-9)

Results Review

The Results Review screen enables operators to evaluate result records for patient and control samples. Operators can review, edit, print and send result records and individual results.

Note: Results Review does not display calibration results. Refer to Assay Calibration Overview (page 10-1) for more information about calibration results.

The Results Review screen and process buttons are described below.

Results Review Screen

The screen displays one line of information for each sample. To display full assay results, touch  to the left of the sample ID. The system displays additional information for each assay processed for that particular sample. To hide the assay information, touch  .

Tell me more about Results Review Screen Information (page 11-3)

Results Review Process Buttons

The Results Review screen includes the following process buttons.

Process Button	Description

(Continued)

Edit Patient Data: Edit and add patient demographic information

Tell me how to Edit Patient Data (page 11-6)

Filter Results: Filter result records to limit the number or types of samples shown on the Results Review screen

Tell me how to Filter Results (page 11-5)

Update List: Re-display the Results Review screen with the most current results that match any applied filter

Tell me how to Update the Results View (page 11-3)

Edit Result: Edit, add, or delete an assay result

Tell me how to Edit Results (page 11-6)

IntelliReport™: Display IntelliReport™ data for a result

Tell me more about the IntelliReport™ (page 11-8)

Report Status: Review Report Status

Tell me more about Report Status (page 11-9)

Set Report Status: Set the report status of selected records. The destination(s) may include a Patient Report, a Laboratory Report and/or the Laboratory Information System.

Tell me how to Set Report Status (page 11-9)

More Options: Includes the following additional features

- Display patient history for an assay
- Recalculate results in a selected result record
- Review Kinetics Plot data

Tell me about More Options (page 11-10)

Monitor Results: Display results as they are completed, including patient, control, and calibration results

Tell me how to Monitor Results (page 11-3)

(Continued)

Select/Deselect All: Either select or deselect all results records in the scrolling list. The count of the Records Selected at the bottom of the screen is updated.

How to Update the Results View

The Results Review screen is a snapshot in time. The system does not automatically update it as more results are processed.

To update the view, touch the Update List process button.

The system re-displays the Results Review screen, updated with the most current results that match any filter you have applied.

How to Monitor Results

The Results Review – Monitor Results screen will appear when the operator selects the Monitor Results process button. The Results Review – Monitor Results screen is intended to display results as they are completed, including patient, control, and calibration results.

Two lines will display for each result value: a Sample ID header line, and an assay mean line, or one line for an SI-Only result. Individual replicates will not be displayed.

When the Stop Monitoring process button is touched the displayed scrolling list of results is not updated with new results. New results may still be received into the input buffer, but they are not added to the scrolling list.

When the Start Monitoring process button is touched, results are optionally filtered according to operator-specified parameters, and displayed in the scrolling list.

Flags and Codes

Tell me about Flags and Codes (page 13-1)

Results Review Screen Information

The following table describes the sample information that is displayed on the Results Review screen.

Sample Information	Complete sample information that is shown on one row of the display.
Sample ID	The unique sample identifier. "Unnamed" appears in the field if the sample is not named. If the sample is STAT, the screen displays an "S" icon to the left of the check box.
Type	The type of sample. QC identifies control samples; blank identifies patient samples.
Loc	The location of the sample by Tray ID and cup position.
Man Dil	The manual dilution factor for the sample (blank if no manual dilution).
Fluid	The body fluid selected for the sample.
Hem	The sample index value for hemolysis.
Ict	The sample index value for icterus.
Tur	The sample index value for turbidity.

Date	The date the sample was metered displayed in the currently configured format.
Time	The time the sample was metered displayed in the currently configured format.
Item Indicators	The number of the selected results records and the total number of result records displayed.
Line and Page Scroll Buttons	Up and down arrow buttons that scroll the screen either up/down one line or up/down a page of information. The results records are displayed in reverse chronological order with the most recent records shown at the beginning of the list.
Expand/Hide Buttons (Plus or Minus Buttons)	The plus (+) button indicates there is more information for the results record; touch the + to expand the information. A minus (-) button indicates all the information is displayed for the results record. Touch the - to hide the information.
Assay Information	The result for one assay that is shown on one row of the display. If a sample ID has results from several assays, the result for each assay is displayed on a separate row.
Assay Name	The unique abbreviation for each assay selected for the sample.
Flag	The flags associated with the result. The screen displays up to two flags separated by commas.
Result	The assay result. This includes semi-quantitative result text as appropriate. “Pending” is displayed for assays that have not started processing. The number of minutes and seconds remaining until completion is displayed for those assays that have begun processing but have not been completed yet. **Note:** Completion time does not include time for Sample Indices completion. **Note:** Derived tests are considered complete when the final component is completed.
Units	The units of measurement for the result.
H	The sample index flag for hemolysis.
I	The sample index flag for icterus.
T	The sample index flag for turbidity.
Dil	The total dilution factor for the assay (the standard dilution + the reflex dilution = the total dilution). A blank indicates there is no dilution for the assay.
Codes	Codes associated with the result. The screen displays up to four codes separated by commas.
Current Sample ID	The sample ID of the currently selected results record. If no record is selected, this display is blank.
Records Selected	The total number of results records that are currently selected. If no records are selected, zero (0) is displayed.
Total Records	The total number of results records that match the current search criteria.

Display Filtering	An indication that the filtering is either On or Off. Filtering is always On unless all results records are selected and the Filter Results dialog box has no choices selected.

Tell me more about Flags and Codes (page 13-1)

Filter Results

To limit the number or types of samples shown on the Results Review screen (for example, if you want to see only results for one patient), you can apply a filter to the result records. Only records that meet the filter's criteria will be shown on the screen. The following criteria can be used to filter records:

- Patient Information
- Physician Information
- Filtering by Sample Type and Priority
- Date and Time

Tell me how to Filter Result Records (page 11-20)

Patient Information

The following Patient information can be typed or modified to filter the result record.

Sample ID	Sample identification (1 - 15 alphanumeric characters)
Patient ID	Patient identification (1 - 20 alphanumeric characters)
Last Name	Patient last name (1 - 20 alphanumeric characters)
First Name	Patient first name (1 - 15 alphanumeric characters)

Physician Information

The following Physician information can be typed or modified to filter the result record.

Physician ID	Physician identification (1 - 15 alphanumeric characters)
Last Name	Physician last name (1 - 20 alphanumeric characters)
First Name	Physician first name (1 - 15 alphanumeric characters)

Sample Type and Priority

The following options are available to filter results according to sample type.

All	Reports results for all sample types (default)

(Continued)

Patient	Reports only patient sample results
Control	Reports only control sample results

The following options are available to filter results according to priority.

All	Reports results for all priorities (default)
Routine	Reports only routine priority results
STAT	Reports only STAT priority results

Date and Time

The following options are available to filter result records.

All Records	Reports all records that match the filter result records criteria
Selected Date Range	Reports all records processed within a specified date/time range
Last 24 Hours	Reports only results processed in the last 24 hours

Patient Data

The Results Review – Edit Patient Data screen enables you to add or edit patient data. Edits result in an "EP" code on the Patient Report. Data not entered at the time of programming can be entered after the sample has been processed.

The Edit Patient Data screen can also be launched from the Sample Programming — Edit Patient Data screen. See Patient Data (page 9-9) for more information. Patient demographic information should be entered on this screen before the sample is processed.

Reports are not automatically sent after patient data is edited; operators need to touch the Set Report Status process button to send a new report.

Tell me more about Report Status (page 11-9)

Tell me how to Add or Edit Patient Data (page 11-18)

Edit Result

The Results Review – Edit Result screen enables you to edit, add, or delete an assay result. All results that have been edited or added are indicated by the "ED" (edited) code.

Each time you edit or add a result, the ranges (such as measuring (reportable) range or reference range) are verified and codes and flags are assigned as appropriate.

The Edit Results process button that launches this screen is included in both the Results Review and Results Review – Edit Patient Data screens.

If the edited assay is a component for a derived test, the derived test is recalculated. For example the T3/T4 ratio will recalculate if the result for TT4 or

TT3 is edited. The Hemolysis, Icterus, and Turbidity flags for the assay are set to NR (Not Run).

See Results Review Screen Information (page 11-3) for more details about the information displayed on this screen.

Edit Assay

Touch the Edit Assay process button on the Results Review – Edit Result screen to edit test results and derived test results. A restricted assay cannot be edited.

Use the following guidelines when editing results:

- Pending results cannot be edited.
- A result can be deleted by replacing the result with blank spaces.
- A mean assay result value that is based on replication can be edited, but the individual replicate values cannot be changed.
- Individual operator requested dilution results can be edited or deleted, but not the reported result for the lowest reported dilution. Appropriate codes and flags are added or removed to the mean and individual replicates.
- Semi-quantitative assays display the result text that cannot be edited in the result column. To change the text, edit the numerical result that is displayed next to the text.

  Tell me how to Review/Edit Assay Configuration (page 17-6)
- If a result record contains an entry of “No Result” for an assay, asterisks appear in place of “No Result” on the Edit/Add Analytes screen. You cannot enter text or “No Result” as part of editing a result.

Use these additional guidelines when editing derived test results:

- The component assays of a derived test can be edited, but not the derived test result. Editing a component of a derived test causes the derived test to be updated and adds or removes the appropriate codes and flags.
- A derived test result can be deleted by replacing the result with blank spaces. This does not cause changes to the component assays.
- Deleting a component assay deletes the derived test.
- A derived test and the component assays of the derived test are automatically added. The derived test cannot be edited and is automatically calculated from the component assays. The added derived test is indicated by the "ED" (edited result) code.

Tell me how to Edit an Assay in a Result Record (page 11-20)

Add Assay

Touch the Add Assay process button on the Results Review – Edit Result screen to add an assay to the result record

This button launches the Edit Results – Add Assay dialog box. This dialog displays assays that are appropriate for the currently configured assay data and the type of body fluid represented by the sample.

An assay supported by the Assay Data Disk (ADD) can be selected and added to the result record. Results for this assay can be entered once it has been added. Adding a derived test will automatically add the component tests needed (if they are not already on the system). Adding assay results is useful when you want to add values from another system or to complete a report.

Tell me how to Add an Assay to a Result Record (page 11-20)

Set Report Status

Touch the Set Report Status process button on the Results Review – Edit Result screen to change the report status of indicated records.

Tell me more about Report Status (page 11-9)

Delete Assay

Touch the Delete Assay process button on the Results Review – Edit Result screen to delete a selected assay from the result record.

A restricted assay cannot be deleted. However, the entire record can be deleted even if it contains a restricted assay.

Tell me how to Delete Records (page 11-12)

Note: If a derived component assay is deleted, then the derived test assay will be removed as well.

Tell me how to Delete an Assay from a Result Record (page 11-21)

IntelliReport™

The Results Review – IntelliReport screen can be used to view the IntelliReport™ verifications that were performed for each completed sample and assay processed. An IntelliReport can be printed, if desired, for an individual result.

The set of verifications performed for each assay varies based on the type of assay. The following IntelliReport screen information corresponds to a single replicate of an assay.

Assay Type	IntelliReport Field
MicroWell	• Sample Metering • Sample Indices • Reagent • Sample and Reagent • Luminometer • Well Wash Verification • Signal Reagent

(Continued)

Colormetric (CM)/Rate	• Sample Metering • Sample Indices • Reflectometer • Reaction Quality
Potentimetric (PM)	• Sample Metering • Sample Indices • Reference (ERF) Metering • Electrometer • Slide Impedance
Immuno-Rate (IR) Assays	• Sample Metering • Sample Indices • WF Metering • Reaction Quality • Magenta Wash Tracker • Reflectometer
MicroTip	• Sample Metering • Sample Indices • Reagent Metering • Photometer • Reaction Quality

Tell me how to Review IntelliReport™ Data (page 11-22)
Tell me how to Print IntelliReport™ Data (page 11-22)

Review and Set Report Status

The system reports results on the Patient Report, the Laboratory Report, and through an interface to a Laboratory Information System. Use the Options & Configuration - Configure Report Control screen to configure default system parameters that control how to print and send reports.

The Results Review screen also enables the operator to review and set report status for selected records.

Tell me more about Result Records (page 11-1)

Review Report Status

Touch the Report Status process button on the Results Review screen to display the Review Report Status dialog. This dialog displays the following information:

- The number of Patient, Laboratory, and Lab Computer reports that are pending
- The number of results marked for Archive
- The date and time the Report Status process button, or the Update button was touched

Set Report Status

The Set Report Status process button on the Results Review, Edit Patient Data, or Edit Results screens opens a dialog that allows the operator to change the report status of indicated records. The destination(s) may include a Patient Report, a Laboratory Report and/or the Laboratory Information System.

Report status does not automatically change after a result value is edited.

The Archive Flag for indicated records can also be set or canceled on the Set Report Status dialog box.

Tell me how to Set Report Status (page 11-22)

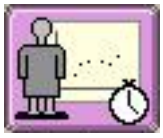
Tell me more about Reports (page 12-1)

More Options

Touch the More Options process button on the Results Review screen to access additional process buttons described below.

See Results Review Screen Information (page 11-3) for more details about the information displayed on this screen.

Patient History

	Touch the Patient History process button to view patient result records over time for a particular assay. Touch More Options if this process button is not initially available.

Touch the Patient History process button to display the Filter Patient Result Records dialog box. Enter the patient and sample criteria before touching OK to view the Results Review – Patient History screen. This screen plots results over time.

- The Result axis represents the result of the selected test.
- The Date axis represents the date and time the selected test completed.
- The plotted points represent the mean concentration of each reportable test result. A solid line connects each result.

  Note: No result values will be plotted for qualitative assays.

Touch the Filter Patient process button to return to the Filter Patient Result Records dialog box.

Touch the Print Report process button to print a report for quantitative and semi-quantitative assays containing the following result information (based on the current filter criteria):

- Time and date of result records
- The reported result
- An indication if the assay is quantitative or semi-quantitative

Note: The Patient History graph is not included in the report; only numbers and text will print. To print the image of the plot, touch [Print Screen] on the keyboard.

Recalculate Results

Touch the Recalculate Results process button to recalculate one or more selected results from a failed calibration. Touch More Options if this process button is not initially available.

Even if a calibration fails, it becomes the current calibration for the assay. All patient and control samples processed after that calibration will not have a result calculated. Rather than processing the samples again, you can recalculate the results and save them in the result record file.

Tell me more about Assay Calibration (page 10-1)

You can recalculate the failed result when there is a valid calibration. To replace the failed calibration, you can restore a previous calibration of the same slide or reagent lot number, enter a user calibration for the same slide or reagent lot number, or run another set of calibrators to generate a new calibration.

Use the following guidelines when recalculating results:

- Results can be recalculated only one time.
- Results to be recalculated must be indicated by the "NC" (not calibrated) code and contain “No Result” as the result.
- Results can be recalculated if the result has been run within 24 hours of the current time.
- The new results are indicated by a "RR" (recalculated results) code and all other appropriate flags and codes are added or removed.
- You can recalculate replicates but not the mean result. The mean result is automatically recalculated when you change a replicate. Appropriate codes and flags are added or removed to the mean and individual replicates.
- You can recalculate the component assays of a derived test but not the derived test result. Editing a component assay of a derived test causes the derived test to be updated and adds or removes the appropriate codes and flags to the component assays and derived test.

Note: The Recalculate Results feature cannot be used if it is disabled in Options & Configuration. See Configure System (page 17-21) for more information.

Tell me how to Recalculate Results (page 11-24)

Kinetics Plot

Touch the Kinetics Plot process button to display the Results Review – Kinetics Plot screen for a selected result record. The Kinetics Plot process button is not enabled if no records are selected. Touch More Options if this process button is not initially available.

The Kinetics Plot graph contains the following elements:

- A “Time, seconds” axis
- An “Absorbance, AU” axis that is dynamically scaled as appropriate for the data

Note: The left-read and right-read points will not be drawn on the screen, only the middle read.

User Defined Assay: This pulldown lists all available user defined assays for the current result record. When a user defined assay is selected or changed, the graphic plot will refresh, displaying data for all replicates of the newly selected user defined assay.

Replicate: This pulldown lists the numbered replicates of the selected user defined assay.

When the replicate selection is changed, the contents of the graphic plot will refresh based on the selected replicate(s).

Touch Print Report to send the following information for all replicates of the currently selected assay to the printer:

- Replicate number
- Time and date of first metering
- Absorbance values (3)
- Response column
- Concentration column

Note: The graph is not included in the report, only numbers and text will print. To print the image of the graph, touch [Print Screen] on the keyboard.

Touch the Export Data process button to display the Select Export Device dialog. The data can be exported to a disc or a USB Flash Drive. The Export Data file will contain the same data as the Print Report. Multiple exports of data can be saved to the same USB Flash Drive if sufficient space is available.

Touch the Export button on the Start Export dialog box to save a comma-separated export file to a USB Flash Drive or disc. This file can then be imported into a spreadsheet. The file name will be selected by the system and will consist of the assay name, the current date and time, and a ".csv" extension. The name of the exported file will be displayed in the Export Successful dialog box.

IMPORTANT: If the removable media already has a file with the same name as the exported file, it may be overwritten.

Note: The graph will not be exported when the Export Data button is pressed, only numbers and text will be exported.

Delete Records

	Touch the Delete Records process button to delete a selected result record from the Results Review screen. Touch More Options if this process button is not initially available.

One or more selected result records can be deleted by touching the Delete Records process button. A Delete Records dialog box will display the number of selected records and prompt the user to touch Delete or Cancel. Once deleted, the entire result record(s) is removed from the system's results database.

Tell me how to Delete an Assay (page 11-8)

General Troubleshooting

If you encounter an assay or system quality control issue, first try to categorize the problem. Most quality control issues can be placed in one of the following categories.

Shifts (page 11-13)	Imprecision/Outliers (page 11-15)	Correlation (page 11-16)
Shifts and Drifts (page 11-14)	Discrepant Results (page 11-15)	Calibration Failure (page 11-17)

Once you categorize the problem, follow the appropriate "To check" and "To do" sections below.

Then, complete the Troubleshooting Worksheet (page 14-17).

If your problem is not resolved, call the Customer Technical Support Center for assistance. A Technical Support Specialist will review the information on the worksheet and assist you in further troubleshooting.

Shifts

Shifts are significant deviations from established means observed after calibration.

To check:

- What was the purpose of recalibration?
- Are any other systems affected?
- Are any other calibrated assays affected?
- Do the calibrator lots match those on the Calibration Report?
- Does the control lot number match that on the assay sheet?
- What are the QC means and ranges in use?
- What is the age of the reagents, calibrators, and reference fluid in use prior to calibration?
- When does the product in use expire?
- What reconstitution protocol was used?
- Is a user adjustment in use?

(Continued)

To do:	• Compare the current calibration to calibration history of the system. • Evaluate the standard deviation in use; it may be too restrictive. • Evaluate how the standard deviation was established. • If a shift after lot change exceeds one standard deviation, evaluate results from five to ten patients between lots.

Shifts and Drifts

Shifts and drifts are significant deviations from established means that are not related to calibration.

To check:	• How long was the drift observed (within shift, within day, within week)? • Is the correct slide or reagent lot in use? • Is the correct calibration in use? • Does changing the reagent resolve the drift? • Does changing the Electrolyte Reference Fluid (ERF) or Immuno-Wash Fluid (IWF) resolve the drift? • Does running QC again resolve the drift? • Does using freshly-made control fluid or a new aliquot of fluid resolve the drift? • What is the condition of the desiccant packs or humidification pack? • Was late shift maintenance performed?

(Continued)

To do:	• Review QC history (fax history to the Customer Technical Support Center) • Review QC data for trends and drifts. • Evaluate the standard deviation in use; it may be too restrictive. • Evaluate how the standard deviation was established. • If fresh control fluid resolves the drift, evaluate the reconstitution protocol. • If fresh ERF or IWF resolves the drift, evaluate seals, reservoir, or possible leaks.

Imprecision/Outliers

Imprecision or outliers are suspect when results from the same sample do not match.

To check:	• When you repeat the assay on the same instrument, do the new results match the original results? If so, check actions for Discrepant Results. • Does the Condition Review screen show relevant codes? • Was the sample protocol followed correctly (container type, tube handling, correct adapters, fibrin in cups)? • Are other assays within the sample affected? • Are other assays in the tray affected? • Did the problem begin following maintenance? • Are other systems affected?
To do:	• Correct any protocol issues. • Verify performance by running precision tests. Include the problem assay with marker assays. • Evaluate precision data for patterns, including any codes generated during the run.

Discrepant Results

Discrepant results are results of individual samples that do not agree with expected values (possibly caused by an interferent).

To check:	• When you repeat the assay on the same instrument, do the new results match the original results? If so, check actions for Imprecision/Outliers. • Is the sample hemolyzed, icteric, or turbid? • Are any interferents present as described in the Instructions for Use for the assay? • What is the patient diagnosis? Is the patient receiving any medications? • What was the sample collection protocol (tube type, tube vendor, handling)?
To do:	• If possible, run the assay using an alternative method. Review the methodology of the alternative method manufacturer. • Check for other analytes in the affected sample.

Correlation

Correlation refers to patient results that do not agree with those obtained through another method.

To check:	• Are both instruments in control? • Does either method have a user adjustment in place? • What was the time difference between runs? • How were the samples handled between runs? • Can you obtain all individual data points for evaluation? • Are you correlating to another instrument? What was the methodology used on that instrument?

(Continued)

To do:	• If two systems are involved, calibrate both using the same calibrators and repeat the correlation. • Minimize the time difference between runs. • Use fresh cups of control fluid for each run to eliminate evaporation effects. • If correlating to another instrument, run calibrators on the instrument as "unknown."

Calibration Failure

The calibration may have failed if you are unable to obtain a valid or acceptable calibration.

To check:	• Are there relevant errors in the Condition Review screen? • Are there relevant messages on the Calibration Report? • Are the calibrator lots in use the same as those on the Calibration Report? • Are the control lots in use the same as those on the assay sheet? • Are you using new slide or reagent/reference or Immuno-Wash Fluid to calibrate? • How does the current calibration compare to calibration history on the system? • How were the reconstitution protocol and pipettes used? • Can you verify calibration replicates across all body fluids? (For derived assays, check all components.) • Are any other assay calibrations affected? • Has the lot in use calibrated properly before?
To do:	• Resolve condition codes before attempting the next calibration. • If other assays calibrated, look for patterns; one calibrator may be causing the problem. • Correct any protocol issues (for example, using room temperature fluids).

Results Procedures

The following table lists the Results topics that reference the procedures included in this section.

Topic Title	Procedure Title
Edit Patient Data (page 11-6)	• Add or Edit Patient Data (page 11-18)
Filter Results (page 11-5)	• Filter Results Records (page 11-20)
Edit Results (page 11-6)	• Edit an Assay in a Results Record (page 11-20) • Add an Assay to a Results Record (page 11-20) • Delete an Assay from a Result Record (page 11-21)
IntelliReport™ (page 11-8)	• Review IntelliReport™ Data (page 11-22) • Print IntelliReport™ Data (page 11-22)
Review and Set Report Status (page 11-9)	• Set Report Status - Results Review (page 11-22)
More Options (page 11-10)	• Recalculate Results (page 11-24)

Add or Edit Patient Data

Add or edit patient information to be printed on the Patient Report.

1 Touch  to display the Results Review screen.

2 Touch a record to select it.

3 Touch Edit Patient Data. The system displays theEdit Patient Datascreen with patient information for the selected record, if present.

4 Type or edit any of the following patient information. Press [Enter] to confirm each entry and move to the next field or touch the next field in which you want to type.

Note: For Birth Date, Collection Date, and Time, use the formats defined through Options & Configuration - Date/Time. Always use four digits for the year.

Patient ID	Patient identification (1–20 alphanumeric characters).
Last Name	Patient's last name (1–20 alphanumeric characters).
First Name	Patient's first name (1–15 alphanumeric characters).

(Continued)

MI	Patient's middle initial (1 alphanumeric character).
Address	Patient address (1–20 alphanumeric characters per line). Press [Tab] or [Enter] to move from one line to the next.
Range Attribute	A defined patient demographic other than sex that has been configured in Options & Configuration - Configure Demographics screen. Some examples include race, smoker, or disease states.
Birth Date	Patient date of birth. Always use four digits for the year.
Age	Patient's age (1–3 alphanumeric characters).
Room	The patient's room identification (10 alphanumeric characters).
Sex	Patient's gender (1 alphanumeric character).
Collection Date	Date that the sample was collected. Always use four digits for the year.
Collection Time	Time that the sample was collected.

5 Type or edit any of the following physician information. Press [Enter] to confirm each entry and move to the next field or touch the next field in which you want to type.

Physician ID	Physician identification (1 - 15 alphanumeric characters).
Last Name	Physician last name (1 - 20 alphanumeric characters).
First Name	Physician first name (1 - 15 alphanumeric characters).
MI	Physician middle initial (1 alphanumeric character).
Address	Physician address (1 - 20 alphanumeric characters).

6 If desired, type notes (such as hemolyzed) in the Comments fields (1 - 20 alphanumeric characters on each line). Text on a line does not wrap from one line to the next. Press [Tab] or [Enter] to move to the next line.

7 Touch Save to save your entries.

8 Touch Return to return to the Results Review screen.

Filter Results Records

1 Touch  to display the Results Review screen.

2 Touch Filter Results.

The system displays the Filter Result Records dialog.

3 Enter one or more filter criteria. All choices on the screen are optional.

- For Patient information, type the information and press [Enter]. If needed, press [Tab] to move to the field you want.
- For Physician information, type the information and press [Enter]. If needed, press [Tab] to move to the field you want.
- For Sample Type and Priority, touch the criteria. The default is All for both Sample Type and Priority.
- For Date and Time, touch All or Selected Date Range. Enter the Date Range or touch Last 24 Hours. The default is the last 24 hours, calculated from the most recent of these two events: the last time the Results Review screen was displayed or the last time the Update List button was touched.

4 Touch OK.

The system displays the Results Review screen with the items that match all the filter criteria.

Edit an Assay in a Results Record

Note: A restricted assay cannot be edited.

1 Touch  to display the Results Review screen.

2 (Optional) Touch Set Filter and decide which records to display.

If you do not define any filter criteria, the system returns all results records that were completed in the last 24 hours

3 Touch the record you want to edit. If needed, expand the record by touching the +. (plus) sign next to it.

4 Touch Edit Result to open the Edit Result screen.

5 Touch the assay you want to edit.

6 Touch Edit Assay.

The Edit Result Value dialog is displayed.

7 Enter the result value for the assay.

8 Press [Enter].

9 Touch Save.

The Edit Result screen is displayed with the new result for the assay. The code ED for Edited Result is also displayed for the assay.

Add an Assay to a Results Record

Note: A restricted assay cannot be added.

1 Touch  to display theResults ReviewResults Review screen.

2 (Optional) Touch Set Filter and decide which records to display.

If you do not define any filter criteria, the system returns all results records that were completed in the last 24 hours

3 Touch the result record you want to add one or more assays to. If needed, expand the record by touching the +. (plus) sign next to it.

4 Touch Edit Result to open the Edit Result screen.

5 Touch Add Assay.

The Add Assay dialog is displayed

6 Touch one or more assays to add to the result record.

7 Touch Done.

The Edit Result Value dialog is displayed with the assay name (or the name of the first assay you selected) displayed.

8 Enter the result for the assay.

9 Press [Enter].

10 Touch Save.

11 Repeat Steps 8, 9, and 10 for all the assays you are adding. Each assay name is displayed on the dialog.

After entering results for all the new assays, the Edit Result screen is displayed. The new assays are listed within the record. Information for each new assay includes the name of the assay, the result that you entered, and the code ED for Edited Result.

Delete an Assay from a Results Record

Note: A restricted assay cannot be deleted.

1 Touch  to display the Results Review screen.

2 (Optional) Touch Set Filter and decide which records to display.

If you do not define any filter criteria, the system returns all results records that were completed in the last 24 hours.

3 Touch the record you want to edit. If needed, expand the record by touching the +. (plus) sign next to it.

4 Touch Edit Result to open the Edit Result screen.

5 Touch the assay you want to delete.

6 Touch Delete Assay.

The Delete Assay dialog is displayed.

7 Touch Delete to confirm the deletion.

The assay is deleted from the result record and the Edit Result screen is displayed.

Review IntelliReport™ Data

1 Touch  to display the Results Review screen.

2 Touch the record you want to examine.

3 Touch IntelliReport.

4 Review the information displayed on the Results Review — Intellireport screen.

- Notice Rep: at the top of the screen. This indicates how many replicates of the assay have been completed. Example: 1/3 indicates you are reviewing the information for the first of three replicates.
- For multiple replicates, use the Next Result or the Previous Result buttons to page through the information.
- Exceptions are displayed in red text.

5 Touch Return to return to the Results Review screen.

Print IntelliReport™ Data

1 Touch  to display the Results Review screen.

2 Touch the record you want to examine.

3 Touch IntelliReport.

4 Review the information displayed on the Results Review — Intellireport screen.

- Notice Rep: at the top of the screen. This indicates how many replicates of the assay have been completed. Example: 1/3 indicates you are reviewing the information for the first of three replicates.
- For multiple replicates, use the Next Result or the Previous Result buttons to page through the information.
- Exceptions are displayed in red text.

5 Touch Print to print the information that is displayed on the screen.

To print a different replicate of the assay, touch Next Result or Previous Result until the replicate is displayed. Then touch Print.

6 Touch Return to return to the Results Review screen.

Set Report Status - Results Review

Access this dialog from within the Results Review screen. These settings change the report status for selected records only and do not affect the report control defaults set in Options & Configuration.

1 Select one or more result record(s) from any of the following screens.

Results Review screen	Select one or more records from the list or Filter Results (page 11-5) to narrow the amount of records to choose from.

(Continued)

Edit Patient Data screen	(Optional) Select a record and touch Edit Patient Data (page 11-6) to make changes before you set report status.
Edit Result screen	(Optional) Select a record and touch Edit Result (page 11-6) to delete or add an assay before you set report status.

2 Touch the Set Report Status process button to access the Set Report Status dialog.

3 For the Patient Report, Laboratory Report, and/or Laboratory computer, touch one of the following buttons to set report status:

Send	Sends a report of the selected record(s) to the designated destination(s)
Off/Cancel	Turns off or cancels a report of the selected record(s) to the designated destination(s)
No Action	Performs no report action for the selected record(s)

4 For the Archive Flag, touch one of the following buttons:

Set	Sets the archive flag for the selected record(s)
Off/Cancel	Turns off or cancels the archive flag for selected record(s)
No Action	Performs no archive action for the selected record(s)

5 Select one of the following options:

Apply to all selected results (#)	Sets the report status for the record(s) that are currently selected. The number of selected results records is listed is parenthesis.
Apply to all listed results (#)	Sets the report status for all the records listed on the results review screen. The number of selected results records is listed is parenthesis. See Filter Results (page 11-5) to limit this list.

6 Touch OK.

The Report Status of the selected record(s) will be set immediately. See Review and Set Report Status (page 11-9) for more information.

Recalculate Results

Only assays that are not restricted and that are either “No Result” and “NC” (not calibrated) are allowed to be recalculated.

1 Touch  to display theResults Review screen.

2 (Optional) Touch Set Filter and decide which records to display.

If you do not define any filter criteria, the system returns all results records that were completed in the last 24 hours

3 Touch the records you want to recalculate.

The last record you select has a check mark next to it and is highlighted; all the others have a check mark next to them.

4 Touch More Options.

The Results Review screen is displayed with different Process Buttons at the bottom of the screen. The records you have selected to recalculate remain selected.

5 Touch Recalculate Results.

The Recalculate Confirmation dialog is displayed. This displays the number of the selected records that can be recalculated and the number of the selected records that cannot be recalculated.

6 Touch Recalculate to recalculate and save results for those records that can be recalculated or touch Cancel to cancel the recalculation.

Chapter 12 Reports

The system provides the following types of reports for presenting assay results:

- Patient Report (page 12-1)
- LABORATORY REPORT (page 12-2)

Additional reports available from the system are:

- CALIBRATION REPORT (page 12-3)
- QC Reports (page 12-8)
- IntelliReport (page 11-8)
- Periodic Maintenance Report (page 16-2)
- Reagent Inventory Report (page 15-10)

Patient Report

The Patient Report is distributed to the patient's doctor, medical personnel, and others outside the laboratory. It includes the following information:

Header	(if configured) Up to four lines of text can be added to the heading of the Patient Report
Patient and Physician Name	Names as supplied through the Patient Data in the sample program
Patient Demographics	Includes patient and physician IDs and addresses; patient birth date, age, and gender; comments; patient room number; range attribute. These values are supplied through the Patient Data in the sample program.
Sample ID	Identifies the sample
Sample Priority	Identifies samples as Routine or STAT
Collected On	Date and time the sample was collected.
Body fluid	Identifies the specimen type (serum, urine, etc.)
Sample Metering Date and Time	Date and time the sample was processed
Assay Name	Name of the assay(s) processed for the sample

(Continued)

flags	Identifies results that are outside specified system ranges
Result	Results of the assay(s)
Sample Indices	(if configured) Indicates levels of Hemolysis (H), Turbidity (T), or Icterus (I) for the sample as identified through MicroSensor™
Reference Ranges	(if configured) Indicates the Reference Range for each quantitative assay.
Result Description	Result text for Qualitative and Semi-Qualitative assays
Print Date and Time	Date and time of report printing

How to Configure the Patient Report

Touch Patient Report on the Options & Configuration - Configure System to define the Patient Report header and to enable Reference Ranges and Sample Indices to print on the Patient Report.

Tell me how to Configure the Patient Report (page 17-47)

Tell me more about Sample Programming and Patient Data (page 9-1)

Laboratory Report

The Laboratory Report displays sample results in sampling order by date and time. The system produces a version of the Laboratory Report that is specific to the type of sample processed (Patient or Quality Control). The report is for laboratory use only.

The following table describes the report items that are included in the Patient and/or QC version of the Laboratory Report:

Report Item	Description
Report Title	Identifies the Laboratory Report
Operator ID	The ID of the operator logged into the Status Console at the time the sample was run
System Name	Name of the system as defined on the Options & Configuration - Configure System screen
Name	Patient or Control name
Sample Priority	Identifies samples as Routine or STAT
Sample ID	Identifies the sample
Control Identifier	“Control” Identifies a Quality Control sample
Sample Metering Date and Time	Date and time the sample was processed

(Continued)

Control Expiration Date	Date the Control expires on
Sample Position	Tray and cup position of the sample in the Sample Supply
Fluid	Identifies the body fluid specimen type (serum, urine, etc.)
Manual dilution factor	Factor used if the sample was manually diluted and the factor entered
Result Record ID	Identifies the result record which is automatically supplied by the system.
Special	Identifies the special fluid type
Comment	Comments about the patient as entered on the Edit Patient Data screen Comments about the control sample as entered on the Sample Programming screen
Sample Indices	Indicates levels of Hemolysis (H), Turbidity (T), or Icterus (I) for the sample as identified through MicroSensor™ (if enabled on the Options & Configuration – Sample Result Options screen). See Configure System (page 17-21) for more information.
Assay Name	Name of the assay(s) processed for the sample
flags	Identifies results that are outside specified system ranges. The report shows up to two flags for a result.
Result	Assay result(s) with units and description. If the operator requests multiple replicates then the result will be the mean of all the replicate results.
Dilution factor	Operator requested dilution factor or reflex dilution factor for the assay
Replicates	Results of any replicates requested for the assay, including operator-requested dilutions
Codes	Up to five test result codes
Print Date and Time	Date and time of report printing

CALIBRATION REPORT

The system prints the Calibration Report following calibration.

The Calibration Report contains the following information:

Report Header	Report title and System Name as defined on the Options & Configuration - Configure System screen
Assay Name and Body Fluids	Abbreviation of the assay name and supported body fluids
Calibration Date and Time	Date and time the calibration was performed
Kit Lot or Calibrator Lot (Not present for user calibrations)	For MicroSlide and MicroTip: Two-digit kit lot number concatenated with a two-digit kit-lot year For MicroWell: Four-digit calibrator lot number
Slide or Reagent Lot	Lot number that identifies slide or reagent packs that were manufactured as a group plus: • MicroSlide: Chemistry ID number and Generation • MicroTip: Pack ID and Generation • MicroWell: Major Protocol Version
Operator ID	The ID of the operator logged into the Status Console at the time the sample was run
Site Temp	Temperature (°C or empty if no temperature result)
Lot Number	IWF (IR assays), ERF (PM assays), or FS Cal 1 (Supplemental kit) Lot Number that identifies Immuno-Wash Fluid or Electrolyte Reference Fluid lot used to calibrate Immuno-rate or Electrolyte assays.
Supply Humidity	Slide Supply humidity only (not available for MicroTip or MicroWell)
User Modified	“User Mod” indicates a user modified calibration
Calibration Parameters	Calibration parameters are identified and reported if the calibration was successful. Different parameters will be listed depending on the calibration model used for the assay. See Calibration Report Parameters (page 12-6) (below) for more information. **Note:** If calibration was not successful, the message CALIBRATION FAILED is reported in place of the calibration parameters.

(Continued)

MicroSlide Calibrator Data	The report lists each calibrator **Bottle** number used to calibrate the assay together with its **Calib Value**, which is the Supplementary Assigned Value (SAV) and associated **Response**.
MicroTip Calibrator Data	The report lists each calibrator **Bottle** number used to calibrate the assay together with the volume (**VOL**) of calibrator fluid used, the calibrator fluid dilution (**DIL**), the calibrator fluid concentration and its 2nd derivative (**Calib Value**), and the average of the measured responses (**Response**).
MicroWell Calibrator Data	The report lists the concentration value for each calibrator (**Calib Value**), the average **Response** value if there are multiple replicates for the same level of calibrator, and any occurrence of **Codes** for the calibrator level.
Response	The report includes the reagent response for each calibrator. The system obtains this reading from the reagent prior to applying any mathematical adjustment. The readings are in the form of: • density (DR) for colorimetric assays • rate (DR/min) for two-point and multiple-point rate assays • millivolts (mv) for potentiometric assays • light units for MicroWells If the calibration used replicates, the report shows the average of the replicate assay responses for MicroWell assays. For MicroWell assays, specific response limits appear beside each calibrator response.
Warning and Condition Messages	A warning message will indicate if the acceptability of a successful calibration should be verified (for example, in a user-modified calibration). If calibration fails, a condition message describes the reason for the failure. The condition message corresponds to a condition reported on the status console at the time the condition occurred.`
Print Date and Time	Date and time of report printing

Tell me more about Assay Calibration (page 10-1)

Calibration Report Parameters

The following calibration parameters are included on the Calibration Report depending on the assay calibration model. Some parameters are common for each assay type, while others are unique for specific calibration models.

Supply	Assay Calibration Model	Unique Parameters	Common Parameters

(Continued)

MicroSlide	End-point Single Wavelength and Enzymatic End-point Colormetric (CM)	N/A	• curve intercept • curve slope • curve curvature or secondary slope
	Two-Point Rate CM	substrate depletion density	
	End-point Dual Wavelength and Dual Wavelength CM	N/A	
	Multi-point Rate CM	• substrate depletion density • substrate depletion delta density • first point reference	
	Fixed-point and Multi-point Immuno-Rate	• substrate depletion density • wash detection tolerance • wash intercept • wash slope • wash curvature	
	Potentiometric	Lists “ionic activity” curve intercepts and slopes and blank correction coefficient for assays using blank correction • ionic activity curve intercept • ionic activity curve slope • iconic activity curvature/slope 2 • blank correction coefficient (if used) • slide impedance curve intercept • slide	

(Continued)

		impedance curve slope	
MicroTip	Logit/Log4 and Logit/Log5	curve shape (4 or 5: B0-B5)	antigen excess limit
	Linear	• curve intercept • curve slope	
	Cubic Spline	• X (concentration) • Y (response) • Y'' (second derivative)	
MicroWell	Curve Fitting	curve shape (a-d, n)	• curve delta • curve delta ratio • curve delta range
	Linear	• curve slope • curve intercept	
	Semi-quantitative	curve shape cut-off	

Quality Control Report

The system prints a Quality Control (QC) Report when you touch Print Record on the Quality Control – Review Records by Assay screen. The report contains information and results for the selected assay/control fluid pair. Each line of the report contains information for each result in the record, in reverse chronological order.

The system will also print a QC Report when you touch Print Event on the Quality Control – Review Records by Control screen.

The Print Data button on the main Quality Control screen gives the operator the option of selecting and printing different types of reports based on data from a selected date range.

Tell me more about the QC Report (page 14-12)

Report Control and Status

The Options & Configuration – Configure Report Control screen enables the operator to configure default system parameters that control how to print and send reports. It is also possible to review and set report status for selected records on the Results Review screen.

Configure Report Control

See Configure Report Control (page 17-27) for more information.

Review and Set Report Status

See Review and Set Report Status (page 11-9) for more information.

Chapter 13 Flags and Codes

Flags (page 13-1) indicate results that are above or below the assay's measuring (reportable) range, supplementary range, or reference range. Flags also indicate quality control results outside the defined baseline.

Codes (page 13-3) indicate conditions that require operator attention. For example, if a lot switch occurs during an assay, the system assigns code "LS" to the result to call your attention to the lot switch.

The system displays flags and codes on the Results Review screen (page 11-1) , on the Laboratory Report (page 12-2), and on the Quality Control Report (page 12-8). The Patient Report (page 12-1) only includes flags.

The system also uploads flags and codes to the Laboratory Information System.

Flags

Flags Displayed on Laboratory, Calibration and Quality Control Reports

Flag	Description	Condition	Action
<	Below Measuring (Reportable) Range.	The result is below the Measuring (Reportable) range.	Follow your laboratory procedures to report or repeat the test.
>	Above Measuring (Reportable) Range	The result is above the Measuring (Reportable) range.	Dilute the sample and repeat the test. Refer to the Instructions for Use for more information.
+2S	QC is at least 2 but less than 3 standard deviations above mean	Control sample result is at least 2 but less than 3 standard deviations above the QC baseline mean.	Review control and analyte results on the Quality Control - Review by Assay screens. Repeat the test.
+3S	QC is at least 3 standard deviations above mean	Control sample result is at least 3 standard deviations above the QC baseline mean.	Review control and analyte results on the Quality Control - Review by Assay screens. Repeat the test.

(Continued)

<SR	Below Supplementary Range	Result is at or below supplementary range lower limit	Follow your laboratory established procedures.
>SR	Above Supplementary Range	Result is at or above supplementary range upper limit	Follow your laboratory established procedures.
-2s	QC is at least 2 but less than 3 standard deviations below mean	Control sample result is at least 2 but less than 3 standard deviations below the QC baseline mean.	Review control and analyte results using Quality Control - Review by Assay screens. Repeat the test.
-3s	QC is at least 3 standard deviations below mean	Control sample result is at least 3 standard deviations below the QC baseline mean.	Review control and analyte results using Quality Control - Review by Assay screens. Repeat the test.
HI	High result	Result is at or above the laboratory's defined reference interval for the analyte.	Follow your laboratory established procedures.
LO	Low result	Result is at or below the laboratory's defined reference interval for the analyte.	Follow your laboratory established procedures.
22s	Two consecutive QC results are 2 or more standard deviations above or below Mean	Two consecutive QC results are at all least 2 standard deviations above or below the QC baseline mean.	Review control and analyte results on the Quality Control - Review by Assay screens.

(Continued)

R4s	QC results changed at least 4 standard deviations	The previous QC result was more than two standard deviations above the mean and the current QC result is more than two standard deviations below the mean, or previous QC result was more than two standard deviations below the mean and the current result is more than two standard deviations above the mean.	Review control and analyte results on the Quality Control - Review by Assay screens.
41s	Four consecutive QC results outside mean by more than 1 standard deviation	Four consecutive QC results are all at least 1 standard deviation above or below the QC baseline mean.	Review control and analyte results on the Quality Control - Review by Assay screens.
10x	Ten consecutive Check Fluid results on one side of the mean	Ten consecutive QC results are all on the same side of the mean.	Review control and analyte results on the Quality Control - Review by Assay screens.

Codes

Codes Displayed on Laboratory, Calibration and Quality Control Reports

Code	Description	Condition	Action
AF	Air Filter Failure	The filtered air operation did not occur during the reading of the well. **No result** is reported.	The test is automatically retested. If the repeated result continues to generate a result code, check the Condition Review screen for potential causes and actions.

(Continued)

AR	Adjusted Result	A user adjustment parameter was applied to the result.	No action necessary. User adjustment parameters are defined on the Options & Configuration - Review/Edit Assay Data screen.
BP	Blank Prediction	The System was unable to compute the result for the blank slide. **No result** is reported.	The test is automatically retested along with the blank assay. If the repeated result continues to generate a result code, check the Condition Review screen for potential causes and actions.
CB	Cuvette Blank	The associated baseline transmittance reading of the test result is above or below configurable limits that are loaded from the Assay Data Disk. **No result** is reported.	The test is automatically retested. If the repeated result continues to generate a result code, check the Condition Review screen for potential causes and actions. Check for an optical problem with the CUVETTE row or with the sample.

(Continued)

CC	Configuration Conflict	A configurable parameter prevented a result from being fully evaluated.	Check the configuration for the affected assay. **Example 1**: An assay with qualitative reporting has one end of its reportable range set so that one of the qualitative categories could never be reached. No qualitative categorization is performed. **Example 2**: A sample program contains a demographic character that is not a valid character at the time of processing. The default reference range will be used instead of a demographic range.
CE	Calibration Expired	The calibration used for result prediction was expired at the time of the result prediction. The setting “Use expired calibration” can be configured to allow using expired calibrations. However, the setting does not apply to restricted assays. (Expired calibrations are never allowed for restricted assays.) **No result** is reported for restricted assays. **Note:** If “Use expired calibration” is not enabled, code II is displayed.	For a restricted assay, calibrate it and repeat the test.

(Continued)

DE	Drop Error	The proboscis was unable to dispense the correct amount of fluid. **No result** is reported.	The test is automatically retested. If the repeated result continues to generate a result code, check the Condition Review screen for potential causes and actions. Check for fibrin in the sample or in the METERING system.
DP	Substrate Depleted	Substrate depletion has occurred in a rate or IR test. **No result** is reported.	The test is automatically reflex diluted if enabled and configured for that assay. Refer to the appropriate Instructions for Use for more information.
EA	Expired Aliquot	The CuveTip in the Disposable Tip Processing Center has expired. **No result** is reported.	The test is automatically retested. If the repeated result continues to generate a result code, check the Condition Review screen for potential causes and actions.

(Continued)

EC	Expired Calibrator	The result prediction was based on a calibration using expired calibrator fluids. The setting "Use expired reagent" can be configured to allow using expired calibrators. However, this setting does not apply to restricted assays. (Expired calibrators are never allowed for restricted assays.) **No result** is reported for restricted assays. **Note:** If "Use expired reagent" is not enabled, code II is displayed.	For a restricted assay, calibrate it and repeat the test.
ED	Edited Result	The Operator edited the replicate result in Results Review. **No Result** is reported for restricted assays. (Editing a result is not allowed for restricted assays.)	No action necessary.
EM	Expired Maintenance Usage Interval	(Applies to MicroWell Assays only) The recommended interval for Subsystem Cleaning, using the Maintenance Pack, has expired. **No result** is reported for restricted assays.	Perform the Subsystem Cleaning procedure as described in V-Docs.
EP	Edited Demographics Data	The operator edited the demographics data value in the result record in Results Review.	No action necessary.

(Continued)

ER	Computational Error	A computational error occurred, such as the log of a negative number or division by zero. **No result** is reported.	The test is automatically retested. If the repeated result continues to generate a result code, check the Condition Review screen for potential causes and actions.
FC	Flagged Component	At least one of the measured components of a derived test has a code, a flag, or a Sample Index (HIT) flag.	Examine the component test results for the actual cause of this code.
FR	Flagged Replicate	Applied to a test mean; at least one replicate was flagged.	Examine the replicate assays for the actual cause of this code.
HN	High Noise	(Applies to multiple point rate assays) The HN code usually occurs on high-activity samples that generate irregular kinetics. **No result** is reported.	The test is automatically reflex diluted if enabled and configured for that assay.
IC	Invalid Component	A derived test result was not computed because one or more component tests failed to predict a result or were outside the range of the System. **No result** is reported.	All component tests are automatically retested. Examine the component test results for the actual cause of this code.

(Continued)

ID	Invalid Dilution	The concentration of the diluted sample fluid is less than the minimum diluted concentration that is loaded from the Assay Data Disk. For Total βHCG, **No result** is reported.	The test is automatically retested. If the repeated result continues to generate a result code, check the Condition Review screen for potential causes and actions. Use the neat or undiluted sample with a lower dilution factor.
II	Insufficient Inventory	There was insufficient inventory of the required wells or reagents for the test before it was scheduled to be processed. **No result** is reported.	The test is retested after a set time interval to allow for replenishment. Check inventory levels using Reagent Management.
IS	Insufficient Sample	The sample had insufficient volume to meter all of the tests programmed. **No result** is reported.	The test is automatically retested. If the repeated result continues to generate a result code, check the Condition Review screen for potential causes and actions. Check the sample for sufficient Fluid.
IT	Incubator Temperature	The incubator temperature was out of tolerance at some point while the test sample was being incubated. **No result** is reported for restricted assays.	Once the system displays "READY," repeat the assay.

(Continued)

KE	Kinetic Error	The multiple point rate test has a high activity or has an interfering substance present. For Immuno-rate tests, the analyte concentration is below the dynamic range or substrate depletion. **No result** is reported.	The test is automatically retested. If the repeated result continues to generate a result code, check the Condition Review screen for potential causes and actions. Refer to the appropriate Instructions for Use for more information.
LS	Lot Switch	A new reagent lot was used to process this test.	Verify that QC was performed before reporting results using the new lot.
LT	Luminometer Temperature	The Luminometer temperature was out of tolerance when the sample was being measured. **No result** is reported for restricted assays.	Check the condition codes for potential causes and actions; check environmental monitoring for out-of-range temperatures.
M1	Category 1 Modified Values	The test data was modified. The new data does not affect the shape of the calibration curve.	Check the settings for the analyte on the Options & Configuration - Review/Edit Calibrations screen and on the Options & Configuration – Configure Assays screen.
M2	Category 2 Modified Values	Test data was modified that does affect the calculation of patient data. Refer to M2 Parameters (page 10-10). The new data is used to generate the calibration curve. **No result** is reported for restricted assays.	Check the settings for the analyte on the Options & Configuration - Review/Edit Calibrations screen. Consult Lab Supervisor or Key Operator to determine if the M2 code is valid.

(Continued)

ME	Mechanical Error	A hardware- or operator-induced error may have occurred. **No result** is reported.	The test is automatically retested. If the repeated result continues to generate a result code, check the Condition Review screen for potential causes and actions. If the condition persists, initialize the System and/or correct the condition manually.
MN	Mean	The test result is a mean of replicate results.	No action necessary.
MW	Multiple Windows	(Applies to multiple point rate assays) Measurements show excessive irregularity and lack of smoothness.	No action necessary.
NC	Not Calibrated	No calibration is currently in use for the requested test. **No result** is reported.	The test is retested after a set time interval. This allows time to restore a valid calibration or calibrate the assay.
NF	No Fluid	The System did not detect any fluid during aspiration. **No result** is reported.	Check for sufficient sample volume and for fibrin in the sample or the sample metering system.

(Continued)

NQ	No Quality Control	No baseline QC data exists for this control fluid.	Add the test to the control fluid definition using Quality Control - Define Controls. Initialize or check the Condition Review screen and perform the recommended procedures. Process the control fluid again.
OC	Operator Requested Concentration	The test was performed with a dilution that was lower than the configured value.	No action necessary.
OD	Operator Requested Dilution; Out-of-Range Dilution	The out of range dilution has been selected in sample programming.	No action necessary.
OR	Outside of Measuring (Reportable) Range	The result is outside of the System's measuring (reportable) range. **No result** is reported.	The test is automatically reflex diluted if enabled. It is a high-concentration sample and configured for that assay and reflex dilution is configured for that assay. Check for measuring (reportable) range flags and follow the recommended actions.

(Continued)

OS	Outside Spline	The slide response is above or below the mathematical spline function for the required test. **No result** is reported.	The test is automatically reflex diluted if enabled. It is a high-concentration sample and configured for that assay and reflex dilution is configured for that assay. Refer to the other codes displayed in the report and the Condition Review screen for more information. A wash error might have occurred (Immuno-rate tests only). If so, follow the actions listed for the WE result code.
PF	Prediction Failure	The System detected an invalid response or no response during assay processing. **No result** is reported.	The test is automatically retested. If the repeated result continues to generate a result code, check the Condition Review screen for potential causes and actions. Also refer to the other codes listed in the report.

(Continued)

PI	Potential Interferent	There is a potential interfering substance to Bu in the sample. The code is reported with the Bc result. **No result** is reported. The PI code can be reported with Bu. In this case, the code indicates that Bc is not readable by the System. As a result, the Bu cannot be reported. The PI code can also be reported with AcP. In this case, the code indicates a substrate depletion condition that shows the probable presence of bilirubin.	If the PI code appears with the Bc result, do not dilute the sample. Repeat the sample using the TBIL slide. Refer to Instructions for Use for more information. If the PI code appears with the Bu result, dilute the sample with a normal patient sample or 7% BSA. Then repeat the test on the BuBc slide. Refer to the appropriate Instructions for Use for more information for both conditions.
RC	Reference Check	The Photometer, Luminometer or MicroWell Incubator reference readings are outside specifications. **No result** may be reported. (**No result** is reported for restricted assays.)	If No result is reported, the test is automatically retested. If the repeated result continues to generate a result code, check the Condition Review screen for potential causes and actions. Also check this screen for related Photometer, Luminometer, MicroWell Incubator, or condition codes and perform the recommended procedures.

(Continued)

RD	Reflex Dilution (Out-of- Range)	The test was a reflex test using more sample dilution than was used in the original test.	No action necessary.
RE	Reagent Expired	The test was processed with an expired reagent pack or expired signal reagent. The setting “Use expired reagent” can be configured to allow using expired reagents. However, this setting does not apply to restricted assays. (Expired reagents are never allowed for restricted assays.) **No result** is reported for restricted assays. **Note:** If “Use expired reagent” is not enabled, code II is displayed.	For restricted assays, load new reagents and repeat the test.
RP	Reflex Test Processed	This result is from a derivative or repeat reflex test.	No action necessary.
RR	Recalculated Result	The test results were recalculated because of an operator action in Results Review.	No action necessary.
RS	Reduced Standard Dilution	The test was a reflex test using more sample than the original test.	No action necessary.

(Continued)

SC	Spread Check Failure	A replicate result exceeded the percentage spread limit for the mean for the reagent lot specified on the ADD.	Check the Condition Review screen for additional condition codes and for codes that occurred at or near the time the replicates were processed. Repeat the assay, sample, or calibration.
SE	Sample Exited/Expired	The sample was removed or moved to the Load/Unload area after initial metering but before sample fluid for the affected test has been metered. This code also occurs if the COVER was opened or the sample expired before some tests could be metered. **No result** is reported.	The test is automatically retested if the sample progresses to the Metering Area within the expiration time. (This does not apply to LAS samples.) Repeat any expired tests with a fresh aliquot of sample.
SP	Multiple Spikes	More than one data spike occurred while reading a multiple point rate test. **No result** is reported.	The test is automatically retested. If the repeated result continues to generate a result code, check the Condition Review screen for potential causes and actions. Refer to the other codes displayed in the report and Condition Review screen for rate lamp condition codes.

(Continued)

TD	Test Deleted	The sample program is deleted before the sample fluid for the affected test has been metered. **No result** is reported.	No action is necessary.
TR	Trim Error	The System could not find a suitable area to read on the curve of a multiple point rate test due to noise or high activity sample. **No result** is reported.	The test is automatically reflex diluted if enabled and configured for that assay. Refer to the appropriate Instructions for Use for more information.
UC	User Calibration	The calibration parameters for this test were input manually. **No result** is reported for restricted assays.	No action necessary.
VS	Viscous Sample	The sample viscosity exceeds a value obtained from the Assay Data Disk. **No result** is reported for restricted assays.	Check for additional codes and flags. **Note:** Higher viscosities report **No result** with an ME flag.
WE	Wash Error	The Immuno-rate (IR) wash was invalid or the Well Wash was invalid. **No result** is reported.	The test is automatically retested. If the repeated result continues to generate a result code, check the Condition Review screen for potential causes and actions.
WT	Well Temperature	The well wash is outside specifications. **No result** is reported for restricted assays.	Check the Condition Review screen for potential causes and actions; check environmental monitoring for out-of-range temperatures.

(Continued)

ZS	Negative Derived Test Result	A derived test was computed by setting a negative component result to zero.	Check for additional codes and flags.

Sample Indices Flags

MicroSensor (Sample Indices) Flags

Flag	Description	Condition	Suggested Actions
H	Hemolysis	The level of hemolysis in the sample may interfere with the accuracy of the assay.	Follow your laboratory established procedures.
I	Icterus	The level of icterus in the sample may interfere with the accuracy of the assay.	Follow your laboratory established procedures.
T	Turbidity	The level of turbidity has exceeded the threshold value for that assay.	Follow your laboratory established procedures.
ES	Examine sample	The system was unable to evaluate the Sample Index, possibly due to Setting a Manual Dilution Factor for a restricted assay.	Examine sample manually.
ME	Mechanical error	A mechanical error occurred in the Sample Indices system or in any subsystem that would prevent a sample index read, or the Sample Indices system was globally disabled when the sample was run.	Initialize the system and/or correct the condition code manually. Refer to V-Docs or condition codes.
NA	Not Available	Sample Indices are disabled.	No action necessary.

(Continued)

NR	Not run	The Sample Index was not run due to a diluted or pretreated sample, Sample Indices were turned off for the sample, or the sample is a control.	No action necessary.
pi	Potential Interferent	The measured level of the Sample Index and the configured assay interference level are both above the measuring (reportable) range of the Index.	Examine sample manually.

Sample Indices Codes

MicroSensor (Sample Indices) Codes

Code	Description	Condition	Suggested Actions
AR	Adjusted Result	A user adjustment parameter was applied to the result.	No action necessary.
ES	Examine sample	The system was unable to evaluate the Sample Index, possibly due to setting a Manual Dilution Factor for a restricted assay.	Examine sample manually.
ME	Mechanical error	A mechanical error occurred in the Sample Indices system or in any subsystem that would prevent a Sample Index read, or the Sample Indices system was globally disabled when the sample was run.	Initialize the system and/or correct the condition code manually. Refer to V-Docs or condition codes.
NA	Not Available	Sample Indices are disabled	No action necessary.

(Continued)

NQ	Not Qualified	No baseline Check Fluid data exists for this MicroSensor Check Fluids. **No Result** posted do to a mechanical error. Occurs if QC test result is outside the index measuring (reportable) range.	Add test to QC file. Refer to QUALITY CONTROL. Establish baseline QC data. Refer to QUALITY CONTROL. Correct the malfunction and repeat the sample.
NR	Not run	The Sample Index was not run due to a diluted or pretreated sample, Sample Indices was turned off for the sample, the sample is a control, or Sample Indices does not support the sample fluid type.	No action necessary.
<	Below Measuring (Reportable) Range	The Sample Index is less than the configured measuring (reportable) range.	No action necessary.
>	Above Measuring (Reportable) Range	The Sample Index is greater than the configured measuring (reportable) range.	No action necessary.
+2s	Above mean by more than 2 standard deviations	The Check Fluid result is at least 2 but less than 3 standard deviations above the baseline mean.	Review control and analyte results on the Quality Control - Review by Assay screens. Repeat the test.
-3s	Below mean by more than 3 standard deviations	The Check Fluid result is at least 3 standard deviations below the baseline mean.	Review control and analyte results using Quality Control - Review by Assay screens. Repeat the test.

(Continued)

-2s	Below mean by more than 2 standard deviations	The Check Fluid result is at least 2 but less than 3 standard deviations below the baseline mean.	Review control and analyte results using Quality Control - Review by Assay screens. Repeat the test.
+3s	Above mean by more than 3 standard deviations	The Check Fluid result is at least 3 standard deviations above the baseline mean.	Review control and analyte results on the Quality Control - Review by Assay screens. Repeat the test.
22s	Two consecutive Check Fluid results outside mean by more than 2 standard deviations	The last 2 Check Fluid results were more than 2 standard deviations above or below the mean for the Check Fluids	Review control and analyte results on the Quality Control - Review by Assay screens.
R4s	Current Check Fluid result outside mean by more than 4 standard deviations	The previous Check Fluid result was more than 2 standard deviations above the mean and the current Check Fluid result is more than 2 standard deviations below the mean, or previous Check Fluid result was more than 2 standard deviations below the mean and the current result is more than 2 standard deviations above the mean.	Review control and analyte results on the Quality Control - Review by Assay screens.
41s	Four consecutive Check Fluid results outside mean by more than 1 Standard Deviation	The Check Fluid result is at least 1 standard deviation above or below the mean baseline for 4 consecutive results.	Review control and analyte results on the Quality Control - Review by Assay screens.

(Continued)

10x	Ten consecutive Check Fluid results on one side of the mean	The Check Fluid result for 10 consecutive results are on the same side of the mean.	Review control and analyte results on the Quality Control - Review by Assay screens.

Chapter 14 Quality Control Overview

What is Quality Control?

Quality Control (QC) is important in determining the performance and accuracy of the system. To perform Quality Control, QC materials are run with either known, or unknown values along with patient samples to determine whether the system is functioning within the established ranges for your lab. VITROS Chemistry Products Performance Verifiers are control fluids manufactured specifically for quality control on VITROS Chemistry and Integrated Systems. VITROS Immunodiagnostic Products Controls are control fluids manufactured specifically for quality control on VITROS Immunodiagnostic and Integrated Systems.

You can load control fluids and process them along with patient samples.

Quality control procedures should be performed in the following order.

1. Define control fluids using the Define Controls screen.
2. Process control fluid samples.
3. Use the Review Data screen to compare the control samples' actual results with expected results to determine system performance.
4. Use the Review Records screen to define intervals and save quality control data over time intervals.
5. Report or graph quality control results using the Review Data or Review Graph screen.

The system saves control results in the QC file in reverse chronological order by control fluid and reagent. The QC file saves up to 2190 results for each assay defined for each control fluid. It saves up to a total of 500 control fluids. When the QC file contains 2190 results, new results overwrite the oldest results, which are permanently removed from the QC file.

When to Perform Quality Control

Ortho Clinical Diagnostics recommends that you perform quality control once every 24 hours. This frequency may vary depending on the requirements and regulations your national, state, provincial, and local governments established for processing control fluids. Your own laboratory procedures may require a different frequency.

Quality control should also be performed:

- After system calibration
- Following non-routine service items (for example, PROBOSCIS/PISTON ASSEMBLY replacement)
- After you update correction factors

How to Access Quality Control

Touch  on the Status Console to display the Quality Control main screen. Use this screen to access other Quality Control features.

Certain Quality Control features require a Key Operator access code. This restriction prevents changes to important parameters by unauthorized personnel. Features that require a Key Operator access code are:

- Define Controls
- Define Baseline
- Delete Controls
- Update Baseline
- Select Rules
- Assign Comments

If you are not logged into the system with the Key Operator access code, the buttons for these functions are disabled and cannot be selected.

Tell me more about system access (page 7-2)

Quality Control Screen

The QUALITY CONTROL main screen is the starting point for all quality control functions. Use this screen to review all controls established for the system.

The following table describes the information and features on this screen:

Screen Features and Information	Description
Defined Controls	Contains a button for each control fluid defined for your system. Use these buttons to select controls for further action.
Assays	Lists the assays defined for each control fluid selected.
Current Control	Displays the Control ID for the current control (the last one selected).
Controls Selected	Displays the number of controls selected.
Total Controls	Displays the total number of controls defined.

Quality Control Process Buttons

The following process buttons are on the main Quality Control screen.

Process Button	Description

(Continued)

Define Controls: Add a new control fluid or edit information for an existing control fluid.

Tell me how to Define Controls (page 14-3)

Set Filter: Limit or expand the displayed Quality Control results based on selected criteria.

Tell me how to Filter Results (page 14-7)

Select Rules: Select rules to apply to the controls.

Tell me how to Select Rules (page 14-4)

Define Baseline: Define baseline statistics for a selected control.

Tell me more about Baseline Statistics (page 14-4)

Review Events and **Review By Assay:** Review Events by Control, or Review Records by Assay.

Tell me more about Quality Control Results Review (page 14-7)

Print Data: Select the type of report(s) (Summary, Graphs, or Records) and date range of data to print.

Tell me how to Print Data (page 14-12)

Delete Controls: Delete a Control from the system (for Key Operators and Service Personnel).

Tell me how to Delete Controls (page 14-25)

Control Fluids

VITROS Chemistry Products Performance Verifiers are control fluids that are designed to work with VITROS Chemistry and Integrated Systems. Ortho Clinical Diagnostics recommends that you use VITROS Chemistry Products Performance Verifiers (where available) for quality control of your system.

VITROS Immunodiagnostic Products Range Verifiers and VITROS Immunodiagnostic Products Controls are control fluids that are designed to work with VITROS Immunodiagnostic and Integrated Systems. Ortho Clinical Diagnostics recommends that you use VITROS Immunodiagnostic Products Controls (where available) for quality control of your system.

Other controls may contain constituents and additives, such as preservatives and stabilizers, which may result in these fluids performing differently. Evaluate

the performance of commercial control fluids on the system before using them routinely.

When choosing control fluids, consider the following:

- **Analyte composition**: The control fluid should contain all analytes you anticipate measuring.
- **Fluid and analyte source**: The control fluid should be appropriate, depending on whether the fluid or analyte is animal, artificial, or human-based.
- **Vial-to-vial variations**: Control fluids may vary in concentrations from vial to vial.
- **Stability of the control fluid**: All analytes in the control fluid should be stable.
- **Range of analyte concentrations**: The control fluid contains analyte concentrations that can evaluate performance near the clinically relevant ranges.

Control fluids may be in liquid form or may be lyophilized. Lyophilized control fluids must be thoroughly reconstituted before use. Refer to the control Instructions for Use for reconstitution steps.

Store, prepare, and process all control fluids according to their Instructions for Use. Refer to the assay Instructions for Use and control fluid Instructions for Use for additional information and special precautions.

How to Match Control Fluids with Sample Programs

Use the Define Controls screen to assign a Control ID (1 to 6 characters, alphanumeric, including embedded spaces) to control fluids. The system uses the Control ID to distinguish control samples from patient samples and to calculate statistical parameters.

Use the Sample Programming screen to define a sample program ID to match the six-character Control ID. **Always use the six characters of the Control ID as the first six characters of the Sample ID**. Use the remaining sample ID characters to allow for additional sample programs for the sample control fluid.

For example, for control fluid LEVEL1, you can define sample programs for LEVEL1A, LEVEL1B, and LEVEL1C.

Tell me more about Sample Programming (page 9-1)

How to Define Control Fluids

Use the Define Controls screen to add a new control fluid or edit information for an existing control fluid. You can define up to 500 control fluids.

Note: You can access this function only if you have Key Operator or Service level access.

Tell me how to Define a Control Fluid (page 14-24)

Tell me how to Edit a Control Fluid (page 14-25)

Tell me how to Delete a Control Fluid (page 14-25)

Baseline Statistics

Baseline statistics refers to the mean, coefficient of variation, and standard deviation defined for each assay and its corresponding Control ID. The system uses baseline statistics to assess system performance and evaluate variation within control results.

You have the option of entering baseline statistics or the system can accumulate results for a control fluid and apply the recorded statistics as the baseline. You can also enter baseline statistics after the control fluid is defined.

After baseline statistics are established, the system assigns flags to results when they fall outside two or three standard deviations (SDs) from the mean.

Select Rules

You can also configure other flag rules to apply to the controls by touching the Select Rules button on the Quality Control screen.

Flag	Results
-2S	Quality Control (QC) result below mean by 2 standard deviations
+2S	QC result above mean by 2 standard deviations
-3S	QC result below mean by 3 standard deviations
+3S	QC result above mean by 3 standard deviations
22s	Two consecutive QC results above or below mean by 2 or more standard deviations (optional)
R4s	Two consecutive QC results changed at least 4 standard deviations (optional)
41s	Four consecutive QC results above or below mean by 1 or more standard deviations (optional)
10x	Ten consecutive QC results are all on the same side of the mean (optional)

Baseline Statistics Definition

Baseline statistics definition is optional for a control definition. Touch the Define Baseline button on the QUALITY CONTROL — Define Controls screen to define your own baseline.

Tell me how to Define Baseline Statistics (page 14-25)

Note: If you touch the Return/Cancel button without saving your entries, the system restores any previous baseline statistics established for the assay and body fluid/control fluid combination.

To update the baseline statistics, touch the Update Baseline button on either of the following Quality Control (QC) screens:

- QUALITY CONTROL — Review Records By Assay
- QUALITY CONTROL — Review Graphs

How to Process Control Samples

You can process control samples in the same way that you process patient samples. If you use bar-coded control tubes and downloaded programs from

the Laboratory Information System (LIS), simply load the control tubes onto the system.

Note: Process commercially available controls (non-VITROS) according to the manufacturer instructions.

Tell me how to process control samples if the tubes are **not** bar-coded (page 14-26)

How to Process VITROS Chemistry Products Controls

VITROS Chemistry Products Performance Verifiers (PVs) are assayed controls designed for use as a daily quality control for MicroSlide and MicroTip assays. PVs provide a way to assess the calibration of the system, monitor the daily performance of the system, and assist in troubleshooting out-of-control conditions indicated by daily quality control results. PVs should be run every 24 hours, following calibration of a new lot of reagents or recalibration of a current lot of reagent and after certain maintenance and service procedures. However, the frequency with which you perform quality control procedures may vary depending on the requirements and regulations for processing control fluids by your national, state, provincial, and local governments. Quality control procedures within your own laboratory may also require a different frequency.

Running quality control verifies that the new calibration parameters are producing results on the PVs which are within published guidelines for that generation of reagents.

Following calibration of a new lot of reagents, perform quality control using a minimum of two replicates of each level from freshly reconstituted performance verifier control material. The average value of the replicates should fall within an established Range of Means (ROM). The range of means appears on the assay sheet for the reagent lot.

When evaluating the performance of a VITROS Chemistry System using Performance Verifiers, the mean based on two or more replicate measurements of these fluids must be within the ROM to be acceptable.

- The mean of two or more measurements can fall anywhere in the ROM (not necessarily in the center) for that particular Gen.
- For calibration verification, the mean of 2 or more replicate measurements of Performance Verifiers (called a Preliminary Baseline Mean) should fall within the ROM listed on the assay sheet.
- When using Performance Verifiers for routinely monitoring a properly operating system, you need to establish a baseline mean. To calculate a baseline mean you must run Performance Verifiers for a minimum of 20 days. This is necessary because the baseline mean established using additional data points is a better estimate of the true mean than the 2-point preliminary baseline mean. The calculated mean should be within the ROM. Each estimate of the mean should be statistically the same as all other estimates of the mean.
- It is not expected that all individual daily QC values will fall within the ROM even if the system is showing acceptable performance. However the mean of a distribution of daily QC values for properly operating systems should always fall within the ROM.

The published within-lab SD on the Performance Verifier assay sheets normally does not change from one lot of Performance Verifiers to another. However, it may be adjusted if the analyte concentration changes significantly. This should not occur very often.

Tell me more about Quality Control (page 14-1)

Tell me more about Performance Verifiers (page 8-19)

Tell me how to Process a Performance Verifier (page 14-27)

How to Process VITROS Immunodiagnostic Products Range Verifiers

The VITROS Range Verifiers have been validated for use on the VITROS System for VITROS Immunodiagnostic Products Reagent Packs and VITROS Immunodiagnostic Products Calibrators. The range verifiers contain low and high concentrations of the analyte, close to the limits of the calibration range, and can be used to verify measurement of the analyte at the limits of that range.

Tell me how to Process a Range Verifier (page 14-28)

How to Process VITROS Immunodiagnostic Products Controls

VITROS Immunodiagnostic Products Controls are control materials formulated for quality control on the system. The recommended frequency for processing quality control is once every 24 hours. However the frequency with which you perform quality control procedures may vary depending on the requirements and regulations for processing control fluids by your national, state, provincial, and local governments. Quality control procedures within your own laboratory may also require a different frequency. You should also perform quality control procedures following calibration and after certain maintenance and service procedures are performed. The quality control results should fall within the acceptable range found on the assay sheet.

Tell me how to Process Immunodiagnostic Products Controls (page 14-28)

Quality Control Results Review

There are two options for reviewing control results. You can:

- Review Events by Control (page 14-7), or
- Review Records by Assay (page 14-8)

The process buttons for both screens are described below.

Filter Results

Limit the displayed results based on selected criteria using the Set Filter button on the QUALITY CONTROL screen or the QUALITY CONTROL — Review Record By Assay screen. The following criteria are available, depending on the screen you are viewing:

To Display	Touch
All available QC results/events	All Results/Events
Only results/events processed within a specified date range	Specific Date Range. Touch Date Range and enter the beginning and ending dates of the range.
The last X results/events (for example, the last 25 results/events)	Specific Quantity of Most Recent Results/Events. Type the number of results/events by which you want to limit the display.

Touch OK to save your filter criteria. The next time you access the screen, the display will show only those records meeting the specified criteria.

Review Events By Control

Use the QUALITY CONTROL — Review Events By Control screen to omit and add results from statistical computation, add comments to results, and print QC results.

Tell me how to access the QUALITY CONTROL — Review Events By Control screen (page 14-29)

The top of the screen lists the following information:

Body Fluid/Control ID	Identifies the body fluid, and Control ID.
Date and Time	Date and time the assay was verified.
Controls Selected	Indicates the current control, and total number of controls selected
Number of Events	Indicates the number of events selected, and the total number of events available.

The following details are listed for each event.

Assay	Indicates the short assay name.
Result	Results of the QC assay.
Units	Indicates the units of measurement.
SDI	Indicates the deviation of an individual value from the mean of a population of analytical data, normalized to the SD for that population. The formula for SDI is (result minus mean/SD).
Codes	Identifies any codes recorded for this result during QC.
Flags	Indicates any flags associated with the QC event.
Man Dil	Indicates any manual dilutions associated with the QC event.
Dil	Indicates any dilutions associated with the QC event.
Omit	Number of any points omitted during QC calculations.
Comments	Comments assigned to this result.

The bottom of the screen indicates the number of results selected, the total number of results available, and whether a filter has been applied to this display.

Review Records By Assay

Use the QUALITY CONTROL — Review Records By Assay screen to review quality control assay-control fluid pairs records, and print QC results.

Tell me how to access the QUALITY CONTROL — Review Records By Assay screen (page 14-29)

The Review Records By Assay screen provides quality control results for the assay. Refer to the table below for more information about this screen.

The top of the screen lists the following information:

Assay/Body Fluid/Units/Control ID	Identifies the assay/body fluid combination, units of measurement, and Control ID
Control/Results Information	Indicates which control is currently being reviewed, and the number of controls selected for review
Results Information	Indicates the number of results selected, the total number of results available, and whether a filter has been applied to this display
Baseline Statistics	Baseline statistics that have been established or calculated for the control
Record Statistics	Actual statistics recorded for the control through QC
Actual Statistics	Mean, standard deviation, and standard deviation index for the result

The following details are listed for each record:

Date and Time	Date and time the assay was verified
Flag	Indicates any flags associated with the QC result
Result	Results of the QC assay
Comments	Comments assigned to this result
Codes	Identifies any codes recorded for this result during QC
Omit	Number of any points omitted during QC calculations

To select a record on the screen, touch the record. A check mark appears to the left of the record information to indicate that the record is selected. To de-select the record, touch it again; the check mark disappears. You can select more than one record on the screen for further action. Use the Select All button to select all of the records on the screen for printing or other action.

Baseline Statistics Updating

To substitute the Record Statistics for the current Baseline Statistics, touch the Update Baseline button. The Update Baseline screen shows the current Record Statistics and current Baseline Statistics. The beginning and ending date, during which the Record Statistics were recorded, are displayed. Touching the Update button overwrites the Baseline Statistics with the Record Statistics. Touching the Save button saves the change(s) and begins using the Records Statistics as the baseline.

Tell me more about Baseline Statistics (page 14-4)

Multiple Controls Review

You can choose multiple controls to review using the QUALITY CONTROL — Review By Assay screen or using the QUALITY CONTROL — Review Events By Control screen. Touch the Next Control button to move forward and review the next selected control. Touch the Previous Control button to move backward and see the previous control.

How to Review QC Graphs

To display a Levey-Jennings graph of the QC results, touch the Review Graphs button on the QUALITY CONTROL — Review By Assay screen. See QC Graphs (page 14-10) for more information about using the graphs.

Assign Comments

You can select comments from a predetermined list and apply them to selected results. You can apply a maximum of three comments to a result. There are five comment categories:

- Performance — Comments that indicate the performance of the system
- Integrity — Comments that indicate the integrity of system consumables
- Rules — Procedural rules determining the state of a control on the system
- Miscellaneous — Additional comments not relevant to the other comment categories
- User — Additional comments that the operator defines

Show me the comments within each category (page 14-15)

How to Print Records

To print reports, touch Print Record. The system displays the Print Data dialog. Touch the fields on this screen to choose what you want to print:

To Display	Touch
A QC Graph	Graphs
The Quality Control Report	Records
Records processed within a specific range of dates	Date Range; type the beginning and ending dates of the range in the fields provided

Touch OK to send your request to the printer.

Omit Result

If you have Key Operator or Service level access, you can choose to omit a result from QC reporting. The Omit Result process button changes to enable omission or inclusion of results. To omit results, touch the result(s) on the QUALITY CONTROL — Review Records By Assay screen or on the QUALITY CONTROL — Review Events By Control screen. Touch the Omit Result button. An "O" appears in the Omit field to indicate that the result will be omitted from reporting. To include the result, touch it and touch the Include Result button.

QC Graphs

Use the Review Graphs screen to see a Levey-Jennings graph of QC results. You can graph one assay/control fluid pair at a time, or you can choose to stack graphs from the Review By Assay screen.

Access the Review Graphs screen:

- From the Review By Assay screen, select an assay/control fluid pair and touch the Review Graphs button.
- From the Review Records screen, touch the Review Graphs button. The resulting graph will show results for the record you were viewing.

On the Review Graphs screen, you can choose to show either Baseline Statistics or Record Statistics.

The graph contains the following information:

- X axis (horizontal) — Represents time. The minimum time unit is one day. Intervals are determined by the number of days, as follows:
  - Less than or equal to 31 days (increment of one day)
  - Greater than 31 and less than 217 days (increments of seven days)

    Note: The week that contains daylight savings time will display 6 days rather than 7.
  - Greater than 217 and less than 930 days (increments of 31 days)
  - Greater than 930 days (no increments displayed; the start and end dates are displayed at the beginning and end of the X axis)
- Y axis (vertical) — Standard deviations with the mean displayed across the middle of the graph. Lines for one, two, and three standard deviations from the mean are displayed as follows:
  - Gray - mean analyte concentration
  - Off-white – 1 SD from the mean
  - Light yellow – 2 SDs from the mean
  - Light red – 3 SDs from the mean

Use the left and right arrow keys under “HIGHLIGHT” to move across the graph and select individual points. The point's value and standard deviation index appear when the point is selected.

A marker above a point represents a baseline change. A marker below a point represents a reagent lot change.

The Omit Result process button on the Review Records screen changes from “Omit Result” to “Include Result”, which enables you to include or omit selected points.

If you chose to omit a result (using the Review Records screen), the point for that result is omitted on the graph and designated by an "O". As a default, any display points that are omitted will be hidden from view. If you touch the Show Omitted button the system displays the points that were omitted. Touch the Hide Omitted button to hide the display points from view again.

Stack Graphs

The Stack Graphs screen, when launched from the Review By Assay screen, provides multiple record graphing. Up to 3 records or assay/control fluid pairs can be viewed at once on the screen. You can view the graphs of multiple level controls for the same assay over the same period of time.

Note: If only one or two controls are selected from the Review By Assay screen, the bottom one or two graph areas appear empty.

Quality Control (QC) Graph Printing

As part of monthly periodic maintenance, print the QC graphs and check for shifts and drifts within the system. See General Troubleshooting (page 11-13) for more information.

Tell me how to print QC Graphs (page 14-30)

The report will print the results in reverse chronological order.

Note: The title will be in Courier 16 Bold font, with all remaining text on the Quality Control Graph having Courier 10 font. The font type cannot be changed.

QC Reports

The system can print three types of reports:

- Summary Report (page 14-12)
- Quality Control Report by Control (prints events) (page 14-13)
- Quality Control Report by Assay (prints records) (page 14-14)

Summary Report

The Print Data button on the QUALITY CONTROL main screen allows you to select the type of report(s) and date range of data to print. The system prints the Summary Report when you are in the Print Data dialog and touch the "Summary" box to mark it, select a date range, and touch OK.

The header of the Summary Report contains the following information:

Header information	
Field Name	**Definition**
Control ID	Control fluid identification
Fluid	Body fluid type
System Name	Name of the system as defined through Options & Configuration
Date Range	Beginning and ending date of any range defined for filtering

Result Records	
Assay	Short Assay Name
Units	Units of measurement used for reporting results
Mean	Mean of baseline statistics at the time the result was generated
SD	Standard deviation of baseline statistics at the time the result was generated
CV (%)	Coefficient of Variation
Points	Number of control results

(Continued)

Flag	Number of flagged control results
Omit	Number of omitted control results

Quality Control Report by Control

The system prints the Quality Control Report by Control when you touch the Print Event button on the Review Records screen. The report contains information and results on one event. Each line of the report contains information for each result replicate in the event, in reverse chronological order.

Note: The title of the Quality Control by Control will be in Courier 16 Bold font. All text on the Quality Control Report By Control other than the title will be in Courier 10 font.

The header of the Quality Control Report by Control contains the following information:

Header information	
Field Name	**Definition**
Control ID	Control fluid identification
System Name	Name of the system as defined through Options and Configuration
Control Name	Name of the control fluid
Lot Number	Control fluid lot number
Fluid	Body fluid type
Expiration Date	Control fluid expiration date
Metering Time	Sample metering time of the result

Event Records	
Assay	Short Assay Name
Results	Result value
Units	Units of measurement used for reporting results
SDI	Standard deviation index of the result at the time it was generated
Omit	Number of omitted control results
Codes	Code(s) for the result (maximum 3), in priority order
Flags	Flag(s) for the result (maximum 3), in priority order
Comments	Comment number(s) for the result (maximum 3), in numeric order

Quality Control Report by Assay

The system prints the Quality Control Report by Assay when you touch the Print Record button on the Review by Assay screen or when you are in the Print Data dialog and touch the "Records" box to mark it, select a date range, and touch OK. The report contains information and results for the selected assay/control fluid pair. Each line of the report contains information for each result in the record, in reverse chronological order.

Note: The title of the Quality Control Report by Assay will be in Courier 16 Bold font. All text on the Quality Control Report By Assay other than the title will be in Courier 8 font. You cannot change the font type or size for either report.

The header of the Quality Control Report by Assay contains the following information:

Header information	
Field Name	**Definition**
Assay and Body Fluid	Assay and body fluid pair, and units of measurement used for reporting results
System Name	Name of the system as defined through Options and Configuration
Control ID	Control fluid identification
Lot Number	Control fluid lot number
Control Name	Name of the control fluid
Expiration	Control fluid expiration date
Filter	Type of filter used (All Results, Date Range, or Number of Results)
Date Range	Beginning and ending date of any range defined for filtering (oldest result to newest)
Number of Results	Number of included results and total number of results
Baseline Statistics	Mean, standard deviation, and coefficient of variation defined for each analyte and its corresponding Control ID. The system uses Baseline Statistics to evaluate quality control results.
Record Statistics	Calculations for each Control ID, based on the control result records that match the search criteria. The system updates the Record statistics any time a change is made.

Result Records	
Date	Sample metering date of the result
Time	Sample metering time of the result

(Continued)

Flag	Flag(s) for the result, in priority order
Result	Result value
Mean	Mean of baseline statistics at the time the result was generated
SD	Standard deviation of baseline statistics at the time the result was generated
SDI	Standard deviation index of the result at the time it was generated
Omit	Contains "O" if the result was omitted from statistical calculations
Code	Code(s) for the result (maximum 4), in priority order
Comments	Comment number(s) for the result (maximum 3), in numeric order

The report includes a baseline change marker at any point that a baseline change occurred.

Assign Comments

The Assign Comments dialog box provides the ability to apply selected comments to individual results and result records. The comments are selected from a predetermined list and can be removed using this dialog box. A maximum of three comments can be applied to a result. The Assign Comments dialog box is launched from any of the following screens:

- Quality Control — Review Records by Assay
- Quality Control — Review Events By Control
- Quality Control — Review Graphs

Note: The Assign Comments button requires Key Operator or Service level access.

Five comment categories are available:

- Performance — Comments that indicate the performance of the system
- Integrity — Comments that indicate the integrity of system consumables
- Rules — Procedural rules determining the state of a control on the system
- Miscellaneous — Additional comments not relevant to the other comment categories
- User — Additional comments that the operator defines

Refer to the sections below for more information about each category.

Performance

Comment Number	Comment
1	Post Calibration QC

(Continued)

2	Recal/repeat acceptable
3	Incorrect calibration used
4	Incorrect QC fluid used
5	Other control fluid acceptable
6	Performance Verifiers run, in control
7	Last QC processed acceptable
8	QC fluid was repeated
9	Expired calibration
10	Calibration restored
11	User Calibration

Integrity

Comment Number	Comment
12	New lot of Reagent
13	Changed Reagent
14	Expired Reagent
15	New lot of Diluent
16	Changed Diluent
17	Expired Diluent
18	New lot of QC Fluid
19	Changed QC Fluid
20	Expired QC Fluid
21	New lot of IWF
22	Changed IWF
23	Expired IWF
24	New lot of ERF
25	Changed ERF
26	Expired ERF
27	Expired Cal Lot

Rules

Comment Number	Comment
28	Range rule violated

(Continued)

29	Systematic error occurred
30	Random error occurred
31	Same side rule violated

Miscellaneous

Comment Number	Comment
32	Supervisor reviewed/accepted
33	Precision test data
34	Post maintenance QC
35	Post service QC
36	New Baseline Implemented
37	New QC lot being evaluated
38	Performed white reference test
39	Refer to printed report
40	Manually diluted

User

Comments under the User category are defined by the operator, and numbered 90 through 99. User Comments are defined using the User Comments screen. Touch QC > Review By Assay > User Comments to access the User Comments screen.

Troubleshooting Worksheet

VITROS 5600 System Integrated

General System Information

System:	
System J Number:	
Date:	
Assay(s):	
Did it affect:	QC ( ) Patients ( ) Both ( )
12–Digit Slide Lot Number:	
11–Digit MicroWell Reagent Lot Number:	

(Continued)

10–Digit MicroTip Reagent Pack Lot Number and 5–Digit Sequence Number:

Other Lot Numbers: UWR: _____ SR: _____ IWF: _____ ERF: _____

Date of Last Calibration:

Date of Last Correction Factor:

Note: MicroSlide only

SYSTEM CODES:

Shifts/Drifts

QC (manufacturer):

_____

Level	J&J Lot #	OEM Lot #	Expiration Date	Mean	Range	Results
L1: _____ _____ –						
L2: _____ _____ –						
L3: _____ _____ –						

Quality Control (QC): QC lot number on bottle matches assay sheet
Yes ( ) No ( )

Calibration Data:

Calibrator	Kit Lot #/Calibrator Lot	Calib Value	Response
1			
2			
3			
4			
5			
6			

(Continued)

Calibration Parameters: (for example, intercept, slope, or B0/B1, etc.)

MicroWell Quality Parameters:

Level	Spread (%)	Spread Limit (%)
1		
2		
3		

Level	Calibrator Signal Index (CSI)	Level	Delta Ratio
1		1	
2		2	
3		3	

Curve Shape Parameters: a: _____ c: _____ n: _____ b: _____ d: _____

User adjustment in use: Yes ( ) No ( ) Slope: _____ Intercept: _____

Calibrator/Kit bottle lot matches Calibration Report: Yes ( ) No ( )

User adjustment in use: Yes ( ) No ( )

Using Aliquots: Yes ( ) No ( )

Date QC made:

Reconstitution Protocol: Diluent ( ) Water ( ) Liquid ( )

Patient Data:

	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6
Previous Lot Cal						
New Lot Cal						

(Continued)

* Please attach previous calibration data and reagent lot number.

Imprecision/Outliers

Results/Repeats: _____ / _____; _____ / _____; _____ / _____;

Frequency (# of samples involved or % of samples tested):

Marker Chemistry Tested:

Assay	Concentration Limit	Reps/Cups	Mean	SD/CV
Na+	Performance Verifier Level I	Na+ 5 reps/4 cups Na+ 1 rep, ALT 1 rep each out of 1 cupNa+ 5 reps/4 cups		
Alt	Performance Verifier Level I	5 reps/7 cups		
BuBc	Performance Verifier Level I	5 reps/7 cups		
Gent	TDM Performance Verifier Level I	6 reps/6 cups		
IgM	Protein Verifier Level I	6 reps/6 cups		
dLDL	Performance Verifier Level I	6 reps/6 cups		
CRBM	TDM Performance Verifier Level III	3 reps/5 cups		
TSH	Total Thyroid Control Level 1, 2, 3	2 reps/6 cups		
TT4	Total Thyroid Control Level 1, 2, 3	2 reps/6 cups		

Discrepant Results

Note: Repeat sample first to verify that result is reproducible.

(Continued)

System Results/Repeats: _____ _____
_____
_____

Comparative Results:

Comparative System Name:

Comparative Methodology:

Sample Type:

Sample Appearance:

Patient History: M / F

Age:

Diagnosis:

Results of other assays:

Drug/Therapy Listings:

Time of dosage and how administered:

Correlation

Number of Patients Tested:

Number of Calibrations:

Time elapse between runs:

J&J Controls/OEM:

Level	Other Method: _____	J&J
1		
2		
3		

(Continued)

	Other Method — (X)	J&J — (Y)
Intercept =		
Slope =		
R =		

Calibration Failure

Assay:

Assay Data Disk (ADD) version:

Malfunction codes:

Action codes:

Flags/Messages on Calibration Report, and System:

Kit Lot/Calibrator Lot	SAV/Calib Value	Response

MicroWell Quality Parameters:

Level	Spread (%)	Spread Limit (%)
1		
2		
3		

(Continued)

Level	Calibrator Signal Index (CSI)	Level	Delta Ratio
1		1	
2		2	
3		3	

Curve Shape Parameters: a: _____ c: _____ n: _____ b: _____ d: _____

User adjustment in use: Yes ( ) No ( )

Slope: _____ Intercept: _____

Other Assays Calibrated? Yes ( ) No ( )

If yes, what are they?

Resolution

Completed By:

Date:

Quality Control Procedures

The following table lists the Quality Control topics that reference the procedures included in this section.

Topic Title	Procedure Title
Control Fluids (page 14-3)	• Define a Control Fluid (page 14-24) • Edit a Control Fluid (page 14-25) • Delete a Control Fluid (page 14-25)
Baseline Statistics (page 14-4)	• Define Baseline Statistics (page 14-25)

(Continued)

How to Process Control Samples (page 14-5)	• Process a Control Fluid without a Bar Code Label (page 14-26) • Process a Performance Verifier (page 14-27) • Process a Range Verifier (page 14-28) • Process Immunodiagnostic Controls (page 14-28)
Quality Control Results Review (page 14-7)	• Access QUALITY CONTROL - Review Events by Control (page 14-29) • Access QUALITY CONTROL - Review Records by Assay (page 14-29)
QC Graphs (page 14-10)	• Generate and Print a QC Graph (page 14-30)

Define a Control Fluid

for Key Operators or Service Personnel

1 Touch  to open the Quality Control - Review by Control screen.

2 Touch Define Controls.

3 Type the Control ID (up to 6 alphanumeric characters) on the Define Controls screen.

4 Press [Enter].

5 Type the Name of the Control (up to 15 characters).

6 Press [Enter].

7 Type the Lot Number (up to 10 characters).

8 Press [Enter].

9 Type the Expiration Date in the configured date format.

10 Press [Enter].

11 Touch a Body Fluid button.

12 Touch the buttons for the assays you want to verify using this control fluid. (Touch Page Down to display additional assays.)

The assays you select appear in the scrolling list on the right side of the screen.

13 (Optional) Touch Define Baseline to define baseline statistics for this control fluid. Enter the baseline information and touch Save on the Define Baseline dialog.

14 On the Define Controls screen, touch Save Control to save your selections.

15 Either repeat steps 3 through 14 to define another control or touch the Return/Cancel button to return to the Quality Control - Review by Control screen.

Edit a Control Fluid

For Key Operators and Service Personnel

1 Touch  to open the Quality Control - Review by Control screen.

2 Touch the button for the control fluid you want to edit.

3 Touch Define Controls.

The system displays the Define Controls screen. Information for the selected control is displayed. If you selected multiple controls on the main screen, information displayed is for the last control selected.

4 Make edits by typing new information in the fields displayed. Press [Enter] to move between fields

5 Change body fluid and assay selections by touching the buttons on the screen.

The scrolling list of assays changes as you make your selections.

6 (Optional) Touch Define Baseline to define baseline statistics for this control fluid. Enter the baseline information and touch Save on the Define Baseline dialog.

7 On the Define Controls screen, touch Save Control to save your selections.

8 Either repeat steps 4 through 7 to define another control or touch the Return/Cancel button to return to the Quality Control - Review by Control screen.

Delete a Control Fluid

For Key Operators and Service Personnel

1 Touch  to open the Quality Control - Review by Control screen

2 Touch the button for the control you want to delete.

3 To delete the control without reviewing all the data associated with it, continue with Step 5.

4 To review the data associated with the control, touch Define Controls.

The system displays the Define Controls screen with the information for the selected control.

5 Touch Delete Controls.

The Delete Control confirmation dialog is displayed.

6 Touch Yes to confirm the deletion or No if you decide not to delete the control.

7 On the Define Controls screen, touch the Return/Cancel button to return to the Quality Control - Review by Control screen.

8 Repeat Steps 2 through 6 to delete additional controls.

Define Baseline Statistics

For Key Operators or Service Personnel

1 From either the Quality Control - Review by Control main screen or the Quality Control - Define Controls screen, select or define a control and then touch Define Baseline.

   The system displays the Define Baseline screen. Any baseline information for the assay(s) selected for the control fluid/body fluid combination is displayed.

2 Type a Mean value for the assay (1–10 characters, numeric, including a floating decimal point).

3 Press [Enter].

4 Type a Standard Deviation (SD) value for the assay (1–5 characters, numeric, including a floating decimal point).

   Note: Alternately, touch Calculate SD to enter the CV% and request the system calculate the SD. Touch OK to return to the Define Baseline screen. Continue with Step 6.

5 Press [Enter].

   The CV% is calculated and displayed.

6 Repeat steps 2 through 5 to define statistics for other assays listed on the screen. If you have defined all of the statistics, continue to Step 7.

7 Touch Save.

8 Touch the Return/Cancel button to return to either the Quality Control - Review by Control main screen or the Quality Control - Define Controls screen.

Process a Control Fluid without a Bar Code Label

Process a control fluid without a bar code label and without a program downloaded from the Laboratory Information System (LIS)

1 Touch  to open the Sample Programming screen.

2 Type the control ID (up to 6 alphanumeric characters) in the Sample ID field.

3 Press [Enter].

4 Type the tray ID number (1 or 2 alphanumeric characters) in the Tray ID field.

5 Press [Enter].

   The cup ID number is displayed in the Cup ID field.

6 If needed, change the cup ID (up to 10 alphanumeric characters) and press [Enter].

7 (Optional) Touch STAT to give the control fluid priority.

8 Touch Save/Next to save the program.

9 Load the control fluid into the SAMPLE SUPPLY.

   Note: Placing a control fluid with a STAT designation in the STAT lane gives it the highest priority.

10 Touch  to begin processing.

Process a Performance Verifier

Read the Instructions for Use (IFU) for the specific Performance Verifier to understand the exact process. This procedure provides a general overview of processing a Performance Verifier.

1 **Reconstitution:** For Performance Verifiers that require reconstitution, complete the following steps. For Performance Verifies that do not require reconstitution, continue with Step 2 (page 14-27).

Note: Each bottle of lyophilate has a corresponding diluent labeled by number. Use the appropriate diluent in the reconstitution of the lyophilate.

a Make sure all materials are at room temperature 18–28 °C (64–82 °F) before reconstitution.

b Slowly invert the diluent bottle several times to mix the contents thoroughly. DO NOT SHAKE.

c Gently tap the lyophilate vial on the counter several times to dislodge any material adhering to the stopper.

d Remove the seal and stopper from each bottle just before adding the diluent. Do not leave vials unstoppered.

e Add the appropriate diluent to each vial. Use a clean, dry pipette for each vial. A Class A volumetric pipette or an automated pipette of equivalent accuracy is recommended because of the importance of this reconstitution procedure to the accuracy of the results. Discard any remaining diluent.

f Replace the stopper and hold it firmly in place. Invert the vial gently. DO NOT SHAKE.

Reconstitution, with occasional inversion, may take up to 30 minutes. Visually verify that all freeze-dried material is dissolved prior to use.

g Keep all fluids tightly stoppered when not in use. At the time of reconstitution, it is recommended the operator date and initial the vial.

Reconstituted product should be used immediately or stored in the refrigerator between 2–8 °C (36–46 °F).

2 **Procedure:** The reported value can be compared with the Range of Means and within-lab standard deviation (SD) on the assay sheet. Complete the following steps.

Note: Be sure to use components from the same lot number when reconstituting the fluids.

a If necessary, remove reconstituted material stored in the refrigerator.

b Remove vials from refrigerator.

c Mix the vial thoroughly by gently inverting several times. DO NOT SHAKE.

d Remove the seal and stopper from each vial just prior to use. Keep all vials tightly stoppered when not in use.

e Place fluid in a cup and cover with a pierceable cap.

f Restopper the vial and immediately return it to the refrigerator.

g Bring the cup to room temperature, 18°-28°C (64°-82°F), before analysis (approximately 10 minutes for refrigerated material).

h Analyze according to instructions found in the system documentation.

i Discard any unused portion in the cup following testing.

Process a Range Verifier

Read the Instructions for Use (IFU) for the specific Range Verifier to understand the exact process. This procedure provides a general overview of processing a range verifier.

Note: It is recommended that range verifiers are processed in duplicate.

1. Mix thoroughly by inversion and bring to 15–30 °C (59–86 °F) before use. Return to 2–8 °C (36–46 °F) immediately after use.
2. Load each range verifier onto the system by transferring an aliquot into a 0.5 mL VITROS Microsample cup or a 2.0 mL or a 0.5 mL cup. See Fill Requirements for Sample Containers (page 8-10)
3. Process in the same manner as samples, according to the procedure in the Instructions for Use. Program range verifiers as STAT samples and load in the STAT lane.
4. Assess the results. Refer to the Instructions for Use for the assay's range verifier.
   - If the result for the high verifier is outside the calibration range specified in the Instructions for Use, repeat the assay
   - If the repeat result is outside the range, dilute the high verifier with the low verifier and vortex mix. Assay the diluted verifier and correct the result by the dilution factor.

     Note: Refer to the Instructions for Use for the exact amounts for the dilution and the exact dilution factor.

Process Immunodiagnostic Controls

Read the Instructions for Use (IFU) for the specific immunodiagnostic control to understand the exact process. This procedure provides a general overview of processing an immunodiagnostic control.

Note: Do not use damaged or incompletely sealed product.

1. Store unopened at the temperature stated in the IFU for the specific control. Do not use beyond the expiration date.
2. Reconstitute the control if the IFU states that this is required.
3. Follow the specific storage directions as stated in the IFU.
4. Mix thoroughly by inversion and bring to 15–30°C before use.
5. Handle controls in stoppered containers to avoid contamination and evaporation. To avoid evaporation, limit the amount of time controls are on board the VITROS System. Return to 2–8°C as soon as possible after use or load only the sufficient amount for a single determination.
6. (Optional) Enter baseline statistics for the control for use on the VITROS system.
7. Load each control onto the system. If instructed by the IFU, transfer an aliquot into a sample container taking account of the volume required by the assay and the minimum fill volume of the container.
8. Place a pierceable cap on each cup.
9. Process the control in the same manner as the samples.

Access QUALITY CONTROL - Review Events by Control

1 Touch  to open the Quality Control - Review by Control screen.

This main screen lists all controls defined for the system.

2 Touch the name of a control to select it.

You may touch more than one control, but only the last one touched is the selected, current control.

3 (Optional) Touch Set Filter and decide which records to display.

Note: The default filter is set to one month before today's date.

a Make a choice on the Set Filter dialog.

b Touch OK.

4 Touch Review Events.

Note: If the Review Events button is grayed out, there are no events to view. Change the filter using the Set Filter dialog.

The Quality Control - Review Events by Control screen is displayed and lists information for the control that you have selected.

5 Review the following information that is displayed on the screen:

- Date/Time
- Controls Selected
- Number of Events
- Assay
- Result Limits
- SDI
- Codes
- Flag
- Man Dil
- Dil
- Omit
- Comments

6 (Optional) Touch an event to select it and then touch a process button at the bottom of the screen to modify the event.

Access QUALITY CONTROL - Review Records by Assay

1 Touch  to open the Quality Control - Review by Control screen.

This main screen lists all controls defined for the system.

2 (Optional) Touch the name of a control.

3 (Optional) Touch Set Filter and decide which records to display.

Note: The default filter is set to one month before today's date.

a Make a choice on the Set Filter dialog.

b Touch OK.

4 On the main screen, touch Review by Assay.

5 On the Quality Control - Review by Control - Review by Assay screen, touch a body fluid, an assay, and a Control ID.

6 (Optional) Touch Set Filter and decide which records to display.

Note: The default filter is set to one month before today's date.

a Make a choice on the Set Filter dialog.

b Touch OK.

7 To review the record, touch Review Records.

The Review Records by Assay screen displays the following statistics for the assay/body fluid/control:

- Number of records
- Baseline statistics
- Record statistics
- Date
- Time
- Flag
- Result
- Mean
- SD
- SDI
- Omit
- Codes
- Comments

8 (Optional) Touch a record to select it. Investigate it or modify it using the process buttons at the bottom of the screen.

Generate and Print a QC Graph

1 Touch  to open the Quality Control - Review by Control screen.

2 (Optional) Touch a control to select it.

3 Touch Review by Assay.

4 On the Quality Control - Review by Assay screen, touch the body fluid, assay, and control that you want to graph.

5 (Optional) Touch Set Filter and decide which records to graph.

Note: The default filter is set to one month before today's date.

a Make a choice on the Set Filter dialog.

b Touch OK.

6 Touch Review Graph to generate a graph and display it in the Quality Control - Review Graphs screen.

7 Review the data displayed graphically and modify it if needed.

8 Touch Print Graph to print the graph.

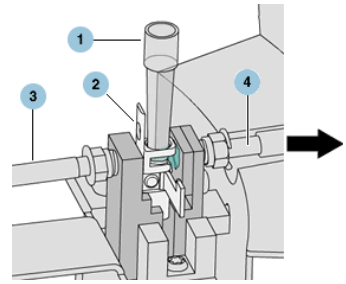
9 Touch Return to return to the Quality Control - Review by Assay screen.

VITROS MicroSensor™ Overview

The system can perform automated semi-quantitative sample quality index determinations on serum, plasma and cerebrospinal fluid samples. This feature is called the VITROS MicroSensor™. The MicroSensor feature is intended to assist laboratory personnel in assessing the suitability of a patient sample for use on the system.

Measurement Theory

The optical absorbance from 400 – 800 nm is automatically read and recorded for each sample. Multi-variant analysis of the spectral data provides estimates of hemolysis, icterus and turbidity indices in the sample.



1 Cuve Tip

2 Tip Lifter

3 Illumination Fiber Bundle (to Reflectometer Lamp)

4 Pickup Fiber

MICROSENSOR

Spectrophotometer

Diffraction Grating

Detector Array

Electronics

Analog to Digital conversion

Software

Communication

The MicroSensor module contains a solid-state spectrophotometer, which utilizes a diffraction grating and a 256-element photodiode array. The module provides energy spectra for samples to the master computer for index determination.

For Hemolysis and Icterus indices, the technique used to calculate the index value utilizes the derivative of the absorbance spectrum [dA÷d**λ**]. The vector dot

product of the derivative absorbance vector and an index-specific coefficient vector provides the index value.

$$H = [dA \div d\lambda] \times [a_H]$$

$$I = [dA \div d\lambda] \times [a_I]$$

Where:

H	= Hemolysis index
I	= Icterus index
$dA \div d\lambda$	= Derivative absorbance vector
a_H	= Hemolysis coefficient vector (522 – 750 nm)
a_I	= Icterus coefficient vector (502 – 776 nm)
×	= Vector dot product (sum of the products of each vector row)

The turbidity index is calculated using absorbance at 700 nm:

$$T = \exp(a_3 A_{700}^{\ 3} + a_2 A_{700}^{\ 2} + a_1 A_{700} + a_0)$$

Where:

T	= Turbidity index
A_{700}	= Absorbance at 700 nm
a_0, a_1, a_2, a_3	= Polynomial coefficients
exp( )	= Exponential function e^x

Sample quality index values are assessed for each sample and assays are flagged as appropriate for each index in accordance with interference information provided in the individual Instructions for Use. The specific index flagging thresholds are transferred to the system by means of the Assay Data Disk (ADD).

VITROS MicroSensor™ Testing Procedure

Sample Requirements

Specimen Types Supported by MicroSensor

- Serum
- Plasma
- Cerebrospinal fluid

Specimen Types NOT Supported by MicroSensor

- Urine
- Whole Blood

- Amniotic fluid
- Diluted samples

  Note: MicroSensor results presented with diluted samples are measured on the original sample, prior to dilution preparation.
- Pre-treated samples (for example, B12, Folate)

IMPORTANT: This information refers only to sample suitability for the sample index measurement.

Storage	Hemolysis	Icterus	Turbidity
Room temperature	24 hours	4 hours	24 hours
Refrigerated	3 weeks	1 week	1 week
Frozen	4 weeks	8 weeks	Not recommended

IMPORTANT: Refer to the individual Instructions for Use for acceptable sample types for each assay.

IMPORTANT: Indices do not require calibration by the system operator.

Material Required But Not Provided:

- VITROS Chemistry Products VersaTips
- VITROS Chemistry Products MicroSensor Check Fluids I and II

System Configuration for MicroSensor

Tell me how to configure the system to perform the sample index determinations (page 14-38)

On means the indices will be printed on the Laboratory Report and may be transmitted to the LIS for all serum/plasma and cerebrospinal fluid samples.

Off means the indices will not be reported on any samples.

Tell me how to configure the system to print the sample index determinations on the Patient Report (page 14-38)

Sample Analyzing

Indices can be performed alone on a sample or along with assays.

Programming Samples with Indices

Program samples as you would normally. If Sample Indices are configured to On, the indices will be processed on all supported sample types. Follow the minimum fill volume requirements (page 8-10) for the cup and tube type in use as specified in V-Docs on the system.

Note: To process an individual sample without sample indices, remove the check mark from the sample indices box on the Sample Programming screen.

Programming Samples for Indices Only

Program MicroSensor Check Fluids or patient samples using the "Indices" button on the Sample Programming screen or through the LIS interface. Follow the minimum fill volume requirements (page 8-10) for the cup and tube type in use as specified in V-Docs on the system.

Note: If you are processing patient samples for indices only, it is not possible to retrieve the sealed CuveTip after the sample indices are performed.

Sample quality index values are assessed for each sample and assays are flagged as appropriate for each index in accordance with interference information provided in the individual Instructions for Use. The specific index flagging thresholds are transferred to the system by means of the Assay Data Disk (ADD).

Sample Lab Report Printout

	Hem	Ict	Tur
Sample ID: 1715	101	<2	<20
PSA = 85 mg/dL			
TropI ES = 3.7 mmol/L	H		

The PSA result is not flagged since a hemolysis index of 101 does not affect the PSA value.

The TropI ES result is flagged since a hemolysis index value of 101 may affect the TropI ES result.

Tell me more about sample index flags (page 13-18)

VITROS Chemistry Products MicroSensor Check Fluids I and II Processing

Materials Provided: Two bottles each of VITROS Chemistry Products MicroSensor Check Fluids I and II (3 mL per bottle).

Refer to the lot-specific MicroSensor Information Sheet for the storage and handling requirements of the Check Fluids.

The MicroSensor Check Fluids should be sampled in the same manner as a patient sample.

Tell me how to process MicroSensor Check Fluids (page 14-39)

Note: Files can be set up for tracking MicroSensor Check Fluid data in the Quality Control screen of the system.

Reported values for the MicroSensor Check Fluids should be evaluated using the range provided on the lot-specific MicroSensor Check Fluid Information Sheet.

MicroSensor Check Fluids should be analyzed as follows and results outside the published ranges should be investigated:

- As part of weekly maintenance
- When the REFLECTOMETER LAMP is replaced
- When the TIP LIFTER is replaced
- When the MICROSENSOR OPTICS are cleaned

Expected Values for VITROS MicroSensor™

Sample Index	Operating Range
Hemolysis	15 – 1000
Icterus	2 – 25
Turbidity	20 – 800

IMPORTANT: Do not dilute samples for sample indices.

Information regarding dilution of VITROS assays can be found in the individual Instructions for Use.

Note: A laboratory with multiple systems may choose to perform a correlation between systems on the sample indices and introduce a user adjust indices (also called Post-Prediction Adjustment or PPA).

Tell me how to Configure User-Adjusted Parameters for Sample Indices (page 14-39)

Tell me more about sample index flags (page 13-18)

User-Adjusted Parameters

The Configure Assays screen enables you to adjust correlation parameters for the sample indices (hemolysis, icterus, turbidity).

Tell me how to Configure User-Adjusted Parameters for Sample Indices (page 14-39)

Limitations and Precautions

The system will not perform indices on the following samples:

- Calibrators
- Controls
- Urines
- Whole Blood
- Amniotic fluid
- Pre-treated samples (B12, Folate)
- System diluted samples

  Note: MicroSensor results presented with diluted samples are measured on the original sample, prior to dilution preparation

Sample quality indices are measurements of the optical characteristics of the sample.

- Hemolysis is not a quantitative measurement of hemoglobin.
- Icterus is not a quantitative measurement of bilirubin.
- Turbidity is not the equivalent of the trigylceride concentration in a sample. Turbidity in a sample may or may not be due to lipids.

Additional sample precautions:

- Older samples may show a decrease in the amount of hemolysis detected due to the presence of methemoglobin.
- Protect samples from light as exposure to light may affect the icterus spectral properties of the sample.
- The Icterus index demonstrates a bias with regard to bilirubin concentration as follows:
  - Samples containing predominantly unconjugated bilirubin may be positively biased.
  - Samples containing predominantly conjugated bilirubin may be negatively biased.
- Freezing samples will affect turbidity assessments.

Known Interferences

Compounds such as biological dyes and certain drugs that absorb within the visible region may affect one or more of the sample indices.

The following were tested and found to affect the sample indices as indicated:

Interferent	Effect on Index
Unlysed red blood cells may interfere with Hemolysis	Hemolysis increases >25%
Unlysed red blood cells may interfere with Icterus	Icterus increases >25%
Unlysed red blood cells may interfere with Turbidity	Turbidity increases >35%
Methemoglobin (100 mg/dL) may interefere with Hemolysis	Hemolysis decreases >25%
Biliverdin (2 mg/dL) may interfere with Turbidity	Turbidity increases >35%
Biliverdin (2 mg/dL) may interfere with Hemolysis	Hemolysis decreases >26%
Biliverdin (4 mg/dL) may interfere with Icterus	Icterus decreases >26%

Conditions Resulting in an Examine Sample "ES" Flag	Effect on Index
Hemolysis values >600 may interfere with Icterus	Icterus increases >25%
Hemolysis values >1000 may interfere with Turbidity	Turbidity increases >35%
Icterus values >20 may interfere with Hemolysis	Hemolysis increases >25%
Turbidity values >600 may interfere with Hemolysis	Hemolysis increases >25%
Turbidity values >500 may interfere with Icterus	Icterus increases >25%
Triglycerides >600 mg/dL may interfere with Hemolysis	Hemolysis increases >25%
Triglycerides >600 mg/dL may interfere with Icterus	Icterus increases >25%
Triglycerides >600 mg/dL may interfere with Turbidity	Turbidity increases >35%

Substances That Do Not Interfere

The substances listed in this table were tested on the VITROS MicroSensor at a value of H of 0, I of 0, T of 0 (pool 1), a value of H of 50, I of 2, T of 50 (pool 2) and a value of H of 300, I of 20, T of 400 (pool 3) using protocols based on

NCCLS Protocol EP 7. The substances were found not to interfere at the concentration shown.

Substances that do not interfere:

Compound	**Concentration**
Amrinone	1.0 mg/dL
Ascorbic Acid	6 mg/dL
Beta Carotene	1.5 mg/dL
Chenodeoxycholic Acid	30 µmol/L
Chloroquine	2000 nmol/L
Cholic Acid	30 µmol/L
Ciprofloxacin	0.5 mg/dL
Clofazamine	1 mg/dL
Cupric Chloride	0.1 mg/dL
Cyanocobalamin	0.2 µg/dL
Daunomycin	7 µg/dL
Dehydrocholic Acid	30 µmol/L
Deoxycholic Acid	30 µmol/L
Diphenhydramine	10 µg/mL
Doxorubicin	18 µg/dL
Estrone	2.0 mg/dL
Folic Acid	2.4 µg/dL
Idarubicin	8 µg/dL
Indomethacin	0.2 mg/dL
Iohexol (Omnipaque)	2.5 g l/dL
Iopamidol (Isovue)	2.0 g l/dL
Iothalamate (Conray 43)	0.6 g l/dL
Lithocholic Acid	30 µmol/L
Meglumine Diatrizoate	0.6 g l/dL
Metrizamide	5 mg l/dL
Myoglobin	5000 µg/L
Nifedipine	20 µg/dL
Novobiocin	15 mg/dL
Oxygent (tested in pool 1 only)	80 g/L

(Continued)

PH (tested in pool 2 only)	5.5
PH (tested in pool 2 only)	8.5
Primaquine	300 ng/mL
Prohance	3.0 mmol/L
Quinacrine	200 ng/ml
Riboflavin	10 µg/dl
Rifabutin	13 µg/dL
Triamterene	6 mg/dL

VITROS® MicroSensor™ Procedures

The following table lists the VITROS MicroSensor™ procedures included in this section.

Topic Title	Procedure Title
VITROS MicroSensor™ Testing Procedure (page 14-32)	• Configure System to Perform Sample Index Determinations (page 14-38) • Configure System to Print Sample Index Values on Patient Reports (page 14-38) • Process MicroSensor Check Fluids (page 14-39) • Configure User-Adjusted Parameters for Sample Indices (page 14-39)

Configure System to Perform Sample Index Determinations

1 Touch Options & Configuration > Configure Systems > Sample/Report Options to display the Options & Configuration— Sample/Result Options screen.

2 Touch On or Off for Sample Indices.

On , the default setting, means that the sample indices tests will be performed, they will be printed on the Laboratory Report, and they will be transmitted to the LIS.

Off means that the sample indices tests will not be performed.

3 Touch Save to save your entry.

4 Touch Return/Cancel to return to the main Options & Configuration screen.

Configure System to Print Sample Index Values on Patient Reports

1 Touch Options & Configuration > Configure Systems > Patient Report to display the Configure Patient Report dialog.

2 Touch the check box for “Print SI values on report.”

3 Touch Save to save the changes and return to the Options & Configuration - Configure Systems screen.

Process MicroSensor Check Fluids

1. Mix the bottles thoroughly by gently inverting several times. **Do not shake**.
2. Remove the cap from each bottle just before use. Keep all bottles tightly capped when not in use.
3. Place 3 or 4 drops of MicroSensor Check Fluid in a sample cup and cover the cup with a pierceable cap.
4. Bring the cup to room temperature, 18– 28 °C (64– 82 °F), before analysis. This takes approximately 10 minutes for refrigerated material.
5. Process the MicroSensor Check Fluid like any sample and compare the results with the results listed on the information sheet.
6. Discard any unused portion in the cup after testing.

Configure User-Adjusted Parameters for Sample Indices

For Key Operators and Service Personnel

1. Touch Options & Configuration > Configure Assays > User Adjust Indices to display the User Adjust Indices dialog.
2. Review and, if needed, edit the slope and intercept for each of the indices. Press [Enter] after each edit.
3. Touch Save to save the edits.

   The Save New Assay Configuration dialog is displayed.
4. Read the message that is displayed in the dialog and touch Yes to save the edits. Touch No to discard the edits.

   The Options & Configuration— Configure Assays screen is displayed.

Intellicheck® Technology

The system uses Intellicheck® Technology, a proprietary technology of Ortho Clinical Diagnostics that is designed to significantly reduce critical errors and minimize operator intervention. Intellicheck is Integrated Process Control, a series of patented and unique technologies that perform, monitor, and verify diagnostic checks throughout sample processing, assay processing, and reporting results. When exceptions are detected, Intellicheck Technology prevents the reporting of results that may be affected.

Intellicheck Technology is automatically configured on your system.

The following topics explain Intellicheck Technology:

- Intellicheck Technology for Subsystems and Processes (page 14-39)
- Notifications from Intellicheck Technology (page 14-40)
- Intellicheck Technology (page 14-41)

Intellicheck® Technology for Subsystems and Processes

Intellicheck Technology monitors the following subsystems and processes. The set of verifications performed for each assay varies based on the type of assay.

For MicroSlide and MicroTip Assays

- Sample Metering
- Sample Indices
- Reagent Metering
- Reference (ERF) Metering

- WF Metering
- Photometer
- Reflectometer
- Electometer
- Reaction Quality
- Slide Impedance
- Magenta Wash Tracker

For MicroWell Assays

- Sample Metering
- Sample Indices
- Sample Dilution
- Reagent Metering
- Signal Reagent
- Well Wash
- Luminometer

For Sample Indices Tests Only

- Sample Metering
- Sample Indices

Notifications from Intellicheck® Technology

When exceptions to Intellicheck Technology verifications occur, results that may be affected by these exceptions are prevented from being reported. The system automatically performs an analysis, determines the next process forward and maintains continuous sample and assay processing. For example, if the system detects a bubble in a sample, only the affected assay is noted with a code, no result is reported, and processing continues for any samples in the Sampling Center.

For each detected exception, Intellicheck Technology provides the following notifications:

- A condition code that details the situation and provides prioritized corrective action steps specific to the exception or condition.
- Codes and Flags that are specific to subsystems and individual components and are clearly displayed, reported and linked with the assay results for on-screen and printed Patient, Calibration and Quality Control reports. These are transmitted to a Laboratory Information System (LIS).
- Automatic system initialization for many of these events, provides continued system operation.
- e-Connectivity, a real-time, secure, two-way interactive connection between your system and Ortho Clinical Diagnostics that automatically transfers system performance data to Customer Technical Support for real-time analysis.

See Condition Codes Overview (page 18-1) for information about codes and suggested actions.

See Flags and Codes (page 13-1) for a list of flags and codes and their meaning

See Options and Configuration (page 17-34) for setting up e-Connectivity

IntelliReport™ in Results Review

IntelliReport™, a component of Intellicheck® Technology, reports real-time status of every result, assures the integrity of every result, and serves as an important record for result quality. The IntelliReport screen in Reports Review documents key Intellicheck Technology verifications performed during sample and assay processing. This provides traceability for each reported result. For every assay result, IntelliReport displays the following information:

- Verification of results
- Acceptable ranges
- Actual readings
- Exceptions to Intellicheck technology verifications

All exceptions are shown in red text on the screen. Note the exception information when contacting Customer Technical Support. This information aids in troubleshooting system problems.

See IntelliReport™ (page 11-8) for details about the information that is displayed on the screen.

Review the IntelliReport™

Use the Results Review — IntelliReport screen to review Intellicheck technology verifications performed for each assay in a result record. Verification data and detected exceptions are provided for each assay, including replicates. The set of verifications performed for each assay varies based on the type of assay.

Tell me how to review the IntelliReport (page 11-22)

Print the IntelliReport™

Print reports documenting Intellicheck Technology verifications.

Tell me how to print the IntelliReport (page 11-22)

Intellicheck® Procedures

The following table lists the Intellicheck® procedures that are referenced in this section.

Topic Title	Procedure Title
Intellicheck® Technology (page 14-39)	• Tell me how to review the IntelliReport (page 11-22) • Tell me how to print the IntelliReport (page 11-22)

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Chapter 15 Reagent Management Overview

The Reagent Management feature enables you to review current inventory information for the reagents loaded on the system. Using this function, you can load and unload reagents as necessary.

Tell me more about Reagents and other Supply Categories (page 8-1)

To access screens used for reagent management, touch Reagents. The system displays the Reagent Management screen.

The Reagent Management screen displays buttons for each assay available on the system. Buttons are displayed in alphabetical order. The information on this screen is updated in real time.

Touch one of the Supply buttons (1 – 4) to select which view is displayed on the screen as defined in the following table.

Supply	Reagent Supply Type	Reagent Button Outline Color
1	Outer MicroSlide Supply that has high humidity	Yellow
2	Inner MicroSlide Supply that has low humidity	White
3	MicroTip Reagent Supply	Gray
4	MicroWell Reagent Supply	White

Note: The reagent button outline color is associated with each reagent name and identifies the supply type it belongs to. If a different outline color appears on a screen, that reagent has been loaded in the wrong supply area.

Touch one of the View buttons to display different types of reagent information: Count, Lot #, Status, Expiration, or Slot #.

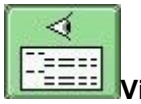
The outlined area around each reagent button provides a place to display associated information depending on the view button that is selected. For

example, touch Count to display the number or volume remaining for each reagent.

Tell me more about Inventory Review (page 15-3)

View Reagents

The following process buttons can be used to view reagent information.

 **View by Reagent**: View all successfully inventoried reagents

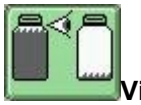
Tell me how to View by Reagent (page 15-5)

 **View SR**: View Signal Reagent (SR) fluid levels and associated information

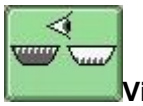
Tell me how to View by View SR (page 15-5)

 **View by Assay**: View assay related information of reagents on the system

Tell me how to View by Assay (page 15-6)

 **View UWR / Waste**: View Universal Wash Reagent (UWR), Liquid Waste volume, and associated information (disabled when the system is in Diagnostics Mode)

Tell me how to View UWR/Waste (page 15-6)

 **View ERF / IWF**: View the number of tests remaining and begin the process of changing the ERF or IWF supply

Tell me how to View ERF/IWF (page 15-6)

Load and Unload Reagents

The following process buttons can be used to load and unload reagents. See Reagent Storage and Use (page 15-7) for more information.

 **Load Unload**: Touch the Load Unload process button to launch the Entering Reagent Load status dialog followed by the Load/Unload Reagents or Preparing to Load/Unload dialog.

 **Manual Load**:Touch the Manual Load process button to launch the Manually Load Cart or Manually Load Pack dialog depending on which supply is selected (1–4).

Inventory Review

Check reagent inventory daily to:

- Evaluate inventory and manage reagent lots
- Keep an adequate supply of calibrated lots on the system to avoid unnecessary interruptions during sample processing
- Monitor reagent levels, status, and time until expiration

Different reagent inventory views can be selected by touching one of the following view buttons on the Reagent Management screen. Each view will display specific information about the loaded reagents as described below:

Button	Displays
Count	Number of tests remaining in inventory for that assay or diluent **Note:** The diluent count is the remaining volume (mL) for MicroTips and remaining tests for MicroWells. **Note:** For assays that require two separate packs, the system maintains a test count independently for each pack. The effective total count is the lower of the individual pack counts.
Lot #	Gen and lot number for MicroSlide and MicroTip reagents Lot number for MicroWell reagents

(Continued)

Status	Current status of the reagent: **Barcode?** — System could not read the reagent bar code. **Remove** — Cartridge is loaded in an incorrect supply. **Dup Seq** — Reagent identification matches one currently onboard the system or one that was previously run until depleted. **Unknown** — Reagent's data is missing from the currently loaded Assay Data Disk information. **Unusable** — One or more of the following conditions: • System encountered two "slide not present" conditions. • A cartridge has been marked as "unusable." • Fluid volume has increased since the last load of a specific reagent sequence number. • A user defined assay pack is added to or deleted from a pack that is onboard, or is no longer being used by any currently defined assay. • The customer lot number for an onboard user defined assay pack has changed. **Bubbles** — The system encountered bubbles in a reagent pack. **UD Info?** — The reagent lot number or reagent shelf expiration date has not been defined for a user defined assay pack. **Inv?** — Inventory is under way or incomplete. **Empty** — Insufficient reagent remains in the supply for processing. **Not Cal** — Reagent lot does not have a current calibration; either calibrate the lot or unload the reagent. **ExpDate?** — Reagent has been scanned but the shelf expiration date is not contained on the Assay Data Disk. **In-Use** — Reagent is being used or is reserved for assay processing. **Current** — Reagent lot has the most recent successful calibration or has been selected as current by operator. **Ready** — Reagent is ready for use in assay processing.
Expiration	Time left before the reagent expires: • The number of days until the reagent reaches either the shelf expiration date or the open expiration date, whichever date is sooner. • The number of hours remaining in yellow bold text with a gray background if the reagent is due to expire in less than twenty-four hours. • “Expired” in bold red text if the expiration date has already been reached. • "Immediate" if any partially depleted reagent is not recognized as having been previously loaded.
Slot #	Slot number in which the reagent is loaded

View Reagents

The process buttons on the Reagent Management screen enable operators to display various views of the reagents used by the system. The following sections describe the content and functionality of these screens.

View by Reagent

Process Button	Description
	The Reagent Management – View Reagent Detail screen displays all successfully inventoried reagents (excluding diluents).

Some reagents may contain additional information in a second level that can be expanded or collapsed.

- The first level includes the reagent name and total tests for all calibrated lots.
- The second level includes lot and pack/cart information.

The Reagent Management – View Reagent Detail screen also includes the following process buttons:

Process Button	Description
View Dil/Anc	Launches the Reagent Management – View Diluents/Ancillary screen that lists each successfully inventoried diluent pack name and the total volume for all lots. Includes expandable lot and bottle information. This information can be sent to the printer by touching the Print Report process button.
Enter Shelf Exp. Date	Launches a dialog box that lists the reagent lots that are currently loaded without a shelf expiration date. Expiration dates can be manually entered and saved for each of these.
Expand All / Collapse All	Expands or collapses additional lot and pack/cart information if available for each reagent
Print Report	Prints Reagent Report Tell me how to Print a Reagent Report (page 15-10).

View SR

Process Button	Description
	The Reagent Management – View SR screen displays Signal Reagent (SR) fluid levels and associated information (such as open and shelf expiration dates) for each SR CAROUSEL position.

The Reagent Management – View SR screen also includes the following process buttons:

(Continued)

Process Button	Description
Manual Load	Launches a dialog box that can be used to manually enter SR expiration and barcode information.
SR Exchange	Launches a dialog box that can be used to exchange SR fluid.

Note: These process buttons are disabled if the required devices are unavailable.

Caution: Do not reload used SR packs. Verify that SR packs are new and have never been used before loading them onto the system. An SR pack can only be unloaded and stored for future use if it has never been used, pierced, or placed in the in-use position on the SR carousel.

View by Assay

Process Button	Description
	The Reagent Management – View by Assay screen displays a scrolling list of assay information that can be expanded or collapsed when a reagent is on-board the system.

The following assay information is included in this list:

- Assay name and the total number of assays that can be processed
- Body fluids available for each assay
- Gen/Lot numbers of the on-board reagent packs
- Number of assays available per lot of diluent and per lot of reagent type available for standard dilutions if the lot is calibrated with a status of current
- Earliest assay calibration expiration date for each lot

View UWR/Waste

Process Button	Description
	The View UWR/Liquid Waste Fluids screen displays Universal Wash Reagent (UWR) and Liquid Waste volume and associated information.

This screen can also be used to replace the UWR, empty the liquid waste, or change both.

View ERF/IWF

Process Button	Description
	The View ERF/IWF Fluids screen enables the operator to begin the process of changing the ERF or IWF supply if MicroImmunoassays are processing.

This screen displays the following information:

- Time Until Load – the amount of the time, in minutes and seconds before the ERF/IWF supply can be loaded on the system, at the moment the display is updated
- Remaining ERF tests and associated information
- Remaining IWF tests and associated information

The View ERF/IWF Fluids screen also includes the following process buttons:

Process Button	Description
Update Load Timer	Updates the “Time Until Load” and informs the operator, via a status message, if re-programming of assays is required. Samples in the Stat Lane will require reprogramming after loading the ERF or IWF supply.
Schedule Load / Done	The Schedule Load process button initiates the ERF/IWF supply loading process and starts the “Time Until Load” countdown. The Done process button initiates the completion of the ERF/IWF loading process.
Load ERF	Initiates the Load ERF process: • The Replace ERF Tip dialog box provides instructions and gives the operator the option of running a Leak/Hysteresis test. • The Load ERF Fluid dialog box provides instructions and prompts the operator to enter an ERF lot number (one alphanumeric character followed by a four-digit number).
Load IWF	Initiates the Load IWF process: • The Replace IWF Tip dialog box provides instructions and gives the operator the option of running a Leak/Hysteresis test. • The Load IWF Fluid dialog box provides instructions and prompts the operator to enter an IWF lot number (one alphanumeric character followed by a four-digit number).

Reagent Storage and Use

This topic describes how to store reagents and how to load and unload them on the system. Reagents can be loaded or unloaded after assays have been completed, or “on-the-fly” while sampling or assays are in progress.

IMPORTANT: Refrigerate all reagent packs that you remove from the MICROIMMUNOASSAY REAGENT SUPPLY. Place MicroWell reagent packs in a Reagent Pack Storage Box from the Maintenance Kitor in their original packaging before you refrigerate them.

Tell me how to Load/Unload Reagents While Sampling or Assays in Progress (page 15-9)

The user interface and the reagent supply LED indicators provide operator assistance during the reagent load and unload process.

Tell me more about the Reagent Supply LED Indicators (page 15-9)

Note: Refer to the Instructions for Use (IFU) for each specific reagent for more information on storage and use.

Reagent Pack Storage

Most reagent packs are supplied ready for use. Store reagents according to the Instructions for Use for each assay or reagent.

Slide Cartridge Storage

Store slide cartridges in a freezer or refrigerator depending on the storage instructions recommended in the Instructions for Use (IFU).

The cartridge's outer carton is labeled with the assay name, slide lot number, expiration date, and required storage temperature. The outer cartons are color-coded to indicate their storage environments; those requiring freezer storage are colored blue and those requiring refrigerator storage are colored lavender.

When kept in the wrapper and stored correctly, slides are stable until the expiration date printed on the carton.

How to Load and Unload Reagents

The MicroImmunoassay Reagent Supply area stores reagents, diluents, and ancillary packs. Reagent loading consists of the operator manually inserting reagents with assistance from the Reagent Management screen and the reagent supply LED indicator.

The MicroImmunoassay Reagent Supply can support 30 VITROS Chemistry reagents (MicroTip) and 31 VITROS Immunodiagnostic reagent packs (MicroWell).

The system identifies each unique pack for inventory purposes. After the system moves the pack into the reagent supply, the reagent supply subsystem scans the bar code label for identification, determines the reagent level, and saves the inventory information. You can manually enter pack identification information if necessary (for example, if the bar code label is unreadable). The Virtual Keypad can be used to enter this information.

Tell me more about the Virtual Keypad (page 6-7)

IMPORTANT: Unless directed otherwise by Customer Technical Support or by the Instructions for Use, leave the caps on the reagent and diluent packs when loading them. The system includes a mechanism that removes and replaces the caps automatically. If you find a pack on the system that is uncapped while not in use, run Quality Control on the pack before using. Discard the pack if it does not pass Quality Control.

Tell me how to load MicroImmunoassay Reagents (V-Docs)

Tell me how to manually load MicroImmunoassay Reagents (V-Docs)

Tell me how to unload MicroImmunoassay Reagents (V-Docs)

How to Load and Unload Slide Cartridges

Use the Reagent Management screen to load and unload slide cartridges.

- Touch the Supply button for the reagent supply type that needs to be loaded. For example, if you are loading Outer MicroSlide Supply cartridges touch Supply 1.
- Touch Load/Unload. The system prepares the supply for loading.

If you are loading a cartridge that requires you to enter lot information (for example, if the bar code on the cartridge is obscured), touch Manual Load. Type the lot number of the cartridge and the date it was opened. Then, load the cartridge normally.

Supply 1 stores 52 MicroSlide cartridges. Supply 2 stores 37 MicroSlide cartridges.

Tell me how to load slide cartridges (V-Docs)

Tell me how to manually load slide cartridges (V-Docs)

Tell me how to unload cartridges (V-Docs)

How to Load/Unload Reagents While Sampling or Assays in Progress

If the Load/Unload process button is touched while sampling or assays are in progress, a Preparing to Load/Unload dialog box will count down the minutes and seconds until this function is available.

A Load/Unload Reagents dialog box will indicate when loading/unloading is available for the selected supply. The dialog box will also count down in minutes and seconds the remaining amount of time that is available to load/unload a reagent.

Note: If the reagent door is still open when this window of time expires, tests in progress will begin to be discarded.

The View ERF/IWF process button also enables the operator to begin the process of changing the ERF or IWF supply if MicroImmunoassays are processing. See View ERF/IWF (page 15-6) for more information.

Reagent Supply LED Indicators

Each reagent supply door has an LED that will turn on to indicate when the reagent supply door can be opened. The LED will also blink when the load/unload time is close to expiring. The LED will be disabled as the supply moves to each available position. As soon as the reagent supply is in position for the next action, the LED will be enabled, once again.

Reagent Waste

The system disposes of used reagent materials by depositing them into waste containers. You can access these containers from the front of the system. These containers should be emptied as part of daily maintenance.

DANGER: MICROSLIDE, MICROTIP AND MICROWELL WASTE ARE BIOHAZARDS. DISPOSE OF THEM APPROPRIATELY ACCORDING TO LOCAL REGULATIONS AND APPROVED LABORATORY PROCEDURES.

Tell me more about Waste Container Status (page 7-8)

Reagent Lots

A group of VITROS MicroTip or MicroSlide reagents with equivalent performance characteristics can utilize a common calibration. These reagents are labeled with the same lot number. Each VITROS Immunodiagnostic reagent is also lot-linked to its associated calibrator lot. The lot number is included on

the reagent labeling and in its bar code information. The system supports multiple reagent lots. For each assay, the system supports up to 25 reagent lots for calibration and use at the same time.

Note: If an assay requires more than one pack to run (e.g., a 3- or 4-reagent assay), only packs of the same generation and/or lot will be run together.

To process assays, the system uses assay reagents of the lot designated by its current calibration. When a reagent lot currently in use becomes depleted, the system automatically switches to the next oldest calibrated lot in the system's inventory.

Reagent Lot Switching

If a reagent lot no longer has inventory, the system selects another on-board lot that can be used in its place when processing samples. This allows assays that require the depleted reagent lot to be processed and obtain valid results. You can also choose to switch to a reagent lot before processing samples by selecting and restoring the calibration for the reagent lot.

Suppose there are two lots for PSA loaded on the system, called Lot A and Lot B. Both lots have successful calibrations and inventory on the system. Lot B is the current lot in use for PSA. That is, the system is using Lot B and the Lot B calibration to generate results for samples.

After running PSA samples for several hours, the system uses up Lot B. Lot B now shows zero inventory. The system switches automatically to Lot A and makes the Lot A calibration the current one. The system now generates PSA assay results with Lot A using the Lot A calibration parameters for the same given reagent type.

If you load more Lot B reagents on the system after the inventory of Lot B becomes zero, Lot A still is the current one in use for PSA due to the automatic lot switching capability. To return Lot B to current status, you would need to restore it for one or more of the fluids supported for PSA or remove all Lot A reagents from the analyzer. (Lot switching would occur again, making Lot B current.)

If you load more Lot B reagents before the on-board inventory reaches zero, or no other calibrated lot of this type resides on the system, Lot B remains the current PSA reagent lot.

ERF and IWF Reservoir Replacement

ERF Reservoir Replacement

Change the Electrolyte Reference Fluid (ERF) reservoir once every 24 hours.

Tell me how to replace the ERF reservoir (V-Docs)

Tell me how to replace the ERF Tip (V-Docs)

IWF Reservoir Replacement

Change the Immuno-Wash Fluid (IWF) reservoir every 72 hours or when prompted. Clean the RESERVOIR COVER SEAL every 72 hours.

Tell me how to replace the IWF reservoir (V-Docs)

Tell me how to replace the IWF Tip (V-Docs)

Print Reagent Report

Touch the Print Report process button on the Reagent Management screen to send a Reagent Report to the printer. This report contains information from the following sources:

- On-board reagents from all supplies with a reagent status of Empty, Not Cal, In Use, Current or Ready
- On-board diluents
- All on-board and off-board reagents that have a current calibration for one or more body fluids

The Reagent Report includes the following information:

Report Contents	**Description**
REAGENT REPORT	Reagent Report Title
System Name	Names of the system the report is printed from
PRINT DATE/TIME	Date and time the report is printed
CALIBRATION DATA	Fluids and Current
REAGENT	The reagent name
TOTAL	The number of tests remaining for each lot
LOT NUMBER	The lot number for each lot that is on-board
FLUIDS	Zero or more of the following separated by commas: Ser, Csf, Uri, Whb, Psm, Amn,
CURRENT	Zero or more of the following separated by commas: S, C, U, W, P, A
Diluents Pack Name	Name of the diluent pack
Diluents Bottle Fluid Name	Name of the diluent bottle
Diluents	Volume remaining (mL)
Diluents Lot Number	10 or 11 digit number

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Chapter 16 Diagnostics Overview

Use the diagnostics features to evaluate your system, its subsystems, and individual component operation. Diagnostics are often used in response to a condition code or customer technical support instruction. System troubleshooting or personal observation may also prompt you to use the Diagnostics screen. Some diagnostic functions are available only to trained service personnel.

The Diagnostics screen provides access to the following features:

Feature	Description
Periodic Maintenance	Provides information needed to regularly maintain the system and a schedule to track activities
System Information	Provides current information about system components
Mechanism Exercise Diagnostics (MEDs)	Moves individual mechanical components for the evaluation of system and subsystem operation
Adjustments	Adjusts subsystems by moving or aligning individual components
Performance Tests	Tests subsystems and selected individual components

Note: Certain Diagnostics features are not available if sampling and assays are in process. If a function is not available, its button is dimmed. If you need to perform the function immediately, touch the Return button to display the Diagnostics screen, then touch the Cancel Assays process button  to cancel all sampling and assays in progress. Touch Yes on the Cancel Assays dialog to confirm, then perform the diagnostics you require.

Tell me how to Cancel All Assays in Process (page 16-11)

IMPORTANT: If you cancel assays, samples being processed will be canceled and assay results will not be reported.

The following process buttons are also available on the Diagnostics screen.

Process Button	Description
Start e-Connectivity	Turns e-Connectivity on or off

(Continued)

Remote Service	Allows the system to be controlled remotely if e-Connectivity is on
Calibrate Touchscreen	Displays the Diagnostics – Calibrate Touchscreen screen Tell me how to Calibrate the Touchscreen (page 16-11)

Using Diagnostics Screens

You can perform any number of MEDs, component tests, or operator adjustments while remaining on the same screen. You do not have to initialize components before beginning a new test, and you do not have to return to a previous screen and begin again.

For example, to perform more than one test within a MEDs subsystem (such as a Routine Lane test and a STAT Lane test for the SAMPLE SUPPLY SUBSYSTEM), you can select the function for the first test, then touch Start. As soon as the test is complete, touch buttons on the same screen for the next test, then touch Start. Do this until all your tests for the SAMPLE SUPPLY are complete. If you change your mind about a selection, simply continue touching the buttons on the screen until you are satisfied with your selection. Your selection will not register or activate until you touch the Start button, Return button, or another process button.

e-Connectivity and Remote Service

This feature enables the operator to have the ability to automatically send and receive data from Ortho Clinical Diagnostics Customer Technical Support. Touch Start e-Connectivity to initiate data exchange, including downloading of assay data and system software, and uploading of datalogger and other files. After e-Connectivity has been established, touch Remote Service to enable remote diagnostics and provide the ability for Customer Technical Support personnel to perform remote control operation, as well as, monitor and review system configuration, data, and performance information. The local operator can disconnect the remote site and take back local control at any time.

An e-Connectivity Log is available on the Diagnostics - System Information screen.

Tell me more about the e-Connectivity Log (page 16-6)

Tell me how to configure e-Connectivity (page 17-34)

Periodic Maintenance

The Periodic Maintenance screen enables the operator to view and maintain a schedule of maintenance activities that must be performed on the system. This maintenance schedule will be presented as lists of activities to be performed on a daily, weekly, monthly, and as required basis. These procedures are required to keep the system operating at an optimal level.

This screen also enables operators to review the maintenance log, configure maintenance lists, and print maintenance reports.

Touch the Operations and Maintenance tab on the V-DOCS screen to access the periodic maintenance procedures.

Tell me more about Maintenance (page 16-14)

Maintenance Features and Activities

The following maintenance features and activities are included on each maintenance interval screen:

Maintenance Interval	Maintenance Features and Activities
Daily	• View and record daily maintenance activities • View daily maintenance history • Maintain ERF • Maintain IWF • Maintain Metering Tell me more about Daily Maintenance (page 16-15)
Weekly	• View and record weekly maintenance activities • View weekly maintenance history • Subsystem Cleaning (MicroWell functionality) Tell me more about Weekly Maintenance (page 16-17)
Monthly	• View and record monthly maintenance activities • View monthly maintenance history • Clean Cuvette Arm • Clean Cuvette Incubator Tell me more about Monthly Maintenance (page 16-18)
As Required	• View and record as-required maintenance activities • View as-required maintenance history • System Cleaning (MicroWell functionality) Tell me more about As Required Maintenance (page 16-19)

Operator ID

A dialog box will prompt system operators to enter a maintenance Operator ID every time a completed activity is saved on one of the Periodic Maintenance screens. This ID can be 1 to 3 alphanumeric characters and is displayed on the Periodic Maintenance – Review Log screen.

Note: The maintenance Operator ID is different than the login Operator ID that is saved with result records.

Tell me more about System Access and Login (page 7-2)

Review Log

Maintenance logs enable operators to document and track the daily, weekly, monthly, and as-required maintenance tasks that have been performed. They also provide helpful information for Service Personnel if system service is needed.

This log is available for viewing by all personnel. System operators with Key Operator or Service Level access are able to review detailed activities, edit, approve and print the maintenance history log. The Review/Edit function is the only way to record maintenance activities for a previous date.

Tell me how to View and Manage Periodic Maintenance Activities (page 16-10)

Configure Periodic Maintenance Lists

System operators with Key Operator or Service level access can move maintenance activities to a list that is scheduled more frequently. For example, a maintenance activity such as “Clean touchscreen monitor and keyboard” can be moved from the weekly list to the daily list. Periodic maintenance activities cannot be moved to a less frequent list. For example, the system will not allow a weekly maintenance activity to be moved to the monthly list.

Note:

Subsystem Cleaning cannot be moved to any other list.

Note: When an activity is moved from one list to another, any associated process buttons will remain on the default list. For example, even if the “Clean Cuvette Incubator” activity on the monthly list is moved to the weekly list, the Clean Cuvette Inc process button remains on the monthly maintenance screen.

Tell me how to Configure Periodic Maintenance Lists (page 16-11)

Print Report

The Print Report process button enables the operator to print a maintenance report for the current month and any previous month for the previous seven years in which the original report can be recreated.

System Information

The System Information screen enables the operator to monitor system performance, perform troubleshooting, and report system information and status to a Customer Technical Support Representative.

System Function	Description
Device Information	Hardware/software versions and checksums of system boards and other devices
Software & Assay Data Version Information	Software and Assay Data versions running on the system, the V-Docs version running on the system, as well as a Reagent Lot version list
Environmental Monitoring	General operating conditions of the subsystems (temperature and humidity readings) and conditions of interest to service personnel (voltage readings, board temperatures, control and monitor thermistor temperatures)

(Continued)

uIA LAS Log	MicroImmunoassay Laboratory Automation System log (when automation is enabled)
uS LAS Log	MicroSlide Laboratory Automation System log (when automation is enabled)
e-Connectivity Log	Log of e-Connectivity communication events
LIS Log	Log of messages sent to and received from the Laboratory Information System (LIS)

Tell me how to Review System Information (page 16-12)

Device Information

Touch Device Information on the System Information screen to display information about the processor boards and bar code readers on the system. The screen provides the following information:

- System Name
- Serial Number
- Digital Signal Processor board identification
- MicroSensor board device information
- Barcode reader device information
- PCI board device information

Software & Assay Data Version Information

The Software & Assay Data Version Information screen displays information about the assays and software installed on the system. The system obtains the software data whenever a new version of software is installed. The system obtains the assay data when you load a new Assay Data Disk or download assay data.

Assay Data	Software and V–Docs Data	Reagent Lot Data
• Release version • Disk generation date • Type • Source • Install date and time	• Release version • Source • Install date and time	• Release version • Disk generation date • Install date

Environmental Monitoring

The Environmental Monitoring screens enable Key Operators and Service Personnel to determine the current operating environment of the system by viewing a list subsystem temperature, humidity and pressure values. This screen will display operating conditions for the subsystems listed below:

- Preliminary Well Wash
- Final Well Wash

- MicroImmunnoassay (µIA) Reagent Supply
- MicroWell Incubator
- Primary Tip Sealer
- Secondary Tip Sealer
- System pressures and ambient temperature
- Slide and Cuvette Supplies
- Slide and Cuvette Incubators

Additional process buttons enable Key Operators and Service Personnel to review detailed environmental information about system components, the cooler, and the thermistors installed for specific components.

Each subsystem is represented by a gauge that indicates the minimum and maximum value of the condition it is measuring. Readings that are within this range will be displayed in black. Out of range readings will be displayed in red. If the current value is above the maximum limit, the gauge will be filled. If the current value is below the minimum limit, the gauge will be empty except for a red ball at the bottom. Additionally, a condition code will be reported that more specifically indicates the nature of the failure.

MicroSlide (µS) LAS Log

Note: This function is only available on systems that are configured for LAS. See Configure Communication (page 17-29) for more information.

Use the Diagnostics - µS Laboratory Automation System Log screen to review complete messages sent to and received from the MicroSlide (µS) Laboratory Automation System (LAS). These messages help to solve communication problems between the system and the LAS.

The µS LAS Log file is not automatically enabled. Turn the µS LAS Log file on or off with the Start Logging and the Stop Logging buttons. If the LAS Log file is enabled, it remains enabled even when you exit this screen.

The system manages the LAS log file without intervention. When a new message causes the current log file to exceed 64K, a new log file is started and the new message is written to it. The current/active log file is closed and becomes the previous log file; the previous log file is deleted.

MicroImmunoassay (µIA) LAS Log

Note: This function is only available on systems that are configured for LAS. See Configure Communication (page 17-29) for more information.

Use the Diagnostics - µIA Laboratory Automation System Log screen to review complete messages sent to and received from the MicroImmunnoassay (µIA) Laboratory Automation System (LAS). These messages help to solve communication problems between the system and the LAS.

The µIA LAS Log file is not automatically enabled. Turn the µIA LAS Log file on or off with the Start Logging and the Stop Logging buttons. If the LAS Log file is enabled, it remains enabled even when you exit this screen.

The system manages the LAS log file without intervention. When a new message causes the current log file to exceed 64K, a new log file is started and the new message is written to it. The current/active log file is closed and becomes the previous log file; the previous log file is deleted.

e-Connectivity Log

The e-Connectivity Log records communication events with the Ortho Clinical Diagnostics Back Office. The log saves basic information that includes a

date/time stamp and a brief description of the event, such as, “Initial Connection Timer expired.”

The e-Connectivity Log screen displays event records in descending chronological order (the most recent record appears at the top of the scrolling window). When the log is full, the system deletes the oldest record in order to provide space for the newest record. The log is intended for operator reference purposes only. The Back Office also logs e-Connectivity communication events.

LIS Log

Use the Diagnostics - LIS Log screen to review complete messages sent to and received from the Laboratory Information System (LIS). Types of messages include test requests and test results. These messages help to solve communication problems between the system and the LIS.

The LIS log file is not automatically enabled. Turn the LIS log file on or off with the Start Logging and the Stop Logging buttons. If the LIS Log file is enabled, it remains enabled even when you exit this screen.

The system manages the LIS log file without intervention. When a new message causes the current log file to exceed 64K, a new log file is started and the new message is written to it. The current/active log file is closed and becomes the previous log file; the previous log file is deleted.

Tell me how to test the LIS Serial Port (page 16-12)

Mechanism Exercise Diagnostics (MEDs)

Mechanism Exercise Diagnostics (MEDs) is an operator diagnostic feature that moves individual subsystems or mechanical components of the system. These diagnostics can be used during troubleshooting procedures to verify subsystems and components are operating properly.

Note: Before using MEDs to resolve a problem, you may find it helpful to use the Initialize process button on the Condition Review screen. See Condition Codes Review (page 18-3) for more information. If re-initialization does not resolve the problem, try to reset the subsystem using MEDs. All MEDs features include a Reset option for the subsystem being exercised.

All sampling and assays in progress should be completed before you select the MEDs function. If not, a Cancel Assays in Progress dialog will alert the operator that the use of this Diagnostic function requires that all assays in progress be canceled. Touch Yes to cancel all assays in progress and continue on to the MEDs screen, or No to return to the main Diagnostics screen.

IMPORTANT: If you cancel assays, samples being processed will be canceled and assay results will not be reported.

MEDs is useful in evaluating a component of a subsystem since it provides the capability to repeat a particular device movement for multiple actuations. MEDs is also useful in situations where a device needs to be cleared of a jam.

MEDs are device specific and include the most basic subsystem commands. Initialization movements can be separated into subsystem level device initializations or component level device initializations.

Generally MEDs provide a way to operate motors in a controlled and monitored manner. Timeouts are maintained, where possible, such that a move failure in normal operation that resulted in an error will also post an error in MEDs. The timeouts will be of most benefit when using the cycle feature of MEDs, since this provides for a known timeout between two defined positions. A normal move operation will use a gross timeout value to position a device at the intended target.

The system initializes when the operator completely exits the Diagnostics screen and returns to System Status (touch the Return process button until the System Status screen is displayed).

Caution: Make sure any mechanical binds or jams are removed prior to resetting a subsystem.

MEDs enables testing of the following:

- Sample Metering
- Sample Supply
- Slide Supplies
- Microwell Reagent Metering
- Incubators & Transports
- VersaTip Ring and Supply
- MicroTip Supply
- MicroSensor
- WF Metering
- ERF Metering
- Electrometer
- Reflectometer
- Photometer
- Well Wash
- Supply 3 & 4
- Tip Sealers
- Luminometer
- Signal Reagent

Each of these devices will be able to perform at least one of the following basic functions:

- Initialize
- Purge
- Index
- Move/Select Position
- Cycle
- Rotate
- Read
- Count
- Pickup/Tip

Tell me how to Use the MEDs Diagnostic Feature (page 16-13)

System Tests and Adjustments

Performance Tests

Performance tests enable you to test selected system components and generate statistics on their operation. The following performance tests are available:

- Scrap Run
- Photometer
- Electrometer
- Reflectometer
- Slide Incubator
- ERF Metering
- WF Metering
- MicroSlide Metering
- MicroImmunnoassay (µIA) Metering
- MicroSensor
- MicroWell Reagent Metering
- MicroWell Wash Metering
- SIGNAL REAGENT METERING
- Luminometer

Performance tests should be run:

- after maintenance functions (as documented in V-Docs)
- after adjustments
- as directed by Customer Technical Support
- as directed by condition code descriptions

Tell me how to Run Performance Tests (page 16-14)

Adjustments

Adjustments are diagnostic functions used to fine-tune or define various system parameters to ensure proper system performance. With the exception of the Correction Factors Adjustment, Water Blank, and IRS Calibration, all other adjustments are only available to trained service personnel.

Tell me how to perform the Correction Factors Adjustment (V-Docs)

Tell me how to perform the Water Blank (V-Docs)

Tell me how to perform the IRS Calibration (V-Docs)

Troubleshooting

Refer to the following general information if errors conditions are encountered on the system.

How to Use Condition Codes

The system contains numerous sensors and other devices that monitor performance. Each assay is also closely monitored through the various subsystems. When the system software identifies deviations from normal operation, it reports a condition code. The system generates a condition code and assigns a severity level to the condition.

Tell me more about Condition Code Review (page 18-3)

How to Re-initialize the System

The initialize process button on the Condition Review screen can be used to initialize reduced subsystems. Re-initialize after performing recommended corrective actions to bring the affected subsystem back to operational status.

Note: If re-initialization does not resolve the problem, try to reset the subsystem using MEDs. All MEDs features include a Reset option for the subsystem being exercised.

How to Use MEDs

Mechanism Exercise Diagnostics (MEDs) is a diagnostic feature that moves individual subsystems to check that their components are operating correctly. MEDs is useful in evaluating a component of a subsystem since it provides the capability to repeat a particular device movement for multiple actuations.

Tell me more about MEDs (page 16-7)

Diagnostics Procedures

The following table lists the Diagnostics topics that reference the procedures included in this section.

Topic Title	Procedure Title
Periodic Maintenance (page 16-2)	• View and Manage Periodic Maintenance Activities (page 16-10) • Configure Periodic Maintenance Lists (page 16-11)
Diagnostics Overview (page 16-1)	• Calibrate the Touchscreen (page 16-11) • Cancel All Assays in Process (page 16-11)
System Information (page 16-4)	• Review System Information (page 16-12) • LIS (Laboratory Information System) Serial Port Test (page 16-12)
Mechanism Exercise Diagnostics (MEDs) (page 16-7)	• Use MEDs Diagnostic Feature (page 16-13)
System Tests and Adjustments (page 16-8)	• Run Performance Tests (page 16-14)

View and Manage Periodic Maintenance Activities

1. Touch **Diagnostics** > Periodic Maintenance > Review Log to access thePeriodic Maintenance — Review Logscreen.
2. Determine the information that you want to review.
   a. Touch one of the View List choices: Daily, Weekly, Monthly, As Required.
      Note: Daily is the default.
   b. Touch Filter to control the information that is displayed. Filter information by date, operator, completion status, and approval status.
3. If desired, review the maintenance tasks for the selected list by touching Activity List.
4. To view the time and items completed, touch a row of information displayed by date and then touch View Details.

5 To view the approved status for tasks or to approve tasks, touch a row of information displayed by date and then touch Review/Edit.

Note: Only key operators and Service Personnel can change items on this screen. Other users may view the information.

6 If desired, touch Print to print the information displayed on the screen.

Configure Periodic Maintenance Lists

Special requirements: Key Operator or Service Personnel

Note: When an activity is moved from one list to another, any associated process buttons will remain on the default list. For example, even if the “Clean Cuvette Incubator” activity on the monthly list is moved to the weekly list, the Clean Cuvette Inc process button remains on the monthly maintenance screen.

1 Touch **Diagnostics** > Periodic Maintenance > Configure Lists to display theConfigure Listsscreen.

2 Select the task you want to move to another maintenance list.

a Touch the maintenance list that currently contains the task: Weekly, Monthly, As Required.

b Touch the task you want to move.

The process buttons that are available become active. A task can be moved only to a more-frequent maintenance list or back to its original, default maintenance list. All tasks on the Daily Maintenance List cannot be moved.

3 Touch the appropriate process button to move the selected task to the new maintenance list.

The tasks is removed from the list; the remaining tasks are not reordered.

4 Touch the appropriate maintenance button to view the task positioned at the bottom of its new maintenance list. It retains the original list abbreviation and the original number.

5 Touch Save to complete the move.

Calibrate the Touchscreen

1 Touch  and then touch Calibrate Touchscreen at the bottom of the screen.

The DIAGNOSTICS – Calibrate Touchscreen screen is displayed.

2 Touch the center of the target in the upper left corner of the screen.

3 Continue touching the center of the target as it moves to the other three corners of the screen.

4 When you have finished, touch Save Calibration to save the calibration.

Cancel All Assays in Progress

1 Touch  to display the Diagnostics screen.

2 Touch Cancel Assays.

Note: The button is available only if there are assays in process.

The Cancel Assays in Progress dialog is displayed.

3 Touch Yes.

The system cancels and purges all assays and calibrations in process.

Review System Information

1 Touch  to display the Diagnostics screen.

2 Touch System Information.

3 Touch the button for the information you want to display.

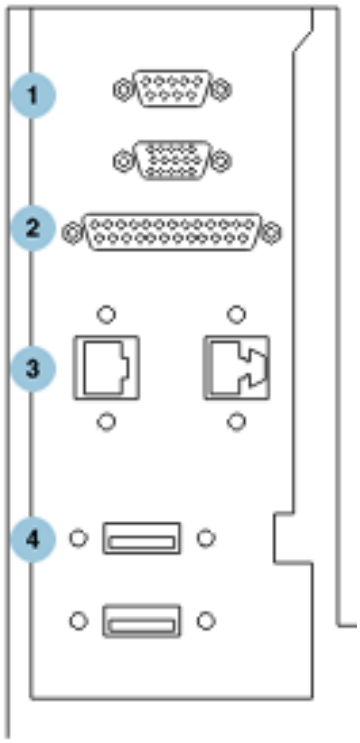
4 Review the information on the screen.

5 Touch Return to return to the Diagnostics screen.

LIS (Laboratory Information System) Serial Port Test

Special requirements: The Loopback Test Tool (Part Number 340031) that is included in the Maintenance Kit that is shipped with the system

1 At the back of the system, unplug the LIS cable from the LIS serial port (2) and plug the Loopback Test Tool into the port.



1	PCI to CAN Interface connection for the LAS	3	Ethernet Ports
2	RS-232 Serial Port for the LIS	4	USB Ports

2 Touch **Diagnostics** > System Information > LIS Log to access the Laboratory Information System Log screen.

3 Touch Start Logging.

4 Touch Log Serial Port and read the status message that is displayed on the screen.

Example:par=none datab=8 stopb=1 baud-9600 +DTR +RTS +cts +dsr -ri +cdIn the message, make sure that there is a plus (+) sign in front of DTR, RTS, cts, and dsr. If the signs are not displayed, there may be a problem with the serial cable within the system or with the MASTER COMPUTERserial port.

Note: The signs in front of the ri and cd codes in the message do not matter.

5 In the DIAGNOSTICS — Laboratory Information System Log screen, notice the messages that are displayed. If results are waiting to upload, the instrument is attempting to start an ASTM communications session with the **<ENQ>** message. The **<ENQ>** message is echoed through the Loopback Test Tool and appears as an LIS response. The instrument then sends an **<EOT>** message.

Note: If the messages are correct, proceed to Step 7 (page 16-13); otherwise, perform Step 6 (page 16-13) to manually send a result to the LIS.

6 If no message is displayed on the DIAGNOSTICS — Laboratory Information System Log screen, select a result record and send it to the LIS manually. Follow these steps:

a Touch  to access the Results Review screen.

b Touch any result that is displayed on the screen to select it.

c Touch the Set Report Status button at the bottom of the screen.

d On the Set report Status screen, touch Send for the Lab Computer.

e Make sure “Apply to all selected results” is selected.

f Touch OK.

g Touch  to return to the DIAGNOSTICS — Laboratory Information System Log screen and return to Step 5 (page 16-13).

7 Unplug the Loopback Test Tooland plug the LIS cable into the LIS serial port.

8 If the messages are not correct, contact Customer Technical Support.

Use MEDs Diagnostic Feature

1 Touch  to display the Diagnostics screen.

2 Touch MEDS to display the Diagnostic – MEDs screen

3 Touch the button for the subsystem you want to check.

The system displays the mechanisms that you can check on the selected subsystem.

4 Touch the button for the mechanism you want to check.

Additional buttons appear for each selection.

5 Touch the button for the action you want to perform.

6 Wait until the action finishes.

7 Touch Return to return to the Diagnostics – MEDs screen.

8 Touch Return again to return to the Diagnostics screen.

Run Performance Tests

1 Touch  to display the Diagnostics screen.

2 Touch Performance Tests to display the Performance Tests screen

3 Touch the button for the performance test you want to run.

The specific performance test screen is displayed.

4 Touch Reset if available.

5 Touch choices on the performance test screen.

6 Touch Start.

The performance test is run and messages are displayed.

7 Touch Return to return to the Performance Tests screen.

Maintenance Overview

Maintenance procedures are tasks that you perform to keep the system operating properly. You should perform these tasks according to the recommended schedule (daily, weekly, monthly, or as required). Ensure that you read all the precautions associated with maintaining the system before any maintenance work is done.

If questions arise about maintenance during daily operation of the system, refer to the maintenance procedures provided in V-Docs. If you still need assistance, contact the Customer Technical Support Center.

Touch the Operations and Maintenance tab on the V-DOCS screen to access the periodic maintenance procedures.

Tell me more about Periodic Maintenance (page 16-2)

Precautions

Assume that all used equipment is contaminated with potentially infectious biological material.

Note: In the United States, use the "Universal Precautions" recommended by OSHA (Occupational Safety and Health Administration) Bloodborne Pathogen Standard 29CFR1910.1030 when handling, cleaning, and packing equipment. In particular:

- Wear gloves, closed shoes, buttoned lab coats, and safety glasses throughout the cleaning and maintenance process.
- Treat all waste materials used in the cleaning process as contaminated. Follow the site procedures for your laboratory to dispose of these materials.
- Handle all equipment with care. Mechanical parts may have edges, pinch points, and corners that potentially could cause injury.
- Fluid may drip from disconnected tubing. If necessary, use an absorbent material to absorb the drops of fluid.

Outside the United States, follow WHO (World Health Organization) and your country's regulations for handling and cleaning bloodborne pathogens.

Tell me more about Safeguards and Precautions (page 3-1)

Special Requirements

The following materials and supplies are commonly required to perform various periodic maintenance activities:

- Clean, lint-free cloth
- Paper toweling
- Cotton swabs
- Soft, nylon-bristle brush
- Distilled or deionized water
- 70% isopropyl alcohol
- Warm, soapy water
- Phillips screwdriver
- Electrostatic discharge (ESD) ground strap
- Electrostatic discharge (ESD) wrist strap
- Lamps (REFLECTOMETER and PHOTOMETER)
- White correction factor slides

Maintenance Activities

Consider the following when performing maintenance activities:

- Completed maintenance activities are listed on the Periodic Maintenance - Review Log screen. This record also includes the maintenance operator ID and the current date and time. There is no operator override option for the recorded date and time.
- Specific activities that have not been completed are listed on the Periodic Maintenance - Review Log screen.
- Some maintenance activities may require software support to complete the required maintenance. This software support may include mechanism initialization and the positioning of mechanisms to allow the operator access to perform a maintenance activity.

Daily Maintenance

The Key Operator should perform all daily maintenance procedures as listed on the Periodic Maintenance – Daily screen. Unless otherwise indicated, leave the system in the operational mode while performing these procedures. Most daily maintenance activities should be performed while the system is not processing samples.

Tell me more about Periodic Maintenance (page 16-2)

The following maintenance procedures are the default activities on the daily maintenance list:

Maintain ERF
Maintain IWF
Perform Metering Maintenance

Empty Liquid and Solid Waste Containers	
Load Supplies and Remove Empty/Outdated Reagents	
Inspect/Clean Universal Sample Trays & Adapters	
Clean SR Dispense Probe	
Perform Quality Control	
Clean Cap Retainers	
ERF Lot Number	(Information only)
ERF Drop Count	(Information only) Number of fluid drops available in the reservoir. The system monitors the status of the fluid and alerts you when its volume is depleted.
IWF Lot Number	(Information only)
IWF Drop Count	(Information only) Number of fluid drops available in the reservoir. The system monitors the status of the fluid and alerts you when its volume is depleted.

Periodic maintenance lists can be configured by Key Operator or Service Personnel. The default daily maintenance activities are listed with a “D” prefix. Different prefixes (“W” – weekly, “M” – monthly, and “A” – as-required) indicate the default frequency of other activities that may have been moved to the daily maintenance list.

Tell me how to Configure Periodic Maintenance Lists (page 16-11)

Touch the Operations and Maintenance tab on the V-DOCS screen to access the periodic maintenance procedures.

How to Track and View Daily Maintenance Activities

The check boxes for all activities that have not been performed since midnight of the current day are highlighted with the DIAGNOSTICS function screen background color (peach) to indicate which activities need attention. This includes activities that have been moved to the daily list from one of the other less frequently scheduled maintenance lists.

The following table identifies the different states of maintenance activity check boxes.

	A peach-colored check box indicates that the maintenance activity requires attention.
	A check indicates that the operator has completed the maintenance activity and touched the check box.
	A white-colored check box indicates that the maintenance activity has been performed as scheduled and a record of it has been saved.

Weekly Maintenance

The Key Operator should perform all weekly maintenance procedures as listed on the Periodic Maintenance – Weekly screen.

Tell me more about Periodic Maintenance (page 16-2)

The following maintenance procedures are the default activities on the weekly maintenance list:

Clean MicroWell Incubator
Clean Primary Tip Sealer
Clean Secondary Tip Sealer
Clean Sample Supply
Clean Tip Locator
Clean DISPENSE BLADE and SENSORS
Clean Leak Pads
Clean Touchscreen Monitor and Keyboard
Perform Subsystem Cleaning
Process VITROS MicroSensor Check Fluids I and II

Periodic maintenance lists can be configured by Key Operator or Service Personnel. The default weekly maintenance activities are listed with a “W” prefix. Different prefixes (“M” – monthly and “A” – as-required) indicate the default frequency of other activities that may have been moved to the weekly maintenance list.

Tell me how to Configure Periodic Maintenance Lists (page 16-11)

Touch the Operations and Maintenance tab on the V-DOCS screen to access the periodic maintenance procedures.

How to Track and View Weekly Maintenance Activities

The check boxes for all activities that require attention are highlighted with the DIAGNOSTICS function screen background color (peach). This includes activities that have been moved to the weekly list from one of the other less frequently scheduled maintenance lists.

The following table identifies the different states of maintenance activity check boxes.

	A peach-colored check box indicates that the maintenance activity requires attention.
	A check indicates that the operator has completed the maintenance activity and touched the check box.

(Continued)

	A white-colored check box indicates that the maintenance activity has been performed as scheduled and a record of it has been saved.

Monthly Maintenance

The Key Operator should perform monthly maintenance procedures as listed on the Periodic Maintenance – Monthly screen.

Tell me more about Periodic Maintenance (page 16-2)

The following maintenance procedures are the default activities on the monthly maintenance list:

Clean Cuvette Arm	Touch Clean Cuvette Arm
Clean Cuvette Incubator	Touch Clean Cuvette Inc
Clean PM Discard Chute	
Clean/Replace PM Evaporation Caps	
Clean PM Incubator Slot and Insert Blade Channels	
Clean MicroSensor Cover and Ring Area	
Inspect/Clean uIA Reagent Supply Top Cover	
Inspect/Clean Supply 3 Pack Opener	
Clean VITROS VersaTip Supply Registration Rails	
Inspect/Clean Reagent Cooler Filter	
Perform System Backup	
Change Vapor Adsorption Cartridge (2 months)	
Inspect/Clean Master Computer Filter (2 months)	
Perform Correction Factors (6 months)	
Replace VITROS VersaTip Loader Compressor Filter (6 months)	

Replace System Filter (6 months)
Perform Pad Reflectance Test (6 months)

The periodic maintenance lists can be configured by Key Operator or Service Personnel. The default monthly maintenance activities are listed with a “M” prefix. An “A” prefix is used to indicate “as-required” activities that may have been moved to the monthly maintenance list.

Tell me how to Configure Periodic Maintenance Lists (page 16-11)

Touch the Operations and Maintenance tab on the V-DOCS screen to access the periodic maintenance procedures.

How to Track and View Monthly Maintenance Activities

The check boxes for all activities that require attention are highlighted with the DIAGNOSTICS function screen background color (peach). This includes activities that have been moved to the monthly list from the as-required list.

The following table identifies the different states of maintenance activity check boxes.

	A peach-colored check box indicates that the maintenance activity requires attention.
	A check indicates that the operator has completed the maintenance activity and touched the check box.
	A white-colored check box indicates that the maintenance activity has been performed as scheduled and a record of it has been saved.

As Required Maintenance

The Key Operator should perform as-required maintenance procedures on an as-needed basis. Generally, a condition code will direct you to perform these procedures, or you may be asked to perform them by Customer Technical Support.

Tell me more about Periodic Maintenance (page 16-2)

The following maintenance procedures are the default activities listed on the Periodic Maintenance – As Required screen:

Replace Desiccant Packs
Replace VITROS FS Humidity Control Pack
Replace Dispense Blade
Replace Proboscis Assembly
Perform Photometer Water Blank

Clean System Cabinetry	
Inspect/Clean Cuvette Supply	
Inspect/Clean MicroTip Supply	
Perform System Cleaning	

The periodic maintenance lists can be configured by Key Operator or Service Personnel. The default “as-required” activities are listed with an “A” prefix. If any of these activities are not included on the Periodic Maintenance – As Required screen, they have been moved to a more frequently scheduled list.

Tell me how to Configure Periodic Maintenance Lists (page 16-11)

Touch the **Operations and Maintenance** tab on the V-DOCS screen to access the periodic maintenance procedures.

How to Track and View As Required Maintenance Activities

As required maintenance activity checkboxes are listed on the Periodic Maintenance – As Required screen. Touch the checkbox next to the activities that are complete and then touch the Save process button to indicate that this work has been done.

The most recent completion date is listed next to each checkbox to indicate that last time this activity was completed.

Chapter 17 Options and Configuration Overview

The Options & Configuration features enable you to set system defaults, customize many system features, and perform system services. Options and Configurations should be modified on an as-needed or periodic basis, since these features are not part of routine system operation.

Some Options & Configuration features change parameters that affect assay processing; therefore, you cannot select them if the system is sampling or processing assays.

Access Restrictions

Access to some of the Options & Configuration features is restricted to Key Operators or Service Personnel. This restriction prevents changing of important operating parameters by unauthorized personnel. If your access level does not permit you to perform a procedure, you may view the procedure's values, or settings only; you cannot change them.

Tell me how to Set System Access (page 7-9)

Options & Configuration Screen

Touch the Options navigation button in the Status Console to display the Options & Configuration screen.

The following table describes the feature buttons displayed on the Options & Configuration screen:

Feature Button	Description
	**Configure Assays**: Configure assay-specific parameters for specific laboratory needs Tell me how to Configure Assays (page 17-3)
	**Review/Edit Calibrations**: Access calibration data for assays processed by the system Tell me how to Review/Edit Calibrations (page 17-10)

System Setup

Feature Button	Description
	**Configure System**: Configure system parameters such as the Date/Time Tell me how to Configure the System (page 17-21)

(Continued)

	**Configure Subsystem**: Configure parameters on a subsystem level Tell me how to Configure the Subsystem (page 17-25)
	**Configure Report Control**: Setup system report parameters for the printer and Laboratory Information System (LIS) Tell me how Configure Report Control (page 17-27)
	**Configure Communication**: Configure protocol for Laboratory Information System (LIS), Ethernet, e-Connectivity® communications, and the Laboratory Automation System (LAS) Tell me how to Configure Communication (page 17-29)
	**Configure Demographics**: Define global demographic attributes to be used when configuring age, sex, and normal ranges for specific assay/body fluids Tell me how to Configure Demographics (page 17-36)

System Services

Feature Button	Description
	**Datalogger**: Select individual or all Datalogger files to be copied to removable media for further analysis Tell me more about the Datalogger (page 17-38)
	**Perform Backup**: Backup all databases or specific data from individual databases Tell me how to Perform a Backup (page 17-39)
	**Usage Counters**: View, reset, export or print the Current Usage Counter and the Cumulative Usage Counter Tell me more about Usage Counters (page 17-39)

Process Buttons

Process Button	Description

(Continued)

View Options Summary: Review the current options and configuration settings for the system

The screen lists the features of the system with their current settings. Settings indicate whether the feature is enabled or disabled, on or off, or not available. To change the settings, use the appropriate Options and Configuration functions.

The screen also displays Total Slide Count, Total Cuvette Count and Total Well Count used by the system.

Load System Data: Install the latest assay data and system software onto the system

Periodically, you will need to update information on your system. Use the Load System Information dialog to install the latest assay data and system software, either from disk or via e-Connectivity®.

See Load System Data (page 17-40) for more information.

Configure Assays

The Options & Configuration – Configure Assays screen enables the operator to configure assay-specific parameters for specific laboratory needs.

The editing of these parameters is only allowed with the Key Operator or Service access code and only while sampling and assay(s) are not in progress.

Features	Sampling?	Assays?	Access?

(Continued)

• Configure Sample Indices Threshold • Configure assay-specific parameters including result, ranges, user adjusted, reflex dilution and processing, and other miscellaneous parameters per assay/body fluid • Configure Alternate Units per assay body/fluid. • Configure age/gender ranges per assay/body fluid • Configure User Adjust Indices • Configure user defined assays and diluents.	No	No	Key Operator or Service

Tell me how to Configure Assays (page 17-43)

The Options & Configuration – Configure Assays screen includes the following process buttons:

- Sample Indices Threshold (page 17-4)
- Review/Edit Configuration (page 17-5)
- User Adjust Indices (page 17-5)
- User Defined Assays (page 17-5)
- User Defined Diluents (page 17-5)

Sample Indices Threshold

Use the Sample Indices Threshold Limits dialog to review and change limits of the indices (Hemolysis, Icterus, and Turbidity) used in sample indices checking. The threshold limit is the limit beyond which Hemolysis, Icterus, or Turbidity will interfere with an assay. Values are 0–9999. The initial limits displayed are currently stored in the database for the selected assay/body fluid. The default threshold limits are loaded from the Assay Data Disk (ADD). Any modification to the values will display the User Modified status of M1 in the Sample Indices Threshold Limits dialog and the Options & Configuration – Review Assay Data screen (located in Options & Configuration – Review/Edit Calibrations).

Note: Touch the Save button after making any parameter adjustments on this screen. Any unsaved changes will be lost when the screen is dismissed.

Note: For restricted assays, you cannot change the values of the three thresholds to be above the default limit, as defined on the ADD.

Note: You cannot disable the Threshold Limits for restricted assays.

Tell me more about the VITROS MicroSensor (page 14-31)

Review/Edit Configuration

The Review/Edit Configuration screen enables the operator to configure assay-specific parameters.

Tell me more about the Review/Edit Configuration screen (page 17-6)

User Adjust Indices

Touch the User Adjust Indices process button to launch a dialog box that allows the operator to set user-adjusted parameters for sample integrity indices. The slope and intercept values can be entered for hemolysis, icterus, and turbidity, the indices measured through sample integrity. You can make this adjustment when you want the system's results for these indices to match those of another manufacturer's analyzer. You should perform a correlation study to determine how much to alter the Ortho Clinical Diagnostics results. The minimum time span for the study is three days and the minimum number of patient samples is 60.

User Defined Assays

Touch the User Defined Assays process button to launch the Options & Configuration – User Defined Assays screen.

Note: User Defined Assays can only be performed on the VITROS Chemistry MicroTip side of the MicroImmunoassay Center.

The User Defined Assay (UDA) feature allows operators to expand the assay menu beyond those assays currently available from Ortho Clinical Diagnostics (OCD). Using the UDA feature, operators can program assay protocols using pre-formatted assay templates and reagents from other vendors, or operators can define their own protocols.

Note: If a lab uses multiple analyzers it is important to note that the same assay number could be used for different user defined assays. This may cause issues when requesting assays via the LIS and reporting results to the LIS.

Templates provide the basis for user defined assays, providing all default parameters and protocol frameworks. When a UDA is created the UDA template assay specified during creation is copied to the new assay number.

The system can accommodate at least 20 UDAs using generic reagents.

Refer to the User Defined Assay Guide for more information.

User Defined Diluents

Touch the User Defined Diluents process button to launch the Options & Configuration – User Defined Diluents screen.

Note: User Defined Assays can only be performed on the VITROS Chemistry MicroTip side of the MicroImmunoassay Center.

The system can accommodate at least 4 User Defined diluents.

Two packs will accommodate the four user defined diluents, one diluent to a bottle. Pack names used for user-defined diluents are UDDL1 and UDDL2. Bottles in each pack are identified by A and B. Pack Name / Bottle combinations will be UDDL1 / A, UDDL1 / B, UDDL2 / A, UDDL2 / B.

Diluent names entered by the user must not be the same as any OCD diluent names or any other user defined diluent names.

Refer to the User Defined Assay Guide for more information.

Review/Edit Configuration

The Review/Edit Configuration screen enables the operator to configure assay-specific parameters as outlined below.

Note: Touch the Save button after making any parameter adjustments on this screen. Any unsaved changes will be lost when the screen is dismissed.

Tell me how to Configure Assays (page 17-43)

The parameters displayed on this screen depend on the particular assay model type that is selected. Touch the Help process button on this screen for more information.

Result Parameters

Result parameters define the units of measure for assay results.

Units Type	The type of units measured for assay results (Conventional, International, or Alternate). The units for the selected type are displayed below the buttons. **Note:** If the assay has no units, or conventional units only, the selection buttons are not available. Refer to the Instructions for Use to determine which units are available for each assay.
Significant Digits	The maximum number of digits that display for all results and numerical data. The system rounds up digits in excess of these limits.
Precision Digits	The maximum number of digits that display to the right of the decimal point. The system rounds up digits in excess of these limits.

Miscellaneous

Short Assay Name	The short assay name is used for screen display and Laboratory Reports.
Full Assay Name	The full assay name appears on the Patient Report (for example, Folic Acid, Vitamin B12, or Folate).

(Continued)

Derived Tests

Note: These fields are displayed for derived tests only.

This configuration feature can be used to report the results of derived tests when programmed, or when their components are programmed. You can choose to have:

- results printed on the Patient Report for all component tests used in calculating the selected derived test
- the selected derived test calculated and printed on the Patient Report whenever all the component tests that constitute the derived test are programmed

Replicates per Calibration (Cal)

The number of replicates to run per calibration level (dependent on the assay type selected). The default values are provided by the Assay Data Disk (ADD). You can configure the system to run additional replicates per calibration level if desired.

Note: For urine calibrations, the number of K^+ and Na^+ replicates must be the same.

Replicates per Assay

The number of replicates to run per assay. The system performs one test per assay unless you select replicate assays during sample programming. This configuration affects all future samples requiring this assay.

Diluent

A reagent used to dilute the sample when dilution is required. A selectable pulldown list includes one or more applicable diluents. When no dilution is recommended for an assay, the diluent listed will be None.

Caution: Do not modify diluent data unless authorized by Customer Technical Support. If a change is authorized, Ortho Clinical Diagnostics will supply data.

The diluent data are used by the system to perform automatic dilutions. Ortho Clinical Diagnostics supplies default values for each assay. You can modify this data when authorized.

(Continued)

Standard Dilution Factor	**Note:** There is a standard dilution factor (1:20) for aHBc-Igm. The dilution factor of the sample performed automatically by the system each time you request a specific assay. **Note:** A standard dilution factor of 1.0 means no dilution. A dilution factor of 2.0 means one part sample and one part diluent. A dilution factor of 3.0 means one part sample plus two parts diluent.
Display Value with Result	**Note:** These fields are displayed for semi-quantitative/qualitative tests only. Check boxes that determine if the Quantitative value is reported along with the Qualitative value on the Lab/Results, Patient, and/or LIS. reports/screens. **Note:** The qualitative value is always displayed on the system.

Ranges

Reference Ranges	Reference Range values for the assay.
Supplementary Ranges	Supplementary Range values for the assay. Touch the Report Results Outside of Supplementary Range checkbox to enable (check), or disable (uncheck) this feature. If this option is not checked, the system will not report results that fall outside the supplementary range.

User-Adjusted Parameters

Use this feature to enter new values for the slope and intercept of quantitative and semi-quantitative/qualitative assays.

If your laboratory wants to adjust results to match an analytical method other than the designated method, you should perform a correlation study to determine how much to alter the Ortho Clinical Diagnostics results. The minimum time span for the study is three days and the minimum number of patient samples is 60. Refer to the NCCLS guidelines on the use of patient sample correlations for method comparisons.

Note: Modification of this data may result in failure to conform with published performance characteristics and/or failure to correlate with the designated method. When running proficiency testing fluids, do not report results as VITROS results from assays using adjusted parameters. Before reporting proficiency testing results, remove the user adjustment from the reported result to ensure that your performance is compared appropriately with other VITROS Systems.

Slope	The value derived as a result of the correlation study performed using the least square linear regression analysis y=m(slope)x+ b for the evaluated test.
Intercept	The value derived as a result of the correlation study performed using the least square linear regression analysis y=mx+ b(intercept) for the evaluated test.

Mean Normal Value

Note: T3U with alternate unit type assays only

% uptake	Edit the mean normal value when alternate units of measure are selected and displayed. 30.8% is the default value. Use either this value or your own laboratory mean for your normal population. Input should be within the range of 26 through 36.

Reflex Dilution

Note: Quantitative and semi-quantitative/qualitative assays only. Disabled for non-dilutable assays.

Reflex Dilution	Reflex dilution refers to the system's ability to repeat an assay when the standard dilution yields a result that is outside the Measuring (Reportable) Range of the system. The system automatically applies the dilution factor and calculates the result. **IMPORTANT:** In order to use reflex dilution, be sure to enable reflex dilutions in Sample/Result Options. (From the Options & Configuration screen, touch Configure System, then touch Sample/Result Options. Touch On for Reflex Dilution.)
Dilution Factor	Value used to calculate a result when a sample is diluted.
Reduction Factor	Value multiplied by the dilution factor to reduce the dilution. This field is used only for specific MicroTip assays.

Review/Edit Configuration Process Buttons

The following process buttons are included on the Review/Edit Configuration screen.

(Continued)

Configure Alternate (Alt) Units	The Configure Alternate Units dialog box contains the following fields: **Conventional Unit**: a display-only indication for the currently selected assay to aid the operator in inputting the correct conversion factor and alternate unit. **Conversion Factor**: text entry field **Alternate Unit**: text entry field
Configure Ranges	**Note:** Quantitative/derived assays only The Configure Ranges screen allows the operator to enter Reference Ranges based on Demographics entered in the Options & Configuration — Configure Demographics screen. Tell me more about How to Configure Demographics (page 17-36)
Report Ranges	**Note:** Semi-quantitative/qualitative assays only The Report Ranges dialog box contains a check box for printing result ranges on the Patient Report.
Configure Reflex	The Configure Reflex Processing screen contains the following fields: **REFLEX TO THE SAME ASSAY**: Select and define the lower and upper result ranges that will cause the system to repeat the same assay. **REFLEX TO SELECTED ASSAY**: Select and define the lower and upper result ranges that will cause the system to run an additional assay. Different assays can be selected for reflex processing based on results that fall within both the lower and upper ranges. **Note:** The assay menu on the Configure Reflex Processing screen will not automatically select a derived test if the components are selected and the flag is set to do so.

Review/Edit Calibrations

The Options & Configuration – Review/Edit Calibrations screen enables the operator to review/edit various assay parameters and calibration parameters used during calibration and prediction. Operators can also modify the calibration records for a specific assay/body fluid (review calibration details, restore calibration, delete calibration).

Tell me more about Assay Calibration (page 10-1)

The following table indicates whether each feature is accessible during sampling or assay processing, and the access level required for use.

Features	Sampling?	Assays?	Access?
Review and Edit Assay Data per assay/body fluid for a specific generation/lot (loaded from the Assay Data Disk). The data displayed depend on the assay type.	No	No	Key Operator or Service
Review and Edit Calibrator Definition per assay/body fluid for a specific generation/lot and calibrator kit/calibrator lot number (Calibrator Value, Dilution Factor). The data displayed depend on the assay type.	No	No	Key Operator or Service
Review Calibrations per assay/body fluid for up to 25 calibration records, review calibration detail (i.e., calibration parameters), make calibration current, make calibration primary, or delete the calibration for the selected record.	No	No	Key Operator or Service
User Calibrate an onboard reagent lot per assay/body fluid. The calibration parameters entered depend on the assay model type/calibration model type.	No	No	Key Operator or Service

(Continued)

Review lot switches from the most recent to the oldest for all assays.	Yes	Yes	All

Tell me how to Review/Edit Calibrations (page 17-43)

Review Assay Data

The Options & Configuration Review Assay Data screen is launched by touching the Review Assay Data process button after selecting a body fluid and assay combination. This screen allows Key Operator or Service Personnel to review or edit assay information for the selected combination.

IMPORTANT: Consult with Customer Technical Support before changing any information on this screen.

Tell me more about the Review Assay Data Screen (page 17-12)

Review Calibrator Definition

The Options & Configuration Review Cal Definition screen is launched by touching the Review Cal Definition process button after selecting a body fluid and assay combination. This screen allows Key Operator or Service Personnel to review or edit lot-specific calibrator definitions.

Tell me more about the Review Cal Definition Screen (page 17-16)

Review Calibrations

Use the Options and Configuration – Review Calibrations screen to review all calibrations for an assay. You can also use this screen to access detailed calibration data, print the Calibration Report, and delete a calibration.

Tell me more about the Review Calibrations Screen (page 17-18)

View Lot Switches

Touch the View Lot Switches button to review detailed information about the 400 most recent automatic lot switches that occurred on the system. Touch the Help button for detailed descriptions about the displayed details.

User Calibrate

Use the Options & Configuration – User Calibrate screen to enter user calibration parameters for a specific reagent lot. Select the reagent lot number by touching the Reagent Lot field, then scroll to find the lot number you want to use. Touch the lot number. The screen displays information specific to the selected reagent lot.

Tell me more about the User Calibrate Screen (page 17-19)

Review Assay Data Screen

The assay data on this screen is specific to a reagent lot, or slide generation (loaded from the Assay Data Disk). The data displayed depends on the particular assay model type. Touch the Help process button on the Options & Configuration – Review Assay Data for more information.

MicroSlide Review Assay Data Screen

The following table lists the specific parameters that are displayed on this screen for each assay model type selected and the common parameters that are listed for all MicroSlide assay model types.

Assay Model Type	Specific Parameters	Common Parameters

(Continued)

MicroSlide Colorimetric (CM) & 2-Point Rate	• Drop Volume (uL) • Calibrator Rep Resp Range	• Measuring (Reportable) Range • Calibration Interval
MicroSlide Potentiometric (PM)	• Slide Impedance Limit • Calibrator MV & Val Resp Range	• Generation Number • K Exponent • Extrema Check (Slope 1&2)
MicroSlide PM with Blank	• Slide Impedance Limit • Initial Value for Blank • Convergence Tolerance Factor • Calibrator MV & Val Resp Range	
MicroSlide Blank Wavelength Corrected	• Drop Volume (uL) • Cal Rep Range - 1st & 2nd read	
MicroSlide Mutliple Point	• Drop Volume (uL) • Calibrator Rep Resp Range • Increasing Rate • Substrate Depletion Delta Density Method • Minimum Points in Window • First Derivative Tolerance • Inside Out Threshold • Spike Derivative Tolerance • SD-T • Regression Method • Substrate Depletion Time 1 & 2 • Critical Activity • Induction Time	
MicroSlide Immuno-Rate (IR)	• Drop Volume (uL) • Calibrator Rep Resp Range • Increasing Rate • Log K-Model • Window Modulator • Lo & Hi Rate Long Window	

(Continued)

	• Min & Max WIndow Length • Regression Method • Algorithm Method • Spike Derivative Tolerance • Substrate Depletion Time • Critical Activity • Induction Time	

MicroTip Review Assay Data Screen

The following table lists the specific parameters that are displayed on this screen for each assay model type selected and the common parameters that are listed for all MicroTip assay model types.

Assay Model Type	Specific Parameters	Common Parameters
MicroTip Endpoint	Blank Absorbance Limits	• Measuring (Reportable) Range • Calibration Interval • Generation Number • Initial Absorbance Limits
MicroTip 2-Pt and 2-Pt with blank	• Second Absorbance Limits • Antigen Excess Factor	
MicroTip Multiple Point	• Antigen Excess Limit • Nonlinearity Limit • Minimum Read Points Allowed • Max SD of Regression Line • Max Relative SD of Regression Line • Linear Kinetics Only	

MicroWell Review Assay Data Screen

The following table lists the parameters that are displayed on this screen for MicroWell assay model types.

Parameter	Description
Reagent Lot	The field displays the reagent lot number for the current calibration. Touch the field to display a drop-down list of all lot numbers currently stored in the database. When you select a number, the screen displays the data for that reagent lot.
User Modified	Indicates whether the assay includes user-modified values

(Continued)

Calibrator Bottles	Number of calibrator bottles required to calibrate this assay
Measuring (Reportable) Range	The range of assay concentrations within which the protocol is capable of accurately making a reading. Values are 10 characters, alphanumeric (including sign and decimal point) from -999999000 to 999999000. **Note:** If the User Adjustment parameters (slope and intercept) for the assay/body fluid have been modified through the Options & Configuration - Configure Assays screen, the screen displays the default values for the Measuring (Reportable) Range and the User-Adjusted Range.
Calibration Interval	The time period from the calibration date until the expiration date defined for the assay

Tell me more about Assay Data Parameters (page 10-11)

Review Calibrator Definition Screen

The following calibrator definitions are included on the Review Cal Definition screen for all MicroSlide and MicroTip assay types.

Common calibrator definitions for MicroSlide and MicroTip assay types	
Gen	Calibrator generation number for the current calibration. (1-2 characters, numeric). Touch the field to display a drop-down list of all generations currently stored on the system. When you select a generation number, the fields on the screen update with the information for that generation.
Cal Kit Lot	Lot number of the calibrator kit for the current calibration (1-4 characters, numeric). Touch the field to display a drop-down list of all calibrator kits currently stored on the system. When you select a calibrator kit lot number, the fields on the screen update with the information for that calibrator kit.
Bottle Number/Level	Calibrator fluid bottle number/level
User Modified	Indicates whether the calibration definition has been changed by the operator

Depending on the type of MicroSlide or MicroTip assay, a subset of the following definitions may appear:

(Continued)

Assay dependent calibrator definitions for MicroSlide or MicroTip assay types	
Calibrator Volume	Amount of calibrator fluid used to perform the calibration (1-5 characters including decimal point, numeric)
Dilution Factor	Automatic dilution factor for the assay to be calibrated (1-5 characters including decimal point, numeric)
Calibrator Value	Known analyte concentration contained in the calibrator (1-10 characters including sign and decimal point, numeric)
Substrate Dep Multiplier	A value used in substrate depletion tests, used for two-point and multiple-point rate assays to prevent high levels of enzymes from being reported inaccurately as lower activity levels
First Point Ref Multiplier	A value used in first point reference tests
Wash Detection Tolerance	A limit to ensure an adequate wash has occurred for MicroSlide Immuno-Rate assays. This is displayed in the same row as the associated calibrator bottle. Values are up to 6 characters, including sign and decimal point.
Calibrator Replicate Response Range	The maximum allowable difference between replicates of the same calibrator.

The following calibrator definitions are included on the Review Cal Definition screen for all MicroWell assay types.

Calibrator definitions for MicroWell assay types	
Reagent Lot	The field displays the reagent lot number for the current calibration. Touch the field to display a drop-down list of all lot numbers currently stored in the database. When you select a number, the screen displays the data for that reagent lot.
Cal Lot	The Calibrator Lot number for the current calibration (1-4 characters, numeric). Touch the field to display a drop-down list of all calibrator lots currently stored on the system. When you select a calibrator lot number, the fields on the screen update with the information for that calibrator lot.

(Continued)

Bottle Number/Level	Calibrator fluid bottle number/level
User Modified	Indicates whether the calibration definition has been changed by the operator
Calibrator Value	Known analyte concentration contained in the calibrator (1-9 characters including sign and decimal point, numeric)

Review Calibrations Screen

The screen lists calibrations in order of ascending reagent lot number, in chronological order (most recent first) within the lot number. When you access the screen, the system displays the current calibration information at the top of the scrolling list. Touch the arrow keys to scroll up and down through the list.

Touch a calibration to select it, then touch a process button to perform the associated function. Information displayed for each calibration is described in the following table.

Review Calibrations Screen Information

Reagent Lot	Number of the reagent lot on which the calibration was performed as described below: The reagent lot number for MicroSlide assays will be the 8 digit number consisting of a Chemistry ID number (2 digits), a Generation number (2 digits) and a lot number identifier (4 digits). The reagent lot number for MicroTip assays will be the 10-digit number consisting of a Pack number (4 digits), a Generation number (2 digits) and a lot identifier number (4 digits). The reagent lot number for MicroWell assays will be a 4-digit number consisting of just the pack lot number. Tell me more about Reagents (page 8-3)
On Board?	Indicates whether a reagent pack with that lot number is loaded on the system. Updates for newly-loaded reagent packs will not appear until you enter the screen again.
Date/Time	Date and time that the calibration curve was generated.
Type	Calibration type
Status	Calibration status

Touch the Help button for detailed descriptions about the process buttons on the Options and Configuration – Review Calibrations screen.

User Calibrate Screen

The fields on the Options & Configuration – User Calibrate depend on the type of assay associated with the reagent lot. Touch a field to change its value.

MicroSlide and MicroTip User Calibrate Screen	
Intercept	(All MicroSlide and MicroTip linear assays) The mathematically established value of the concentration at which it intercepts the slope line. The value may be negative or positive.
Slope	(All MicroSlide and MicroTip linear assays) The mathematical relationship between analyte concentration and either the electrical output value of a potentiometric slide or the reflectance values of a colorimetric or rate slide. The value may be negative or positive.
Curvature / Slope 2	(All MicroSlide assays) An adjustment value associated with overall deviations from the basic response function of the assay
Blank Correction Coefficient	(MicroSlide potentiometric and blank-corrected potentiometric assays) A correction factor used in blank corrected colorimetric assays to remove the effect of an interfering substance
Impedance Slope	(MicroSlide potentiometric and blank-corrected potentiometric assays) Slope value determined during the slide impedance test.
Impedance Intercept	(MicroSlide potentiometric and blank-corrected potentiometric assays) Intercept value determined during the slide impedance test
Sub Dep Check, Density	(MicroSlide 2-Point and Multiple-Point assays) Point at which a substrate depletion check for density occurs
Sub Dep Check, Delta Density	(MicroSlide 2-Point, Multiple-Point, and Immuno-rate assays) Point at which an initial substrate depletion check for density occurs
First Point Reference Value	(MicroSlide Multiple-Point assays) Initial point at which reading begins

(Continued)

IR Wash Tolerance	(MicroSlide Immuno-rate assays) Predefined concentration used to determine whether a wash error has occurred
IR Wash Intercept	(MicroSlide Immuno-rate assays) Intercept value used in IR wash detection calculations
IR Wash Slope	(MicroSlide Immuno-rate assays) Slope value used in IR wash detection calculations
IR Wash Curvature	(MicroSlide Immuno-rate assays) Curvature value used in IR wash detection calculations
B0-B3	(MicroTip Log4/Log5 calibrations) Coefficients for Log 4 or Log 5 used to generate a calibration curve
Level 1-6 X, Y, Y”	(MicroTip Cubic Spline) Parameters in cubic spline assays used to determine the fit to the calibration curve
Antigen Excess Limit	(MicroTip 2–pt Linear and Cubic Spline) The upper antigen limit that prevents reporting of results affected by antigen excess. Values are up to 15 characters, including sign and decimal point.
Date/Time	The date and time fields are used to populate the creation time of the calibration. This creation time is also used to calculate the expiration time of the calibration.

MicroWell User Calibrate Screen

User Modified	(Information only) An indication whether the reagent lot was modified by the user. Yes means it was modified, for example, calibrator concentrations, or Measuring (Reportable) Range. No means it was not modified.
Level	(Information only) The analyte concentration level in the calibrator.
Calibrator Value	(Information only) The known analyte concentration contained in the calibrator.
Response	User-provided mean responses for each of the levels. Values are up to 10 characters, including sign and decimal point.

(Continued)

Date/Time	The date and time fields are used to populate the creation time of the calibration. This creation time is also used to calculate the expiration time of the calibration.

Note: The "UC" code on reports identifies user-calibrated results.

Configure System

The Options & Configuration – Configure System screen enables the operator to establish/modify a variety of system-wide parameters.

The following table indicates whether each feature is accessible during sampling or assay processing, and the access level required for use.

Features	Sampling?	Assays?	Access?
Configure current date and time	No	No	All
Configure format for date and time display throughout the system	Yes	Yes	All
Configure Sound	Yes	Yes	All
Configure Sample/Result Options	No	No	Key Operator or Service
Configure Thresholds	No	No	Key Operator or Service
Configure Assay Menu	No	No	Key Operator or Service
Configure Display/Report	No	No	Key Operator or Service
Configure Calibrator Rules	No	Yes	Key Operator or Service
Enter System Name and J Number	Yes	Yes	Service (all) Key Operator (name)
Configure Patient Report	No	No	Key Operator or Service
Configure Screen Saver	Yes	Yes	All
Select Positive Sample ID (PSID) Checkdigit Symbology	No	Yes	Key Operator or Service

(Continued)

Enter Maximum Water Blank Standard Deviation (SD)	No	No	Key Operator or Service
Enter site temperature tolerance	Yes	Yes	Key Operator or Service

Tell me how to Configure the System (page 17-44)

How to Set the Date and Time

The Options & Configuration – Date/Time screen can be used to set the date and time and the display format.

Tell me how to Set the Date and Time (page 17-44)

How to Set Sound Options

The Options & Configuration – Sound screen can be used to set the volume and tone selection for the following system process conditions:

- Touch
- Prompt Alert
- STAT Complete
- Attention Condition
- Action Condition
- Malfunction Condition
- Shutdown Condition

Tell me how to Set Sound Options (page 17-44)

How to Set Sample/Result Options

The Options & Configuration – Sample/Result Options screen can be used to set the following to On/Off or Yes/No:

- Sample Indices

  Note: For restricted assays, the system overrides the global setting for Sample Indices in Options & Configuration and enables Sample Indices.
- All Reprocessing (When Off, Reflex Dilution, Routine Reprocessing, and STAT Reprocessing buttons are disabled.)
- Reflex Dilution
- Routine Reprocessing

  Note: For more information about this option, touch the Help button on the Options & Configuration – Sample/Result Options screen.
- STAT Reprocessing
- Result Record Retention
- Recalculate Results
- Use Expired Reagents
- Use Expired Cals

The following Sample Program Auto Deletion settings are also available on this screen:

- Auto Delete (On, Off - If Auto Delete is Off, the rest of the options in this list are disabled.)
- Priority (STAT, Routine, All)
- Designation (Assigned, Unassign, All)
- Type (Download, Manual, All)
- Deletion Interval (Hours or Days)

Tell me how to Set Sample/Result Options (page 17-44)

How to Configure Thresholds

The Options & Configuration – Configure Thresholds screen can be used to configure the following thresholds.

- Assay
- Diluents
- Ancillary
- Signal Reagent
- Consumables

Tell me how to Configure Thresholds (page 17-45)

How to Configure the Assay Menu

The Options & Configuration – Configure Assay Menu screen can be used to configure the appearance of the Assay Menu on your system. This configuration will be reflected on all the screens that include the Assay Menu.

Tell me how to Configure the Assay Menu (page 17-45)

How to Configure the Display/Report

The Options & Configuration – Configure Display/Report screen can be used to specify the order that assays are displayed by the system and on Laboratory and Patient Reports.

Tell me how to Configure the Display/Report (page 17-46)

How to Select Bar-Coded Calibrator Rules

The Select Bar-Coded Calibrator Rules dialog box can be used to determine which assay lots to calibrate when using bar-coded calibrators. The following rules can be selected:

- New Lot or Lot Uncalibrated by ADD Load
- Calibration with a Current/Failed Status
- Number of Days the Current Assay Calibration will expire in

Tell me how to Configure Bar-Coded Calibrator Rules (page 17-46)

How to Configure the System Name

The System Name dialog box can be used to set the system name and J Number.

Note: The system J Number is entered during the manufacturing process and/or during system installation. It is used to used to uniquely identify every system's Datalogger files/records. Operators should not edit or modify this value.

Tell me how to Configure the System Name (page 17-46)

How to Configure the Patient Report

The Configure Patient Report dialog box can be used to include header information, reference ranges, and indices on the Patient Report.

- Up to four lines of Patient Report header information can be added (such as report title and name and address of the laboratory).
- Reference ranges can be included on the report.
- Sample Indices (hemolysis, icterus, and turbidity) can also be included on the report.

Tell me how to Configure the Patient Report (page 17-47)

Tell me more about the Patient Report (page 12-1)

How to Configure the Screen Saver

The Configure Screen Saver dialog box can be used to define the screen saver delay.

How to Configure PSID Checkdigit

The Configure PSID Checkdigit dialog box can be used to enable or disable the check digit for Positive Sample Identification (PSID) bar code symbologies.

A check digit is a character included within a bar code that is used when the system reads the bar code. The check digit increases bar code integrity by signaling the system to perform a mathematical check to ensure an accurate read. Ortho Clinical Diagnostics highly recommends check digit use. The probability of misreads with the check digit enabled is significantly reduced.

Note: In addition to the symbologies listed on the screen, the system supports Code 128 symbology. Code 128 symbology always uses a check digit.

Tell me how to Configure PSID Checkdigit (page 17-47)

Tell me more about PSID (page 8-22)

Tell me more about bar codes and check digits (page 8-20)

How to Configure the Water Blank Standard Deviation

The Water Blank procedure uses water to set a zero-absorption reference for the PHOTOMETER. The system accepts readings with a standard deviation above and below that reference point. Use the Maximum Water Blank SD dialog to set that standard deviation.

The maximum water blank standard deviation value is supplied on the Assay Data Disk. If the water blank reading falls outside one or more standard deviations, this may indicate a system problem. If this happens, do not manually update the Maximum Water Blank SD field. Contact Customer Technical Support.

Caution: Do not change this value unless instructed to do so by Customer Technical Support.

Tell me how to Configure Standard Deviation for Water Blank Procedure (page 17-47)

How to Configure Site Temperature Tolerance

The Configure Site Temperature dialog box can be used to define the tolerance for the nominal site temperature (°C).

[°C] = ([°F] – 32) × 5÷9

Tell me how to Configure Site Temperature Tolerance (page 17-47)

Configure Subsystems

The Options & Configuration – Configure Subsystems screen enables the operator to configure parameters on a subsystem level.

The following table indicates whether each feature is accessible during sampling or assay processing, and the access level required for use.

Features	Sampling?	Assays?	Access?
Enable/disable assay processing by subsystem	No	No	Key Operator or Service
Enable/disable environmental control for a subsystem	No	No	Service
Enable/disable environmental monitoring for a subsystem	No	No	Service
Select Sample Cup	No	No	Key Operator or Service

Tell me How to Configure Subystems (page 17-47)

Assay Processing

Assay Processing refers to the way the system handles sample testing.

To enable a feature, touch its check box. A check mark appears in the box. To disable a feature, touch the box again. The check mark disappears and the feature cannot be used. When a subsystem is disabled, the assays or samples associated with the selected subsystem will not be processed and will be indicated on the Status Console.

Processing Feature	Description
MicroWell Assay Processing	Enables the system to evaluate samples using a process that incubates, mixes, and washes MicroWells, and adds a Signal Reagent to perform a reading of the MicroWells using enhanced chemiluminescence technology.

(Continued)

Dilution & MicroTip Processing	Enables the system to dilute samples and obtain results using the diluted sample, and to process MicroTip assays via MicroImmunoassay metering.
PM MicroSlide Processing	Enables the system to evaluate samples using potentiometry, which calculates analyte concentration by measuring voltage produced by ionization in a specially prepared slide.
Rate/CM MicroSlide Processing	Enables the system to evaluate samples using colorimetric principles, reading the analyte's value and determining the change between readings.
IR MicroSlide Processing	Enables immuno-rate assay analysis, the VITROS® technology that measures concentration of proteins, hormones, and drugs in blood.
MicroSensor Processing	Enables the system to use the MicroSensor subsystem to evaluate sample indices. **Note:** Restricted assays cannot be processed if the Microsensor subsystem is disabled.
STAT Lane Metering Position	Enables the system to process STAT samples ahead of any other samples that may be awaiting analysis.
Routine Metering Positions	If you disable this feature (if a check mark does not appear in the Enable box), sample metering occurs only at the STAT Lane Metering Position. This feature enables both metering arms to access samples at the four metering positions in the SAMPLE SUPPLY.
VersaTip Supply	Enables the VersaTip loader to automatically load VersaTips to the MicroImmunoassay and Sample Supply VersaTip ring.

Environmental Control

The Environmental Control screen controls temperature and humidity within the internal environment of the system, to help other subsystems function at optimum level.

Monitor and Control Options	Description

(Continued)

Enable Monitor	The system monitors the subsystem regularly for environmental changes. If the system detects a variance that is outside the normal range for that subsystem, it alerts you through a condition code. If Enable Monitor is not selected for a subsystem, the system still monitors for environmental changes but does not flag variances with a condition code.
Enable Control	The system monitors conditions for the selected subsystem and makes adjustments to bring conditions within range. For example, if a temperature reading is below or above what is best for the subsystem, the system raises or lowers the temperature so it returns within range.

Tell me about System Information and Environmental Monitoring (page 16-4)

Sample Cup

The Select Sample Cup dialog box provides the ability to modify sample cup type. Touch one of the following buttons to select the cup type: (None, Micro, 0.5mL, 2.0mL).

Tell me more about Containers (page 8-7)

Configure Report Control

The Options & Configuration – Configure Report Control screen enables the operator to configure default system parameters that control how to print and send reports. It is also possible to review and set report status for selected records on the Results Review screen. See Review and Set Report Status (page 11-9) for more information.

The following table indicates whether each feature is accessible during sampling or assay processing, and the access level required for use.

Features	Sampling?	Assays?	Access?
Set on/off configuration for printers 1 and 2	Yes	Yes	All
Set off/send configuration for Patient Report, Lab Report, and Laboratory Computer	Yes	Yes	All
Set designation printer for reports	Yes	Yes	All

(Continued)

Set on/off configuration for transmission to the Laboratory Information System	Yes	Yes	All

Tell me how to Configure Report Defaults (page 17-48)

Printer Status

Use these buttons to inform the system which printers are powered on and ready to receive reports, and which printers are powered off:

- Touch On or Off for Printer 1
- Touch On or Off for Printer 2

Note: If you select On, the system assumes that the printer is both energized and online (ready to receive reports). If you select Off, the system assumes that the printer is de-energized or offline (not ready to receive reports).

Paper Size and Conservation

The paper size that reports are printed on can be selected by touching Letter (8-1/2" x 11") or A4 (210 by 297 mm or 8.27” x 11.69”) for each printer.

The Paper Conservation can be turned On or Off. If Off is touched, then one Lab Report will print on a page. If On is touched, then the printer will wait 5 minutes after the first report is added to the page, or 3 minutes after the last report was added to the page before printing.

Report Status

These buttons set the default control parameters for Patient, Laboratory, or Laboratory Computer reports.

- Touch Off if you do not want to generate the Patient Report, Laboratory Report, or reporting to the lab computer.
- Touch Send to generate and immediately release Patient and Laboratory Reports to their destination or sample results to the laboratory computer.

Note: Calibration and miscellaneous reports (such as condition codes and Quality Control Reports) are always on and released to the printers, indicated by a permanent “Send” status on the screen.

Tell me how to Release Reports (page 17-48)

Printer Destination

These buttons identify Printer 1 or Printer 2 as the destination for Patient, Laboratory, Calibration, or miscellaneous reports.

- Touch 1 to print the associated report on Printer 1
- Touch 2 to print the associated report on Printer 2

Note: Printers that are not connected will display “not found” next to the printer number and no On/Off buttons will be displayed.

Copies

Enter the number of Patient Report copies (1 to 5) that you want to print.

Transmit/Receive

Enables the system to receive requests from the laboratory computer as well as transmit results to it. When the box is not checked there is no communication to the LIS. Reports are not transmitted or received. You can not stop the system from just receiving downloads.

Switch Printers

An option that, when touched, changes the printer assignments. Printer 1 becomes Printer 2; Printer 2 becomes Printer 1. This is available if two printers are connected to the system.

Configure Communication

The Options & Configuration – Configure Communication screen enables the operator to configure protocol for the Laboratory Information System (LIS), Ethernet, e-Connectivity® communications, and the Laboratory Automation System (LAS).

The following table indicates whether each feature is accessible during sampling or assay processing, and the access level required for use.

Features	Sampling?	Assays?	Access?
Configure Laboratory Information System (LIS) protocol, including Host Query	Yes	Yes	Key Operator or Service
Configure Serial and Ethernet connections for the LIS	Yes	Yes	Key Operator or Service
Configure MicroImmunoassay LAS	Yes	Yes	Key Operator or Service
Configure MicroSlide LAS	Yes	Yes	Key Operator or Service
Configure Ethernet Connections	Yes	Yes	Key Operator or Service
Configure e-Connectivity®, including enabling/disabling data exchange, remote connectivity, and alert notification	Yes	Yes	Key Operator or Service

Tell me more about the LAS and LIS Logs (page 16-4)

LIS Configuration

These selections define the way your system communicates with a Laboratory Information System (LIS).

Note: All of the computer configuration values you enter using this feature must match those values actually used to configure the laboratory computer.

IMPORTANT: If changing from ASTM to HL7 or HL7 to ASTM, the system needs to have a proper shutdown and reset in order to make the change effective.

Tell me more about the Configure LIS Screen (page 17-30)

Ethernet Configuration

Use this screen to set up communications between your system and other devices using an Ethernet connection.

Tell me more about the Configure Ethernet Screen (page 17-33)

e-Connectivity® Configuration

e-Connectivity enables OCD support personnel to send data (such as software updates) to your system, to perform remote diagnostics for you, and, with your permission, to remotely control your system for diagnostic purposes.

Tell me more about the Configure e-Connectivity Screen (page 17-34)

LAS Configuration

These selections define the way your system communicates with a Laboratory Automation System (LAS) for both MicroImmunoassay (uIA) and MicroSlide (uSlide) reagents.

Note: Buttons will not be available if LAS is not enabled.

Tell me more about the Configure LAS Screen (page 17-35)

Configure LIS Screen

Use the Options & Configuration – Configure LIS screen to configure Laboratory Information System (LIS) protocol, serial port, or ethernet port information.

Tell me more about the LIS Logs (page 16-4)

LIS Protocol Configuration

Use these selections to configure the method used for LIS communication.

None	Indicates no communication with an LIS. Touch this button if your lab is not connected to an LIS. **Note:** If the Protocol is set to None, then no communication can occur regardless of the setting for Transmit/Receive on the Options & Configuration – Configure Report Control screen.
ASTM	Indicates LIS communication using the communications protocol created by the American Society for Testing and Materials (ASTM). Touch this button to enable communications with an LIS.

(Continued)

ASTM-IP	Indicates LIS communication using Ortho Clinical Diagnostics' implementation of ASTM over IP.
HL7	Indicates LIS communication using the communications protocol created by Health Level Seven, a non-profit organization involved in developing international healthcare standards.
Character Encoding	Identifies the character set used to encode LIS transmissions: **UTF-8** - Touch this button for Unicode Transformation Format. **Extended ASCII** - Touch this button for American Standard Code for Information Interchange.
Enable Host Query	Touch this button to enable your system to send queries to the host LIS computer.
Host Query Timeout	Type the number of seconds (1.5 through 9.9) for your system to wait for a response to a host query before cancelling the communication.
Upload Individual Results	Touch this button to enable your system to upload individual assay results as they are completed.
Enable Asynchronous Messages	Enables your system to upload individual system condition codes as they are generated. If the system is configured with a Laboratory Automation System (LAS), the automation status will also be sent.
Frame Size	Used to configure LIS screen (default is 64000).

Configure LIS Result Formatting

Once an LIS Protocol is selected, touch the Result Formating process button to display the Configure LIS Result Formatting dialog box. The following fields can be selected to configure result formatting.

Upload Extended Result Data	Touch this button to enable your system to upload extended result records. Extended result records include additional data for reagents, calibrators, and QC.
Include Measuring Range Flag in Result	Touch this button to enable (check) and disable (uncheck) the inclusion of the Measuring (Reportable) Range flag in the result field.

(Continued)

Include Qualitative Text Comment	Touch this button to enable (check) and disable (uncheck) the inclusion of a qualitative text comment.

LIS Serial Port Configuration

Use these selections to configure the serial port for connection to the LIS (ASTM protocol). Touch the down arrow to display choices for each of the configuration options. Touch your choice to select it.

Parity	Choose Odd, Even, or None to select parity.
Baud Rate	Choose 9600, 19200, 38400, 57600 and 115200 to select the speed of communications for the port.
Stop Bits	Touch 1 or 2 to select the number of stop bits.
Data Bits	Data Bits is always set to 8 for the LIS serial port.
Flow Control	The Flow Control is always OFF and is not configurable.

LIS Ethernet Port Configuration

If the selected LIS Protocol is ASTM-IP or HL7, the LIS Ethernet Port configuration parameters are displayed.

Server IP Address	Enter the Server IP address using the Internet Address Format. The default is 10.8.74.160.
Server Port	Enter the Server Port integer value in the range 1-65535. The IP Port default is 65535.

Configure LIS Process Buttons

Save	Touch the Save button to save any configuration changes made to the Configure LIS screen.
Connect LIS	Touch the Connect LIS process button to reset the current LIS connection.

(Continued)

Result Formatting	The Result Formatting process button is enabled after selcting an LIS Protocol. Touch Result Formatting to display the Configure LIS Result Formatting dialog box. This dialog includes the following options. All, some, or none of these options can be selected. • Upload Extended Result Data • Include Measuring Range Flag in Results • Include Qualitative Text Comment

Configure Ethernet Screen

Use the Options & Configuration – Ethernet screen to configure devices, routing and domain name service.

Devices

You can enable two devices for Ethernet communication. A device can be a computer, printer, or other peripheral. One device is the Ethernet connection to the sample metering control system. Its configuration will only change for OCD internal development purposes.

IP	Internet Protocol address identifying the device as a sender or receiver of information
Netmask	A string of 0s and 1s that mask or screen out the network part of the IP address so that only the host computer part of the address remains; used for routing purposes
DHCP	Touch the toggle button to enable or disable DHCP.

Routing

The routing indicates the network paths through which information travels between your system and the enabled devices. Type routing information in the fields provided. Currently-defined routing information appears in a window in the screen.

Gateway	Network
Destination	The IP address of the final point in the defined route
Netmask	A string of 0s and 1s that screen out the network portion of the IP address so that only the host computer portion remains

Domain Name Service

The domain name locates an organization or entity on the Internet. For example, you can set up a domain name covering a group of incorporated laboratories.

Enable	Touch this check box to enable the domain name. A check mark appears in the box. To disable the domain name, touch the check box again. The check mark disappears, and the system cannot recognize the domain.
Host Name	Identifies the system that has full information exchange access with the other systems in the domain.
Domain Name	The part of the Uniform Resource Locator (URL) that tells a domain name server using the domain name system whether and where to forward a request for information.
Name Server (1–3) IP	Internet Protocol address (which represents a physical point on the network) mapped to the domain name.

Ethernet Connection Process Buttons

The following process buttons are included on the Configure Ethernet screen.

Save	Touch the Save button to save any configuration changes made to the Ethernet Configuration screen.
Ping Host	Touch the Ping Host Process Button to send three ping packets to a host IP address and display the returned results.
Network Information	Touch the Network Information Process Button to view or print updated data from your Ethernet network connection. This data may include error messages or other notifications from the network administrator.

Configure e-Connectivity® Screen

Use the Options & Configuration – Configure e-Connectivity screen to configure data exchange, remote connection and server information.

Data Exchange Information

Activate and schedule the exchange of data between your system and Ortho Clinical Diagnostics.

(Continued)

Enable Data Exchange	Activates data exchange between your system and OCD. Enabling data exchange allows your system to send information directly to OCD and to receive information from OCD. Touch the check box to activate the feature. A check appears in the box. To deactivate the feature, touch the check box again. The check box disappears and data exchange cannot occur.
Time	Time of day for daily data exchange to occur. Enter this time in the format configured for your system.
Enable Alerts	Allows e-connectivity messages to be displayed. The default is not checked.

Remote Connection Information

Use these options to enable a remote diagnostics connection and define timeout parameters for e-Connectivity.

Enable Remote Connection	Enables remote diagnostics between OCD and your system. Remote diagnostics allow OCD to electronically evaluate software and subsystems for troubleshooting purposes.
Connection Timeout	Defines the length of time a connection will be attempted before canceling.
Activity Timeout	Defines the length of time a remote connection will stay live without any remote 'activity'.
Ping Interval	Defines the length of time between attempts to verify connection.

Server Information

You can enable a primary and secondary e-Connectivity server.

e-Connect Server IP	Address of the e-Connectivity server
e-Connect Server Port	Port of the e-Connectivity server

Configure LAS Screen

Use the Options & Configuration – Configure LAS screen to configure Laboratory Automation System (LAS) protocol and serial port information.

Tell me more about the LAS Logs (page 16-4)

LAS Protocol Configuration

Use these selections to configure the method used for LAS communication

LAS Protocol	**None** - Indicates no communication with an LAS. Touch this button if your lab is not connected to an LAS. **VITROS** - Indicates LAS communication using a three wire RS-232 interface. Touch this button to enable communications with an LAS.
Character Encoding	Identifies the character set used to encode LAS transmissions. **UTF-8** - Touch this button for Unicode Transformation Format **Extended ASCII** - Touch this button for American Standard Code for Information Interchange.

LAS Serial Port Configuration

Use these selections to configure the serial port for connection to the Laboratory Automation System (LAS). Touch the down arrow to display choices for each of the configuration options. Touch your choice to select it.

Parity	Choose Odd, Even, or None to select parity.
Baud Rate	Choose 9600, 19200, 38400, or 56000 to select the speed of communications for the port.
Stop Bits	Touch 1 or 2 to select the number of stop bits.
Data Bits	8
Flow Control	Off

Configure Demographics

The Options & Configuration – Configure Demographics screen enables the operator to define global system demographic attributes. These attributes are used when configuring normal ranges for specific assay/body fluids and are reflected on the Options & Configuration – Configure Ranges screen (Configure Assays > Review/Edit Configuration > Configure Ranges)

The editing of these parameters is only allowed with the Key Operator or Service access code and only while sampling and assay(s) are not in progress.

Features	Sampling?	Assays?	Access?

(Continued)

• The ability to configure demographic name attributes • The ability to configure demographic sex attributes • The ability to configure age unit attributes	No	No	Key Operator or Service

Tell me how to Configure Demographics (page 17-48)

Name Attributes

A unique demographic name and a unique associated demographic name character can be configured by the operator. Once entered, these demographic names can be used to configure ranges for each assay.

Tell me more about How to Configure Assays (page 17-3)

The demographic name character associated with each demographic name is entered in the Sample Programming - Edit Patient Data screen to associate a patient with a corresponding demographic name.

Tell me more about Patient Data (page 9-9)

These name attributes are also referred to as “range attributes.”

Note: If the name associated with a demographic name character is changed, the system will not distinguish between the original name and the new name. For example, if the demographic character “S” is associated with “Smoker” and later it is changed to be associated with “Senior”, all existing result records and sample programs that have a demographic character of “S” will be associated with the new demographic name “Senior.”

Sex Attributes

A unique sex demographic name and a unique associated sex demographic character can be configured by the operator. The default values are Male (M), Female (F) and Other (O). The sex demographic character can be entered in the Sample Programming – Edit Patient Data screen to associate a patient with the corresponding sex demographic name.

Tell me more about Patient Data (page 9-9)

Note: If the operator changes the meaning of a sex demographic character, the system will not distinguish between the original meaning and the new meaning. For example if the user configured the sex demographic character “M” to mean “Male” and later configured the sex demographic character “M” to mean “Mammal”, all existing result records and sample programs that have a sex demographic character of “M” will now be associated with the sex demographic “Mammal.”

Age Units

Age Units consist of a unique age unit name and a unique associated age unit character. Only the age unit character is editable by the operator. The age unit character is entered in the Sample Programming – Edit Patient Data screen to associate a patient with the corresponding age unit name.

The demographic age unit defaults are Days (D), Weeks (W), Months (M), and Years (Y).

System Services

The System Services functions, located on the Options & Configuration screen, allow you to retrieve records from the system Datalogger, archive records onto an export device for backup, and access current and cumulative assay usage data for the system using the following buttons:

- Datalogger (page 17-38)
- Perform Backup (page 17-39)
- Usage Counters (page 17-39)

The following table indicates whether each feature is accessible during sampling or assay processing, and the access level required for use.

Features	Sampling?	Assays?	Access?
Review Datalogger files, start a new file, and save files to disk	Yes	Yes	All
Back up all or specific databases	Yes	Yes	All except Export Adjustments and Export Service Log (requires Service access)
View or print usage information for the system	Yes	Yes	All except Reset Counters (requires Key Operator access)

Datalogger

The Datalogger is a software feature permitting storage of pertinent assay, system, and environmental information for later retrieval and investigation.

The Datalogger screen displays a scrolling list of defined Datalogger files on the fixed disk. Files appear in alphanumeric order. Each file name contains up to eight characters plus a three-digit file name extension.

The **Environmental Logging Interval** section of the Datalogger screen allows you to choose how often information regarding environmental conditions of subsystems is logged: 1, 5, 10, 15, 30, or 60 minutes. The default is 60 minutes.

The **Sample ID Logging** option allows you to include (On) or exclude (Off) Sample ID information in the data log. The default is On.

The **Encrypt Sample IDs** option allows you to encrypt (On) or not encrypt (Off) Sample IDs in the event log. The default is On.

Touch the Decrypt Sample IDs process button to display the Decrypt or Encrypt Sample ID dialog box. When the Encrypt button is touched, the contents of the Sample ID text entry field shall be replaced with the cipher text version of the Sample ID text entry field. This will reoccur if the Encrypt button is pressed multiple times. When the Decrypt button is touched, the contents of the Sample ID text entry field shall be replaced by the contents of the field after being run

through the decryption algorithm, and should match the original plain text, including multi-byte precomposed UTF8 characters.

Note: If text is entered, then encrypted and decrypted, the original plain text should be displayed. The text in this field is case sensitive, both for plain text and enciphered text.

Tell me how to Start a New Data Log File (page 17-48)

Tell me how to Export a Data Log File (page 17-49)

Perform Backup

Files are backed up with 2 files for each database: A compressed (Zip) file containing all data, and a text file that contains the date/time, checksum, system J Number, current software version, and database schema version.

Backup files for full backups contain the following data:

- Results
- Sample programs
- Panels
- Calibration programs
- Calibrations
- Controls
- Quality Control results
- Configuration
- Configurable assay data
- Condition codes
- Pack sequence number history, including open dates and last known volumes
- Adjustments
- Usage Counters
- Consumables
- Periodic Maintenance
- UDA

The following data can be backed up outside of a full backup:

- QC Results

  Note: QC backups can be shared with third party QC vendors but cannot be used to restore QC records. This is an export of the QC data only.

- Adjustments

  Note: Adjustment backups can be used to restore adjustment information to the system by Service Personnel only.

Tell me how to perform a System Data Backup (V-Docs)

Tell me how to Restore from Backup (page 17-49)

Usage Counters

The Options & Configuration – Usage Counters screen enables the operator to view, reset, export or print the Current Usage Counter and the Cumulative Usage Counter.

Use this screen to view and print usage information for the system. The system has two separate counters: the Current Usage Counter and the Cumulative Usage Counter. These counters are incremented any time a replicate (a single instance of an assay performed on a sample) is performed. The Current Usage Counter tracks tests performed in the time period (e.g., last day, week, or month). The Cumulative Usage Counter collects the same usage information, and keeps a running total since the system first started processing tests (or when last reset).

The screen displays the assays down the left side and shows the body fluid(s) within assay. Usage information for each body fluid is displayed, with a total for the assay.

Load System Data

Periodically, system information will need to be updated. Touch the Load System Data process button on the Options & Configuration screen to update assay data or software. The Load System Information dialog prompts the operator to select the type of information (Assay Data or Software) and source (disk or Downloaded files) for the data load process.

Ortho Clinical Diagnostics provides these updates to you either on disk or via e-Connectivity®. If you receive updates via e-Connectivity, the system provides notification that an update is available through the  icon on the System Status screen. If you load updates from disk, be sure to have the disks ready before starting the procedure.

Carefully read all communications that accompany assay and software updates.

Assay Data

Periodically, you will need to update the system's assay information by loading new data from the Assay Data Disk (ADD). The loaded assay information includes calibration information, protocol information, and reagent information.

Tell me more about the Assay Data Disk (page 10-2)

Caution: If an assay or diluent on the ADD shares the same name as a User Defined Assay (UDA) or User Defined Diluent (UDD) that is currently on the system, the ADD load fails and a condition message is displayed for each duplicate name. You must then rename the UDA or UDD before the ADD can be successfully loaded. Refer to the User Defined Assay Guide for more information.

Note: User Defined Assays are unaffected by ADD loads and as such do not become uncalibrated or unsupported.

Assay Configuration

Before the assay data is loaded an Assay Configuration dialog box will prompt the operator to select Retain Configuration or Restore Defaults.

Select Retain Configuration to retain the following user-modified data:

- M1 fields (page 10-9)
- Reagent Reps per Cal (if modified)
- Reagent Reps per Assay
- Water Blank Standard Deviation

Select Restore Defaults to apply all the pertinent assay data on the Assay Data Disk during the assay database update.

Regardless of the user selection for Retain or Restore, the assay database shall be updated to retain the following data.

- Reference Range
- Supplementary Range
- User Adjustment Parameters (Slope, Intercept)
- Sample Indices User Adjustment Parameters (Slope, Intercept)
- Last reagent lot used
- Site Temperature
- Units Type Selection
- Display derived test components on Patient Report
- Report derived test when components programmed
- Full Assay Name
- Short Assay Name
- Blank on Report
- Precision and Significant Digits
- Assay Menu Positions (Location Rank, Display On Menu Flag)
- Reflex Dilution (Enabled/Disabled) Status
- User Defined Diluents
- User Defined Assays
- Reflex to same or selected assay
- Display/Reports assay ordering (Report Ranks)
- Units Types Available
- Alternate Conversion Factor
- Alternate Units String
- Selected Derived Equation
- Assay/Diluent Inventory Thresholds
- Demographic Specific Reference Ranges
- Display Qualitative Value flags
- Report Qualitative Ranges on Report flag
- Suppress Outside Supplementary Range flag

Load Method and Alternative Assays

When loading assay data, a Load Method dialog box will prompt the operator to select All Assay Data or New Lots before the assay data is loaded. If All Assay Data is selected, an Alternative Assays dialog box will prompt the operator to decide how to handle duplicate assays. If Use Current is selected, the entire ADD will be loaded based on the Assay Configuration options described above. If Choose Alternative Assay is selected, a series of dialog boxes will display alternative options to choose from for each duplicate assay. An Alternative Assay Summary dialog box will then display the chosen duplicate assay options.

Tell me How to Load Assay Data (page 17-49)

Software

There are two parts involved in the system software update process. (1) Load the data from the software disk to the system hard drive, and (2) install the loaded software.

Note: It is recommended that you back up the existing system data (page 17-39) before updating the software.

Tell me how to Load a Software Update (page 17-51)

Tell me how to Install a Software Update (page 17-51)

Options and Configuration Procedures

The following table lists the Options and Configuration topics that reference the procedures included in this section.

(Continued)

Topic Title	Procedure Title
Options and Configuration Overview (page 17-1)	• Set System Access (page 7-9)
Review/Edit Configuration (page 17-6)	• Configure Assays (page 17-43)
Review/Edit Calibrations (page 17-10)	• Review/Edit Calibrations (page 17-43)
Configure System (page 17-21)	• Configure the System (page 17-44) • Set the Date and Time (page 17-44) • Set Sound Options (page 17-44) • Set Sample/Result Options (page 17-44) • Configure Thresholds (page 17-45) • Configure Assay Menu (page 17-45) • Configure Display/Report (page 17-46) • Configure Bar-Coded Calibrator Rules (page 17-46) • Configure the System Name (page 17-46) • Configure the Patient Report (page 17-47) • Configure PSID Check Digit (page 17-47) • Configure Standard Deviation for Water Blank Procedure (page 17-47) • Configure Site Temperature Tolerance (page 17-47)
Configure Subsystems (page 17-25)	• Configure Subsystems (page 17-47)
Configure Report Control (page 17-27)	• Configure Report Defaults (page 17-48) • Release Reports (page 17-48)
Configure Demographics (page 17-36)	• Configure Demographics (page 17-48)
System Services (page 17-38)	• Start a New Data Log File (page 17-48) • Export a Data Log File (page 17-49) • Restore Database from Backup (page 17-49)

(Continued)

Load System Data (page 17-40)	• Load Assay Data (page 17-49) • Load a Software Update (page 17-51) • Install a Software Update (page 17-51)

Configure Assays

Note: The configuration of restricted assays cannot be edited.

1 Touch  to display the Options & Configuration screen.

2 Touch the Configure Assays button to display the Options & Configuration—Configure Assaysscreen.

3 Touch the buttons to select a body fluid and assay combination.

4 Touch the Review/Edit Configuration button.

The screen displayed varies depending on the requested body fluid and assay combination. Some assays display data not available or not used by other assays.

5 To change a value, touch the field and type the new value. Press [Enter] or [Tab] to move between fields.

6 Touch Save.

Review/Edit Calibrations

Note: Calibrations for restricted assays cannot be edited.

1 Touch  to display the Options & Configuration screen.

2 Touch Review/Edit Calibrations to display the Review/Edit Calibrations screen.

3 Touch the buttons to select a body fluid and assay combination.

4 Touch a process button to perform the associated function.

- Touch Review Assay Data to display parameters for processing the selected assay and predicting results.
- Touch Review Cal Definition to display the calibrator values for the calibrators.
- Touch Review Calibrations to display all calibrations for the selected assay.
- Touch User Calibrate to perform a user calibration of a reagent lot by entering calibration parameters.

  Note: User calibrations are not available for restricted assays.

Configure the System

1 Touch  to display the Options & Configuration screen.

2 Touch the Configure System button.

3 Touch a button for the subsystem you want to configure.

- Date/Time
- Sound
- Sample Result Options
- Thresholds
- Assay Order
- Calibrator Rules
- System Name
- Patient Report
- Screen Saver
- PSID
- Max Water Blank SD

  Note: Do not modify the Water Blank SD value without instructions from Customer Technical Support.

- Site Temperature

Set the Date and Time

1 Touch Options & Configuration > Configure System > Date/Time to display the Options & Configuration — Date/Time screen.

2 Touch the buttons to choose the date format.

3 Touch the Date field and type the date. Press [Enter].

4 Touch the Time field and type the time. Press [Enter].

5 Touch Save.

Set the Sound Options

1 Touch Options & Configuration > Configure System > Sound to display the Options & Configuration — Sound screen.

2 Touch the buttons to enable tones for system events listed on the screen.

3 Touch the arrows below the Volume heading to raise or lower the volume.

4 Touch Save.

Set Sample/Result Options

1 Touch Options & Configuration > Configure System > Sample/ Result Options to display the Options & Configuration — Sample/ Result Options screen.

2 Touch On or Offto enable or disable Sample Indices, All Reprocessing, Reflex Dilution, Routine Reprocessing, Sample Program Auto Deletion, STAT Reprocessing, Result Record Retention, Recalculate Results, Use Expired Reagents, and Use Expired Cals.

Note: Sample Program Auto Deletion is not available for restricted assays.

3 If Sample Program Auto Deletion is on, touch a target to select a deletion interval for sample Program priority, designation, and type.

4 Touch Save.

Configure Thresholds

1 Touch Options & Configuration > Configure System > Thresholds to display the Configure Thresholds screen.

2 Touch the name of the assay to configure thresholds. Use Page Up or Page Down to see the entire list.

3 Touch a button at the bottom of the screen to configure a particular threshold for the assay.

- Assay — configure Count, Open/Shelf Expiration, and Cal Expiration
- Diluents — configure Volume and Open/Shelf Expiration
- Ancillary — configure Volume and Open/Shelf Expiration
- Signal Reagent — configure Count and Open Expiration
- Consumables — configure ERF Count, IWF Count, and UWR Volume
- Consumables — configure UWR Volume

4 Touch Save on each threshold dialog.

Configure Assay Menu

1 Touch Options & Configuration > Configure system > Assay Menu to display the Configure Assay Menu screen.

2 Touch a body fluid.

The assays for the body fluid are listed on the right side of the screen. Use Page Up or Page Down to see the entire list.

3 Touch the name of an assay and then an empty rectangle in the assay menu area.

The assay name is moved from the assay list to the rectangle.

4 Continue moving assays from the assay list to the rectangles you touch. This action creates the customized assay menu for the body fluid.

5 If desired, touch Arrange Remaining to allow the system to move the remaining assays from the assay list to the assay menu area.

The system retains the order of the assays in the list and fills the empty rectangles from top left to bottom right.

6 If desired, touch one of the following process buttons:

- Clear Assay — moves the selected assay back to the assay list
- Clear Menu — moves all assays back to the assay list
- Restore defaults — restores assays to the last-saved positions in the assay menu

7 Touch Save when finished with the assay menu for the selected body fluid.

8 Repeat Steps 4 through 7 for each body fluid.

Configure Display/Report

1. Touch Options & Configuration > Configure system > Display/ Report to display the Configure Display/Report screen.
2. Review the list of assays on the right side of the screen. Use the drop down list of choices to organize the list and use Page Up and Page Down to see the entire list.
3. Touch the name of an assay and then an empty rectangle in the assay display area.

   The assay name is moved from the assay list to the rectangle.
4. Continue moving assays from the assay list to the rectangles you touch. This action creates the customized assay display.
5. If desired, touch Arrange Remaining to allow the system to move the remaining assays from the assay list to the assay display area.

   The system retains the order of the assays in the list and fills the empty rectangles from top left to bottom right.
6. If desired, touch one of the following process buttons:
   - Clear Menu — moves all assays back to the assay list
   - Restore defaults — restores assays to the last-saved positions in the assay display
7. Touch Save.

Configure Bar-Coded Calibrator Rules

1. Touch Options & Configuration > Configure system > Calibrator Rules to display theSelect Bar-Coded Calibrator Rulesscreen.
2. Touch the check box to enable the rule.
   - New Lot or Lot Uncalibrated by ADD load
   - Calibration with a Current/Failed Status
   - Current Calibration That Will Expire in
3. If you enabled **Current Calibration that will expire in**, enter the number of days for each assay type.
   - Days For MicroSlide Assays
   - Days For MicroWell Assays
4. Touch Save.

Configure the System Name

Field Engineers complete this procedure.

1. Touch Options & Configuration > Configure System > System Name to display the System Name dialog.
2. Touch the System Name field and type the name of the system (1–7 characters, alphanumeric) to be shown on reports. Press [Enter].
3. Type the J number (the serial number identifying the system; 1–9 characters, alphanumeric).
4. Touch the Save button.

Configure Patient Report

1. Touch Options & Configuration > Configure System > Patient Report to display the Configure Patient Report dialog.
2. Type up to four lines of Patient Report header information such as report title, name, and the address of the laboratory. Type up to 80 characters of header information in each of the lines provided. Press [Enter] or [Tab] to move from line to line.
3. To print reference ranges on the report, touch the check box for this option.

   A check mark is displayed in the box to indicate this option is selected.
4. To print Sample Indices (hemolysis, icterus, and turbidity) on the report, touch the check box for this option.

   A check mark is displayed in the box to indicate this option is selected.
5. Touch Save to save your selections.

Configure PSID Check Digit

1. Touch Options & Configuration > Configure system > PSID to display the Configure PSID Checkdigit dialog.
2. Touch the check box corresponding to selected symbologies to enable the check digit for each symbology. A check mark indicates that a symbology is enabled. To disable the check digit, touch the box to remove the check mark.
3. Touch the Save button.

Configure Standard Deviation for Water Blank Procedure

IMPORTANT: Do not change this value unless instructed to do so by Customer Technical Support.

1. Touch Options & Configuration > Configure System > Max Water Blank SD to display the Max Water Blank ID dialog.
2. Type a standard deviation in the field provided. The standard deviation is a number from 0.01 through 0.030.
3. Touch the Save button.

Configure Site Temperature Tolerance

1. Touch Options & Configuration > Configure System > Site Temperature to display the Configure Site Temperature dialog.
2. Touch the Site Temperature field and type the optimum temperature (in degrees Celsius). Use one decimal point.
3. Touch the ± field and type the number of degrees of tolerance, plus or minus, allowed for the site temperature. For example, if the Site Temperature is 23.0 and the ± value is 5.0, the site temperature can range from 18.0 ° to 28.0 °C.
4. Touch the Save button.

How to Configure Subsystems

1. Touch  to display the Options & Configuration screen.
2. Touch the Configure Subsystems button.
3. Touch a button for the subsystem you want to configure.

Configure Report Defaults

1 Touch  to display the Options & Configuration screen.

2 Touch Configure Report Control.

3 Touch the buttons on the screen to make your selections.

Touch Help on the Configure Report Control screen for instructions on using the screen.

4 Touch Save.

5 Touch Return/Cancel to return to the Options & Configuration screen.

Release Reports Through Configure Reports

1 Touch  to display the Options & Configuration screen.

2 Touch Configure Report Control.

3 Touch Send for the reports you want to release

The Patient Report and the Laboratory Report are sent to their destination printer. The Lab Computer report is sent to the Laboratory Computer

4 Touch Save to save your selections.

This action sets the default to Send for the reports you selected.

5 Touch Return/Cancel to return to the Options & Configuration menu.

Configure Demographics

1 Touch  to display the Options & Configuration screen.

2 Touch Configure Demographics.

3 On the Configure Demographics screen, enter descriptive text and a one-character code for the demographics you wish to define in the Attribute, Sex, and Age Units categories.

Note: The descriptive text can be up to 15 characters.

4 Press [Enter] after each entry.

5 Touch Save when the entries are completed.

Start a New Data Log File

1 Touch  to display the Options & Configuration screen.

2 Touch Datalogger to display the Datalogger screen.

3 Touch Start New Log File to end the current data log and begin a new log file.

The previous data log file appears in the list of closed files.

Export a Data Log File

1 Touch  to display the Options & Configuration screen.

2 Touch Datalogger to display the Datalogger screen.

3 Select the files you want to export in the Log file. Files are listed on the right side of the screen.

- Touch Select All to select all the files.
- Touch the files you want to select. Use Page Up or Page Down to see all the files.

4 Touch Export Data to display the Export Data dialog.

5 Touch the device type to be used for this export and then touch Continue.

The Start Export dialog is displayed.

6 Follow the instructions on the Start Export dialog and then touch Export.

- If there is sufficient space on the export device, the Copy Status dialog shows the activity as the data log files are saved the export media.
- If the USB Flash Drive has insufficient space to save the date, a message is displayed. Replace the USB Flash Drive with one that has sufficient space and touch Export again.
- If the disk has insufficient space to save the data log files, the Insert New Disk dialog appears. Touch OK to overwrite the existing data to save the new files. Otherwise, touch Cancel and insert a new disk.

7 After the files have been saved, touch OK and then remove the export device.

Restore Database from Backup

1 Touch  to display theSystem Statusscreen.

2 Touch Shutdown.

3 After the system shuts down operational tasks, touch System Menu to display theSystem Menuscreen.

4 Touch Restore Database to install the backup. Follow the prompts on the screen to complete the backup loading process.

5 Run QC and perform calibrations if required.

Load Assay Data

IMPORTANT: Before loading a new Assay Data Disk (ADD), review the ADD History Chart for important loading instructions.

1 Touch  to display the Options & Configuration screen.

2 Touch the Load System Data button.

The Load System Information dialog is displayed.

3 Under Type Of Information, touch Assay Data.

4 Under Source: touch one of these buttons:

- DVD if loading data from the Assay Data Disk (ADD).
- Download button if loading data received through e-Connectivity®. Download is available only if you have e-Connectivity enabled.

Note: If loading from the ADD, load it in the DVD-RW drive on the MASTER COMPUTER.

5 Touch Next to open the Load Method dialog.

a Choose All Assay Data to load all the information on the Assay Data Disk (ADD).

b Choose New Lots to load only the new reagent lots from the ADD.

6 Touch Next.

a If you chose All Assay Data, complete Steps 7 through 13.

b If you chose New Lots, complete Steps 10 through 13.

7 On the Assay Configuration dialog, choose one of these options:

- Retain Configuration — to continue using the current assay configuration
- Restore Defaults — to restore the system default configuration

8 Touch Next.

9 On the Alternative Assays dialog, choose one of these options:

- User Current — to continue using the current assays
- Choose Alternative Assay — to chose alternative options for each duplicate assay

a If you chose Use Current, touch Next and continue on to steps 10.

b If you chose Choose Alternative Assays, touch Next and chose one of the alternative options available from a series of dialog boxes that will be displayed for each duplicate assay. Use the Next and Back buttons to navigate through each duplicate assay.

c Review the Alternative Assay Summary dialog and touch Back to make changes or Next to continue.

10 Review the information on the Assay Data Version dialog. If the information under New Assay Data is newer than the information listed under Current Assay Data, touch Next.

Note: If the information under New Assay Data is not newer than the information listed under Current Assay data, touch Back to make sure that you loaded the latest Assay Data Disk in the DVD-RW drive.

11 Review the list of assays displayed in the Assay Data Loaded dialog box. Pay particular attention to those assays that have become uncalibrated or unsupported from loading the new assay information.

12 Touch Finish when you are done reviewing the assay information.

13 If you loaded data from the Assay Data Disk, remove the disk and store it in a safe location.

14 Review install dates and the ADD data release version (DRV) information for All Reagent Lot Loads. Access this information with Diagnostics > System Information > Software & Assay Data Version Information.

15 If needed, calibrate the assays that require new calibrations.

Load a Software Update

1 Touch  to display the Options & Configuration screen.

2 Touch the Load System Data button.

The Load System Information dialog is displayed.

3 Under Type Of Information, touch Software.

4 Under Source: touch one of these buttons:

- DVD if loading data from a disk.
- Download button if loading data received through e-Connectivity®. Download is available only if you have e-Connectivity enabled.

Note: If loading from a disk, load it in the DVD-RW drive on the MASTER COMPUTER.

5 Touch Next.

The Software Version dialog box appears.

6 If the information listed for New Software Version is newer than the information listed for Current Software Version, touch Next. Otherwise, touch Cancel and make sure that you loaded the latest software version.

The Load Status dialog shows the activity as the software data loads onto the system. A confirmation dialog is displayed with the software has loaded successfully.

7 Touch OK.

8 If you loaded data from a disk, remove it and store it in a safe location.

Install a Software Update

1 Touch  to display the System Status screen.

2 Touch Shutdown.

3 After the system shuts down operational tasks, touch System Menu to display the System Menu screen.

4 Touch the Install New Software to install the software. Follow the prompts on the screen to complete the software loading process.

5 Run QC and perform calibrations if required. See software release notes.

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Chapter 18 Condition Codes Overview

The system contains numerous sensors and other devices that monitor performance. When the system software detects changes from normal operation, the system reports the condition via the Condition Review screen.

When the software senses a condition, it generates a six-character alphanumeric condition code (for example, MGB-100) to describe the condition. The first two characters indicate the hardware or software subsystem in which the condition occurred. For example, the hardware subsystem identifiers are:

Subsystem Identifier	SUBSYSTEM
MB	MicroImmunoassay Reagent Supply (Supply 4)
MF	MicroWell Reagent Metering
MG	MicroWell Incubator
MH	Luminometer
MJ	Well Wash Metering and Universal Wash Fluid
MK	Signal Reagent
TA	Slide Supply (Supply 1 and Supply 2)
TB	MicroImmunoassay Reagent Supply (Supply 3)
TC	CuveTip Ring
TD	Sample Supply
TE	MicroSlide Metering
TF	ERF Metering
TG	MicroSlide Incubator
TH	Reflectometer
TJ	Wash Fluid Metering
TK	Cuvette Supply
TL	MicroTip Supply
TM	MicroImmunoassay Metering
TN	Cuvette Incubator
TP	Photometer

(Continued)

TQ	Command Center
TR	Front Card Rack
TS	MicroSensor
TT	VersaTip Supply
TU	Side Card Rack
TV	Power
TW	Waste (Slide,Disposable, and MicroWell)
TX	Frame/Cabinetry
TY	Electrometer
TZ	Secondary Tip Sealer

The characters after the first two letters further narrow the location of the hardware condition. Each condition code includes a condition message that you can review. An indicator on the Status Console shows the number of conditions you have not reviewed within each severity level. If all messages have been reviewed, the indicator displays nothing for that level.

Severity Levels

Severity levels indicate the urgency of the condition. Severity levels are:

- Transient — Conditions that are temporary system conditions and do not normally affect system operation. Transient conditions do not require operator action, so no audible alert accompanies them. The system logs them to the condition log file and you can review them on the Condition Review screen. The system does not report transient conditions to the Status Console.
- Attention — Conditions that eventually will affect system operation if left uncorrected. For example, a low fluid threshold level is reached.
- Action — Conditions that prevent execution of some but not all requests. You should take immediate operator action to correct the condition. Examples are empty reagent pack conditions or an unsuccessful calibration.
- Malfunction — Conditions that prevent continued operation of one or more subsystems (such as the incubator or reagent supply). If possible, the system completes processing of current assays in the affected subsystem before deactivating the subsystem. This method of selective deactivation minimizes loss of valid assay results while preventing damage to system components.
- Shutdown — Conditions of sufficient urgency to warrant reloading the control program or resetting the system. Shutdown conditions usually indicate an unusual condition in system control software. A Shutdown indicator remains on the Status Console until you reset the system.

IMPORTANT: The shutdown severity level requires operator interaction. The system does not de-energize itself.

You can configure the audible tone accompanying each level of condition code. Touch the Configure System button on the Options & Configuration screen and then touch Sound to set the tone.

Condition Codes Review

To review condition codes, touch  on the status console. The system displays the Condition Review screen listing conditions that apply to the current state of the system. For each condition, the screen lists:

- Severity level
- Date and time the condition was recorded
- Condition code
- Short description of the condition

Condition Review List Updates

When a condition occurs, it does not appear on the Condition Review list until you update the list, or touch the Conditions button again from the status console. If you are in the Condition Review screen, and new condition codes have been reported, the Update List button becomes active. Touch the Update List button to refresh the screen and list any new conditions that have been reported. New records appear in bold text and previous records appear in grey. The count of new records resets to zero and "New codes" disappears from the status line.

Condition Code Description Review

The system displays a detailed explanation of the condition once you touch the View Description button on the Condition Review screen. This information includes:

- Severity level
- Full explanation of the meaning of the condition
- Actions you can take to resolve the condition

Tell me how to View Details about a Condition (page 18-5)

View Description Troubleshooting

You can use the View Description screen to troubleshoot conditions being reported by the system by following the "Actions" suggested on the screen. The View Description screen should be able to guide you through a series of steps that will resolve the condition(s) listed on the screen.

Tell me how to Troubleshoot a Problem with View Description (page 18-5)

At times the "Action" may prompt you to initialize the system after performing the recommended corrective actions to bring the affected subsystem back to operational status. See Troubleshooting (page 16-9) for more information.

If your system continues to post condition codes after you have followed the “Actions” suggested on the screen, contact Customer Technical Support.

Condition Codes Filter

A filter restricts the Condition Review screen to display only certain severity levels or certain condition codes.

In the FILTER CONDITION CODES dialog you can:

- Touch a field in the SEVERITY area to select the lowest severity level of conditions to display. For example, if you touch Action, the Condition Review screen will list only conditions with a severity level of Action and higher.

- Touch the All Codes button in the CODES area to select all condition codes for display.
- Touch the Specific Condition Code button and type in a condition code to display. This filter is helpful if you want to isolate a particular condition for troubleshooting.

Tell me how to Filter Condition Codes (page 18-6)

Condition Counts Review

The Review Counts screen provides a count of each type of condition code reported by the system, either since the last count reset or currently in Condition Review. To view the screen, touch the Review Counts button on the Condition Review screen.

You can change the Review Counts display using one of the following methods:

- Touch Since Last Reset to show counts recorded (up to 999,999) since the count was last reset to zero.
- Touch In Condition Review to show counts of condition codes currently available in Condition Review.
- Touch Locate after entering a specific condition code in the locate field. The Review Counts display will show counts for that condition code.

In Condition Review is the default selection, and displays the total number of recorded condition code records in the status line. If Since Last Reset is selected, the status line displays the total number of recorded condition code records and the date and time of last count reset.

Condition Count Reset

If you need to reset all of the condition counts to zero, touch the Reset Counts button on the Review Counts screen.

Tell me how to Reset Condition Count (page 18-6)

Condition Information Printing

You can print condition information from both the Condition Review screen and the Review Counts screen.

If you want to print information about records selected from the Condition Review list, refer to How to Print Condition Information (page 18-7).

If you want to print a summary of condition counts from the Review Counts list, refer to how How to Print Condition Summary Information (page 18-7).

Auto-Recovery

If a mechanical condition occurs during sample processing, the system automatically attempts to correct the condition.

Tell me more about auto-recovery (page 9-12)

Text Substitution

Short code descriptions are dynamic in order to replace characters depending on the system condition.

There are two reasons for text substitution:

- Software exception codes that have additional data for use during troubleshooting
- Generic codes with a %s or %d are used to allow substitution of specific information (analyte name, sample ID, tray ID, etc.)

Condition Code Procedures

The following table lists the Condition Code topics that reference the procedures included in this section.

Topic Title	Procedure Title
Condition Codes Review (page 18-3)	• View Details about a Condition (page 18-5) • Troubleshoot a Problem with View Description (page 18-5) • Filter Condition Codes (page 18-6) • Reset Condition Count (page 18-6) • Print Condition Information (page 18-7) • Print Condition Summary Information (page 18-7)

View Details about a Condition

1 Touch  to display the Condition Review screen.

2 Touch the condition to select it.

3 Touch View Description.

Note: If a condition is not selected, the system displays the Enter Condition Code dialog. Type the condition code that you would like to review and touch OK.

4 Review the information on the screen.

5 Touch Return to return to the Condition Review screen.

Troubleshoot a Problem with View Description

1 Touch  to display the Condition Review screen.

2 Touch the condition to select it.

3 Touch View Description.

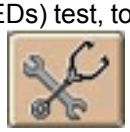
Note: If a condition is not selected, the system displays the Enter Condition Code dialog. Type the condition code that you would like to review and touch OK.

Detailed information is displayed about the selected condition. Information includes:

- The severity level.
- A full explanation of the meaning of the condition code.
- Actions to take to resolve the condition.

4 Read the first action listed.

5 Perform the recommended tasks.

If you need to perform a system test or procedures, such as a Mechanism Exercise Diagnostics (MEDs) test, touch the appropriate button on the status console (for example, the  button). In most cases, a link in the condition code description takes you to the instructions for performing a recommended procedure.

6 Verify that the condition has been corrected by performing the procedure that caused it to occur.

7 If the condition occurs again, touch  to return to the Condition Review screen to review the condition and possible actions to correct it.

Filter Condition Codes

1 Touch  to display the Condition Review screen.

2 Touch Filter List.

TheFilter Condition Codescreen is displayed.

3 Choose the filter criteria.

- Severity — Transient, Attention, Action, Malfunction, and Shutdown
- Date Range — All or Select Date Range

  Touch 24 Hours from Current Time and the system will calculate the 24 hour period.
- Codes — All or Specific Code

  For Specific code, type the first three values, press Tab, and type the last three values. Press [Enter]

4 Touch OK.

The Condition Codes that match all the filter criteria are displayed.

Reset Condition Count

Reset Condition Count removes the contents of the scrolling list on the Review Counts screen and changes the Last Reset date and time to the current date and time.

1 Touch  to display the Condition Review screen.

2 Touch the condition to select it.

3 Touch Review Counts.

The Review Counts screen is displayed.

4 Review the information on the screen.

5 Touch Reset Counts to set the counts of the codes to zero.

6 Touch Yes on the confirmation dialog.

The system removes the contents of the scrolling list. The "Last Reset" date and time changes to the current date and time.

Print Condition Information

1 Touch to display the Condition Review screen.

2 Select conditions to print.

- Touch a condition record to select it.
- Touch multiple records.
- Touch Select All to select all the condition records.

Note: If you select multiple records, they will print in chronological order, with the most recent condition printed first.

3 Touch Print.

Print Condition Summary Information

1 Touch to display the Condition Review screen.

2 Touch Review Counts.

The Review Counts screen is displayed.

3 Review the information. Use the choices on the screen to change the information, if needed.

4 Touch Print.

A summary of condition information from the Review Counts list you are viewing is printed

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