

Performance. Capacity. Simplicity.

UniCel® DxC 800 Synchron® Clinical System

General Chemistry

Lab Automation

Information Systems

Immunodiagnosics

Centrifugation

Molecular Diagnostics

Disease Management

Hematology

Hemostasis

Flgs Cytometry

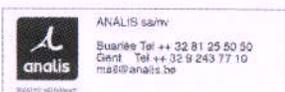
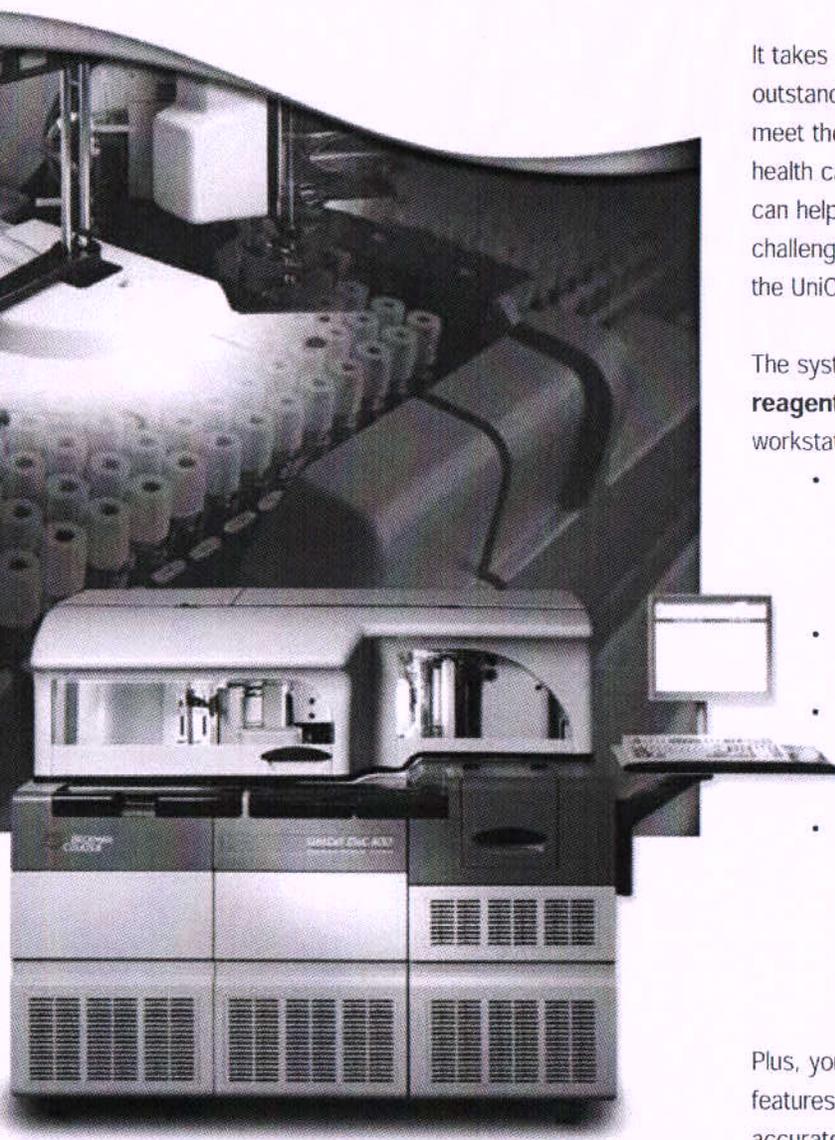
Primary Care

It takes powerful technology and outstanding support to help your laboratory meet the challenges of today's fast-paced health care environment. Beckman Coulter can help your lab stay on top of its challenges with the next generation – the UniCel® DxC 800 Clinical System.

The system's **onboard capacity of 70 reagents** helps your lab consolidate workstations. Plus, the DxC 800 delivers:

- A peak throughput of 1440 tests per hour, perfect for labs that process more than 500 chemistry tubes per day.
- Enhanced user **software that's very intuitive and easy to learn.**
- Low maintenance requirements – **no daily maintenance** and minimal weekly maintenance.
- Optional **closed-tube sampling capability to enhance your laboratory's performance**, while reducing exposure to biohazards and the potential for errors.

Plus, you can take advantage of many more features designed to help you deliver accurate test results, when they are needed.



UniCel® DxC 800 Specifications

Measurement Principles

ISE (Ion Selective Electrode)
Conductivity Electrode
Glucose Oxygen Sensor
Colorimetric
Immuno-turbidimetric
CEDIA*
Enzyme Immunoassay
Rate
Endpoint

Detection Systems

Cartridge chemistry detector:
Type: Multi-wavelength, diffraction grating spectrophotometer
Light source: Pulsed xenon lamp
Detector: Diode array for 340, 380, 410, 470, 520, 560, 600, 650, 670, 700 nm wavelengths

NIPIA detector (PRO option):
Type: Light emitting diode
Detector: Photo diode array for 940 nm wavelength

Modular detectors:
5 ISE
2 Electrochemical
4 Colorimetric

Throughput

1440 tests/hour maximum *p. 1.3*
11 critical care chemistries in 42 seconds
(ALB, BUN, CALC, CO₂, CL, CRE, GLU, PHOS, K, NA, TP, UREA)

Reaction Carousel Temperature

Cuvette chemistry methods:
37°C (± 0.2°C)
Other module temperatures:
37°C and 41°C, chemistry method dependent
ISE methods:
ambient room temperature

Cartridge Reagent Compartment Temperature

+2°C to +8°C

Reagent Capacity

70 methods simultaneously on board
59 cartridge chemistries
5 ISE chemistries
6 modular chemistries

Chemistry Menu Capacity

> 100 preprogrammed, bar-coded methods currently available
On-board data storage for 100 user-defined methods

BarCode Reagent Features

Automatic tracking of:
Number of tests
Available tests
Expiration date
Lot number
Calibration expiration *p. 1.40*

Calibration Types

Single-point, 2-point, multi-point
Linear and non-linear models
(chemistry method dependent)

Sample Management/Capacity

100 samples input queue, continuous loading *p. 1.5*
140 samples total

Bar-code symbologies:
Code 39 (Code 3 of 9 or SD-3)
Code 128 (USD-6)
Interleaved 2 of 5 (USD-1)
Codabar (USD-4)

Sample volume as low as 3 µL
Sample serum indices (hemolysis, lipemia, icterus assessment)
Sample probe obstruction detection and correction

Sample Types

Serum
Plasma
Urine
CSF
Whole blood hemolysate

Sample Container Types

BD Hemogard*
Greiner*
Sarstedt*

Sample Container Sizes

Primary tubes:
10.25 X 64 mm (3 mL)
13 X 75 mm (5 mL)
13 X 100 mm (7 mL)
16 X 75 mm (7 mL)
16 X 100 mm (10 mL)

Closed Sample Containers (PRO option)

Hemogard
13 x 75 mm
13 x 100 mm
16 x 100 mm

Greiner
13 x 75 mm
13 x 75 mm non-ridged
13 x 100 mm
13 x 100 mm non-ridged

Sarstedt (with CTS upgrade)
15.3 x 92 mm serum/gel in 16 x 100 mm sample rack
15 x 75 mm serum in modified sample rack

Sample cups: *p. 1.6*
0.5 mL, 2.0 mL

SYNCHRON Microtubes™

Reporting Units Available

(chemistry method dependent)

Weight/Volume:
pg/mL, ng/mL, µg/mL,
pg/dL, ng/dL, µg/dL, mg/dL, g/dL
mg/L, g/L

Mass/Volume:
nmol/L, µmol/L, mmol/L

Units/Volume and miscellaneous units:
mEq/L
nKat/L, µKat/L
µIU/L, IU/mL
mIU/L, U/L, IU/L, mA, mA/min
%, nIU/dL, mIU/mL

Communication Modes

Unidirectional, bidirectional, bidirectional with true Host Query
RS-232C Serial

Power and Environmental Requirements

Analyzer:
220 VAC, nominal
15A at low line, exclusive of power on surge
50/60 Hz, nominal

Computer console and monitor:
115 VAC, 4A, nominal or 230 VAC, 2A, nominal
50/60 Hz, nominal

Printer:
120 VAC or 220 VAC, nominal
50/60 Hz

Heat output (analyzer only):
7,500 BTU/hour

Ambient operating environment:
Ambient Temperature: +18°C to +32°C
Relative Humidity: 20 to 85% relative, non-condensing

Dimensions and Weight

Analyzer only:
Height: 62 inches (157.5 cm)
Length: 70 inches (177.8 cm)
Depth: 41 inches (104.1 cm)
Weight: 1725 pounds (782.4 kg) without liquids
Zero rear clearance required

System Console Computer

3.5 inch, 1.44 MB floppy diskette
≥ 2.0 GB hard disk drive
128 MB RAM
CD-ROM

Water Requirements

0.6 L/minute peak flow rate
16 L/hour minimum continuous flow rate
NCCLS Type II deionized, < 10 CFU/mL

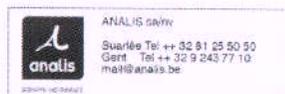
Drain Requirements

Minimum rate of 16 L/hour
< 36 inches (91.4 cm) above the floor

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REKLAMINIS

BUKLETAS Nr. 2

The Perfect Blend of
Chemistry and Productivity

UniCel[®] DxC Synchron[™] Clinical Systems

General Chemistry

Lab Automation

Information Systems

Immunodiagnosics

Centrifugation

Molecular Diagnostics

Disease Management

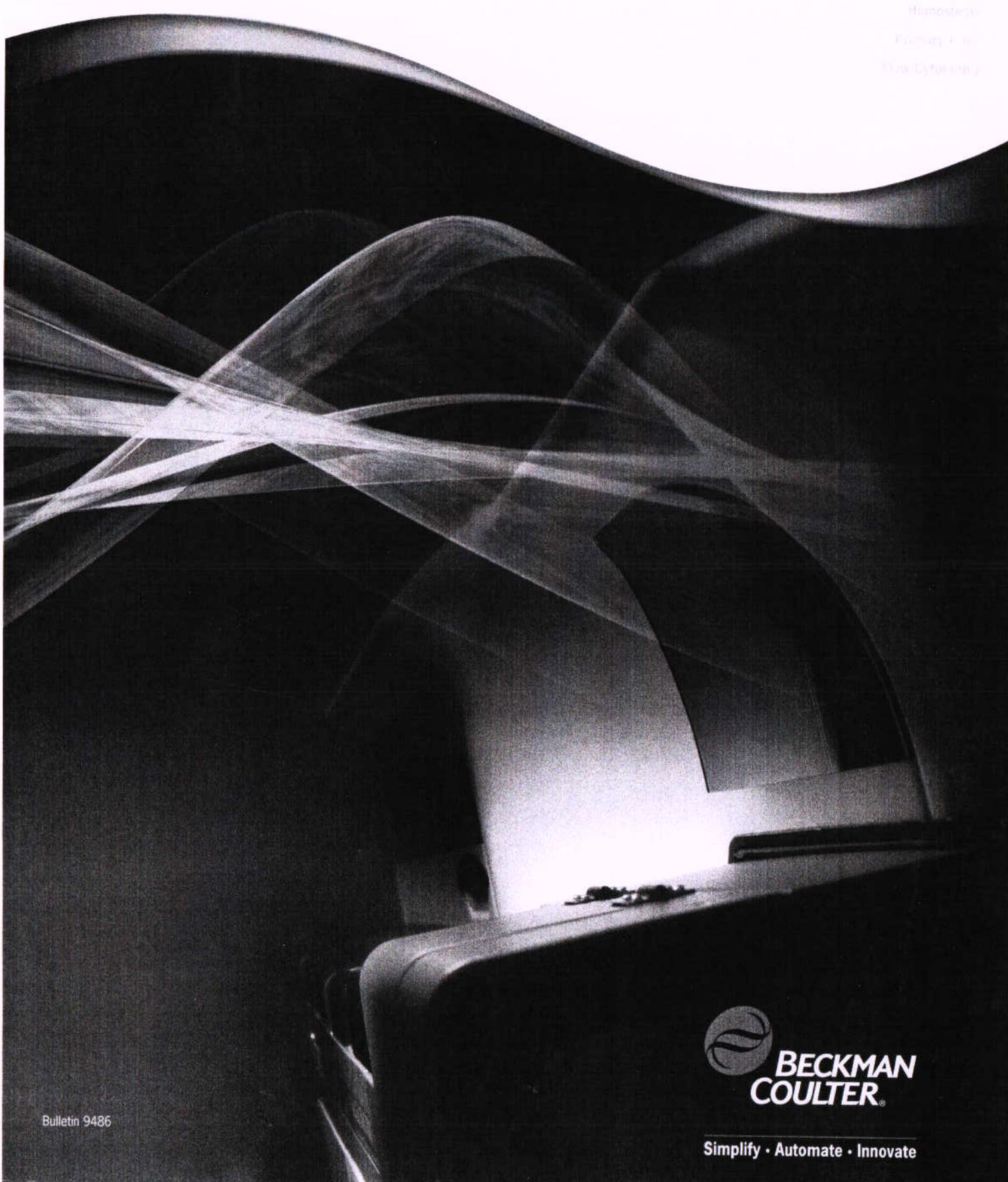
Cellular Analysis

Hematology

Hemostasis

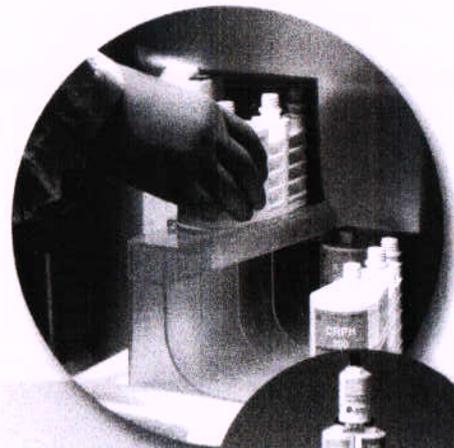
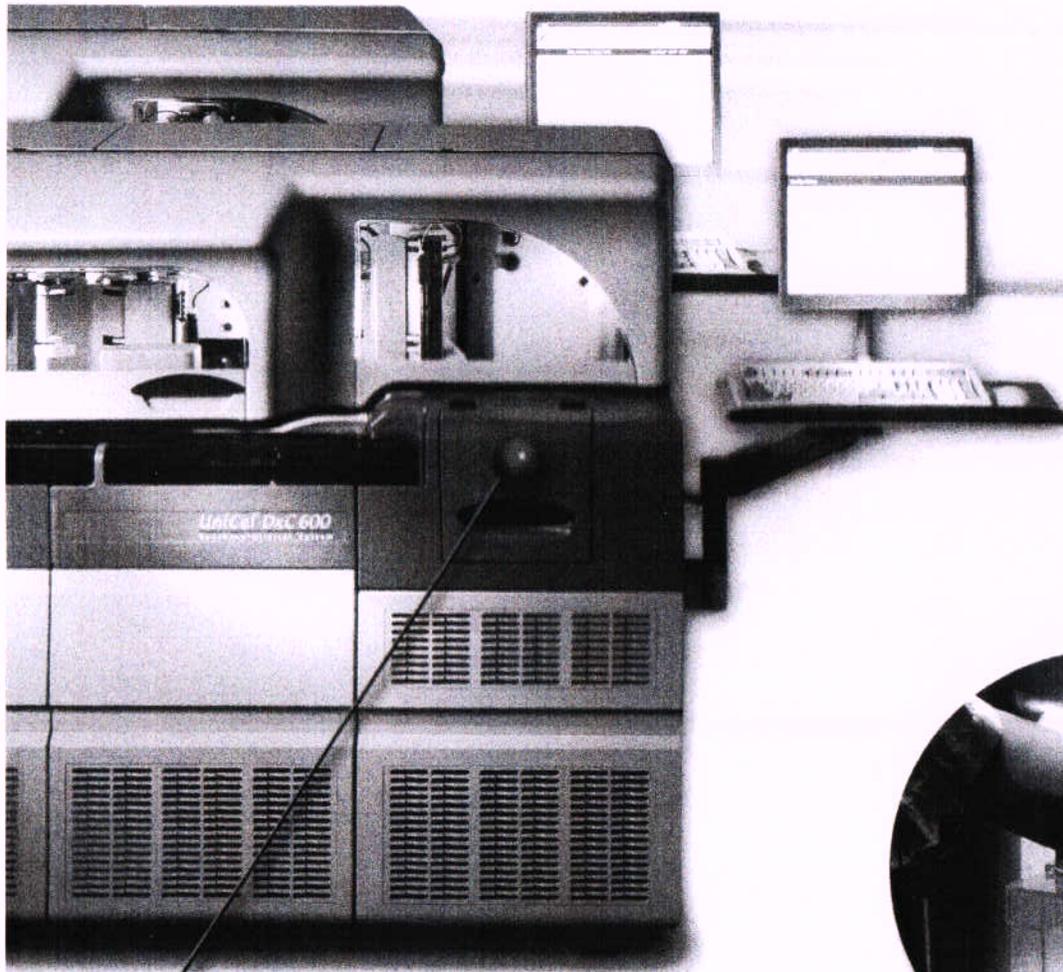
Primary Care

Flow Cytometry



Connection to automation

With the ability to connect to Beckman Coulter's automation solutions*, UniCel DxC systems can streamline your lab's testing process even more by eliminating manual sample-processing steps. Connecting to automation helps prevent bottlenecks in the lab and improves test turnaround time and productivity.



Reagent capacity for your workload

With an onboard capacity of 70 different reagents, you can configure the DxC 800 system to meet your laboratory's specific testing patterns. The DxC 600 offers 65 different reagents on board at once.

Choose from a menu that includes more than 100 liquid, ready-to-use reagents. Your lab can consolidate your testing for everything from proteins to drugs of abuse to therapeutic drug monitoring.

- Liquid reagents eliminate time-consuming reagent preparation.
- Most reagents are packaged with enough volume for hundreds of tests, minimizing operator intervention with the system.
- If reagents are required, operators can load while the system is running.
- No need to interrupt workflow to reconfigure on-board menu.

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UniCel® DxC 600/800 SYNCHRON® Clinical Systems **Published Specifications**

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4.0 CHEMISTRY PERFORMANCE CHARACTERISTICS

4.1 System Test Menu:

See Chemistry Abstract in Appendix A.

Same as LX20 V4.3 plus the following cartridge chemistries: Lithium, Albumin, Total Protein, Creatinine, reformulated Phosphorus (PHS)
No-Maintenance Disposable Chloride Electrode Tip

4.2 Performance Specifications:

See Chemistry Abstract in Appendix A for by-analyte information on:

- Methodology, measurement principle, reaction type
- Sample types and sample volumes
- Reagent information: reagent volume used per test, storage temperature, on-instrument stability, tests per container and reagent preparation information where applicable.
- Measurement time or reaction read time.
- Measurement temperature and regulation
- Analytical range and ORDAC/URDAC range where applicable
- Default reporting units and reference range
- Calibration frequency and Within-lot calibration frequency
- Enzyme verification capability
- Precision specification

5.0 OPERATING CHARACTERISTICS

5.1 System Modes of Operation: Same as LX20

Routine: Daily analysis management of patient & QC samples

STAT Interrupt: Prioritizes STAT patient samples, processing and results

Calibration: Manage calibration initiation and calibration results.

Maintenance: Software routines for maintenance

Diagnostics: Software routines to assist in diagnostics & troubleshooting

Service: For BCI service personnel

5.2 Walk-away On-Board Sample Capacity:

DxC 600: up to 14 racks or 56 samples of walkaway capacity.

DxC 800: up to 25 racks or 100 samples of walkaway capacity (same as LX20)

5.3 Sample Processing Capabilities:

5.3.1 Sample Identification: Same as LX20

User-Programmable Feature: The DxC600/800 has an on-board laser barcode reader that will identify barcodes placed on sample containers. The user may configure the instrument to read any or all of the following symbologies:

- Codabar
- Interleaved 2 of 5
- Code 39
- Code 128

5.3.2 Closed Tube (CTS) Cap Piercing: Same as LX20 Pro.

Optional Feature: Ability to aspirate samples for testing without the need to remove the cap.

See Section 3.3 for supported tubes and associated hardware.

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- 5.3.3 Obstruction Detection/Correction: Same as LX20
User-Programmable Feature: The DxC600/800 sample probes automatically detect complete obstruction of the sample probe and self correct without operator intervention.
- 5.3.4 Liquid Level Sense of Sample: Same As LX20
Standard Feature: Using an RF (Radio Frequency) scheme developed by BCI, the DxC600/800 sample probes automatically check for the presence of a sample after each sample aspiration.
- 5.3.5 Test Scheduling: Same As LX20
Standard Feature: The DxC600/800 automatically schedules testing based on the tests ordered to optimize throughput

5.4 Reagent Management Capabilities:

5.4.1 Reagent Configuration Capacity:

- Up to 180 cc reagents may be configured at any given time
- Up to 100 UDR (User Defined Reagents) may be defined at any given time.
- User can load multiple cartridges of the same chemistry.

5.4.2 Reagent Identification and Tracking: Same as LX20

Standard Feature: When a barcoded BCI reagent is loaded, the DxC600/800's on-board barcode reader scans the reagent barcode and then automatically retains lot number, serial number, expiration date, load date, days usable on system, tests remaining, calibration status and within lot calibration status. Up to 500 BCI cartridges and their parameters may be stored in memory at any given time, even when the cartridge is removed and replaced on the system.

5.4.3 On-Board Reagent Capacity:

- DxC600: 65 = (5 ISE + 1 MC + 59 CC)
- DxC800: 70 = (5 ISE + 6 MC + 59 CC)

✓ 5.4.4 Liquid Level Sense of cc Reagents: Same as LX20 *p.2.1.*

Standard Feature: DxC600/800 automatically monitors the volume level of reagent in the cartridge compartments and will alert user when conditions require attention.

5.4.5 Cycle Counting of Bulk Reagent: Same as LX20

Standard Feature: DxC600/800 automatically monitors the volume of bulk reagent used and will alert user when conditions require attention.

✓ 5.4.6 Reagent Load/Calibration Management: Same as LX20 *p.2.1.*

5.4.6.1 Overview:

Standard Feature: Reagent Load/Calibration allow the user to:

- Load/unload CC and MC reagents, using the bar code system when system is in standby or while running.
- Initiate calibration & automatically confirm a calibration meets passing specification.
- Display/print the report of reagent & calibration status.

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6.0 SOFTWARE

6.1 User Interface:

In English, French, Italian, German, Spanish and Japanese

6.2 LIS Communications:

Interface Options: CX7 compatible or LX20 interfaces

Communications Mode: Unidirectional, Bidirectional or Bidirectional with Host Query
DxC600/800 are compatible with DL2000

p. 2.14.

6.3 Data Input Devices:

104-key keyboard (in English, French, Italian, German, Spanish and Japanese) mouse, touch screen, LIS, CD, diskette

6.4 Data Output Devices:

Touch screen, laser printer, LIS, CD, diskette, modem

6.5 System Setup Features:

6.5.1 Serum Index: Same as LX20

Programmable Feature: When this feature is enabled, the system automatically analyzes every sample for the detection of hemolysis, icterus and lipemia. A numeric value (index) for the relative concentration (range) is reported for each of the parameters. See attached Chemistry Abstract for additional information.

✓

6.5.2 Automatic ORDAC/URDAC: Same as LX20

Programmable Feature: This feature may be enabled/disabled on selected analytes. When enabled, if a sample result exceeds the instrument printable range range, the system will automatically rerun the sample with a smaller sample size, larger sample size or perform an on-line dilution. See attached Chemistry Abstract for the analytes with this feature.

p. 2.1.

6.5.3 Manual ORDAC: Same as LX20

Programmable Feature: This feature may be enabled on a selected sample and analyte during sample programming when a test result is know to exceed the usable range. The system will automatically run the sample with a smaller sample size, larger sample size or perform an on-line dilution. See attached Chemistry for the analytes with this feature.

6.5.4 Date/Time: Same as LX20 Programmable Feature: The user may select from a variety of options to display the order and format of the date/time.

6.5.5 Demographic Setup: Same as LX20

Programmable Feature: The user has the option to determine which of the 12 demographic fields will be displayed on the screen. The fields are: last name, first name, middle initial, date of birth, age, sex, patient comment, doctor, location, collection date, collection time, collected by.

- 6.5.6 Report Setup: Same as LX20
Programmable Feature: This feature allows the user to select from the following options:
- Enable/disable printing of Patient and Control Reports.
 - Define a Report Header to print at the top of each report
 - Select from 5 Patient Report formats.
 - Select from 3 Control Report formats.
 - Define Inter-Laboratory information to print in a report.
- 6.5.7 Chemistry Menu Configuration: Same as LX20
Programmable Feature: The user may select and position the order of analytes to be displayed on the screens and reports. The user may also define a name for each analyte as it should appear on a printed chartable report.
- 6.5.8 Default Sample Type: Same as LX20
Programmable Feature: The user may select a default sample type for all programmed samples. The sample type may be changed for individual samples in the Sample Programming Screen
- 6.5.9 Replicates: Same as LX20
Programmable Feature: User may enter from 1 to 20 replicates per sample.
- 6.5.10 Sample Comments: Same as LX20
Programmable Feature: The user may define up to 20 sample comments for use in the Sample Programming Screen.
- 6.5.11 Units/Precision: Same as LX20
Programmable Feature: The user has the option to select the desired units and number of decimal places for each analyte displayed and/or printed.
- 6.5.12 Maximum Sample Program Age: Same as LX20
Programmable Feature: The user may define the time limited allowed before the same sample ID can be reloaded on the system. This feature is useful when sample IDs are reused regularly.
- 6.5.13 Panel Definitions: Same as LX20
Programmable Feature: The user may define up to 50 groupings of analytes that are commonly programmed and run together.
- 6.5.14 Default Panel Selection: Same as LX20
Programmable Feature: The user may select one of the defined panels as the default. When the instrument receives a sample ID with no programming or the Host Query times out, the instrument will automatically run the default panel.
- 6.5.15 Special Calculations: Same as LX20
- 6.5.15.1 Special Calculations Predefined by BCI:
Programmable Feature: The user may enable/disable 14 pre-defined special calculations. When the special calculation is enabled, the value is reported when the appropriate chemistries for the equation are programmed and run for a given sample ID. The predefined special calculations are: Osmolality (2), Anion Gap (2), A/G Ratio, Indirect Bilirubin, BUN/Creatinine Ratio, Urea/Creatinine

Ratio, Free Thyroxine, Creatinine Clearance (2), Apo A/Apo B Ratio, Apo B/ApoA Ratio, Hemoglobin A1c

- 6.5.15.2 Operator Defined Special Calculations:
Programmable Feature: The user define and enable/disable 25 special calculations. When the special calculation is enabled, the value is reported when the appropriate chemistries for the equation are programmed and run for a given sample ID.
- 6.5.15.3 Timed Urine Calculations:
Programmable Feature: When Timed Urine is designated as a sample type, the user may enter the Timed Urine Parameters of Total Collection Time and Total Volume. The system will automatically calculate a result as a function of the collection period.
- 6.5.16 Reference Range: Same as LX20
Programmable Feature: User may define reference ranges for each analyte by age group, gender and sample type. Up to 32 age ranges may be defined. In addition, the operator may select one reference range as the default when there are no demographics associated with the sample.
- 6.5.17 Critical Range: Same as LX20
Programmable Feature: The user may define critical ranges for each analyte by age group, gender and sample type when the reference range is defined. When the Critical Results Rerun option is enabled and an analyte exceeds the defined critical range, the system will automatically rerun the analyte.
- 6.5.18 Reportable Ranges: Same as LX20
- 6.5.18.1 Analytical Range:
Standard Feature: The Analytical Range is an internal system limit verified by BCI. A result exceeding the Analytical Range is flagged OIR HI or OIR LO. See attached Chemistry Abstract for the analytical ranges by analyte.
- 6.5.18.2 Instrument Printable Range:
Standard Feature: The Instrument Printable Range is an internal system limit allowing for the printing/reporting of a result exceeding the Analytical Range, given small precision variations. A result exceeding the Instrument Printable Range is suppressed.
- 6.5.18.3 Reportable Range:
Programmable Feature: The user may enter a reportable range verified at the user's site. The Reportable Range may or may not be the same as the Analytical Range. A result exceeding the Reportable Range is Range is flagged OIRR HI or OIRR LO.
- 6.5.19 Immediate Reporting: Same as LX20
Programmable Feature: The user may enable the option to print and/or send-to-host sample results as they are completed on the system. When the STAT reporting option is selected, the user may choose between sending MC chemistry results as they become available or sending MC chemistry results when they are all completed.

- 6.5.20 User-Defined Chemistries: Same as LX20
Programmable Feature: The user may define and store up to 100 UDR (User Defined Reagent) parameter sets to be included as part of the system's test menu. The minimum parameter requirements to define a UDR are::
- Chemistry name
 - Primary Wavelength
 - Secondary Wavelength
 - Sample Volume
 - Reagent Dispense Volume
 - Blank Start and Blank End Read Times
 - Reaction Start and Reaction End Read Times

- 6.5.21 Password Setup: Same as LX20 Programmable Feature: The user may define password security for up to 100 users. The following areas are password secured:
- Results: Editing
 - Reagent Calibration: Modify setpoints, Slope/Offset Adjustment, Within-Lot Calibration, Enzyme Validator.
 - Quality Control
 - System Setup
 - Utilities: Clear Event Log

- 6.6 Sample Programming: Same as LX20
Samples may be programmed via connection with an LIS or at the DxC Console
- Sample Identification Options: by Sample ID or rack/cup position or both
Modes of Programming: Barcode or Rack/Position Mode.
Sample ID Storage: Up to 10,000 unit Sample IDs & their programs
Test Selection Options: by panels, individually
Sample Description Options: Sample type, sample comments, Patient ID, Patient demographics.
Sample Options: Sample replicates, Test replicates, Off-line dilution factor, Serum Index, Manual ORDAC, Control sample, STAT designation

6.7 Results Management:

- 6.7.1 Results Recall Same as LX20
This feature allows patient and control results to be recalled, reviewed, updated, and printed. Results can be recalled, displayed, and printed by:
- Individual Sample ID or a list of Sample IDs
 - Rack and position
 - Patient ID
 - Run date and time
- 6.7.2 Data Storage
The system retains a maximum of 150,000 results and 10,000 sample programs.
- 6.7.3 Critical Results Rerun Editing
When the Critical Results Rerun feature is enabled, the user may select the result to be deleted.

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6.7.4 Absorbance Versus Time

This feature may be used to view/print the absorbance over time of a specific sample and test.

✓ 6.8 Quality Control

6.8.1 Control Definition:

Programmable Feature: The user may define up to 100 controls. Control identification requires a control name, lot number, QC file number, sample type, the assigned mean, assigned SD and one chemistry selection. The maximum number of configurable chemistries per control is 175. A maximum of 8 control ID barcodes may be defined.

6.8.2 Statistics:

When controls are defined and run, the system will automatically maintain a running update on the number of results, mean, SD and CV. The first 4 Westgard rules are applied.

6.8.3 Summary Reports

The user may display/print QC reports in 2 formats: Summary with accumulated results or Inter-Laboratory.

6.8.4 Chart Reports:

The user may display/print QC results in the Levey-Jennings format.

6.8.5 Other QC Features:

- Ability to archive and retrieve QC data
- Ability to delete QC data points.
- View/print QC log with ability to enter action comments.

6.8.6 Auto Generation of Control:

Programmable Feature: When the Auto Generation of Control feature is enabled, the automatic Multiple Cartridge option is available. With the Multiple Cartridge option, the system will automatically run all runnable on-board cartridges for an autogenerated control

✓ 6.9 Electronic Maintenance Log: p. 2.1.

The user has access to an on-board electronic maintenance log which provides a means of recording scheduled and unscheduled maintenance. It also alerts the user when maintenance is due.

6.10 Software Upgrades: Same as LX20

Upon availability from BCI, the user may upgrade the system's operating software and/or chemistry database parameters.

6.11 Utilities:

6.11.1 Alignment:

The system has 49 software alignment routines to assist the advanced user in aligning hardware.

6.11.2 Diagnostic Routines

The system has 38 software diagnostics routines to assist the advanced user in troubleshooting.

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6.11.3 Event Log

The system has an automated electronic log that captures all significant instrument events as a troubleshooting tool.

6.11.4 Backup/Restore:

The user can backup and restore data and alignment files.

6.11.5 Modem:

Optional Feature: When the system is connected to a modem, BCI will have the ability to monitor instrument performance and reagent metering.

6.12 On-Line Help

- Electronic Instructions for Use Manual in multi-languages accessible through the DxC console using a web browser.
- Web browser has a search engine, which allows the user to quickly locate information in the Instructions for Use Manual by entering the desired text.

CE

A13914-AB
October 2005



**UniCel[®] DxC Synchron[®]
Clinical Systems**

Instructions For Use

For *In Vitro* Diagnostic Use Only
This manual is intended for
UniCel[®] DxC 600
UniCel[®] DxC 800

EC REP

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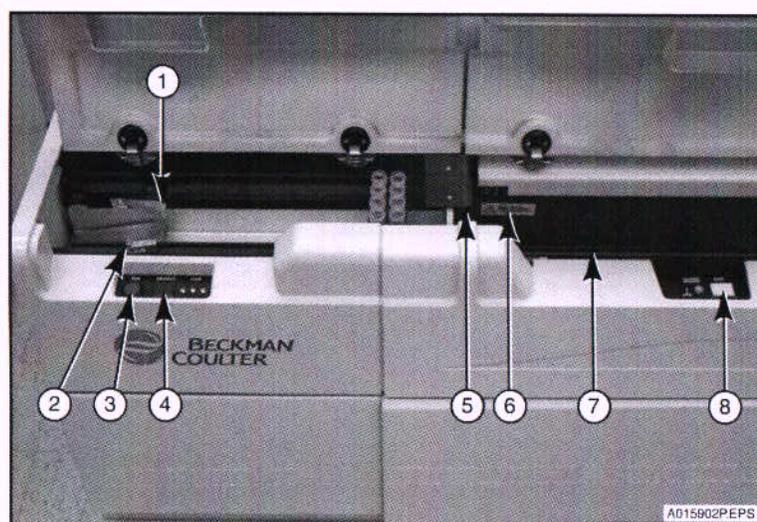
Autoloader/Offload Track

When viewed from the front of the system, the autoloader is on the left and holds up to 25 sample racks in preparation for presentation to the DxC 800 system. The DxC 600 system has room to load a maximum of 14 racks. (Refer to [Figure 2.4](#).)

There is also space for 25 sample racks in the offload track as they are removed from the Sample Carousel upon completion. Combined, these two components allow for over one hour of uninterrupted sample processing, with no operator intervention involved.

NOTICE

When loading racks onto the autoloader, make sure that they are placed firmly down into the autoloader.



- | | |
|-------------------------|------------------|
| 1. Pushers | 5. Sample gate |
| 2. Autoloader | 6. Shuttle |
| 3. Run button | 7. Offload track |
| 4. Priority load button | 8. Stop button |

Figure 2.4 Sample Loading Area

Priority Load Position

p1.5 { Between the Autoloader and the Sample Gate is the Priority Load position. This position is used in conjunction with the **PRIORITY LOAD** button when a rack is to be loaded onto the Sample Carousel into a *reserved priority position* so that it can be run in a higher priority than other racks on the Autoloader. (Refer to [Figure 2.4](#).)

Priority Load Button

P. 1.5

Typically, rack placement and removal is under microprocessor control. The operator may choose to use the reserved positions by pressing the PRIORITY LOAD button and placing the priority rack in the space provided by the system. (Refer to [Figure 2.4](#).) The rack will load into one of the reserved positions on the Sample Carousel.

PRIORITY LOAD only prioritizes the loading of the rack. It does not alter the sample priority (STAT or routine) previously designated in Sample Programming.

Pushers

Pushers collect and move to the Sample Gate any racks loaded onto the system. They are activated when the RUN button is pressed. (Refer to [Figure 2.4](#).)

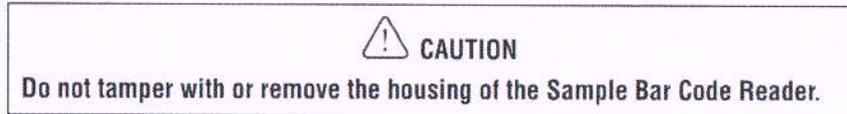
Sample Gate

The Sample Gate is the mechanism that moves racks from the load tray to the shuttle during the load process. It also moves samples from the shuttle to the unload track during the unload process. (Refer to [Figure 2.4](#).)

Shuttle

The Shuttle moves the rack from the gate area onto the Sample Carousel. (Refer to [Figure 2.4](#).)

Bar Code Reader (Sample)



The Bar Code Reader is a Class II fixed-beam laser scanner. It is used to read the rack bar code, the sample bar code (if present), and the background bar codes as the rack travels past. The rack bar code and sample bar code (if present) are used to identify the sample and link it to the appropriate sample programming.

There are two background bar codes that are used to determine whether a rack position is empty or occupied, and if occupied, whether the sample is in a cup or tube.

Refer to "[Symbols and Labels](#)" in CHAPTER 1, *General Information*, for a description of the CAUTION labels for the bar code reader.

Theory of Operation

Introduction

The UniCel DxC Synchron Clinical Systems are microprocessor-controlled, random access clinical analyzers capable of processing a wide variety of operator-selected chemistries in a single run. } p. 1.9, p. 1.7.

Cartridge Chemistries (CC)

The optical system of the DxC enables rate, endpoint, and nonlinear analyses to be performed simultaneously. These analyses are referred to as cartridge chemistries because the reagents are stored in cartridges.

Cartridge Chemistry (CC): Sample and Reagent Processing

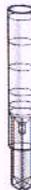
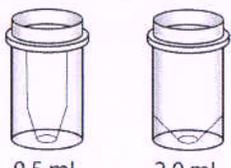
During operation, a number of events occur simultaneously and are under direct control of the instrument microprocessors.

Sample Preparation by Container Type

P.113.

Table 3.2 shows how to prepare different sample containers.

Table 3.2 Preparation of Sample Containers

If running a sample from a...	Then...
Primary Tube  <small>A014510L.EPS</small>	<ul style="list-style-type: none"> Use the sample template in the Appendix to determine adequate sample volume. Remove the stopper. For CTS systems, remove the stopper, if not a validated closed tube.
Secondary Tube  <small>A014496L.EPS</small>	<ul style="list-style-type: none"> Remove the cap. Determine sufficient volume. Check for fibrin or other materials resulting from storage.
Beckman Coulter Synchron Microtube™  <small>A014497L.EPS</small>	<ul style="list-style-type: none"> Pipette the sample into a Synchron Microtube™. Verify there are no bubbles at the bottom of the tube. Place into a 13 × 100 "reserved" rack.
Autoanalyzer Cup  <small>E014498L.EPS</small>	<ul style="list-style-type: none"> Place the cup into a rack. <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> Place in 15 × 85 tube (with sample bar code on tube). Verify there are no bubbles in sample. If cup is placed in a tube with a Bar Coded label a "reserved rack" must be used.
BD Microtainer®  <small>A014499L.EPS</small>	<ul style="list-style-type: none"> Place Microtainer in adapter P/N 472987. <p>(refer to figure to the right)</p> <ul style="list-style-type: none"> Verify there are no bubbles in sample. If cup is placed in a tube with a Bar Coded label a "reserved rack" must be used.  <small>A014500L.EPS</small>
0.5 mL Cup Insert (P/N 476399) (reusable)  <small>A011538L.EPS</small>	<ul style="list-style-type: none"> Place the metal Cup Insert into a 16 × 100 mm rack (P/N 471921 – blue or 474463 – purple). Insert a 0.5 mL Autoanalyzer cup into the Cup Insert. Run in the "reserved rack" mode.

Auto Serum Index/ORDAC

Auto ORDAC

p. 1.8.
Auto ORDAC permits the enabling or disabling of the automatic Overrange Detection and Correction (ORDAC) function for specified chemistries (refer to the Synchron Clinical Systems *Chemistry Information Manual* for a list of chemistries offering ORDAC). When a chemistry result exceeds the instrument printable range and Auto ORDAC is enabled, the sample will automatically rerun with either:

- a smaller sample size or
- an on-line sample dilution (chemistry dependent). *p. 1.8*

When Auto ORDAC for Ig-A and Haptoglobin is enabled, the URDAC feature is also enabled. Ig-A and Haptoglobin URDAC is used to analyze samples with concentrations below the analytical range. In this case, the system takes a larger sample volume.

(The manual ORDAC function in Sample Programming is used for samples which are known to exceed the usable range. Chemistries designated with manual ORDAC at the time of programming are run at the ORDAC sample volume.) *p. 1.8*

From the Setup Screen, select <1> **Auto Serum Index/ORDAC** to enable or disable ORDAC. The default for Auto ORDAC is **OFF**.

The Automatic ORDAC screen may be viewed at any time, however the system must be in *Standby* to modify the ORDAC selection.

NOTICE

The analytical ranges for each analyte are system limits found in the respective CISs. These are the ranges that Beckman Coulter has verified can be achieved by the system. There is no flagging associated with values exceeding these limits.

The instrument printable ranges for each analyte are internal system limits. These ranges actually exceed the analytical ranges by a certain limit. This allows for precision variations and still permits a result to print even though it exceeds the analytical range slightly. Results outside this range will be suppressed. The suppressed results will be flagged OIR HI or OIR LO (**O**ut of **I**nstrument **R**ange).

CHAPTER 6 Quality Control

Quality Control

Introduction

This task is performed when your laboratory protocol indicates that control material should be analyzed. A daily analysis of at least two levels of control materials is highly recommended. In addition, these controls should be run with each new calibration, with each new lot of reagents, and after specific maintenance or troubleshooting activities. However, users should determine their own frequency based on the NCCLS Proposed Guideline C24-P INTERNAL QUALITY CONTROL TESTING: PRINCIPLES AND DEFINITIONS.

Quality Control Program

The system Quality Control program provides the capability of monitoring system and chemistry performance by performing real-time analysis of control data.

p. 2.3.

The QC data is presented in both a summary format and in a chart format. Westgard QC rules are applied to the data to aid in determining chemistry and system reliability.

Determination of QC Flags

The DxC uses the Z-score method for standardizing the scale of a normally distributed measurement variable. For an individual control result, the Z-score represents the distance in standard deviations from the assigned mean. The Z-score is calculated from the following equation where:

X = the individual control result

\bar{X} = the assigned mean for the control

SD = the assigned standard deviation for the control

$$Z = \frac{X - \bar{X}}{SD}$$

E014425L.EPS

Each time a control result is received, the Z-score is calculated. If the Z-score is less than ± 2 SD, the result is within the assigned control range (the assigned mean ± 2 assigned standard deviations) and is considered acceptable.

Note: Results are flagged at time of run. Flagging is not changed if the operator modifies the assigned mean and/or SD.

Programming Functions

Introduction

Entering a dilution factor and programming a Manual Overrange Detection and Correction (ORDAC) feature are discussed below.

Entering a Dilution Factor

A dilution factor may be entered to be applied to the results of a specified sample. The dilution factor represents an off-line dilution prepared by the operator. The default dilution factor is 1X. Each result for the sample will be multiplied by the factor. Any final result generated by the system will be multiplied by the factor.

Programming a Manual ORDAC

For samples with analytes of known concentration that exceed the analytic range, the manual ORDAC feature may be selected. ORDAC compensates for extremely high concentrations by taking either a smaller sample volume or diluting the sample on-line. Selecting manual ORDAC in Sample Programming sends the request to run the test in ORDAC the first time it is run, unlike chemistries selected for Automatic ORDAC (which are run undiluted first and then rerun using ORDAC when recovery is out of range).

p. 1.8.

ORDAC is NOT available for uric acid that is run on urine samples.

Note: All ORDAC results are designated in the instrument code section on the appropriate results report.

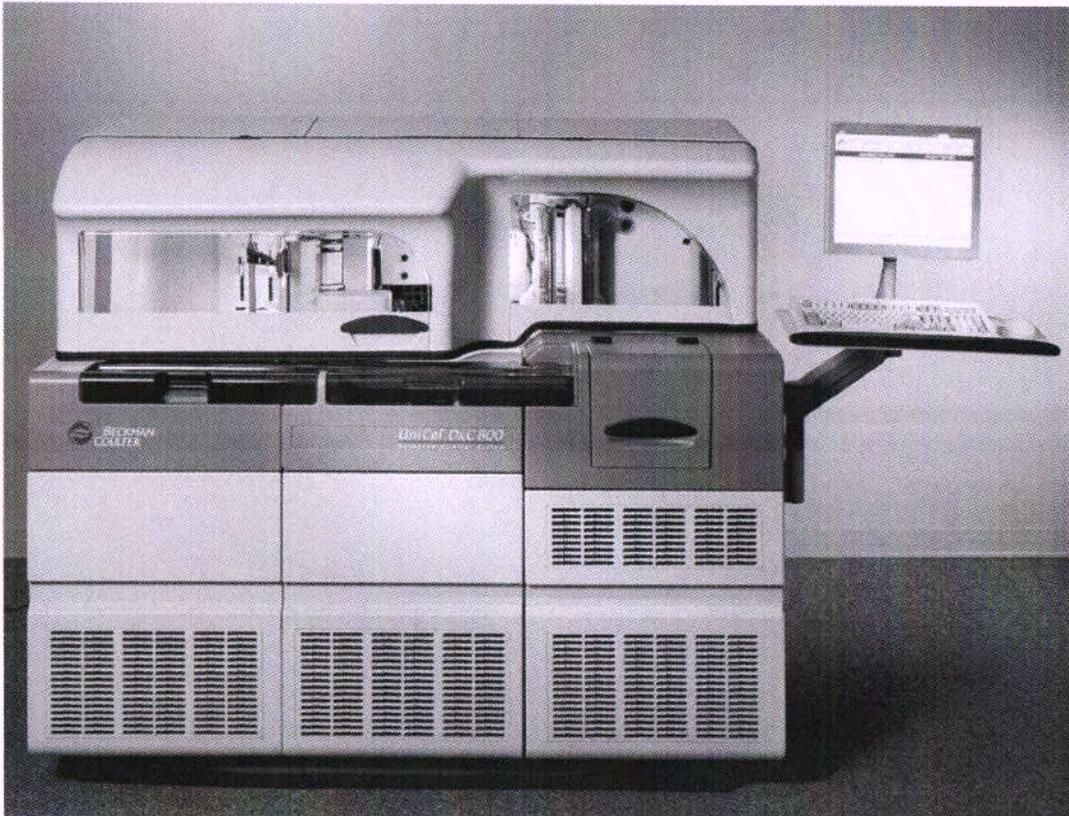
NOTICE

Results which include the "less than" (<) sign are also multiplied. For example, a CRP result with a sample dilution of 4, that should be reported out as "<0.5", will be reported out as "<2.0".



UniCel[®] DxC Synchron[®]

Klinikinės chemijos sistemos



„Naudojimo instrukcija“

Mėginių paėmimo sistema

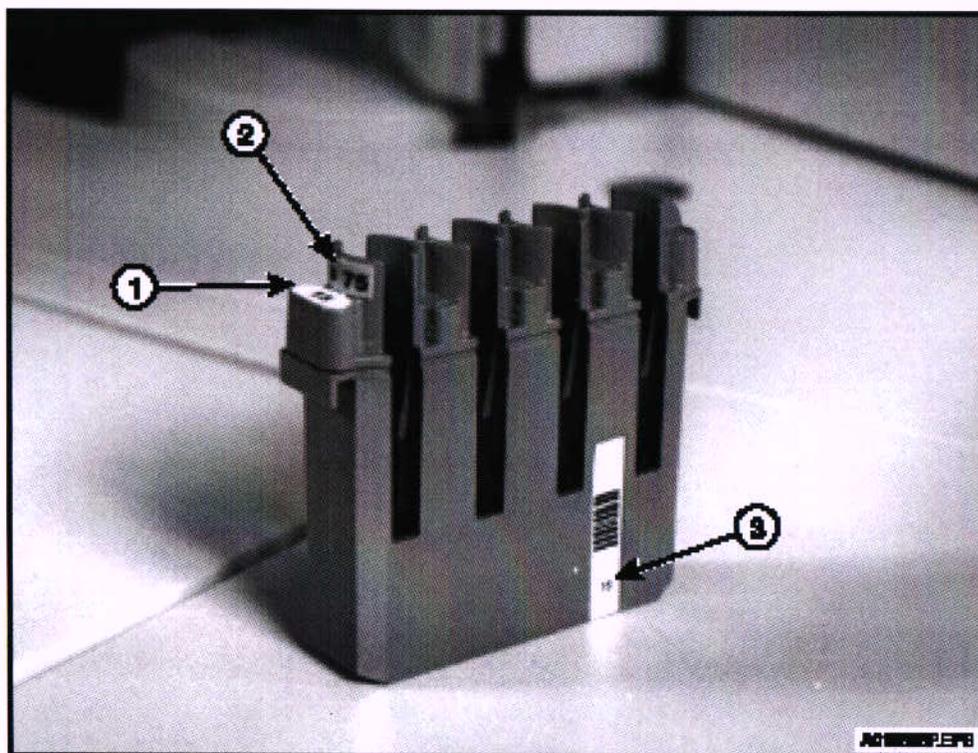
Įvadas

Mėginių paėmimo sistema sudaryta iš sekančių komponentų:

- Mėginio stovų
- Autokrautuvo/Iškrovimo tako
- Skubių mėginių pakrovimo pozicijos
- Šaudyklės
- p.1.1.4 • Brūkšninio kodo skaitymo įrenginio
- Kamštelių pradūrimo modulio (neprivalomas)
- Mėginių karuselės
- Mėginių zondo/maišyklės modulio
- Plovimo vonelių modulio
- p.1.1.11 • Užsikimšimo nustatymo modulio

Mėginių paėmimo moduliai yra naudojami pakrauti į sistemą mėginiams, tiekti mėginius tyrimams ir laikinai sauguti mėginius kol bus atlikti visi tyrimai.

Stovo identifikacijos lipdukai

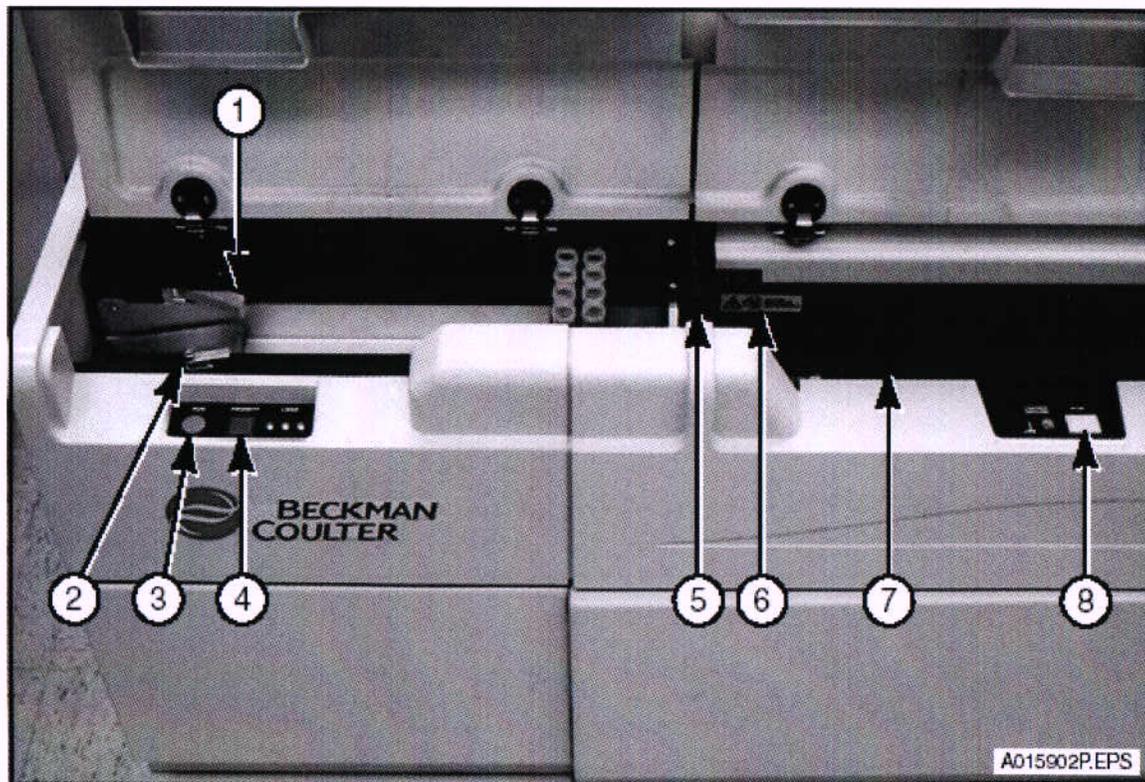


1. Skaitinis stovo identifikatoriaus numeris.
2. Stovo išmatavimų lipdukas.
3. Stovo identifikavimo brūkšninio kodo lipdukas.

Pav. 2.3 Stovas

Autokrautuvo/Iškrovimo takas

DxC 800 autokrautuvas gali talpinti 25 mėginių stovus, DxC 600 – 14 mėginių stovų.



- | | |
|--------------------------------------|------------------------|
| 1. Stūmikliai | 5. Mėginių vartai |
| 2. Autokrautuvas | 6. Šaudyklė |
| 3. Paleidimo mygtukas | 7. Iškrovimo takas |
| 4. Skubių mėginių pakrovimo mygtukas | 8. Sustabdymo mygtukas |

Pav. 2.4 Mėginių pakrovimo zona

p. 1.5 **Skubių mėginių pakrovimo pozicija**

Tarp autokrautuvo ir mėginių vartų yra skubių mėginių pakrovimo pozicija. Ji naudojama kartu su skubių mėginių pakrovimo mygtuku, kad pakrauti mėginius į rezervuotą skubiems mėginiams poziciją mėginių karuselėje.

Šaudyklė

Šaudyklė ištraukia mėginių stovus iš mėginių karuselės.

Brūkšninio kodo skaitymo įrenginys (mėginiams)

p. 1.4.1 Brūkšninių kodų skaitymo įrenginys yra II klasės lazerinis skeneris. Jis naudojamas nuskaityti stovo ir mėginių brūkšniniams kodams.

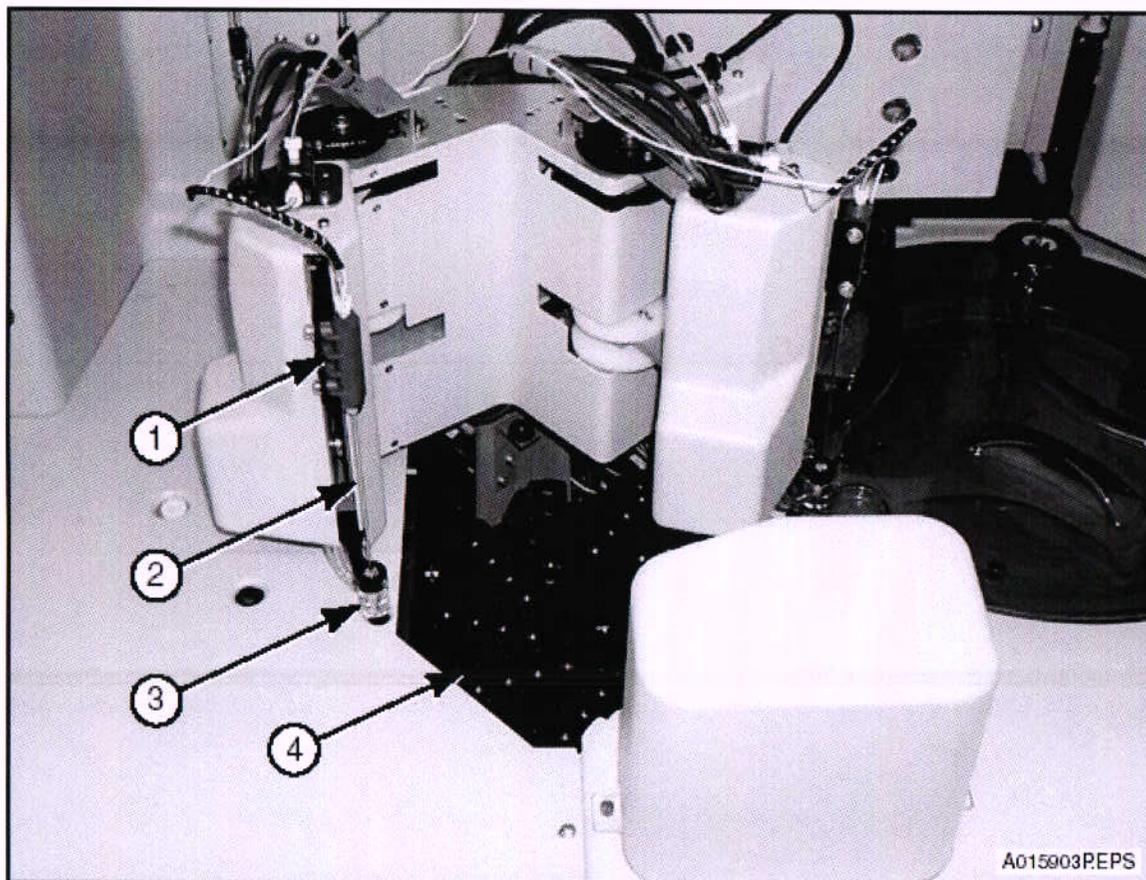
Kamštelių pradūrimo modulis (Neprivalomas)

p. 1.12

Kamštelių pradūrimo modulis leidžia mėginio zondui pasiekti mėginį, nenuėmus kamštelio nuo mėgintuvėlio. Tame pačiame mėginių stovė gali būti įdėti tuo pačiu metu mėgintuvėliai su kamšteliais ir be kamštelių.

Mėginių karuselė

Mėginių karuselė yra variklio pasukama ir turi 10 pozicijų. Normalaus darbo metu, ji naudoja 8 pozicijas, likusios paliekamos skubiems mėginiams.



1. Skysčio lygio jutiklio mazgas
2. Mėginio zondas (konteinerinės chemijos CC)
3. Žiedinis ploviklis
4. Mėginių karuselė.

Pav. 2.5 Mėginių karuselės zona

Mėginių programavimas ir tyrimas

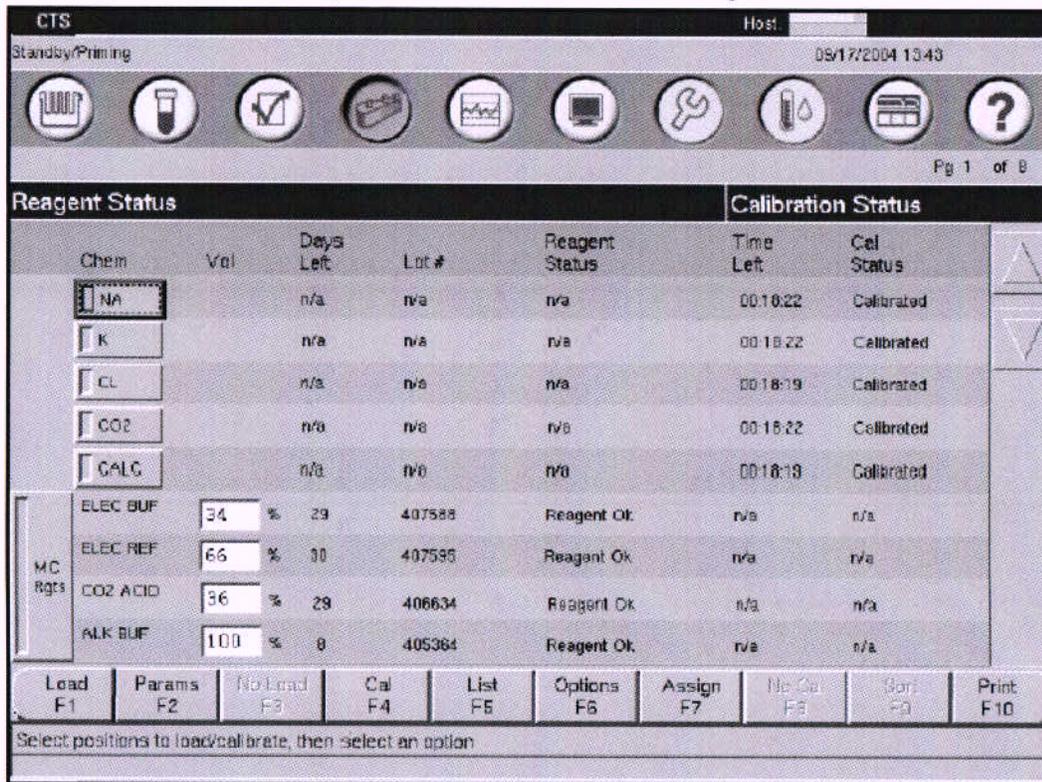
Mėginių su brūkšniniais kodais tyrimas

Paprastai, ankstesnio mėginių programavimo nereikia ištrinti prieš sudedant mėginius su brūkšniniu kodu į prietaisą. Jei laboratorijoje pasikartoja mėginio identifikatoriai (Sample ID), tai ankstesnis mėginių programavimas privalo būti ištrinti.

Žingsnis	Veiksmas
1	Sudėkite mėgintuvėlius į stovą taip, kad brūkšniniai kodai būtų matyti pro stovo plyšius toje pat pusėje, kur yra stovo brūkšninis kodas.
2	<p>Jei tyrimai bus atliekami iš uždarytų mėgintuvėlių, patikrinkite ar nesimato kraujo ant mėgintuvėlio kamštelio viršaus. Jei matosi kraujas, nuvalykite guminį kamštelį su ant pagaliuko užvyniota vata.</p> <p>Jei sistema neturi uždarytų mėgintuvėlių pradūrimo ar naudojami mėgintuvėliai netinkami pradūrimui, nuimkite kamštelius.</p>
3	<p>Rutininiams mėginiams ar, jei sistema yra parengties (Standby) režime: pirmumo mėginiai (mėginiai kuriuos reikia atlikti skubiai) turi būti patalpinami į autokrautuvą pirmiausia.</p> <ul style="list-style-type: none"> Į autokrautuvą įdėkite stovą su brūkšninių kodų etiketėmis, atsuktomis į dešinę ir Paspauskite RUN <p><i>p. 1.5</i> Ekstriniams (STAT) mėginiams: Jei sistema dirba ir autokrautuve yra kiti stovai,</p> <ul style="list-style-type: none"> Paspauskite PRIORITY. Stovo stūmiklis grįžta viena pozicija atgal, taigi ekstrinis (STAT) stovas gali būti įdėtas prieš kitus stovus. Paspauskite RUN

Rgts/Cal ekrano apžvalga

Jei Rgts/Cal simbolis yra raudonas ar geltonas pasirinkite jį ir ieškokite analičių, kurios yra išryškintos raudona ar geltona spalva. (Žiūrėkite į 5.1 pav.) Raudonai išryškintos analizės nebus tiriamos. Geltonai išryškintos analizės tiriamos, bet prieš pradėdami patikrinkite reagento tūrį. Įdėkite naują reagentą, jei reagento tūris nėra pakankamas laukiamiems tyrimams atlikti.



Reagent Status				Calibration Status			
Chem	Vol	Days Left	Lot #	Reagent Status	Time Left	Cal Status	
NA		n/a	n/a	n/a	00:10:22	Calibrated	
K		n/a	n/a	n/a	00:15:22	Calibrated	
CL		n/a	n/a	n/a	00:18:19	Calibrated	
CO2		n/a	n/a	n/a	00:15:22	Calibrated	
CALC		n/a	n/a	n/a	00:18:19	Calibrated	
MC Rgts	ELEC BUF	34 %	29	407588	Reagent Ok	n/a	n/a
	ELEC REF	66 %	30	407595	Reagent Ok	n/a	n/a
	CO2 ACID	36 %	29	406634	Reagent Ok	n/a	n/a
	ALK BUF	100 %	0	405364	Reagent Ok	n/a	n/a

Load F1 Params F2 No-Load F3 Cal F4 List F5 Options F6 Assign F7 No-Cal F8 Sort F9 Print F10

Select positions to load/calibrate, then select an option

Pav. 4.1 Reagento pakrovimo/kalibravimo langas

Reagentų pakrovimo užsakymas gali būti pateikiamas tuo pat metu arba atskirai modulinės chemijos (MC) ir konteinerinės chemijos (CC) prietaiso dalims ir gali būti atlikti, kol sistema yra parengties (Standby) ar tyrimo (Running) režimuose. Sistema automatiškai registruoja reagentų lygį visuose konteineriuose. Reagento būklės pranešimai yra surašyti 5.1 lentelėje.

Lentelė 4.1 Reagento būklės pranešimai

Pranešimas	Paaškinimas
Load requested (Užsakytas pakrovimas)	Reagento pozicijoje užsakytas reagento pakrovimas, bet sistema tęsia tyrimus
Parameters Required (Reikalingi parametrai)	Praleisti reagento konteinerio parametrai, kai konteineris buvo įdėtas, jie nebuvo įvesti.
Reagent Ok (Reagentas tvarkoje)	Nėra jokių klaidų požymių
Reagent Expired (Baigėsi reagento galiojimo laikas)	Reagentas viršijo laikymo termino stabilumo datą
Days Exceeded (Viršytas dienų skaičius)	Reagentas pakrautas sistemoje buvo daugiau negu leistina.

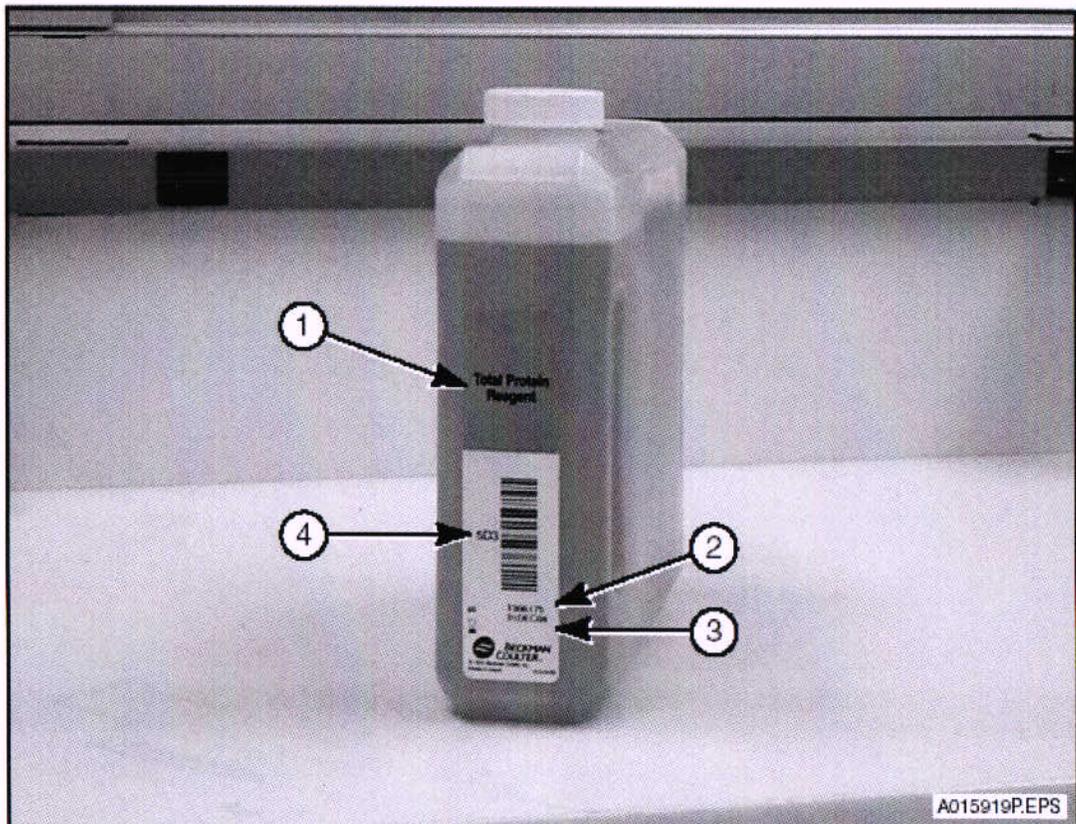
0 Test Available (Liko 0 testų)	Reagentas pilnai sunaudotas; reagento konteineris tuščias
Level pending (Lygio nustatymas)	Reagento konteineris buvo įdėtas ir laukia lygio nustatymo
Level Sense Error (Lygio nustatymo klaida)	Reagento lygio patikrinimas nepavyko. Nepavyko viename ar daugiau skyrių tinkamai nustatyti reagentą
n/a	Reagento būklė nėra tinkama analitėms (pvz. Elektrolitų analitėms)

Reagento pakrovimas/iškrovimas

MC reagentų informacija

DxC sistema pakrauna ir iškrauna modulinės chemijos reagentus (MC), naudodama brūkšnių kodų sistemą. Reagento brūkšninio kodo informacija apima:

- Serijos numerį
- Partijos numerį
- Galiojimo datą
- Reagento pavadinimą



1. Reagento pavadinimas
 2. Serijos numeris

3. Partijos numeris
 4. Galiojimo data

Pav. 4.2 MC reagento informacija

Žingsnis	Veiksmas (tęsinys)
6	<p>Kiekvieno naujo reagentų butelio brūkšninio kodo nuskaitymui naudokitės rankiniu brūkšninio kodo skaitymo įrenginiu. Parodydama sėkmingą brūkšnio kodo nuskaitymą sistema „pyptels“.</p> <p>Patikrinkite monitoriuje, kad įsitikintumėte, kad parodomi reagento duomenys. Kai tik nuskenuojama, reagento lange atsiranda dabartinė reagento informacija. Jei brūkšninis kodas negali būti nuskenuotas, reagentas gali būti pakrautas rankiniu būdu. Jei brūkšninis kodas negali būti nuskenuotas, rankiniu būdu ištrinkite reagentą, pasirinkdami Clear [F1], įrašykite naują informaciją ir pasirinktą reagento butelį įdėkite į sistemą.</p>
7	Uždarykite duris ir pasirinkite Done [F10] . Pakrautiems cheminiams reagentams toliau pereikite prie 8 žingsnio.
8	Prieš tiriant pacientų mėginius pakrautus reagentus sukalibruokite ir atlikite kokybės kontrolę (QC).

CC reagento informacija

p. 2.2
p. 3.1

DxC sistema naudoja konteinerių brūkšninį kodą reagentų pavadinimo, partijos numerio, galiojimo datos (pvz. 200601) bei konteinerio serijos numerio nustatymui ir duomenų įrašymui. Žiūrėkite į Pav. 4.7. Be to, sistema išsaugoja atmintyje pakrautų ir iškrautų konteinerių kalibravimo būseną.

- Reagentai gali būti pakraunami, kai sistema atlieka tyrimus, yra laukimo ar parengties (Standby) būsenoje.
- Reagentų paruošimo instrukcijų ieškokite reagentų dėžutėse ar reagentų paruošimo kortelėse.
- Prieš pakrovimą dangteliai nuo konteinerių turi būti nuimti.
- Prieš pakrovimą patikrinkite ar konteinerių skyriuose nėra burbulų. Burbulų pašalinimui naudokite lazdelę su vatos antgaliu.

Kokybės kontrolės grafikas (Levey – Jennings)

Ivadas

p. 2.3

Kokybės kontrolės grafikas atvaizduoja kontrolės rezultatus už pasirinktą periodą (pagal nutylėjimą yra parenkama einamoji data) grafinėje formoje, atvaizduojant matavimų taškų poziciją priskirto vidurkio reikšmės atžvilgiu ir atvaizduojant standartinį nuokrypį. Rezultatai pateikiami pagal datą ir laiką, pirmiausia pateikiamas naujausias rezultatas. Kokybės kontrolės grafikas prieinamas iš standžiojo disko arba disketės.

Išpėjimas: spalvinis žymėjimas paremtas priskirta vidurkio reikšme ir standartinio nuokrypio (SD) reikšme, kurios buvo kontrolės atlikimo metu. Jei priskirta vidurkio reikšmė ir/arba standartinio nuokrypio reikšmė pakeičiama, spalvinis žymėjimas nepasikeis.

Priėjimas prie kokybės kontrolės grafikų

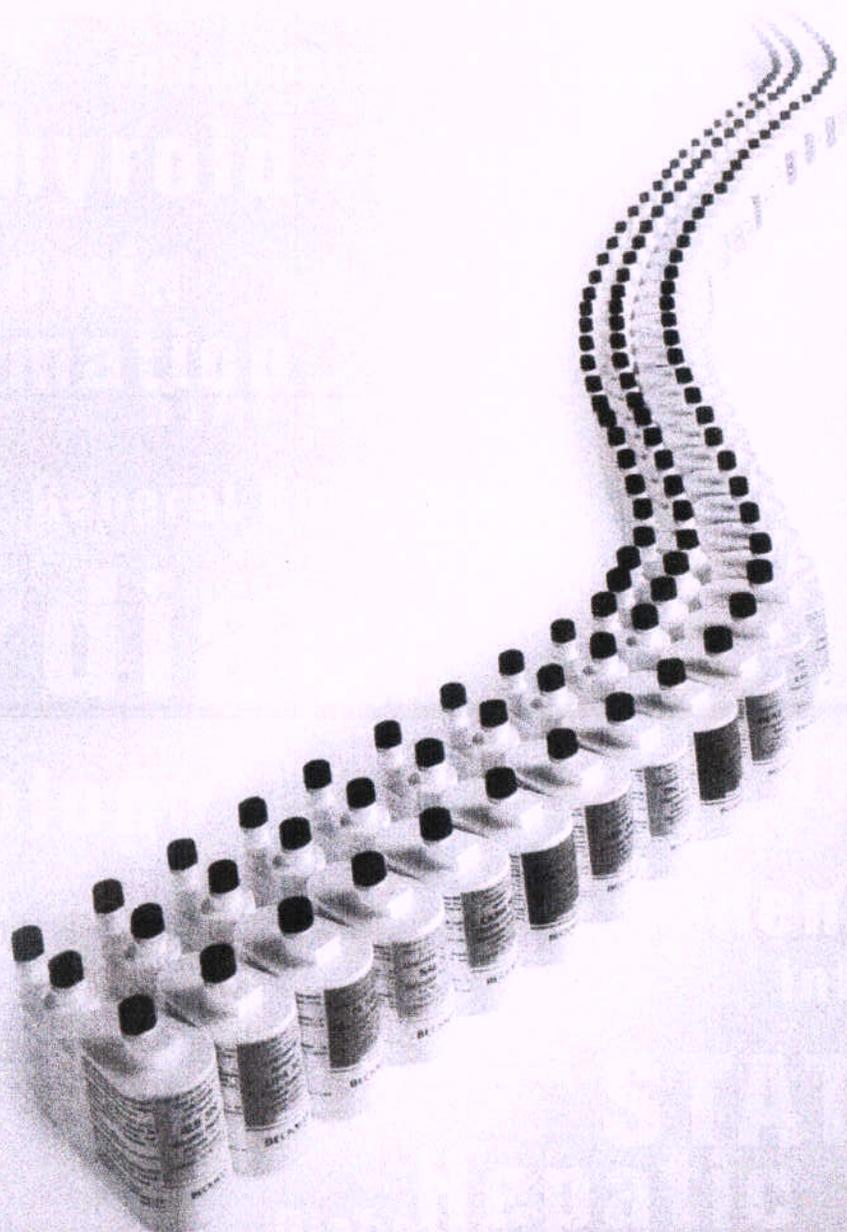
Atlikite žemiau nurodytus žingsnius, kad prieiti prie kokybės kontrolės (QC) grafikų.

Žingsnis	Veiksmas
1	Iš meniu juostos išrinkite kokybės kontrolės (QC) simbolį
2	Iš kokybės kontrolės (QC) lango pasirinkite jau apibrėžtą kontrolę arba klaviatūros pagalba surinkite norimos peržvelgti kontrolės numerį.
3	Pasirinkite Chart [F7] .
4	Įrašykite kokybės kontrolės (QC) grafiko pradžios ir pabaigos datas į datos intervalo laukelius arba paspauskite [Enter] , kad pasirinkti dabartinę, siūlomą data pagal nutylėjimą. Judėjimui tarp laukelių naudokitės [Tab] klavišu. Išpėjimas: Jei pasirinktoms datoms duomenų nėra, pasirodys pranešimas „No Data Available“ (Duomenų nėra).
5	Nustatytos išrinktai kontrolei analitės yra pateikiamos sąrašė. Visos analitės rodomos kaip pasirinktos. Patogumui yra du būdai atrinkti analites į grafikus: <ul style="list-style-type: none"> • Jei reikia išsirinkti didžiąją dalį rodomų analičių grafikų sudarymui, pasirinkite visas analites, kurios NETURI BŪTI naudojamos grafikų sudarymui. Tada pasirinkite <Remove>.

Chemistry quick reference. //

The **power** of menu.

Synchron LX® Clinical Systems
UniCel® DxC Clinical Systems



Chemistry

Lab Automation

Information Systems

Molecular Diagnostics

Immunodiagnosics

Centrifugation

Disease Management

Hematology

Hemostasis

Flow Cytometry

Primary Care

Chemistry Quick Reference

Chemistry Name	Acetaminophen	Alanine Aminotransferase	Alanine Aminotransferase (IFCC) <i>p. 4.3</i>
Measurement Principle	Immuno-turbidimetric	Henry	P5P Activated
Chemistry Abbreviation	ACTM	ALT	ALT-
Reaction Type	Rate 1	Rate 1	Rate 1
Primary Wavelength	340 nm	340 nm	340 nm
Reaction Period	Start: 112 seconds Stop: 160 seconds	Start: 112 seconds Stop: 176 seconds	Start: 224 seconds Stop: 304 seconds
Sample Type	Serum/Plasma	Serum/Plasma	Serum/Plasma
Sample Size			
Serum/Plasma	5 µL	23 µL	23 µL
Urine	N/A	N/A	N/A
CSF	N/A	N/A	N/A
URDAC	N/A	N/A	N/A
ORDAC	N/A	3 µL	3 µL
Reference Interval			
Serum/Plasma	See Chemistry Information Sheet	M 17-63 IU/L F 14-54 IU/L	M 45 IU/L F 34 IU/L
Urine	N/A	N/A	N/A
CSF	N/A	N/A	N/A
Analytical Range			
Serum/Plasma	10-300 µg/mL	5-400 IU/L	5-400 IU/L
Urine	N/A	N/A	N/A
CSF	N/A	N/A	N/A
URDAC	N/A	N/A	N/A
ORDAC	N/A	350-2600 IU/L	350-2600 IU/L <i>p. 4.3</i>
Precision Specification (Use the greater number)			
Serum/Plasma	4% or 2.0 µg/mL	3.5% or 3 IU/L	3.5% or 3 IU/L
Urine	N/A	N/A	N/A
CSF	N/A	N/A	N/A
ORDAC	N/A	10%	10%
Reagent Volume	A 230 µL B 40 µL C 32 µL	A 242 µL B 8 µL C N/A	A 250 µL B 8 µL C N/A
Kit Size	1 x 100 tests/cartridge	2 x 200 tests/cartridge 2 x 400 tests/cartridge	2 x 100 tests/cartridge 2 x 300 tests/cartridge
On-Instrument Stability	42 days	30 days	10 days
Storage Temperature	+2 to +8°C	+2 to +8°C	+2 to +8°C
Calibration Frequency	14 days	N/A	5 days
Within-Lot	60 days	N/A	30 days
Compatible Anticoagulants	Lithium Heparin Sodium Heparin EDTA	Ammonium Heparin EDTA Lithium Heparin Sodium Heparin	Ammonium Heparin EDTA Lithium Heparin Sodium Heparin
Reagent Part Number	472169	442620 2 x 200 tests/cartridge 476826 2 x 400 tests/cartridge	467840 300 tests/cartridge 467848 100 tests/cartridge
Calibrator Part Number	469630	N/A	441350
Control Part Number	657365, 472461, 67, 72	657365	657365
Comment		Transfer C into A (P/N 442620) Pour vial into A (P/N 476826).	Transfer C into A (P/N 467848) Calibration required.

Chemistry Quick Reference

Chemistry Name	Albumin	Alkaline Phosphatase	Alkaline Phosphatase (IFCC/DGKCh) <i>p. 4.20</i>
Measurement Principle	BCP	Kinetic Rate	Kinetic Rate
Chemistry Abbreviation	ALB	ALP	ALP
Reaction Type	Endpoint 2	Rate 1	Rate 1
Primary Wavelength	600 nm	410 nm	410 nm
Reaction Period	Start: 75 seconds Stop: 105 seconds	Start: 128 seconds Stop: 280 seconds	Start: 128 seconds Stop: 280 seconds
Sample Type	Serum/Plasma	Serum/Plasma	Serum/Plasma
Sample Size			
Serum/Plasma	3 µL	5 µL	5 µL
Urine	N/A	N/A	N/A
CSF	N/A	N/A	N/A
URDAC	N/A	N/A	N/A
ORDAC	N/A	3 µL	3 µL
Reference Interval			
Serum/Plasma	3.5-5.0 g/dL SI Units 35-50 g/L	38-126 IU/L SI Units 0.65-2.14 µkat/L	See Chemistry Information Sheet
Urine	N/A N/A	N/A N/A	N/A
CSF	N/A N/A	N/A N/A	N/A
Analytical Range			
Serum/Plasma	1.0-7.0 g/dL SI Units 10-70 g/L	5-1000 IU/L SI Units 0.1-16.7 µkat/L	5-1000 IU/L SI Units 0.1-16.7 µkat/L
Urine	N/A N/A	N/A N/A	N/A N/A
CSF	N/A N/A	N/A N/A	N/A N/A
URDAC	N/A N/A	N/A N/A	N/A N/A
ORDAC	N/A N/A	800-1650 IU/L 13.3-27.5 µkat/L	<i>p. 4.19</i> <u>800-1650 IU/L</u> 13.3-27.5 µkat/L
Precision Specification (Use the greater number)			
Serum/Plasma	3.0% or 0.20 g/dL SI Units 3.0% or 2 g/L	3.5% or 3 IU/L SI Units 3.5% or 0.05 µkat/L	3.5% or 3 IU/L SI Units 3.5% or 0.05 µkat/L
Urine	N/A N/A	N/A N/A	N/A N/A
CSF	N/A N/A	N/A N/A	N/A N/A
ORDAC	N/A N/A	10% 10%	10% 10%
Reagent Volume	A 300 µL B N/A C N/A	A 228 µL B 22 µL C N/A	A 228 µL B 22 µL C N/A
Kit Size	2 x 300 tests/cartridge	2 x 200 tests/cartridge 2 x 400 tests/cartridge	2 x 200 tests/cartridge 2 x 400 tests/cartridge
On-Instrument Stability	30 days	10 days	30 days
Storage Temperature	Room Temperature	+2 to +8°C	+2 to +8°C
Calibration Frequency	14 days	N/A	10 days
Within-Lot	90 days	N/A	30 days
Compatible Anticoagulants	Ammonium Heparin EDTA Lithium Heparin Sodium Heparin	Ammonium Heparin Lithium Heparin Sodium Heparin	Ammonium Heparin Lithium Heparin Sodium Heparin
Reagent Part Number	442765	442670 2 x 200 tests/cartridge 476821 2 x 400 tests/cartridge	442670 2 x 200 tests/cartridge 476821 2 x 400 tests/cartridge
Calibrator Part Number	442600	N/A	441350
Control Part Number	657365	657365	657365
Comment			Calibration required.

Chemistry Name	Ammonia		Amylase		Antistreptolysin-O <i>p.4.5</i>
Measurement Principle	Enzymatic		Enzymatic-DS		Immunoturbidimetric
Chemistry Abbreviation	AMM		AMY		ASO-
Reaction Type	Endpoint 2		Rate 1		Rate 1
Primary Wavelength	340 nm		340 nm		340 nm
Reaction Period	Start: 304 seconds Stop: 352 seconds		Start: 200 seconds Stop: 264 seconds		Start: 8 seconds Stop: 40 seconds
Sample Type	Plasma		Serum/Plasma/Urine		Serum/Plasma
Sample Size					
Serum/Plasma	40 µL		12 µL		6 µL
Urine	N/A		12 µL		N/A
CSF	N/A		N/A		N/A
URDAC	N/A		N/A		N/A
ORDAC	N/A		3 µL		3 µL
Reference Interval					
Serum/Plasma	16-60 µg/dL	SI Units 9-35 µmol/L	36-128 U/L	SI Units 0.3-1.07 µkat/L	<145 IU/mL
Urine	N/A	N/A	1-17 U/hr	0.01-0.14 µkat/hr	N/A
CSF	N/A	N/A	N/A	N/A	N/A
Analytical Range					
Serum/Plasma	16-1700 µg/dL	SI Units 9-1000 µmol/L	5-800 U/L	SI Units 0.04-6.68 µkat/L	25-800 IU/mL
Urine	N/A	N/A	5-800 U/L	0.04-6.68 µkat/L	N/A
CSF	N/A	N/A	N/A	N/A	N/A
URDAC	N/A	N/A	N/A	N/A	N/A
ORDAC	N/A	N/A	600-2400 U/L	5.01-20.04 µkat/L	640-1600 IU/ml <i>p.4.5</i>
Precision Specification (Use the greater number)					
Serum/Plasma	2% or 8.5 µg/dL	SI Units 2% or 5 µmol/L	3.5% or 3 U/L	SI Units 3.5% or 0.03 µkat/L	4% or 10 IU/mL
Urine	N/A	N/A	3.5% or 3 U/L	3.5% or 0.03 µkat/L	N/A
CSF	N/A	N/A	N/A	N/A	N/A
ORDAC	N/A	N/A	10%	10%	4%
Reagent Volume					
A	180 µL		238 µL		250 µL
B	40 µL		N/A		50 µL
C	6 µL		12 µL		N/A
Kit Size	2 x 25 tests/cartridge		2 x 200 tests/cartridge		2 x 100 tests/cartridge
On-Instrument Stability	30 days		30 days		60 days
Storage Temperature	+2 to +8°C		+2 to +8°C		+2 to +8°C
Calibration Frequency	5 days		N/A		30 days
Within-Lot	N/A		N/A		60 days
Compatible Anticoagulants	EDTA Sodium Heparin		Ammonium Heparin Lithium Heparin Sodium Heparin		EDTA Lithium Heparin Sodium Heparin
Reagent Part Number	439770 ✓		442775		469165 ✓
Calibrator Part Number	Included		N/A		469965
Control Part Number	465990, 93, 96		657365		450162, 63, 64
Comment					

Chemistry Name	Aspartate Aminotransferase (IFCC) <i>p.4.3</i>		Blood Urea Nitrogen	Carbamazepine
Measurement Principle	P5P Activated		Enzymatic	Immunoturbidimetric
Chemistry Abbreviation	AST-		BUN	CAR
Reaction Type	Rate 1		Rate 1	Endpoint 2
Primary Wavelength	340 nm		340 nm	340 nm
Reaction Period	Start: 224 seconds Stop: 304 seconds		Start: 32 seconds Stop: 64 seconds	Start: 528 seconds Stop: 584 seconds
Sample Type	Serum/Plasma		Serum/Plasma/Urine	Serum/Plasma
Sample Size	Serum/Plasma 23 µL Urine N/A CSF N/A URDAC N/A ORDAC 3 µL		3 µL 3 µL (1:10 dil.)* N/A N/A N/A N/A	3 µL N/A N/A N/A N/A
Reference Interval	Serum/Plasma M 35 IU/L F 31 IU/L Urine N/A CSF N/A		8-26 mg/dL 12-20 g/24 hr N/A	See Chemistry Information Sheet N/A N/A
	SI Units M 0.58 µkat/L F 0.52 µkat/L N/A N/A		SI Units 2.9-9.3 mmol/L 0.43-0.71 mol/24 hr N/A	
Analytical Range	Serum/Plasma 10-400 IU/L Urine N/A CSF N/A URDAC N/A ORDAC <u>350-2600 IU/L</u> <i>p.4.3</i>		5-100 mg/dL 50-1000 mg/dL N/A N/A N/A	2-20 µg/mL N/A N/A N/A N/A
	SI Units 0.2-6.7 µkat/L N/A N/A N/A 5.8-43.3 µkat/L		SI Units 1.8-35.7 mmol/L 17.9-357 mmol/L N/A N/A N/A	SI Units 8.5-84.6 µmol/L N/A N/A N/A N/A
Precision Specification (Use the greater number)	Serum/Plasma 3.5% or 3 IU/L Urine N/A CSF N/A ORDAC 10%		3% or 2 mg/dL 3% or 3 mg/dL N/A N/A	5% or 0.6 µg/mL N/A N/A N/A
	SI Units 3.5% or 0.05 µkat/L N/A N/A 10%		SI Units 3% or 0.71 mmol/L 3% or 1.07 mmol/L N/A N/A	SI Units 5% or 2.5 µmol/L N/A N/A N/A
Reagent Volume	A 250 µL B 8 µL C N/A		A 285 µL B 15 µL C N/A	A 230 µL B 30 µL C 32 µL
Kit Size	2 x 100 tests/cartridge 2 x 300 tests/cartridge		2 x 300 tests/cartridge	2 x 100 tests/cartridge
On-Instrument Stability	10 days		30 days	42 days
Storage Temperature	+2 to +8°C		+2 to +8°C	+2 to +8°C
Calibration Frequency Within-Lot	5 days 30 days		24 hours 30 days	14 days 60 days
Compatible Anticoagulants	Ammonium Heparin EDTA Lithium Heparin Sodium Heparin		EDTA NH ₄ , NA, Li-Heparin Sodium Fluoride/Potassium Oxalate	Lithium Heparin Sodium Heparin
Reagent Part Number	467845 2 x 300 tests/cartridge 467849 2 x 100 tests/cartridge		442750	469112
Calibrator Part Number	441350		442600	469600
Control Part Number	657365		657365	657365, 472461, 67, 72
Comment	Transfer C into A (P/N 467845) Calibration required.		DIL 1 required for on-board urine sample dilution.	

*Reaction volume, actual sample volume required differs due to on-board dilution. Refer to Chemistry Information Sheets for details.

Chemistry Quick Reference

Chemistry Name	<u>Cholesterol</u>	Cholinesterase	Cholinesterase (DGKCh)
Measurement Principle	Enzymatic	S-Butyrylthiocholine Iodide	S-Butyrylthiocholine Iodide
Chemistry Abbreviation	CHOL	CHE	CHE
Reaction Type	Endpoint 2	Rate 1	Rate 1
Primary Wavelength	520 nm	410 nm	410 nm
Reaction Period	Start: 320 seconds Stop: 352 seconds	Start: 16 seconds Stop: 64 seconds	Start: 16 seconds Stop: 64 seconds
Sample Type	Serum/Plasma	Serum/Plasma	Serum/Plasma
Sample Size			
Serum/Plasma	3 µL	3 µL	3 µL
Urine	N/A	N/A	N/A
CSF	N/A	N/A	N/A
URDAC	N/A	N/A	N/A
ORDAC	2 µL	N/A	N/A
Reference Interval			
Serum/Plasma	See Chemistry Information Sheet	5859-13060 U/L SI Units 98-218 µkat/L	M 4620-11500 U/L F 3930-10800 U/L SI Units M 79-192 µkat/L F 66-180 µkat/L
Urine	N/A	N/A	N/A
CSF	N/A	N/A	N/A
Analytical Range			
Serum/Plasma	5-750 mg/dL SI Units 0.13-19.43 mmol/L	250-20000 U/L SI Units 4-334 µkat/L	250-20000 U/L SI Units 4-334 µkat/L
Urine	N/A	N/A	N/A
CSF	N/A	N/A	N/A
URDAC	N/A	N/A	N/A
ORDAC	600-1000 mg/dL SI Units 15.54-25.9 mmol/L	N/A	N/A
Precision Specification (Use the greater number)			
Serum/Plasma	3% or 5 mg/dL SI Units 3% or 0.13 mmol/L	3.5% or 60 U/L SI Units 3.5% or 1 µkat/L	3.5% or 60 U/L SI Units 3.5% or 1 µkat/L
Urine	N/A	N/A	N/A
CSF	N/A	N/A	N/A
ORDAC	10%	N/A	N/A
Reagent Volume	A 290 µL B N/A C 10 µL	A 300 µL B 15 µL C N/A	A 300 µL B 15 µL C N/A
Kit Size	2 x 300 tests/cartridge	2 x 250 tests/cartridge	2 x 250 tests/cartridge
On-Instrument Stability	30 days	42 days	42 days
Storage Temperature	+2 to +8°C	+2 to +8°C	+2 to +8°C
Calibration Frequency	14 days	N/A	7 days
Within-Lot	90 days	N/A	30 days
Compatible Anticoagulants	Ammonium Heparin Lithium Heparin Sodium Heparin	Ammonium Heparin	Ammonium Heparin
Reagent Part Number	467825	443797	443797
Calibrator Part Number	442600	N/A	441350
Control Part Number	657365 or 469905, 465980, 981, 982	657365	657365
Comment		Reagent preparation required.	Reagent preparation and calibration required.

Chemistry Quick Reference

Chemistry Name	C-Reactive Protein* <i>p.4.11</i>	Creatine Kinase	Creatine Kinase (IFCC) <i>p.4.3</i>
Measurement Principle	Immunoturbidimetric	Rosalki	NAC Activated
Chemistry Abbreviation	C-RP	CK	CK-
Reaction Type	Rate 1	Rate 1	Rate 1
Primary Wavelength	600 nm	340 nm	340 nm
Reaction Period	Start: 1 second Stop: 32 seconds	Start: 184 seconds Stop: 240 seconds	Start: 144 seconds Stop: 208 seconds
Sample Type	Serum/Plasma	Serum/Plasma	Serum/Plasma
Sample Size			
Serum/Plasma	6 µL	13 µL	12 µL
Urine	N/A	N/A	N/A
CSF	N/A	N/A	N/A
URDAC	N/A	N/A	N/A
ORDAC	3 µL	3 µL	3 µL
Reference Interval			
Serum/Plasma	< 0.75 mg/dL SI Units < 7.5 mg/L	M 49-397 IU/L F 38-234 IU/L	M 171 IU/L F 145 IU/L
Urine	N/A N/A	N/A N/A	N/A N/A
CSF	N/A N/A	N/A N/A	N/A N/A
Analytical Range			
Serum/Plasma	0.10-25 mg/dL SI Units 1.0-250 mg/L	5-1200 IU/L	5-1200 IU/L
Urine	N/A N/A	N/A N/A	N/A N/A
CSF	N/A N/A	N/A N/A	N/A N/A
URDAC	N/A N/A	N/A N/A	N/A N/A
ORDAC	20-50 mg/dL 200-500 mg/L <i>p.4.11</i>	860-4100 IU/L	860-4100 IU/L <i>p.4.3</i> 14.3-68.3 µkat/L
Precision Specification (Use the greater number)			
Serum/Plasma	5.0% or 0.05 mg/dL SI Units 5% or 0.5 mg/L	3.5% or 5 IU/L	3.5% or 5 IU/L
Urine	N/A N/A	N/A N/A	N/A N/A
CSF	N/A N/A	N/A N/A	N/A N/A
ORDAC	10% 10%	10% 10%	10% 10%
Reagent Volume	A 250 µL B 50 µL C N/A	A 238 µL B 22 µL C N/A	A 242 µL B 22 µL C N/A
Kit Size	2 x 200 tests/cartridge	2 x 200 tests/cartridge 2 x 400 tests/cartridge	2 x 200 tests/cartridge
On-Instrument Stability	60 days	30 days	21 days
Storage Temperature	+2°C to +8°C	+2 to +8°C	+2 to +8°C
Calibration Frequency Within-Lot	30 days 60 days	N/A N/A	21 days 30 days
Compatible Anticoagulants	EDTA Lithium Heparin Sodium Heparin	Ammonium Heparin EDTA Lithium Heparin Sodium Heparin	Ammonium Heparin EDTA Lithium Heparin Sodium Heparin
Reagent Part Number	969620	442635 2 x 200 tests/cartridge 476836 2 x 400 tests/cartridge	467830
Calibrator Part Number	469965	N/A	441350
Control Part Number	450162, 63, 64	657365	657365
Comment		Transfer C into A (P/N 442635) Pour vial into A (P/N 476836)	Transfer C into A. Calibration required.

*Not available in the U.S. or Canada

Chemistry Quick Reference

Chemistry Name	Digoxin	Direct Bilirubin	Gamma-Glutamyl Transferase
Measurement Principle	Immunoturbidimetric	Diazo	Szasz
Chemistry Abbreviation	DIGN	DBIL	GGT
Reaction Type	Rate 1	Endpoint 2	Rate 1
Primary Wavelength	560 nm	560 nm	410 nm
Reaction Period	Start: 416 seconds Stop: 464 seconds	Start: 416 seconds Stop: 448 seconds	Start: 64 seconds Stop: 184 seconds
Sample Type	Serum/Plasma	Serum/Plasma	Serum/Plasma
Sample Size			
Serum/Plasma	15 µL	10 µL	13 µL
Urine	N/A	N/A	N/A
CSF	N/A	N/A	N/A
URDAC	N/A	N/A	N/A
ORDAC	N/A	N/A	3 µL
Reference Interval	See Chemistry Information Sheet	0.1-0.5 mg/dL	7-50 IU/L
Serum/Plasma		SI Units 1.7-8.6 µmol/L	SI Units 0.1-0.9 µkat/L
Urine	N/A	N/A	N/A
CSF	N/A	N/A	N/A
Analytical Range			
Serum/Plasma	0.2-4.5 ng/mL	0.1-10 mg/dL	5-750 IU/L
Urine	N/A	N/A	N/A
CSF	N/A	N/A	N/A
URDAC	N/A	N/A	N/A
ORDAC	N/A	N/A	550-3000 IU/L
Precision Specification (Use the greater number)			
Serum/Plasma	5% or 0.1 ng/mL	5% or 0.15 mg/dL	3.5% or 3 IU/L
Urine	N/A	N/A	N/A
CSF	N/A	N/A	N/A
ORDAC	N/A	N/A	10%
Reagent Volume	A 185 µL B 15 µL C 25 µL	A 310 µL B 10 µL C N/A	A 237 µL B 23 µL C N/A
Kit Size	2 x 100 tests/cartridge	2 x 200 tests/cartridge 2 x 300 tests/cartridge	2 x 200 tests/cartridge 2 x 400 tests/cartridge
On-Instrument Stability	30 days	30 days	7 days
Storage Temperature	+2 to +8°C	Room Temperature	+2 to +8°C
Calibration Frequency	14 days	14 days	N/A
Within-Lot	42 days	90 days	N/A
Compatible Anticoagulants	Lithium Heparin Sodium Heparin EDTA	EDTA NH ₄ , NA, Li-Heparin Sodium Citrate Sodium Fluoride/Potassium Oxalate	Ammonium Heparin Lithium Heparin Sodium Heparin
Reagent Part Number	650182	439715 2 x 200 tests/cartridge 476856 2 x 300 tests/cartridge	442650 2 x 200 tests/cartridge 476846 2 x 400 tests/cartridge
Calibrator Part Number	469630	465915	N/A
Control Part Number	657365, 472461, 67, 72	667710, 20, 30, 40	657365
Comment			

Chemistry Name	Gamma-Glutamyl Transferase (IFCC) <i>p.4.3</i>		Gentamicin	Glucose	
Measurement Principle	Szasz		Immunoturbidimetric	UV-Hexokinase	
Chemistry Abbreviation	GGT		GEN	GLU	
Reaction Type	Rate 1		Endpoint 2	Endpoint 2	
Primary Wavelength	410 nm		380 nm	340 nm	
Reaction Period	Start: 64 seconds Stop: 184 seconds		Start: 600 seconds Stop: 648 seconds	Start: 184 seconds Stop: 208 seconds	
Sample Type	Serum/Plasma		Serum/Plasma	Serum/Plasma/Urine/CSF	
Sample Size	13 µL		3 µL	3 µL	
Serum/Plasma	13 µL		3 µL	3 µL	
Urine	N/A		N/A	3 µL	
CSF	N/A		N/A	3 µL	
URDAC	N/A		N/A	N/A	
ORDAC	3 µL		N/A	N/A	
Reference Interval	SI Units		SI Units		SI Units
Serum/Plasma	M 55 IU/L F 38 IU/L	M 0.92 µkat/L F 0.63 µkat/L	See Chemistry Information Sheet		79-115 mg/dL 4.4-6.4 mmol/L
Urine	N/A	N/A	N/A	N/A	1-15 mg/dL 0.06-0.83 mmol/L
CSF	N/A	N/A	N/A	N/A	40-70 mg/dL 2.2-3.9 mmol/L
Analytical Range	SI Units		SI Units		SI Units
Serum/Plasma	5-750 IU/L	0.1-12.5 µkat/L	0.5-12 µg/mL	1-25.1 µmol/L	5-700 mg/dL 0.3-38.8 mmol/L
Urine	N/A	N/A	N/A	N/A	5-700 mg/dL 0.3-38.8 mmol/L
CSF	N/A	N/A	N/A	N/A	5-700 mg/dL 0.3-38.8 mmol/L
URDAC	N/A	N/A	N/A	N/A	N/A
ORDAC	550-3000 IU/L <i>p.4.3</i>	9.2-50 µkat/L	N/A	N/A	N/A
Precision Specification (Use the greater number)	SI Units		SI Units		SI Units
Serum/Plasma	3.5% or 3 IU/L	3.5% or 0.05 µkat/L	5% or 0.2 µg/mL	5% or 0.4 µmol/L	2% or 2 mg/dL 2% or 0.11 mmol/L
Urine	N/A	N/A	N/A	N/A	2% or 2 mg/dL 2% or 0.11 mmol/L
CSF	N/A	N/A	N/A	N/A	2% or 2 mg/dL 2% or 0.11 mmol/L
ORDAC	10%	10%	N/A	N/A	N/A
Reagent Volume	A 237 µL B 23 µL C N/A		A 245 µL B 40 µL C 30 µL		A 273 µL B 27 µL C N/A
Kit Size	2 x 200 tests/cartridge 2 x 400 tests/cartridge		2 x 100 tests/cartridge		2 x 300 tests/cartridge
On-Instrument Stability	30 days		42 days		30 days
Storage Temperature	+2 to +8°C		+2 to +8°C		+2 to +8°C
Calibration Frequency	7 days 30 days		14 days 60 days		14 days 90 days
Compatible Anticoagulants	Ammonium Heparin Lithium Heparin Sodium Heparin		Lithium Heparin Sodium Heparin EDTA		NH ₄ , NA, Li-Heparin Sodium Fluoride/Potassium Oxalate
Reagent Part Number	442650 2 x 200 tests/cartridge 476846 2 x 400 tests/cartridge		469137		442640
Calibrator Part Number	N/A		471080		442600
Control Part Number	657365		657365, 472461, 67, 72		657365
Comment	Calibration required.				

Chemistry Quick Reference

Chemistry Name	IBCT (Total Iron Binding Capacity)	Immunoglobulin A <i>p. h. 16</i>	Immunoglobulin G <i>h. 16</i>
Measurement Principle	FerroZine*	Immunoturbidimetric	Immunoturbidimetric
Chemistry Abbreviation	IBCT	Ig-A	Ig-G
Reaction Type	Endpoint 2	Endpoint 2	Endpoint 2
Primary Wavelength	560 nm	340 nm	340 nm
Reaction Period	Start: 544 seconds Stop: 592 seconds	Start: 432 seconds Stop: 480 seconds	Start: 264 seconds Stop: 320 seconds
Sample Type	Serum/Plasma	Serum/Plasma	Serum/Plasma
Sample Size			
Serum/Plasma	25 µL	10 µL (1:20 dil.)**	4 µL (1:20 dil.)**
Urine	N/A	N/A	N/A
CSF	N/A	N/A	N/A
URDAC	N/A	5 µL (neat)	N/A
ORDAC	N/A	4 µL (1:100 dil.)**	4 µL (1:100 dil.)**
Reference Interval			
Serum/Plasma	261-478 µg/dL SI Units 46.7-85.6 µmol/L	66-436 mg/dL SI Units 0.7-4.4 g/L	791-1643 mg/dL SI Units 7.9-16.4 g/L
Urine	N/A N/A	N/A N/A	N/A N/A
CSF	N/A N/A	N/A N/A	N/A N/A
Analytical Range			
Serum/Plasma	10-1000 µg/dL SI Units 1.8-179.1 µmol/L	40-700 mg/dL SI Units 0.4-7 g/L	200-3200 mg/dL SI Units 2-32 g/L
Urine	N/A N/A	N/A N/A	N/A N/A
CSF	N/A N/A	N/A N/A	N/A N/A
URDAC	N/A N/A	6-50 mg/dL 0.06-0.5 g/L	N/A N/A
ORDAC	N/A N/A	560-8000 mg/dL 5.6-80 g/L	2560-12000 mg/dL 25.6-120 g/L
Precision Specification (Use the greater number)			
Serum/Plasma	4% or 10 µg/dL SI Units 4% or 1.8 µmol/L	5% or 5 mg/dL SI Units 5% or 0.05 g/L	5% or 20 mg/dL SI Units 5% or 0.2 g/L
Urine	N/A N/A	N/A N/A	N/A N/A
CSF	N/A N/A	N/A N/A	N/A N/A
ORDAC	N/A N/A	10% 10%	10% 10%
Reagent Volume	A 200 µL B N/A C 10 µL	A 200 µL B 30 µL C N/A	A 200 µL B 30 µL C N/A
Kit Size	2 x 100 tests/cartridge	2 x 150 tests/cartridge	2 x 150 tests/cartridge
On-Instrument Stability	60 days	60 days	60 days
Storage Temperature	+2 to +8°C	+2 to +8°C	+2 to +8°C
Calibration Frequency Within-Lot	14 days N/A	14 days 90 days	14 days 90 days
Compatible Anticoagulants	Sodium Heparin	Ammonium Heparin Lithium Heparin Sodium Heparin EDTA	Ammonium Heparin Lithium Heparin Sodium Heparin
Reagent Part Number	465970	467920	467925
Calibrator Part Number	442772	468405	468405
Control Part Number	657365	450120, 25, 30 657365	450120, 25, 30 657365
Comment	Sample preparation required.	DIL 1 required for on-board sample dilution.	DIL 1 required for on-board sample dilution.

*FerroZine is a registered trademark of Hach Chemical Co.

**Reaction volume, actual sample volume required differs due to on-board dilution. Refer to Chemistry Information Sheets for details.

Chemistry Name	Immunoglobulin M <i>p.h.15</i>	Iron	LDL Cholesterol <i>p.h.12</i>
Measurement Principle	Immuno-turbidimetric	FerroZine*	Homogeneous, Colorimetric
Chemistry Abbreviation	Ig-M	FE	LDLD
Reaction Type	Endpoint 2	Endpoint 2	Endpoint 2
Primary Wavelength	340 nm	560 nm	560 nm
Reaction Period	Start: 432 seconds Stop: 480 seconds	Start: 544 seconds Stop: 592 seconds	Start: 656 seconds Stop: 720 seconds
Sample Type	Serum/Plasma	Serum/Plasma	Serum/Plasma
Sample Size	24 µL (1:20 dil.)** Urine N/A CSF N/A URDAC N/A ORDAC 3 µL (1:100 dil.)**	25 µL N/A N/A N/A N/A	3 µL N/A N/A N/A N/A
Reference Interval	43-279 mg/dL Urine N/A CSF N/A	M 45-182 µg/dL F 28-170 µg/dL N/A N/A	See Chemistry Information Sheet N/A N/A
	SI Units 0.4-2.8 g/L	SI Units M 8.1-32.6 µmol/L F 5-30.4 µmol/L	
Analytical Range	25-2400 mg/dL Urine N/A CSF N/A URDAC N/A ORDAC 1920-12000 mg/dL	5-500 µg/dL N/A N/A N/A N/A	10-550 mg/dL N/A N/A N/A N/A
	SI Units 0.3-24 g/L 19.2-120 g/L	SI Units 0.9-89.5 µmol/L N/A N/A N/A N/A	SI Units 0.26-14.2 mmol/L N/A N/A N/A N/A
Precision Specification (Use the greater number)	5% or 5 mg/dL Urine N/A CSF N/A ORDAC 10%	2.5% or 3.5 µg/dL N/A N/A N/A	2% or 2 mg/dL N/A N/A N/A
	SI Units 5% or 0.05 g/L	SI Units 2.5% or 0.6 µmol/L	SI Units 2% or 0.05 mmol/L
Reagent Volume	A 200 µL B 30 µL C 21 µL	A 200 µL B N/A C 10 µL	A 210 µL B 70 µL C N/A
Kit Size	2 x 150 tests/cartridge	2 x 200 tests/cartridge	2 x 100 tests/cartridge
On-Instrument Stability	60 days	60 days	30 days
Storage Temperature	+2 to +8°C	+2 to +8°C	+2 to +8°C
Calibration Frequency Within-Lot	14 days 60 days	14 days N/A	30 days 60 days
Compatible Anticoagulants	Ammonium Heparin Lithium Heparin Sodium Heparin EDTA	Ammonium Heparin Lithium Heparin Sodium Heparin	EDTA Lithium Heparin Sodium Heparin
Reagent Part Number	467930	467910	969706
Calibrator Part Number	468405	442772	Included
Control Part Number	450120, 25, 30, 657365	657365	469905, 980, 982
Comment	DIL 1 required for on-board sample dilution.		

*FerroZine is a registered trademark of Hach Chemical Co.

**Reaction volume, actual sample volume required differs due to on-board dilution. Refer to Chemistry Information Sheets for details.

Chemistry Quick Reference

Chemistry Name	Lactate	Lactate Dehydrogenase (IFCC) <i>p.4.3</i>	Lactate Dehydrogenase
Measurement Principle	Enzymatic	Lactate to Pyruvate	Pyruvate to Lactate
Chemistry Abbreviation	LAC	LD	LD-P
Reaction Type	Endpoint 2	Rate 1	Rate 1
Primary Wavelength	520 nm	340 nm	340 nm
Reaction Period	Start: 224 seconds Stop: 272 seconds	Start: 64 seconds Stop: 128 seconds	Start: 16 seconds Stop: 56 seconds
Sample Type	Plasma/CSF	Serum/Plasma	Serum/Plasma
Sample Size			
Serum/Plasma	3 µL	13 µL	5 µL
Urine	N/A	N/A	N/A
CSF	3 µL	N/A	N/A
URDAC	N/A	N/A	N/A
ORDAC	N/A	3 µL	3 µL
Reference Interval			
Serum/Plasma	4.5-19.8 mg/dL SI Units 0.5-2.2 mmol/L	248 IU/L SI Units 4.13 µkat/L	266-500 IU/L SI Units 4.4-8.3 µkat/L
Urine	N/A N/A	N/A N/A	N/A N/A
CSF	<25.2 mg/dL < 2.8 mmol/L	N/A N/A	N/A N/A
Analytical Range			
Serum/Plasma	2.7-99 mg/dL SI Units 0.3-11.1 mmol/L	5-750 IU/L SI Units 0.1-12.5 µkat/L	20-2500 IU/L SI Units 0.3-41.7 µkat/L
Urine	N/A N/A	N/A N/A	N/A N/A
CSF	2.7-99 mg/dL 0.3-11.1 mmol/L	N/A N/A	N/A N/A
URDAC	N/A N/A	N/A N/A	N/A N/A
ORDAC	N/A N/A	<i>p.4.3</i> 600-2700 IU/L 10-45 µkat/L	N/A N/A
Precision Specification (Use the greater number)			
Serum/Plasma	3% or 1.2 mg/dL 3% or 0.13 mmol/L	3.5% or 5 IU/L 3.5% or 0.08 µkat/L	3.5% or 15 IU/L 3.5% or 0.25 µkat/L
Urine	N/A N/A	N/A N/A	N/A N/A
CSF	3% or 1.2 mg/dL 3% or 0.13 mmol/L	N/A N/A	N/A N/A
ORDAC	N/A N/A	10% 10%	10% 10%
Reagent Volume	A N/A B 327 µL C N/A	A 251 µL B N/A C 9 µL	A 242 µL B 8 µL C N/A
Kit Size	2 x 35 tests/cartridge	2 x 200 tests/cartridge 2 x 300 tests/cartridge	2 x 200 tests/cartridge
On-Instrument Stability	14 days	30 days	30 days
Storage Temperature	+2 to +8°C	+2 to +8°C	+2 to +8°C
Calibration Frequency Within-Lot	7 days N/A	14 days 30 days	N/A N/A
Compatible Anticoagulants	Sodium Fluoride/Potassium Oxalate, ONLY	Sodium Heparin Lithium Heparin Ammonium Heparin	Sodium Heparin
Reagent Part Number	445875	442655 2 x 200 tests/cartridge 476841, 2 x 300 tests/cartridge	442660
Calibrator Part Number	442600	441350	N/A
Control Part Number	667840, 41, 42	657365	657365
Comment	Reagent preparation required.	Calibration required.	

Chemistry Name	Lipase		Magnesium		Micro Total Protein <i>p.h.4.</i>	
Measurement Principle	Enzymatic		Calmagite		Pyrogallol Red	
Chemistry Abbreviation	LIP		MG		M-TP	
Reaction Type	Rate 2		Endpoint 2		Endpoint 2	
Primary Wavelength	560 nm		520 nm		600 nm	
Reaction Period	Start: 32 seconds Stop: 64 seconds		Start: 64 seconds Stop: 96 seconds		Start: 240 seconds Stop: 272 seconds	
Sample Type	Serum/Plasma		Serum/Plasma/Urine		Urine/CSF	
Sample Size						
Serum/Plasma	4 µL		3 µL		N/A	
Urine	N/A		3 µL (1:10 dil.)*		10 µL	
CSF	N/A		N/A		5 µL	
URDAC	N/A		N/A		N/A	
ORDAC	2 µL		N/A		N/A	
Reference Interval						
Serum/Plasma	22-51 U/L	SI Units 0.36-0.85 µkat/L	1.8-2.5 mg/dL	SI Units 0.74-1.03 mmol/L	N/A	SI Units N/A
Urine	N/A	N/A	72.9-121.5 mg/24 hr	3-5 mmol/24 hr	1-14 mg/dL	0.01-0.14 g/L
CSF	N/A	N/A	N/A	N/A	15-45 mg/dL	0.15-0.45 g/L
Analytical Range						
Serum/Plasma	10-200 U/L	SI Units 0.17-3.40 µkat/L	0.1-7 mg/dL	SI Units 0.04-2.88 mmol/L	N/A	SI Units N/A
Urine	N/A	N/A	1-70 mg/dL	0.4-28.8 mmol/L	6-150 mg/dL	0.06-1.5 g/L
CSF	N/A	N/A	N/A	N/A	6-300 mg/dL	0.06-3.0 g/L
URDAC	N/A	N/A	N/A	N/A	N/A	N/A
ORDAC	180-400 U/L	3.06-6.8 µkat/L	N/A	N/A	N/A	N/A
Precision Specification (Use the greater number)						
Serum/Plasma	7% or 7 U/L	7% or 0.12 µkat/L	2.5% or 0.11 mg/dL	2.5% or 0.04 mmol/L	N/A	N/A
Urine	N/A	N/A	3% or 0.8 mg/dL	3% or 0.3 mmol/L	4% or 2 mg/dL	4% or 0.02 g/L
CSF	N/A	N/A	N/A	N/A	4% or 2 mg/dL	4% or 0.02 g/L
ORDAC	10%	10%	N/A	N/A	N/A	N/A
Reagent Volume	A 660 µL (wash) B 167 µL C 50 µL		A 280 µL B 28 µL C N/A		A N/A B 300 µL C N/A	
Kit Size	2 x 30 tests/cartridge 2 x 60 tests/cartridge		2 x 100 tests/cartridge		2 x 50 tests/cartridge	
On-Instrument Stability	21 days		7 days		30 days	
Storage Temperature	+2 to +8°C		Room Temperature		+2 to +8°C	
Calibration Frequency	5 days 60 days		7 days 90 days		14 days 90 days	
Compatible Anticoagulants	Lithium Heparin Sodium Heparin		Ammonium Heparin Lithium Heparin Sodium Heparin		N/A	
Reagent Part Number	465126 2 x 30 tests/cartridge 476851 2 x 60 tests/cartridge		445360		445860	
Calibrator Part Number	441350		442600		445930	
Control Part Number	657365		657365		C-390, C-396	
Comment			DIL 1 required for on-board urine sample dilution.			

*Reaction volume, actual sample volume required differs due to on-board dilution. Refer to Chemistry Information Sheets for details.

Chemistry Quick Reference

Chemistry Name	Microalbumin		Pancreatic Amylase <i>p.h.18</i>		Phenobarbital
Measurement Principle	Immunoturbidimetric		Immunoinhibition EPS Substrate		Immunoturbidimetric
Chemistry Abbreviation	MA		PAM		PHE
Reaction Type	Endpoint 2		Rate 1		Rate 1
Primary Wavelength	380 nm		410 nm		340 nm
Reaction Period	Start: 312 seconds Stop: 376 seconds		Start: 304 seconds Stop: 368 seconds		Start: 112 seconds Stop: 160 seconds
Sample Type	Urine		Serum/Plasma/Urine		Serum/Plasma
Sample Size					
Serum/Plasma	N/A		10 µL		3 µL
Urine	10 µL		10 µL		N/A
CSF	N/A		N/A		N/A
URDAC	N/A		N/A		N/A
ORDAC	3 µL		3 µL		N/A
Reference Interval					See Chemistry Information Sheet
Serum/Plasma	N/A	SI Units N/A	0-46 U/L	SI Units 0-0.8 µkat/L	N/A
Urine	<1.9 mg/dL	<19.0 mg/L	<320 U/L	<5.3 µkat/L	N/A
CSF	N/A	N/A	N/A	N/A	N/A
Analytical Range					
Serum/Plasma	N/A	SI Units N/A	7-600 U/L	SI Units 0.12-10 µkat/L	5-80 µg/mL
Urine	0.2-30 mg/dL	2.0-300 mg/L	7-600 U/L	0.12-10 µkat/L	N/A
CSF	N/A	N/A	N/A	N/A	N/A
URDAC	N/A	N/A	N/A	N/A	N/A
ORDAC	24-97 mg/dL	240-970 mg/L	480-1800 U/L	8-30 µkat/L	N/A
Precision Specification (Use the greater number)					
Serum/Plasma	N/A	SI Units N/A	3.5% or 5 U/L	SI Units 3.5 or .08 µkat/L	4% or 1 µg/mL
Urine	5.4% or 0.125 mg/dL	5.4% or 1.25 mg/L	3.5% or 5 U/L	3.5 or .08 µkat/L	N/A
CSF	N/A	N/A	N/A	N/A	N/A
ORDAC	5.4%	5.4%	10%	10%	N/A
Reagent Volume	A 215 µL B 25 µL C N/A		A N/A B 200 µL C 40 µL		A 210 µL B 55 µL C 30 µL
Kit Size	2 x 100 tests/cartridge		2 x 60 tests/cartridge		2 x 100 tests/cartridge
On-Instrument Stability	60 days		30 days		42 days
Storage Temperature	+2 to +8°C		+2 to +8°C		+2 to +8°C
Calibration Frequency	30 days		N/A		14 days
Within-Lot	60 days		N/A		60 days
Compatible Anticoagulants	N/A		EDTA Lithium Heparin Sodium Heparin		Lithium Heparin Sodium Heparin EDTA
Reagent Part Number	475100		969650		469785
Calibrator Part Number	475089		N/A		469600
Control Part Number	465290, 300		657365		657365, 472461, 67, 72
Comment					

Chemistry Quick Reference

Chemistry Name	<u>Total Bilirubin</u> <i>p. 4.9</i>		Total Protein	Transferrin	
Measurement Principle	Jendrossik-Grof		Biuret	Immunoturbidimetric	
Chemistry Abbreviation	TBIL		TP	TRFN	
Reaction Type	Endpoint 2		Endpoint 2	Endpoint 2	
Primary Wavelength	520 nm		560 nm	340 nm	
Reaction Period	Start: 120 seconds Stop: 152 seconds		Start: 150 seconds Stop: 180 seconds	Start: 432 seconds Stop: 480 seconds	
Sample Type	Serum/Plasma		Serum/Plasma	Serum/Plasma	
Sample Size	8 µL		6 µL	6 µL (1:20 dil.)*	
Serum/Plasma	N/A		N/A	N/A	
Urine	N/A		N/A	N/A	
CSF	N/A		N/A	N/A	
URDAC	N/A		N/A	N/A	
ORDAC	N/A		N/A	N/A	
Reference Interval	0.4-2 mg/dL		6.5-8.1 g/dL	M 180-329 mg/dL F 192-382 mg/dL	
Serum/Plasma	SI Units 6.8-34.2 µmol/L		SI Units 65-81 g/L	SI Units M 1.8-3.3 g/L F 1.9-2.8 g/L	
Urine	N/A	N/A	N/A	N/A	N/A
CSF	N/A	N/A	N/A	N/A	N/A
Analytical Range	0.1-30 mg/dL		3.0-12.0 g/dL	70-850 mg/dL	
Serum/Plasma	SI Units 1.7-513 µmol/L		SI Units 30-120 g/L	SI Units 0.7-8.5 g/L	
Urine	N/A	N/A	N/A	N/A	N/A
CSF	N/A	N/A	N/A	N/A	N/A
URDAC	N/A	N/A	N/A	N/A	N/A
ORDAC	N/A	N/A	N/A	N/A	N/A
Precision Specification (Use the greater number)	SI Units		SI Units		SI Units
Serum/Plasma	3% or 0.15 mg/dL	3% or 2.6 µmol/L	3.0% or 0.3 g/dL	3.0% or 3 g/L	5% or 5 mg/dL
Urine	N/A	N/A	N/A	N/A	N/A
CSF	N/A	N/A	N/A	N/A	N/A
ORDAC	N/A	N/A	N/A	N/A	N/A
Reagent Volume	A 255 µL B 25 µL C N/A		A 300 µL B N/A C N/A	A 200 µL B 25 µL C N/A	
Kit Size	2 x 300 tests/cartridge 2 x 400 tests/cartridge		2 x 300 tests/cartridge		2 x 150 tests/cartridge
On-Instrument Stability	30 days		20 days		60 days
Storage Temperature	Room Temperature		Room Temperature		+2 to +8°C
Calibration Frequency Within-Lot	14 days 90 days		7 days 90 days		14 days 90 days
Compatible Anticoagulants	Ammonium Heparin EDTA Lithium Heparin Sodium Heparin		Lithium Heparin Sodium Heparin		Ammonium Heparin Lithium Heparin Sodium Heparin
Reagent Part Number	442745 2 x 300 tests/cartridge 476861* 2 x 400 tests/cartridge		442740		467942
Calibrator Part Number	465915		442600		468405
Control Part Number	657365, 667710, 20, 30, 40		657365		450120, 25, 30, 657365
Comment	442745 Transfer 0.1 mL C into B 476861 Transfer 0.2 mL C into B Reagent preparation required				DIL 1 required for on-board sample dilution.

*Reaction volume, actual sample volume required differs due to on-board dilution. Refer to Chemistry Information Sheets for details.

Chemistry Name	Triglyceride <i>p.4.213</i>	Triglyceride Glycerol Blanked	Urea
Measurement Principle	Enzymatic/GPO-Trinder	Enzymatic/GPO-Trinder Glycerol Blanked	Enzymatic
Chemistry Abbreviation	TG	TG-B	UREA
Reaction Type	Endpoint 2	Endpoint 2	Rate 1
Primary Wavelength	520 nm	520 nm	340 nm
Reaction Period	Start: 352 seconds Stop: 384 seconds	Start: 544 seconds Stop: 576 seconds	Start: 32 seconds Stop: 64 seconds
Sample Type	Serum/Plasma	Serum/Plasma	Serum/Plasma/Urine
Sample Size			
Serum/Plasma	3 µL	3 µL	3 µL
Urine	N/A	N/A	3 µL (1:10 dil.)*
CSF	N/A	N/A	N/A
URDAC	N/A	N/A	N/A
ORDAC	N/A	N/A	N/A
Reference Interval			
Serum/Plasma	See Chemistry Information Sheet	See Chemistry Information Sheet	17.4-55.8 mg/dL SI Units 2.9-9.3 mmol/L
Urine	N/A	N/A	26-43 g/24 hr 0.43-0.71 mol/24 hr
CSF	N/A	N/A	N/A N/A
Analytical Range			
Serum/Plasma	10-1000 mg/dL SI Units 0.1-11.3 mmol/L	10-1000 mg/dL SI Units 0.1-11.3 mmol/L	10.7-213.8 mg/dL SI Units 1.8-35.7 mmol/L
Urine	N/A N/A	N/A N/A	107.2-2138.4 mg/dL SI Units 17.9-357 mmol/L
CSF	N/A N/A	N/A N/A	N/A N/A
URDAC	N/A N/A	N/A N/A	N/A N/A
ORDAC	N/A N/A	N/A N/A	N/A N/A
Precision Specification (Use the greater number)			
Serum/Plasma	3% or 5 mg/dL SI Units 3% or 0.1 mmol/L	3% or 5 mg/dL SI Units 3% or 0.1 mmol/L	3% or 4.3 mg/dL SI Units 3% or 0.7 mmol/L
Urine	N/A N/A	N/A N/A	3% or 6.6 mg/dL SI Units 3% or 1.1 mmol/L
CSF	N/A N/A	N/A N/A	N/A N/A
ORDAC	N/A N/A	N/A N/A	N/A N/A
Reagent Volume	A 285 µL B 15 µL C N/A	A 275 µL B 15 µL C 10 µL	A 285 µL B 15 µL C N/A
Kit Size	2 x 300 tests/cartridge	2 x 300 tests/cartridge	2 x 300 tests/cartridge
On-Instrument Stability	30 days	30 days	30 days
Storage Temperature	+2 to +8°C	+2 to +8°C	+2 to +8°C
Calibration Frequency	14 days	14 days	24 hours
Within-Lot	90 days	90 days	30 days
Compatible Anticoagulants	Ammonium Heparin EDTA Lithium Heparin Sodium Heparin	Ammonium Heparin EDTA Lithium Heparin Sodium Heparin	EDTA NH ₄ , NA, Li-Heparin Sodium Fluoride/Potassium Oxalate
Reagent Part Number	445850	445850	442820
Calibrator Part Number	442600	442600	442600
Control Part Number	657365 or 469905 465980, 981, 982	657365 or 469905, 465980, 465981, 465982	657365
Comment	Mix C into A.		DIL 1 required for on-board urine sample dilution.

*Reaction volume, actual sample volume required differs due to on-board dilution. Refer to Chemistry Information Sheets for details.

STAT CHEMISTRIES

Chemistry Name	Sodium	Total Protein <i>p.4.6</i>	Ureat <i>p.4.24</i>
Measurement Principle	Indirect ISE/LAS glass membrane	Colorimetry/Biuret	Conductivity/Urease
Chemistry Abbreviation	NA	TPm	UREAm
Reaction Type	Endpoint	Timed Rate	Timed Rate
Primary Wavelength	N/A	545 nm	N/A
Reaction Period	17.8-18.7 seconds	4.0-7.7 seconds	11.3-14.6 seconds
Sample Type	Serum/Plasma/Urine	Serum/Plasma/CSF	Serum/Plasma/Urine
Sample Size			
Serum/Plasma	40 µL*	8 µL	10 µL
Urine	40 µL*	N/A	10 µL (1:10 manual dilution)
CSF	N/A	60 µL	N/A
ORDAC	N/A	N/A	5 µL
Reference Interval			
Serum/Plasma	136-144 mmol/L	6.1-7.9 g/dL	2.9-7.1 mmol/L
Urine	40-220 mmol/24 hr	N/A	0.43-0.71 mol/24 hr
CSF	N/A	15-45 mg/dL	N/A
		SI Units	
		61-79 g/L	
		N/A	
		150-450 mg/L	
Analytical Range			
Serum/Plasma	100-200 mmol/L	1-12 g/dL	0.4-53.6 mmol/L
Urine	10-300 mmol/L	N/A	3.57-535.7 mmol/L**
CSF	N/A	10-1500 mg/dL	N/A
ORDAC (Serum)	N/A	N/A	46.4-107.1 mmol/L <i>p.4.21</i>
ORDAC (Urine)	N/A	N/A	464.3-1071.4 mmol/L** <i>p.4.24</i>
ORDAC (CSF)	N/A	N/A	N/A
Precision Specification (Use the greater number)			
Serum/Plasma	1% or 1 mmol/L	2% or 0.2 g/dL	3% or 0.5 mmol/L
Urine	4% or 2 mmol/L	N/A	3% or 1.1 mmol/L
CSF	N/A	5% or 5 mg/dL	N/A
ORDAC	N/A	N/A	5%
Reagent Volume	3.3 mL ISE Reference 1.3 mL ISE Buffer	630 µL	765 µL
On-Instrument Stability	30 days	60 days	15 days
Storage Temperature	Room Temperature	Room Temperature	+2 to +8°C
Calibration Frequency	24 hours	14 days	3 days
Compatible Anticoagulants	Ammonium Heparin Lithium Heparin Sodium Heparin	Ammonium Heparin EDTA Lithium Heparin Sodium Heparin	NH ₄ , NA, Li - Heparin Sodium Fluoride/Potassium Oxalate EDTA
Reagent Part Number	467935 ISE Reference 467915 ISE Buffer A28937 ISE Reference A28945 ISE Buffer	465986 ✓	472482
Calibrator Part Number	471288, 471291, 471294	471288, 471291, 471294	471288, 471291, 471294
Control Part Number	657365	657365	657365
Comment			1:10 offline dilution for urine

*Not available on UniCel DxC 600.

*Total volume required to complete sodium, potassium, chloride, CO₂ and calcium analyses.

**Range for 1:10 manual dilution.