Abbott

Alinity ci-series Operations Manual

For use with the Alinity c processing module and the Alinity i processing module

80000071-110

Introduction

The Alinity ci-series of analyzers has a scalable design to provide full integration of multiple clinical chemistry and immunoassay systems, all of which are controlled by one user-friendly interface. This intuitive user interface provides a real-time display of each system's status and a to-do list of scheduled maintenance activities, which minimizes system interaction and optimizes productivity. The Alinity ci-series analyzers have also incorporated numerous features to prevent and reduce errors and to increase walkaway time.

Related information…

Alinity ci-series hardware overview, page 58

Alinity system software overview, page 142

Required consumables, page 150

Required accessories, page 161

Automatic processing module activities, page 166

Operating instructions, page 507

2. Onboard vial rack: Bar-coded for identification with the letter U. Holds six vials of calibrators or controls. The rack is stored in the reagent carousel.
3. Sample rack: Bar-coded for identification. Holds six primary tubes, aliquot tubes, or sample cups. Any combination of tubes and cups can be used in the rack.
4. Sample gauge: Used to verify that the amount of sample in an aliquot tube exceeds 8 mm.

Related information…

Required accessories, page 161

Loading area, page 74

Reagent and sample manager (RSM) sample processing for onboard calibrators and controls, page 671

Onboard storage criteria for calibrator and control vials, page 672

Trays

Trays are accessories that are used to hold multiple racks of samples, calibrators, and controls and to hold reagent cartridges. Trays of racks and cartridges are loaded on the reagent and sample manager (RSM). Each tray holds a maximum of five racks or cartridges. Empty trays with no handles may remain on the loading area to create five positions to load racks or cartridges one at a time.

NOTE: Racks and cartridges cannot be loaded or removed from the five position routine tray after the tray is loaded on the RSM.

System characteristics

System characteristics provide a basic overview of the Alinity ci-series.

For additional characteristics that are specific to a processing module, see the appropriate module type.

Table 5: System characteristics

Primary components	• System control module • Reagent and sample manager • Processing module
Bar code reader	Located on the RSM transport
Onboard data storage	2 solid-state hard drives
Operator interface	• Touchscreen monitor • Bar code scanner
Priority scheduling	• 0 to 25 configurable priority positions per processing module • Unlimited temporary priority positions
Quality control	• Levey-Jennings and Westgard rules • Control range tracking
Stored data protection	Uninterruptible power supply (UPS) (optional)

Related information...

Performance characteristics and specifications, page 469
Processing module characteristics (c-series), page 470
Processing module characteristics (i-series), page 471

Processing module characteristics (c-series)

Table 6: Processing module characteristics (c-series)

Detection technology: • Photometric • Potentiometric	 End-point and rate Integrated chip technology (ICT) ion-selective electrodes
Pipetting capability	Robotic precision with clot detection

Related information...

System characteristics, page 470

Processing module characteristics (i-series)

Table 7: Processing module characteristics (i-series)

Detection technology	Chemiluminescent microparticle immunoassay (CMIA)
Emission measurement	The optics measures the chemiluminescent emission from reaction vessels and outputs the data that corresponds to the quantity of emission detected.
Pipetting capability	Robotic precision with clot detection

Related information…

System characteristics, page 470

– 25% STAT – 65% routine • Time to first result **NOTE:** The time to first result starts at aspiration and does not include sample handling.	• 29 min (routine) • 36 min to 43 min (pretreatment) • 15 min (STAT)* * The estimated processing time including sample handling is 18 min.
System status transition times: Processing module (i-series): • Offline to Stopped • Stopped to Idle • Stopped to Running • Idle to Running Reagent and sample manager: • Offline to Stopped • Stopped to Idle • Stopped to Running • Idle to Running	 3 min 3 min 7 min 4 min to 7 min* * If the pretreatment path is repopulated with reaction vessels, the duration of initialization is 7 min. 1 min 15 s 30 s 30 s

Related information...

Operational specifications, page 472

System capacities

System capacities include storage information for the software data, processing modules, and the reagent and sample manager.

Related information...

Specifications and requirements, page 472

Software data storage capacities, page 475

Processing module capacities (c-series), page 476

Processing module capacities (i-series), page 477

Reagent and sample manager capacities, page 478

Software data storage capacities

Table 10: Software data storage capacities

Assay files	200 assay files
Calibrations:	

• ICT Reference Solution reservoir • Alkaline Wash reservoir • Acid Wash reservoir	1 L 0.5 L 0.5 L
Reagent carousel positions	70 **NOTE:** Four of the 70 positions are available for the storage of onboard vial racks.
Reaction carousel	187 cuvettes
Reaction cuvettes: • Minimum volume • Maximum volume	 80 µL 360 µL
High-concentration waste bottle: • Volume • Weight	 10 L 10 kg (22 lb)

Related information…

System capacities, page 475

Processing module capacities (i-series)

Table 12: Processing module capacities (i-series)

Bulk solutions: • Pre-Trigger Solution • Trigger Solution • Concentrated Wash Buffer	 975 mL 975 mL 2 L
Bulk solution reservoirs: • Pre-Trigger Solution reservoir • Trigger Solution reservoir • Concentrated Wash Buffer reservoir • Diluted wash buffer reservoir	 1 L 1 L 2 L 4 L
Biohazard bag size	• 18.9 L (5.0 gal) • 39.37 cm (15.5 in.) x 57.15 cm (22.5 in.)
Process path positions	46
Pretreatment path positions	61
Reagent carousel positions	47
Reaction vessel (RV): • Total volume • Maximum reaction mixture volume	 1000 µL 400 µL
RV hopper	1000 RVs
Solid waste:	

• Container capacity • Waste chute capacity	• 1000 RVs • 5 h of run time at 200 RVs/h • 50 RVs before system operation is paused • 208 RVs total capacity • 30 min of run time when the waste container is removed during assay processing

Related information...

System capacities, page 475

Reagent and sample manager capacities

Table 13: Reagent and sample manager capacities

Bays	5 per processing module
Priority positions	Configurable 0 to 25
Racks: • Sample rack • Vial rack • Onboard vial rack	6 positions per rack
Trays	• 5 sample racks or 30 positions • 5 reagent cartridges

Related information...

System capacities, page 475

Physical specifications

The approximate physical specifications for the Alinity ci-series are described in the table for the following configurations:

Stand-alone processing module	Includes the specifications for the processing module (Alinity c or Alinity i), the reagent and sample manager (RSM), and the system control module (SCM)
Each additional processing module	Includes the specifications for one processing module (Alinity c or Alinity i)

All weights include fluids and bulk solutions at capacity to depict a worst-case scenario.

Consumable inventory management

Consumable inventory management includes procedures to prepare and replenish supplies and to empty waste. Use the Supplies screen to view and manage in-use supply inventory.

Before performing sample processing, verify that onboard consumable inventory is adequate.

Related information…

Operating instructions, page 507

Supplies screen, page 590

Cal/QC Inventory screen, page 617

Supplies screen

On the Supplies screen, the operator can view the following information:

- c-series
  - Percentage of bulk solutions
  - Percentage of onboard solutions in the sample wash solution area
  - Status of the liquid waste in the high-concentration waste bottle
  - Status of the ICT module
- i-series
  - Percentage of bulk solutions
  - Status of the reaction vessel (RV) waste
  - Status of RVs

The operator can perform the following functions:

- c-series: Update the inventory for bulk solutions, onboard solutions, the liquid waste, and the ICT module.
- i-series: Update the inventory for bulk solutions, RVs, and the RV waste.

NOTE: The c-series and the i-series calculate the supply volume and the percent-remaining information on required tests for samples that have been scheduled on the reagent and sample manager.

Related information…

Consumable inventory management, page 590

Supplies screen element descriptions (c-series), page 591

Supplies screen, Supply Details flyouts for Alkaline Wash, Acid Wash, and ICT Reference element descriptions (c-series), page 596

Supplies screen, Supply Details flyout for ICT Module element descriptions (c-series), page 598

Reagent and sample management

Reagent and sample management includes procedures for the following activities:

- Manage reagent carousel inventory.
- Prepare, load, and unload samples.
- Initiate sample processing.

Related information...

Operating instructions, page 507
Load racks and cartridges into trays, page 622
Load trays on the reagent and sample manager (RSM), page 623
Load racks on the reagent and sample manager (RSM), page 625
Load bar-coded specimens for batch processing, page 626
Load cartridges on the reagent and sample manager (RSM), page 629
Load onboard vial racks or cartridges on a specific processing module, page 632
Load onboard solutions and sample diluents on the reagent and sample manager (RSM) (c-series), page 634
Assign a temporary priority position to load racks and cartridges, page 636
Unload trays from the reagent and sample manager (RSM), page 637
Reagent carousel inventory management, page 638
Sample management, page 666

Load racks and cartridges into trays

Perform this procedure to load prepared racks and cartridges into trays.

CAUTION: Biological RISKS. This activity or area may expose you to potentially infectious material.

CAUTION: Chemical Hazard. This activity or area exposes you to a chemical hazard.

IMPORTANT: When transporting or loading racks, avoid splashing the sample outside the sample cups and tubes.

1. Position the rack or cartridge so that the rack handle or cartridge handle is located at the front of a tray.
2. To load the rack or cartridge into a tray, slide the rack or cartridge into the front of the tray (indicated with an arrow) until the rack or cartridge stops.

   To load the rack or cartridge into a five position routine tray, place the rack handle or cartridge handle over the front edge of the tray to secure the rack or cartridge in place.

Calibration sample processing

When multiple reagent lots for an assay are loaded on the system and before the sampling process for a calibration order begins, the system determines which lots to calibrate by using the calibration status of the reagent lot and the selected order options for the reagent and module according to the following rules.

NOTE: For c-series photometric assays that are configured to perform calibrations by cartridge, the reagent lot is composed of the reagent lot number and the reagent cartridge serial number. This combination of the two numbers is evaluated for calibration processing. The calibration-by-cartridge option is unavailable for i-series assays.

If the **Reagent Selection** option is **Module**, the following conditions are applicable for each selected module that has an instrument status of Running or Processing when the calibrator samples are scanned:

- The system calibrates all reagent lots that are loaded on the system when no reagent lots for the assay have a calibration status of Active or Pending QC.
- The system calibrates all reagent lots that are loaded on the system when all reagent lots for the assay have a calibration status of Active or Pending QC.
- The system calibrates only the reagent lots that are loaded on the system that do not have a calibration status of Active or Pending QC when some reagent lots for the assay have a calibration status of Active or Pending QC and some do not.

NOTE: The **Module** option is available only for multimodule systems that have more than one module of the same type.

If the **Reagent Selection** option is **Auto**, the following conditions are applicable for all modules that have an instrument status of Running or Processing when the calibrator samples are scanned:

- The system calibrates all reagent lots that are loaded on the system when no reagent lots for the assay have a calibration status of Active or Pending QC.
- The system calibrates all reagent lots that are loaded on the system when all reagent lots for the assay have a calibration status of Active or Pending QC.
- The system calibrates only the reagent lots that are loaded on the system that do not have a calibration status of Active or Pending QC when some reagent lots for the assay have a calibration status of Active or Pending QC and some do not.

Related information...

Sample processing, page 666
Create a calibration order, page 719

Reagent and sample manager (RSM) processing priorities

After a rack or cartridge is loaded on the reagent and sample manager (RSM), the RSM transport moves the rack or cartridge to or from a processing module location. The RSM transport performs the processing priorities in the following order:

1. Unload a completed sample rack from a module-specific sample positioner.
2. Load priority retest sample racks on the designated module-specific sample positioner in the order in which the racks are presented to the RSM.

   NOTE: If both lanes of the module-specific sample positioner are occupied, when a routine sample rack is available, the rack is removed from the sample positioner and processing for the routine sample is delayed until the sample positioner is available.
3. Load priority sample racks, vial racks, or onboard vial racks on the designated module-specific sample positioner in the order in which the racks are presented to the RSM.

   NOTE: If both lanes of the module-specific sample positioner are occupied, when a routine sample rack is available, the rack is removed from the sample positioner and processing for the routine sample is delayed until the sample positioner is available.
4. Load priority cartridges or onboard vial racks in the reagent storage area in the order in which the cartridges or racks are presented to the RSM.
5. Load routine retest sample racks on the designated module-specific sample positioner.
6. Load routine sample racks on the designated module-specific sample positioner in the order in which the racks are presented to the RSM.
7. Load routine cartridges in the reagent storage area in the order in which the cartridges are presented to the RSM.
8. Unload cartridges or onboard vial racks from the reagent storage area.

NOTE: If the Alinity ci-series is connected to a laboratory automation system (LAS), specimen interleaving occurs.

On the Alinity c-series, sample processing for specimens that are currently aspirated at the sample positioner is completed for all samples in a rack before sample processing begins for an LAS specimen.

If an LAS specimen is being aspirated, the system completes sample processing before it begins to process a rack on the sample positioner.

On the Alinity i-series, if specimens in a rack on the sample positioner are being aspirated, the system continues to process these specimens for approximately 10 minutes before it begins to process an LAS specimen. The approximate 10-minute maximum delay before the LAS specimen is processed ensures that calibrations are not interrupted and prevents aspiration point time-outs at the LAS.

If an LAS specimen is being aspirated, the system completes the processing of the LAS specimen before it begins to process a rack on the sample positioner.

Related information…

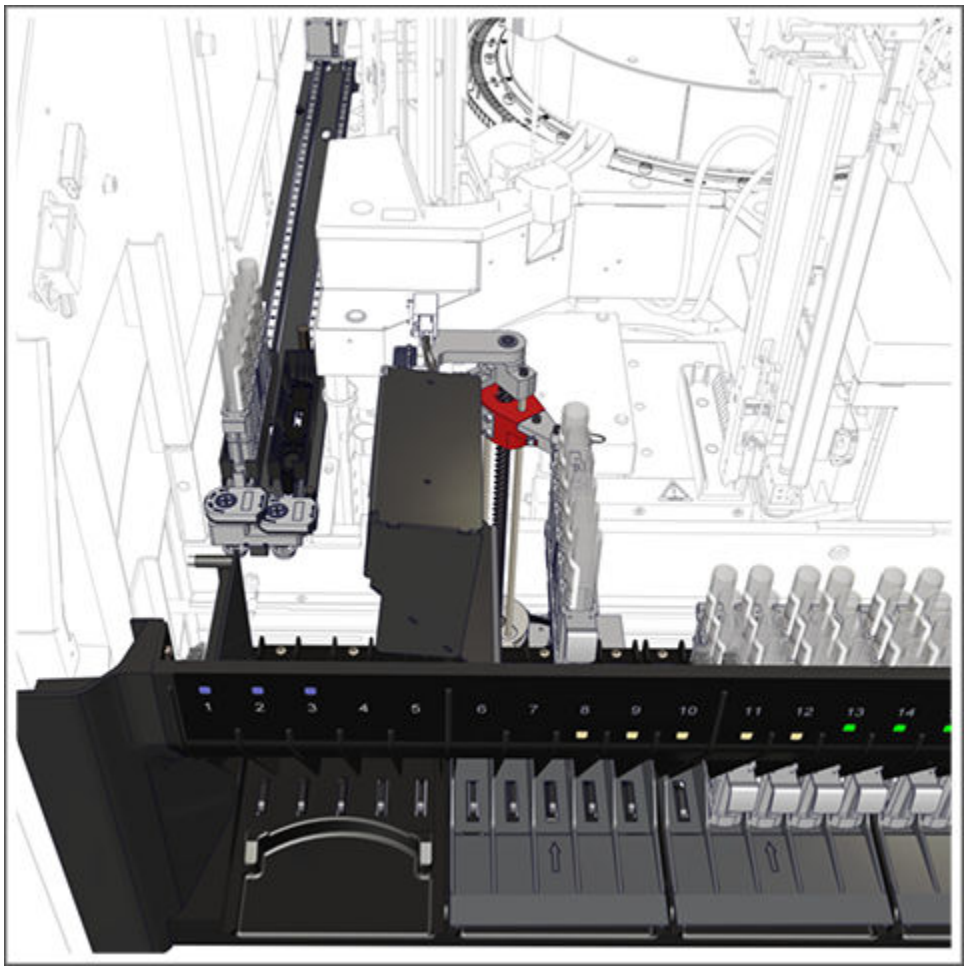
Sample processing, page 666

Reagent and sample manager (RSM) sample processing

After a sample rack or vial rack for immediate use is loaded on the loading area of the reagent and sample manager (RSM), the rack is moved to the aspiration location.

On a multimodule system, samples are routed to the first available processing module. If multiple processing modules are available, the system first routes the samples to the numbered module that has the lowest number.

Figure 149: RSM sample processing



After a sample rack or a vial rack for immediate use is loaded on the loading area of the RSM and a run is initiated, the RSM performs the following functions:

1. The RSM transport moves to the position of the first rack according to the system software prioritization and picks up the rack. The status indicator on the RSM is amber, which indicates that the rack is being accessed by the RSM transport.
2. The RSM transport positions the rack for the bar code reader to identify the rack ID and the SID. Then the RSM transport returns the rack to its original position on the loading area.
3. The system software determines if an order is present in the software for each sample in the rack. If no orders are present and the system is configured for host order queries, the user interface computer sends a query to the host.

NOTE: If a calibration order already exists for an assay, the existing order prevents the creation of an automated calibration order.

Related information...

Automated ordering, page 682

Prepare and load calibrator and control vials into vial racks for immediate use, page 676

Prepare and load calibrator and control vials into vial racks for onboard storage, page 656

Create a new calibrator master lot (c-series), page 326

Create a new calibrator master lot (i-series), page 328

Import calibrator data (c-series), page 329

Automated retest of specimens

Automated retest is the process that the system uses to generate rerun orders for specimen tests automatically. For each test, the system can generate a maximum of four automatic rerun orders.

Retest rules are not applied to the following items:

- Calibrator tests
- Control tests
- Tests that are performed with a manual dilution
- Assays that have an assay status of Correlation
- Tests that are performed from a specimen that is run on a laboratory automation system

Automated retest has two steps:

1. The system compares test results to the configured retest rules, starting with the first rule. If a test result meets the criteria of a retest rule, the system generates a rerun order without further evaluation of the configured retest rules.

   NOTE: If the rerun order that is generated is used for a different assay, the order is suppressed if a test for the specimen is present that has a status of Pending, Scheduled, Running, or Complete. The order is not suppressed if the test is a calculated assay or the system-ordered constituent of a calculated assay.

   The rerun order is scheduled and uses the **Automatic** option of reagent selection. The rerun order is displayed with the **R** processing code on the Sample Status screen, the **All Orders** tab of the Orders screen, and the **Rerun** tab of the Orders screen.

   The system can be configured to reposition specimens for retest automatically. Specimens that are loaded on the reagent and sample manager (RSM) are moved to the sample aspiration point and rerun orders are generated automatically. If the system is not configured to reposition specimens automatically, the specimens must be loaded manually on the RSM.

2. The system compares the specimen rerun test results to the configured retest rules. If a rerun test result meets the criteria of a retest rule, the system generates a second rerun order. This rerun order is displayed and processed in the same manner as the first order.

Quality control analysis

Quality control analysis is the process by which quality control (QC) data is monitored. QC data includes both unreleased and released control results. The Alinity ci-series monitors QC data with Levey-Jennings graphs, Westgard rules, control range tracking, and QC data summaries.

To help ensure quality results and maintain optimal system performance, comply with the following requirements:

- Carefully follow all directions in the operations manual and the reagent manufacturer's assay documentation.
- Do not use expired or contaminated consumables.
- Perform maintenance procedures and calibration procedures as recommended.

IMPORTANT: Quality control issues must be evaluated and resolved before specimens are tested.

The system evaluates quality control (QC) results by assay for each control lot. If reagents are configured to be disabled when a control failure occurs, and a control failure occurs for one or more reagent cartridges, the failure prevents the use of one or more of the cartridges on the module on which the failure occurred.

A system configuration parameter determines whether controls are run for an assay for each reagent lot or each reagent cartridge. If quality control is run for each reagent cartridge and any control level fails, the individual reagent cartridge is disabled. If quality control is run for each reagent lot and a tested control level fails, all reagent cartridges for that lot are disabled, including any cartridges that are subsequently loaded on the system. The system enables the reagent cartridge or the reagent lot after the failed QC result is rerun and the result is within acceptable limits.

Related information...

Operating instructions, page 507
Westgard rule application, page 762
Levey-Jennings (Graph) screen, page 766
Quality Control Summary screen, page 773

Westgard rule application

When Westgard rules are configured, the Alinity ci-series compares a control result at completion against the expected mean and standard deviation for the control level. Previous results, released and unreleased, for the same assay and module are considered in the analysis. Control results that are marked as excluded are not considered.

Related information...

Quality control analysis, page 762

Westgard rule descriptions, page 763
Westgard rule run descriptions, page 765
Configure Westgard rules, page 388

Westgard rule descriptions

Control results for an assay are evaluated at completion against all Westgard rules that are enabled for the assay. Westgard rules that are configured as a failure are evaluated first, and then the rules that are configured as a warning are evaluated.

NOTE: When one-material (1M) rules are evaluated, previous control results that have the same control name, control level name, and control lot number are considered.

When across-materials (xM) rules are evaluated, previous control results that have the same control name, the same control lot number, and different control level names are considered.

If a control result meets the failure criteria for only one Westgard rule, the result is flagged with the corresponding rule flag. If the failure criteria for more than one Westgard rule is met, only one rule flag is applied to the control result according to the following order:

1. 1-3s
2. 2-2s 1R 1M
3. 2-2s 1R xM
4. 2-2s xR 1M
5. R-4s
6. 4-1s 1m
7. 4-1s xM
8. 10-x 1M
9. 10-x xM
10. 1-2s

When a failure is identified, no further evaluation occurs. A CNTL flag is applied to each patient result associated with an assay that has a control failure. The CNTL flag is not applied to patient results for control failures that are configured as a warning.

The following list provides descriptions of the Westgard rules:

1-2s	Control rule to test whether a control measurement exceeds the control limits of Mean (x) + 2 standard deviation (SD) or x - 2 SD.
1-3s	Control rule to test whether a control measurement exceeds the control limits of x + 3 SD or x - 3 SD.

2-2s 1R 1M Control rule to test whether two consecutive control measurements for the same control material within the same run exceed the same control limit of either x + 2 SD or x - 2 SD. Both control results must fall on the same side of the mean.

2-2s 1R xM Control rule to test whether two consecutive control measurements across control materials within the same run exceed the same control limit of either x + 2 SD or x - 2 SD. Both control results must fall on the same side of the mean. The two control results must have different control level names.

2-2s xR 1M Control rule to test whether two consecutive control measurements for the same control material across two different runs exceed the same control limit of either x + 2 SD or x - 2 SD. Both control results must fall on the same side of the mean. The previous consecutive control result can be obtained during any previous run.

R-4s Control rule to test whether the range, or difference, between control measurements that are run within 30 minutes of each other exceeds 4 SD. The two control results must have the same control name, can have the same or different control level names, and do not need to be consecutive. The current control result is compared against each control result, which is older than the current result by 30 minutes or less. Each result must be greater than 2 SD, but in opposite directions.

4-1s 1M Control rule to test whether four consecutive control measurements for the same control material exceed the same control limit of either x + 1 SD or x - 1 SD. All four control results must fall on the same side of the mean. The previous control results can be obtained during any run.

4-1s xM Control rule to test whether four consecutive control measurements across control materials exceed the same control limit of either x + 1 SD or x - 1 SD. All four control results must fall on the same side of the mean. The previous control results can be obtained during any run. For this rule, both control results with the same or different control level names are considered.

10-x 1M Control rule to test whether 10 consecutive control measurements for the same control material fall on the same side of the mean. If a control result falls on the mean, the rule

does not fail. The previous control results can be obtained during any run.

10-x xM — Control rule to test whether 10 consecutive control measurements across control materials fall on the same side of the mean. If a control result falls on the mean, the rule does not fail. The previous control results can be obtained during any run. For this rule, both control results with the same or different control level names are considered.

Related information...

Westgard rule application, page 762
Westgard screen element descriptions, page 387

Westgard rule run descriptions

Westgard rule run descriptions identify the options to define quality control run intervals on the Alinity ci-series. A time-based quality control run is configured by using a start time and a time interval to define the number of hours in the run. The run period is used to evaluate the following Westgard rules:

- 2-2s 1R 1M
- 2-2s 1R xM
- 2-2s xR 1M
- 4-1s 1M
- 4-1s xM

The following list provides Westgard rule run descriptions:

Start time for the first run — The quality control shift start time is defined for each c-series processing module and each i-series processing module by configuring the **Shift Start Time** parameter on the Modules screen. The system creates quality control orders at the configured time for those controls for which the **Automated** and **Use Module Shift Time** options are enabled.

The quality control shift start time is defined for a control by configuring the **Start Time** parameter in the **Control Configuration** area of the Control Create/Edit screen. The system creates quality control orders at the configured time for the control when the **Automated** option is enabled.

Run period length — On a control-level basis, the **Time Interval (Minutes)** parameter defines the time interval in minutes after the shift start time for additional control orders to be created. If the

configured time interval cannot be divided equally into timed run periods in the 24-hour day, the last run is composed of the remaining hours.

If the assay time interval is configured, the configured assay time interval supersedes the configured control level time interval if both intervals are defined for the same quality control lot number.

Related information...

Westgard rule application, page 762
Configure c-series module settings, page 193
Configure i-series module settings, page 194

Levey-Jennings (Graph) screen

On the Levey-Jennings (Graph) screen, the operator can perform the following functions:

- View a maximum of six Levey-Jennings graphs for each assay and the statistical data for the same control name and lot number for a specific processing module.
- View the Levey-Jennings graphs for the same assay, control name, and lot number for a maximum of four processing modules of the same type in a multimodule system.
- Change the criteria for a Levey-Jennings graph and its data.
- Include or exclude points from a Levey-Jennings graph.
- Print a Levey-Jennings report.
- Recalculate the Westgard analysis for a Levey-Jennings point.
- View the details of a selected Levey-Jennings point.
- Add a comment to a Levey-Jennings point.

Related information...

Quality control analysis, page 762
Levey-Jennings (Graph) screen element descriptions, page 766
Point Details screen element descriptions, page 769
Display the value for a Levey-Jennings point, page 771
Exclude or include a Levey-Jennings point, page 771
View the details for a Levey-Jennings point, page 772
Add a comment to a Levey-Jennings point, page 772

Levey-Jennings (Graph) screen element descriptions

The Levey-Jennings (Graph) screen displays the quality control graphs for the selected assays.

Elements

Control	Displays the name of the control.
Lot Number	Displays the lot number of the control.
Exp. Date	Displays the expiration date of the control lot.
Comparison Type	Displays the source of the mean and standard deviation (SD) used to compare to the expected mean and SD. The following comparison types are available in the drop-down list: • None • Manufacturer • Module Cumulative • System Cumulative
Selected Data Range	Displays control data for the date range selected on the Quality Control Summary screen.
Displayed Data Range	Displays the date range of the displayed points. As the graph is navigated, the displayed data range changes to reflect the points being viewed.

Selected assays area

Assay name tabs	Display the names of the selected assays on the tabs at the right side of the screen.

Graph area

Level	Displays the name of the control level.
Module	Displays the number of the module used to process one or more controls.
Mean	Displays the expected mean value as configured.
SD	Displays the expected SD value as configured.

Control Range	Displays the expected control range as configured.
Comparison Mean	Displays the mean used to compare to the expected control mean. Information that is displayed is determined by the comparison type selected.
Comparison SD	Displays the SD used to compare to the expected control SD. Information that is displayed is determined by the comparison type selected.
N	Displays the number of control points covered by the selected date range.
Mean	Represented by the center line of the graph and indicates the expected control mean.
+1 SD and -1 SD	Represented by the first line above and below the mean (green area).
+2 SD and -2 SD	Represented by the second line above and below the mean (yellow area).
+3 SD and -3 SD	Represented by the third line above and below the mean (red area).
Points	Control results that fall within the defined control range and do not fail configured Westgard rules are represented by a black dot and are graphed in the order of completion. Control points that caused a warning condition based on the Westgard analysis are represented by a yellow dot. Control points that failed Westgard analysis are represented by a red dot. Control points beyond +/- 3 SD are shown as a horizontal line. Excluded control points are represented by a white circle with a black dot.

Function buttons

QC Summary	Navigates to the Quality Control Summary screen.
Print	Displays the Print flyout.
Point Details	Navigates to the Point Details screen.

Text Size	This function button is unavailable on this screen.

Related information...

Levey-Jennings (Graph) screen, page 766
Descriptions of screen elements, page 143
Print flyout element descriptions, page 789

Point Details screen element descriptions

The Point Details screen displays the details for the selected control value.

Control Information area

Control Name	Displays the name of the control.
Control Lot	Displays the lot number of the control.
Operator ID	Displays the identification of the operator logged onto the system when the control result was generated or released.
Control Level	Displays the name of the control level.
Control Lot Exp.	Displays the expiration date of the control lot.
Time of Completion	Displays the date and time that the control result was generated.
Assay Name	Displays the name of the assay file.
Assay Number	Displays the number of the assay file.

Point Information area

Point Value	Displays the control result.
Flags	Displays the flags associated with the quality control result.
Codes	Displays the processing codes associated with the control result.
Point SD	Displays the standard deviation of the control result.
Mean	Displays the expected mean value as configured.

Maintenance and diagnostics

The system software provides a user-friendly interface to perform and track maintenance and diagnostic activities.

The Procedures screen displays maintenance and diagnostic procedures that can be performed. After initiating a procedure, follow step-by-step instructions through the procedure to completion. The online log indicates the date and time that the procedure is completed. The performance of the procedure is tracked in the online log.

If a maintenance procedure or a diagnostic procedure requires the cover interlocks to be overridden by using the procedure key, the interlocks can be overridden **only** by trained operators. Be aware that potential mechanical hazards and Biological RISK may be present. Be aware of moving parts. Do not reach into the paths of moving parts.

Related information...

Service, maintenance, and diagnostics, page 875
Procedures screen, page 876
Procedures Log screen, page 893
Descriptions of maintenance and diagnostic procedure statuses, page 898
Maintenance procedure descriptions, page 899
Unscheduled cleaning, page 915
Diagnostic procedure descriptions, page 917

Procedures screen

On the Procedures screen, the operator can view the following information:

- Scheduled maintenance procedures to perform by category
- Available diagnostic procedures to perform by category
- In-process maintenance procedures or in-process diagnostic procedures

A trained operator can perform the following functions:

- Access details for a maintenance procedure or a diagnostic procedure.
- Perform a maintenance procedure or a diagnostic procedure.
- Print a maintenance procedure or a diagnostic procedure.
- Access maintenance logs or diagnostic logs.
- Schedule the start time for an automated maintenance procedure.

Related information...

Maintenance and diagnostics, page 876
Procedures screen element descriptions, page 877