MEHARRY MEDICAL COLLEGE
Consolidated Clinical Laboratories

Alinity I Operation Manual

Version 1.0 *Controlled document*

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SUPERSEDES: Procedure titled _____

This operation manual is available online and updated automatically as we are connected to Abbott via Abbott link. This manual is meant to be read by staff to get ready and familiar. Nut the real source is the online

1. PURPOSE

The purpose of this document is to provide information to the Lab staff regarding the system features, technology, principles, calibration, quality control, periodic maintenance, troubleshooting and data management of Abbott Alinity-i analyzer.

2. SCOPE

The scope applies to the entire Lab operating and maintaining the Abbott Alinity-I analyzer.

3. ABBREVIATIONS AND DEFINITIONS

QC: Quality Control.

RSM: Reagent and sample manager.

SCM: System control module.

4. RESPONSIBILITIES

The selection and assessment of any instrument used in laboratory is the responsibility of the laboratory management.

Biomedical team at each facility are responsible for the installation, validation and provision of preventive maintenance and technical support.

HOL/Pathologists are responsible for assurance of quality of the examination and interpretation of results.

Laboratory Manager/Supervisor/Technologists/Technicians are responsible for ensuring compliance to procedure.

5. PROCEDURE

5.1. Test Information

The Abbott Alinity-i analyzer system accommodates many laboratory environments and workflow styles. As a result of this flexibility, operating the Abbott Alinity-i analyzer system can be as easy as loading specimens, removing specimens, and reviewing system and supply status. “Abbott Alinity-i analyzer System User Manual” can be used for detailed information.

5.1.1. Primary components of the Alinity-i

The Alinity-i consists of three primary components:

Figure 1. 1: Primary components of Alinity-i

1) Processing Module

Performs all sample-processing activities from sample aspiration to final result reporting. The type and number of processing modules determine the system configuration.

2) Reagent and Sample Manager (RSM)

Transports reagents, samples, calibrators, and controls through the Alinity ci-series. Each system has one primary RSM regardless of the type and number of processing modules.

3) System Control Module (SCM)

Provides a common user interface among all Alinity products.

5.1.2. Home Screen Overview

The 'Home screen' provides access to multiple functions that can be performed on the Alinity-i

analyzers.On the Home screen, the operator can view the following information:

1) System information and module status information

2) System conditions and module conditions that require an operator response

The operator can perform the following functions:

1) Start, run, pause, and stop modules.

2) Shut down the computer.

3) Perform maintenance tasks

To perform certain tasks, the operator may need to cycle power to the entire Alinity-i series, to the reagent and sample manager (RSM), or to one or more processing modules.

To cycle power, the specific component must be powered off and then must be powered on after a certain time period has elapsed. After the power is on, a start must be performed to transition the instrument status to Idle.

Based on the instrument status of the RSM and the processing module, a pause may be required so that the following tasks can be performed:

4) Maintenance and diagnostics
5) Component replacement

Circumstances for start-up, shutdown, etc.

1) Load samples, reagents, and solutions.
2) Perform maintenance or diagnostic procedures
3) Replace components
4) Troubleshooting
5) Emergency shutdown

5.1.2.1. Menu Bar

The red triangle (alert badge) navigates to the Alerts tab in the Alert Center flyout. The number of alert messages in the Alert Center is displayed next to the alert badge. Alerts are generated for system problems that require immediate attention

1) Alert Centre – Notification Badge

The amber circle (notification badge) navigates to the Notifications tab in the Alert Center flyout. The number of notification messages in the Alert Center is displayed next to the notification badge. Notifications are generated for system problems that do not require immediate attention.

Figure 1. 2: Alinity-i Home Screen

2) **Alert Center button:** Displays the Alert Center flyout.
3) **Home icon:** Navigates to the Home screen.

4) **Sample Status icon:** Navigates to the All Samples tab on the Sample Status screen.

5) **Orders icon:** Navigates to the All Orders tab on the Orders screen.

6) **Results icon**: Navigates to one of the following tabs on the Results screen:

a) Unreleased tab when no badge is present and the system is configured for manual or hold release of specimen results.

b) Specimen tab when no badge is present and the system is configured for automatic release of specimen results.

c) Exception tab when an amber badge is present, indicating that one or more test exceptions have been generated.

7) QC icon: Navigates to one of the following views:

a) The All view on the Quality Control screen when no badges are present.

b) The module-specific view for the lowest numbered module with a module-specific Badge.

c) An amber badge is displayed on the QC icon when one or more quality control (QC) tests completed processing and generated a Westgard warning.

d) A red badge is displayed on the QC icon when one or more QC tests completed processing and are out of range or generated a Westgard failure.

8) **CAL icon**: Navigates to one of the following views:

a) The All view of the Current tab on the Calibration Status screen when no badges Are present.

b) The module-specific view for the lowest numbered module with a module-specific badge.

c) An amber badge is displayed on the CAL icon when a calibration is within 1 hour of expiration.

d) A red badge is displayed on the CAL icon when a calibration has expired or failed.

9) **Reagents icon**: Navigates to one of the following views:

a) The All view of the Current tab on the Reagents screen when no badges are present.

b) The module-specific view for the lowest numbered module with a module-specific badge.

c) An amber badge is displayed on the Reagents icon when a low alert status is applied to one or more items in the reagent carousel or when an item in the reagent carousel or on the RSM is within 1 hour of lot or onboard stability expiration.

d) A red badge is displayed on the Reagents icon when a cartridge or rack has a load status error or when a cartridge or rack with a status other than OK, Mixing, Low Alert, or Disabled is displayed on the Current tab.

10) **Supplies icon**: Navigates to the Supplies screen.

a) If no badges are present, the module 1 view is displayed. If badges are present, the module-specific view for the lowest numbered module with a module-specific badge is displayed.

b) An amber badge is displayed on the Supplies icon when one or more inventory items have exceeded the configured low alert setting.

c) A red badge is displayed on the Supplies icon when an inventory item has a status other than OK, Overridden, or Low.

11) **System button**: Displays a menu of commands. The following list describes the default menu commands:

Cal/QC Inventory Navigates to the Cal/QC Inventory screen. The Cal/QC Inventory icon can be configured to display on

the menu bar.

12) **Procedures Log:** Navigates to the Procedures Log screen.
13) **Abbott Mail:** Navigates to the Abbott Mail screen.
14) **Configure**: Navigates to the Configure screen. The Configure icon can be configured to display on the menu bar.
15) **System Logs:** Navigates to the System Logs screen.
16) **Utilities:** Navigates to the Utilities screen.

5.1.2.2. Operations Manual (Help)

1) Displays the online Alinity ci-series Operations Manual. The Operations Manual (Help) icon can be configured to display on the menu bar.
2) Commands configured as icons are not displayed in the menu.
3) **Procedures icon:** Navigates to the Maintenance tab, the Diagnostics tab, or the In Process tab on the Procedures screen.
4) An amber badge is displayed on the Procedures icon when a maintenance procedure or a diagnostic procedure that is in process has a status of "Waiting user response."
5) A red badge is displayed when a maintenance procedure is overdue.
6) **Create Order icon:** Navigates to the Specimen tab on the Create Order screen.

5.1.2.3. Screen Header

1) **Home/System name**: Displays the screen title and the configured system name.
2) **Help button:** Displays Help from the operations manual for the active screen.
3) **Notepad button:** Displays the Notepad flyout. A notification badge showing the number of unread notes is displayed on the Notepad button when a note for the logged-on operator has not been viewed. The badge is removed after all unread notes have been viewed.
4) **Lock button:** Locks the screen and displays the Log On screen. The operator must enter a user name and password to unlock the screen.
5) **Logged on:** Displays the user name of the operator logged on the system.
6) **Time:** Displays the current system time.
7) **Date:** Displays the current system date.
8) **Software version:** Displays the current version of software installed on the system.
9) **Abbott A symbol:** Displays the Print to File dialog box. The operator can print the screen to a file or a configured printer.

5.1.2.4. System Status Bar

The System Status bar provides system-monitoring information and status information for devices connected to the system. The following statuses may be displayed on the System Status bar: Host, Printer, Alinity PRO, LAS, Abbott Link, and Abbott Mail.

1) **Host button:** Displays the Host Connection Status flyout. The button is displayed only when the system is configured for the host computer. The status of the host communication is indicated by the following button colors:
2) **Green:** The system is communicating with the host and detects no errors.
3) **Red:** Communication is unavailable.
4) **Printer button:** Displays the Printer Status/Queue fly out. The button is displayed only when the system is configured for a printer. The status of the printer connection is indicated by the following button colors:
   - **Green:** The printer interface detects no errors.
   - **Yellow:** The printer is low on ink or is out of paper.
   - **Red:** Communication is unavailable.
5) **Alinity PRO button:** Displays the Alinity PRO Connection Status flyout. The button is displayed only when the system is configured for an Alinity PRO interface. The status of the Alinity PRO connection is indicated by the following button colors:
   - **Green:** The system is communicating with Alinity PRO and detects no errors.
   - **Red**: Communication with the Alinity PRO has an error.
6) **LAS button:** Displays the LAS Connection Status flyout. The button is displayed only when the system is configured for a laboratory automated system (LAS) interface. The status of the LAS connection is indicated by the following button colors:
   - **Green**: The system is communicating with the LAS and detects no errors.
   - **Yellow**: The system is connecting to the LAS.
   - **Red**: Communication with the LAS has an error condition or is disabled.
7) **Abbott Link button**: Displays the Abbott Link Connection Status flyout. The button is displayed only the system is configured for Abbott Link. The status of the Abbott Link communication is indicated by the following button colors:
   - **Green**: The system is communicating with Abbott Link.
   - **Red**: Communication is unavailable.
8) **Mail button**: Navigates to the All tab on the Abbott Mail Inbox screen. The button is displayed only when the system is configured for Abbott Link. A badge displays the number of new mail items received since the last time the Abbott Mail Inbox was viewed.

5.1.2.5. Information Area

10) **RSM image:** Displays the RSM, the RSM name (if configured), and the current status for the RSM.
11) **Processing Module Image**: Displays the module type, the module name (if configured), the module number, and the current status of the processing module. A separate image is displayed for each processing module in the system. The following status updates are displayed on the processing module image:

a) Instrument Status

b) Reagent Status

c) Supply Status

d) QC Status

e) Calibration Status

f) Maintenance

g) Tests In Progress

h) Displays the current status of the RSM and individual processing modules. The instrument status is indicated by the following colors:

- **Green**: The instrument status of the module is Running or Processing.
- **Yellow**: The instrument status of the module is Idle, Initializing, Warming, Pausing, or Maintenance.
- **Red**: The instrument status of the module is Offline or Stopped.

12) Reagent Status button: Navigates to the Current tab on the Reagent Status screen for the module selected. The status of reagents loaded in the reagent carousel and loading area of the RSM is indicated by the following colors:

- **Green**: The cartridge status is OK, Mixing, Overridden, or Disabled.
- **Yellow**: The volume of one or more reagent carousel items is below the configured low alert setting.
- **Red:** One or more reagent carousel items have a cartridge status of Expired, LLS Error, Empty, No Assay, Incomplete, BC Fail, Load Error, or Undefined. A reagent status of Empty triggers a red status only if no additional tests for the reagent are present on the module.

13) Supply Status button: Navigates to the Supplies screen for the module selected. The status of supplies loaded on the system is indicated by the following colors:

- **Green:** The status of all supply items and the waste container is OK.
- **Yellow:** The volume of a supply item is at or below the configured low alert setting, the waste container is near capacity, or the ICT module has exceeded the warranty period (number of days on the system or number of samples processed).
- **Red:** A supply item is empty or the waste container is full.

14) QC Status button: Navigates to the Quality Control Summary screen. The status of the quality control is indicated by the following colors:

- **Green**: All control results are within the acceptable range. No Westgard failures or warnings for the module are present.
- Yellow: A Westgard warning has occurred on the module
- **Red**: A control result, lot, or level for the module is out of range or has a Westgard failure status.

15) Calibration Status button: Navigates to the Current tab on the Calibration Status screen for the module selected. The status of current assay calibrations is indicated by the following colors:

- **Green:** All calibrations for onboard reagents are Active, Pending QC, or in process.
- **Yellow:** One or more calibrations for onboard reagents are within 1 hour of expiration.
- **Red:** One or more calibrations for onboard reagents have expired or failed or are not active.

7) Maintenance button: Navigates to the Maintenance tab or the In Process tab on the Procedures screen for the module selected. The status of the system maintenance is indicated by the following colors:

- **Green:** All required maintenance procedures have been performed. Navigates to the Maintenance tab.
- **Yellow:** A maintenance procedure or a diagnostic procedure is in process and requires an operator response.

Navigates to the In Process tab.

- **Red:** One or more maintenance procedures are overdue. Navigates to the Maintenance tab.

8) **Tests In Progress button:** Displays the total number of tests in progress (Scheduled, In Process, and Running). If no tests are in progress on the module, three dashes are displayed. Navigates to the All-Orders tab on the Orders screen.

9) **Total Samples**: Displays the total number of samples with a status of Scheduled, Running, or In Process. Navigates to the Sample Status screen.

10) **Sample Status button**: Navigates to the Sample Status screen.

11) **Exceptions:** Displays the number of exceptions in the Exception tab on the Results screen that have not been rerun or released. Navigates to the Exception tab on the Results screen.

12) **Exceptions button:** Navigates to the Exception tab on the Results screen.

13) **Orders Pending**: Displays the number of specimen orders with a status of pending, scheduled, running or in process. Navigates to All orders tab on the Orders screen.

14) **Orders button:** Navigates to the All-Orders tab on the Orders screen.

5.1.2.6. Function buttons

1) **Shutdown:** Displays a message requesting confirmation to shut down the system.

2) **Start:** Initializes and homes the RSM or one or more selected processing modules, and transitions the instrument status from Stopped to Idle.

3) **Stop:** Displays a message requesting confirmation to transition the instrument status of the RSM or the selected processing module from Running, Processing, or Idle to Stopped.

4) **Pause:** Displays a message requesting confirmation to transition the instrument status of the RSM from Running to Idle or to transition the instrument status of the selected processing module from Running or Processing to Idle.

5) **Text Size:** This function button is unavailable on this screen.

5.1.3. PROCESSING MODULE – ALINITY-i

5.1.3.1. Procedure key of the Alinity-i

The procedure key provides access to the front and rear processing center covers of the Alinity ci-series processing modules and the reagent and sample manager by overriding the interlocks for the processing module and system control module covers. The procedure key can be used to perform maintenance procedures, diagnostic procedures, and component replacement procedures.

Figure 1. 3: Procedure key of Alinity-i

5.1.3.2. Processing module – Alinity-i front view

The Alinity-i processing module is an immunoassay analyzer that performs sample processing. The processing module processes a maximum of 200 chemiluminescent microparticle immunoassay (CMIA) tests per hour and has 47 positions in the reagent carousel at a controlled temperature.

Processing modules perform all sample-processing activities from sample aspiration to final result reporting.

Figure 1. 4: Front view of Alinity-i processing module

1) Front processing center cover: Provides access to the components that perform assay-processing activities. The front processing center cover is monitored by two sensors. If the cover is opened during Initializing status, running status, or Processing status, the reagent and sample manager and the processing module transition to Stopped status.

2) RV hopper cover: Provides access to the RV hopper to replenish reaction vessels.

3) Bulk solution door: Provides access to the bulk solution storage area and the RV waste storage area.

5.1.3.3. Front electronics door: Provides access to the processing module electronics and embedded computer, and the procedure lock. Processing module – Alinity-i rear view

Figure 1. 5: Rear view of Alinity-i processing module

1) Rear processing center cover: Provides access to the components that perform assay-processing activities. The rear processing center cover is monitored by one sensor. If the cover is opened when the instrument status of the processing module is 'Initializing', 'Running', or 'Processing', the status transitions to 'Stopped'.

2) Rear access panel: Provides additional access to processing center components.

3) Rear electronics panel: Provides access to instrument electronics.

4) Processing module main power breaker: Powers on and powers off the power supply.

5.1.3.4. Rear fluidics panel: Provides access to pumps and syringes. Processing center – Alinity-i

The processing Centre is the main activity area of the processing module. Samples and reagents are dispensed and mixed in reaction vessels (RVs) in the process and pretreatment paths where assay processing is performed

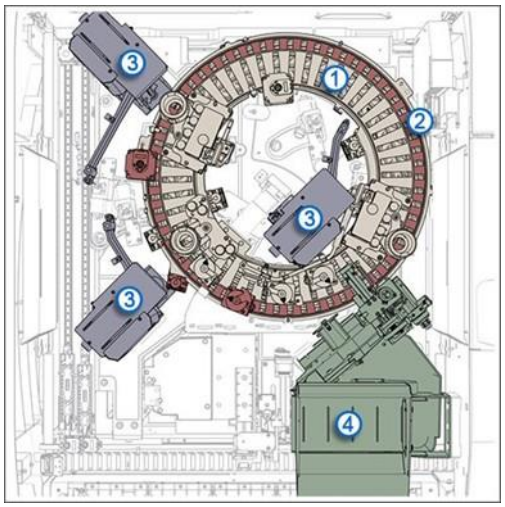


Figure 1. 6: Processing Centre

1) Process path: Provides incubation at a controlled temperature, liquid aspiration, and wash points as necessary for assay processing.
2) Pretreatment path: Provides incubation at a controlled temperature for pretreatment assay protocols.
3) Pipetting hardware: Aspirates and dispenses samples and reagents.
4) RV loader: Provides the onboard storage for RVs and transports RVs to the process and pretreatment paths.

5.1.3.5. Supply center – Alinity-i

The supply Centre is the onboard storage area for bulk solutions and reaction vessel (RV) solid waste.

Figure 1. 7: Supply Centre

1) Bulk solution storage area: Provides the onboard storage for replacement bulk solution bottles.
2) Bulk solution reservoir area: Provides the onboard storage for in-use bulk solutions.
3) RV waste storage area: Provides the storage for used RVs.

5.1.3.6. Bulk solution storage area – Alinity-i

The bulk solution storage area, which is located on the bulk solution door, provides the onboard storage for replacement bulk solution bottles. Bulk solutions from the replacement bottles fill onboard bulk solution reservoirs. Each bottle has a unique keyed cap that locks into its appropriate key slot in a bottle holder.

Figure 1. 8: Bulk solution storage area

1) Concentrated Wash Buffer: Mixed with purified water and then pumped to sample and reagent pipettor assemblies and to wash zones during assay processing.
2) Trigger Solution: Produces the chemiluminescent reaction that provides the final read.
3) Pre-Trigger Solution: Separates the acridinium dye from the conjugate that is bound to the microparticle complex. This action prepares the acridinium dye for the addition of Trigger Solution.
4) Bottle release button: Releases a bulk solution cap from a bottle holder to remove and replace a bulk solution bottle.
5) Bottle holder: Stores a replacement bulk solution bottle. Contains a mechanism that pierces the bulk solution septum.

5.1.3.7. Reservoir area – Alinity-i

The bulk solution reservoir area, which is located in the supply Centre, provides the onboard storage for bulk solutions in use during assay processing. When onboard bulk solution reservoirs are empty, bulk solutions from replacement bottles on the bulk solution door fill the reservoirs without an interruption in system operation. Concentrated Wash Buffer from its onboard bulk solution reservoir is diluted tenfold by the system and is stored in a 4 L diluted wash buffer reservoir for use during assay processing.

Figure 1. 9: Reservoir area

1) Reservoir bottle tray: Holds transfer pumps, bulk solution reservoirs, and the vacuum and waste accumulator. Slides out to access the bulk solution reservoirs.
2) Transfer pump rack: Holds transfer pumps for the Pre-Trigger Solution, the Trigger Solution, and the Concentrated Wash Buffer. The pumps transfer bulk solutions from replacement bottles to bulk solution reservoirs.
3) Concentrated Wash Buffer reservoir: Holds in-use Concentrated Wash Buffer.
4) Trigger Solution reservoir: Holds in-use Trigger Solution.
5) Pre-Trigger Solution reservoir: Holds in-use Pre-Trigger Solution.

5.1.3.8. Pump drawer – Alinity-i

1) Diluted wash buffer reservoir: Holds diluted wash buffer for use during assay processing.

Figure 1. 10: Pump Draw

5.1.3.9. RV waste storage area – Alinity-i

The RV waste storage area, which is located in the supply center, provides storage for the RV waste container and holds used reaction vessels (RVs).

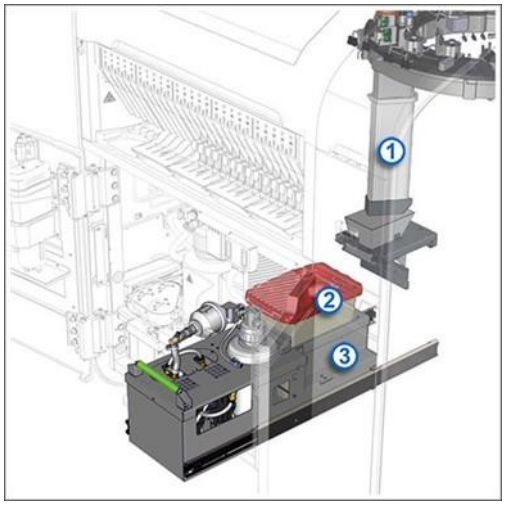


Figure 1. 11: RV Waste storage area

1) RV waste chute: Directs the used RVs into the RV waste container. The RV waste container can be removed during assay processing. When the container is removed, the RV waste chute closes and holds 50 RVs before the processing module pauses.

2) RV waste container: Holds the used RVs.

3) RV waste storage tray: Holds the RV waste container.

5.1.3.10. Reagent supply center – Alinity-i

The reagent supply center provides cooled storage at a controlled temperature for reagent cartridges, maintenance solutions, and frequently used calibrators and controls. Cartridges and vial racks are loaded on the reagent and

sample manager (RSM) and are transferred to the reagent positioner by the RSM.

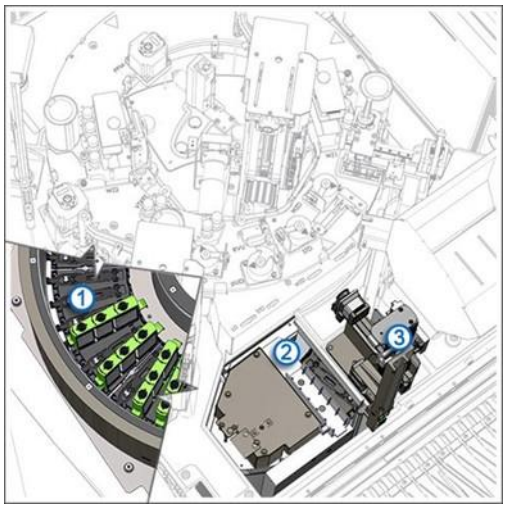


Figure 1. 12: Reagent supply center

1) Reagent carousel: Holds reagent cartridges, maintenance solutions, and frequently used calibrators and controls. The carousel rotates to provide reagent access to reagent 1 and reagent 2 pipettors.

2) Reagent positioner: Positions cartridges and onboard vial racks to load in the reagent carousel or onto the loading area. When the reagent positioner is in the open position, the cartridge or rack can be transferred to the loading area. When the reagent positioner is in the closed position, the cartridge or rack can be transferred to the reagent carousel.

3) Reagent transport: Places cartridges and onboard vial racks in the reagent carousel or onto the reagent positioner.

5.1.3.11. Reagent carousel – Alinity-i

The reagent carousel is a rotating, circular device that performs the following functions:

4) Holds a maximum of 47 bar-coded reagent cartridges, maintenance solutions, and vial racks in a cooled environment at a controlled temperature.

5) Provides microparticle dispersion by continuous rotation of microparticle reagent bottles.

6) Rotates to position reagent cartridges and onboard solutions so that reagents or solutions can be aspirated and dispensed.

7) Rotates to position vial racks for transfer to the sample positioner so that calibrators and controls can be aspirated and dispensed.

Figure 1. 13: Reagent carousel

8) Reagent segment: A section of the reagent carousel that holds a maximum of six cartridges or vial racks. The reagent carousel has a total of eight reagent segments. One segment contains the reagent carousel calibration target. This segment holds a maximum of five cartridges or vial racks.

9) Reagent position: A section of a reagent segment that holds one cartridge or vial rack.

10) Reagent carousel calibration target: A calibration target that is used to align the reagent pipettor to cartridges and vials.

5.1.3.12. Processing center interior lights

Processing center interior lights are located on the top panel of the Alinity i. The interior lights provide additional lighting when routine maintenance and system troubleshooting is performed. With either the front processing center cover or the rear processing center covers opened the interior lights can be turned on. The interior lights are turned on by pressing the interior light button located on the front edge of the top panel, indicated by the light icon if present.

The interior lights come on at a preset level of intensity. The light intensity may be adjusted through any of eight levels by pressing and holding either the front light button or the rear light button. When the light intensity reaches either the lower extreme or upper extreme the light intensity cycle will reverse. A single press to either the front light button or the rear light button will turn off the interior light. Closing both the front processing center cover and the rear processing center cover of a processing module will turn off the interior light. The power is supplied to the interior light by the system control module so the interior light will work with the processing module power turned off.

Figure 1. 14: Processing center interior light button

5.1.4. Reagent and Sample Manager (RSM)

The reagent and sample manager (RSM) is a transport system used to load calibrators, controls, specimens, reagents, and onboard solutions. The design of the RSM provides random and continuous access to load and unload sample racks, calibration and control racks, and reagent cartridges.

One primary RSM transports samples and reagents through an Alinity-i regardless of the number of processing modules.

The RSM performs the following functions:

1) Lifts racks and cartridges from the loading area and moves them past the bar code reader.

2) Positions racks and cartridges for the bar code reader to identify samples, reagents, and solutions.

3) Moves racks and cartridges to the appropriate processing module or returns them to the loading area.

Figure 1. 15: Reagent and Sample Manager

1) Sample positioner: Positions racks at the sample aspiration position. Each module has two sample positioners. A rack exchange occurs between the loading area and one sample positioner while the other sample positioner positions samples for aspiration.

2) RSM bar code reader: An imaging camera that reads bar code labels on samples, racks, and cartridges.

3) RSM transport: Transports racks and cartridges from the loading area to be read by the bar code reader and to be placed on the module-specific sample positioner or reagent positioner.

4) Loading area: Positions racks and cartridges for loading and unloading.

5.1.4.1. Loading Area

Figure 1. 16: Loading Area

1) Priority button: Temporarily assigns an RSM position as a priority position.
2) Priority position: Designated with a blue status indicator. Racks or cartridges inserted in this position are processed before other positions.
3) Status indicators: Indicate the status of sample processing and when samples and reagents can be accessed.
4) Tray: Holds racks and cartridges to load on the reagent and sample manager (RSM). Each tray holds a maximum of five racks or cartridges. Empty trays may remain on the loading area to create five positions to load racks or cartridges one at a time.
5) Position: Holds one rack or cartridge. Each processing module has 25 positions.
6) Bay: Holds trays that are used to position racks and cartridges for assay processing. Each processing module contains five bays.

5.1.4.2. Loading Area Status Indicators

Three status indicators (blue, green, and amber) are located above each reagent and sample manager (RSM) position to indicate the status of sample processing and when racks and cartridges can be accessed.

Figure 1. 17: Alinity-i loading area

The following list shows the position status:

INDICATORS OFF	No rack or cartridge is inserted in the position. [1]

GREEN (STEADY)	The rack or cartridge is inserted but is not in process. The rack or cartridge can be accessed. [2]

AMBER (STEADY)	The rack or cartridge is in process. The rack or cartridge cannot be accessed. [4]
GREEN (BLINKING)	Processing is completed. The rack or cartridge can be accessed. If a test is added or a rerun is scheduled before the rack is removed from the loading area, the status indicator for the position changes to amber and the rack cannot be accessed.
AMBER (BLINKING)	Unloading of a cartridge or vial rack is in process. The position is reserved and is unavailable to load a rack or cartridge.
AMBER AND GREEN (ALTERNATING)	A bar code scan error or other error occurred. The rack or cartridge can be accessed.
BLUE	The RSM position is designated as a priority position. [3]

Table 1. 1: Position Status.

5.2. Examinations and Principle of the Procedure Used for Examinations

The Alinity-i series uses the chemiluminescent microparticle immunoassay (CMIA) method. The Alinity-i analyzers have 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-i analyzers have also incorporated numerous features to prevent and reduce errors and to increase walkaway time.

5.3. Required Equipment

1) Alinity i
2) Millipore water purifier
3) Racks: Sample , control and calibrator racks.

5.4. Required Reagents

1) Alinity Buffer solution.
2) Alinity Pre-trigger solution.
3) Alinity Trigger solution.
4) Alinity assay reagent packs.
5) Alinity assay calibrators.
6) Alinity assay controls.
7) Alinity Consumables: Reaction vessels , Sample cups.

5.5. Primary Specimen Type/Preserving/Stability and Other Criteria

Serum, plasma, saliva, body fluid.

5.6. Work Environment

The Alinity-i analyzer must only be operated in a location that meets all of the ambient condition requirements listed below:

Installation location indoors in dry areas free from drafts and excessive dust.
Alinity-i analyzer should be installed on a level surface in an area where ambient temperatures remain between **18°C (64°F) and 40°C (104°F).**

The operating room must be equipped with appropriate ventilation.

Solid, level, vibration-proof floor capable of bearing the weight of the analyzer.

Relative humidity up to 80% (maximum; preferably 60-70%), non-condensing.

Avoid direct exposure to sunlight.

Safety at work environment is defined on laboratory Safety Procedures. For further details, refer to **"Procedure for Laboratory Safety Practices"**.

5.7. Priming of Device

Analyzer is primed during daily maintenance. Please see Break Down and Maintenance section.

To perform certain tasks, the operator may need to cycle power to the entire Alinity-i series, to the reagent and sample manager (RSM), or to one or more processing modules.

To cycle power, the specific component must be powered off and then must be powered on after a certain time period has elapsed. After the power is on, a start must be performed to transition the instrument status to Idle.

Based on the instrument status of the RSM and the processing module, a pause may be required so that the following tasks can be performed:

- Maintenance and diagnostics.
- Component replacement.

Circumstances for start-up, shutdown may include:

- Load samples, reagents, and solutions
- Perform maintenance or diagnostic procedures
- Replace components
- Troubleshooting
- Emergency shutdown

For more details, refer to "Procedural step" subsections pertaining to cycle power process functions (5.10.7 to 5.10.22).

5.8. Calibration and Quality Control Procedures

For assays, please see the Alinity i specimen, calibration and control orders procedure and the Alinity QC Monitoring procedure.

Performed by equipment vendor on a regular basis and recorded in the equipment maintenance folder.

5.9. Method Validation/Verification

Performance characteristics of the examination are verified by the laboratory. Refer to verification/validation data for the examination. Refer to **"Procedure for the Method Validation/Verification** for various aspects of verification/validation processes."

5.10. Procedural Steps

5.10.1. Cycle power to the system

Required instrument status: Offline, Stopped, Warming, Or Idle.

Perform this procedure to cycle power to the system control module (SCM), the RSM, and one or more processing modules to re-establish communication among the system components, to store configuration information, or to troubleshoot the system.

1) On the menu bar, tap the Home icon.

2) On the Home screen, tap Shutdown.

3) When a confirmation message is displayed, tap Yes. The user interface (UI) computer powers off when the system software completes the shutdown.

4) Open the SCM front door.

5) Move the SCM power switch downward.

Figure 1. 18: SCM power switch

6) Locate the main power breaker for each Alinity-i processing module

Figure 1. 19: Alinity-i processing module main power breaker

7) Power off the main power breaker of each Alinity-i processing module.

8) Ensure that each processing module remains powered off for 1 minute.

9) Power on the UI computer. See 5.10.3.

10) Wait for the Log On screen to display on the UI computer.

11) Move the SCM power switch upward to power on the RSM and the SCM bar code scanner.

12) Power on the main power breaker of each Alinity-i processing module.

13) After the power is turned on, the RSM and the processing modules initialize and the instrument statuses transition to Stopped.

14) Log on to the system software.

15) To transition the instrument statuses to Idle, start the RSM and each processing module.

16) Close the SCM front door.

5.10.2. Cycle power to the processing module and the reagent and sample manager (RSM)

PROCESSING MODULE	OFFLINE, STOPPED, WARMING, OR IDLE
Reagent and sample manager (RSM):	Offline, Stopped or Idle

Table 1. 2: RSM status

The instrument status for each processing module and the RSM must be one of the required statuses to ensure that sample processing is not interrupted.

Perform this procedure to cycle power to the RSM and one or more processing modules to re-establish communication with the system control module (SCM), to store configuration information, or to troubleshoot the system.

1) Open the SCM front door.

2) Move the SCM power switch downward.

3) When the SCM power switch is turned off, the power is turned off to the RSM for each processing module in a multi-module system and for the SCM bar code scanner.

Figure 1. 20: SCM power switch

4) Open the front electronics door of one or more of the processing modules.

5) Locate the processing module power switch for one or more of the processing modules.

Figure 1. 21: Alinity-i processing module power switch

6) Move the processing module power switch downward to power off one or more of the processing modules.

7) Ensure that each processing module remains powered off for 1 minute.

8) Move the SCM power switch upward to power on the RSM and the SCM bar code scanner.

9) Move the processing module power switch upward to power on one or more of the processing modules.

10) After the power is turned on, the RSM and one or more of the processing modules initialize and the instrument statuses transition to Stopped.

11) To transition the instrument statuses to Idle, start the RSM and one or more of the processing modules.

12) Close the front electronics door of one or more of the processing modules.

13) Close the SCM front door.

5.10.3. Power on the user interface (UI) computer

Perform this procedure to power on the user interface (UI) computer.

1) Open the SCM front door.
2) Press the power switch on the front of the UI computer.
3) Wait for the Log On screen to display on the UI computer.
4) If the power to the processing module and the reagent and sample manager (RSM) is on, cycle power to the processing module and the RSM.
5) Use the main power breaker to cycle power to the Alinity-i processing module.
6) If the power to the processing module and the RSM is off, power on the processing module and the RSM.

5.10.4. Power off the user interface (UI) computer

The instrument status for each processing module and the RSM must be one of the required statuses to ensure that sample processing is not interrupted (refer to table 1. 1).

Perform this procedure to power off the user interface (UI) computer.

1) On the menu bar, tap the home icon.
2) On the Home screen, tap Shutdown.
3) When a confirmation message is displayed, tap Yes. The UI computer powers off when the system software completes the shutdown.

5.10.5. Power on the processing module

Prerequisite: Confirm that the following criteria are met to ensure the appropriate initialization of communication between the system components:

The system control module is powered on and the user interface is displayed

One or more processing modules have been powered off for a minimum of 1 minute

Perform this procedure to power on one or more of the processing modules.

If only the front power switch of a processing module is off, the reagent carousel power is maintained.

1) Locate the main power breaker of the processing module.

Figure 1. 22: Alinity-i processing module main power breaker

2) If the main power breaker of the processing module is off, move the breaker to the ON/I position.

3) Open the front electronics door of the processing module. Locate the power switch of the processing module.

Figure 1. 23: Alinity-i processing module power switch

4) If the power switch of the processing module is off, move the switch upward to power on the processing module.

5) After the power is turned on, the processing module initializes and the instrument status transitions to Stopped.

6) To transition the instrument status to Idle, start the processing module.

7) Close the front electronics door of the processing module.

5.10.6. Power off the processing module

5.10.6.1. Required instrument status

OFFLINE, STOPPED, WARMING, OR IDLE

The instrument status for each processing module must be one of the required statuses to ensure that sample processing is not interrupted.

Perform this procedure to power off one or more processing modules during component replacement or troubleshooting.

1) If only the front power switch of a processing module is off, the reagent carousel power is maintained. To turn off all power to the processing module, move the main power breaker of the module to the off position.

2) Open the front electronics door of the processing module.

3) Locate the power switch of the processing module (see Figure 1.7).

Figure 1. 24: Alinity-i processing module power switch

4) Move the processing module power switch downward to power off the processing module.

5) To power off all processing modules in a multimodule system, the power must be turned off separately for each module.

6) To turn off all power to the processing module, perform steps 3.2.6.5, and 3.2.6.6. If the reagent carousel power does not need to be turned off, proceed to step 3.2.6.7.

7) Locate the main power breaker of the processing module (see Figure 1.8).

Figure 1. 25: Alinity-i processing module main power breaker

8) Move the main power breaker of the processing module to the OFF/O position to turn off all power to the processing module.

9) Let the processing module power remain off for a minimum of 1 minute before the power is turned on again.

10) Close the front electronics door of the processing module.

11) To power off the Alinity-i processing module for more than 7 days, perform a long-term shutdown.

5.10.7. Power on the reagent and sample manager (RSM)

Prerequisite: Confirm that the user interface computer is powered on and the user interface is displayed to ensure the appropriate initialization of communication between the system components.

Perform this procedure to power on the reagent and sample manager (RSM). The SCM power switch provides power to the RSM.

1) Open the SCM front door (see Figure 1.9).

Figure 1. 26: Alinity-i SCM power switch

2) Move the SCM power switch upward.

3) When the SCM power switch is turned on, the power is turned on for the RSM of each processing module in a multimodule system. After the power is turned on, the RSM initializes and the instrument status transitions to Stopped.

4) To transition the instrument status to Idle, start the RSM.

5) Close the SCM front door.

5.10.8. Power off the reagent and sample manager (RSM)

REQUIRED INSTRUMENT STATUS:	OFFLINE, STOPPED, WARMING, OR IDLE

Table 1. 3: Power off the reagent and sample manager (RSM)

5.10.8.1. Required Instrument Status

OFFLINE, STOPPED, WARMING, OR IDLE

The instrument status for the RSM must be one of the required statuses to ensure that sample processing is not interrupted.

Perform this procedure to power off the RSM to perform maintenance or troubleshooting procedures.

1) Open the system control module (SCM) front door (see Figure 1.10).

Figure 1. 27: Alinity-i SCM power switch

2) Move the SCM power switch downward.

3) When the SCM power switch is turned off, the power is turned off for the RSM of each processing module in a multimodule system and for the SCM bar code scanner.

4) Close the SCM front door.

5.10.9. Start the processing module and the reagent and sample manager (RSM)

5.10.9.1. Required Instrument Status

STOPPED OR IDLE.

Perform this procedure to complete the following tasks:

1) Initialize a processing module or the reagent and sample manager (RSM) and transition the instrument status from Stopped to Idle.

2) Reinitialize a processing module or the RSM when the instrument status is Idle.

3) Prepare for sample processing.

4) On the menu bar, tap the home icon.

5) On the Home screen, perform one of the following steps:

6) Tap one or more of the processing modules or the RSM.

7) Tap one or more of the processing modules and the RSM.

8) Tap Start.

5.10.10. Pause the processing module

5.10.10.1. Required Instrument Status: Running or Processing

Perform this procedure to transition the instrument status of the processing module from Running or Processing to Idle. The instrument status must be Idle to perform the following tasks:

Maintenance and diagnostics, Component replacement.

1) On the menu bar, tap the home icon.
2) On the Home screen, tap one or more of the processing modules.
3) Tap Pause.
4) When a confirmation message is displayed, tap Yes.
5) When the processing module is paused, the instrument status of the module transitions to Pausing. Then, the processing module performs the following steps:
6) Completes the aspiration for the test in process and completes one or two additional aspirations for the sample in process.
7) Returns the sample rack to the reagent and sample manager.
8) Transitions to Idle status. All scheduled tests remain as scheduled until the instrument status of the processing module transitions to Idle. After the processing module transitions to Idle status, all scheduled tests become exceptions.
9) The instrument status of the processing module transitions to Idle unless the Run button is selected to initiate a run before the status transitions.
10) Do not lift a front or rear processing center cover before the instrument status of the processing module transitions to Idle.

5.10.11. Pause the reagent and sample manager (RSM)

5.10.11.1. Required Instrument Status: Running

Perform this procedure to transition the instrument status of the reagent and sample manager (RSM) from Running to Idle. The instrument status must be Idle to perform the following tasks:

1) Perform maintenance procedures or diagnostic procedures.
2) Remove a rack or cartridge when the status indicator is amber.
3) Stop the transportation of samples to one or more of the processing modules.
4) On the menu bar, tap the Home icon.
5) On the Home screen, tap the RSM.

6) Tap Pause.

7) When a confirmation message is displayed, tap Yes.

NOTE: When the RSM is paused, the instrument status of the RSM transitions to Pausing. The processing module completes sample aspiration for all scheduled tests and the RSM returns the racks to their original locations. Scheduled loading and unloading of reagent cartridges are completed. The instrument status of the RSM transitions to Idle unless the Run button is selected to initiate a run before the status transitions.

NOTE: Do not lift a front processing center cover before the instrument status of the processing module transitions to Idle.

5.10.12. Stop the processing module and the reagent and sample manager (RSM)

5.10.12.1. Required Instrument Status: Running, Processing Or Idle

Perform this procedure to transition the instrument status of the system from Running, Processing, or Idle to Stopped.

1) On the menu bar, tap the Home icon.

2) On the Home screen, perform one of the following steps:

3) Tap one or more of the processing modules or the RSM.

4) Tap one or more of the processing modules and the RSM.

5) Tap Stop.

6) When a confirmation message is displayed, tap Yes.

5.10.13. Perform and Emergency Shutdown

Perform this procedure to shut down the system when an emergency situation occurs.

1) Locate the main power breaker for the system control module (SCM) and all processing modules

Figure 1. 28: Alinity-i processing module main power breaker

2) Move each main power breaker to the OFF/O position.

3) Unplug the power connector from the power supply.

IMPORTANT: To remove all power to all processing modules and the reagent and sample manager, unplug the power connector from the power supply for each processing module and the SCM.

5.10.14. Long-term Shutdown

If the Alinity i-series needs to be shut down for more than 7 days, a long-term shutdown procedure must be performed. The procedure flushes the system with water and air to remove bulk solutions from pumps and tubing. The procedure prevents salt buildup, which may cause damage to the system. Contact an Abbott Laboratories representative to perform the long-term shutdown procedure.

5.10.15. Log On Screen

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

1) System information.

2) Status information.

3) The operator can log on to the system.

5.10.16. Log On screen element descriptions

On the Log On screen, the operator can log on to the system and can view system and status information for all modules.

5.10.17. Log On area

This area is used to enter an operator ID and a four-digit numeric pin to log on to the system. The system has three types of access levels: General, Supervisor, and Administrator.

LOG ON	Displays elements that are used to enter an operator id or to display the identification of the previous operator. The default logon is admin (system administrator). The following elements are available:
, + DONE	The Plus button displays a box that is used to enter the operator ID. The operator ID can contain a maximum of 12 alphanumeric characters. The + Done button displays the operator ID that was entered. The button switches between and + Done.
FOUR OPERATOR LOGON BUTTONS	Display the identification of the last four operators who logged on to the system.
FOUR CIRCLES	Indicate the entry of the four-digit PIN. As each digit of the PIN is entered, each circle is shaded.

NUMERIC KEYPAD	Displays buttons that are used to enter the four-digit PIN for the operator ID. The Clear All button is used to clear all digits that were entered. The Backspace button is used clear the last digit that was entered. If the system is configured for a password-controlled logon, the challenge ID and password must be configured before the password- controlled logon is used.

Table 1. 4: Log On area.

5.10.18. System Information area

Displays the current statuses of tests in process on the system.

TIME OF COMPLETION	Displays the completion time for the last test in process on the system.
TOTAL SAMPLES	Displays the total number of samples that have a status of Scheduled, Running, or In Process.
ORDERS PENDING	Displays the number of specimen orders that have a status of Pending, Scheduled, Running, or In Process.
EXCEPTIONS	Displays the number of exceptions that have not been rerun or released. The number is displayed in red text.

Table 1. 5: System Information area

5.10.19. System Status area

Displays badges to indicate the statuses of instruments, reagents, and supplies for all system modules.

5.10.19.1. Instrument status icons

Displays the overall instrument status for all system modules. The instrument status is indicated by the following badges:

GREEN CHECK MARK	The instrument status for all modules is Running or Processing.
AMBER CIRCLE	The instrument status for one or more modules is Idle, Initializing, Warming, Pausing, or Maintenance.
RED TRIANGLE	The instrument status for all modules is Offline or Stopped.

Table 1. 6: Instrument status icons

5.10.19.2. Reagent Status icons

Displays the overall reagent status for all system modules. The status of reagents loaded on the system is indicated by the following badges:

GREEN CHECK MARK	The reagent status for all modules is OK, Mixing, Overridden, or Disabled.
AMBER CIRCLE	One or more reagent carousel inventory items have reached or exceeded the configured low alert setting.

RED TRIANGLE	One or more cartridges or racks have a status of Expired, LLS Error, Empty, No Assay, Incomplete, BC Fail, or Undefined.

Table 1. 7: Reagent status icons

5.10.19.3. Supply Status icons

Displays the overall status of supplies for all system processing modules. The status of the supplies is indicated by the following badges:

GREEN CHECK MARK	The status of supply items and waste containers for all processing modules is OK.
AMBER CIRCLE	One or more supply items have reached or exceeded the configured low alert setting.
RED TRIANGLE	One or more supply items are empty or expired, or the waste container is full.

Table 1. 8: Sample status icons

5.10.20. Function button

?	Displays help from the operations manual for the active screen, flyout, or message code.

Table 1. 9: Function button

5.10.21. Log On

Perform this procedure to log on to the Alinity-i series.

If the Log On screen is displayed, proceed to the below steps. If any other screen is displayed, tap the Lock button.

Tap an operator logon button.

If the appropriate operator logon button is not displayed, perform the following steps:

1) Tap the Plus button. 
2) Type the operator ID.
3) Tap the + Done button.

To display the Home screen, tap the four-digit PIN for the operator ID.

5.10.22. Lock the User Interface

Perform this procedure to lock the user interface.

1) When the user interface is locked, the operator is not logged off. Any samples that are in process generate results with the last logged-on operator ID until a new operator logs on.
2) On the screen header, tap the Lock button. 

NOTE: When the SCM power switch is turned off, the power is turned off to the RSM for all processing modules in a multimodule system.

5.10.23. Procedure key for the System Control Module (SCM)

The system control module (SCM) contains the following items:

1) A user interface computer provides the software interface to the Alinity-i and provides an interface to a host or middleware computer.
2) Hardware and software operate the reagent and sample manager (RSM).
3) The power supply operates the user interface computer and the RSM.

Figure 1. 29: Procedure key for the System Control Module

5.10.23.1. Front View of the SCM

Figure 1. 30: SCM Front View

1) Adjustable monitor: Displays the user interface of the Alinity ci-series and accepts on-screen selections from the operator.
2) Front SCM cover: Provides access to the RSM transport . The front SCM cover is monitored by a sensor. If the

cover is opened when the instrument status of the RSM is Initializing or Running, the status transitions to Stopped.

3) SCM shelf: Provides a small shelf for the operator and provides access to remove the bar code scanner.

4) Bar code scanner: Provides a means to scan sample bar codes and supply bar codes.

5) SCM front door: Provides access to the user interface computer and the procedure lock.

5.10.23.2. Rear View of the SCM

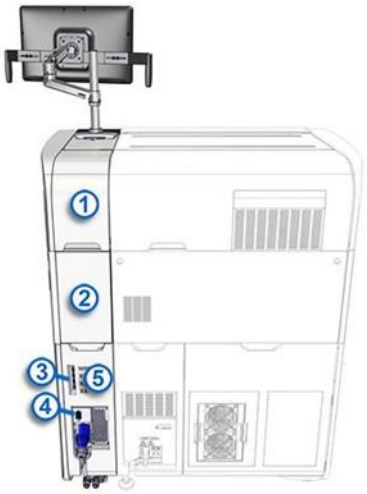


Figure 1. 31: SCM Rear View

1) Rear SCM cover: Provides access to the user interface computer power strip.

2) Rear SCM upper access panel: Provides access to the Ethernet switch.

3) Network connectors: Provide connections for external devices, such as the host interface and Abbott Link.

4) SCM main power breaker: Powers on and powers off the SCM power supply.

5) Rear SCM lower access panel: Provides access to the power supply and RSM electronics.

5.10.24. Alinity-i Distance Alert

The distance alert illuminates one of three colors (red, amber, or green) based on the status of the workstation.

Figure 1. 32: Alinity-i distance alert

The following list provides descriptions of each color. If multiple conditions are present, the colors are illuminated in the following order:

RED (BLINKING)	The instrument status of one or more processing modules in the workstation transitions from 'Running' or 'Processing' to 'Stopped' or 'Offline' without an operator request to transition the status. A critical alert message is generated and is displayed on the user interface.
RED	The instrument status of one or more processing modules in the workstation is Running, Processing, or Pausing, and one of the following conditions is present: If the distance alert is configured for notifications, a red badge is displayed on any icon on the menu bar. An alert message that has not been cleared is present in the Alert Centre. If the distance alert is configured for notifications, a red badge is displayed on any icon on the menu bar. An alert message that has not been cleared is present in the Alert Centre.
AMBER	The instrument status of one or more processing modules in the workstation is Running, Processing, or Pausing, and one of the following conditions is present: If the distance alert is configured for notifications, an amber badge is displayed on any icon on the menu bar except the Results icon. If the distance alert is configured for exception notifications, an amber badge is displayed on the Results icon.
	A notification message that has not been cleared is present in the Alert Centre.
GREEN (BLINKING)	The instrument status of one or more processing modules, but not all modules, in the workstation is Running or Processing.
GREEN	The instrument status of all processing modules in the workstation is Running or Processing.

DISTANCE ALERT OFF	The distance alert is not illuminated when one of the following conditions is present: The distance alert is disabled. The user interface computer is shut down. The instrument status of one or more processing modules in the workstation is not Running, Processing, or Pausing.

Table 1. 10: Description of Colors.

5.10.25. Specimen, Calibration and Control Orders

Order requests for specimens, calibrator samples, and quality control samples can be created automatically or manually by an operator.

5.10.25.1. Automated ordering

Automated creation of order requests is available for specimens, calibration, and controls. The following list shows capabilities listed by sample type:

Specimen: Automated specimen ordering is available by using the host computer download, the host order query, and the automated retest process.

Control: Automated control ordering is available by using the system configuration parameters.

Calibration: Automated calibration ordering is available by using system configuration parameters.

5.10.25.2. Host orders

Automated specimen ordering is available by using host computer downloads or host order queries. For automated ordering by a host computer, the system must be configured to communicate with the host.

5.10.25.3. Host computer download

Specimen orders are downloaded from the host computer to the user interface (UI) computer. When the bar code reader scans a bar-coded specimen, and the host computer has downloaded an order to the UI computer, the system processes the order.

If the system is configured for a laboratory automation system (LAS) track, when the LAS sends sample information to the UI computer and the host computer has downloaded an order to the UI computer, the system processes the order.

Rerun orders that are sent by the host computer are rerun if the specimen has not been unloaded from the reagent and sample manager (RSM). Orders that are downloaded can be viewed on the Orders screen.

Orders that are downloaded can be viewed on the Orders screen.

5.10.25.4. Host order query

A specimen order is downloaded from the host computer to the UI computer after a request is sent from the UI computer. The following activities occur after a specimen is loaded on the RSM or the LAS:

- When the RSM bar code reader scans a bar-coded specimen on the RSM, and an order does not exist on the

UI computer, the UI computer sends a query to the host computer.

- When the LAS sends specimen arrival information to the UI computer and an order does not exist, the UI computer sends a query to the host computer.

If the host computer has an order request for the specimen, the order is sent to the UI computer. When the order is received, the order can be viewed on the Orders screen.

If the host computer has no order requests for the specimen (or no record of the sample), a message is generated and is displayed on the Interfaces tab of the System Logs screen.

5.10.25.5. Automated quality control ordering

Automated control ordering is the process that the system uses to order quality control tests automatically. The control SID is associated with a predefined test list. Automated control orders are created in the following ways:

- When a control sample bar code label from an onboard vial rack, a vial rack, or a sample rack is scanned.
- When the system software periodically evaluates the control vials that are stored in onboard vial racks in the reagent carousel.
- When the configured time interval or test interval is exceeded.

Controls are evaluated for automated orders in three ways:

- When they are scanned by the reagent and sample manager (RSM).
- Every 15 minutes when they are stored on the system and the instrument status of the processing module is Processing.
- Every 15 minutes when they are stored off the system and at least one processing module has an instrument status of Processing.

5.10.25.6. Evaluation by the RSM

Control vials in vial racks and onboard vial racks and bar-coded samples in sample racks are evaluated when they are scanned by the RSM bar code reader for each processing module that has an instrument status of Running or Processing.

The rack ID of a vial rack or an onboard vial rack notifies the system software that calibrators or controls are loaded in the rack. The SID for controls in a vial rack or an onboard vial rack is composed of the control lot number, the control level, and the vial serial number. The SID for controls in a sample rack is composed of the control lot number and level, and QQQ is added to the beginning of the SID.

The scanned bar code is compared to the configured single-constituent and multiconstituent controls. If the bar code corresponds to a configured control lot number and level, and an order for the control is present in the system software, the order is completed. The order is not completed for a control vial that has a vial status of Empty, Expired, or LLS Error. Orders for assays that are disabled for onboard use in a multiconstituent control that is stored on the reagent carousel become exceptions when the orders are run.

If no control order is present in the system software and the control vial meets the criteria to create an automated order, the system automatically creates the order and processes the tests for the SID. The order that is created can be viewed on the Orders screen.

5.10.25.7. Evaluation of controls stored on the system

Control vials that are stored on the system are evaluated for automated control orders every 15 minutes on each processing module that has an instrument status of Processing (and when the instrument status transitions from

Stopped or Idle to Running or Processing).

On multimodule systems, automated control orders are evaluated on all processing modules on which the analyte can be run.

Automated control orders are not created for multiconstituent control assays that are disabled for onboard use when the control is located in an onboard vial rack that is assigned a position in the reagent carousel.

5.10.25.8. Evaluation of controls not stored on the system

After the evaluation of control vials that are stored on the system is completed, control vials that are stored off the system are evaluated for automated control orders. The evaluation occurs every 15 minutes when at least one processing module has an instrument status of Processing (and when the instrument status transitions from Stopped or Idle to Running or Processing). If one processing module has an instrument status of Processing, the evaluation is performed for all processing modules that have an instrument status of Running or Processing. Only the default lot number is evaluated and only for those controls that have the Automated parameter on the Control Configuration screen configured as Yes. A notification instructs the operator to load the control vials and orders are created when the vials are loaded.

Notification does not occur in the following instances:

- When a control order is present for the specified assay and control level.
- If the control lot number is expired.
- When no reagent cartridge is available for the assay.

5.10.25.9. Creation of automated orders when the Automated parameter is enabled

Automated control orders are created for controls that have the Automated parameter on the Control Configuration screen configured as Yes if the following criteria are met:

- No order has been created since the configured shift start time.
- The order is created for all analytes that use the control lot number and level with an onboard reagent lot or reagent lot and cartridge combination for assays configured to run controls by using a cartridge.
- The time interval or test interval has been exceeded.
- The order is created for each onboard reagent lot or reagent lot and cartridge combination.

The time interval is determined from the configured shift start time and resets daily at the shift start time. Orders that are created when the time interval is exceeded are created independently from manual orders and those orders created as the result of a configured test interval.

Orders are created for a calculated assay only when the Start Time parameter on the Control Configuration screen is defined for the control level.

After the initial configuration, the test interval for an assay begins when an order for the control lot number and level is completed without a Westgard failure or a quality control (QC) range failure. The interval is based on the number of specimen tests initiated for the assay since the last completed control result for the assay and control level. The test interval resets after every completed control result for the control level and analyte.

The most recent control result for the analyte generated a Westgard failure or a QC range failure.

Orders are created for the onboard reagent lot or reagent lot and cartridge combination.

Orders are not created if the control is in an onboard vial rack that has been assigned a position in the reagent carousel.

A usable calibration is present for the assay that has not been verified by quality control or a calibration order for the assay has a status of Scheduled or Running.

5.10.25.10. Creation of automated orders when the Automated parameter is disabled

The Control Configuration screen configured as No when control samples are scanned by the RSM bar code reader if no order has been created since the configured shift start time.

The order is created for all analytes that use the control lot number and level if an onboard reagent lot or reagent lot and cartridge combination is present.

Regardless of the configured option for the Automated parameter, automated control orders are not created in the following instances:

- A control order that has a status of Pending is present.
- The reagent cartridge status is Disabled.
- The control vial status is Empty, Expired, or LLS Error.
- Assays that have an assay status of Correlation are present.

5.10.25.11. Automated calibration ordering

Automated calibration ordering is the process that the system uses to create calibration orders automatically. Automated calibration orders are created in the following ways:

- When a bar code label from an onboard vial rack or a vial rack is scanned.
- When the system software periodically evaluates the calibrator vials that are stored in onboard vial racks in the reagent carousel.

Calibrator vials in vial racks and onboard vial racks are evaluated when they are scanned by the RSM bar code reader for each processing module that has an instrument status of Running or Processing.

The rack ID of a vial rack or an onboard vial rack notifies the system software that calibrators or controls are loaded in the rack. The SID for calibrators in a vial rack or an onboard vial rack is composed of the calibrator lot number and the vial serial number.

The scanned bar code is compared to the configured calibrator set. If the bar code corresponds to a configured calibrator lot number and an order for the calibrator set is present in the system software, the order is completed. No automated orders are created. The order is not completed for a calibrator vial in the calibrator set that has a vial status of Empty, Expired, or LLS Error.

If no calibration order is present in the system software and the calibrator vial meets the criteria to create an automated order, the system automatically creates and processes the order. The order that is created can be viewed on the Orders screen.

Calibrator vials that are stored on the system are evaluated for automated calibration orders every 15 minutes on each processing module that has an instrument status of Processing (and when the instrument status transitions from Idle to Running or Processing).

On multimodule systems, automated calibration orders are evaluated on all processing modules on which the analyte can be run.

Automated calibration orders are created if the following criteria are met:

1) No calibration with a status of Active or Overridden is present for the assay.

2) Orders are created for each uncalibrated onboard reagent lot or reagent lot and cartridge combination for assays configured to run calibrations by using a cartridge.

3) All onboard reagent lots or reagent lot and cartridge combinations have a status of Active or Overridden, but one or more lots or lot and cartridge combinations will expire within 1 hour if calibrators are stored on the reagent supply center or within 8 hours for all other calibrators.

4) Orders are created for the onboard reagent lots or reagent lot and cartridge combinations that will expire if a calibration is not in process.

5) The calibrator is a single-constituent calibrator, all onboard reagent lots or reagent lot and cartridge combinations have a status of Active or Overridden, and no calibrations are in process.

6) Orders are created for all onboard reagent lots or reagent lot and cartridge combinations.

7) Order are not created if the calibrator is in an onboard vial rack that has been assigned a position in the reagent carousel.

8) The calibrator is in an onboard vial rack and a calibration that has a status of Active is present, but the calibration will expire before the onboard vial rack is evaluated again, and no calibrations are in process.

9) The order is created for each onboard reagent lot or reagent lot and cartridge combination that will expire.

10) The assay is a c-series assay that uses the factor data reduction method, and the calibration is expired or will expire before the next evaluation interval.

11) Orders are created for all onboard reagent lots or reagent lot and cartridge combinations.

12) Automated calibration orders are not created in the following instances:

13) A calibration order for the same assay is present.

14) The reagent cartridge status is Disabled.

15) The vial status of any calibrator vial in the calibrator set is Empty, Expired, or LLS Error.

16) Assays that have an assay status of Correlation are present.

5.10.25.10. 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.

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.

The system suppresses a second rerun order if the order is based on the same retest rule criteria as the first rerun order.

5.10.26. Orders screen

On the Orders screen, the operator can view specimen, control, calibration, and rerun orders. The operator can perform the following functions:

- Find information about a specific order based on specified search criteria.
- Access the order information.
- Add a comment to a test order.
- Delete an order.
- Create a new specimen order, control order, or calibration order.

5.10.27. Orders screen elements descriptions

All Orders tab, Rerun tab, Specimen tab, Control tab, Calibration tab

Displays rerun, specimen, control, and calibrator test orders. Order status information can be filtered by order type by selecting the Rerun tab, Specimen tab, Control tab, or Calibration tab.

ELEMENT	DESCRIPTION

Rack/P	Displays the rack ID (Rack) and position (P) number. The rack/position can be sorted in ascending order, first alphanumerically by rack, and then numerically by position. NOTE: If the system is configured for a laboratory automation system (LAS) and the specimen is run on the LAS, the Rack/P is displayed as LAS/1 or LAS/2.
SID	Displays the sample identification of the order, which can be one of the following items: The bar code number or identification assigned to the specimen. The control lot number and control level number. Bar- coded controls include a serial number when quality controls are run in a vial rack. Bar-coded controls include the prefix QQQ followed by the control lot number and level when the controls are run in a sample rack. The calibrator lot number and calibrator level number. The SID can be sorted alphanumerically in ascending order.
Name	Displays the name, which can be one of the following items: The patient's name.

	The control name and, if configured, the control level number and control level name for control orders. The calibrator or calibrator set name, CAL (only for i-series), and the calibrator level for calibration orders.
Assay	Displays the name of the test ordered.
Test Type	Displays the sample type for the order: Specimen, Control, or Calibrator. The Test Type column is displayed only on the All Orders tab and the Rerun tab.
Status	Displays the current test status (Pending, Scheduled, Running, In Process, or Complete) of the assay ordered.
Time	Displays the estimated time that the order will be completed (in a 24-hour format). Time information is displayed for all samples with a status of Running.
Codes	Displays the processing codes to indicate processing conditions.

Table 1. 11: Elements

ELEMENT	DESCRIPTION
Create Order	Navigates to the Create Order screen.
Select All	Selects or deselects all items in a list. The button switches between Select All and Deselect All.
Search	Displays the Search fly out.
Print	Displays the Print fly out.
Details	Navigates to the Details screen for the selected items on the current screen.
Delete	Displays a message requesting confirmation to delete the selected items
Text Size	Increases or decreases the size of text displayed.

Table 1. 12: Function Buttons.

5.10.28. Orders screen, Search flyout element descriptions

In the Search fly out of the Orders screen, the operator can enter specific data that is used to filter the data on the screen.

ELEMENT	DESCRIPTION
Module	Displays check boxes that are used to search by the module. The module number for the specimen results of calculated assays is 6 (the system control module). The module number for control results of calculated assays is the processing module used to produce the constituent results.

Name	Displays a text box that is used to search by the name, which can be one of the following items: The patient's name. The control name and, if configured, the control level number and control level name for control orders. The calibrator or calibrator set name, CAL (only for i-series), and the calibrator level for calibration orders.

ELEMENT	DESCRIPTION
SID	Displays a text box that is used to search by the sample identification of the order, which can be one of the following items: The bar code number or identification assigned to the specimen. The control lot number and control level number. Bar- coded controls include a serial number when quality controls are run in a vial rack. Bar-coded controls include the prefix QQQ followed by the control lot number and level when the controls are run in a sample rack. The calibrator lot number and calibrator level number.
Rack	Displays a text box that is used to search by the rack identification number.
PID	Displays a text box that is used to search by the patient identification number.
Position	Displays a drop-down list that is used to search by the rack or bay position.
RSM Position	Displays a drop-down list that is used to search by a position on the reagent and sample manager.
Assay	Displays a text box that is used to search by the assay name.
Time From	Displays a spin box that is used to enter a search start time. To enter the search start time, use the system-configured format (HH:MM) and type the time in the box or tap the Up Arrow and Down Arrow buttons. If the system is configured for the 12-hour clock format, tap the AM or PM button to configure the time of day.
Time To	Displays a spin box that is used to enter a search end time. To enter the search end time, use the system-configured format (HH:MM) and type the time in the box or tap the Up Arrow and Down Arrow buttons. If the system is configured for the 12-hour clock format, tap the AM or PM button to configure the time of day.
Status	Displays check boxes that are used to search by the test status. The Search flyout has four test statuses: Pending In Process Scheduled Running

Test Type	Displays check boxes that are used to search the results for a specific sample type. The Search flyout has three test types: Specimen Control Calibrator

Table 1. 13: Search fly out element description

DONE	Saves changes and either displays the previously viewed screen or closes the flyout.
CANCEL	Cancels selections or entries and displays the previously viewed screen or flyout.
?	Displays Help from the operations manual for the active screen, flyout, or message code.

Table 1. 14: Search fly out function buttons description

5.10.29. Order details screen

On the Order Details screen, the operator can view the details for a specimen test order, a control test order, or a calibrator test order.

The operator can add a comment to a specimen test order, a control test order, or an individual calibrator test order.

5.10.30. Order Details (Single specimen, control and calibrator) screen element descriptions

The Order Details screen displays the order details for specimens, controls, and calibrators.

SID	Displays the sample identification.
RACK / POSITION	Displays the rack ID and position number. NOTE: If the system is configured for a laboratory automation system (LAS) and the specimen is run on the LAS, the Rack/ Position is displayed as LAS/1 or LAS/2.
OPERATOR ID	Displays the identification of the operator logged on when the test was ordered.
TEST TYPE	Displays the sample type for the test: Specimen, Control, or Calibrator.
MODULE / POSITION	Displays the module number and position of the rack on the loading area.
TIME OF COMPLETION	Displays the date and time that the tests in process were completed.
STATUS	Displays the current status (Pending, Scheduled, Running, In Process, or Complete) of the assay ordered.
PID	Displays the patient identification. This element is displayed only for specimens.
GENDER	Displays the gender of the patient. This element is displayed only for specimens.
CONTROL LOT	Displays the lot number of the control. This element is displayed only for controls.
CALIBRATOR LOT	Displays the lot number of the calibrator. This element is displayed only for calibrators.
TIME OF COMPLETION	Displays the date and time that the tests in process were completed.
NAME	Displays the name of the patient.

DATE OF BIRTH	Displays the date of birth for the patient. This element is displayed only for specimens.
DRAW DATE / TIME	Displays the date and time that the sample was drawn. This element is displayed only for specimens.
LOT EXPIRATION	Displays the date and time of the control or calibrator lot expiration. This element is not displayed for specimens.

Table 1. 15: Test information area

ASSAY NAME	Displays the name of the assay file.
ASSAY NUMBER	Displays the number of the assay file.
ASSAY VERSION	Displays the version number of the assay file.
DILUTION	Displays the type of dilution used to process the test.

CODES	Displays the processing codes associated with the test.
REFERENCE ASSAY	Displays the photometric reference assay.

Table 1. 16: Assay information area

REAGENT LOT	Displays the master lot number for the reagent.
REAGENT SN	Displays the serial number of the reagent cartridge.
REAGENT LOT EXPIRATION	Displays the expiration date of the reagent cartridge.

Table 1. 17: Reagent information area

DOCTOR	Displays the name of the patient's doctor. This element is displayed only for specimens.
LOCATION	Displays the location associated with the patient. This element is displayed only for specimens.
COMMENT	Displays a text box that is used to enter a comment for the test.

Table 1. 18: Additional information area

DONE	Saves changes and either displays the previously viewed screen or closes the flyout.
CANCEL	Cancels selections or entries and displays the previously viewed screen or flyout.
PREVIOUS	Displays the previous item when multiple items are selected.
NEXT	Displays the next item when multiple items are selected.
TEXT SIZE	This function button is unavailable on this screen.

Table 1. 19: Function buttons

5.10.31. Order Details (Bar-Coded Batch Specimen) screen element descriptions

The Order Details screen displays the order details for a bar-coded batch specimen order.

STARTING SID	Displays the SID of the first sample in the batch order.

ENDING SID	Displays the SID of the last sample in the batch order.
OPERATOR ID	Displays the identification of the operator logged onto the system when the batch was entered.
TEST TYPE	Displays the sample type for the test: Specimen.
SAMPLES SCANNED	Displays the number of samples scanned in the batch order by the RSM bar code reader.
STATUS	Displays the current status (Pending or In Process) of the batch order.
BATCH NAME	Displays the name of the batch. The default batch name is Batch XX:XX:XX, where XX:XX:XX is the time that the batch was ordered in hours, minutes, and seconds.

Table 1. 20: Batch Information Area

ASSAY	Displays the name of the assay file that is part of the batch order.
DILUTION	Displays the type of dilution used to process the test.
REPLICATES	Displays the number of replicates for the specific assay and dilution factor.

MODULE SELECTION	Displays the module number of the processing module used to perform the assay. If only one processing module of the same type is configured for a system or if a specific module is not identified, the module selection is Auto.

Table 1. 21: Assay Information Area

COMMENT	Displays a text box that is used to enter a comment for the batch order. Comments are displayed and are printed with each sample order in the batch. Comments can have a maximum of 50 characters.

Table 1. 22: Additional Information Area

DONE	Saves changes and either displays the previously viewed screen or closes the flyout.
CANCEL	Cancels selections or entries and displays the previously viewed screen or flyout.
TEXT SIZE	This function button is unavailable on this screen.

Table 1. 23: Function Information Area

5.10.32. Add a comment to an order

Perform this procedure to add a comment to a specimen order, a bard-coded batch order, a control order, or a calibration order.

1) On the menu bar, tap Orders.

2) In the list on the Orders screen, tap one or more tests (or tap Select All).

3) To filter the list, tap a tab (or tap Search).

4) Tap Details.

5) In the Comment box on the Order Details screen, type additional information that is associated with the test.

6) Comments are displayed and are printed with the test. In addition, comments for samples are displayed if comments were entered when the order was created.

7) For batch orders, if the test status is In Process, a comment for the batch order cannot be entered. However, a comment can be entered when the batch order is created or if the test status is Pending.

8) If more than one order was selected, tap Next or Previous to display each order, and then type a comment for each order.

9) To save the comments, tap Done.

5.10.33. Create Order screen

On the Create Order screen, the operator can create an order when the following situations occur:

1) The system is not connected to a host computer.

2) The host computer is not functioning.

3) An additional test is needed.

The operator can perform the following functions:

1) Add information that is specific to a specimen.

2) Add assay options that are specific to a test.

5.10.33.1. Create Order screen, Specimen tab, Single Specimen element descriptions

On the Specimen tab, the operator can create a single specimen order when the Single Specimen option in the Order Type area is selected.

SINGLE SPECIMEN OPTION	Orders one or more tests as a single sample. (Default)
BAR-CODED BATCH OPTION	Orders the same tests for multiple bar-coded specimens.

Table 1. 24: Order type Area

SID	Displays a text box that is used to enter the bar code number or identification assigned to the specimen. The SID can have a maximum of 20 alphanumeric characters, which are defined by Abbott Laboratories as A through Z, a through z, 0 through 9, and special characters , / > < ? ; :] [\ } { ' - = ~ ! @ # $ % ^ & *) (_ + and <space>. IMPORTANT: Contact the host computer vendor to verify if the host computer handles special characters (if used in SIDs) as characters rather than functions. Some computers may interpret special characters as a line return, line feed, delimiter, or wildcard character.
RACK	Displays a text box that is used to enter the rack ID in which samples are placed for processing. This element is optional when bar-coded samples are used.
POSITION	Displays a text box that is used to enter the position of the sample in the rack. This element is optional when bar-coded samples are used.
MANUAL DILUTION: 1:	Displays a text box that is used to enter the dilution factor to calculate the sample concentration automatically and to report the result.

DESIGNATE SAMPLE STAT	Displays a check box that is used to display the S code on the Orders screen, the Results screen, and the Sample Status screen. The operator must priority load the samples with the S code to process the samples first.
COMMENTS	Displays a text box that is used to enter comments for the sample. Comments are displayed and can be printed for each test ordered for the sample. Comments can have a maximum of 50 characters.

Table 1. 25: Sample data area

ALL OPTION	Displays all assays that are available on the system.
I-SERIES OPTION	Displays all assays that are available on one or more Alinity-i processing modules.
CALCULATED OPTION	Displays all calculated assays.
PANELS	Displays all assay panels that are available.
ASSAYS	Displays all assays that are available for a selected module.
NUMBER OF SELECTED ASSAYS	Displays the number of assays that are selected.

Table 1. 26: Assay Area

ORDER STATUS	Navigates to the orders screen.
PATIENT DETAILS	Displays the Patient Details flyout.
ASSAY OPTION	Displays the Assay Options flyout.
ADD ORDER	Saves the order and clears the screen to accept a new order.
TEXT SIZE	This function button is unavailable on the screen.

Table 1. 27: Function buttons

5.10.33.2. Create Order screen, Specimen tab, Bar-coded Batch element descriptions

On the Specimen tab, the operator can create a bar-coded batch order when the Bar-Coded Batch option in the Order Type area is selected.

SINGLE SPECIMEN OPTION	Orders one or more tests as a single sample. (Default)
BAR-CODED BATCH OPTION	Orders the same tests for multiple bar-coded specimens.

Table 1. 28: Specimen tab.

STARTING SID	Displays a text box that is used to enter the starting SID of the batch to be processed. The SID can have a maximum of 20 alphanumeric characters, which are defined by Abbott Laboratories as A through Z, a through z, 0 through 9, and special characters , / > < ? ; :] [\ } { ' - = ~ ! @ # $ % ^ & *) (_ + and <space>. IMPORTANT: Contact the host computer vendor to verify if the host computer handles special characters (if used in SIDs) as characters rather than functions. Some computers may interpret special characters as a line return, line feed, delimiter, or wildcard character.

ENDING SID	Displays a text box that is used to enter the starting SID of the batch to be processed. The SID can have a maximum of 20 alphanumeric characters, which are defined by Abbott Laboratories as A through Z, a through z, 0 through 9, and special characters , / > < ? ; :] [\ } { ' - = ~ ! @ # $ % ^ & *) (_ + and <space>. IMPORTANT: Contact the host computer vendor to verify if the host computer handles special characters (if used in SIDs) as characters rather than functions. Some computers may interpret special characters as a line return, line feed, delimiter, or wildcard character.
BATCH NAME	Displays a text box that is used to change the default name of the batch order. The default batch name is BATCHXX:XX:XX, where XX:XX:XX is the time that the batch was ordered in hours, minutes, and seconds. The batch name can have a maximum of 20 alphanumeric characters.
MANUAL DILUTION: 1:	Displays a text box that is used to enter the dilution factor to calculate the sample concentration automatically and to report the result.
COMMENTS	Displays a text box that is used to enter comments for the batch. Comments are displayed and can be printed for each sample ordered for the batch. Comments can have a maximum of 50 characters.

Table 1. 29: Sample data-type area

ALL OPTIONS	Displays all assays that are available on the system.
I-SERIES OPTION	Displays all assays that are available on one or more Alinity-i processing modules.
C-SERIES OPTION	Displays all assays that are available on one or more Alinity-c processing modules.
CALCULATED OPTION	Displays all calculated assays.
PANELS	Displays all assay panels that are available.
ASSAYS	Displays all assays that are available for a selected module.
NUMBER OF SELECTED ASSAYS	Displays the number of assays that are selected.

Table 1. 30: Assays Area

ORDER STATUS	Navigates to the Orders screen.
ASSAY OPTIONS	Displays the Assay Options flyout.
ADD ORDER	Saves the order and clears the screen to accept a new order.
TEXT SIZE	This function button is unavailable on this screen.

Table 1. 31: Functions buttons

5.10.33.3. Create Order screen, Specimen tab, Patient Details flyout element descriptions

In the Patient Details flyout on the Specimen tab, the operator can enter patient demographic information for the specimen.

SID	Displays the bar code number or identification assigned to the specimen.

PID	Displays a text box that is used to enter the patient identification number. A maximum of 20 alphanumeric characters can be entered. NOTE: When entering a PID, enter only details that are known to be accurate. The PID is recognized as a different and unique patient if previously entered information is edited.
LAST NAME	Displays a text box that is used to enter the last name of the patient. A maximum of 20 alphanumeric characters can be entered.
FIRST NAME	Displays a text box that is used to enter the first name of the patient. A maximum of 20 alphanumeric characters can be entered.
M.	Displays a text box that is used to enter the middle name of the patient. A maximum of 12 alphanumeric characters can be entered.
DATE OF BIRTH	Displays a text box that is used to enter the date of birth for the patient. This information provides an age-specific reference range if the assay is configured to provide reference ranges.
GENDER	Displays the following options that are used to select the gender of the patient: Male Female Unknown NOTE: This option provides a gender-specific reference range if the assay is configured to provide reference ranges.
DRAW DATE	Displays a text box that is used to enter the date that the sample was drawn. To enter the draw date, tap the calendar inside the box. To configure the month and year, tap the Left Arrow or Right Arrow button, and then tap the day.
TIME	Displays a spin box that is used to enter the time that the sample was drawn. To enter the draw time, use the system- configured format (HH:MM) and type the time in the box or tap the Up Arrow and Down Arrow buttons. If the system is configured for the 12-hour clock format, tap the AM or PM button to configure the time of day.
LOCATION	Displays a text box that is used to enter the location associated with the patient. A maximum of 20 alphanumeric characters can be entered.
DOCTOR	Displays a text box that is used to enter the name of the patient's doctor. A maximum of 20 alphanumeric characters can be entered.

Table 1. 32: Elements

DONE	Saves changes and either displays the previously viewed screen or closes the flyout.
CANCEL	Cancels selections or entries and displays the previously viewed screen or flyout.
?	Displays Help from the operations manual for the active screen, flyout, or message code.

Table 1. 33: Function buttons

5.10.33.4. Create Order screen, Specimen tab, Assay Options flyout element descriptions

In the Assay Options flyout on the Specimen tab, the operator can enter assay-specific information for each test included in the specimen order.

SELECTED ASSAYS	Displays the names of the assays selected for the order.
RACK / POSITION	Displays the rack ID and position number.
SID	Displays the bar code number or identification assigned to the specimen.
MODULE SELECTION	Displays Auto and Module options that are used to select a processing module that performs the assay. If only one processing module type is configured for a system or if a specific module is not identified, the Auto option is enabled and the Module option is not displayed: Auto The system scheduler selects the processing module. Module Displays an option for each processing module that performs the assay. Module options are used to override the system scheduler. NOTE: Module options are available only for multimodule systems that have more than one module of the same type.
DILUTION PROTOCOLS / NUMBER OF REPLICATES	Displays the dilution protocols that are available for the selected assay and displays drop-down lists that are used to select the correct number of replicates for the corresponding dilution protocol.

Table 1. 34: Elements

DONE	Saves changes and either displays the previously viewed screen or closes the flyout.
CANCEL	Cancels selections or entries and displays the previously viewed screen or flyout.
?	Displays Help from the operations manual for the active screen, flyout, or message code.

Table 1. 35: Function button

5.10.33.5. Create Order screen, Control tab element descriptions

On the control tab, the operator can create a control order.

RACK	Displays a text box that is used to enter the rack ID in which samples are placed for processing. This element is optional when bar-coded samples are used.

POSITION	Displays a text box that is used to enter the position of the sample in the rack. This element is optional when bar-coded samples are used.

Table 1. 36: Orders area

CONTROL NAME	Displays a drop-down list that is used to select the control identification name.
CONTROL LOT	Displays a drop-down list that is used to select the control lot number.
CONTROL LEVEL	Displays a drop-down list that is used to select the control level.
MANUAL DILUTION: 1:	Displays a text box that is used to enter the dilution factor to calculate the sample concentration automatically and to report the result.
DESIGNATE SAMPLE STAT	Displays a check box that is used to display the S code on the Orders screen, the Results screen, and the Sample Status screen. The operator must priority load the samples with the S code to process the samples first.

Table 1. 37: Control Data Area

ALL OPTION	Displays all assays that are available on the system.
I-SERIES OPTION	Displays all assays that are available on one or more Alinity-i processing modules.
C-SERIES OPTION	Displays all assays that are available on one or more Alinity-c processing modules.
CALCULATED OPTION	Displays all calculated assays.
PANELS	Displays all assay panels that are available.
ASSAYS	Displays all assays that are available for a selected module.
NUMBER OF SELECTED ASSAYS	Displays the number of assays that are selected.

Table 1. 38: Assays Area

ORDER STATUS	Navigates to the Orders screen.
ASSAY OPTIONS	Displays the Assay Options flyout.
ADD ORDER	Saves and navigates to the order on the Orders screen.
TEXT SIZE	This function button is unavailable on this screen.

Table 1. 39: Function Buttons

5.10.33.6. Create Order screen, Control tab, Assay Options flyout element descriptions

In the Assay Options flyout on the Control tab, the operator can enter assay-specific information for each test included in the control order.

SELECTED ASSAYS	Displays the names of the assays selected for the order.
RACK/POSITION	Displays the rack ID and position number.
CONTROL LOT	Displays the lot number of the control.
CONTROL NAME	Displays the name of the control.
CONTROL LEVEL	Displays the name of the control level.

REAGENT SELECTION	Displays Auto, Select Cartridge, and Module options that are used to select a reagent cartridge and a processing module that performs the assay. If only one processing module type is configured for a system, the Module option is not displayed: Auto - The system scheduler selects the reagent cartridge.
	Select Cartridge - Displays an option that is used to designate the reagent cartridge. When the option is selected, the following information is available: Module ID: Displays the number of the processing module where the reagent cartridge is located. Position: Displays the reagent carousel position where the reagent cartridge is located Reagent Lot: Displays the reagent cartridge lot number. Serial Number: Displays the reagent cartridge serial number. Cartridge Status: Displays the reagent cartridge status. Module - Displays an option that is used to designate the processing module. When the option is selected, a check box is displayed for each processing module that performs the assay. Module check boxes are used to override the system scheduler. Note: Module check boxes are available only for multi-module systems that have more than one module of the same type.
DILUTION PROTOCOLS / NUMBER OF REPLICATES	Displays the dilution protocols that are available for the selected assay and displays drop-down lists that are used to select the correct number of replicates for the corresponding dilution protocol.

Table 1. 40: ELEMENTS

DONE	Saves changes and either displays the previously viewed screen or closes the flyout.
CANCEL	Cancels selections or entries and displays the previously viewed screen or flyout.
?	Displays Help from the operations manual for the active screen, flyout, or message code.

Table 1. 41: Function Buttons.

5.10.33.7. Create Order screen, Calibration tab element descriptions

On the Calibration tab, the operator can create a calibration order.

RACK	Displays a text box that is used to enter the rack ID in which samples are placed for processing. This element is optional when bar-coded samples are used.
STARTING POSITION	Displays a text box that is used to enter the position of the first calibrator.

Table 1. 42: Sample Data Area

ALL OPTION	Displays all assays that are available on the system.
I-SERIES OPTION	Displays all assays that are available on one or more Alinity-i processing modules.

PANELS	Displays all assay panels that are available.
ASSAYS	Displays all assays that are available for a selected module. The default master lot number for a calibrator set is displayed with the assay name. The default master lot number for a blank calibrator set is listed after the calibrator set master lot number for c-series assays that use a blank calibrator set.
	If an alternate calibrator master lot number is selected for a manual calibration order, the selected calibrator master lot number is displayed. NOTE: Only the default master lot number for a blank calibrator can be used to create a manual order. The assay name and the calibrator master lot number are displayed in red text if the calibrator master lot number is expired. The assay name and the blank calibrator master lot number are displayed in red text if the blank calibrator master lot number is expired. Lot numbers are not displayed for c-series assays that use the factor data reduction method.
NUMBER OF SELECTED ASSAYS	Displays the number of assays that are selected.

Table 1. 43: Assays Area

ORDER STATUS	Navigates to the Orders screen.
ASSAY OPTIONS	Displays the Assay Options flyout.
ADD ORDER	Saves and navigates to the order on the Orders screen.
TEXT SIZE	This function button is unavailable on this screen.

Table 1. 44: Function Buttons

5.10.33.8. Create Order screen, Calibration tab, Assay Options flyout element descriptions

In the Assay Options flyout on the Calibration tab, the operator can enter assay-specific information for each test included in the calibration order.

SELECTED ASSAYS	Displays the names of the assays selected for the order.
CALIBRATOR LOT	Displays the lot number of the default calibrator or displays a drop-down list that is used to select an alternate calibrator lot for the selected assay if more than one lot was configured.
CALIBRATOR EXPIRATION DATE	Displays the expiration date of the calibrator lot.
CALIBRATION TYPE	Displays the type of assay calibration to be performed for the selected assay or displays a drop-down list that is used to select an alternate calibration type if more than one type was configured.

REAGENT SELECTION	Displays Auto, Select Cartridge, and Module options that are used to select a reagent cartridge and a processing module that performs the assay. If only one processing module type is configured for a system, the Module option is not displayed: Auto - The system scheduler selects the reagent cartridge. Select Cartridge - Displays an option that is used to designate the reagent cartridge. When the option is selected, the following information is available: Module ID: Displays the number of the processing module where the reagent cartridge is located. Position: Displays the reagent carousel position where the reagent cartridge is located. Reagent Lot: Displays the reagent cartridge lot number.
	Serial Number: Displays the reagent cartridge serial number. Cartridge Status: Displays the reagent cartridge status. Module - Displays an option that is used to designate the processing module. When the option is selected, a check box is displayed for each processing module that performs the assay. Module check boxes are used to override the system scheduler. NOTE: Module check boxes are available only for multi-module systems that have more than one module of the same type.

Table 1. 45: ELEMENTS

DONE	Saves changes and either displays the previously viewed screen or closes the flyout.
CANCEL	Cancels selections or entries and displays the previously viewed screen or flyout.
?	Displays Help from the operations manual for the active screen, flyout, or message code.

Table 1. 46: Function Buttons

5.10.34. Create a single specimen order

Perform this procedure to create a specimen order manually.

1) On the menu bar, tap Orders.

2) On the Orders screen, tap Create Order.

3) Under Sample Data on the Specimen tab of the Create Order screen: Enter the SID.

To ensure that the processed tests include the correct information, confirm that the SID is not reused before previously pending orders are completed or are deleted.

4) Enter the rack ID and the position number.

If bar-coded samples are used, the rack ID and the position number are not required. If a rack and a position are entered and the bar code on the sample is not read, the system automatically uses the scanned rack ID as the unique rack ID and the sample is processed as entered.

If the specimen was diluted manually, type the dilution factor in the Manual Dilution: 1: box.

Not all assays support manual dilutions. Assays that do not support manual dilution are displayed as unavailable when a manual dilution is selected. For dilution information, see the assay documentation.

To display the STAT processing code for the SID, tap the Designate Sample STAT check box.

Samples that are designated as STAT must be priority loaded to be processed as STAT samples.

5) In the Comments box, type additional information that is associated with the sample. Comments are displayed and are printed with each test that is ordered for the sample.

6) Under Assays, tap an assay panel to run (or tap one or more of the individual assays to run).

7) The number of selected assays is displayed.

To filter the list of available assays, tap the option for i-series, c-series, or calculated.

To order a calculated assay, perform one of the following steps:

8) Tap only the calculated assay.

The system automatically orders the assays that are necessary to complete the calculation but does not release or report the results ordered by the system.

Constituent assays for some calculated immunoassays that are installed from an assay file (assay numbers 3000 through 3999) cannot be ordered automatically by the system and must be ordered separately. For specific assay requirements, see the assay documentation.

9) Tap the calculated assay and one or more of its constituent assays.

The system automatically orders the additional constituent assays that are necessary to complete the calculation but does not release or report the constituent results ordered by the system.

10) Tap the calculated assay and all of its constituent assays.

The system releases and reports all results.

11) Tap Assay Options.

For each selected assay in the Assay Options flyout, perform the following steps if these situations occur:

12) If more than one processing module of the same type is configured for a system, under Module Selection, tap Module to specify a processing module, and then tap the appropriate module check boxes to override the system scheduler

13) Under Dilution Protocols/Number of Replicates, if the default number of replicates for one or more dilutions is incorrect, tap the correct number of replicates for each dilution.

IMPORTANT: For i-series assays, do not order more than 10 tests for each sample that is loaded in sample cups.

For c-series ICT assays, do not order more than 15 tests for each sample that is loaded in sample cups or tubes.

The total number of tests for each sample includes all assays, replicates, dilutions, and available reagent lots for the order. Ensure that the total number of tests for a c-series sample does not exceed 220.

14) To save the assay option selections, tap Done.

15) Tap Patient Details. In the Patient Details flyout, enter the patient demographic information. If a draw date or a time is entered, both the draw date and the time must be entered.

16) To save the patient demographic information, tap Done.

17) To save the specimen order, tap Add Order.

18) To view the specimen order, tap Order Status.

5.10.35. Create a bar-coded batch specimen order

Perform this procedure to order the same tests for multiple bar-coded specimens. When running a bar-coded batch order:

- Do not load calibrators.
- Do not leave empty spaces in a rack.

Do not add a test to an order within a batch. If a test is added to an order that is part of the batch order, the additional test is processed instead of the batch tests. Separately order the additional test and load the sample after batch processing is completed.

1) To save the patient demographic information, tap Done.

2) On the menu bar, tap Orders.

3) On the Orders screen, tap Create Order.

4) Under Order Type on the Specimen tab of the Create Order screen, tap Bar-Coded Batch.

5) Under Sample Data, perform the following steps:

6) Enter the starting SID.

7) Enter the ending SID.

The ending SID must be different than the starting SID.

Batch processing begins on the sample labeled with the starting SID and continues until the sample labeled with the ending SID is processed. All samples between the starting SID and the ending SID, regardless of the sequence or SID, are included in the batch process.

8) Edit the default name of the batch order if necessary.

The default batch name is BATCHXX:XX:XX, where XX:XX:XX is the time that the batch was ordered in hours, minutes, and seconds. The batch name can have a maximum of 20 alphanumeric characters.

9) If each specimen was diluted manually, type the dilution factor in the Manual Dilution: 1: box.

Not all assays support manual dilutions. Assays that do not support manual dilution are displayed as unavailable when a manual dilution is selected. For dilution information, see the assay documentation.

10) In the Comments box, type additional information that is associated with the sample.

Comments are displayed and are printed with each sample order in the batch. Comments can have a maximum of 50 characters.

11) Under Assays, tap an assay panel to run (or tap one or more of the individual assays to run). The number of selected assays is displayed.

12) To filter the list of available assays, tap the option for i-series, c-series, or Calculated.

13) To order a calculated assay, perform one of the following steps:

14) Tap only the calculated assay.

The system automatically orders the assays that are necessary to complete the calculation but does not release or report the results ordered by the system.

Constituent assays for some calculated immunoassays that are installed from an assay file (assay numbers 3000 through 3999) cannot be ordered automatically by the system and must be ordered separately. For specific assay requirements, see the assay documentation.

15) Tap the calculated assay and one or more of its constituent assays.

The system automatically orders the additional constituent assays that are necessary to complete the calculation but does not release or report the constituent results ordered by the system.

16) Tap the calculated assay and all of its constituent assays.

The system releases and reports all results.

17) Tap Assay Options.

For each selected assay in the Assay Options flyout, perform the following steps if these situations occur:

18) If more than one processing module of the same type is configured for a system, under Module Selection, tap Module to specify a processing module, and then tap the appropriate module check boxes to override the system scheduler.

19) Under Dilution Protocols/Number of Replicates, if the default number of replicates for one or more dilutions is incorrect, tap the correct number of replicates for each dilution.

For i-series assays, do not order more than 10 tests for each sample that is loaded in sample cups.

20) To save the assay option selections, tap Done.

21) To save the batch order, tap Add Order.

22) To view the batch order, tap Order Status.

5.10.36. Create a control order

Perform this procedure to create a control order manually.

1) On the menu bar, tap Orders.

2) On the Orders screen, tap Create Order.

3) On the Create Order screen, tap the Control tab.

4) Under Orders on the Control tab, enter the rack ID and the position number that correspond to the sample location.

If bar-coded samples are used or if the control product is located in the reagent carousel, the rack ID and the position number are not required.

5.10.36.1. Under Control Data

1) Tap a control name in the Control Name drop-down list.

2) Tap a control lot in the Control Lot drop-down list.

3) Tap a control level in the Control Level drop-down list.

4) If the control was diluted manually, type the dilution factor in the Manual Dilution: 1: box.

5) To display the STAT processing code for the control, tap the Designate Sample STAT check box.

Controls that are designated as STAT must be priority loaded to be processed as STAT controls.

6) Under Assays, tap an assay panel to run (or tap one or more of the individual assays to run). The number of selected assays is displayed.

To filter the list of available assays, tap the option for i-series, c-series, or Calculated.

When a multiconstituent control vial is located on the reagent carousel, orders for assays that are disabled for onboard use become exceptions when the orders are run.

Multiconstituent control assays that are disabled for onboard use can be ordered from vials in a vial rack, from a sample in a sample cup, or from a bar-coded sample tube in a sample rack that has QQQ added to the beginning of the SID.

7) Tap Assay Options.

For each selected assay in the Assay Options flyout, perform the following steps:

1) Tap a Reagent Selection option to designate the reagent cartridge or the processing module to run the control:

2) The default is Auto. The system determines which reagent cartridge is used to perform the test according to reagent inventory processing.

If more than one reagent cartridge is loaded in the reagent carousel, tap Select Cartridge, and then tap a reagent cartridge in the list.

If more than one processing module of the same type is configured for a system, tap Module to specify a processing module, and then tap the appropriate module check boxes to override the system scheduler.

Under Dilution Protocols/Number of Replicates, if the default number of replicates for one or more dilutions is incorrect, tap the correct number of replicates for each dilution.

For i-series assays, do not order more than 10 tests for each sample that is loaded in sample cups.

3) To save the assay option selections, tap Done.

4) To save the control order, tap Add Order.

5) To view the control order, tap Order Status.

5.10.37. Create a calibration order

Perform this procedure to create a calibration order manually.

If the calibrators are in vials, a manual order is not required. The vials can be loaded into a vial rack and can be presented to the reagent and sample manager (RSM) for immediate use.

1) On the menu bar, tap Orders.

2) On the Orders screen, tap Create Order.

3) On the Create Order screen, tap the Calibration tab.

4) Under Sample Data on the Calibration tab, enter the rack ID and the starting position.

The rack ID and the starting position specify the use of samples that are loaded on the RSM. However, the ID and the position are not required if the calibration uses bar-coded samples, the calibration uses only water, or the calibrator product is loaded in the reagent carousel.

5) Under Assays, tap an assay panel to calibrate (or tap one or more of the individual assays to calibrate).The number of selected assays is displayed.

If multiple c-series assays that use a blank calibrator set are selected, a blank calibrator is required for each calibrator set even if all the calibrator sets compose one rack.

To filter the list of available assays, tap the option for i-series or c-series.

6) Tap Assay Options.

7) For each selected assay in the Assay Options flyout, perform the following steps:

8) In the Calibrator Lot drop-down list, tap a calibrator lot or confirm the default data.

Only the default master lot number for the blank calibrator can be used for a manual order.

If an adjust type is available, tap it to perform an adjust calibration.

Tap a Reagent Selection option to designate the reagent cartridge or the processing module to perform the calibration:

The default is Auto. The system determines which reagent cartridge is used to perform the calibration according to calibration sample processing.

If more than one reagent cartridge is loaded in the reagent carousel, tap Select Cartridge, and then tap a reagent cartridge in the list.

If more than one processing module of the same type is configured for a system, tap Module to specify a processing module, and then tap the appropriate module check boxes to override the system scheduler.

9) Tap Assay Options.

10) To save the assay option selections, tap Done.

11) To save the calibration order, tap Add Order.

12) To view the calibration order, tap Order Status.

5.10.38. Add a test to a specimen order

Perform this procedure to add a test to a specimen order.

If a calculated assay is added and new constituent results are wanted for the calculation, add the constituent assays in addition to the calculated assay.

Do not add a test to an order within a batch. If a test is added to an order that is part of a batch order, the additional test is processed instead of the batch tests. Separately order the additional test and load the sample after batch processing is completed.

1) On the menu bar, tap Orders.

2) On the Orders screen, tap Create Order.

3) Under Sample Data on the Specimen tab of the Create Order screen:

4) Enter the SID of the original specimen.

If the original specimen was diluted manually, type the dilution factor of the specimen in the Manual Dilution: 1: box.

6) Under Assays, tap an assay panel to run (or tap one or more of the individual assays to run). The number of selected assays is displayed.

To filter the list of available assays, tap the option for i-series, c-series, or Calculated.

To order a calculated assay, perform one of the following steps:

5) Tap only the calculated assay.

The system automatically orders the assays that are necessary to complete the calculation but does not release or report the results ordered by the system.

Constituent assays for some calculated immunoassays that are installed from an assay file (assay numbers 3000 through 3999) cannot be ordered automatically by the system and must be ordered separately. For specific assay requirements, see the assay documentation.

6) Tap the calculated assay and one or more of its constituent assays.

The system automatically orders the additional constituent assays that are necessary to complete the calculation but does not release or report the constituent results ordered by the system.

7) Tap the calculated assay and all of its constituent assays.

The system releases and reports all results.

8) Tap Assay Options.

9) For each selected assay in the Assay Options flyout, perform the following steps if these situations occur.

If more than one processing module of the same type is configured for a system, under Module Selection, tap Module to specify a processing module, and then tap the appropriate module check boxes to override the system scheduler.

Under Dilution Protocols/Number of Replicates, if the default number of replicates for one or more dilutions is incorrect, tap the correct number of replicates for each dilution.

For i-series assays, do not order more than 10 tests for each sample loaded in sample cups.

10) To save the assay option selections, tap Done.

11) To save the additional specimen order, tap Add Order.

12) To view the additional specimen order, tap Order Status.

13) Comments area - Displays a text box that is used to enter comments for the sample. Comments are displayed and can be printed for each test ordered for the sample. Comments can have a maximum of 50 characters.

14) Testing Profile area - Displays the active testing profiles.

15) If a testing profile is selected, all of the assays in the profile are selected in the Assays area.

16) Assays area - Displays all assays that are available.

ORDER STATUS	Navigates to the Orders screen.
ADD ORDER	Saves and navigates to the order on the Orders screen.
ASSAY OPTIONS	Displays the Assay Options flyout.
TEXT SIZE	This function button is unavailable on this screen.

Table 1. 47: Function Buttons

5.10.39. Create Order screen – Control tab element descriptions

On the Control tab, the operator can create a control order.

ORDER TYPE	Used to enter the order type of the control order. The order type has three options: • Assay Control • Release Control • Customer Control

Table 1. 48: Control Orders area

CONTROL SET NAME	Displays a drop-down list that is used to select the control identification name.
CONTROL LOT	Displays a drop-down list that is used to select the control lot number.
CONTROL NAME	Displays a check box that is used to indicate the controls in the controls set that are ordered.

Table 1. 49: Control Selection area

Assays area - Displays all assays that are available.

PATH / LANE	Displays the process path and lane of the assay.
ASSAY	Displays the name of the assay file.
LOCATION	Displays the location of the reagent cartridge on the reagent carousel.

CAL STATUS	Displays the calibration status for the assay that uses the reagent kit.
REAGENT LOT	Displays the lot number for the reagent.
REAGENT STATUS	Displays the status of the reagent cartridge. For statuses other than OK and Mixing, the reagent kit is displayed in red.
REMAINING TESTS	Displays the estimated number of tests that remain in the reagent kit.
TESTS PENDING QC	Displays the tests that have a status of Pending QC.

Table 1. 50: Select Reagent Cartridge area

ORDER STATUS	Navigates to the Orders screen.
ADD ORDER	Saves and navigates to the order on the Orders screen.
TEXT SIZE	This function button is unavailable on this screen.

Table 1. 51: Function Buttons

5.10.40. Create Order screen – Calibration tab element descriptions

On the Calibration tab, the operator can create a calibration order.

ASSAY SELECTION	Displays a list of all assays that are available.

Table 1. 52: Control Data Area

PATH / LANE	Displays the process path and lane of the assay.
LOCATION	Displays the position of the reagent cartridge in the reagent carousel.
CAL STATUS	Displays the calibration status for the reagent lot.
REAGENT LOT	Displays the lot number of the reagent kit.
REAGENT STATUS	Displays the reagent cartridge status.
REMAINING TESTS	Displays the remaining tests for the reagent cartridge.
TEST PENDING QC	Displays the number of tests with a status of Pending QC.

Table 1. 53: Reagent Selection area

CALIBRATOR LOT	Displays a drop-down list that is used to select the calibrator lot number.
CALIBRATOR EXPIRATION DATE	Displays the expiration date of the selected calibrator.

Table 1. 54: Additional Selection area

ORDER STATUS	Navigates to the Orders screen.
ADD ORDER	Saves and navigates to the order on the Orders screen.
TEXT SIZE	This function button is unavailable on this screen.

Table 1. 55: Function Buttons

5.10.41. Create Order screen – Assay options flyout elements descriptions

In the Assay Options flyout, the operator can set assay options for the selected assay.

ASSAY	Displays the assay name selected.
REPLICATES	Displays a drop-down list of the number of replicates.

DILUTION PROTOCOL	Displays options for dilution.

Table 1. 56: Dilutions area

DONE	Saves changes and either displays the previously viewed screen or closes the flyout.
CANCEL	Cancels selections or entries and displays the previously viewed screen or flyout.

Table 1. 57: Function Buttons

5.10.42. Create a specimen order

Perform this procedure to create a manual specimen order.

1) On the menu bar, tap Orders.

2) On the Orders screen, tap Create Order.

3) Under Orders on the Specimen tab:

4) Enter the sample ID (SID).

The handheld bar code scanner can be used to enter the SID.

5) Reenter the SID to confirm the SID was entered correctly.

6) Enter the rack ID and the position number.

The handheld bar code scanner can be used to enter the rack ID.

7) Tap an option in the Sampling Priority area.

The rack ID and position are optional when creating an order. Samples designated as STAT must be loaded in the priority bay to be processed as STAT samples.

8) In the Comments box, type additional information that is associated with the sample.

Comments are displayed and printed with each test ordered for the sample.

9) To specify the assays to run, perform one or both of the following steps:

26) Under Profile, tap the active test profile.

27) Under Assays, tap one or more of the assays.

28) Tap Assay Options.

29) In the Assay Options flyout, perform the following steps:

30) Select the number of replicates to order from the drop-down list.

31) Tap the required dilution, if available.

32) Tap Next to go to the next assay.

33) To save the assay option selections, tap Done.

34) To save the specimen order, tap Add Order.

35) To view the specimen order, tap Order Status.

?	Displays Help from the operations manual for the active screen, flyout, or message code.

Table 1. 58: Function button

5.10.43. Log On

Perform this procedure to log on to the Alinity-i series.

If the Log On screen is displayed, proceed to the below steps. If any other screen is displayed, tap the Lock button.

Tap an operator logon button.

If the appropriate operator logon button is not displayed, perform the following steps:

1) Tap the Plus button.
2) Type the operator ID.
3) Tap the + Done button.

To display the Home screen, tap the four-digit PIN for the operator ID.

5.10.44. Lock the User Interface

Perform this procedure to lock the user interface:

1) When the user interface is locked, the operator is not logged off. Any samples that are in process generate results with the last logged-on operator ID until a new operator logs on.
2) On the screen header, tap the Lock button.

For more details, refer to **"Procedure for Quality Assurance"**.

5.10.45 Verify the supply and waste inventory

Perform this procedure to verify the supply and waste inventory before sample processing is initiated or when a status indicator is displayed.

NOTE: The status that is displayed reflects the inventory that remains after the system processes samples that are scanned by the RSM bar code reader.

Orders can be created when inventory levels are insufficient. However, when sample processing is initiated while the levels are insufficient, tests become exceptions and are not processed.

On the menu bar, tap Supplies.

On the Supplies screen, tap a Module button.

Verify the supply and waste inventory.

5.10.46 Replace bulk solutions and update the inventory

Perform this procedure to replace and update the bulk solution inventory when a bottle is empty, has reached the onboard stability expiration date, or is expired.

NOTE: For bulk solutions that have an onboard stability claim, onboard stability tracking occurs when the bottle is replaced and is updated. To achieve the maximum usage of the bulk solution, do not replace the solution until the total percent of the remaining solution is below the low alert setting.

Verify that a new bulk solution is within the expiration date on the bulk solution bottle label. Do not use solutions that are expired.

NOTE: When bulk solution bottles are installed, the Alinity i-series tracks and maintains a record of the bulk solution lot number, the expiration date and, when applicable, the onboard stability.

On the menu bar, tap Supplies.

On the Supplies screen, tap a Module button.

NOTE: On the Supplies screen, the bar code scanner is activated. The operator must be on the module-specific Supplies screen before scanning an inventory bar code.

Use the bar code scanner to scan the bar code on the new bulk solution bottle.

Under Supply Details in the flyout, the system automatically updates the bulk solution with the lot number and expiration date of the new bottle.

If the bar code cannot be scanned, manually enter the lot number and the expiration date, and perform the following steps:

a. Tap Update for the new bulk solution.

b. Under Supply Details in the flyout, enter the expiration date and the lot number.

c. To save the information, tap Done.

Open the bulk solution door.

Press the bottle release button to disengage the empty bulk solution bottle from the bottle holder.

NOTE: The color of the bulk solution cap matches the color of the bottle release button.

Remove and discard the empty bulk solution bottle according to the laboratory waste disposal procedures of the facility.

Remove the protective cover from the cap of the new bulk solution bottle.

Invert the new bulk solution bottle and place it in the bottle holder.

Push down the bottle until it locks. Close the bulk solution door.

NOTE: When the bulk solution door is closed, the door sensor confirms that the bottle was replaced.

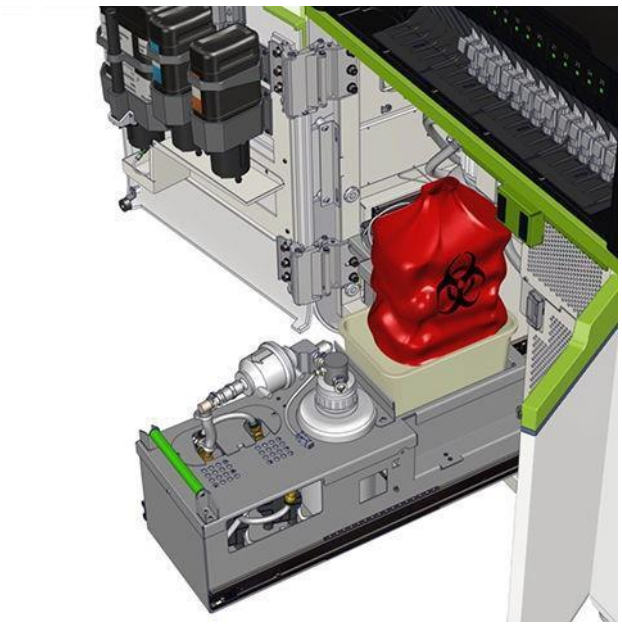
To confirm manually that the bottle was replaced, tap Replaced on the Supplies screen.

5.10.47 Remove the RV waste and update the inventory

Required materials Biohazard bag

Perform this procedure to empty the RV waste container and to update the RV waste status.

Open the bulk solution door and the front electronics door



Pull out the RV waste storage tray.

Remove and discard the biohazard bag and its contents according to the laboratory biohazard waste disposal procedures of the facility.

Install a new biohazard bag in the RV waste container.

NOTE: The biohazard bag must fit snugly and must be opened fully in the RV waste container so that reaction vessels can drop freely into the container.

Slide the RV waste storage tray into the RV waste storage area until the RV waste chute is fully open.

Close the bulk solution door and the front electronics door.

On the menu bar, tap Supplies.

On the Supplies screen, tap a Module button.

Tap Update for the RV waste.

Under Supply Details in the flyout, tap the Emptied RV Waste check box.

To save the information, tap Done.

5.10.48 Replenish reaction vessels (RVs) and update the inventory

Perform this procedure to replenish and update the reaction vessel (RV) inventory when the inventory is low or is empty.

On the menu bar, tap Supplies.

On the Supplies screen, tap a Module button.

NOTE: On the Supplies screen, the bar code scanner is activated. The operator must be on the module-specific Supplies screen before scanning an inventory bar code.

Tap Update for the RVs.

Use the bar code scanner to scan the bar code on the new RV bag (or manually enter the lot number in the Lot Number box).

Under Supply Details in the flyout, the system automatically updates the RVs with the lot number of the new RV bag.

NOTE: To ensure that the bar code is read, perform the following steps:

– Verify that RVs are present behind the bar code on the RV bag to provide a contrast for the bar code.

– Place the RV bar code 10 cm to 13 cm (4 in. to 5 in.) from the bar code scanner.

– Center the bar code scanner beam on the bar code label.

If one or more full bags of RVs are added to the RV hopper, tap Add 500 RVs after each bag is added.

If a partial bag of RVs is added to the RV hopper, enter the estimated number of RVs that are added.

The maximum capacity of the RV hopper is 1000 RVs.

To save the information, tap Done.

Open the RV hopper cover.

To add a full bag of RVs, pour all contents of the bag into the RV hopper.

To add a partial bag of RVs, pour some contents of the bag into the RV hopper and estimate the quantity of RVs that were added.

NOTE: Do not overfill the RV hopper.

Close the RV hopper cover.

5.10.49 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

Load racks and cartridges into trays

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

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

Position the rack or cartridge so that the rack handle or cartridge handle is located at the front of the tray, which is indicated by an arrow.

Slide the rack or cartridge into the tray until the rack or cartridge stops.

Confirm that the rack or cartridge is flush against the back of the tray.

5.10.50 Load trays on the reagent and sample manager (RSM)

Perform this procedure to load trays in routine positions or priority positions on the reagent and sample manager (RSM). Empty trays may remain on the loading area to create five positions to load racks or cartridges one at a time.

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

For routine loading on the RSM, confirm that the status indicators above the bay positions to load are not illuminated, which indicates that the positions are available.

For priority loading on the RSM, confirm that the status indicators above the bay positions to load are blue, which indicates that the positions are available.

Hold the tray handle, which is indicated with an arrow, and slide the tray into a bay on the RSM until the tray stops.

If the tray contains racks or cartridges, green status indicators are illuminated.

5.10.51 Load racks on the reagent and sample manager (RSM)

Required instrument status

Processing module:	Warming, Idle, Running, Processing, or Pausing
Reagent and sample manager (RSM):	Running

Perform this procedure to load prepared sample racks or vial racks on the RSM. Racks can be loaded in routine positions or priority positions:

For routine loading on the RSM, confirm that the status indicators above the bay positions to load are not illuminated, which indicates that the positions are available.

For priority loading on the RSM, confirm that the status indicators above the bay positions to load are blue, which indicates that the positions are available.

Hold the rack handle and slide the rack into a routine position or a priority position on the RSM until the rack is flush against the back of the tray. Confirm that the green status indicator illuminates.

If the position on the RSM does not contain a tray, load the rack into a tray and slide the tray into the RSM.

NOTE: For calibrator and control vials that have an onboard stability claim, onboard stability tracking occurs after the vial is scanned by the bar code reader.

For calibrators that have an in-use stability claim, in-use stability tracking occurs after the vial is scanned by the bar code reader. After the vial is unloaded from the RSM, the timer for in-use stability tracking stops

5.10.52 Load bar-coded specimens for batch processing

Perform this procedure to load bar-coded specimens for batch processing.

IMPORTANT: When loading specimens for batch processing, do not load calibrators or leave empty spaces between samples. Empty spaces are identified as invalid samples and generate a message code. The functionality for host query and laboratory automation system is unavailable when a batch order is being processed.

Samples with explicit orders and controls can be processed within a batch order. The system runs only the explicit orders associated with a sample and does not create batch orders for the sample.

Locate the sample rack that contains the sample labeled with the starting SID that was entered in the batch order.

Verify that the sample is loaded in position 1 of the rack.

Position the rack so that the rack handle is located at the front of the tray, which is indicated by an arrow.

Slide the rack into the tray until the rack stops.

Confirm that the rack is flush against the back of the tray.

Load additional racks from the left side to the right side of the tray until the tray is full or all samples are loaded.

If more than one tray is needed, repeat steps 3.3.4.2 through 3.3.4.5 with additional trays until all samples are loaded.

Ensure that the sample labeled with the ending SID is loaded at the end of all samples in the batch.

Confirm that the status indicators above the bay positions to load are not illuminated, which indicates that the positions are available.

Hold the tray handle, which is indicated with an arrow, and slide the tray into the bay that is leftmost on the reagent and sample manager until the tray stops.

The green status indicators will illuminate.

If more than one tray is needed, repeat steps mentioned above with additional trays by using the next bay on the right side of the loaded bay until all samples are loaded

5.10.53 Load cartridges on the reagent and sample manager (RSM)

Required instrument status

Processing module:	Warming, Idle, Running, Processing, or Pausing
Reagent and sample manager (RSM):	Running

Perform this procedure to load prepared cartridges on the RSM. The RSM automatically loads cartridges in the reagent carousel. Cartridges can be loaded in routine positions or priority positions. If one cartridge of a two-cartridge reagent set is loaded in a priority position, both cartridges will be priority loaded.

If a reagent cartridge is loaded, and a specific processing module is not specified, and more than one module is eligible to accept the cartridge, the cartridge is loaded on the module with the lowest usable, onboard total test count for the reagent.

If a diluent cartridge or an onboard solution cartridge is loaded, and a specific processing module is not specified, and more than one module is eligible to accept the cartridge, the cartridge is loaded on the module with the lowest usable, onboard total volume for the diluent or onboard solution.

If a maintenance cartridge is loaded, and a specific processing module is not specified, and more than one module is eligible to accept the cartridge, the cartridge is loaded on the lowest numbered, eligible module.

NOTE: To ensure correct tracking status, do not move the cartridges to a processing module that is controlled by a different system control module.

For routine loading on the RSM, confirm that the status indicators above the bay positions to load are not illuminated, which indicates that the positions are available.

For priority loading on the RSM, confirm that the status indicators above the bay positions to load are blue, which indicates that the positions are available.

Hold the cartridge handle and slide the cartridge into a routine position or a priority position on the RSM until a green status indicator illuminates.

If the position on the RSM does not contain a tray, load the cartridge into a tray and slide the tray into the RSM.

NOTE: Some assays require two reagent cartridges. These reagent cartridges are indicated with 1/2 and 2/2 on them. Both reagent cartridges must be loaded, but they do not need to be inserted into adjacent positions. After the reagent cartridges are loaded on the RSM and the bar code reader scans the bar code label, the system software links the two reagent cartridges as a set. If a two-cartridge reagent set is removed from the system, the reagent set must be replaced as a set.

NOTE: For products that have an onboard stability claim, onboard stability tracking occurs after the cartridge is scanned by the bar code reader. After the cartridge is unloaded from the reagent carousel and is removed from the RSM, the timer for onboard stability tracking stops.

5.11. Break Down and Maintenance

Regular preventive maintenance is performed by the equipment vendor as per manufacturers recommended intervals and recorded in the equipment maintenance folder.

Regular daily, and weekly maintenance procedures are performed by the medical technologist.

5.11.1. Overview of Maintenance Procedures

Proper maintenance of the Alinity System is important. These suggestions, which are especially useful for integrated and multi-module systems, are provided to help you determine efficient strategies for performing maintenance procedures and reducing downtime. Maintenance includes Daily and weekly. Performed by the technologist. Preventative Periodic maintenace is performed by the vendor every 6 months.

When scheduling and performing maintenance procedures:

a) Schedule maintenance procedures during times of slower workflow.

b) Verify adequate supplies are on board the system, or available to load, prior to initiating a maintenance procedure.

c) Perform procedures within the daily and weekly maintenance categories on different shifts or days. To avoid having these procedures scheduled for the same day, perform some of them early to stagger the schedule.

d) NOTE: All maintenance procedures must be performed on or before the day they are due.

5.11.2. Log-in screen

Figure 1. 33: Login Screen.

a) On the keypad, log-in using the last 4 digits of your badge number. The main screen shown below will appear.

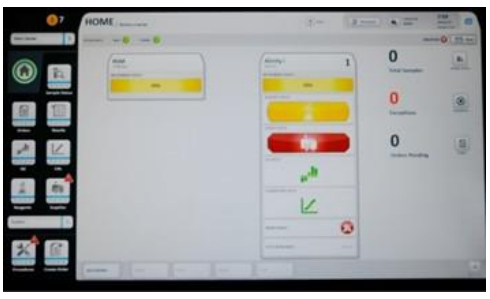


Figure 1. 34: log-in using the last 4 digits of your badge number.

b) On the bottom left corner of the screen, click on the 'Procedure' icon. The following screen appears.

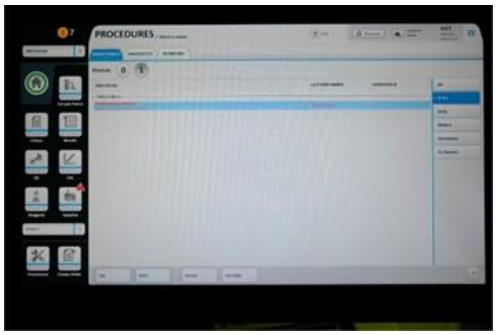


Figure 1. 35: 'Procedure' icon.

c) On the 'Maintenance' tab of the 'Procedure screen' a prompt will be shown reminding you of the maintenance procedure that are scheduled to be performed. Click on the red text to begin the procedure.

5.11.3. Maintenance screen

From this screen you can view information for maintenance procedures and initiate a procedure. You can also access windows to view version and detail information for each procedure, and print the Procedure report.

The procedures display by module and by maintenance category, e.g., daily, weekly, etc.

5.11.4. Perform a maintenance procedure

a) Select the procedure to be performed from the screen shown below.

Figure 1. 36: Select the procedure to be performed.

b) A screen similar to that shown below will appear. Follow the on-screen prompts to complete the process.

Figure 1. 37: Perform procedure screen

5.11.5. Access the Maintenance log screen

a) Select the desired 'Module' option on the Maintenance screen.

b) Select 'F2 - Maint. Log'. The Maintenance log screen for the selected module displays.

5.11.6. Approve the Maintenance log

a) Use the 'previous / next' buttons on the Maintenance log screen to display the desired month.

b) Select 'F4 – Approve'. The Approve maintenance log window for the selected month displays.

c) Select the 'Approve log' check box.

d) Select 'Done' to approve the Maintenance log. The status of the monthly maintenance log changes from unapproved to approved, and displays the Operator ID, date, and time of approval.

5.11.7. Add a comment to a maintenance procedure

Maintenance log comments are particularly useful when used to document why a procedure could not be completed when scheduled or why an as-needed procedure was performed.

a) Use the 'previous / next' buttons on the Maintenance log screen to select the desired month.

b) Use the 'up/down' arrows to select the desired maintenance procedure.

c) Use the 'left/right' arrows to select the desired date.

d) Select 'F5 – Details'. The Details for maintenance log window for the selected procedure and date displays.

e) Enter a comment in the 'Comment' data entry box.

f) Select 'Done' to save your changes.

5.11.8. Regular maintenance processes

The following maintenance processes are performed by the technologist who also initials the maintenance log sheets when the procedure has been performed.

5.11.8.1. Daily maintenance (Alinity-i)

Perform this daily maintenance procedure at the beginning of day to complete the following tasks:

1) Clean and condition the sample pipettor probe.

2) Clean wash zone 1 and 2 probes with 0.5% bleach.

3) Flush and prime the Pre-trigger and trigger solution.

4) This maintenance procedure can be performed concurrently on systems that have redundant Alinity i processing modules and while the reagent and sample manager (RSM) is in running status and is processing samples on a different module in a multinodular system. This procedure leaves the RSM in running status at the end of the procedure.

5) Update reagents.

6) Update inventory supplies.

7) Empty waste.

8) Check and update calibrations.

Estimated time is 25 minutes

Required instrument status:

1) RSM: Idle or Running.

2) Processing Module: Warming or Idle.

Procedure key setting:

1) **System control module (SCM)** : Off.

2) To perform this procedure, the SCM procedure key must be positioned at the Off setting. To perform this procedure while the RSM is in the running status, the SCM procedure key cannot be positioned at the On setting.

3) **Processing Module**: Optional ON.

The front processing center cover cannot be opened during this procedure regardless of whether the processing module procedure key is positioned at the ON setting. The rear processing center cover can be opened when processing module procedure key is positioned at the On setting.

Perform the daily maintenance by following steps above and follow the on-screen prompts to complete the process.

5.11.8.2. Weekly maintenance (Alinity-i)

Perform the weekly maintenance procedure to remove manually the salt buildup from the reagent 1, reagent 2 and sample pipettor probes and from the wash zone 1 and 2 probes. Also to remove the salt buildup from all the wash cups (reagent 1 and 2, and sample). Using Cotton swabs and Distilled water.

1) Manual Pipettor probe Cleaning

a) Estimated Time: 5 minutes

b) Required instrument status: Stopped, Warming, or Idle

c) Procedure key setting: Processing module: Required On

d) Perform the maintenance by following steps 5.11.2, 5.11.3, 5.11.4, 5.11.5, 5.11.6, 5.11.7 above and Follow theon-screen prompts to complete the process.

2) Manual Wash Zone Cleaning

a) Estimated Time: 5 minutes.

b) Required instrument status: Stopped, Warming, or Idle.

c) Procedure key setting: Processing module: Required On.

d) Perform the maintenance by following steps 5.11.2, 5.11.3, 5.11.4, 5.11.5, 5.11.6, 5.11.7 above and Follow theon-screen prompts to complete the process.

3) Manual wash Cup Cleaning

a) Estimated Time: 10 minutes.

b) Required instrument status: Stopped, Warming, or Idle.

c) Procedure key setting: Processing module: Required On.

d) Perform the maintenance by following steps 5.11.2, 5.11.3, 5.11.4, 5.11.5, 5.11.6, 5.11.7 above and Follow theon-screen prompts to complete the process.

e) Wipe instrument exterior (see 5.11.8.3 below).

f) Clean racks and trays (see 5.11.8.3 below).

g) Wipe loading bay (see 5.11.8.3 below).

5.11.8.3. Cleaning

The exterior of all Alinity modules, loading bays, racks, QC racks and trays are wiped with a soft cloth soaked in 5% cryocide and left to dry. Alternatively, 'Caviwipes' biological cleaning wipes may be used.

5.11.8.4. Maintenance log sheets

All procedures mentioned above are recorded on a manual log sheet for each Alinity Analyzer. This is reviewed by the Supervisor or Senior Supervisor.

5.12. Medical Indications:

Not Applicable.

5.13. Biological Reference Intervals:

Not Applicable.

5.14. Alert/Critical Values:

Not Applicable.

5.15. Result Verification:

As per **"Procedure for the Method Validation/Verification and Measurement Uncertainty"**.

5.16. Precautions for Variations

Not Applicable.

5.17. Interferences and Cross Reactions

Assay interference can be exogenous which are not associated with properties of the individual specimen and may reflect a system failure e.g.: blockage of probes, inadequate mixing of reagents etc. or endogenous interferences that are specimen – dependent caused by interaction between components in the specimen such as normal serum components in excess (lipids, hemoglobin, hyperbilirubinemia etc.), anti-analyte and anti-reagent antibodies, or a high dose hooking.

5.18. Determination of Nonconformities

Non-Conformities and corrective action are in accordance with **“Procedure for Identification and Control of Non-Conformities”**.

6. RECORDS

All records are managed according to **“Procedure for Control of Records”**.

7. REFERENCES

1) Alinity i operation manual.