# Alinity c Operations Manual

***Version 1*** ***Controlled document***

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**ANNUAL REVIEW:**

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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 operation staff regarding the system features, technology, principles, calibration, quality control, periodic maintenance, troubleshooting and data management of Abbott Alinity C analyzer.

# 2. SCOPE

The scope applies to the entire network staff operating and maintaining the Abbott Alinity c 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 Lab Management.

Service and Application Department are responsible for the installation, validation and provision of preventive maintenance and technical support.

Head of Laboratory/Pathologists, Laboratory Manager/Supervisor, Technologist/Technician are responsible to verify that the method is performing as expected and to implement quality assurance procedures (calibration, QC, periodic maintenance) to monitor its performance as per regulations and continuously demonstrate that the instrument is fit for patient examinations.

# 5. PROCEDURE

## 5.1. Test Information

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


**Figure 1.1**: Primary components of Alinity-c.

### 5.1.1. Primary components of the Alinity-c

The Alinity-c consists of three primary components:

**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-c 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:

**a)** Start, run, pause, and stop modules.

**b)** Shut down the computer.

**c)** Perform maintenance tasks.

To perform certain tasks, the operator may need to cycle power to the entire Alinity-c 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:

**3)** Maintenance and diagnostics.

**4)** Component replacement.

## Circumstances for start-up, shutdown, etc.

**a)** Load samples, reagents, and solutions.

**b)** Perform maintenance or diagnostic procedures.

**c)** Replace components.

**d)** Troubleshooting

**e)** 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 Center – 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-c 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 rangeor of 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, orLow.

**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 todisplay 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 Proceduresscreen.

**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 username and password to unlock the screen.
5) **Logged on:** Displays the username 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 isconfigured 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 colours:
   - **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.

1) **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

1) **RSM image:** Displays the RSM, the RSM name (if configured), and the current status for the RSM.

2) **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.

3) **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.

4) **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.

5) **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.

6) **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. Navigate 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. Navigate 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. Navigate to the 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 module from Running or Processing to Idle.

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

## 5.1.3. PROCESSING MODULE – ALINITY-C

### 5.1.3.1. Procedure key of the Alinity-c

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.

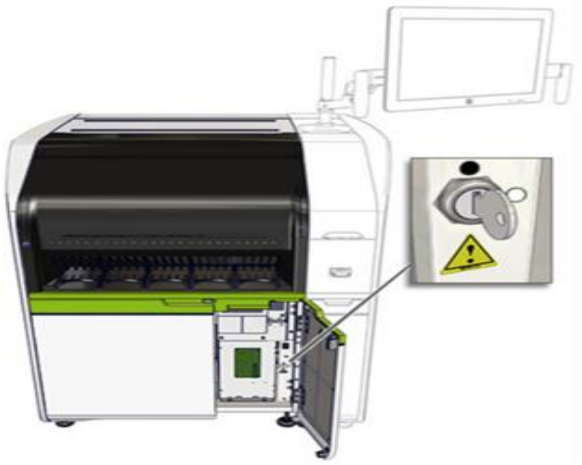

**Figure 1.3**: Procedure key of Alinity-c.

### 5.1.3.2. Processing module – Alinity-c front view

The Alinity c processing module is a chemistry analyzer that performs sample processing. The processing module processes a maximum of 1350 photometric and potentiometric tests per hour and has 70 positions in the reagent carousel at a controlled temperature.


**Figure 1.4**: Front view of Alinity-c 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) Bulk solution door: Provides access to the bulk solution storage area.

3) Front electronics door: Provides access to the processing module electronics and embedded computer, and the procedure lock.

### 5.1.3.3. Processing module – Alinity-c rear view

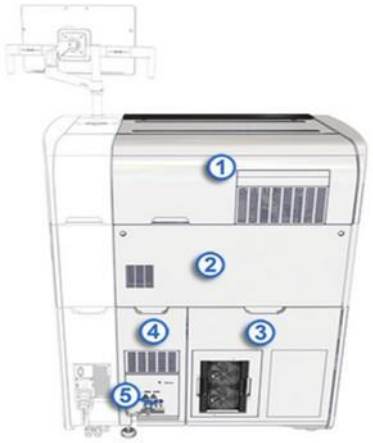


**Figure 1.5**: Rear view of Alinity-c processing module.

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 lower access panel: Provides access to the water management unit.
4) Power supply panel: Provides access to the processing module power supply.
5) Processing module main power breaker: Powers on and powers off the power supply.

### 5.1.3.4. Processing center – Alinity-c

The processing Center 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.

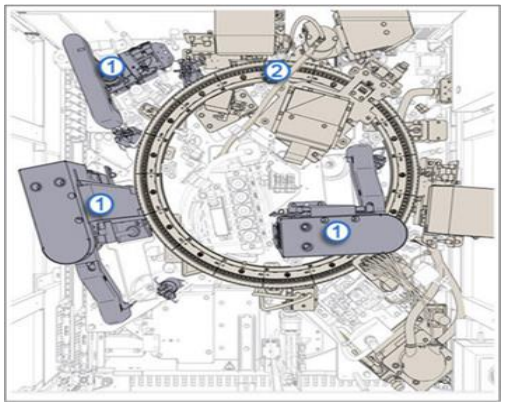


**Figure 1.6**: Processing Center Alinity-c.

1) Pipetting hardware: Aspirates and dispenses sample and reagents.

**2)** Reaction carousel hardware: Positions the cuvettes for sample and reagent dispense, mixing, photometric or potentiometric analysis, and cuvette washing.

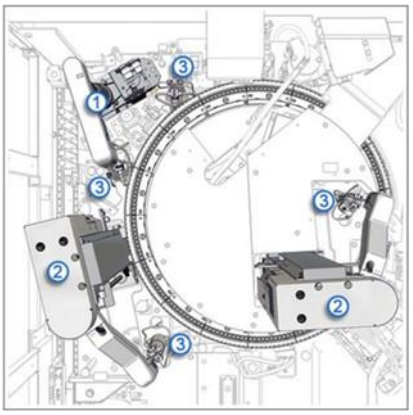

**Figure 1.7**: Pipetting hardware components Alinity c.

**3)** Sample pipettor (S): Aspirates and dispenses samples into cuvettes and transfers diluted samples from one cuvette to another.

**4)** Reagent pipettors (R1 and R2): Aspirate and dispense reagents and onboard solutions into cuvettes. The R1 pipettor also aspirates and dispenses diluents.

**5)** Wash cups (SW, WB, LASW, R1W, and R2W): Wash any fluid that remains from the interior and exterior surfaces of probes.

### 5.1.3.5. Pipettors – Alinity-c

Pipettors detect, aspirate, transfer, and dispense samples and reagents into cuvettes. These pipettor assemblies include a fluid sense and a pressure-monitoring system to help identify aspiration errors. Three pipettors that have the following functions are located on the system:

**a)** The sample pipettor (S) detects, aspirates, transfers, and dispenses samples into cuvettes. It also transfers diluted samples from the cuvette that is used to make the dilution into the cuvette that is used for the reaction.

**b)** The reagent 1 pipettor (R1) detects, aspirates, transfers, and dispenses diluents, reagents, and onboard solutions into cuvettes.

**c)** The reagent 2 pipettor (R2) detects, aspirates, transfers, and dispenses reagents and onboard solutions into cuvettes.

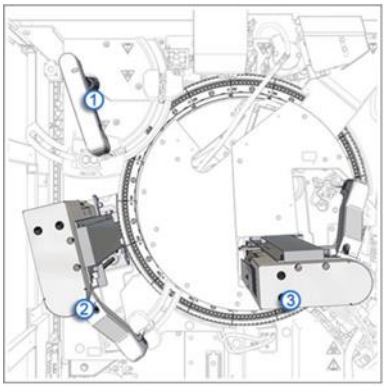

**Figure1.8**: Pipettors (Alinity c).

1) Sample pipettor
2) Reagent 1 pipettor
3) Reagent 2 pipettor

#### 5.1.3.6. Wash cups– Alinity-c

## The Alinity-c wash cups are active wash stations that use system water to clean the pipettors. The system has five pipettor wash cups.

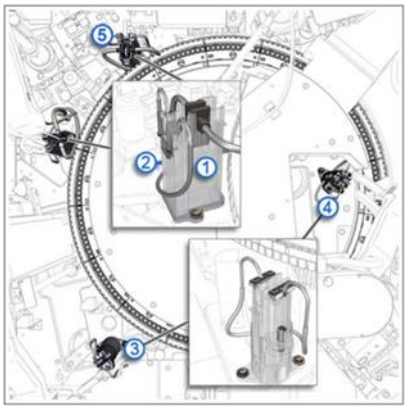


**Figure 1.9**: Wash cups (Alinity c).

1) Sample wash cup (SW): Washes the fluid that remains from the probe exterior and interior between samples to eliminate carryover.
2) Whole blood wash cup (WB): Washes the exterior of the sample probe before a whole blood sample is dispensed into the cuvette.
3) Reagent 1 pipettor wash cup (R1W): Washes any fluid that remains from the probe exterior and interior.
4) Reagent 2 pipettor wash cup (R2W): Washes any fluid that remains from the probe exterior and interior.
5) Laboratory automation system wash cup (LASW): Washes the fluid that remains from the sample probe exterior and interior after whole blood samples to eliminate carryover. This wash cup is used only on systems that are connected to a laboratory automation system (LAS).

### 5.1.3.7. Sample wash solution area– Alinity-c

The sample wash solution area stores sample onboard wash solutions that are used for the Smart Wash function and maintenance procedures. The area provides space for two sample tubes in a removable sample wash solution holder.

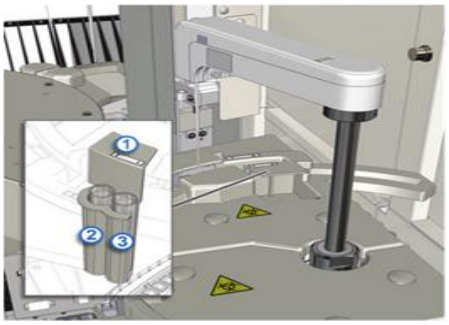


**Figure1.10**: Sample wash solution area (Alinity c).

1) Sample wash solution holder.
2) Detergent A.
3) Acid Probe Wash.

### 5.1.3.8. Reaction carousel hardware – Alinity-c

The reaction carousel hardware components position the cuvettes for sample and reagent dispense, mixing, photometric or potentiometric analysis, and cuvette washing.


**Figure1.11**: Reaction carousel hardware (Alinity c).

1) Mixers: Mix sample with reagent
2) ICT unit: Measures potentiometric assays (sodium, potassium, and chloride) by using integrated chip technology (ICT)
3) Lamp: Provides the light source for photometric measurement

4) ICT high-concentration waste area: Receives liquid waste from the ICT unit.

5) Cuvette washer: Washes and dries the cuvettes.

6) Water bath overflow and waste area: Receives overflow from the water bath, excess water from the sample pipettor, and liquid waste from the ICT Reference Solution cup.

7) Cuvette segments: Hold the cuvettes in the reaction carousel.

8) Reaction carousel: Positions the cuvettes for sample processing.

9) High-concentration waste pump: Works with the cuvette washer to aspirate waste from the cuvettes to the optional high-concentration waste bottle or the drain.

#### 5.1.3.9. Reaction carousel– Alinity-c

The reaction carousel supports a variety of assay protocols and has 17 cuvette segments surrounded by a 37°C water bath. The carousel rotates counterclockwise to position the cuvettes at the following locations:

- Sample dispense.
- Reagent 1 dispense
- Reagent 2 dispense
- ICT sample aspiration
- Mixing
- Photometric read position
- Diluted sample aspiration

**Figure1.12**: Reaction carousel (Alinity c).

### 5.1.3.10. Cuvette segments– Alinity-c

Cuvette segments suspend cuvettes in the reaction carousel. Each cuvette segment holds 11 cuvettes. The Alinity c processing module contains 17 segments for a total of 187 cuvettes in the reaction carousel.

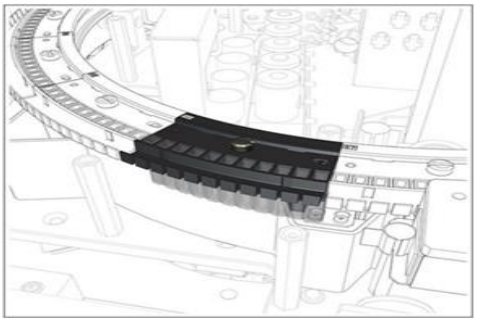

**Figure 1.13**: Cuvette segment.

### 5.1.3.11. Lamp– Alinity-c

The lamp is an optical device that provides the light source for photometric assay measurement.

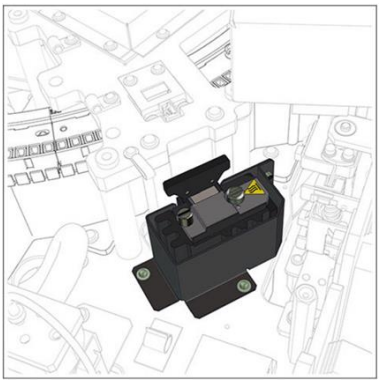

**Figure 1.14**: Lamp (Alinity c).

### 5.1.3.12. Mixers– Alinity-c

The Alinity c processing module has two mixers that mix sample with reagent in the cuvette. After each mixing operation, the exterior of the mixer is washed in the wash cup located beneath the mixer.

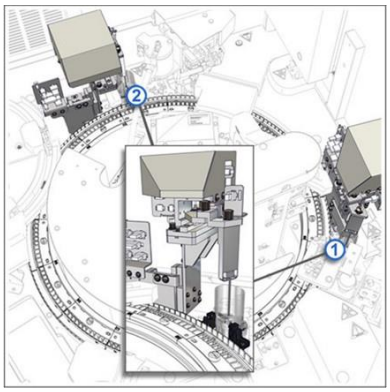


**Figure 1.15**: Mixers (Alinity c).

Mixer 1: Mixes the sample with reagent 1 or a diluent.

Mixer 2: Mixes the sample and reagent 1 mixture with reagent 2.

### 5.1.3.13. Supply and pump center– Alinity-c

The cuvette washer is a device with eight nozzles that perform the following functions before and after each cuvette is used. The nozzles are listed in order from right to left on the cuvette washer:

**Nozzle 1** Dispenses water and aspirates the sample and reagent mixture to waste

**Nozzle 2** Dispenses Alkaline Wash to clean the cuvette and aspirates the Alkaline Wash to waste

**Nozzle 3** Dispenses Acid Wash to clean the cuvette and aspirates the Acid Wash to waste

**Nozzles 4 and 5** Dispense water to rinse the cuvette and aspirate the water to waste

**Nozzle 6** Dispenses water into the cuvette for the water blank measurement, which ensures cuvette integrity

**Nozzle 7** Aspirates the water that remains in the cuvette to waste

**Nozzle 8** Dries the cuvette

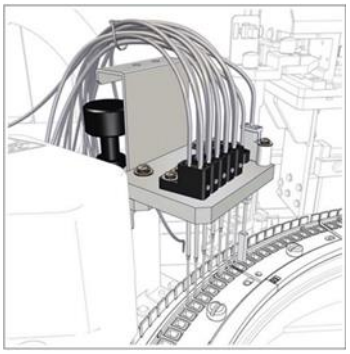

**Figure 1.16**: Cuvette washer (Alinity c).

### 5.1.3.14. ICT Unit– Alinity-c

The integrated chip technology (ICT) unit has an ICT probe and an ICT module. It is used to perform the indirect potentiometric analysis of sodium (Na+ ), potassium (K+ ), and chloride (Cl- ).

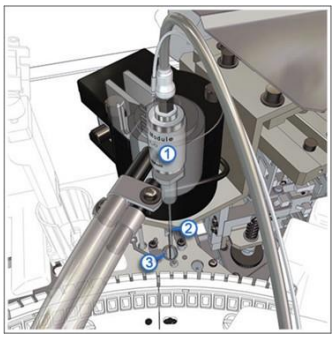

**Figure 1.17**: ICT unit (Alinity c).

**1)** ICT module: Measures electrolytes (Na+, K+, and Cl-) at a temperature of 37°C by using integrated chip technology.

**2)** ICT probe: Connects to the ICT module in the ICT unit. The ICT probe aspirates the diluted sample from the cuvettes or ICT Reference Solution from the ICT Reference Solution cup into the ICT module for processing.

**3)** ICT Reference Solution cup: Located beneath the ICT probe when the ICT unit is in the home position. It contains preheated ICT Reference Solution that is aspirated by the ICT probe and measured by the ICT module. Sensors in the cup confirm that the cup fills completely and that sufficient solution aspirates during measurement.

### 5.1.3.15. ICT Reference Solution warming ring– Alinity-c

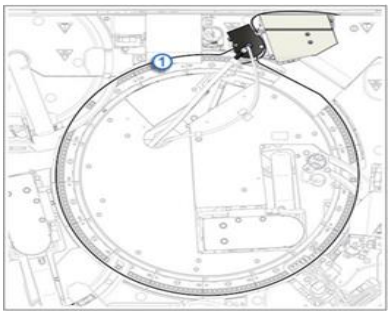

**Figure 1.18**: ICT Reference Solution warming ring.

ICT Reference Solution warming ring: A narrow metal tube located in the water bath. The warming ring heats the reference solution to 37°C before the ICT Reference Solution cup is filled.

### 5.1.3.16. ICT high-concentration waste area– Alinity-c

Liquid waste from the ICT unit collects in a high-concentration waste compartment, and then the waste is removed through the high-concentration waste tubing.

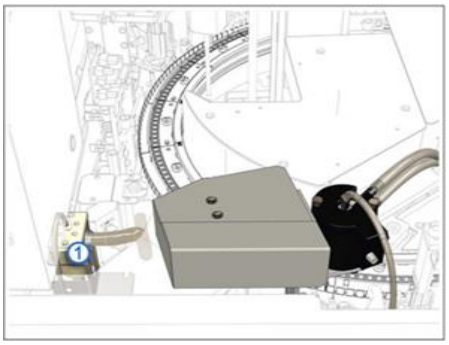


**Figure 1.19**: ICT high-concentration waste area (Alinity c).

### 5.1.3.17. Water bath overflow and waste area– Alinity-c

The water bath overflow and waste area is a waste collection compartment that receives overflow from the water bath, excess water from the sample pipettor, and liquid waste from the ICT Reference Solution cup. Water from the sample pipettor and waste from the ICT Reference Solution cup collect in a low concentration waste compartment, and then the water and waste are removed through the low concentration waste tubing.

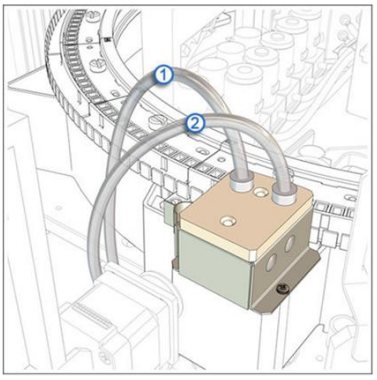


**Figure 1.20**: Water bath overflow and waste area (Alinity c).

**1)** Sample tubing: Delivers excess purified water from the sample pipettor into the low-concentration waste compartment.

**2)** ICT Reference Solution cup low-concentration waste tubing: Delivers liquid waste from the ICT Reference Solution cup into the low-concentration waste compartment.

### 5.1.3.18. High-concentration waste pump (Alinity c) –Alinity-c

The high-concentration waste pump works with the cuvette washer to aspirate waste from the cuvettes to the optional high-concentration waste bottle or the drain.

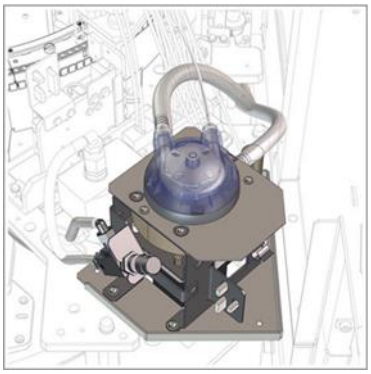

**Figure 1.21**: High-concentration waste pump (Alinity c).

### 5.1.3.19. Supply and pump center–Alinity-c

The supply and pump center is the onboard storage area for processing module pumps, bulk solutions, and sample and reagent syringes and drives.

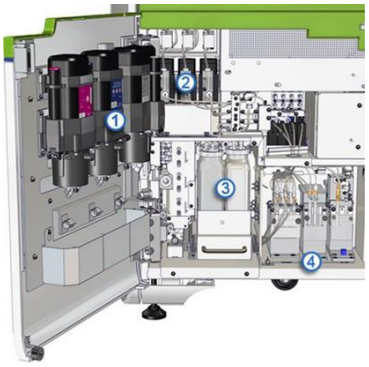


**Figure 1.22**: Supply and pump Center.

**1)** Bulk solution storage area: Provides the onboard storage for replacement bulk solution bottles.

**2)** Sample and reagent syringe area: Houses the sample and reagent syringes and drives.

**3)** Bulk solution reservoir area: Provides the onboard storage for the ICT Reference Solution, Alkaline Wash, and Acid Wash that are in use.

**4)** Pump center: Houses the processing module pumps.

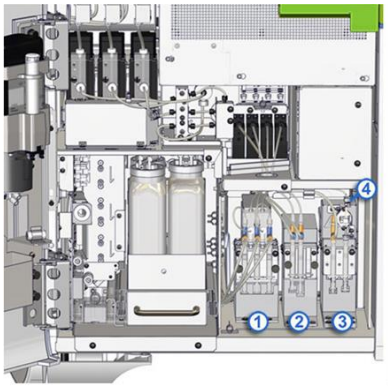


**Figure 1.23:** Pump center.

**1)** Wash solution pump: Delivers diluted Alkaline Wash and Acid Wash solutions to the cuvettes during daily

operation and maintenance procedures.

2) ICT Reference Solution pump: Uses the syringe on the left side of the pump to deliver ICT Reference Solution into the ICT Reference Solution cup. After the ICT Reference Solution is measured, the ICT Reference Solution pump uses the syringe on the right side of the pump to drain the cup.

3) ICT aspiration pump: Uses the syringe on the right side of the pump to deliver samples or ICT Reference Solution into the ICT module for measurement. After measurement is completed, the ICT aspiration pump uses the syringe on the left side of the pump to aspirate waste from the ICT high concentration waste area to the high-concentration waste tubing.

4) ICT aspiration valve: Controls the direction of liquid flow while the ICT aspiration pump operates.

### 5.1.3.20. Bulk solution storage area – Alinity-c

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.

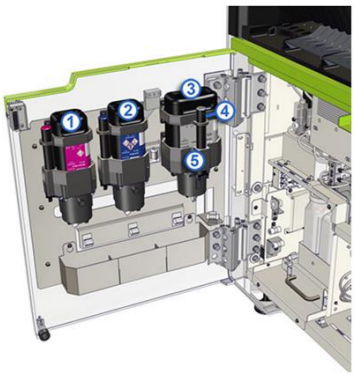


**Figure 1.24**: Bulk solution storage area.

1) Alkaline Wash: Used by the cuvette washer to clean the cuvettes after sample analysis.

2) Acid Wash: Used by the cuvette washer to clean the cuvettes after sample analysis.

3) ICT Reference Solution: Aspirated and analyzed by the ICT module before and after each sample to provide a reference potential that is used in result calculation.

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.

### 5.1.3.21. Reservoir area – Alinity-c

The bulk solution reservoir area, which is in the supply center, 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.

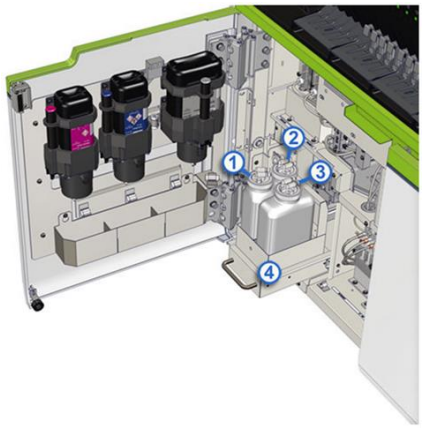


**Figure 1.25**: Reservoir area.

**1)** Alkaline Wash reservoir: Holds in-use Alkaline Wash solution.

**2)** Acid Wash reservoir: Holds in-use Acid Wash solution.

**3)** ICT Reference Solution reservoir: Holds in-use ICT Reference Solution.

### 5.1.3.22. Sample and reagent syringe area (Alinity c)

The sample and reagent syringe area holds the sample and reagent syringes and drives. Each drive supports a syringe that aspirates and dispenses samples, reagents, and onboard solutions.

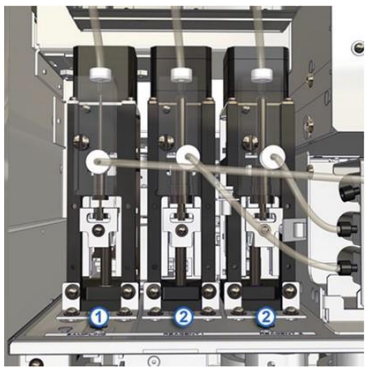


**Figure 1.26**: Sample and reagent syringe area.

**1)** Sample syringe: Aspirates and dispenses the sample.

**2)** Reagent syringes 1 and 2: Aspirates and dispenses the reagent and onboard solutions.

### 5.1.3.23. Reagent supply center (Alinity c)

The reagent supply center provides cooled storage at a controlled temperature for reagent cartridges, onboard solutions, sample diluents, 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 transport.

**1)** Reagent carousel: Holds reagent cartridges 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.

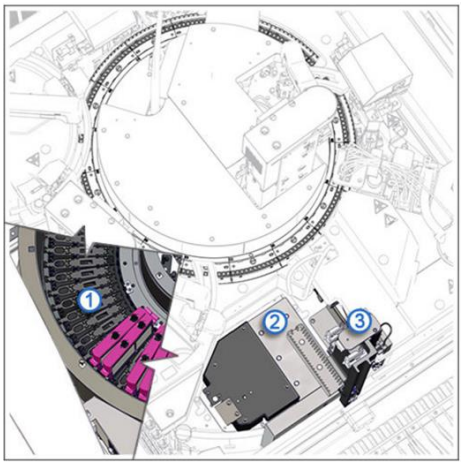


**Figure 1.27**: Reagent supply center (Alinity c).

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

## 5.1.3.24. Reagent carousel – Alinity-c

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

**2)** Holds a maximum of 70 bar-coded reagent cartridges, onboard solutions, sample diluents, and vial racks in a cooled environment at a controlled temperature.

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

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

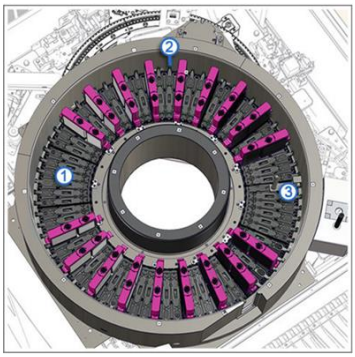


**Figure1.28**: Reagent carousel (Alinity c).

**5)** Reagent segment: A section of the reagent carousel. The reagent carousel has two types of segments and 12 total segments:

- Eleven segments can hold a maximum of six cartridges. Vial racks cannot be stored in these segments.
- The twelfth segment contains the reagent carousel calibration target. This segment can hold a maximum of four cartridges or vial racks.
- The total capacity of the 12 segments is 70 cartridges.

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

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

## 5.1.3.25. Processing center interior lights

Processing center interior lights are located on the top panel of the Alinity ci series. 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 1.29**: 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-c regardless of the number of processing modules. The RSM performs the following functions:

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

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

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

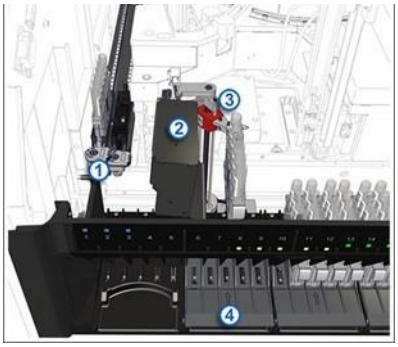


**Figure 1.30**: Reagent and Sample Manager

**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 1.31**: 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 1.32**: Alinity-c 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.<br>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

Principles of operation for the c-series provide an overview of photometric and potentiometric detection technologies, the assay processing, and the Smart Wash feature used for analyte measurement. The principles also include an overview of sample interference indices for lipemic, hemolyzed, and icteric samples. Required Equipment. The c-series uses photometric detection technology to measure sample absorbance for the quantitation of analyte concentration.

Photometric technology is the measurement of the amount of light that a sample absorbs. A beam of light is passed through a sample and the intensity of light that reaches a detector is measured. Beer's Law establishes the mathematical relationship between the absorbance of the solution and the concentration of the analyte. The absorbance of the solution changes as the reaction progresses. Measurements occur either when all the reactant is depleted, and the reaction is stable (end-point assays) or when the reactant reaches a stable rate (rate assays).

The c-series uses potentiometric detection technology to measure the electrical potential in a sample. In addition, the c-series uses an integrated chip technology (ICT) module to measure potentiometric assays (electrolytes).

## 5.3. Required Equipment

**1)** Alinity c Analyzer

**2)** Millipore water purifier

**3)** Racks: Sample, control and calibrator racks.

**4)** Trays

For further information on device management, refer to "**Procedure to Device Management**".

## 5.4. Required Reagents

Abbott prepackaged reagent cartridges contain a two-dimensional bar code. Each bar code includes the following information:

• Reagent identifier • Reagent serial number • Test size (number of tests for each cartridge) • Expiration date • Onboard stability time

**1)** Alinity Alkaline wash.

**2)** Alinity Acid wash.

**3)** Alinity ICT Reference solution

**4)** Alinity assay reagent packs.

**5)** Alinity assay calibrators.

**6)** Alinity assay controls.

**7)** Alinity Consumables: Sample cups.

**8)** Test reagents

### 5.4.1. Required consumables and Reagents

Required consumables are replenishable items that are needed for sample processing on the Alinity ci-series. Be sure to maintain an adequate inventory of required consumables.

Reagent kits and components

Reagent kits are one or more cartridges that contain all the necessary reagent components for an Alinity ci-series assay.

Reagent cartridges can be stored on the system according to the assay-specific instructions. For more information about onboard storage, see the assay documentation.

Abbott prepackaged reagent cartridges contain a two-dimensional bar code. Each bar code includes the following information:

**a)** Reagent identifier

**b)** Reagent serial number

**c)** Test size (number of tests for each cartridge)

**d)** Expiration date

**e)** Onboard stability time

**f)** Master calibration information for assays that use the 2-point adjustment calibration method (only for Alinity i-series)


**Figure 1.33**: Reagent cartridges and components.

1) Alinity i reagent cartridge: Provides the necessary components for an Alinity ci-series chemiluminescent microparticle immunoassay assay. Each reagent bottle in the cartridge contains an integrated septum unless otherwise indicated in the assay documentation.

2) Alinity c reagent cartridge: Provides the necessary components for an Alinity ci-series photometric or potentiometric assay.

3) Alinity Reagent Replacement Cap: Seals a reagent cartridge to prevent reagent leakage when the cartridge is removed from the system and is stored in an external refrigerator. The original cap is not used to prevent analyte cross contamination.

#### 5.4.1.1. Controls

Controls are samples that contain known concentrations of analyte. Controls are available as single-constituent and Mult constituent controls. Some controls can be stored for use in the reagent carousel. To identify the controls that are required for an assay, see the assay documentation.


**Figure 1.34**: Alinity ci-series controls.

1) Single-constituent control: An assay-specific sample that contains known concentrations of an analyte.

2) Mult constituent control: A sample that contains multiple analytes.

3) Alinity ci-series Calibrator/Control Replacement Caps: Replace the original caps on calibrator and control vials that are loaded on the reagent and sample manager for calibration and control testing. The replacement cap seals the vial to prevent leakage when the vial is removed from the system and is stored in an external refrigerator. The original cap is not used to prevent analyte cross contamination

#### 5.4.1.2. Calibrators

Calibrators are samples that contain known concentrations of analyte. A variety of single constituent and multi constituent calibrators are used on the Alinity c-series. Single-constituent calibrators are used on the Alinity i-series. Some calibrators can be stored in the reagent carousel. To identify the required calibrators for an assay, see the assay documentation.

**Figure 1.35**: Alinity ci-series calibrators.

1. Alinity i calibrators: Include single-constituent calibrators that are used in the calibration of i-series assays.

2. Alinity c calibrators: Include single-constituent and multi constituent calibrators that are used in

thecalibration of c-series photometric assays.

3. Alinity c ICT calibrators: Used in the calibration of c-series potentiometric assays.

4. Alinity ci-series Calibrator/Control Replacement Caps: Replace the original caps on calibrator and control vials that are loaded on the reagent and sample manager for calibration and control testing. The replacement cap seals the vial to prevent leakage when the vial is removed from the system and is stored in an external refrigerator. The original cap is not used to prevent analyte cross contamination.

### 5.4.1.3. Bulk solutions (c-series)

Bulk solutions are liquid solutions that are provided in large quantities for use during sample processing. The Alinity c-series uses three bulk solutions. Each bulk solution bottle is loaded on the bulk solution door.

**Figure 1.36**: Bulk solutions (c-series).

**1)** Alkaline Wash (0.5 L bottle): An alkaline wash solution that is used by the cuvette washer to clean the cuvettes after sample analysis. Alkaline Wash is stored at a temperature of 15°C to 30°C and is stable on the system for 30 days.

**2)** ICT Reference Solution (975 mL in a 1 L bottle): A mid concentration standard solution that is aspirated and analyzed by the ICT module before and after each sample. The solution provides a reference potential that is used in result calculation. ICT Reference Solution is stored at a temperature of 15°C to 30°C and is stable on the system for 90 days.

**3)** Acid Wash (0.5 L bottle): An acidic wash solution that is used by the cuvette washer to clean the cuvettes after sample analysis. Acid Wash is stored at a temperature of 15°C to 30°C and is stable on the system for 30 days.

### 5.4.1.4. Onboard solutions (c-series)

Onboard solutions are detergents that are used to wash sample probes, reagent probes, mixers, and reaction cuvettes. The solutions are used by the Smart Wash feature during system operation. They may also be used during some maintenance and diagnostic procedures. Onboard solutions include Acid Probe Wash, Detergent A, and Detergent B. For specific information about each solution, see the product documentation.


**Figure 1.37**: Onboard solutions (c-series).

### 5.4.1.5. Maintenance solutions (c-series)

The c-series maintenance solutions are liquid solutions that are supplied as a three-component kit and are used during the automated daily maintenance procedure. The large bottle of the maintenance cartridge is filled with Water Bath Additive, an antimicrobial solution that is used to prevent and control microbial contamination in the water bath. During maintenance, the solution is dispensed into the water bath. The small bottle of the maintenance cartridge is empty and is reserved for the reconstituted Cleaning Solution. Cleaning Solution is supplied as a lyophilized material with a diluent. The reconstituted cleaning solution is added to the small bottle. During daily maintenance, the reconstituted cleaning solution is used to clean sample and reagent probes, mixers, the ICT probe, and the ICT module. The maintenance solutions are stored at a temperature of 15°C to 30°C and are stable on the system for 14 days or 12 tests, whichever occurs first.


**Figure 1.38**: Maintenance solutions (c-series).

### 5.4.1.6. ICT module (c-series)

The ICT module is an integrated chip that is a component of the ICT unit and contains the sodium (Na+), potassium (K+), chloride (Cl-), and reference electrodes. The warranty for the ICT module is 20,000 samples or 3 months afterinstallation, whichever occurs first.


**Figure 1.39**: ICT module (c-series).

#### 5.4.1.7. Sample cups

Sample cups are 1400 µL disposable containers that hold samples. Volume graduation marks at 125 µL, 500 µL, and 1400 µL eliminate the need to pipette with precision. To facilitate the positive identification of samples, sample cups can be placed in sample tubes that have bar code labels.

**Figure 1.40**: Sample cup.

For further information on reagent management, refer to "**Procedure for Reagent Management**".

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

Specimen Type: Serum/Plasma.

For further information refer to the "**Procedure for Specimen Management**" and Specific test SOP.

## 5.6. Work Environment

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

- **a)** Installation location indoors in dry areas free from drafts and excessive dust.
- **b)** Alinity-c 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.
- **c)** 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.

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-c 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:

**a)** Maintenance and diagnostics.

**b )** Component replacement.

Circumstances for start-up, shutdown may include:

**a)** Load samples, reagents, and solutions

**b)** Perform maintenance or diagnostic procedures

**c)** Replace components

**d)** Troubleshooting

**e)** 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 Traceability

### 5.8.1. Calibration guidelines

After an assay is installed that requires a calibration, an active calibration must be generated. A calibration is not required every time that an assay is run. However, a recalibration is required with certain variables.

#### 5.8.1.1. Mandatory assay calibration

A calibration must be performed when:

**a)** A new reagent lot number is used.

**b)** Assay documentation states that a calibration is required when a reagent cartridge is changed.

**c)** Documentation that accompanies a new version of an existing assay file states that a calibration is required.

**d)** A new assay file that requires a calibration is installed.

**e)** The calibration has expired.

#### 5.8.1.2. Optional assay calibration

A calibration may need to be performed when:

**a)** Assay control values do not meet required specifications. For specific information about quality control, see the manufacturer's documentation.

**b)** Certain system maintenance procedures or component replacement procedures are performed.

**c)** • Certain errors occur. To determine whether a recalibration is required when an error occurs, see assay specificmessage codes.

Running all levels of appropriate controls is recommended when an assay is calibrated.

### 5.8.2. Calibration types and methods

Calibration types and methods define the system-specific processes that are used to create a calibration curve or determine a cutoff value.

### 5.8.2.1. Calibration method (c-series potentiometric)

The potentiometric calibration method is used to calculate results for the ICT assays of sodium (Na+), potassium (K+), and chloride (Cl-). Serum and urine calibrators are available for use and contain known concentrations of electrolytes. The serum calibrators are protein-based materials.

The urine calibrators are aqueous-based materials that span a greater concentration range.

The millivolts measured by each electrode of the ICT module are plotted against the known concentration of electrolyte in the calibrator. The slope of the calibration is expressed as a percentage of the ideal slope. Electrolyte determinations are made at 37°C. Therefore, the ideal slope of the electrode is 100% (61.5 millivolts per decade).

The potentiometric calibration method is specific to these assays, is defined in the system software, and has three components:

**a)** Electromotive force measurement

**b)** Slope calculation

**c)** Sample measurement

Details about mentioned method see Abbott Alinity ci operation manual.

### 5.8.2.2. Calibration types and methods (c-series photometric)

Two c-series assay calibration types, full and adjustment, apply only to photometric assays and indicate whether a calibration curve is created or adjusted.

The photometric calibration methods use measured absorbance values to plot a calibration curve or to determine a cutoff value.

The system software provides six full calibration methods and three adjustment calibration types.

The type and method are defined in each assay parameter file.

For information about calibration types and methods for an assay, see the assay documentation.

**1)** Full calibration (c-series photometric)

A full calibration for an assay is the measurement of a reagent blank and all specified data points. The absorbance value for each point is plotted against the known concentration and the system software generates a new calibration curve. Unknown samples are then evaluated against the calibration curve.

A full calibration is necessary to update the full calibration interval.

**2)** Absorbance method (c-series photometric)

The absorbance data reduction method uses the comparison between the absorbance of the sample and the absorbance of water to calculate results. For end-point assays, the data is expressed as absorbance. For rate assays, the data is expressed as the rate of absorbance change per minute.

**3)** Factor method (c-series photometric)

The factor data reduction method uses a reagent blank and a fixed calibration factor value to calculate results. This method is applicable to assays for which the reaction is linear and stable across all reagent lots. This method is used to measure enzyme activity in a sample at a predictable and steady rate that can be determined for the chromophore, wavelengths, and processing module in use.

The enzyme activity or the sample concentration is calculated by using the following equation:

$$X = (A - A\ blk) \times Factor$$

Where:

- **X:** Activity or concentration of the unknown sample
- **A:** Absorbance or absorbance change of the unknown sample
- **A blk:** Absorbance or absorbance change of the reagent blank

**Factor:** Calibration factor

**4)** Linear method (c-series photometric)

The linear data reduction method uses a reagent blank and one to six calibrators to generate a point-to-point calibration curve. The slope is calculated for each segment of the curve between calibrator levels.

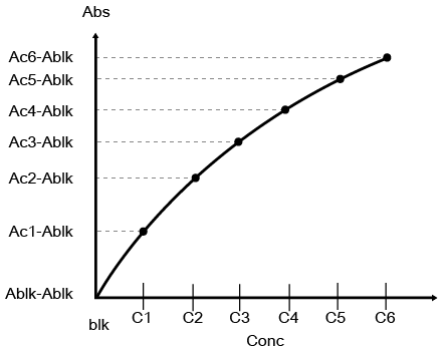


**Figure 1.41**: Linear calibration curve for six calibrators.

Where:

- **Abs:** Absorbance
- **Conc:** Concentration
- **Blk:** Concentration of the reagent blank
- **C1 to C6:** Concentration of the calibrator
- **A blk:** Absorbance or absorbance change of the reagent blank
- **Ac1 to Ac6:** Absorbance or absorbance change of the calibrator

**5)** Logit-4 method (c-series photometric)

The logit-4 data reduction method uses a reagent blank and three to six calibrators to generate a calibration curve. This method is applicable to assays for which the absorbance or absorbance change increases as the calibrator concentration increases.

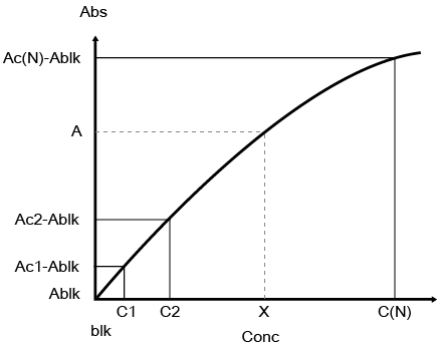


**Figure 1.42**: Logit-4 calibration curve for three to six calibrators

Where:

- **Abs:** Absorbance
- **Conc:** Concentration
- **Blk:** Concentration of the reagent blank
- **C1 to C(N):** Concentration of the calibrator
- **X:** Concentration of the unknown sample
- **A blk:** Absorbance or absorbance change of the reagent blank
- **Ac1 to Ac(N):** Absorbance or absorbance change of the calibrator
- **A:** Absorbance or absorbance change of the unknown sample

An approximation is calculated by using the following equation:

$$A = \frac{Kc}{1 + \frac{1}{e^{a + b \times \ln X}}} + Ablk$$

Where:

- **A:** Absorbance or absorbance change of the unknown sample
- **Kc, a, b:** Constants of the approximation expression
- **A blk:** Approximate value of the absorbance or absorbance change of the reagent blank
- **X:** Concentration of the unknown sample ln Natural log

When the concentration is near zero, the logit-4 calibration curve converges asymptotically

toward the absorbance or absorbance change of the reagent blank as the concentration approaches zero. A graph may not show this convergence if the scale is too large.

The approximation expression is simple and the constant is determined through an approximation

by nonlinear regression. Therefore, the curve may not consistently pass through the absorbance (or absorbance change) data points of the calibrator.

**6)** Spline method (c-series photometric)

The spline data reduction method uses a reagent blank and three to six calibrators to generate a calibration curve. The concentration axis of the calibration curve graph is divided into multiple sections. The sections correspond to the concentrations of the calibrators. Each section of the curve is interpolated by using a polynomial equation so that the adjoining sections are connected smoothly.

**7)** Use cal factor blank method (c-series photometric)

The use cal factor blank calibration method uses the factor and reagent blank of a calibration curve generated for another assay (reference assay) to calculate results. This method is used when two or more assays use the same reagent and have the same sample volume to reagent volume ratios. The reference assay is defined in an assay parameter file.

**8)** Adjustment calibration (c-series photometric)

An adjustment calibration uses one of the following measurement options:

**a)** A new measurement of a reagent blank.

**b)** A new measurement of one specific point of a full calibration curve.

**c)** A new measurement of a reagent blank and one specific point of a full calibration curve.

The system software uses the new measurements to adjust the existing calibration data points and then generates a new calibration curve.

The adjustment calibration interval is updated when either a full calibration or a designated adjustment calibration is performed.

The c-series provides the following adjustment options:

**a)** Blank adjustment

**b)** 1-point adjustment

**c)** 2-point adjustment

**9)** Blank adjustment (c-series photometric)

In a blank adjustment, the system reanalyzes only the reagent blank. The following figure shows how the calibration curve is adjusted with the new reagent blank data. The calibration curve is plotted as absorbance (Abs) versus concentration (Conc).

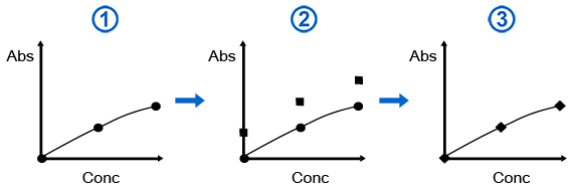


**Figure 1.43**: Blank adjustment (c-series photometric).

Graphics [1], [2], and [3] display the adjustment that occurs for each calibration to correct the calibrator absorbances by the blank absorbance:

**1)** The closed circles in graphic [1] represent the blank and calibrator absorbance and concentration data before adjustment.

**2)** A new blank measurement and adjustment is performed in graphic [2].

The new blank absorbance value is subtracted from itself and the original, blank-corrected calibrator absorbance values.

**3)** The system software generates a new calibration curve. This calibration curve is represented by the closed diamonds in graphic [3]. The blank and calibrator absorbance values reflect the correction by the new blank absorbance value. The existing calibration factors are unchanged.

**10)** 1-point adjustment (c-series photometric)

In a 1-point adjustment, the system reanalyzes one calibrator. The calibrator used is defined on the Calibration tab of the Assay Parameters screen. The following steps show how the calibration is adjusted with the new calibrator data. The calibration is plotted as absorbance (Abs) versus concentration (Conc).

**11)** 2-point adjustment (c-series photometric)

In a 2-point adjustment, the system reanalyzes the reagent blank and one calibrator. The calibrator used is defined on the Calibration tab of the Assay Parameters screen. The following steps show how the calibration is adjusted with the new calibrator data. The calibration is plotted as absorbance (Abs) versus concentration (Conc).

For information on traceability, refer to "**Abott Alinity C Calibration Traceability Record**".

## 5.9. Quality Control Procedures

Controls are samples that contain known concentrations of analyte. Controls are available as single-constituent and multi constituent controls. Some controls can be stored for use in the reagent carousel. To identify the controls that are required for an assay, see the assay documentation.

### 5.9.1. Alinity ci-series controls


**Figure 1.44**: Alinity ci-series controls.

1) Single-constituent control: An assay-specific sample that contains known concentrations of an analyte.
2) Multi constituent control: A sample that contains multiple analytes.
3) Alinity ci-series Calibrator/Control Replacement Caps: Replace the original caps on calibrator and control vials that are loaded on the reagent and sample manager for calibration and control testing. The replacement cap seals the vial to prevent leakage when the vial is removed from the system and is stored in an external refrigerator. The original cap is not used to prevent analyte cross contamination.

Before run controls need to configure controls.

### 5.9.2. Rerun Options (Control Order) flyout element descriptions

In the Rerun Options flyout, the operator can order a rerun on a control test.

#### 5.9.2.1. Elements

1) **Sample ID:** Displays the control lot number and control level number. Barcoded controls include a serial number when quality controls are run in a vial rack. Bar-coded controls may include the prefix QQQ followed by the control lot number and level or may contain a user-defined control bar code SID when the controls are run in a sample rack.
2) **Assay:** Displays the name of the test ordered.
3) **Rack:** Displays the rack ID if it was entered in the original order.
4) **Position:** Displays the rack position if a rack ID was entered in the original order.
5) **Control Name:** Displays the control name.
6) **Assay:** Displays the name of the assay ordered.

7) **Control Level:** Displays the control level.

8) **Result:** Displays the value and unit of the test result.

9) **Control Lot:** Displays the control lot.

10) **Reagent Selection:** Displays the following options:

11) **Auto:** The system scheduler selects the reagent cartridge.

12) **Select Cartridge:** Displays an option that is used to designate the reagent cartridge.

### 5.9.3. Quality Control Summary screen, Search flyout element descriptions

In the Search flyout of the Quality Control Summary screen, the operator can enter specific data that is used to filter the data on the screen.

#### 5.9.3.1. Elements

1) **Control Name:** Displays a text box that is used to search by the control name.

2) **Lot:** Displays a text box that is used to search by the control lot number.

3) **Level:** Displays a text box that is used to search by the level of the control that was processed.

4) **SID:** Displays a text box that is used to search by the sample identification (SID) of the control.

The control SID is 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 may include the prefix QQQ followed by the control lot number and level or may contain a user-defined control bar code SID when the controls are run in a sample rack.

5) **Assay:** Displays a text box that is used to search by the assay name.

6) **Results with Flags:** Displays a check box that is used to search for control results that have flags.

#### 5.9.3.2. Function Buttons

1) **Done:** Saves changes and either displays the previously viewed screen or closes the flyout.

2) **Cancel:** Cancels selections or entries and displays the previously viewed screen or flyout.

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

### 5.9.4. Quality Control Summary Screen

On the Quality Control Summary screen, the operator can view the statistical data for all assay control levels.

NOTE: Statistical calculations are performed for all released results, including quality control results for a specific processing module, assay, control name, lot number, and level combination.

The quality control summary data is not displayed if the values for expected mean and expected standard deviation (1 SD) are not defined for the control.

The operator can perform the following functions:

**a)** Find information about a specific control based on specified search criteria.

**b)** Access quality control information.

**c)** Create a Levey-Jennings graph for a selected assay control level.

**d)** Print the QC Analysis Report and the QC Summary Report.

The system administrator can clear a control failure for an assay for a specific control, lot number, and level.

### 5.9.5. Quality control Analysis

Quality control analysis is the process by which quality control (QC) data is monitored. QC data includes both unreleased and released control results. The Alinity ci-series monitors QC data with Levey-Jennings graphs, Westgard rules, control range tracking, and QC data summaries. To help ensure quality results and maintain optimal system performance, comply with the following requirements:

**a)** Carefully follow all directions in the operations manual and the reagent manufacturer's assay documentation.

**b)** Do not use expired or contaminated consumables.

**c)** Perform maintenance procedures and calibration procedures as recommended.

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

For further information Refer to "**Procedure for Quality Assurance**".

## 5.10. 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 and Measurement Uncertainty"** for various aspects of verification/validation processes."

## 5.11. Procedural Steps

### 5.11.1. 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 1.45:** SCM power switch.

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

**Figure 1.46:** Alinity-c processing module main power breaker.

**7)** Power off the main power breaker of each Alinity-c 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-c 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.

### 5.11.2. 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.

**Figure 1.47**: SCM power switch

**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.

**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 1.48**: Alinity-c 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.

### 5.11.3. 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-c processing module.

**6)** If the power to the processing module and the RSM is off, power on the processing module and the RSM.

### 5.11.4. 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.

### 5.11.5. 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.

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.

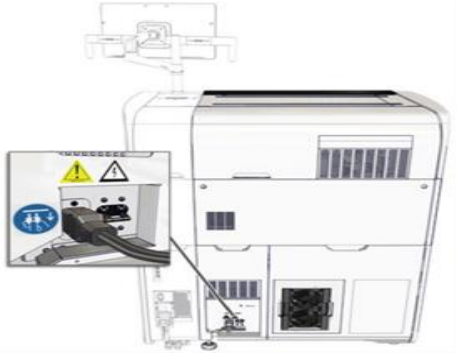

**Figure 1.49**: Alinity-cprocessing module main power breaker.

**Figure 1.50**: Alinity-c 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.

## 5.11.6. Power off the processing module

### 5.11.6.1. 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.

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.

**Figure 1.51**: Alinity-c processing module power switch.

**Figure 1.52:** Alinity-c 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-c processing module for more than 7 days, perform a long-term shutdown.

### 5.11.7. 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.

**Figure 1.53**: Alinity-c 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.

### 5.11.8. Power off the reagent and sample manager (RSM)

Required Instrument Status: Offline, Stopped, Warming, Or Idle.

#### 5.11.8.1. 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.

**Figure 1.54**: Alinity-c SCM power switch.

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

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.

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

#### 5.11.9.1. 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.

## 5.11.10. Pause the processing module

### 5.11.10.1. 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.

## 5.11.11. Pause the reagent and sample manager (RSM)

### 5.11.11.1. 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.

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

## 5.11.12.1. 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.

On the menu bar, tap the Home icon.

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

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

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

Tap Stop.

When a confirmation message is displayed, tap Yes.

## 5.11.13. Perform and Emergency Shutdown

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

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

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

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

**Figure 1.55**: Alinity-c 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.

## 5.11.14. Long-term Shutdown

If the Alinity c-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.

## 5.11.15. Log On Screen

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

**a)** System information.

**b)** Status information.

**c)** The operator can log on to the system.

## 5.11.16. 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.

## 5.11.17. 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.<br>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.<br>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 1.3:** Log On area.

## 5.11.18. 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 1.4**: System Information area.

## 5.11.19. System Status area

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

## 5.11.20. 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 1.5**: Instrument status icons.

## 5.11.21. 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 1.6**: Reagent status icons.

### 5.11.22. 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 1.7**: Sample status icons.

### 5.11.23. Function button

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

**Table 1.8**: Function button.

## 5.11.24. Log On

Perform this procedure to log on to the Alinity-c 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:

**a)** Tap the Plus button.

**b)** Type the operator ID.

**c)** Tap the + Done button.

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

## 5.11.25. Lock the User Interface

Perform this procedure to lock the user interface.

**a)** 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.

**b)** 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.

## 5.11.26. Procedure key for the System Control Module (SCM)

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

**a)** A user interface computer provides the software interface to the Alinity-c and provides an interface to a host or middleware computer.

**b)** Hardware and software operate the reagent and sample manager (RSM).

**c)** The power supply operates the user interface computer and the RSM.

**Figure 1.56**: Procedure key for the System Control Module.

### 5.11.26.1. Front View of the SCM


**Figure 1.57**: 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.

### 5.11.26.2. Rear View of the SCM

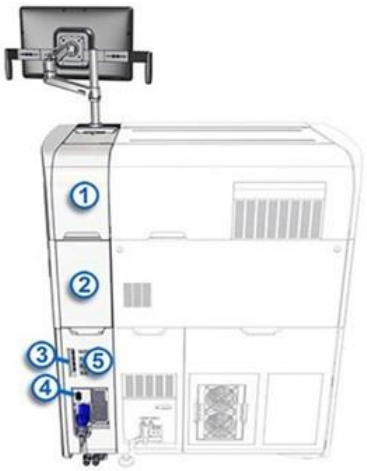


**Figure 1.58:** SCM Rear View.

**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.

## 5.11.27. Alinity-c Distance Alert

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

**Figure 1.59**: Alinity-c 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:<br>If the distance alert is configured for notifications, a red badge is displayed on any icon on the menu bar.<br>An alert message that has not been cleared is present in the Alert Center.<br>If the distance alert is configured for notifications, a red badge is displayed on any icon on the menu bar.<br>An alert message that has not been cleared is present in the Alert Center. |

| | |
|---|---|
| **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:<br>If the distance alert is configured for notifications, an amber badge is displayed on any icon on the menu bar except the Results icon.<br>If the distance alert is configured for exception notifications, an amber badge is displayed on the Results icon.<br>A notification message that has not been cleared is present in the Alert Center |
| **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.<br>The user interface computer is shut down.<br>The instrument status of one or more processing modules in the workstation is not Running, Processing, or Pausing. |

**Table 1.9**: Description of Colors.

## 5.11.28. Specimen, Calibration and Control Orders

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

### 5.11.28.1. 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.

### 5.11.28.2. 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.

### 5.11.28.3. 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.

### 5.11.28.4. 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:

**a)** 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.

**b)** 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.

### 5.11.28.5. 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:

**a)** When a control sample bar code label from an onboard vial rack, a vial rack, or a sample rack is scanned.

**b)** When the system software periodically evaluates the control vials that are stored in onboard vial racks in the reagent carousel.

**c)** When the configured time interval or test interval is exceeded.

## Controls are evaluated for automated orders in three ways:

**a)** When they are scanned by the reagent and sample manager (RSM).

**b)** Every 15 minutes when they are stored on the system and the instrument status of the processing module is Processing.

**c)** Every 15 minutes when they are stored off the system and at least one processing module has an instrument status of Processing.

### 5.11.28.6. 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 multi constituent 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 multi constituent 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.

### 5.11.28.7. 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 multi constituent 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.

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 multi constituent control assays that are disabled for onboard use whenthe control is located in an onboard vial rack that is assigned a position in the reagent carousel.

### 5.11.28.8. 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:

**a)** When a control order is present for the specified assay and control level.

**b)** If the control lot number is expired.

**c)** When no reagent cartridge is available for the assay.

### 5.11.28.9. 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:

**a)** No order has been created since the configured shift start time.

**b)** 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.

**c)** The time interval or test interval has been exceeded.

**d)** 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.

### 5.11.28.10. 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)** A control order that has a status of Pending is present.

**b)** The reagent cartridge status is Disabled.

**c)** The control vial status is Empty, Expired, or LLS Error.

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

### 5.11.28.11. 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:

**a)** When a bar code label from an onboard vial rack or a vial rack is scanned.

**b)** 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.

### 5.11.28.12. 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:

**a)** Calibrator tests.

**b)** Control tests.

**c)** Tests that are performed with a manual dilution.

**d)** Assays that have an assay status of Correlation.

**e)** 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.

**2)** 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.

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.

### 5.11.29. Orders screen

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

**a)** Find information about a specific order based on specified search criteria.

**b)** Access the order information.

**c)** Add a comment to a test order.

**d)** Delete an order.

**e)** Create a new specimen order, control order, or calibration order.

## 5.11.30. 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.<br>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:<br>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.<br>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:<br>The patient's name. |
| | The control name and, if configured, the control level number and control level name for control orders.<br>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 1.10**: 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 1.11**: Function Buttons.

## 5.11.31. 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:<br>The patient's name.<br>The control name and, if configured, the control level number and control level name for control orders.<br>The calibrator or calibrator set name, CAL (only for i-series), and the calibrator level for calibration orders. |
| 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:<br>The bar code number or identification assigned to the specimen.<br>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.<br>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.<br>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.<br>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:<br>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:<br>Specimen Control Calibrator |

**Table 1.12**: 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 1.13**: Search fly out function buttons description.

## 5.11.32. 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.

## 5.11.33. 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.<br>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 1.14:** 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 1.15**: 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 1.16**: 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 1.17**: 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 1.18**: Function buttons.

### 5.11.34. 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 1.19**: 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 1.20**: 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 1.21**: 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 1.22**: Function Information Area.

## 5.11.35. 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.

## 5.11.36. 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.

### 5.11.36.1. 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 1.23**: 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 , / > < ? ; : ] [ \ } { ' - = ~ ! @ # $ %<br>^ & * ) ( _ + and <space>.<br>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 1.24**: 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-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 1.25**: 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 1.26**: Function buttons.

### 5.11.36.2. 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 1.27**: 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>.<br>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>.<br>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 1.28**: 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-c 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 1.29**: 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 1.30**: Functions buttons.

### 5.11.36.3. 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.<br>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<br>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 1.31**: 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 1.32**: Function buttons.

### 5.11.36.4. 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:<br>Auto The system scheduler selects the processing module.<br>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 1.33**: 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 1.34**: Function button.

### 5.11.36.5. 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 1.35**: 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 1.36**: 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-c 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 1.37**: 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 1.38**: Function Buttons.

### 5.11.36.6. 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** | Select Cartridge - Displays an option that is used to designate the reagent cartridge. When the option is selected, the following information is available:<br>Module ID: Displays the number of the processing module where the reagent cartridge is located.<br>Position: Displays the reagent carousel position where the reagent cartridge is located Reagent Lot: Displays the reagent cartridge lot number.<br>Serial Number: Displays the reagent cartridge serial number. Cartridge Status: Displays the reagent cartridge status.<br>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.<br>Module check boxes are used to override the system scheduler.<br>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 1.39**: 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 1.40**: Function Buttons.

## 5.11.36.7. 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 1.41:** 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-c processing modules. |
| **PANELS** | Displays all assay panels that are available. |
| **ASSAYS** | Displays all assays that are available for a selected module.<br>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.<br>If an alternate calibrator master lot number is selected for a manual calibration order, the selected calibrator master lot number is displayed.<br>NOTE: Only the default master lot number for a blank calibrator can be used to create a manual order.<br>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.<br>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 1.42**: 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 1.43**: Function Buttons.

## 5.11.36.8. 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:<br>Auto -The system scheduler selects the reagent cartridge.<br>Select Cartridge - Displays an option that is used to designate the reagent cartridge. When the option is selected, the following information is available:<br>Module ID: Displays the number of the processing module where the reagent cartridge is located.<br>Position: Displays the reagent carousel position where the reagent cartridge is located.<br>Reagent Lot: Displays the reagent cartridge lot number.<br>Serial Number: Displays the reagent cartridge serial number. Cartridge Status: Displays the reagent cartridge status.<br>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.<br>NOTE: Module check boxes are available only for multi-module systems that have more than one module of the same type |

**Table 1.44**: 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 1.45**: Function Buttons.

## 5.11.37. 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.

## 5.11.38. 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.

## 5.11.39. 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.

### 5.11.39.1. 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 multi constituent control vial is located on the reagent carousel, orders for assays that are disabled for onboard use become exceptions when the orders are run.

Multi constituent 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.

### 5.11.40. 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.

## 5.11.41. 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.

**5)** 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:

**6)** 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.

**7)** 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.

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

The system releases and reports all results.

**9)** Tap Assay Options.

**10)** 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.

**11)** To save the assay option selections, tap Done.

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

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

**14)** 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.

**15)** Testing Profile area - Displays the active testing profiles.

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

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 1.46**: Function Buttons.

## 5.11.42. 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:<br>• Assay Control<br>• Release Control<br>• Customer Control |

**Table 1.47**: 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 1.48**: 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.<br>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 1.49**: 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 1.50**: Function Buttons.

## 5.11.43. 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 1.51**: 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 1.52**: 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 1.53**: 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 1.54**: Function Buttons.

## 5.11.44. 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 1.55**: 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 1.56**: Function Buttons

## 5.11.45. 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:

**10)** Under Profile, tap the active test profile.

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

**12)** Tap Assay Options.

**13)** In the Assay Options flyout, perform the following steps:

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

**15)** Tap the required dilution, if available.

**16)** Tap Next to go to the next assay.

**17)** To save the assay option selections, tap Done.

**18)** To save the specimen order, tap Add Order.

**19)** To view the specimen order, tap Order Status.

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

**Table 1.57**: Function button.

### 5.11.46. Log On

Perform this procedure to log on to the Alinity-c 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.

### 5.11.47. 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.

## 5.12. 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.

## 5.12.1. 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 maintenance is performed by the vendor every 6 months.

When scheduling and performing maintenance procedures:

Schedule maintenance procedures during times of slower workflow.

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

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.

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

## 5.12.2. Log-in screen


**Figure 1.60**: Login Screen.

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

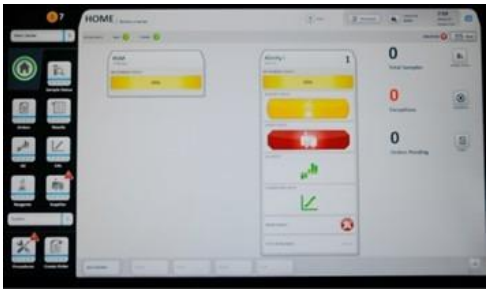


**Figure 1.61**: log-in using the last 4 digits of your badge number.

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

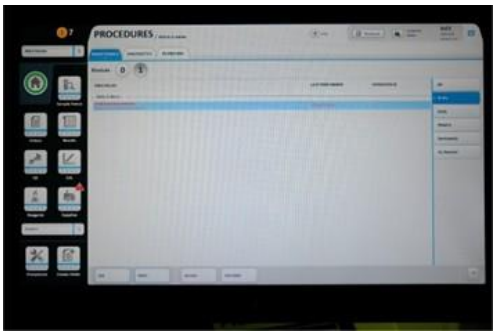


**Figure 1.62**: 'Procedure' icon.

**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.

### 5.12.3. 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.

### 5.12.4. Perform a maintenance procedure

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


**Figure 1.63**: 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 1.64**: Perform procedure screen.

### 5.12.5. 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.

### 5.12.6. 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.

### 5.12.7. 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.

### 5.12.8. 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.

#### 5.12.8.1. Daily maintenance (Alinity-c)

Perform this Daily maintenance procedure to complete the following tasks:

**1)** Flush the water lines of the sample, the reagent, and the cuvette washer.

**2)** Exchange the water in the water bath.

**3)** Add Water Bath Additive to the water bath.

**4)** Wash the ICT module with ICT Reference Solution and Cleaning Solution.

**5)** Drain and fill the ICT Reference Solution cup.

**6)** Wash the sample and reagent probes and the mixers with Acid Probe Wash and Detergent A.

**7)** Clean the sample probe, the R2 probe, and the mixers with Cleaning Solution.

**8)** Clean the sample probe exterior (only for whole blood).

Estimated time is 12 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 Offsetting. 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.

### 5.12.8.2. Weekly maintenance (Alinity-c)

Perform this Weekly maintenance procedure to wash all cuvettes and to fill them with Detergent A solution.

- Estimated Time: 30 minutes.

### 5.12.8.3. 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, 'Cavi wipes' biological cleaning wipes may be used.

### 5.12.8.4. 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. Refer to "**Alinity C User Maintenance Form**"

## 5.13. Medical Indications

Test results must be used with other clinical data, such as symptoms, other test results, the patient history, clinical impressions, the clinical evaluation information, and other diagnostic procedures. Consider all data for patient care management. If test results are inconsistent with the clinical evidence, additional testing is recommended to confirm the results. Errors can occur because of potential operator errors and system technology limitations.

For further details refer to individual test SOP.

## 5.14. Biological Reference Intervals

Refer to individual test SOP.

## 5.15. Alert/Critical Values

Refer to individual test SOP.

## 5.16. Result Verification

**5.16.1. Results screen**

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

**a)** Specimen and control results

**b)** Specimen and control exceptions

The operator can perform the following functions:

**a)** Find information about a specific test based on specified search criteria.

**b)** Access result information.

**c)** Release or delete a result.

**d)** Rerun a test.

### 5.16.2. Results screen, Unreleased tab element descriptions

The Unreleased tab displays completed specimen and control results that have not been released. The Unreleased tab is not displayed if patient and control release modes are set to automatic or automatic with exceptions.

#### 5.16.2.1. Elements

1) **Module ID:** Displays the module number of the module used to process the test. The module number for specimen results of calculated assays is 6 (system control module). The module number for control results of calculated assays is the processing module used to produce the constituent results.
2) **R/P:** Displays the rack ID (R) and position (P) number.

NOTE: If the system is configured for a laboratory automation system (LAS) and the specimen is run on the LAS, the R/P is displayed as LAS/1.

3) **SID:** Displays the sample identification, which can be one of the following items:
   **a)** The bar code number or identification assigned to the specimen.
   **b)** The control lot number and control level number. Barcoded controls include a serial number when quality controls are run in a vial rack. Bar-coded controls may include the prefix QQQ followed by the control lot number and level or may contain a user-defined control bar code SID when the controls are run in a sample rack.
   **c)** The calibrator lot number and calibrator level number.
4) **Name:** Displays the name, which can be one of the following items:
   **a)** The name of the specimen.
   **b)** The control name and, if configured, the control level number and control level name for control orders.
   **c)** The calibrator or calibrator set name, CAL (only for i-series), and the calibrator level for calibration orders.
5) **Assay:** Displays the name of the test.
6) **Result:** Displays the value and unit of the test result.
7) **Interpretation:** Displays the interpretation of the test result.
8) **Flag:** Displays the flags associated with specimen results and quality control results. All results with flags are displayed in red text.
9) **Code:** Displays one or more single-character codes to indicate processing conditions.
10) **Time:** Displays the date and time that the test completed processing.

#### 5.16.2.2. Function buttons

1) **Select All:** Selects or deselects all items in a list. The button switches between Select All and Deselect All.
2) **Search:** Displays the Search flyout.
3) **Print:** Displays the Print flyout.

4) **Details:** Navigates to the Details screen for the selected items on the current screen.

5) **Rerun:** Displays the Rerun Options flyout.

6) **Release:** Moves the selected test results to the Specimen tab or the Control tab.

7) **Delete:** Displays a message requesting confirmation to delete the selected items.

8) **Text Size:** Increases or decreases the size of text displayed.

Any further information regarding individual specimen, controls, and calibrator results see Abbott Alinity ci operation manual.

## 5.17. Precautions for Variations

#### 5.17.1. Sample results observed problems (c-series)

Observed problems for sample results include problems that occur with the sample results on the c-series processing module.

### 5.17.1.1. 1 mL wash solution syringe leaks (c-series)

| PROBABLE CAUSE | CORRECTIVE ACTION |
|---|---|
| The syringe is not tightened at the check valve connection. | Tighten the check valve connection. |
| The syringe plunger is damaged. | Replace the 1 mL syringes (c-series), |
| The check valve is defective. | Replace the check valves (c-series), |
| The tubing is crimped or damaged. | Contact Customer Service to resolve any hardware failure. |

**Table 1.58**: Function button.

### 5.17.1.2. Bubbles in ICT module tubing (c-series)

| PROBABLE CAUSE | CORRECTIVE ACTION |
|---|---|
| The ICT Reference Solution reservoir is empty, but the bottle sensor failed to detect it. | • Replace the ICT Reference Solution bottle.<br>• Perform replace bulk solutions and update the inventory,<br>• Contact Customer Service to resolve any hardware failure. |
| The ICT module O-rings are missing or are not seated correctly, or extra O-rings from a previous ICT module are present. | Reseat the ICT module O-rings or remove the extra O rings. If necessary, perform Replace the ICT module or the ICT probe (c-series). |
| The check valve is defective. | Replace the check valves (c-series), |
| The tubing is crimped or damaged. | Contact Customer Service to resolve any hardware failure. |
| The ICT probe is not connected correctly. | Tighten the probe to the ICT module by hand. |
| The ICT aspiration tubing is not connected correctly. | Tighten the tubing connections at the top of the ICT module and at the top of the 1 mL syringes in the ICT aspiration pump. |

| | |
|---|---|
| The ICT probe is damaged. | Replace the ICT probe. Perform Replace the ICT module or the ICT probe (c-series), |

| PROBABLE CAUSE | CORRECTIVE ACTION |
|---|---|
| The ICT check valves are not functioning. | Perform Triannual maintenance procedure 5834 Check and Change ICT Check Valves (c-series) |
| The 1 mL syringes in the ICT aspiration pump or the ICT Reference Solution pump are not seated correctly. | Reseat the 1 mL syringes. |
| The 1 mL syringes in the ICT aspiration pump or the ICT Reference Solution pump are leaking. | Perform Triannual maintenance procedure 5833 Change 1 mL Syringes (c-series), |
| Hardware failure. | Contact Customer Service to resolve any hardware failure. |

**Table 1.59**: Function button.

### 5.17.1.3. Bubbles in sample or reagent probe tubing (c-series)

| Probable cause | Corrective action |
|---|---|
| The tubing connection to the sample or reagent syringe is loose. | Tighten the tubing connections to the syringe body. |
| The probe tubing is damaged | Perform Replace the reagent probe tubing (c-series), or replace the sample probe tubing (c-series), |
| A syringe seal or an O-ring has failed. | Perform Quarterly maintenance procedure 5801 Sample Syringe Maintenance (c-series), or 5803<br>Reagent Syringe Maintenance (c-series) |
| The tubing is crimped or damaged. | Contact Customer Service to resolve any hardware failure. |

**Table 1.60**: Function button.

### 5.17.1.4. ICT aspiration pump syringe or ICT Reference Solution pump syringe leaks (c-series)

| Probable cause | Corrective action |
|---|---|
| The ICT aspiration pump syringe or the ICT Reference Solution pump syringe is damaged. | Replace the 1 mL syringes (c-series) |
| The connections between the ICT aspiration pump syringe or the ICT Reference Solution pump syringe and the check valve or the tubing are loose. | Tighten the connections to the 1 mL syringes in the ICT aspiration pump or the ICT Reference Solution pump. |

**Table 1.61**: Function button.

### 5.17.1.5. ICT probe leaks (c-series)

| Probable cause | Corrective action |
|---|---|
| The ICT module O-rings are missing or are not seated correctly, or extra O-rings from a previous ICT module are present. | Reseat the ICT module O-rings or remove the extra O rings. If necessary, perform Replace the ICT module or the ICT probe (c-series) |

| | |
|---|---|
| The ICT probe is not connected correctly. | Tighten the probe to the ICT module by hand. |
| The ICT aspiration tubing is not connected correctly. | Tighten the tubing connections. |
| The ICT probe is damaged. | Replace the ICT probe. Perform Replace the ICT module or the ICT probe (c-series) |

**Table 1.62**: Function button.

### 5.17.1.6. Lamp is not on (c-series)

| PROBABLE CAUSE | CORRECTIVE ACTION |
|---|---|
| The cable terminals are not securely connected to the terminal block. | Perform Quarterly maintenance procedure 5806 Change Lamp (c-series) |
| The lamp is out. | Perform Quarterly maintenance procedure 5806 Change Lamp (c-series) |

**Table 1.63**: Function button.

### 5.17.1.7. Liquid at the top of the cuvettes after washing (c-series)

| PROBABLE CAUSE | CORRECTIVE ACTION |
|---|---|
| The cuvette washer is not functioning correctly | Perform Weekly maintenance procedure 5601 Clean Cuvettes with Detergent A (c-series), and observe the cuvette washer nozzles for hanging drops, leaks, or blockage in the tubing. |
| The cuvette dry tip is damaged. | Replace the cuvette dry tip (c-series) |
| The reagent probe is damaged. | Replace the reagent probes (c-series) |
| The reagent probe is out of alignment. | Perform Pipettors diagnostic procedure 4103 R1 Pipettor Calibration (c-series) or 4104 R2 Pipettor Calibration (c-series) |
| Hardware failure. | Contact Customer Service to resolve any hardware Failure. |

**Table 1.64**: Function button.

### 5.17.1.8. Mixer is bent or is making an unexpected noise (c-series)

| PROBABLE CAUSE | CORRECTIVE ACTION |
|---|---|
| A mixer is installed incorrectly or is out of alignment | Replace the mixers (c-series) |

**Table 1.65**: Function button.

### 5.17.1.9. Reagent probe tubing is discolored or contains precipitate (c-series)

| PROBABLE CAUSE | CORRECTIVE ACTION |
|---|---|
| The reagent probe tubing is discolored or contains precipitate. | Replace the reagent probe tubing (c-series) |

**Table 1.66**: Function button.

### 5.17.1.10. Sample or reagent probe is damaged or clogged (c-series)

| PROBABLE CAUSE | CORRECTIVE ACTION |
|---|---|
| Particulate matter in the sample caused an obstruction in the probe. | Use a cleaning wire to dislodge particulate matter from the probe. |
| The sample or reagent probe is damaged. | Replace the damaged probe. Perform Replace the sample probe (c-series) or replace the reagent probes (c-series). |
| A syringe seal or an O-ring has failed. | Perform Quarterly maintenance procedure 5801 Sample Syringe Maintenance (c-series) or 5803 |
| | Reagent Syringe Maintenance (c-series). |

**Table 1.67**: Function button.

### 5.17.1.11. Sample or reagent probe tubing leaks (c-series)

| PROBABLE CAUSE | CORRECTIVE ACTION |
|---|---|
| The sample or reagent probe tubing is damaged. | Replace the reagent probe tubing (c-series) or<br>Replace the sample probe tubing (c-series) |
| A syringe seal or an O-ring has failed. | Perform Quarterly maintenance procedure 5801 Sample Syringe Maintenance (c-series) or 5803<br>Reagent Syringe Maintenance (c-series). |

**Table 1.68**: Function button.

### 5.17.1.12. Sample or reagent syringe leaks (c-series)

| PROBABLE CAUSE | CORRECTIVE ACTION |
|---|---|
| The tubing connection to the sample or reagent syringe is loose. | Tighten the tubing connections to the sample or reagent syringe |
| A syringe seal or an O-ring has failed. | Perform Quarterly maintenance procedure 5801 Sample Syringe Maintenance (c-series) or 5803<br>Reagent Syringe Maintenance (c-series) |
| Hardware failure. | Contact Customer Service to resolve any hardware failure. |

**Table 1.69**: Function button.

For further information see Alinity ci operation manual.

## 5.18. 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.

## 5.19. 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 the **“Procedure for Control of Records”**.

## 7. REFERENCES

**1)** Alinity ci-series Operations Manual.