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Abbott Alinity ci-series Operation and Maintenance

Abbott Alinity ci-series Operation and Maintenance, Continued

Purpose

This procedure provides instructions to perform testing on the Abbott Alinity ci-series analyzers. It includes instructions for processing, storing, and testing specimens, as well as procedures for instrument calibration, quality control, and maintenance.

Principles of Operation

The **Alinity c** processing module is a fully automated chemistry analyzer allowing random and continuous access, as well as priority and automated retest processing using photometric and potentiometric detection technology. The Alinity c processing module uses photometric detection technology to measure sample absorbance for the quantification of analyte concentration and uses potentiometric detection technology to measure the electrical potential in a sample. In addition, the Alinity c processing module uses an integrated chip technology (ICT) module to measure potentiometric assays (electrolytes).

The **Alinity i** processing module is a fully automated immunoassay analyzer allowing random and continuous access, as well as priority and automated retest processing using chemiluminescent microparticle immunoassay (CMIA) technology. CMIA technology is used to determine the presence of antigens, antibodies, and analytes in samples.

Refer to Alinity reagent package inserts for additional information.

Scope

This procedure is intended for all personnel trained and competent (e.g., Clinical Laboratory Scientists, Medical Laboratory Technicians, and Laboratory Assistants) in performing and implementing any of the activities described in this procedure.

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Safety Precautions

All staff members performing these procedures must adhere to regional and local workplace safety policies. These will include but may not be limited to:

- Equipment safety, proper body mechanics, sharps exposure
- Proper use of gloves/personal protective equipment while performing these procedures
- Exposure to body fluids
- Proper handling of regular and biohazardous waste
- Proper cleaning of work area
- Proper handwashing
- Proper storage and disposal of chemical hazardous waste

While operating the system, comply with the following precautions:

- Close all system doors and covers unless instructed otherwise for a maintenance procedure or a troubleshooting procedure.
- Do not disconnect any electrical connection during normal system operation.
- Respond to system notifications that relate to waste levels during system processing.
- Do not replace any fuses. Fuses are not replaceable by the operator.

Specimen Sources

The following specimen sources are acceptable for testing:

- Serum
- Plasma
- Urine
- Body Fluid
- CSF

Specimen Collection and Processing

Follow established regional procedures for specimen collection.

Note: See analyte reference guide for analyte-specific specimen and processing requirements

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Specimen Storage and Stability

When storing specimens, comply with the following requirements:

- Separate serum specimens or plasma specimens from clots, serum separators, or red blood cells when freezing the specimens.
- Mix and centrifuge serum specimens or plasma specimens after any freeze-thaw cycle or to remove red blood cells or other particulate matter. For information about limitations and interfering substances, see the product documentation.
- Avoid multiple freeze-thaw cycles. After thawing a specimen, thoroughly mix it at a low speed or gently invert it. Mixed specimens produce consistent test results.

Note: See analyte reference guide for analyte-specific specimen storage and stability requirements.

Specimen Rejection

The followings specimens will be rejected:

- Specimens improperly labeled or unlabeled
- Specimens collected in the wrong container
- Specimens not meeting storage and stability requirements

Equipment

- Alinity c-series / Alinity i-series Analyzer
  - Operating Temperature: 15 – 30°C
  - Operating Humidity: 20 – 85% (non-condensing)

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Materials The following table contains a list of reagents/materials available for the Alinity test system.

Note: Required materials may vary per site depending on test menu. Equivalent alternatives may be used as appropriate. Refer to product inserts for handling, storage, and stability requirements.

Description	Catalog Number	OneLink
Alinity Reagent Cartridges	See analyte reference guide	
Alinity Calibrators	See analyte reference guide	
Quality Control Material		
Bio-Rad Unassayed Chemistry	Level 1: 691 Level 2: 692	10008873 10008874
Bio-Rad Immunoassay Plus	Level 1: 361 Level 3: 363	10008806 10008808
Bio-Rad Cardiac Markers	Level 1B:27105 Level 2: 147 Level 3: 148	10446364 10008773 10008774
Bio-Rad Pediatric	Level 1: 354 Level 2: 355	10294417 10285526
Bio-Rad Ethanol/Ammonia	Level 1: 544 Level 3: 546	10008830 10008832
Bio-Rad Urine Chemistry	Level 1: 397 Level 2: 398	10008818 10008819
Bio-Rad Spinal Fluid	Level 1: 751 Level 2: 752	10008881 10008882
Bio-Rad Liquichek Specialty Immunoassay	Level 1: 364 Leve 3: 366	10008809 10008811
Bio-Rad Lyphochek Specialty Immunoassay	Level 1: 27124 Level 3: 27126	10540487 10540489
Immunalysis Fentanyl Urine	QC Set: 04Z44-10	10927309
ARK Methotrexate II	QC Set: 5071-0003-01	10927631

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Materials,
Continued

Description	Catalog Number	OneLink
Linearity / Calibration Verification Material		
Mainestandards GC1	1100ab	10926598
Mainestandards GC2	1200ab	10926599
Mainestandards GC3	1300ab	10926600
Mainestandards GC4	1400ab	10926601
Mainestandards FERT1	502ab	10926608
Mainestandards FERT2	504ab	10926609
Mainestandards hsTROPONIN	405ab	10926607
Mainestandards BF	205bf	10926602
Mainestandards BF2	206ro	10926603
Mainestandards CM1	401ab	10926605
Mainestandards CM2	402ab	10926606
Mainestandards PCT	403ab	10829638
Mainestandards TDM1	301ab	10926604
Mainestandards THY	901ab	10531483
Mainestandards UC1	701ab	10926610
Mainestandards UC4	704ab	10927281
AUDIT Linearity FD iPTH for Abbott	K957M-5	10926425

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Materials,
Continued

Description	Catalog Number	OneLink
Supplies		
Sample Cups	01R3801	10835339
Alinity ci-series Reagent Replacement Caps	04R4701	10835344
Calibrator/Control Replacement Caps	04R1001	10835343
ICT Reference Solution	08P76-40	10846080
Acid Wash	08P77-40	10835370
Alkaline Wash	08P78-40	10835371
Detergent A	08P96-70	10835372
Detergent B	08P97-80	10900130
Acid Probe Wash	01R60-70	10835342
ICT Module	09D28-04	10846084
Empty Reagent Cartridge, Black	04S17-50	10845726
Empty Reagent Cartridge, Clear	04S17-40	10835345
Concentrated Wash Buffer	06P13-68	10835351
Pre-Trigger Solution	06P12-70	10932972
Trigger Solution	06P11-70	10932973
Probe Conditioning Solution	01R5840	10835340
Reaction Vessels	06P14-01	10835352

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Calibration Frequency

Calibrations must be performed at the following frequencies:

- A new reagent lot number is used.
- Assay documentation states that a calibration is required when reagent cartridge is changed.
- Documentation that accompanies a new version of an existing assay files that a calibration is required.
- A new assay file that requires a calibration is installed.
- The calibration has expired.
- If results for the QC solutions are outside acceptable limits and the system cannot be corrected to bring control values into the acceptable range
- If QC results show an unusual trend or shift
- If certain system maintenance procedures or component replacement procedures are performed as required by the manufacturer.

Calibrations may also be performed as needed when:

- Assay control values do not meet required specifications.
- Certain system maintenance procedures or component replacement procedures are performed.
- Certain errors occur. To determine whether a recalibration is required when an error occurs, see assay specific message codes.

Calibration Procedure

Follow the steps below to create a calibration order manually.

NOTE: 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.

Step	Action
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. **NOTE:** Rack ID and position are not required if using barcoded samples, the calibration uses only water, or if the calibrator product is loaded in the reagent carousel.

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Abbott Alinity ci-series Operation and Maintenance, Continued

Calibration Procedure, Continued

Step	Action
5	Under **Assays**, tap an assay panel to calibrate (or tap one or more of the individual assays to calibrate). **NOTE:** 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.
6	Tap **Assay Options**.
7	For each selected assay in the Assay Options flyout, perform the following steps: • In the Calibrator Lot drop-down list, tap a calibrator lot or confirm the default data. Tap a **Reagent Selection** option to designate the reagent cartridge or the processing module to perform the calibration.
8	Tap **Done** then **Add Order** to save the calibration order.
9	Follow Quality Control Procedure to verify calibration.
10	Document and evaluate calibration results. Do not perform patient testing until calibration is verified.

Quality Control Frequency

At least two levels of quality controls are required to be run at least:
- Every 8 hours for ICT tests (Sodium, Potassium, Chloride),
- Every 24 hours for all other non-ICT tests,
- To verify instrument operation if unexpected results are obtained,
- After performing a calibration (calibration verification), and
- At the frequency defined in any local policies if more stringent.

Quality Control Procedure

Follow the steps below to perform quality control:

Step	Action
1	Follow quality control manufacturer's instructions for control preparation.
2	Verify expiration dates, bring quality control materials to room temperature, and mix gently prior to analysis.
3	Analyze each level of QC material using the control-specific Sample ID. When ordering QC manually
4	Document all results on the appropriate QC log.
5	Evaluate results for acceptability using the established / verified control ranges. **IMPORTANT:** Quality control issues must be evaluated and resolved before patient results are reported.

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Quality Control Trouble-shooting

Follow the steps below to troubleshoot out-of-range quality control results:

Step	Action
1	• Review previous QC results for shifts/trends. • Verify acceptable control range. • Ensure QC solutions have been brought to room temperature and are not expired.
2	Repeat test using the same QC bottle
3	Repeat test using a fresh QC bottle
4	Repeat test using a fresh reagent
5	Recalibrate the test and repeat QC
6	• If quality control results are still unacceptable after recalibration, call Abbott Technical Support 1-877-422-2688 (ext. 1) and notify a Lead or Manager. • Take instrument out of service and do not perform patient testing until the issue is resolved.
7	Document all corrective actions on appropriate log

Startup, Shutdown and Emergency Shutdown

Follow the steps below to startup or shutdown the analyzer.

Step	Action
	Startup
1	Power on the UI computer. Wait for the Log On screen to display on the UI computer.
2	Move the SCM power switch upward to power on the RSM and the SCM barcode scanner.
3	Move the power switch upward to power on each Alinity c processing module.
4	Power on the main power breaker of each Alinity i processing module.
5	Log on to the system software.
6	To transition the instrument statuses to Idle, start the RSM and each processing module.
7	Close the front electronics door of each Alinity c processing module.
8	Close the SCM front door.

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Abbott Alinity ci-series Operation and Maintenance, Continued

Startup, Shutdown and Emergency Shutdown, Continued

Step	Action
	Shutdown
1	On the menu bar, tap the **Home** icon.
2	On the Home screen, tap **Shutdown.** When a confirmation message is displayed, tap Yes.
3	Open the SCM front door and move the SCM power switch downward.
4	Open the front electronics door of each Alinity c processing module in the system and move the power switch downward to power off each module.
5	Locate the main power breaker for each Alinity i processing module. Power off the main power breaker of each Alinity i processing module.
6	Ensure that each processing module remains powered off for 1 minute.
	Emergency Shutdown
1	Locate the main power breaker for the system control module (SCM) and all processing modules.
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.

Long-term shutdown (i-series)

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

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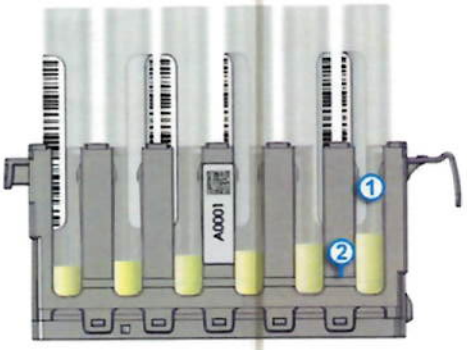
Logging on

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

Step	Action
1	If the Log On screen is displayed, proceed to step 2. If any other screen is displayed, tap the **Lock** button.
2	Tap the 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.
3	To display the Home screen, tap the four-digit PIN for the operator ID.

Loading Samples into Sample Racks

Follow the steps below to load aliquot tubes, primary tubes, or sample cups that contain samples (specimens, calibrators, or controls) into sample racks.

Step	Action
1	If loading calibrators or controls, verify that they are within the expiration date.
2	Refer to the assay documentation to determine the minimum sample volume that is required in the sample cup for the tests to be processed. **NOTE:** The minimum sample volume information is printed in the Order List Report.
3	Use the sample gauge to verify that the sample volume in an aliquot tube is adequate: a. Load the aliquot tube into the sample rack so that the sample volume is visible in the sample rack window [1]. b. Verify that the amount of sample in the aliquot tube exceeds the 8 mm sample gauge line [2]. 

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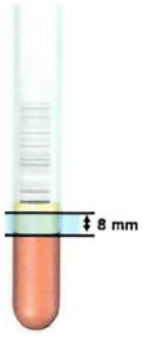
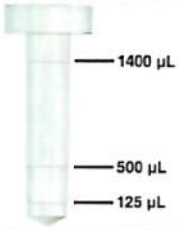
Loading Samples into Sample Racks, Continued

Step	Action
4	Verify that the sample volume is above the separation point (clot, gel separator, or plasma or red cell interface) in a primary tube is a minimum of 8 mm. 
5	Use the sample cup volume graduation marks to verify that the sample volume in a sample cup is adequate. 
6	If loading non-barcoded sample, review the Order List Report to ensure that each sample is loaded in the correct rack and position. **IMPORTANT:** The operator has a responsibility to load the correct sample in the correct rack and position.
7	Load the sample into the sample rack so that the sample barcode, if used, is visible in the sample rack window and the barcode fills the width of the window. **IMPORTANT:** If loading sample cups or tubes, ensure that they are pushed down completely in the sample rack and they are not tilted.

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Abbott Alinity ci-series Operation and Maintenance, Continued

Loading Racks on the Reagent and Sample Manager (RSM)

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

IMPORTANT:

- When transporting or loading racks, avoid splashing the sample outside the sample cups and tubes.
- Ensure all caps and tabs are removed prior to loading.
- Follow all applicable reagent preparation steps prior to loading.

Step	Action
1	For routine loading on the RSM, confirm that the status indicators above the bay positions to load are not illuminated, which indicates that the positions are available. For priority loading on the RSM, confirm that the status indicators above the bay positions to load are blue, which indicates that the positions are available.
2	Hold the rack handle and slide the rack into a routine position or a priority position on the RSM until the rack is flush against the back of the tray. Confirm that the green status indicator illuminates. If the position on the RSM does not contain a tray, load the rack into a tray and slide the tray into the RSM.

NOTES:

- To ensure correct tracking status, do not move the cartridges to a processing module that is controlled by a different system control module.
- Some assays require two reagent cartridges. These reagent cartridges are indicated with 1/2 and 2/2 on them. Both reagent cartridges must be loaded, but they do not need to be inserted into adjacent positions. After the reagent cartridges are loaded on the RSM and the barcode reader scans the barcode label, the system software links the two reagent cartridges as a set. If a two-cartridge reagent set is removed from the system, the reagent set must be replaced as a set.

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Abbott Alinity ci-series Operation and Maintenance, Continued

Batch Specimen Processing

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

IMPORTANT:

- When transporting or loading racks, avoid splashing the sample outside the sample cups and tubes.
- Ensure all caps are removed prior to loading.

Step	Action
1	Load samples on sample racks. Do not load calibrators or leave empty spaces between samples.
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**: 1. Enter or scan the starting SID (position 1 of first rack) 2. Enter or scan the ending SID (last position of last rack) 3. If a manual dilution was performed, add the dilution factor.
6	Under **Assays**, select the panel or individual assays to run.
7	Under **Assay Options**, specific modules, dilution protocols, and replicates can be selected as applicable.
8	Select **Done** to save the assay option selections.
9	Select **Add Order** to save the batch order.
10	Locate the sample rack that contains the sample labeled with the starting SID that was entered in the batch order.
11	Verify that the sample is loaded in position 1 of the rack and load the rack onto the RSM.
12	If additional sample racks are needed, load them on the RSM ensuring that the sample labeled with the ending SID is loaded at the end of all samples in the batch.
13	Confirm that the status indicators above the bay positions to load are not illuminated, which indicates that the positions are available.

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Trouble-shooting: General

Steps to troubleshoot the analyzer when unexpected or questionable results are obtained and/or if an analyzer issue is suspected (e.g. message code appears on the SCM), include but are not limited to:

- Look up message codes using the "?" symbol in the flyout and follow instructions in the Online Help (OLH) to troubleshoot and resolve issue.
  - If multiple message codes appear at the same time, it is generally recommended to review the earlier messages to determine the root cause of the issue.
- For additional troubleshooting steps, reference the Alinity ci-series Operations Manual.
- Perform Quality Control or calibration verification to verify instrument operation.
- Recalibrate assays if necessary.
- Assess impact to patient results.
- Call Abbott Technical Support 1-877-422-2688 (ext. 1) and follow manufacturer recommended instructions.
- Notify a Lead or Manager.

Note: All issues and corrective actions must be documented. Do not perform patient testing until all issues are resolved.

Trouble-shooting: Cycling power to the system

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

Step	Action
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. **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.
6	Open the front electronics door of each Alinity c processing module in the system.

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Abbott Alinity ci-series Operation and Maintenance, Continued

Trouble-shooting: Cycling power to the system, Continued

Step	Action
7	Locate the power switch for each Alinity c processing module.
8	Locate the main power breaker for each Alinity i processing module.
9	Move the power switch downward to power off each Alinity c processing module. Power off the main power breaker of each Alinity i processing module.
10	Ensure that each processing module remains powered off for 1 minute.
11	Power on the UI computer.
12	Wait for the Log On screen to display on the UI computer.
13	Move the SCM power switch upward to power on the RSM and the SCM barcode scanner.
14	Move the power switch upward to power on each Alinity c processing module. Power on the main power breaker of each Alinity i processing module. **NOTE:** After the power is turned on, the RSM and the processing modules initialize and the instrument statuses transition to Stopped.
15	Log on to the system software.
16	To transition the instrument statuses to Idle, start the RSM and each processing module.
17	Close the front electronics door of each Alinity c processing module.
18	Close the SCM front door.

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Downtime Procedure

The table below describes different downtime scenarios and potential procedures to continue operations.

If ...	Then, as applicable...
The analyzer becomes inoperable	• Use an alternative analyzer, or • Send samples to another Medical Center, Urgent Care Laboratory, or Regional Reference Laboratory.
Data Innovations Instrument Manager is down	• Manually order tests on the analyzer. • Review results for acceptability – Perform any required dilutions, – Evaluate serum indices, – Check for signs of contamination (e.g. critical high potassium and critical low calcium) • Manually enter results in Cerner as needed – Check for transcription errors – Review results against previous results – Follow Critical Notification protocol for all critical results
Cerner is down	• Manually order tests in Instrument Manager • Manually print/fax patient reports from Instrument Manager to requesting departments as needed. • Reconcile results once Cerner is back in service.
KP HealthConnect is down	• Manually order tests in Cerner using downtime requisition forms.

Abbott Alinity ci-series Operation and Maintenance, Continued

Maintenance Procedures (Alinity c)

The table below describes the maintenance procedures required for the Alinity c.

Frequency	Maintenance Procedures
Daily	• Flush the water lines of the sample, the reagent, and the cuvette washer. • Wash the ICT module with ICT Reference Solution and Cleaning Solution. • Drain and fill the ICT Reference Solution cup. • Wash the sample and reagent probes and the mixers with Acid Probe Wash and Detergent A. • Clean the sample probe, the R2 probe, and the mixers with Cleaning Solution. • Clean the sample probe exterior (only for whole blood).
Weekly	• Wash all cuvettes and fill them with Detergent A solution.
Monthly	• Clean the ICT drain tip
Quarterly	• Replace the sample syringe O-ring and sample syringe seal tips 1 and 2. • Replace the wash solution syringe O-ring and wash solution syringe seal tips 1 and 2. • Replace the reagent syringe O-rings and reagent syringe seal tips 1 and 2. • Change the lamp.
Triannual	• Change the 1 mL syringes on the following: – ICT Reference Solution pump – ICT aspiration pump – Wash solution pump • Check and change the ICT aspiration check valve and to confirm the functionality of the ICT Reference Solution check valves • Test the functionality of the high-concentration waste sensor and clean the sensor
As Needed	• Clean the processing module wash cups • Clean the exterior surfaces of the sample probe, the R1 probe, and the R2 probe. • Clean mixer 1 and 2. • Clean the cuvette washer nozzles. • Wash all cuvettes with Alkaline Wash, Acid Wash, and water. • Clean manually the loading area, sample positioners, and reagent positioner of the module-specific reagent and sample manager (RSM).

Note: These lists are not all inclusive. Refer to the analyzer and Operations Manual for more information.

Maintenance Procedures (Alinity i)

The table below describes the maintenance procedures required for the Alinity i.

Frequency	Maintenance Procedures
Daily	• Clean and condition the sample pipettor probe. • Clean wash zone 1 probes and wash zone 2 probes with 0.5% sodium hypochlorite solution. • Flush and prime the Pre-Trigger Solution and the Trigger Solution. • Flush the Pre-Trigger Solution reservoir.
Weekly	• Manually remove the salt buildup from the reagent 1, reagent 2, and sample pipettor probes. • Manually remove the salt buildup from the wash zone 1 and wash zone 2 probes. • Manually remove the salt buildup from the reagent 1, reagent 2, and sample wash cups (including the induction heater wash cup where applicable) and the wash cup baffles.
Semi-Yearly	• Manually remove the dust buildup from the processing module air filters. Rotating between two sets of air filters is recommended because the filters must be dry when they are reinstalled.
As Needed	• Manually clean the loading area, sample positioners, and reagent positioner of the module-specific reagent and sample manager (RSM).

Note: These lists are not all inclusive. Refer to the analyzer and Operations Manual for more information.

Non-controlled Documents

The following non-controlled documents support this policy:

- College of American Pathologists, All Common and Chemistry Testing Checklist
- Alinity ci-series Operations Manual
- Alinity Reagent Instructions for Use
- Quality Control Instructions for Use

Signature Manifest

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Abbott Alinity ci-series Operation and Maintenance

Operations Director Approval

Name/Signature	Title	Date	Meaning/Reason
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Medical Director Approval

Name/Signature	Title	Date	Meaning/Reason
Mark Taira (P161328)	CLIA Director	09 Jan 2025, 04:37:32 PM	Approved