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Document Contact	Kelly Walewski: Supv, Laboratory
Area	Laboratory-Chemistry
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Abbott Alinity Immunoassay System Analyzer Operation

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

To describe how to operate the Abbott Alinity Immunoassay System Analyzer

II. PRINCIPLE:

The ALINITY immunoassays utilize a two-step process to determine the presence of these analytes in human serum (or plasma) using CMIA (chemiluminescent microparticle immunoassay) technology with flexible assay protocols, referred to as Chemflex.

A. Sample and anti-analyte (or in the case of antibody testing – antigen) coated paramagnetic microparticles are combined. The analyte present in the sample binds to the anti-analyte/ antigen coated microparticles.

B. A magnet attracts the paramagnetic microparticles (bound to specific analyte) to the wall of the reaction vessel.

C. The wash zone manifold washes the reaction mixture to remove unbound materials.

D. After washing, anti-analyte/antigen acridinium-labeled conjugate is added to create a reaction mixture.

E. Following another wash cycle, Pre-Trigger (hydrogen peroxide) and Trigger (sodium hydroxide) solutions are added to the reaction mixture.

F. The resulting chemiluminescent reaction is measured as relative light units (RLUs).

G. The Alinity i System optics obtains the RLU readings, and then converts them to assay-specific analyte concentration units or qualitative interpretations for index (cutoff) assays.

III. CLINICAL SIGNIFICANCE:

Refer to **Attachment A** for Clinical Significance.

IV. OBJECTIVE:

The *ALINITY i Systems* are fully automated immunoassay systems allowing random and continuous access sample processing as well as priority processing.
Please note that the complete Operations Manual for the *ALINITY ci System* can be accessed directly from the Home instrument screen. The operator may do so by either:

A. Tap System from the side menu bar and then tap Operations Manual (Help)
B. Tap the Help button located at the top of an active screen.

V. SPECIMEN COLLECTION AND HANDLING:

A. **Collection Requirements**
    1. Follow all usual precautions for collecting blood by venipuncture to avoid specimen hemolysis.
    2. Verify the correct specimen type is used. The ALINITY i system does not verify specimen type.

B. **Specimen Preparation and Storage**
    1. Ensure that serum specimens collected in tubes containing a gel separator have at least 8mm of serum above the gel to avoid contamination of the specimen during pipetting.
    2. Inspect all samples for bubbles. Remove bubbles with a clean applicator stick prior to analysis. Use a new applicator stick for each sample to prevent cross contamination.
    3. Ensure complete clot formation in serum specimens has taken place prior to centrifugation (if applicable). Some specimens, especially those from patients receiving anticoagulant or thrombolytic therapy may exhibit increased clotting times. If centrifuged before a complete clot forms, the presence of fibrin may cause erroneous results.

C. **Sample Volume:**
Required sample volume can be obtained by printing the Order List Report after order is placed. The stated volume includes the 50µL dead space using an Abbott short sample cup.

D. **Specimen Handling**
    1. For optimal results, serum and plasma specimens should be free of fibrin, red blood cells, or other particulate matter. Centrifuge specimens containing fibrin, red blood cells, or particulate matter prior to use to ensure consistency.
    2. If proper specimen collection and preparation cannot be verified, or if samples have been disrupted due to transportation or sample handling, an additional

centrifugation step is recommended. Centrifugation conditions should be sufficient to remove particulate matter. Aliquots poured versus pipetted from specimen tube types that do not include serum separators are at higher risk of including particulates and generating erroneous results.

3. To prevent cross contamination, use of disposable pipettes or pipette tips is recommended.
4. Prepare frozen specimens as follows.
    a. Frozen specimens must be completely thawed before mixing.
    b. Mix thawed specimens thoroughly by low speed vortexing or by rocking for 10 minutes. Visually inspect the specimens. If layering or stratification is observed, continue mixing until specimens are visibly homogeneous. If samples are not mixed thoroughly, inconsistent results may be obtained.

E. **Specimen Stability**
See **Attachment G** for a detailed list of specimen stability guidelines.

VI. REAGENTS:

A. **Reagent Handling**

1. Do not use reagent kits beyond the expiration date.
2. **Do not pool reagents within a kit or between kits.**
3. Reagent kits are mixed upon arrival in the laboratory before storing. Mix unopened reagent kits by gently rotating the kit over and back for a full 180 degrees, 5 times with the green label facing up and then 5 times with the green label facing down. Place a check in the square on the reagent kit to indicate that the inversions have been completed.
4. Store the reagent in an upright position for at least an hour before use. Refer to the **Reagent Reference Guide (Attachment B)** for handling specific to each reagent.
5. If the reagent cartridge is dropped, mixed or shaken, place in a upright position for 1 hour before use.
6. Reagents may be stored on or off the ALINITY i System. If reagents are removed from the system, store them at 2-8°C with a new replacement cap in an upright position.

B. **Indications of Reagent Deterioration**

1. When a control value is out of the specified range, it may indicate deterioration of the reagents or errors in technique. Associated test results are invalid, and samples must be retested. Assay recalibration may be necessary. For troubleshooting information, refer to the ALINITY ci-System Operations Manual, Section 10.

C. Note: Refer to **Attachment B** for a detailed list of reagent preparation and storage requirements.

VII. EQUIPMENT COMPONENTS:

The *ALINITY i* consists of three primary components.

A. SCM (System Control Module) provides a common user interface across all ALINITY products. From the SCM you can:
    1. Scan Bar codes
    2. Configure the system
    3. Enter patient, control, and calibration orders
    4. Review patient results, control data, and calibration results
    5. Control the processing module(s) and the sample handler
    6. Perform system diagnostics and maintenance procedures
    7. Receive test orders and diagnostic data from a host computer
    8. Transfer test results to a host computer

B. PM (Processing Module) performs all sample processing activities from aspiration to final read.

C. RSM (Reagent and sample manager) transports reagents, samples, calibrators, and controls through the Alinity system.

VIII. SUPPLIES:

A. **Reagent Cartridges: Reagent cartridges are containers used in the reagent supply centers to hold the reagents used during operation.**

B. **Calibrators: Calibrators are samples that contain known concentrations of an analyte.**

C. **Reaction Vessels**

D. **Sample Cups**

E. **Bulk Solutions**
    1. Trigger Solution
    2. Pre-trigger Solution
    3. Concentrated Wash Buffer

F. **Diluent**
    1. Multi-Assay Manual Diluent
    2. HBsAG Qualitative Confirmatory Manual Diluent

G. **Aliquot tubes: Sarstedt SC TUBE 6.5 mL 13x90**

H. **False bottom Aliquot tubes: Sarstedt FB Tube 2.5 mL**

IX. MAINTENANCE:

Maintenance is performed Daily, Weekly, and As Needed. Refer to the on-board system maintenance procedures for details and instructions. The maintenance procedures are accessed by selecting Procedures from the menu bar. The Maintenance tab is the default. The scheduled maintenance procedures are displayed on the “To Do” tab. The daily, weekly, semi yearly and as needed tabs are selected to display procedures in the selected category. Select the desired procedure and then select **Perform**. To perform the procedure, tap Proceed. Follow the instructions in the Instructions box. Tap any icon on the menu bar to leave the procedure while in progress. When the procedure requires operator response, an amber badge is displayed on the Procedures icon. The In Process tab of the Procedures screen displays procedures in process.

X. CALIBRATION:

A. **Calibration is required when:**

1. A new reagent lot number is used
2. A new assay file that requires a calibration is installed
3. Documentation accompanying a new version of an existing assay file states calibration is required
4. The calibration curve has expired
5. At least every six months

B. **Barcoded calibrator samples are automatically processed in the following conditions**:

1. On-board reagent lots do not have an Active calibration curve.
2. A calibration is not in progress.
3. The expired calibration has not been overridden

C. **Calibration Procedure**

1. The ALINITY will test calibrators in duplicate. The calibrators should be priority loaded.
2. A single sample of each control level must be tested to evaluate the assay calibration. Ensure that control values are within the ranges specified.
3. Once an ALINITY calibration is accepted and stored, all subsequent samples may be tested without further calibration unless:
    a. A reagent kit with a new lot number is used or
    b. Controls are out of range.
4. For detailed information on how to perform an assay calibration, refer to the ALINITY ci System Operations Manual, Section 6.

D. **Multiple reagent lots**

1. When multiple reagent lots for an assay are loaded on the system and the sampling

process for a calibration order is ready to begin, the system determines the lots to calibrate by using the following rules:

a. If all reagent lots do not have a current calibration status of Active or Pending quality control (QC), the system calibrates all lots on the system

b. If all reagent lots for the assay currently have a calibration status of Active or Pending QC, all reagent lots loaded on the system will be re-calibrated when a calibrator is loaded unless the operator manually orders the calibration on a designated lot.

c. If some reagent lots have a status of Active or Pending QC and some do not, the system calibrates only the reagent lot without an active calibration.

2. After calibrators are processed, the system verifies the results by comparing them to the assay-specific calibration parameter specifications. If the results of a calibration fall within the specified range for that assay, the new calibration curve replaces any previous calibration curve and the previous calibration curve status changes to inactive. If the results of a calibration do not fall within the specified range, then the new calibration curve is assigned a status of failed; if there is an existing calibration curve for that assay, it is not replaced.

E. **Curve storage**

1. The ALINITY system stores active, inactive and failed calibration curves.
2. The active calibration is stored as the active curve for that reagent lot.
3. A new calibration replaces the previous calibration curve, which then becomes inactive.
4. The new calibration will automatically default to the active curve for the onboard reagent lot.
5. The instrument will store one active curve for up to FOUR different reagent lot numbers of each assay.

a. A new calibration will replace the oldest active curve if a fifth reagent lot calibrates successfully.
NOTE: A calibration with a status of Pending QC is considered an active curve but, cannot be used to process tests until at least one level of control completes.

6. A calibration may be manually failed by selecting the Fail Curve button on the Calibration curve window when the module is in a Stopped or Idle status.
Note: Refer to **Attachment C** for a detailed list of calibrators.

XI. QUALITY CONTROL:

A. **Quality Control Frequency**

1. At least two levels of quality control material are used daily and assigned to specific work shifts.

2. After a calibration, all levels of controls must be run.
3. Quality Control is run on all reagent packs.
4. Results should not be reported when QC limits are exceeded unless approved by supervisory staff.

B. **Quality Control with Barcode**

1. Load barcoded QC sample onto the analyzer.
2. All tests associated with that bar code will run without being manually ordered on the instrument.
3. To run one specific analyte by bar code, it will need to be manually ordered.
    a. From the Menu select Orders.
    b. Select Create Order, select the Control Tab and then select the desired control.
    c. If the desired lot number does not display in the lot box, select the Control Lot button and select the desired lot from the drop down list.
    d. Select the Control Level option and select the desired level from the drop down list.
    e. Select the desired Panels and/or Assays.
    f. Select QC Barcode SID and select the desired Barcode.
    g. Select the Assay
    h. Select Assay options to specify assay options. Select the assay if more than one assay is selected.
    i. Select Done to save changes.
    j. Select Add Order.

XII. SPECIAL SAFETY PRECAUTIONS:

Universal precautions are indicated when handling patient specimens and quality control materials. Spills and accidents should be addressed immediately.

XIII. PROCEDURE:

A. **Loading Reagent Cartridges:**

1. Verify the expiration date of the reagent. Do not use expired reagents.
2. Do not mix the reagent before loading unless specifically directed in the **Reagent Reference Guide (Attachment B).** Reagents are mixed upon arrival in the lab and must stand upright the required amount of time before loading to allow bubbles which form during mixing to settle. The box will be checked on the reagent package to confirm that the reagent was mixed. The resting time is specified for each reagent in **Attachment B**.
3. Reagents are loaded when the RSM is in Running status and the Processing

module is in Warming, Idle, Running, Processing or Pausing.

4. Remove the cartridge cap.
5. Confirm the status indicators above the bay position on the RSM is not illuminated indicating the position is available.
6. Hold the cartridge handle and slide the cartridge into a position on the RSM until the green status indicator illuminates.
7. If the assay requires two reagent cartridges it will be indicated with 1/2 and 2/2 on the cartridges. Both cartridges must be loaded but they do not need to be inserted in adjacent positions.
8. Reagent inventory will automatically update on the system.
   CAUTION: Reagent bubbles may interfere with proper detection of reagent level in the cartridge, causing insufficient reagent aspiration which could impact results.

B. **Loading Bulk Solutions**

1. Check consumable inventory using the Supplies screen. Supplies can be accessed from the menu bar. NOTE: The percentage of bulk solution available is a combination of the bottle and the reservoir. The bulk solution bottle can be changed while the instrument is running. The instrument uses the bulk solution from the reservoir. Do not allow the reservoir percentage to drop to 0%.
2. On the Supplies screen, tap a supply. Scan the bar code on the bottle using the bar code scanner.
3. The bulk solution can also be manually updated.
   a. Tap update for the new bulk solution
   b. Under Supply Details, enter the expiration date and the lot number.
4. Open the bulk solution door.
5. Press the bottle release button to disengage the empty bulk solution bottle from the bottle holder.
6. Remove and discard the empty bulk solution bottle.
7. Remove the protective cover from the cap of the new bulk solution bottle.
8. Invert the new bulk solution bottle and place it in the bottle holder.
9. Push down the bottle until it locks.

C. **Calibration Procedure:**

1. **Creating an Assay Calibration Order**
   a. Barcoded Calibrators are loaded in the **V racks** and do not need to be manually ordered**.** Calibrators without bar codes are manually ordered and loaded in the **R racks**.
   b. To manually order a calibration, from the Alinity Home screen, select **Orders** on the menu bar.
   c. Select **Create Order** and toggle to the Calibration Tab.

d. Select the desired assay(s) from the Assays list.
e. Select Assay options to specify calibration options if needed.
    i. Select a calibrator lot number
    ii. Select a reagent cartridge
    iii. Select Done to save changes and return to the Calibration order screen.
f. Select add order to add the calibration order.
g. New Calibrator Lot numbers are entered in Configuration
    i. Select System from the menu bar.
    ii. Select Configure, Assay, Calibrator Set
    iii. Select specific assay
    iv. Select View/Edit
    v. Enter the master lot and expiration date and default the calibrator.
    vi. Select Done.

2. **Loading Calibration Vials**
    a. Verify the calibrator is within the expiration date.
    b. Label the cap of all vials. Open each vial taking care to keep labeled caps separated from each other to avoid contamination.
    c. Inspect the vial for bubbles. Remove bubbles with a clean applicator stick before processing.
    d. Place each vial in the vial rack so the bar code is visible in the rack window. Vials are loaded in sequential order beginning with spot "1".
    e. Racks can be loaded as priority by pressing the blue priority button on the left side of the RSM. The button illuminates blue for 10 seconds. Insert the rack in any available position on the RSM.
    f. Confirm the status indicators above the bay position on the RSM is not illuminated indicating the position is available.
    g. Hold the rack handle and slide the rack into an available position on the RSM until the green status indicator illuminates.
    h. Barcoded Calibrators must be removed when testing is complete to stop the expiration timer. Alinity tracks calibrator stability and will register as expired if instrument tracking time exceeds the time allowed unrefrigerated. Return calibrators to the storage specified in **Attachment C, Calibrator Reference Guide** immediately after removal from the instrument.

D. **Running Samples**

1. **Ordering samples**

a. Samples with a bar code can be loaded on the analyzer. Instrument Manager (IM) communicates orders to the instruments and the instrument transmits results back to IM.

b. Samples can also be manually ordered on the instrument.

i. Select **Orders** on the menu bar.

ii. **Create orders** and toggle to the **Specimen Tab.**

iii. Enter the SID bar code, select tests and **Add Order.**

2. **Sample Loading**

a. Load Samples into sample racks (r-racks) so that the sample bar code is visible in the sample rack window.

b. Initialize the Processing Module(s) from the **Home** screen by selecting the module(s) and **Run**. Note: If the module is Stopped select **Start** to bring the status to **Idle** before initiating **Run**.

c. Place rack on the Reagent and Sample Manager (RSM). Ensure that the space is empty and not illuminated with a light before loading carrier. Samples can be loaded with a Stat Priority by pressing the blue priority button on the left side of the RSM and loading the sample rack within 10 seconds.

d. The status of the sample bay or carrier can be determined by the color of the light associated with each bay.

i. Carriers with solid green lights are waiting to be tested.

ii. Carriers with blinking green lights have been sampled and can be removed.

iii. Positions with solid Amber are in process and bay cannot be accessed.

iv. Positions with blinking Amber are waiting for an unloading cartridge or vial and are not available.

v. Alternating Green and Amber blinking are available but there is a problem that will need to be addressed by the operator.

e. Check the status of the samples before unloading by reviewing, **Sample Status** screen. Handle any exceptions as needed.

E. **Shutdown/Start Up to the System Control Center (SCC)**

1. The Processing module must be **Offline**, **Stopped**, **Warming** or **Idle**. The RSM must be **Offline, Stopped or Idle**.

2. On the menu bar Select the Home Icon. On the Home screen, tap **Shutdown**.

3. Select **Yes** to confirm shutdown. The user interface (UI) computer powers off when the system software completes the shutdown.

4. Open the System control module (SCM) front door and move the SCM power switch downward.

5. Locate the main power breaker for the Alinity i processing module on the back of the instrument in the lower left hand corner of the processing module. Power off the module. **Note: The processing module power breaker is located to the right of the SCM power breaker.**
6. Wait at least 1 minute before powering on the module.
7. Power on the UI computer.
8. Wait for the Log On screen to display on the UI computer.
9. Move the SCM power switch upward to power on the RSM and the SCM bar code scanner.
10. Power on the main power breaker on the Alinity i processing module.
11. Log on the system software. Tap operator button **Admin** and enter the PIN number **8642.** Note: The RSM and the processing modules initialize and the instrument statuses transitions from Offline to Stopped.
12. To transition the instrument statuses to **Idle,** start the RSM and the processing module.
13. Close the SCM front door.

F. **Emergency Shutdown-** Perform this procedure to shut down the system when an emergency situation occurs.

1. Locate the main power breaker for the system control module and all processing modules on the back lower left hand side of the instrument.
2. Move each main power breaker to the OFF/O position.
3. Unplug the power connector from the power supplies to remove power from the processing module and the RSM.

XIV. CALCULATIONS AND INTERPRETATIONS:

Patient and control results are automatically uploaded to the Instrument Manager (IM). Results needing operator attention remain in the Review Queue until released by the operator. Samples requiring a dilution are automatically requested by the IM. The operator may also program instrument dilutions. The patient result is automatically calculated using the dilution factor. Manual dilutions must be programmed by the operator for the dilution factor to be applied.

Samples that generate an error code are held at the instrument as exceptions. The error code is reviewed using the on-line Operations Manual. When an error code indicates the result is low, the sample is repeated to verify and reported as “less than”. When an error code indicates that the result is high, the sample is diluted to rule out interferences. The result reported will follow the Reportable Range guideline for each assay.

XV. REFERENCE RANGES:

Refer to **Attachment D** for a list of reference ranges.

XVI. REPORTABLE RANGE:

Refer to **Attachment E** for a list of reportable ranges.

XVII. LIMITATIONS:

A. Assay results MUST be used with other clinical data, including, but not limited to: patient symptoms, other test results, patient history, clinical impressions, information available from clinical evaluation, and other diagnostic procedures. All data MUST be considered for patient care management.

B. If assay results are inconsistent with clinical evidence, additional testing is suggested to confirm the result.

C. The Alinity System has been validated for its intended use. However, errors can occur due to potential operator errors and Alinity System technology limitations.

XVIII. INTERFERING SUBSTANCES:

Consult the Package Inserts accompanying each test for specific information on interferences with endogenous substances and drugs.
Refer to **Attachment F** for interference due to hemolysis, lipemia and icterus.

XIX. WARNINGS:

A. CAUTION: This product requires the handling of human specimens. It is recommended that all human sourced materials be considered potentially infectious and be handled in accordance with the OSHA Standard on Bloodborne Pathogens. BioSafety Level 2 or other appropriate BioSafety practices should be used for materials that contain or are suspected of containing infectious agents.

B. The following warnings and precautions apply:

1. Contains sodium azide. EUH032 Contact with acids liberates very toxic gas.
2. This material and its container must be disposed of in a safe way.
   NOTE: Refer to Section 8 of the Alinity System Operations Manual for proper handling and disposal of reagents containing sodium azide.

XX. REFERENCES:

A. Abbott Alinity ci-series System Operation Manual, Abbott Laboratories, Abbott Park, IL. 12-14-2017

B. Alinity System Quick Reference Guide, Abbott Laboratories, Abbott Park, IL 2017

Attachments

Abbott Alinity Immunoassay Attachment A_Clinical Significance.pdf

Abbott Alinity Immunoassay Attachment B_Reagent Reference Guide.pdf

Abbott Alinity Immunoassay Attachment C_Calibrator Reference Guide.pdf

Abbott Alinity Immunoassay Attachment D_Reference Range.pdf

Abbott Alinity Immunoassay Attachment E_Analytical Measuring Range.pdf

Abbott Alinity Immunoassay Attachment F_HIL Interference.pdf

Abbott Alinity Immunoassay Attachment G_Specimen Stability.pdf

Abbott Alinity Immunoassay Attachment H_Infectious Disease Reporting Guide.pdf

Abbott Alinity Immunoassay Attachment I_Fluid Guide.pdf

Approval Signatures

Step Description	Approver	Date
CLIA Directors	Ann Marie Blenc: System Med Dir, Hematopath	8/9/2024
System Medical Director	Caitlin Schein: Staff Physician	7/25/2024
Medical Director	Subhashree Mallika Krishnan: Staff Physician	7/17/2024
Technical Director	Qian Sun: Tech Dir, Clin Chemistry, Path	7/17/2024
Policy and Forms Steering Committee Approval (if needed)	Kelly Walewski: Supv, Laboratory	7/17/2024
Lab Manager	Leah Korodan: Mgr, Division Laboratory	7/17/2024
	Kelly Walewski: Supv, Laboratory	7/17/2024

Applicability

Royal Oak