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Document Contact	Colette Kessler: Mgr, Division Laboratory
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Abbott Architect Immunoassay System Analyzer Operation

Document Type: Procedure

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I. PURPOSE AND OBJECTIVE:

To describe how to operate the Abbott Architect Immunoassay System Analyzer

II. PRINCIPLE:

The ARCHITECT 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 ARCHITECT iSystem 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 ARCHITECT *i* 2000SR and *i* 1000SR systems are fully automated immunoassay systems allowing random and continuous access sample processing as well as priority processing. The ARCHITECT *i* 2000SR processes up to 200 CMIA tests per hour, using up to 25 onboard reagent kits (100 and/or 500 tests) in a temperature-controlled reagent carousel and provides STAT processing. The ARCHITECT *i* 1000SR processes up to 100 CMIA tests per hour, using up to 25 onboard reagent kits (100 tests) in a temperature controlled reagent carousel and provides STAT processing.
Please note that the complete Operations Manual for the ARCHITECT *i* 2000SR and *i* 1000SR can be accessed directly from the instrument screen. The operator may do so by:

A. Selecting Overview icon
B. Selecting Operations Manual

V. SPECIMEN COLLECTION AND HANDLING:

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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 ARCHITECT 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. Frozen specimens must be completely thawed before mixing.
5. Mix thawed specimens thoroughly by low speed vortexing or by inverting 10 times. 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 H** for a detailed list of specimen stability guidelines.

VI. REAGENTS:

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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. Before loading the reagent kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that may have settled during shipment.
   Septums MUST be used to prevent reagent evaporation and contamination and to ensure reagent integrity. Reliability of assay results cannot be guaranteed if septums are not used according to the instructions in the package inserts.
4. To avoid contamination, wear clean gloves when placing a septum on an uncapped reagent bottle.
5. Once a septum has been placed on an open reagent bottle, **do not invert the bottle** as this will result in reagent leakage and may compromise assay results.
6. Over time, residual liquids may dry on the septum surface. These are typically dried salts and have no effect on assay efficacy.
7. Reagents may be stored on or off the ARCHITECT iSystem. If reagents are removed from the system, store them at 2-8°C (with septums and replacement caps) in an upright position. For reagents stored off the system, it is recommended that they be stored in their original trays and boxes to ensure they remain upright. **If the microparticle bottle does not remain upright (with a septum installed) while in refrigerated storage off the system, the reagent kit must be discarded.** For information on unloading reagents, refer to the ARCHITECT System Operations

Manual, Section 5.

B. **Indications of Reagent Deterioration**

C. 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 ARCHITECT System Operations Manual, Section 10.

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

VII. EQUIPMENT COMPONENTS:

The ARCHITECT consists of three primary components.

A. SCC (System Control Center) provides a common interface across all ARCHITECT System Configurations. From the SCC you can:

1. Configure the system
2. Enter patient, control, and calibration orders
3. Review patient results, control data, and calibration results
4. Control the processing module(s) and the sample handler
5. Perform system diagnostics and maintenance procedures
6. Receive test orders and diagnostic data from a host computer
7. Transfer test results to a host computer

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

C. RSH (Robotic Sample Handler) transports samples through the ARCHITECT system. The complete Operations Manual can be accessed from the instrument screen. The Operator selects Overview icon and then Operations Manual.

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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. **Diluents**

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

G. **Aliquot tubes: Sarstedt SC TUBE 6.5 mL 13x90 (60.503.010)**

H. **False bottom Aliquot tubes:** Sarstedt FB Tube 2.5 mL (60.614.065)

IX. MAINTENANCE:

Maintenance is performed Daily, Weekly, and As Needed. Refer to the onboard system maintenance procedures for details and instructions. The maintenance procedures are accessed by selecting System from the menu bar and selecting Maintenance. The scheduled maintenance procedures are displayed on the "To Do" tab. The daily, weekly, and as needed tabs are selected to display procedures in the selected category. Select the desired procedure and then select **F5- Perform**. A confirmation message displays. Select **OK** to perform. The maintenance perform window displays with a description of the procedure and instructions. You may close the window to access other screens and windows by selecting the "Close Window" button.

X. CALIBRATION:

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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. **Bar coded calibrator samples are automatically processed in the following conditions**:

1. Onboard 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 ARCHITECT 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 assay control values are within the ranges specified in the respective control package insert.
3. Once an ARCHITECT 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.
For detailed information on how to perform an assay calibration, refer to the ARCHITECT 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 recalibrated.
    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 ARCHITECT 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.
Note: Refer to **Attachment C** for a detailed list of calibrators.

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XI. QUALITY CONTROL:

At least two levels of quality control material are used daily and assigned to specific work shifts. After a calibration, all three levels of controls must be run. Results should not be reported when QC limits are exceeded unless approved by supervisory staff.

A. **Quality Control with Barcode**

1. Load barcoded QC sample onto the analyzer.
2. All tests associated with that barcode will run without being manually ordered on the instrument.
3. To run one specific analyte by barcode, it will need to be manually ordered.
    a. From the Control order screen select Multi-constituent.
    b. Select the Control List button and then select the desired control
    c. If the desired lot number does not display in the lot box, select the Lot list button and select the desired lot.
    d. Select the desired Level options.
    e. Select the desired Panels and/or Assays.
    f. Select F5 Assay options to specify assay options. Use previous/ next buttons to display each assay if more than one selected.
    g. Select Done to save changes.
    h. Select F2- Add Order.

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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: (*i* 2000SR)**

1. Verify the expiration date of the reagent. Do not use expired reagents.
2. Invert the reagent cartridge gently to insure homogeneity (30 times).
3. Remove the cartridge cap and place a septum on each cartridge.
4. Remove air bubbles. (An applicator stick can be used for this purpose).
5. Ensure the analyzer is in the Ready state, with the lid indicator light illuminated and open the analyzer lid.
6. Open the reagent access cover.
7. Press the carousel advance button to advance the reagent supply center carousel.
8. Place the reagent cartridge in an open position.

9. Close the reagent access cover.
10. Close the lid of the analyzer.
11. Select F5 – Scan on the Reagent status screen to update the reagent inventory.

B. **Loading Reagent Cartridges: (*i* 1000SR)**

1. Verify the expiration date of the reagent. Do not use expired reagents.
2. Invert the reagent cartridge gently to insure homogeneity (30 times).
3. Remove the cartridge cap and place a septum on each cartridge.
4. Remove air bubbles. (An applicator stick can be used for this purpose).
5. Install the cartridges onto one of the reagent carriers.
6. Ensure the analyzer and Rack Sample Handler (RSH) are in the Running state.
7. Load the carrier into any of the Immunoassay side loading bays.
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.

C. **Loading Bulk Solutions (*i*2000SR and *i*1000SR)**

1. Check consumable inventory before processing samples using the Supply status screen.
2. View the bulk solutions and the solutions in the reagent supply centers. The system must be in ready to load or update bulk supplies.
3. From the Snapshot screen select **F-7 Pause** to change status from running to ready.
4. Adjust levels if necessary by selecting **F3-Adjust level**.
5. Update supplies when replacing by selecting **F2- Update supplies**. **DO NOT** combine partial bottles of bulk solution.
6. Scan barcodes to update Lot Numbers and Expiration dates.
7. Select Done.
8. The supply status screen displays the updated level. The system automatically flushes the replaced solution before testing is performed.

D. **Calibration Procedure: Creating an Assay Calibration Order**

1. From the ARCHITECT SCC (System Control Center), select **Orders** from the menu bar.
2. Select **Calibration order**.
3. Select the desired assay(s) from the Assays list.
4. Select F5 - Assay options to specify calibration options (optional).
   a. Enter a calibrator lot number in the Lot data entry box.
   b. Enter the calibrator expiration date in the Expiration date data entry box.

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c. Use the previous/next buttons to display each assay, if more than one assay was selected.

d. Enter the data then repeat for each assay.

5. Select **Done** to save the changes and return to the Calibration order screen.
6. Select **F2 - Add order** to add the calibration order.

E. **Running Samples**

1. **Front Loading without Automation**

a. Place Samples in specimen racks.

b. Initialize the Processing Module(s) from the Snapshot screen by selecting the module(s) and **F8- Run**. Note: If the module is Stopped select **F-5 Start-up** to bring the status to ready before initiating Run.

c. Place carrier on the Rack Sample Handler (RSH). Ensure that the space is empty and not illuminated with a light before loading carrier. Samples with Stat Priority are loaded in Bay 1.

d. Carriers with solid green lights are waiting to be tested. Carriers with blinking green lights have been sampled. Alternating Green and Amber blinking are sampled but there is a problem that will need to be addressed by the operator.

e. Check the status of the samples before unloading by going to Overview, Sample Status screen. Handle any exceptions as needed.

2. **Front Loading with Automation**

a. Place the appropriate module offline on the Integrated User Interface (IUI).

b. The spur should be online. If the spur is not online, press the green button on the spur keypad to initialize. When the green light next to each queue is illuminated, a sample tube can be placed in the carrier at the appropriate gate for sample processing.

c. If the yellow light is illuminated and blinking, sample carriers are scheduled to move and a sample tube should not be placed in the carrier at this time. A blinking yellow light could also indicate an error has occurred. If the yellow light is illuminated and solid, a sample should not be placed in a carrier at this time. The spur could be in stopped or initializing. If both lights are off, the spur is powered off.

d. The ARCHITECT *i* spur has three tube carrier queues for sample tubes that need to be front loaded. The Priority Input Queue contains 6 sample carriers and Routine Input Queue contains 11 sample carriers. The Output Queue contains 4 sample carriers. The spur should always contain 21 sample carriers total.

e. Samples can be placed in the first carrier of each input queue and processing will start when the tube detect sensor detects a tube.

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f. Once the sample has been aspirated, it will wait in the Output Queue until the tube is removed from the carrier.

g. Calibrators must be ordered, have a barcode and be loaded in the correct order before running.

h. QC does not need to be ordered but must have a barcode.

i. All patient samples must have a barcode.
Note: Everything that is loaded on the ARCHITECT *i* system using an automation line must be spun, uncapped and have a barcoded label. The power switch is used to turn the power to the ARCHITECT *i* spur on or off. Never turn the power switch to OFF unless directed to do so by an Abbott Representative.

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

1. Select F3 – Shutdown on the Snapshot Screen.
2. Select OK to confirm shutdown.
3. Wait for the information window to display, then simultaneously press CTRL+ALT+DELETE, confirm Exit.
4. If the dialog window displays “Shutdown Computer”, select OK. IF the red Power Off button displays, select the button
5. Locate the central processing unit (CPU). Press and hold the power switch to power off the SCC.
6. Turn off the power to the processing module by moving the power switch down.
7. Press the power switch on the front of the CPU to turn on the SCC.
8. Wait for the Log On window to display. Log on before turning the instrument back on.
9. Ensure the processing module has been powered off for five minutes, then move the power switch up to turn power back on.

G. **Emergency Shutdown**

1. Press the emergency stop button located on the front of the analyzer. For multi-module systems use the emergency stop button for the processing module farthest to the right when facing the system to stop the sample handler and the processing module.
2. The analyzer may also be powered down by moving the power switch located on the lower left rear of the analyzer down.

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

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

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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 ARCHITECT System Operations Manual for proper handling and disposal of reagents containing sodium azide.

XX. REFERENCES:

A. Abbott ARCHITECT System Operation Manual, Abbott Laboratories, Abbott Park, IL. 12-14-2017

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

Attachments

Attachment A - Abbott Architect IM Clinical Significance

Attachment B - Abbott Architect IM Reagent Reference Guide

Attachment C - Abbott Architect IM Calibrator Guide

Attachment D - Abbott Architect IM Reference Ranges

Attachment E - Abbott Architect IM Reportable Ranges

Attachment F - Abbott Architect IM Hemolysis

Attachment G - Abbott Architect IM Test by Campus

Attachment H - Abbott Architect IM Specimen Stability

Attachment I - Abbott Architect IM Infectious Disease Reporting Guide

Attachment J - Abbott Architect IM Fluid Reference Guide

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Approval Signatures

Step Description	Approver	Date
Medical Directors	Jeremy Powers: Chief, Pathology	4/17/2023
Medical Directors	Muhammad Arshad: Physician	3/23/2023
Medical Directors	Ann Marie Blenc: System Med Dir, Hematopath	3/23/2023
Medical Directors	Vaishali Pansare: Chief, Pathology	3/23/2023
Medical Directors	Ryan Johnson: OUWB Clinical Faculty	3/22/2023
Medical Directors	John Pui: Chief, Pathology	3/22/2023

Policy and Forms Steering Committee Approval (if needed)	Colette Kessler: Mgr, Division Laboratory	3/22/2023
Policy and Forms Steering Committee Approval (if needed)	Ilene Hirsch: Project Mgr Policy	3/16/2023
	Caitlin Schein: Staff Physician	3/16/2023
	Nga Yeung Tang: Tech Dir, Clin Chemistry, Path	3/8/2023
	Qian Sun: Tech Dir, Clin Chemistry, Path	3/3/2023
	Brittnie Berger: Dir, Lab Operations C	3/3/2023
	Elzbieta Wystepek: Dir, Lab Operations B	2/22/2023
	Kimberly Geck: Dir, Lab Operations B	2/21/2023
	Colette Kessler: Mgr, Division Laboratory	2/21/2023
	Colette Kessler: Mgr, Division Laboratory	2/21/2023