Status **Active** PolicyStat ID **16088338**

Beaumont

Origination	12/2/2019
Last Approved	10/25/2024
Effective	10/25/2024
Last Revised	4/18/2024
Next Review	10/25/2026

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Area	Laboratory-Chemistry
Applicability	All Beaumont Hospitals

Abbott ARCHITECT Chemistry System Analyzer Operation

Document type: Procedure

I. PURPOSE AND OBJECTIVE:

To describe how to operate the Abbott ARCHITECT Chemistry System Analyzer

II. INTRODUCTION:

The Abbott ARCHITECT c4000, c8000 and c16000 Chemistry Analyzers are fully-automated clinical chemistry systems allowing random, continuous access and priority processing. The analyzer is designed for the in-vitro determination of a variety of chemistries by photometric or potentiometric measurement.

III. CLINICAL SIGNIFICANCE:

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

IV. SPECIMEN COLLECTION AND HANDLING:

The Abbott ARCHITECT c System can be used to analyze, serum, plasma, urine, cerebral spinal fluid (CSF), and other body fluids. Consult the online, Beaumont Laboratory Test Directory or the assay specific package insert for appropriate specimen types. Samples can be tested in the primary collection tube, Abbott Sample Cups, and false bottom aliquot tubes.

A. **Collection Requirements:**

1. Follow all universal 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.

3. It is common for PEAK Therapeutic Drug measurements to be drawn 1 hour following the cessation of an IV infusion as indicated in the Lab Test Directory. Dosage date and time are included in the report when indicated at collection. Results are evaluated in the Laboratory Information System using the reference range for a PEAK measurement.
4. It is common for TROUGH Therapeutic Drug measurements to be drawn just prior to the next dosage administration as indicated in the Lab Test Directory. Dosage date and time are included in the report when indicated at collection. Results are evaluated in the Laboratory Information System using the reference range for a TROUGH measurement.

B. **Specimen Preparation and Storage**

1. Ensure that specimens collected in tubes containing a gel separator have 8mm of serum above the gel to avoid contamination of the specimen during pipetting.
2. Visually inspect all samples for bubbles prior to loading. Remove with a clean applicator stick prior to analysis. Use a new applicator stick for each sample to prevent cross contamination.
3. Verify serum and plasma specimens are free from fibrin, red blood cells, or other particulate matter.
4. Ensure complete clot formation in serum specimens has taken place prior to centrifugation. 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.
5. Samples that have been stored frozen must be completely thawed and then mixed well prior to testing. To ensure proper mixing, vortex samples for 20 seconds, place on a rocker for 10 minutes, or invert 30 times.
6. Remove tops from specimen tubes prior to loading on the sample handler.
7. Samples tested by automated track analysis are loaded at the IOM (Input Output Module). Samples may be loaded with or without the cap as determined by the lane that the sample is loaded. Samples may be loaded before or after centrifugation as determined by the lane that the sample is loaded. The lanes are marked for guidance. Inspect the sample when loading to ensure that the tube is sufficiently filled. Microtainer samples and short draws will be aliquoted to a false bottom tube before loading on the IOM. Analyzers that are connected to a track may be loaded directly using the sample carousel.
8. Refer to **Attachment H** for Specimen Stability
9. **Sample Volume:** Required sample volume can be obtained from the Order List Report after order is placed. The stated volume includes the 50 µL dead space using an Abbott sample cup.

V. REAGENTS:

References Reagents, typically consisting of an R1 and R2 cartridge, are obtained from Abbott Diagnostics, Abbott Park, IL, USA. Some reagents are ready to use and some require preparation. Refer to **Attachment B** (Architect Chemistry Reagent Reference Guide) for a detailed list of preparation and storage requirements.

VI. EQUIPMENT:

The ARCHITECT consists of three primary components. The complete Operations Manual can be accessed from the instrument screen. The Operator selects Overview ICON and then Operations Manual.

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.

VII. SUPPLIES:

A. **Reagent cartridges**
Reagent cartridges are containers used in the reagent supply centers to hold the reagents used during operation. They may also hold Wash Solution, Saline and Water Bath Additive.

B. **Calibrators**
Calibrators are samples that contain known concentrations of analyte. A variety of calibrators (single and multiconstituent) are used on the system. See **Attachment C** for required calibrators.

C. **ICT module**
The ICT module is an integrated chip located within the ICT unit that contains the Na+, K+, Cl-, and reference electrodes. The warranty for the ICT module is 20,000 samples or three months post-installation, whichever comes first. ICT module expires 9 months after manufacture.

D. **ICT cleaning fluid**
ICT Cleaning Fluid is a cleaning agent prepared by the operator and used during daily maintenance procedures to clean the ICT module. The ICT Cleaning Fluid is supplied as a two-part product, consisting of a liquid and a powder.

E. **Bulk solutions**
Bulk solutions are liquid solutions provided in large quantities that are used in sample processing. Three bulk solutions are loaded onto weighted platforms behind the supply center door of the processing module. These include ICT reference solution, Alkaline Wash, and Acid Wash.

1. **ICT reference solution**
ICT Reference Solution (2000 mL bottle) is a mid-concentration standard. It is aspirated and analyzed by the ICT module before and after each sample to provide a reference potential used to calculate results.
2. **Alkaline wash**
Alkaline Wash (500 mL bottle) is an alkaline wash solution used by the cuvette washer to clean the cuvettes after sample analysis.
3. **Acid wash**
Acid Wash (500 mL bottle) is an acidic wash solution used by the cuvette washer to clean the cuvettes after sample analysis. A dilution of the acid wash solution may also be used for probe washing.

F. **Sample Cups**

1. Aliquot tubes- Sarstedt SC TUBE 6.5 mL 13x90 (60.503.010)
2. False bottom Aliquot tubes- Sarstedt FB Tube 2.5 mL (60.614.065)

VIII. MAINTENANCE:

A. Maintenance is performed Daily, Weekly, Monthly, Quarterly, 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, Monthly, Quarterly, 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.

IX. CALIBRATION:

A. Manufacturer calibrators or water blank are used to calibrate each assay at specified intervals. Refer to **Attachment C** for a detailed list of calibrators.

1. Calibration must be performed when:
    a. A new reagent lot number is used.
    b. Documentation accompanying a new version of an existing assay file states calibration is required.
    c. A new assay file that requires calibration is installed.
    d. The calibration curve has expired.
    e. A calibration or recalibration has a status of Failed.

2. Calibration may be necessary when:
    a. Assay control values are out of specification.
    b. Certain system maintenance/component replacement procedures are performed.
    c. Certain specific error codes are obtained.
    Note: A Calibration with a status of Pending quality control (QC) is considered an active curve but, cannot be used to process tests until at least one level of control is completed successfully. A calibration may be manually failed by selecting the Fail Curve button on the Calibration curve window.

B. **Automated Assay Calibration**
Automated assay calibration is the process the system uses to automatically order calibrations by associating a SID (sample ID) with a predefined calibrator. For automated assay calibration a barcode label is used for each calibrator level. Assays using water as a blank do not require a barcoded calibrator. The water is dispensed by the sample probe. When a barcode is configured and scanned the system automatically processes the tests configured for that SID. The orders may be viewed on the order status screen. The Order List may be printed to obtain calibrator volumes necessary for calibration.

C. **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 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. For the **c16000** the calibration status is specific to one line. If a reagent with an active calibration status is moved from one line (A or B line) to the other and is then scanned, the calibration status for the new location is NO CAL. To avoid recalibration:
    a. Do not move reagents from one line to the other.
    b. Do not load on a different line when replacing reagents.

D. **Curve storage**
The ARCHITECT system stores active, inactive and failed calibration curves.
1. Active calibrations:
    a. Stores the processing module-specific calibration as the active curve for that reagent lot.
    b. Replaces the previous calibration curve, which becomes inactive.

c. Automatically defaults to the active curve for the onboard reagent lot.

d. Stores one active curve for up to FOUR different reagent lot numbers of each assay.

e. Replaces the oldest active curve if a fifth reagent lot calibrates successfully.

2. Inactive calibrations:

a. Stored for 3 months.

b. All calibration curves are removed from the system when the last kit of a reagent master lot is deleted.

c. Deletion occurs when the reagent kit storage capacity is exceeded.

X. QUALITY CONTROL:

A. The following are minimum requirements and should take into account the Quality Control (QC) stability by test:

1. For electrolytes (Na, K, Cl) by ion selective electrodes (ISE)

a. Run serum QC materials 2 levels every 8 hours; laboratories may elect to include CO2 in this electrolyte QC protocol.

b. Run urine QC materials 2 levels twice daily for electrolytes

2. For all other high volume tests (routine or stat)

a. Run at least 2 levels of QC material twice daily.

3. For low volume tests, depending on individual lab workflow

a. Run at least 2 levels of QC material when samples(s) are received OR

b. Run at least 2 levels of QC material every 24 hours

4. After a calibration, all control levels must be run

5. Results should not be reported when QC rules are violated unless approved by supervisory staff.

XI. SPECIAL SAFETY PRECAUTIONS:

Universal precautions are indicated when handling patient specimens and quality control materials. Spills and accidents should be addressed immediately. Refer to the appropriate safety data sheet (SDS) for specific reagent information.

XII. PROCEDURE:

A. **Start-up/Shutdown Analyzer**

1. **Power off the Analyzer**

a. Select F3- Shutdown on the Snapshot screen. A confirmation message displays.

b. Select OK to initiate shutdown.

c. Wait for the information window to display, and then simultaneously press the CTRL+ALT+DELETE keys. The Confirm Exit window displays.

d. Perform one of the following:

i. If the dialog window displays leave the “Shutdown the computer” option selected, select OK and then wait for the information window to display.

ii. If the red power off button displays, select  .

e. Locate the central processing unit (CPU) to access the power switch.

f. Press and hold the power switch on the front to turn off the power to the SCC.

g. Turn off power to the processing module(s) by moving the power switch down. The power switch is in the rear of each testing analyzer, except for the rack sample handler (RSH). The RSH power switch is located on the left side of the integrated system.

2. **Power on the Analyzer**

a. Press the power switch on the front of the CPU to turn on the SCC.

b. Wait for the Log on window to display. It may take several minutes.

c. Ensure the processing module(s) have been powered off for 1 minute and then move the power switch up to turn on power.

d. Log on to the SCC as a general operator or system administrator.

e. To change the status of the processing module(s) from Stopped to Ready select F-5 Startup from the Snapshot screen.

3. **Emergency Shutdown**

a. 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.

b. The analyzers may also be powered down by moving down the power switch located on the rear of each analyzer.

B. **Loading Supplies**

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. View the onboard solutions in the sample carousel.

4. From the Snapshot screen select **F-7 Pause** to change status from running to ready.

5. Adjust levels if necessary by selecting **F3-Adjust level**.

6. Update supplies when replacing by selecting **F2- Update supplies**. **DO NOT** combine partial bottles of bulk solution.
7. Scan Barcodes to update Lot Numbers and Expiration dates.
8. Select Done.
9. The supply status screen displays the updated level. The system automatically flushes the replaced solution before testing is performed.

C. **Loading Reagent Cartridges**

1. Verify the expiration date of the reagent. Do not use expired reagents.
2. Invert the reagent cartridge gently to ensure homogeneity.
3. Remove the cartridge cap.
4. Remove air bubbles. (An applicator stick can be used for this purpose).
5. When the module is Scheduled Pause, the reagent carousel advance buttons will illuminate when the reagent supply center is available for loading.
6. Press the carousel advance button to advance the reagent supply center carousel.
7. Place the reagent cartridge in an open position using the reagent carriers if needed. Ensure that the reagent is placed on the correct Line.
8. Close the reagent supply center cover.
9. **Select F5 – Scan** on the Reagent status screen to update the reagent inventory.

D. **User Defined Reagents**

User defined reagents include sample diluents and reagents not supplied by Abbott.

1. **Configure a reagent Kit**
    a. The operator needs to be signed in as 'ADMIN" (password: ADM).
    b. Select System, Configuration, Assay Categories, Reagent settings, F-6 Configure.
    c. From the displayed Reagent Settings window, select the Lot number list button, and then select New Lot from the list.
    d. Enter the lot number.
    e. Enter a unique serial number to identify the cartridge.
    f. Select the Cartridge size.
    g. Select Add Kit.
    h. Select Done to save changes.
2. **Loading a reagent Kit**
    a. Select Reagent, Reagent Status
    b. Select **F-6 Assign Location**
    c. Select the desired reagent from the reagent kits table.
    d. Note the displayed cartridge size.

e. Label the cartridge with the reagent name and expiration date.

f. Pour the reagent into the specified cartridge type.

g. Remove air bubbles, if present, with a clean applicator stick and place the cartridge in the assigned location in the reagent supply center.

h. Select **Done** on the Assign location wheel to return to the Reagent Status screen.

i. Scan the reagent carousel to update.
NOTE: User defined reagent can be reset when using the same lot number by selecting the reagent and selecting **F-8 Reset** on the Reagent Status screen

E. **Ordering a Calibration**

1. Check the Calibration Status Screen to determine calibrations required.
2. From the **Orders** menu, select **Calibration order**.
3. Select **QC-Cal** from the menu bar and then select **Calibration.**
4. Select the carrier or carousel button.
5. In the C field enter the carrier ID manually or by scanning the barcode label attached to the carrier.
6. In the P field, enter the position. Enter 1-5 for carrier or enter 1-30 if the carousel was selected.
7. In the Assays section, select the assays to be calibrated.
8. Verify the calibrator lot number to ensure that the correct set points are used for calibration.
9. Select F-5 Assay options to specify calibration lot number if the calibrator lot number is different from the displayed lot number.
Note: The system assigns all selected assay calibrators to positions. It starts with C/P entered and assigns the calibrators in the next sequential carriers.
10. Click Done and **F-2 Add order**.
11. From the Order menu, Click Order Status
12. Click **F4- Print** to print the Order List Report
13. Load and run calibrators using Order List Report for volumes and carrier locations.

F. **Entering New Calibrator Set Points**

1. The operator needs to be signed in as ‘ADMIN” (password: ADM).
2. Go to System, Configuration, QC-Cal Settings, Calibrator Set, Choose Calibrator, Configure.
3. Select the dropdown box next to the lot number.
4. Select New Lot
5. Select assays by highlighting.

6. Select Define data and enter the new values.
7. New calibrator lot can be added while the system is in running, but will not default to this lot number.
8. System must be in ready to change the default calibrator.

G. **Ordering QC**

1. From Orders menu, select Control Order
2. From the Control order screen select the appropriate option (Single Analyte or Multi-constituent).
3. Select carrier or carousel button
4. Enter Carrier ID in C field
5. Enter a position in the P field.
6. Select the Control List button and then select the desired control
7. If the desired lot number does not display in the lot box, select the Lot list button and select the desired lot.
8. Select the desired Level option.
9. Select the desired Panel and/or Assays.
10. Select **F5 Assay** options to specify assay options. Use previous/ next buttons to display each assay if more than one selected.
11. Select Done to save changes.
12. Select **F2- Add Order**.
    NOTE: Controls can be ordered manually or by loading a barcoded carrier tube. If a barcoded tube is used, all tests associated with the barcode will be tested. If the barcoded carrier tube will be used when ordering single tests or repeats, you must manually order the test and make sure that your barcode matches the QC for that order.

H. **Disable a reagent**

1. Reagents can be patient disabled from the Reagent Status Screen.
2. Highlight the reagent.
3. Select F-7 Details.
4. Select the disable for patient testing box.

I. **Testing Samples- Automation Track**

1. Place on the Sample Carousel for direct instrument loading. The Sample Carousel must be paused prior to opening the door to load samples. A solid green light on the Pause Button indicates the carousel may be loaded. Samples to be tested using the automation line are loaded at the IOM.
2. Samples to be tested using the automation line are moved to the instruments by RFID carriers on the track. Samples can be directed with a STAT Priority using the designated STAT Line at the IOM when loading. Samples tested by the automated

track will be moved to an IOM for operator intervention if designated. Completed samples are taken to the storage units.

J. **Testing Samples- Integrated/Standalone Systems**

1. Place samples in the sample rack(s) for direct instrument loading.
2. 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.
3. Place carrier on the 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 or on the carousel.
4. Carriers with solid green lights are waiting to be tested
5. Carriers with blinking green lights have been sampled. Alternating Green and Amber blinking lights are sampled but there is a problem that will need to be addressed by the operator.
6. Check the status of the samples before unloading by going to Overview, Sample Status screen. Handle any exceptions as needed.

XIII. CALCULATIONS AND INTERPRETATIONS:

A. 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. Refer to the IM Operating Procedure.

B. Toxicology reports include the following information:

1. Substances or classes of substances analyzed as part of the toxicology test.
2. Specimen type.
3. Report status for positive results (ie, unconfirmed, confirmed or pending confirmation).
4. Assay cut-off concentration for each drug or drug class.
5. A statement that drug screening results are to be used only for medical treatment purposes.
6. A statement that unconfirmed screening results must not be used for non-medical purposes (ie, employee testing).

C. 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 at the instrument for the dilution factor to be applied.

D. Samples that generate an error code are held at the instrument in exceptions. The error code is reviewed using the online Operations Manual.

E. Instrument result exception error codes that indicate a result is “unable to calculate, result is low” are repeated to verify and reported as “less than”. (examples 1056 and 1452)

F. Instrument result exception error codes that indicate a result is “unable to calculate, absorbance exceeded” are diluted to rule out interference in the sample. The result reported will follow the Reportable Range guideline for each assay. (examples 1051 and 1350)

XIV. REFERENCE RANGES:

Refer to **Attachment D**.

XV. REPORTABLE RANGE:

Refer to **Attachment E.**

XVI. LIMITATIONS:

A. Increased levels of lactic acid and LD in postmortem samples may cause falsely elevated ethyl alcohol results. Published data indicate that such elevations are unlikely in living persons.

B. Assay results MUST be used with other clinical data. 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.

XVII. INTERFERING SUBSTANCES:

Refer to **Attachment F** for Interference due to Hemolysis, Lipemia and Icterus. Consult the Product Information sheets for each test for specific information on interferences with endogenous substances and other drugs.

XVIII. 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

C. Nacca N, et al., Clin Toxicol. 2018; 56:189-92.

D. Nine JS, et al., J Anal Toxicol. 1995; 19:192-6.

Attachments

Abbott Architect Chemistry Attachment A - Clinical Significance

Abbott Architect Chemistry Attachment B - Reagent Reference Guide

Abbott Architect Chemistry Attachment C - Calibrators

Abbott Architect Chemistry Attachment D - Reference Ranges

Abbott Architect Chemistry Attachment E - Reportable Range

Abbott Architect Chemistry Attachment F - Hemolysis, Icterus, Lipemia Interference

Abbott Architect Chemistry Attachment G - Tests by Campus

Abbott Architect Chemistry Attachment H - Specimen Stability

Abbott Architect Chemistry Attachment I - Fluid Reference Guide

Approval Signatures

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Applicability

Dearborn, Farmington Hills, Grosse Pointe, Royal Oak, Taylor, Trenton, Troy, Wayne