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| **Abbott Architect c4000 Operating Procedure** | | |
| **Purpose** | This document provides instructions for Abbott Architect c4000 OPERATING PROCEDURE. The c4000 is an *in vitro* diagnostic device intended to duplicate manual analytical procedures such as pipetting, mixing, heating, and measuring spectral intensities to determine a variety of analytes in human body fluids. |
| **Instrument** | Abbott Architect c4000, St. Paul |
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| **Policy Statements** | This procedure is intended for all personnel responsible for the operation of the Abbott Architect c4000. Personnel operating the Abbott Architect c4000 must demonstrate applicable competence in its operation and maintenance. |
| **Materials** | |  |  |  | | --- | --- | --- | | **Reagents** | **Supplies** | **Equipment** | |  | Numerous supplies are needed to operate the Abbott Architect. Refer to the operator’s guide for more information. | Abbott Architect c4000  Serial Number: c461801  St Paul Customer #: 50066117 | |
| **Sample** | Refer to the Specimen Collection Manual for detailed instructions on specimen collection.  **Type:** Specimens for assay on the Abbott Architect c4000 include serum and plasma. Collection containers include microtainers and evacuated collection tubes suitable for serum or plasma. See individual analyte procedures for specific test requirements.  **Volume:** See the reagent manufacturer's assay specific documentation (such as a package insert or reagent application sheet).   * Insufficient sample or air bubbles in a sample cup could cause incorrect results. * See individual analyte procedure for specific test volumes required.   **Stability:** See individual analyte procedures for specific stability.  **Criteria for Rejection:** Unlabeled specimens will be rejected. Refer to the individual analyte procedures for more specific criteria.  **Interfering substances:**  Refer to the individual analyte procedures or the product inserts for specific interferences.  **Sample Preparation:** Refer to the [Specimen Collection Manual](http://khan.childrensmn.org/References/labsop/index.php?view=folder&folder=gen) for pre-analytic handling procedures. Once specimens are delivered to the laboratory, the following steps are taken:   1. Electronically receive the sample into the Laboratory computer system. 2. Prepare sample for separation. (See individual assay procedures.) 3. Refer to the processing procedure manual for proper labeling of false-bottom tube and sample cups. 4. Aliquot sample to a properly labeled, appropriate sample container.   Evaluate specimen integrity (See individual assay procedures.) |
| **Special Safety Precautions** | * Follow standard precautions for protection from biohazards when placing specimens on instrument and when performing maintenance and troubleshooting procedures. * All components that come in contact with patient specimen should be considered potential biohazards and should be treated accordingly. * Proper personal protective equipment should be used at all times when operating the Abbott Architect c4000   The following reagents and supplies must be disposed of in hazardous waste containers.  **Recap and dispose of in Alkaline/caustic waste container**   * + Alkaline wash   + Detergent B   + Total protein reagent   + Glucose reagent   + Creatinine R1 reagent   **Recap and dispose of in Acid waste container**   * Direct bilirubin reagent * Total bilirubin reagent * Phosphorus reagent * Acid wash * Creatinine R2 reagent   **Dispose of in Regulated Medical Waste (RMW) (red biohazard trash)**   * Mulitconstituent calibrator * Clinical Chemistry calibrator * CRP calibrator * CO2 (Carbon dioxide calibrator   All other reagents, if empty, can be placed in regular trash bins. If not completely empty, dispose of in regulated medical waste (red trash). |
| **Procedure** | The [Abbott Architect Operations Manual](https://starnet.childrenshc.org/References/labsop/chem/operator/abbott-architect-operations-manual.pdf) and Quick Reference Guide are comprehensive reference manuals describing use of the entire Abbott Architect c4000 System. Primary Operators should be familiar with the Manufacturer’s instructions and refer to them as needed. |
| **Maintenance** | The maintenance screen is accessed by selecting **System** in the top row and then **Maintenance** from the drop down menu. Maintenance procedures are organized into tabs along the right side of the screen. Each tab will list the corresponding procedures as well as the last time the procedure was performed. The **To Do** tab lists any procedures that are due to be performed. The **In Process** tab lists the procedures that are currently in process, if any. |
| **Daily Maintenance** | |  |  | | --- | --- | |  | | | The analyzer must be in **Ready** status to perform daily maintenance  Under the System Menu, select Daily on the maintenance screen  Select the maintenance procedure you wish to perform and Click **F5- perform**  The Maintenance Perform window displays.  A description of the procedure displays on the Instructions box.  Select **Proceed**, and then follow the instructions in the INSTRUCTIONS box. | | | 6024 Check 1 mL Syringes | Openthe bottom left door and Inspect the connections and interior of the 1 mL syringes for leaks | | 6028 Check Di Water Purity | View the Check off sheet for the Evoqua MEDICA Pro. Bacterial contamination and cleaning are done every 6 months by the Manufacturer. | | 6070 Daily Maintenance | This is an automated routine that takes about 15 minutes. Before beginning replace the cups in the sample wash container and fill with new solutions. ICT diluent and Water Bath Additive should already be onboard but ensure that the volume is sufficient. Water bath additive must be in position A4. | | 9100 Inspect Mixers | Open the back of the instrument to inspect the Mixers. Check to see that the screws which hold the mixers in place are still present. | |
| **Weekly Maintenance** | |  |  | | --- | --- | | The analyzer must be in **Ready** status to perform weekly maintenance  Under the System Menu, select Weekly on the maintenance screen  Click **F5- perform on selected task**  The Maintenance Perform window displays.  A description of the procedure displays on the Instructions box.  Select **Proceed**, and then follow the instructions in the INSTRUCTIONS box. | | | 6019 Check ICT Components | The ICT probe will move up and down several times. Check to see that the probe does not drip and there are no bubbles in the tubing. | | 6021 Clean Mixers | The system will park the mixers in the extended position. Use two swabs moistened with 70% isopropyl alcohol to **gently** wipe the mixers on both sides at once to avoid bending them. Repeat using swabs moistened with DI water. Be careful, the mixers are fragile. | | 6023 Clean Sample/ Reagent Probes | The system will park the probes in an accessible position. Use two swabs moistened with detergent A to wipe the probes from opposing sides. Repeat using swabs moistened with DI water. Be careful not to push down on the probe arms, this can cause the probes to crash and bend. | | 6056 Clean Cuvettes with Detergent | This is an automated routine that takes about 25 minutes. Detergent A should already be on board, verify that there is sufficient volume before beginning. | | 6308 Check HC waste Pump Tubing | Inspect the high concentration waste pump tubing for blockage. | |
| **Monthly Maintenance** | |  | | --- | | The analyzer must be in **Ready** status to perform monthly maintenance  Under the System Menu, select Monthly on the maintenance screen  Click **F5- perform** on a selected task  The Maintenance Perform window displays.  A description of the procedure displays on the Instructions box.  Select **Proceed**, and then follow the instructions in the INSTRUCTIONS box.  6016 check dispense Components  6018 clean Cuvette Washer Nozzles  6026 Check Syringes and Valves  6300 Clean ICT Drain Tip | |
| **Quarterly Maintenance** | |  | | --- | | Under the System Menu, select Quarterly on the maintenance screen  Click **F5- perform on a selected task**  The Maintenance Perform window displays.  A description of the procedure displays on the Instructions box.  Select **Proceed**, and then follow the instructions in the INSTRUCTIONS box on the analyzer.  1003 Change Lamp  6301 sample Syringe Maintenance  6302 Wash Syringe maintenance  6303 Reagent Syringe Maintenance  6304 Change 1 mL syringes  6305 Change ICT Asp Check Valve  6306 Check ICT Ref Check Valve | |
| **As Needed Maintenance** | Refer to the [Abbott Architect Operations Manual](https://starnet.childrenshc.org/References/labsop/chem/operator/abbott-architect-operations-manual.pdf) for the following as-needed maintenance procedure |
| **Power off SSC** | |  |  | | --- | --- | | 1 | Ensure both Sample Handler and Processing Modules are either Ready, Stopped or Offline | | 2 | Select **F3-Shutdown** from Snapshot screen. | | 3 | Select **OK** to confirm shutdown. | | 4 | Press **Ctrl+Alt+Delete** keys when message displays | | 5 | Select **Shutdown the computer** and press **OK** when message displays. | | 6 | Turn off power to SCC when screen instructs you. (SCC power button is located on the front of the CPU. You may need to press the button for several seconds for the power to go off) | | 7 | Turn off power to Processing Module. (The power switch is a white lever or a black toggle switch. It is located above the power cord on the lower left rear of the processing module). | |
| **Power on SSC** | |  |  | | --- | --- | | 1 | Turn power on to SCC. | | 2 | Allow the system software to initialize. | | 3 | Wait for Snapshot Screen to display. | | 4 | Turn on power to the Processing module. (Sample handler and processing module stay in Offline status approximately 5 minutes prior changing to stopped) | | 5 | Select the Sampler Handler and Processing Module graphics. | | 6 | Select **F5- Start-up** (**Note:** If PM power is on when you power on the SSC, communication will not be established between the system components, and the SH and PM status will remain Offline indefinitely. If this occurs, power off the PM, wait 30 seconds and power on the PM) | |
| **Logging In** | **It is important that all employees who use the Abbott Architect c4000 are logged into their defined user name. This is important for maintenance log sheets as there will not be a paper copy for daily signoff. The Maintenance Log will be printed and reviewed once per month by the Technical Specialist or Designee.**  Defined User name: tech code,  General Architect Login:  Username: ADMIN  Password: ADM |
| **Calibration**  **Calibration (cont.)**  **Calibration (cont.)** | Each day assure all methods have enough calibrated reagent available for the entire days test requirements. The Architect computer system tracks usage of reagent on a weekday and weekend rotation to anticipate reagent needs.  Mandatory assay calibration is required when   * A new reagent lot number is used * Documentation accompanying a new version of an existing assay file states calibration is required * A new assay file that requires a calibration is installed * The calibration curve has expired.   Optional assay calibration would include   * troubleshooting QC, * Certain system maintenance/component replacement procedures are performed, * Certain errors occur. (To determine whether recalibration is necessary when an error occurs, see assay-specific error codes).  |  |  |  | | --- | --- | --- | | **Step** | **Action** | **Related Document** | | 1. | **Checking Calibration Status**   1. Review the c4000 processing module graphic on the snapshot screen 2. Select Calibration Status from the QC-Cal drop-down menu. The latest calibration information is displayed for each assay and reagent lot that is currently loaded. 3. Select F3-Find from the calibration status screen to search calibration curves using various criteria. | [Operating Procedure](http://khan.childrensmn.org/References/labsop/chem/operator/abbott-architect-operations-manual.pdf) | | 2. | **Order Calibration:**     1. From the Orders menu, select calibration order 2. Select the carrier button to enter position of sample 3. In the ‘C’ field, enter the carrier ID which is located on the bar code label attached to the carrier ( one letter followed by 3 numbers) 4. In the ‘P’ field, enter the position. Enter 1-5 for starting position. 5. In the assays section, select the assays to be ordered and/or select desired panels) 6. If the calibration has more than 5 calibrators you will need sequential carrier ID rack 7. Click F5- Assay Options to access the Assay Options window 8. Enter information in appropriate fields. The correct calibration lot number and expiration date must be entered in order for it to appear on the Calibration Curve window and the Cal Curve Details report. 9. Click the up and down arrows on the Assay options window to display the previous and next calibration orders. 10. Click Done. 11. Click F2- Add Order 12. From the order menu, click Order Status 13. Click F4- Print to print the Order List Report 14. Load the calibrators as printed on the Order List Report 15. Run the Calibrators | [Operating Procedure](http://khan.childrensmn.org/References/labsop/chem/operator/abbott-architect-operations-manual.pdf) | |  | **Review Calibration Details**   1. From the Calibration status screen, select one or more assays 2. Click F5- Details |  | |  | **Print Calibration Reports**   1. From the QC-CAL menu, select Calibration status 2. Click F4- Print |  | |  | Calibration status ‘Active’   * An acceptable calibration curve has been generated. Calibrations are not deemed valid until ACCEPTABLE QUALITY CONTROLS have been generated per the Unity Real Time QC program.   Calibration status ‘Failed’   * Calibration failed curve validity * Calibration did not complete due to hardware error * The user manually failed the calibration   Calibration ‘Pending QC’: A calibration curve has been generated but at least one control has not completed.  Calibration ‘No Cal’: The reagent is a new lot OR requires calibration by kit |  | |
| **Generating QC Barcodes** | Each level and lot number of quality control will have its own unique barcode. These barcodes are generated from the barcode generator on Bio-Rad’s website. When lot numbers are changed, barcodes will also be changed to reflect the matching lot number.  Generating QC Labels Using QCNet   |  |  | | --- | --- | | 1 | Open [www.QCNet.com](http://www.QCNet.com) in an internet browser. Make sure pop-up blockers are OFF. | | 2 | Login to the site  Username: Chem1stry  Password: biorad | | 3 | Lab Tools🡪Barcode Label Generator | | 4 | Select the instrument from the dropdown box | | 5 | Select Code 128 for the Symbology list | | 6 | Make sure ‘show text with barcode’ box is checked | | 7 | Type Sunquest name in ‘text before lot’ box using the following specifications: (The Xs are the lot number, replacing the 0 of the master lot with the level of QC. For example, lot 56920 level 1 is 56921.)  UNASSAYEDXXXX1: BioRad Unassayed level 1  UNASSAYEDXXXX2: BioRad Unassayed Level 2  EVESXXXXX: Evening BioRad Unassayed. The last number will distinguish between level 1 and level 2, as shown for UNASSAYED QC above.  NIGHTSXXXXX: Nights BioRad Unassayed, Lot number will distinguish the difference between levels  PEDIATRIC2XXXX2: Bio-Rad Pediatric Level 2  IMMUNOLOGYXXXX1: Bio-Rad Immunology Level 1  IMMUNOLOGYXXXX3: Bio-Rad Immunology Level 3  LEVLOXXXXX: ARC Levetiracetam Control Low (Level 1 in Unity Real Time (URT))  LEVHIXXXXX: ARC Levetiracetam Control High (Level 2 in URT)  BHOBLOXXXX: Stanbio TDM B-hydroxybutyrate Low (Level 1 in URT)  BHOBHIGHXXXXX: Stanbio TDM B-hydroxybutyrate High (Level 2 in URT)  TOPLOXXXXX: ARC Topiramate Control Low (Level 1 in URT)  TOPMEDXXXXX: ARC Topiramate Control Medium (Level 2 in URT)  LAMLOXXXXX: ARC Lamotrigine Control Low (Level 1 in URT)  LAMMEDXXXX: ARC Lamotrigine Control Medium (Level 2 in URT) | | 8 | Select Other from the product drop down box | | 9 | Select the correct lot number from the ‘lot’ drop down box (not required. Any lot may be chosen and the box unchecked for ‘print level’.) | | 10 | Make sure ‘print lot’ and ‘print level’ boxes are NOT checked. | | 11 | Output type **5260** – 30 Labels per sheet | | 12 | Click generate barcode and click OK when pop-up appears | | 13 | The **File Download** box will appear. Click ‘Open’ and the labels will open in Adobe Acrobat format. | | 14 | Click **File** and **Print**. Make sure the page scaling is ‘none.’ | | 15 | Print on regular paper, cut out a barcode, and affix it to a false bottom tube. The same false bottom tube may be used for the duration of the lot number. | | 16 | Ensure the barcode is configured in Abbott Architect software according to [Operations Manual](https://starnet.childrenshc.org/References/labsop/chem/operator/abbott-architect-operations-manual.pdf) instructions. | |
| **Quality Control** | QC assessment is required on each method each day of patient testing. Refer to the procedure [CH 2.18 Westgard Rules in Chemistry](https://starnet.childrenshc.org/References/labsop/chem/quality/ch-2.18-westgard-rules-in-chemistry.pdf) and the individual assay procedures for specific information on Quality Control frequency, materials and handling, requirements, and response codes.  **Do not load or run patients until QC has been entered into URT and reviewed, and all rule failures have been resolved, per CAP Regulations.**  QC is performed after all PMs and all replacements of critical components of the analyzer to ensure optimum performance. |
| **Adding new lots of QC** | To add a new lot of QC complete the following:   1. Select System 🡪 Configuration 2. Select QC/Cal Settings 3. Select QC Multiconstituent 4. Click on the correct QC material 5. Select F6 Configure 6. Lot Number: Click the drop down box and choose New Lot 7. Lot Number: Type the Master Lot number (ends with a “0”) 8. Select Level 9. Expiration date: Enter the Master Expiration date 10. Highlight all the assays by clicking on them 11. Click Define Data 12. Click ok: Do not enter any data here. All ranges are in URT and should not be in instrument. Enter past the error displayed by the Architect. 13. Repeat for additional levels of QC, starting with step 8 as the master lot number has already been configured. |
| **Configuring QC barcodes on the C4000** | Once a new barcode is made for QC do the following steps:   1. Select System 2. Select Configuration 3. Select QC/Cal settings 4. Select Multiconstituent Barcode SID 5. F6 configure 6. Click on the old barcode that is being replaced 7. Name: Type the new barcode name, ensuring capital letters match the barcode. Alternatively, you may scan the barcode. You may need to turn caps lock OFF to get the entered value to match the barcode. 8. Lot: click on dropdown box, click on the correct lot and correct level of QC 9. Select Add 10. Enter additional barcodes starting with step 6 as needed. 11. Select Done when finished. |
| **Daily Startup**  **Plan My Day** | Plan my day is a feature on the Abbott Architect c4000, which displays consolidated information and statuses for reagent inventory, assay calibrations, supplies inventory, QC, and system maintenance. These may require operator intervention to successfully process samples uninterrupted within the user defined timeframe.   |  |  | | --- | --- | | **How to use Plan My Day** | | | 1 | Click on Overview | | 2 | Click on Plan My Day | | 3 | Change time to be 23 hours and 59 minutes in the future (or 1 minute in the past). Touch the Update icon, shown below. | | 4 | **F4- Print 🡪 All categories 🡪 Done** |   Five different category tables will print out to inform the operator of tasks that need to be performed.    #3  **Reagent Category:** The displayed information is associated with reagents that may require operator intervention in order to successfully process samples without interruption. This information shows if a kit needs to be replaced or if additional kits need to be added.  **Calibrations Category:** The displayed information is associated with calibrations that may require operator intervention in order to successfully process samples without interruption. Reagent calibrations expiring in the next 24 hours must be calibrated.  **Supplies Category:** The displayed information is associated with supplies that may require operator intervention in order to successfully process samples without interruption. Replace supplies as needed for the next 24 hours of operation.  **QC Category:** The displayed information is associated with QC that may require operator intervention in order to successfully process samples without interruption. Investigate any failures, however, ranges on the analyzer are not current and may need to be removed to remove flags. Contact Technical Specialist for further information, if needed.  **Maintenance Category:** The displayed information is associated with maintenance that may require operator intervention in order to successfully process samples without interruption. Perform maintenance as required, ensuring that a user is logged onto the analyzer (NOT ADMIN) during the procedure(s).  To enter comments as you would on a paper maintenance log (for example, if there is an instrument error), select the colored box that shows on the maintenance log for any maintenance item and select Details. In the white box, type the applicable comment. One it is saved (select Done), the colored box on the maintenance log will contain an asterisk, indicating a comment has been entered. This comment will then print on the maintenance log when it is reviewed monthly. |
| **Check Supply Status**  **Check Reagent Status** | |  |  | | --- | --- | | 1 | From the snapshot screen, check the supply status portion of the processing module graphic | |  |  | | 2 | Verify supplies are within expiration date listed on the label | | 3 | Click the supply status portion of the graphic to access the supply status screen | | **Check Reagent Status** | | | 1 | From the snapshot screen, determine the total number of reagents onboard the processing module | | 2 | Attend to reagents that display a caution symbol , replacing if necessary. | | 3 | Click on **Reagent Status** to access the reagent status screen | | 4 | Determine the reagent status conditions using the colors on the carousel graphic.    •White - No reagent is loaded in the position  • Green - Reagent with an OK status loaded in the position  • Gold - Reagent with a Low Alert, Overridden, or Disabled status loaded in  the position  • Red - Reagent with an error condition that requires your attention loaded in  the position | | 5 | On the reagent table, click the reagent status column to sort data and display all kits that require operator attention. Use the green arrows to scroll down the list. | | 6 | Select **View All** for more information about the reagents loaded on the system. | | 7 | Click **F5-Print** to print the Reagent Status Report | | 8 | From the Reports Available, select **Reagent Status Report**, and click **Done**. | |
| **Load Barcoded Reagent** | 1. Instrument should be the ready state. 2. Verify the expiration date of the reagent. DO NOT use the reagent if the Expiration date is exceeded. 3. Invert the reagent cartridge gently to ensure a homogenous solution. 4. Remove the cap and save in bin for recapping old reagents. 5. Remove air bubbles, if they exist, with a clean applicator stick. 6. Open the reagent supply center access door. 7. Verify the reagent supply center access button (labeled 1 in the photo below) is illuminated before accessing the reagent supply center. Press the reagent supply center access button (1) to open the cover. 8. Press the carousel advance button (labeled 2 in the photo below) after the button illuminates to advance the reagent supply center to access the position. 9. Load the reagent cartridge(s) in any open position, ensuring you are not blocking the barcode reader from reaching the inner reagent wheel, as this is not a valid reagent position. 10. Press the reagent supply center access button to close the cover as indicated by the number 1 in the photo below.     **Note**:  Once you place a new reagent(s) on a processing module and the bar code reader scans the bar code label, the system software links individual R1 and R2 cartridges together as a kit. If the cartridges are not kept together, the reagent status of Missing bottle or Extra bottle displays. |
| **Configuration of Non-barcoded Reagents and Diluents** | Instrument should be the **Ready** state. All third party assays and Saline must be configured prior to assigning the location.  To configure Non-barcoded reagent:   1. System🡪configuration 2. Assay settings (Top Middle) 3. Reagent settings (left column) 4. Choose the reagent that is being configured (Middle) 5. F6 Configure ( Bottom) 6. Lot number click the drop down box    1. Choose the current lot or if the reagent is a new lot choose new lot and type the new lot in the empty white space. 7. Serial number: Set to the current month and date as a four digit number. For example, October 8th = 1008 8. R1/R2: drop down box choose container you used. Refer to assay procedure for cartridge sizes. (Usually R1 55mL and R2 20mL) 9. Add Kit (right) 🡪click done 10. Follow required instructions below to assign reagent location. |
| **Loading Non-barcoded Reagent** | Instrument should be the **Ready** state. All third party assays must be configured prior to assigning the location following the procedure above, **Configuration of Non-barcoded Reagents and Diluents**. Then, to assign location of non-barcoded reagents:   1. Select **F6 - Assign location** on the **Dis**. The Assign location window displays. 2. Select the desired reagent from the **Reagent kits** table. 3. Select the desired Reagent supply center option, and then enter the desired location in the data entry box. 4. Select Add. The assigned position(s) displays in the Reagent kits table. 5. Verify the expiration date of the reagent. DO NOT use the reagent if the expiration date is exceeded. 6. Remove and discard the cap. 7. Remove air bubbles, if they exist, with a clean applicator stick. 8. Open the reagent supply center access door. Verify the reagent supply center access button (1) is illuminated before accessing the reagent supply center. 9. Place the reagent cartridge(s) in the reagent supply center 10. Close the reagent supply center access door 11. Select done on the Assign location window to return to the Reagent status screen.   NOTE: You MUST ensure the reagents are placed into the correctly assigned R1 and R2 positions on the reagent wheel.  **NOTE: Reagents must be UNASSIGNED in the instrument software when physically removed from the reagent wheel or the instrument will continue to operate using the previously defined reagent**. Follow directions in the section below, titled **Unloading Reagents**. |
| **Loading sample diluents** | Instrument should be the ready state. To load sample diluent(s), the kit/wedge must first be configured following the procedure above, **Configuration of Non-barcoded Reagents and Diluents.** Then:   1. Select F6 - Assign location on the Reagent status screen. The Assign location window displays. 2. Select the desired sample diluent from the Reagent kits table. 3. Select the desired Reagent supply center option, and then enter the desired location in the data entry box. 4. Select Add. The assigned position displays in the Reagent kits table. 5. Note the displayed reagent cartridge size. 6. Verify the expiration date of the sample diluent. DO NOT use the sample diluent if the expiration date is exceeded. 7. Pour the sample diluent into the specified reagent cartridge type. 8. Remove air bubbles, if they exist, with a clean applicator stick. 9. Label the container(s) with the name and expiration date. 10. Open the reagent supply center access door. 11. Verify the reagent supply center access button (labeled 1 in the photo previously shown) is illuminated before accessing the reagent supply center. 12. Remove and replace the sample diluent(s) in the reagent supply center 13. Close the reagent supply center access door. 14. Select Done on the Assign location window to return to the Reagent status screen. |
| **Unloading Reagents** | |  |  | | --- | --- | | Barcoded reagents | 1. Open the Supply Center Access door 2. Remove the desired reagent kits 3. Close the Supply Center Access door 4. Initiate or resume sample processing, or select F5/Scan on the Reagent status screen to update the reagent inventory 5. Dispose of as indicated in special safety precautions | | Non-Bar coded reagents | 1. Open the reagent supply access door. 2. Press the carousel advance button advance the reagent supply center to access the position. 3. Remove the reagent kit(s) and place a container cap on the kit(s). 4. Press the reagent supply center access button to close the cover 5. Select F6/Assign Location on the Reagent Status screen. The Assign Location window displays. 6. Touch the desired reagent from the Reagent kits table (left side). 7. Select Unload. The assigned position no longer displays in the Reagent kits table. 8. Select Done to return to the Reagent status screen. 9. Dispose of as indicated in special safety precautions | |
| **Replacing Consumables** | |  |  | | --- | --- | | **Updating Sample Supply** | | | 1 | From the Supply Status Screen Click **F2- Update Supplies** | | 2 | * Place a check mark under the replace column of the consumable that is being replaced. * Check that the lot number and expiration date are the same. If they are different, type in the new lot number and expiration date. * Place the new consumable(s) on the instrument. * Dispose of as indicated in special safety precautions when removing used consumables. | |
| **Programming Sample Data** | |  |  | | --- | --- | | **Barcoded Samples** | | |  | **Orders** 🡪 **Patient Order**   1. On the patient order screen, ensure the cursor appears in the sample ID field 2. Scan the bar code label on the patient sample tube 3. Select the assays or panels to be run 4. Click F2- Sample details to add patient information 5. Select F5- Assay Options- to specify assay options such as replicates or dilutions. 6. Click F3- Add order. | | **Manual Patient Orders** | | |  | **Orders** 🡪 **Patient Order**   1. Select the carrier button to enter position of sample 2. In the C field, enter the carrier ID 3. In the P field, enter the position 4. In the SID field, enter sample/barcode ID 5. In the Assays section, select the assays to be ordered 6. Click F2- Sample details to add patient information 7. Select F5- Assay Options- to specify assay options such as replicates or dilutions. 8. Click F3- Add order. | |
| **Loading Samples** | |  |  | | --- | --- | | **Verify, Load, and Run** | | | 1 | Verify sample integrity, sufficient volume, and approved sample type per assay-specific package inserts. | | 2 | Print the Order List report to ensure that you load the samples in the correct Carrier and Position. | | 3 | Place the sample in the carrier so the bar code label is visible in the bar code window | | 4 | Verify RSH Status   1. Prior to loading carriers, verify the RSH status is either in Ready or Running Status. | | 5 | Verify both of the indicators below the desired section are off. | | 6 | Position the carrier so that the sample barcode labels are facing to the right. | | 7 | Push the carrier into the priority or the routine section until the indicator illuminates. | |
| **Removing Samples in Process** | |  |  | | --- | --- | | Never remove or add samples or sample carriers on the RSH when an amber indicator is illuminated unless you perform one of the following: | | | 1 | Pause the RSH   1. Click on Sampler handler Graphic 2. Click **F7- Pause** and wait for the steady green indicator to illuminate | | 2 | Suspend the RSH   1. From the sample status screen, select the patient sample 2. Click **F6- Suspend** and wait for the steady green indicator to illuminate. 3. After removing the desired sample, perform one of the following   ●Order re-runs for exceptions  ●Reload tray for sample processing | |
| **Interpretation/Results/Alert Values** | Refer to individual assay procedure for interpretation/results and alerts. |
| **Dilutions** | Refer to individual assay procedure for dilution information. |
| **References** | 1. Abbott Architect Operations Manual, Abbott Diagnostics Division, Abbott Park, IL, April 2016. |
| Training Plan/ Competency Assessment | Use Abbott Architect training checklist located on the G: Lab drive for initial employee training. StaffReady will be used to perform Competency Assessments after initial training on the Abbott Architect c4000. |
| **Historical Record** | |  |  |  |  | | --- | --- | --- | --- | | **Version** | **Written/Reviewed By** | **Effective Date** | **Summary of Revisions** | | 1 | Stephen Gripentrog, Erin Bartos | October 15, 2019 | Initial Version | |  |  |  |  | |  |  |  |  | |