|  |  |  |
| --- | --- | --- |
| **Abbott Architect i1000SR Operating Procedure** | | |
| **Purpose** | This document provides instructions for ABBOTT ARCHITECT i1000SR OPERATING PROCEDURE. The Architect i1000SR is intended for *In Vitro* diagnostic use only. The system is designed to perform automated immunoassay tests, utilizing CMIA (chemiluminescent microparticle assay) detection technology.  Features of the Abbott Architect i1000SR System include the following:   * System integration and a common software user interface to provide single sample management and result reporting capabilities * Touch screen allows easy navigation * On board operators guide to provide immediate access to information about the currently displayed screen, window or error message. * Offers STAT processing * On board procedure log to provide current and accurate maintenance records * Sample carriers accommodate a variety of test tubes * Sample handlers allow loading of up to 65 samples * Clot detection to ensure accurate sampling * Sampler handler design provides continuous sample access * Simplified troubleshooting due to direct access to error messages to help provide probable cause and corrective action information. * Up to 100 tests/hour * Automatic Dilution * Reagent capacity of 25 and reagent onboard stability of 14-30 days |
| **Instrument** | Abbott Architect i1000SR Minneapolis- Serial Number: i1SR60652 |
| **Policy Statements** | This procedure is intended for all personnel responsible for the operation of the Abbott Architect i1000SR.  Personnel operating the Abbott Architect i1000SR must demonstrate competence in its operation and maintenance. |
| **Materials** | |  |  |  | | --- | --- | --- | | **Reagents** | **Supplies** | **Equipment** | | Individual Analyte Reagents  RVs  Wash Buffer  Pre-Trigger Solution  Trigger Solution | Numerous supplies are needed to operate the Abbott Architect. Refer to the operator’s guide for more information. | Abbott Architect i1000SR  SN: i1SR60652 | |
| **Sample** | Refer to the Specimen Collection Manual for detailed instructions on specimen collection.  **Type:** Specimens for assay on the Abbott Architect i1000SR 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 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. See the individual analyte procedures for more specific information.  **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. ([SCM 5.0](http://khan.childrensmn.org/Manuals/Lab/SOP/Gen/SpecCol/205648.pdf)) 2. Prepare sample for separation. (See individual assay procedures.) 3. Refer to the processing procedure manual for proper labeling of false-bottom tube and SSC. 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 i1000SR   The following reagents must be disposed of in hazardous waste containers.  **The following reagents need to be re-capped and placed in the Acid Flex Waste**   1. 2nd Generation Testosterone Assay Specific Diluent (pH 2.1) 2. PreTrigger Solution (pH 2.1)   **The following reagents need to be re-capped and placed in the Caustic/Base Flex Waste**   1. B12 Pretreatment Reagent 1 (Contains NaOH) 2. Folate Pretreatment Reagent 1 (Contains KOH) 3. Trigger Solution (pH 13)   **The following reagents need to be re-capped and placed in the Micro Methanol Bin (Virology)**   1. Vitamin D Reagent Kit Pretreatment Reagents 1 & 2 (contains methanol)   All other reagents, if empty, can be placed in regular trash bins. |
| **Procedure** | The Abbott Architect Operator’s Guide and Quick Reference Guide are comprehensive reference manuals describing use of the entire Abbott Architect i1000SR System. Primary Operators should be familiar with the Manufacturer’s instructions and refer to them as needed. |
| **Daily Maintenance** | |  |  | | --- | --- | |  | | | 1 | Under the System Menu, select Daily on the maintenance screen | | 2 | Click **F5- perform** | | 3 | The Maintenance Perform window displays. | | 4 | A description of the procedure displays on the Instructions box. | | 5 | Click **Proceed** | | 6 | Add tap water to fill the white WZ Probe Maintenance Water Bottle ½ to ¾ | | 7 | Remove any carriers in the RSH sections 12 and 13. | | 8 | Place the reagent carrier with the WZ Probe Maintenance Water Bottle in RSH section 12. | | 9 | Select **Proceed** to continue. Estimated time: 10 Minutes | | 10 | Select **Done** to return to the Maintenance Screen. | |
| **Weekly Maintance**  **Probe Cleaning** | |  |  | | --- | --- | | 1 | Under the System Menu, select Weekly on the maintenance screen | | 2 | Select Probe Cleaning | | 3 | Click **F5- Perform** | | 4 | The Maintenance Perform window displays. | | 5 | A description of the procedure displays on the Instructions box. | | 6 | Click **Proceed** | | 7 | Open the processing center cover. | | 8 | Moisten a cotton swab with DI water | | 9 | Wipe each wash zone probe with the moistened cotton swab. | | 10 | Continue to wipe until all buffer build up is removed (3-4 times per probe). | | 11 | Moisten a new cotton swab with DI water, then wipe the wash zone manifold where the probe enters the manifold. | | 12 | Ensure the probes are properly aligned in the wash zone manifold. | | 13 | Select **Proceed** to continue. Estimated time: 5 minutes. | | 14 | Select **Done** to return to the Maintenance Screen. | |
| **Weekly Maintance**  **Pipettor/WZ Probe Cleaning** | |  |  | | --- | --- | | 1 | Under the System Menu, select Weekly on the maintenance screen | | 2 | Select Pipettor/WZ Probe Cleaning | | 3 | Click **F5- Perform** | | 4 | The Maintenance Perform window displays. | | 5 | A description of the procedure displays on the Instructions box. | | 6 | Click **Proceed** | | 7 | Prepare 500mL of a 0.5% sodium hypochlorite solution | | 8 | Remove any carriers in RSH sections 12 and 13. | | 9 | Fill the Maintenance Cleaning Bottle with 25-30mL of a 0.5% sodium hypochlorite solution prepared with tap water. Once prepared, the solution is stable for 30 days. | | 10 | Place the Maintenance Cleaning Bottle with the bleach solution in the yellow position of the reagent carrier. | | 11 | Place the reagent bottle containing the Probe Conditioning Solution with, a septum, in the pink position of the same reagent carrier. | | 12 | Place the reagent carrier in the RSH section 12. | | 13 | Select **Proceed** to continue. Estimated time: 15 minutes. | | 14 | Select **Done** to return to the Maintenance Screen. | |
| **Weekly Maintance**  **Wash Cup Cleaning** | |  |  | | --- | --- | | 1 | Under the System Menu, select Weekly on the maintenance screen | | 2 | Select Wash Cup Cleaning | | 3 | Click **F5- Perform** | | 4 | The Maintenance Perform window displays. | | 5 | A description of the procedure displays on the Instructions box. | | 6 | Click **Proceed** | | 7 | Open the processing center cover. | | 8 | Remove the wash cup baffle and rinse the baffle with deionized water. If the wash cup baffle cannot be cleaned thoroughly, replace it with a new baffle. | | 9 | Clean the was cup with a cotton top swab moistened with deionized wahter making sure all the visible residue is removed. | | 10 | Close the processing center cover. | | 11 | Select **Proceed** to continue. Estimated time: 2 minutes. | | 11 | Select **Done** to return to the Maintenance Screen. | |
| **Monthly Maintenance** | |  |  | | --- | --- | | 1 | Under the System Menu, select Monthly on the maintenance screen | | 2 | Select Air Filter Cleaning | | 3 | Click **F5- Perform** | | 4 | The Maintenance Perform window displays. | | 5 | A description of the procedure displays on the Instructions box. | | 6 | Click **Proceed** | | 7 | Open Both Front Doors. | | 8 | The Card cage/SCC door filter is located in the Card cage/SSC door. Use the tab to slide the air filter up and out of the door. | | 9 | Place a clean, dry filter in the slot and slide into place. | | 10 | Close both of the front doors. | | 11 | Click **Proceed** | | 12 | Rinse the dirty filters with tap water and allow them to air dry before they are placed into storage. | | 13 | Select **Done** to return to the Maintenance Screen. | |
| **As Needed Maintenance** | Refer to the Abbott Operator’s Manual for the following as-needed maintenance procedure (hyperlink inserted below)   * Pipettor Calibration * Air Flush * Flush Fluids * Prime Wash Zone * Prime Pre-Trigger and Trigger * Internal Decontamination * Temperature Check-Manual * Temperature Status * Buffer Run   [As Needed Maintenance](http://khan.childrensmn.org/References/labsop/chem/operator/abbott-architect-operations-manual.pdf) |
| **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 i1000SR 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.**  General Architect Login:  Username: ADMIN  Password: ADM |
| **Plan My Day** | Plan my day is a feature on the Abbott Architect i1000SR, 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. Hit Update. | | 4 | **F4- Print** |   Five different category tables will print out to inform the operator of tasks that need to be performed.  **Reagent Category:** The displayed information is associated with reagents that may require operator intervention in order to successfully process samples without interruption. This information will help determine 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. This information will help determine what kits may need to be calibrated.  **Supplies Category:** The displayed information is associated with supplies that may require operator intervention in order to successfully process samples without interruption. This information will help determine what supplies may need to be replaced or added.  **QC Category:** The displayed information is associated with QC that may require operator intervention in order to successfully process samples without interruption. This information will help determine what QC has Westgard failures.  **Maintenance Category:** The displayed information is associated with maintenance that may require operator intervention in order to successfully process samples without interruption. This information will help determine what maintenance needs to be performed. |
| **Calibration** | 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 i1000SR processing module graphic on the snapshot screen 2. Select calibration status from the QC-Cal icon. 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 serch 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) |  | |
| **Calibration**  **Continued** | |  |  |  | | --- | --- | --- | | **Step** | **Action** | **Related Document** | | 2. | 1. Click F5- Assay Options to access the Assay Options window 2. Enter information in appropriate fields. The correct calibration 3. lot number and expiration date must be entered in order for it 4. to appear on the Calibration Curve window and the Cal Curve 5. Details report. 6. Click the up and down arrows on the Assay options window to 7. Display the previous and next calibration orders. 8. Click Done. 9. Click F2- Add Order 10. From the order menu, click Order Status 11. Click F4- Print to print the Order List Report 12. Load the calibrators as printed on the Order List Report 13. Run the Calibrators | [Operating Procedure](http://khan.childrensmn.org/References/labsop/chem/operator/abbott-architect-operations-manual.pdf) | | 3. | 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 Cont’d** | |  |  |  | | --- | --- | --- | |  | Calibration says ‘Active’   * calibration completed successfully   Calibration says ‘Failed’   * Calibration failed curve validity * Calibration did not complete due to hardware error * The user manually failed the calibration   Calibration says ‘Pending QC’   1. A calibration curve has been generated but at least one control has not completed |  | |
| **Quality Control** | QC assessment is required on each method each day of patient testing. Refer to the procedure [CH 2.07 Quality Control in Chemistry](http://khan.childrensmn.org/Manuals/Lab/SOP/Chem/Quality/201755.pdf)and the individual assay procedures for specific information on Quality Control frequency, materials and handling, requirements, and response codes.  QC is performed after all PMs and all replacements of critical components of the analyzer to ensure optimum performance. |
| **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 BioRad’s site. 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 | | 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 | | 8 | Select the control name in the ‘product’ drop down box | | 9 | Select the correct lot number from the ‘lot’ drop down box | | 10 | Make sure ‘print lot’ and ‘print level’ boxes are 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.’ | |
| **Quality Control** | |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Control Name** | **Architect Control Name** | **Tests** | **SunQuest**  **Code** | **Control**  **Instructions and**  **Stability** | | **Liquichek Specialty Immunoassay Control** | LIQ SPC IA | Anti-Tg  Anti-TPO  VitD\_25-OH | Level 1: LQSI1  Level 2: LQSI2  Level 3: LQSI3 | Thaw at room temperature.  Store: 2-8°C  Stability: 30 Days | | Lyphochek Specialty Immunoassay Control | LYP SPC IA | PCT  iPTH STAT | Level 1: LYSI1  Level 2: LYSI2  Level 3: LYSI3 | Reconstitute with 2mL of DI water let vials sit for 15 minutes and gently swirl. Aliquot controls.  Stable: 30 days  Temperature: -20 to -70°C. | | Lyphochek Immunoassay Plus | LYPHO IAP | AFP\_3  ARCH B12  CORTISOL  DHEA-S  \_Estradiol  Folate II  \_FT3  Insulin  \_TT3  FT4\_6  TSH | Level 1: LYIP1  Level 2: LYIP2  Level 3: LYIP3 | Reconstitute with 5mL of DI water let vials sit for 15 minutes and gently swirl.  Stable: 3 days  Temperature: 2-8°C. | | Viroclear | VIROCLEAR | AUSAB-Dil  HBsAgQu  Anti-HCV | VIROC | Stable: 60 days  Temperature: 2-8°C | | Virotrol 1 | VIROTROL 1 | HBsAgQu  Anti-HCV | VIRO1 | Stable: 60 days  Temperature: 2-8°C | | Virotrol 2 | VIROTROL 2 | AUSAB-Dil | VIRO2 | Stable: 60 days  Temperature: 2-8°C | | HIV Ag/Ab Combo  Control Negative | HIV NEG | HIV Ag/Ab\_ | HIVN | Stable: Manufacture  Expiration date  Temperature: 2-8°C | | HIV Ag/Ab Combo  Control Positive 1 | HIV1P | HIV Ag/Ab\_ | HIV1P | Stable: Manufacture  Expiration date  Temperature: 2-8°C | | HIV Ag/Ab Combo  Control Positive 2 | HIV2P | HIV Ag/Ab\_ | HIV2P | Stable: Manufacture  Expiration date  Temperature: 2-8°C | | HIV Ag/Ab Combo  Control Positive 3 | HIV3P | HIV Ag/Ab\_ | HIV3P | Stable: Manufacture  Expiration date  Temperature: 2-8°C | | HIV Ag/Ab Combo  Control Positive 4 | HIV4P | HIV Ag/Ab\_ | HIV4P | Stable: Manufacture  Expiration date  Temperature: 2-8°C | |
| **Daily Start Up**  **Check Supply Status**  **Check Reagent Status** | |  |  | | --- | --- | | **Check Supply 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 | | 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. | | 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**. | |
| **Preparing New Reagents** | |  |  | | --- | --- | | 1 | Verify that the required assay reagent components are present as per the assay-specific package insert. | | 2 | Verify the reagent is within the manufacture expiration date on the bottle, DO NOT use if the expiration date is exceeded. | | 3 | Write the open date and your initials on each bottle with a permanent marker. Do not write near any of the barcodes as this will prevent the barcode reader from recognizing the reagent. | | 4 | Ensure the reagent bottles are intact and do not have signs of leakage, such as crystal formation. | | 5 | Invert the (pink) microparticle bottle ***gently*** 30 times to resuspend any particles. DO NOT use if microprticles do not resuspend. | | 6 | Inspect the bottom of the bottle to make sure particles are resuspended. If microparticles still adhere to the bottom or cap, continue to ***gently*** invert the bottle until the microparticles have been completely resuspended. | | 7 | Open the reagent bottles and **keep the caps in a designated bag**. (These used caps will be used to recap the reagents that must be discarded in hazardous waste containers). DO NOT USE THESE CAPS TO RECAP REAGENTS THAT ARE REMOVED FROM THE ANALYZER TO EXTEND THEIR STABILITY. ONLY USE THESE CAPS FOR RECAPPING HAZARDOUS WASTE. | | 8 | Remove any air bubbles with a clean applicator stick. | | 9 | Wear gloves to prevent contamination and obtain a septum. | | 10 | Carefully seat a septum onto the top of each bottle. Ensure that the reagent does not contaminate your gloves.   * Once a septum is placed on the bottle, do not invert the bottle. This will cause the liquid to spill. | |
| **Loading Reagents** | |  |  | | --- | --- | | 1 | Place the regent carrier on a work surface with the handle to the left | | 2 | Place the bottle with the yellow color band securely into the position with the yellow seat. Repeat for pink and green bottles. | | 3 | Ensure reagents are seated all the way on the carrier and that the reagent barcode is visible. | | 4 | The RSH must be in **RUNNING** status to load reagents. | | 5 | Verify the indicators below the desired section are off, which indicates the section is available. | | 6 | Load the reagent carrier into the section by pushing it in until the indicator illuminates.   * Once reagent(s) are placed on the RSH and the bar code reader scans the bar code label, the system links the individual bottles together as a kit. If the bottles are not kept together, the reagent status of “missing or extra bottle” displays. * Onboard stability is tracked after the reagent carrier is scanned by the bar code reader. Once the reagent carrier has been unloaded and removed from the RSH, the onboard stability tracker stops. This is why it is important to write the open date on the reagents. | |
| **Unloading Reagents** | |  |  | | --- | --- | | 1 | Select the **Refresh** button to display all records. | | 2 | Select the Page Scroll button and verify there are no scheduled tests for the reagent to be unloaded.   * If a reagent kit is unloaded, all scheduled tests for the reagent kit will go to exceptions. | | 3 | Select desired reagent kit(s) to be unloaded, and then select **F7 Unload**. The reagent carrier will be unloaded to an available section of the RSH. | | 4 | **Important**: For reagents that are removed to extend their onboard stability, use CLEAN, NEW green caps. Do not use previously used caps. Remove septum from Microparticle bottle, as the microparticles will need to be resuspended manually prior to reloading the reagent on the instrument for future use because the microparticles would get stuck in the septum and would cause changes to the reagent concentration. | | 5 | The following reagents must be disposed of in hazardous waste containers.  **The following reagents must be re-capped and placed in the Acid Flex Waste**   1. 2nd Generation Testosterone Assay Specific Diluent (pH 2.1) 2. PreTrigger Solution (pH 2.1)   **The following reagents must be re-capped and placed in the Caustic/Base Flex Waste**   1. B12 Pretreatment Reagent 1 (Contains NaOH) 2. Folate Pretreatment Reagent 1 (Contains KOH) 3. Trigger Solution (pH 13)   **The following reagents need to be re-capped and placed in the Micro Methanol Bin (Virology)**   1. Vitamin D Reagent Kit Pretreatment Reagents 1 & 2 (contains methanol)   All other reagents, if empty, can be placed in regular trash bins. | |
| **Emptying Solid Waste** | |  |  | | --- | --- | | 1 | Open the Supply and Waste Center door | | 2 | Disconnect the quick disconnect fitting on the liquid waste container, if present | | 3 | Grasp the handle and pull out the waste drawer | | 4 | Lift the solid waste container out of the drawer | | 5 | Remove the biohazard bag and discard its contents in a biohazard waste receptacle. | | 6 | Change the biohazard waste bag if it is visibly soiled. | | 7 | Replace the solid waste container and liquid waste container into the waste drawer and push the waste drawer back into place. | | 8 | Reconnect the quick disconnect fitting on the liquid waste container. | | 9 | Update Supply Status. (See procedure below) | |
| **Replenish RVs** | |  |  | | --- | --- | | 1 | Open the RV hopper cover | | 2 | Add RVs | | 3 | Close the RV hopper cover | | 4 | Update the Supply Status (See procedure below) | |
| **Prepare and Replenish Wash Buffer Solution** | |  |  | | --- | --- | | 1 | Invert the one liter concentrated wash buffer bottle several times to ensure a homogenous solution | | 2 | Start with a completely empty preparation container. Rinse one time with deionized water prior to reconsituting the wash buffer. | | 3 | ADD THE DI WATER FIRST TO AVOID FOAMING: Slowly add deionized water into the preparation container until the liquid reaches the black sharpie marker line. | | 3 | Pour the entire bottle of concentrated wash buffer into the preparation container containing deionized water. The final volume must be between the solid green lines. If the final volume is over the top solid green line, you MUST remake the wash buffer, or the system will not perform as it should due to dilute wash buffer. | | 4 | Open the supply waste center door | | 5 | Put the heavy metal end of the transfer tubing into the preparation container | | 6 | Attach the transfer tubing to the quick disconnect above the waste area. Make sure it snaps into place completely. | | 7 | Update the Supply Status. (See procedure below) | |
| **Replace Pre-Trigger/Trigger Solution** | |  |  | | --- | --- | | 1 | Open the supply and waste center door. | | 2 | Invert the bottle several times to ensure a homogenous solution. | | 3 | Slide the pre-trigger/trigger tray out. | | 4 | Move the bottle to be replaced to the bottle exchange position in the middle of the tray. | | 5 | Place the new bottle in the correct location in the tray. | | 6 | Remove the cap from the new bottle. | | 7 | Remove the level sensor and aspirating mechanism from the used bottle.. | | 8 | Place the level sensor into the new bottle with the arrow on the cap facing the front, so the aspirating mechanism is parallel to the sides of the bottle. | | 9 | Tighten the cap. | | 10 | Discard the used bottle. | | 11 | Slide in the pre-trigger/trigger tray. | | 12 | Update the Supply Status.(See procedure below) | |
| **Updating the Status Supply** | |  |  | | --- | --- | | **Updating Sample Supply** | | | 1 | From the Supply Status Screen Click **F2- Update Supplies** | | 2 | From the **Update Supplies** window, select appropriate check boxes next to solutions that were replaced, RVs added, and/or Waste emptied. | | 3 | Click **Done.**  If the Add buffer box was checked:   1. A message appears reminding you to verify the transfer tubing connection. Click **OK** once you hve verified the transfer tubing connection. The supply screen displays a wash buffer status of “**FILL IN PROGRESS.”**This will update once the fill is complete 2. Once the fill is complete, push the gray button to disconnect the wash transfer tubing. 3. Remove the tubing from the preparation container 4. Drain any liquid remaining in the transfer tubing into the sink 5. Dry the outside of the tubing with a clean, soft, lint-free tissue and then store tubing into clean, dry place. | | 4 | Click **F1-Exit** to return to the snapshot screen. Check that the status on the supply portion has also been updated to a status of OK. | |
| **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 ran 4. Click F2- Sample details to add patient information 5. Select F5- Assay Options- to specify assay options 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 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 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 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, sample carriers, or carrier trays 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. Architect i1000SR System Quick Reference Guide, Abbott Laboratories, Abbott Park, IL 60064. Revised May 2012 2. Architect i1000SR Operator’s Manual. Abbott Laboratories, Abbott Park, IL 60064. Revised 2016-04-29. 3. Abbott Architect Safety Data Sheet, Abbott Diganostics, Abbott Park, IL 60064. Revised 2016-04-09 4. BioRad Lyphochek Specialty Immunoassay Control Product Insert, Bio-Rad Laboratories, Irvine, CA 92618 Janurary 2018 5. BioRad Liquichek Specialty Immunoassay Control Product Insert, Bio-Rad Laboratories, Irvine, CA 92618 September 2017. 6. BioRad Lyphochek Immunoassay Plus Control Product Insert, Bio-Rad Laboratories, Irvine, CA 92618 May 2017. 7. BioRad Viroclear Control Product Insert, Bio-Rad Laboratories, Irvine, CA 92618 July 2017. 8. BioRad Virotrol I Control Product Insert, Bio-Rad Laboratories, Irvine, CA 92618 September 2013. 9. BioRad Virotrol II Control Product Insert, Bio-Rad Laboratories, Irvine, CA 92618 October 2017. 10. Abbott Architect HIV Ag/Ab Combo Controls, Abbott Diganostics, Abbott Park, IL 60064 January 2014. |
| Training Plan/Competency Assessment | Use [Abbott Architect Training Checklist](file:///G:\LAB\Chemistry\Abbott%20Architect\Training\Architect%20i1000%20Training%20Checklist.pdf) for initial employee training. Staff Ready will be used to perform Competency Assessments after initial training on the Abbott Architect. |
| **Historical Record** | |  |  |  |  | | --- | --- | --- | --- | | **Version** | **Written/Reviewed By** | **Effective Date** | **Summary of Revisions** | | 1 | Kelsi Brown/E. Bartos | 3/29/2018 | New Procedure | |  |  |  |  | |  |  |  |  | |