CHEM.ARCH.1.0 ARCHITECT SYSTEM OVERVIEW

STATEMENT OF PURPOSE

The Abbott Architect System is an open, fully automated clinical chemistry and immunoassay system allowing random and continuous access and priority processing.

SCOPE

The Architect System and all of the components is the scope of this procedure.

DOCUMENT OWNER

Manager, Regional Chemistry

RELATED DOCUMENTS

CHEM.ARCH.5.0	Architect ci Series System Calibration
CHEM.ARCH.6.0	Architect ci Series System Quality Control

SPECIMEN

Refer to individual Architect System assay procedures.

REAGENTS

Refer to individual Architect System assay procedures.

CALIBRATION

Refer to Architect *ci* Series System Calibration procedure, CHEM.ARCH.5.0.

QUALITY CONTROL

Refer to lab quality control policy and procedures.

PROCEDURE

A. System Overview

The ARCHITECT integrated system is a fully-automated clinical chemistry and immunoassay system consisting of a *c* System and an *i* System processing module that form a single workstation. Various models and instrument platforms are in operation at the different MACL laboratories. See Figure 1 of one model.

Figure 1: Primary components of integrated system

Legend:

Figure 1 ①. *System control center*, Computer system that provides user control of the processing module(s) and related components through a centralized interface. The computer may be located on a stand or inside the right-side cover of the *i* System processing module.

Figure 1 ②. *Processing module (c System)*, Diagnostic module that performs sample processing using potentiometric and photometric methods.

Figure 1 ③. *Processing modules (i System)*, Diagnostic module with priority processing capability that performs sample processing using the CMIA(chemiluminescent microparticle immunoassay) method.

Figure 1 ④. RSH - robotic sample handler: Transport module that presents samples to the processing module(s) for analysis and retesting.

B. System Control Center

The SCC (System Control Center) is a computer system that provides the software interface to the ARCHITECT System and can provide an interface to a host computer. From the SCC you can:

- Access the Operations Manual
- Configure the system
- Enter patient, control, and calibration orders
- Review patient results, control data, and calibration results
- Control the processing module(s) and the sample handler
- Perform system diagnostics and maintenance procedures
- Receive test orders and diagnostic data from a host computer
- Transfer test results to a host computer

Figure 2: Snapshot screen

1. Access Overview - Plan my day

The Plan my day feature will help you maximize the workflow of the ARCHITECT System in your laboratory. From one screen you can determine what actions to take, within a user-defined timeframe, in regards to the following statuses:

- Reagent inventory
- Calibrations
- Supplies inventory
- Maintenance

a. Access the Plan my day screen:

1) Select **Overview** from the menu bar, and then select **Plan my day**.

2) Enter the desired end time using the 24 hour clock and select update

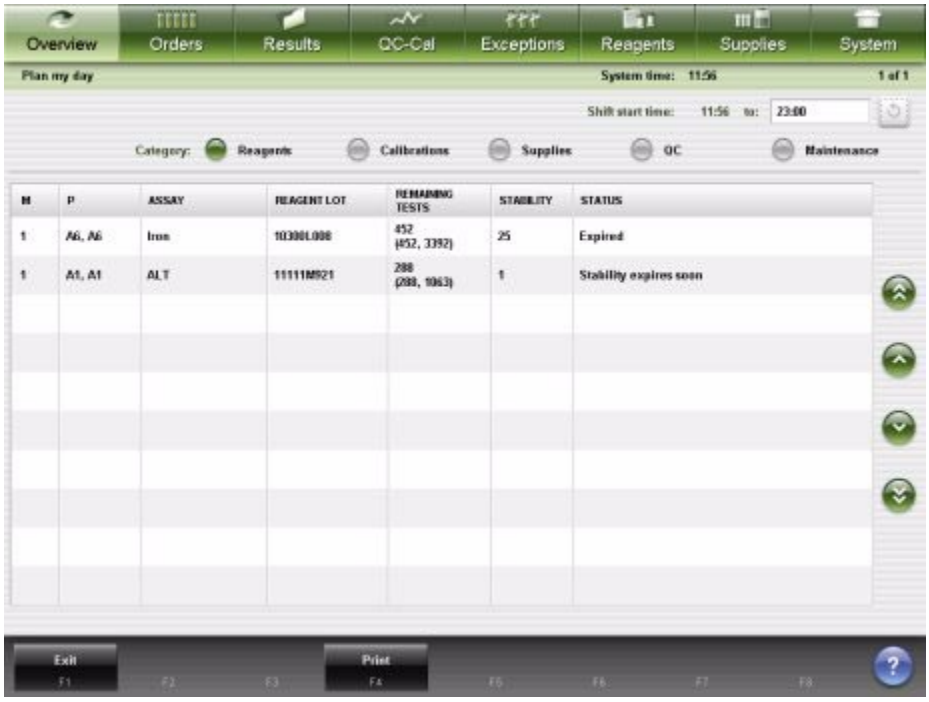
a) Reagent Inventory

From the reagents view of the Plan my day screen you can view:

- Module ID
- Reagent position(s)
- Assay name
- Reagent lot number
- Remaining reagent tests

- Remaining on-board stability
- Reagent status

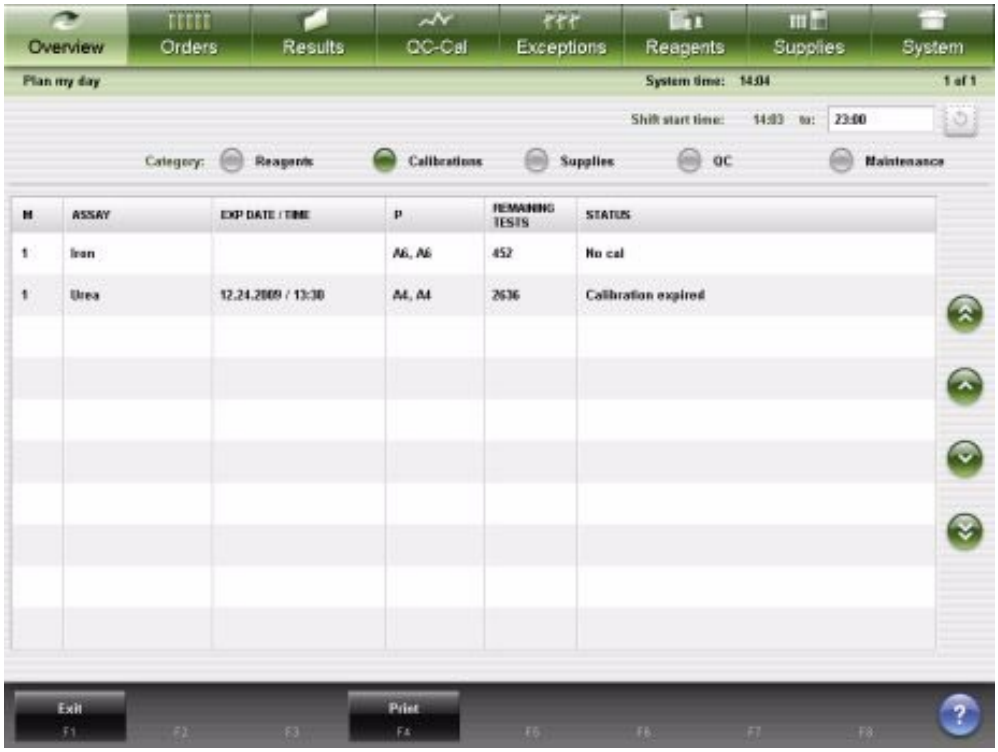
An ellipsis (...) displays when the system cannot display all data on a screen. View the printed report to see all data.



b) Calibrations

From the Calibrations view of the Plan my day screen you can view:

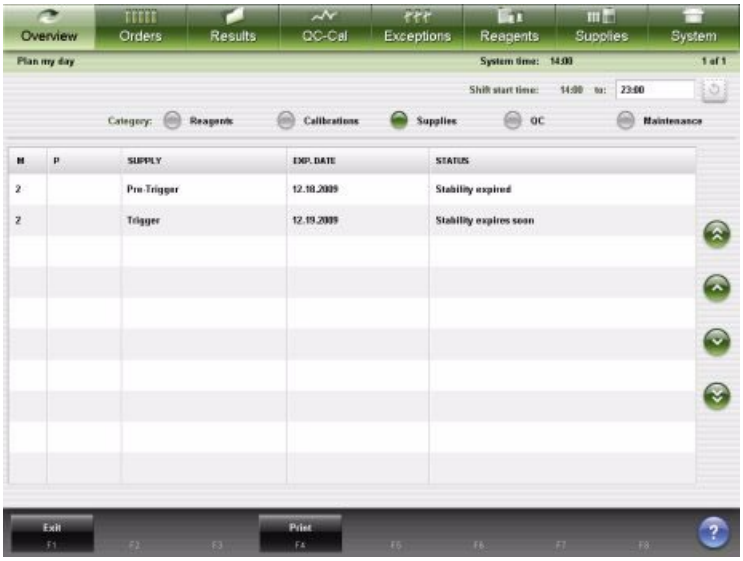
- Module ID
- Assay name
- Calibration expiration date and time
- Reagent position(s)
- Remaining reagent test counts
- Status description for assay calibration curves



c) Supplies

From the Supplies view of the Plan my day screen you can view:

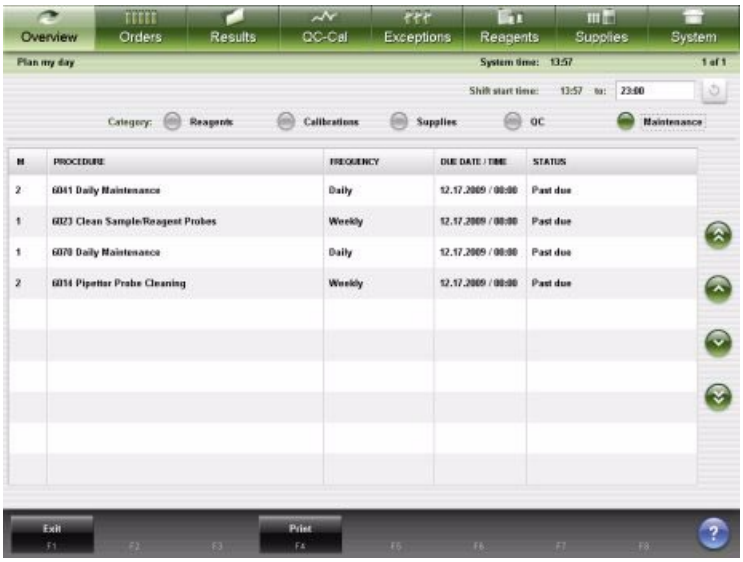
- Module ID
- On-board solution position(s)
- System Inventory Name
- System Inventory Status



d) Maintenance

From the Maintenance view of the Plan my day screen you can view:

- Module ID
- Procedure number and name
- Frequency
- Due date and time
- Maintenance Status



C. c System Processing Module

The c System processing module is a chemistry analyzer that performs sample processing. It processes photometric and potentiometric tests making use of reagents in a temperature-controlled reagent supply center. The sample handler configuration is the robotic sample handler, which automatically positions samples for retest.

Figure 3: c System Processing Module

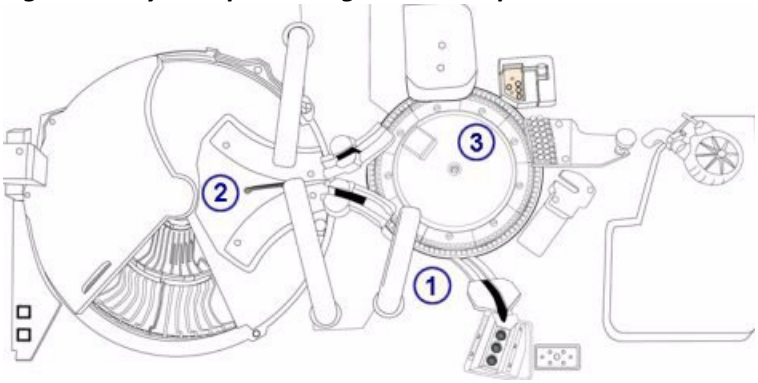
Legend:

Figure 3 ①. Front processing center cover: Provides access to the components that perform assay processing activities.

Figure 3 ②. Supply and pump center door: Provides access to bulk solution storage and pump center.

Figure 3 ③. Card cage door: Provides access to the card cage.

Figure 4: c System processing center components



Legend:

①. Sample hardware components: Provide sample aspiration and dispense.

②. Reagent hardware components: Provide reagent aspiration, dispense, and positive identification.

a. Adding reagent

b. If the module status is Scheduled pause, the button will illuminate when the reagent supply center becomes available. It may take up to five minutes after you pause the module for the reagent supply center to become available.

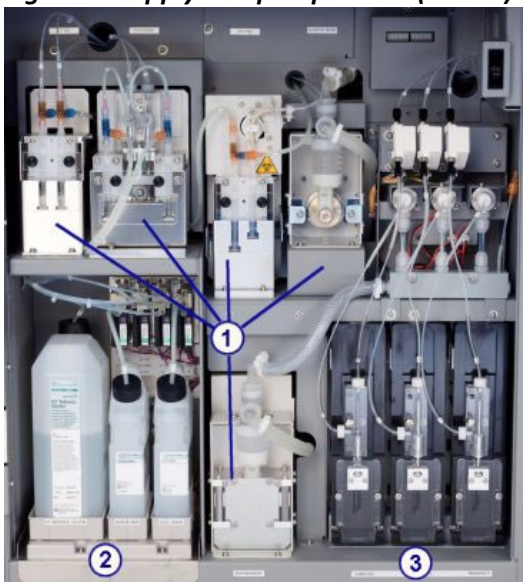
c. Reagents cannot be added while module is in running.

d. When done loading reagent, put module back in running and the module will scan the new bottles.

e. While supply door is open, you may remove any empty or expired reagent.

③. Reaction carousel hardware components: Position the cuvettes for sample and reagent dispense, mixing, photometric or potentiometric analysis, and cuvette washing.

Figure 5: Supply and pump center (c 4000)



Legend:

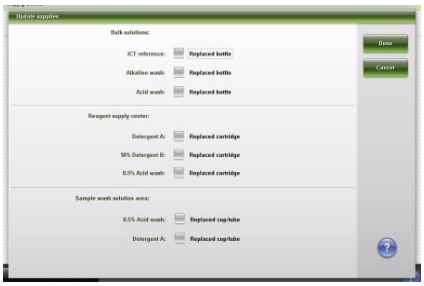
①. Pump center: Houses the processing module pumps.

②. Bulk solution supply center: Provides onboard storage for ICT Reference Solution, Alkaline Wash, and Acid Wash. Module must be in **Ready or Stopped** status to load bulk solutions.

③. Sample and reagent syringes area: Houses the sample and reagent syringes and drives.

a. Loading Bulk Solutions

Then update:



D. i System Processing Module

The I System is an immunoassay analyzer that performs sample processing. It processes CMIA (chemiluminescent microparticle immunoassay) tests using a one step 11 STAT protocol. It has the capability to load onboard reagent kits in a temperature-controlled reagent carousel and provides stat processing.

Figure 6: i 1000SR processing module (front view)

Legend:

①. Processing center cover: Provides access to the components that perform assay processing activities.

②. SCC articulated arm: Provides access to the SCC monitor, keyboard, and mouse.

③. Supply and waste center door: Provides access to the bulk storage and waste storage area.

④. Card cage and SCC center door: Provides access to the card cage and SCC

Figure 7: Supply and waste center (i 1000SR)

Legend:

Figure 7 ①. *Pre-trigger/trigger storage area (i 1000SR)* Provides onboard storage for Pre-Trigger Solution and Trigger Solution.

Figure 7 ②. *Wash buffer storage area (i 1000SR)* Provides onboard storage for the wash buffer.

Figure 7 ③. *Waste storage area (i 1000SR)* Provides storage for liquid and solid waste. (When on central plumbing bottle will not be present.)

a. Loading Bulk Supplies

To access the Supply status screen:
Snapshot screen, then select the **Supplies** button

RV's, Wash buffer, and waste can be updated while running but the Trigger and Pre-trigger can only be replaced while module is in a **Ready** or **Stopped** status.

Then update:

E. Loading Reagents

To prepare new reagent bottles:

1. Verify the required assay reagent components are present.
2. Verify the reagent component is within the expiration date on the bottle label. DO NOT use if the expiration date is exceeded.

3. Ensure the reagent bottles are not leaking.
4. Invert the microparticle bottle gently 30 times to resuspend microparticles that may have settled during shipment.
5. Inspect the bottle to ensure microparticles are resuspended. If microparticles still adhere to the bottle or cap, continue to invert the bottle until the microparticles have been completely resuspended.
6. Open the reagent bottle and discard the white cap.
7. Seat the septum on top of bottle.
8. Then snap bottles on reagent loader. (bottle color matches seat)

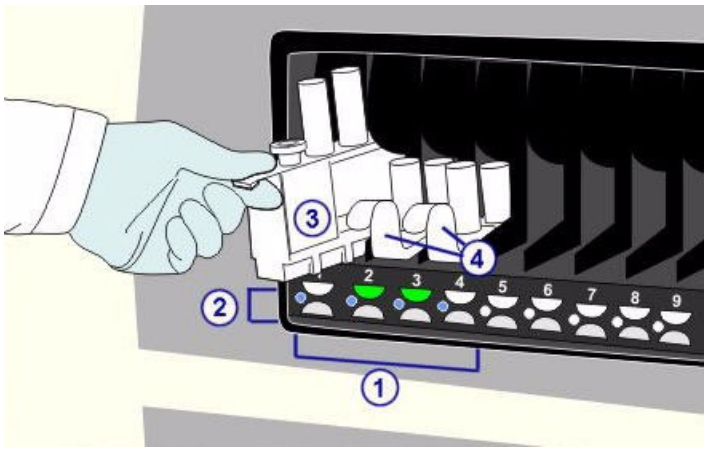
9. Load on I side of instrument. The RSH will pick up loader and store.
10. Reagents **can** be loaded while instrument is in **running**.

IMPORTANT: Do not mix reagent kit components from different reagent lots and do not pool.

F. Robotic Sample Handler (RSH)

The RSH (robotic sample handler) is a transport system used for loading calibrators, controls, and patient samples and presenting them to a *c* and/or *i* processing module. The design of the RSH allows random and continuous access, and sample positioning for automatic retesting. Two types of bays position samples for either routine or priority processing.

Figure 1.7



Legend:

① Priority sections:
- For sample carriers - positions samples for priority processing (blue light section)
- For reagent carriers (i 1000SR) - positions reagent carriers for loading the reagent carousel

② Status indicator: Indicates the status of sample processing and when you can access samples:
- Indicators off - no sample or reagent carriers are loaded in the section.
- Green (steady) - sample or reagent carriers are loaded, but processing has not begun. You can access the samples.
- Amber (steady) - sample or reagent carriers are processing and you cannot access them.
- Green (blinking) - processing is complete and you can access the sample or reagent carrier.

NOTE: If you add or rerun tests for a sample before it is unloaded, the indicator for the section changes back to amber while the sample is re-aspirated.

- Amber (blinking) - unloading a reagent carrier is in process so this section is unavailable for loading carriers.
- Amber and green (alternating) - bar code scan or other error occurred. You can access the carriers.

③ Sample carrier: Holds five primary tubes, aliquot tubes, or sample cups, which you may mix within a sample carrier.
- Specimens are processed faster when C and I side specimens are not loaded into the same carrier.

④ Reagent carrier (i 1000SR): Holds up to three reagent bottles. Two reagent carriers are required for assays that have more than three reagent bottles.

G. Operating Procedure

1. The instrument online Operations Manual is used for all Architect platforms. Select the information specific to the model of the on-site platform where applicable.
2. To access the Operations Manual:
   a. Select **Overview**.
   b. Select **Operations manual**.
3. Choose from the following tabs:
   a. **Contents** – displays all of the manual sections.
      i. See Section 5 for Operating Instructions.
      ii. See Section 6 for Calibration procedures.
   b. **Index** – displays in alphabetical order the contents of the operations manual.
      i. Scroll down to find a category
      or
      ii. Type in a keyword to find a specific category.
   c. **Search** – displays a search field.
   d. **Favorites** – displays all topics added as a Favorite.

REFERENCES

A. Operation Manuals, www.abbottdiagonostics.com/support/technical_library/operation_manuals, Abbott Laboratories, Inc., 2012.