

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

Overview	TTTTT Orders	Results	~~ 0C-Cal	FFF Exceptions	Reagents	III Supplies	System
Snapshet				100			
Ope	rator: ADMIN		Pate: 12.17.2009	,	Time: 10:41		
	Ready	1 .0000	Ready	2 200050	Ready	677 1935	435 1917
9998			CESS 0	PROC	BS 0	Renuns	Exceptions
		E REA	JENTS 16	F. PEAGE	NTS 21		521
		CAL	STATUS OK	TITT WA	ок	Printer	US
		1 LOU	о ок	Lin nom	ок	[- av]	
		was	пе ОК	U WAST	е ок	ARM	
						1 Updates	Sample find
.F1	Log an F2	Shudowa F3	Fr.	Statt-up 75	Step P	nuse R	. 3

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.

0	rerview	TITTI Orders	Results	~~~ 0C-Cal	fff Exceptions	Reagents	III Supplies	System
Plar	my day					System time: 1	1.56	1 of 1
						Shift start time:	11:56 to: 23:00	0
		Category: 🔴	Reagents 🥘	Calibrations	🔘 Supplie	e 🛞 oc		faintenance
н	p	ASSAY	REAGENTLOT	REMAINING	STABLITY	STATUS		
1	A6, A6	Iron	103001.008	452 (452, 3392)	25	Expired		
1	A1, A1	ALT	11111M921	288 (288, 1063)	۱	Stability expires soo		8
								0
								0
								0
	Exit F1	F2.	ra (700)	Print F4	16)	16	F1	2

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



OV	erview	TITTT Orders	Results	~~ 0C-Cal	Př Excep	f tions	Reagents	III E Suppl	ies	System
Plan	my day						System time:	14.04		1 of 1
							Shift start time:	14:03 to:	23:00	0
		Category: 🛞	Reagents	Calibration	· @ \$	applies	i i i i i i i i i i i i i i i i i i i		🛞 Nai	ntenance
н	ASSAY	1907 1	ATE / TIME	р	REMAINING TESTS	STATUS	i.			
6	Iran			A6, A6	452	No cal				
	Urea	12.24	.2009 / 13:30	м, м	2636	Calibra	fian expired			8
										0
										0
	Exit			Print			_	-		9
			63	FA						

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

OV	rerview	TITTI Orders	Results	~~~ ls⊃-⊃Ω	FFF Exceptions	Reagents	III E Supplies	System
Plan	my day					System time:	14.00	1 af 1
						Shift start time:	14:00 to: 23:4	0
		Category: 🔘	Reagents	Celibrations	🔵 Supplier	• 🛞 oc	Θ	Maintenance
н	p	SUPPLY		ENP. DATE	STA	rus		
2		Pre-Trigger		12.18,2009	Stab	ility expired		
2		Trigger		12.19.2009	Stal	illity expires soon		0
								0
								9
								Θ
-	Exit			Print	-	-	-	2
	- 51	168	8	F£	36	16	<i>B</i>	FR 🔍



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

Ove	rview	Orders	Results	QC-Cel	FFF Exceptions	Reagen	its Sup	pies	System
Plan r	ny day					System tin	ne: 13:57		1 of 1
		100 ¹⁷ 1000		192 - 55 I III - 5 I II		Shift start tie	ne: 13:57 0	23:00	0
		Category: 🛞	Reagents	Calibrations	Supplies	0	oc		faintenance
	PROCEDU	u.		IREQUENCY	r DUED	ATE I TIME	STATUS		
6	6041 Daily	y Maintenance		Daily	12.17	2009 / 00:00	Past due		
È.	6023 Clea	n Sample Reagent	Probes	Weekly	12.17	2009 / 00:00	Past due		6
8.3	6070 Daily	y Naintenance		Daily	12.17	2009 / 08:00	Past due		-
	6014 Pipe	ttar Prabe Cleaning	ı.	Woekly	12.17	2009 / 00:00	Past due		6
									6
									6

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.







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

- Sample hardware components: Provide sample aspiration and dispense.
 Reagent hardware components: Provide reagent aspiration, dispense, and positive identification.
 - a. Adding reagent





- 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

Overview	TTTTT Orders	Results	~~~ 0C-Cal	FFF Exceptions	Reagents	Supplies	System
apply Status							
Module) z					
ICT reference			Reagent supply	center		Sample wash solution	0.85
-		A1 - Deterge	ant A		1	0.5% Acid wash	
Alkaline was	J 100%/2000 mL	A2 - 10% Det	100% / 90 est orgent B			ОК	
	J 1005/500 mL	A) - 0.5% Ac	100%/90 ml		2	Detergent A	
Acid wash							
	<] 100%/500 mL		**				
Exit	Update supplies			11.	112		6

Then update:

- Uptive supplies		
Balk salutions:		
ICT reference:	Replaced bottle	Dime
Alkaline wash:	Feplaced bottle	Cancel
Actid wash:	Feplaced bottle	
Reagent supply center:		
Detergent A:	Explaced cartridge	
19% Detergent B:	📃 Replaced cartridge	
0.5% Acid worsh:	Replaced cartridge	
Sample worth solution area:		
8.5% Acid wash:	Explaced cap/lake	
Datargant A:	Replaced cup take	

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.







Legend:

- 1. Processing center cover: Provides access to the components that perform assay processing activities.
- SCC articulated arm: Provides access to the SCC monitor, keyboard, and mouse.
- **2**. **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

Overview	TTTTT Orders	Results	~~~ 0C-Cal	FFF Exceptions	Reagents	Supplies	System
Supply status		.					
Module							
Selid was	Ti Valu	ne cemaining 1000		Wash huffer	Mahanaa	an afailan - 35 Unor	
		% comaining: 100 %			1	emaining: 100 %	
				Trigger			
					Volume e	emaining: 975 mL	
					1	emaining: 100 % Stability: 28 day	•
RVs remi	aining: 1200			Pre-Trigger			
1111	TATIAT		111	- i	Volume n	emaining: 975 ml.	
D			1200		1	emaining: 100 % Stability: 28 day	x
E-IN	Hadato susalias	_	_	_	_	_	6
F1	F2						C

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:

1	Solid waste:	Emptied solid waste	Date
	Liquid waste:	Emptied liquid waste	Cancel
	RVs added:	Filled hopper	
	Wash huffer:	Add buffer	1
	Trigger:	Replaced bottle	
-	Pre-Trigger:	Replaced hotle	2

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.





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.



A 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

a.

- 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:
 - **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, <u>www.abbottdiagonostics.com/support/technical_library/operation_manuals</u>, Abbott Laboratories, Inc., 2012.