



**ABBOTT HEALTHCARE PVT.LTD.**

*Page  
9 of 15*

*INSTALLATION / OPERATIONAL/PERFORMANCE QUALIFICATION*

*Document No.:*

*IQ/OQ/PQ/ ABBOTT ARCHITECT i1000SR*


*Revision No.:*

*01*

*Equipment ID:*

*i1SR65336*

## Operational Qualification

 <b>Abbott</b> A Promise for Life	<b>ABBOTT HEALTHCARE PVT.LTD.</b>		<i>Page</i> <b>10 of 15</b>
	<i>INSTALLATION / OPERATIONAL/PERFORMANCE QUALIFICATION</i>		
<i>Document No.:</i>	<i>IQ/OQ/PQ/ ABBOTT ARCHITECT i1000SR</i>	<i>Revision No.:</i>	<b>01</b>
<i>Equipment ID:</i>	<i>i1SR65336</i>		


Purpose: To have complete certification on Operational Qualification for Architect i1000SR

Scope & Criteria.

- Start up Procedure
- Instrument Calibration Check

Startup Procedure

1. Power on the Main Power Switch
2. Switch on the CPU and wait until the Snap shot screen appear in the screen as "OFFLINE "
3. Switch on the Instrument and wait till the screen changes from "OFFLINE " to "STOPPED"
4. Select the RSH module and Module 1 and give startup
5. Wait until the snap short changes to "READY" then bring the system to "Running "Mode
6. Load the Reagents and then the samples to perform the test.

 <b>Abbott</b> A Promise for Life	<b>ABBOTT HEALTHCARE PVT.LTD.</b>		<i>Page</i> <b>11 of 15</b>
	<i>INSTALLATION / OPERATIONAL/PERFORMANCE QUALIFICATION</i>		
<i>Document No.:</i>	<i>IQ/OQ/PQ/ ABBOTT ARCHITECT i1000SR</i>	<i>Revision No.:</i>	<b>01</b>
<i>Equipment ID:</i>	<i>i1SR65336</i>		

Comments: Checked the startup procedure and found ok

Scope : To check the instrument calibration performance.

1.Wash Cup Pre-alignment

To set the pipettor probe position at the wash cup required for flushing the system. This procedure is used during i1000SR installation.

Commend : Passed

2. Pipettor Calibration

Pipettor probe positioning is set for all positions required for aspirating and dispensing specimens and reagents during processing. Probe straightness is determined.

Commend : Passed


3. Carrier Transport Calibration

To align the carrier transport to the reagent carousel latch actuator and a sample carrier to the load/unload area.

Commend : Passed

4.WZ Aspiration Test

Wash zone aspiration is tested during this procedure. The wash zone dispenses and aspirates buffer from 14 RVs. The operator is instructed to remove the RVs and determine if the RV is half full of buffer. Wash zone aspiration is tested during this procedure. The wash zone dispenses and aspirates buffer from 14 RVs. The operator is instructed to remove the RVs and determine if the RV is half full of buffer.

 <b>Abbott</b> <small>A Promise for Life</small>	<b>ABBOTT HEALTHCARE PVT.LTD.</b>		<i>Page</i>
	<i>INSTALLATION / OPERATIONAL/PERFORMANCE QUALIFICATION</i>		<i>12 of 15</i>
<i>Document No.:</i>	<i>IQ/OQ/PQ/ ABBOTT ARCHITECT i1000SR</i>	<i>Revision No.:</i>	<i>01</i>
<i>Equipment ID:</i>	<i>i1SR65336</i>		

Commend : Passed

5.1022 Optics Background

Three background readings are taken during this procedure. One with no RV in position, the second with an empty RV and the third with Pre-Trigger solution in the RV. Normalization and linearity parameters are not used during this procedure. Raw counts must be between 3 RLU - 500 RLU.

Commend : Passed

6.Optics Verification


To verify the optics CMIA reader is working as expected. Normalization and linearity factors are verified by taking five reads from the three levels of optics normalization solution and comparing the reads to the standard. The three reads taken are 376, 1,504, and 94,000 attomoles. Background levels are also verified.

Comments : Passed

7.Residual Volume

Fifteen numbered and weighed RVs are loaded by the user during this procedure. Wash Buffer is dispensed into then aspirated out of the RVs. After aspiration the user removes and reweighs the RVs to determine residual volume. The difference between the weights for each RV is determined. This average difference should be <9 µL (mg) and a S.D. <2 µL (mg).



Commend : Passed

 <b>Abbott</b> A Promise for Life	<b>ABBOTT HEALTHCARE PVT.LTD.</b>		<i>Page</i> <b>13 of 15</b>
	<b>INSTALLATION / OPERATIONAL/PERFORMANCE QUALIFICATION</b>		
<i>Document No.:</i>	<b>IQ/OQ/PQ/ ABBOTT ARCHITECT i1000SR</b>	<i>Revision No.:</i>	<b>01</b>
<i>Equipment ID:</i>	<b>i1SR65336</b>		

8. Visual inspection: (No special tools required)

The fluid remaining in the RVs may be used as a qualitative visual indication of Wash Zone function. The final RV should have approximately 2 drops in the bottom and no evidence of splashing in the RV.

Commend : Passed

Performed by	Signature	Date
Arun Kuriakose Technical Service Specialist		24/11/2021
Medical Trust Hospital	Signature  Dr. Deepa	Date 24/11/2021



**ABBOTT HEALTHCARE PVT.LTD.**

*Page  
14 of 15*

*INSTALLATION / OPERATIONAL/PERFORMANCE QUALIFICATION*

*Document No.:*

*IQ/OQ/PQ/ ABBOTT ARCHITECT i1000SR*


*Revision No.:*

*01*

*Equipment ID:*

*i1SR65336*

## Instrument Verification Test

 <b>Abbott</b> A Promise for Life	<b>ABBOTT HEALTHCARE PVT.LTD.</b>		<i>Page</i>
	<i>INSTALLATION / OPERATIONAL/PERFORMANCE QUALIFICATION</i>		<i>15 of 15</i>
<i>Document No.:</i>	<i>IQ/OQ/PQ/ ABBOTT ARCHITECT i1000SR</i>	<i>Revision No.:</i>	<i>01</i>
<i>Equipment ID:</i>	<i>i1SR65336</i>		

Purpose: To have complete certification on Instrument Verification Test for Architect i1000SR

1.Scope: To Calibrate TSH Assay and Check for Precision and

1. Ordered the TSH Assay from the order list
2. Ran the Assays and the calibration got passed and RLU value are within the limits

Comments: Assays Passed

2. Scope: To check Precision of the instrument with TSH Assay

Comments: Precision are with in the manufacture limits

Performed by	Signature	Date
Arun Kuriakose Technical Service Specialist		24-11-2021
Medical Trust Hospital	Signature 	Date 24/11/2021