		INS	STALLATION R	EPORT	REPORT NO.: 24112021
	ABBOTT HEALTHCAP DIAGNOSTICS DIVISION	RE (P) LTD ON			
G Block, E	Floor 13-19, Bandra Kurla Comple	lealthcare Pvt. L Godrej BKC, Plo ex Near MCA Clu 00051. India			×
				MODEL:	Architect i1000Sr
	Medica	al Trust Hospit	al	SERIAL NUMBER:	I1SR65336
WORK STAR	TED	WORK ENDE	D	INSTALLATION DEGLIS	DEMENT CHECK
WORK STAK		WORK ENDE	D	INSTALLATION REQUIR UPS/REQUIRED VOLTA	
D/	23-11-21	DATE:	24-11-21	EARTHING VOLTAGE:	0.30v
TIME:	9:00am	TIME:	5:00pm	SPACE AVAILABILITY AS PER SPECS: YES ■ NO □ ROOM TEMP AS PER SPECS : YES ■ NO □	
CUSTOMER TRAINING CARRIED OUT ON : NA  Carried out HW & SW installation , Calibrated the system , performed Biological Standardization, Found results to be within limits			system , performed	ASSAY CALIBRATED TSH	
CUSTOMER F	REMARK			COMMENT:	
CUSTOMER S	SIGN :	Day	Deeper Juda	AF.S.E'S NAME: Arun Kur SIGN:	riakosa

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- ALL -44	ABBOTT HEALTHCARE PVT.LTD.		
Abbott A Promise for Life	INSTALLATION / OPERATIONAL/PERFORMANCE QUALIFICATION		14 of 16
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Equipment ID:	I1SR65336	Revision No.:	01

## Performance Qualification

<b>—</b> All.	ABBOTT HEALTHCARE PVT.LTD.		
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Equipment ID:	I1SR65336	Revision No.:	01

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

Performance qualification validates the test procedure performed on the new instrument. Performance qualification not only validates instrument performance but also test procedure.

All in-house protocols are validated for performance qualification of instrument and method.

1.Scope: To Calibrate HIV, Anti-HCV, HBsAgQ2 Assay.

- 1) Ordered the HIV, Anti-HCV, HBsAgQ2 Assay from the order list.
- 2) Ran the Assays and the calibration got passed and RLU value are within the limits.
- 3) IQC performed and recovery found satisfactory.

Comments: Assays Passed /Failed.

- 2. Scope: To check Precision of the instrument with HIV, Anti-HCV, HBsAgQ2 Assay
  - 1) Run Precision and the Result are attached along with the PQ.

Comments: Precision study: Passed / Failed

3.Scope: To perform the carry over study for HIV, Anti-HCV, HBsAgQ2 Assay

1) Carryover study performed, and the Result are attached along with the PQ

Comments: Carryover study: Passed / Failed

- Abbett	ABBOTT HEALTHCARE PVT.LTD.		
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4. Scope: To perform the Method Comparison study for HIV, Anti-HCV, HBsAgQ2 Assay

1) Method comparison study study performed, and the Result are attached along with the PQ

Comments: Method Comparison: Passed / Failed

Performed by	Signature	Date
Jithin Preetha Lead-TechnicalApplication Specialist	JITHIA PREETINA	04/12/2021
	Signature	Date
Medical Trust Hospital, Cochin Microbiology Department	Aust	4/12/21