

Abbott (Diagnostics Division)

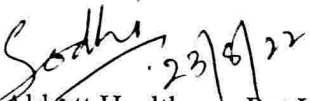
405, KORTI SHIKHAR BUILDING,
JANAKPURI DISTT. CENTRE,
NEW DELHI - 110 058
TEL : +91 11 25619194 FAX: +91 11 25613392

Dated- 14th March 2021

Certificate of Calibration

This is to certify that the below mentioned instrument installed in Biochemistry Diagnostic laboratory GMC Srinagar, associated S.M.H.S Hospital has been calibrated by us on 23th August 2022. The next calibration is due on or before 22nd August 2023. The values are falling within the specified range.

Instrument Model- **Architect Plus C4000**
Serial No. C462208
Software Version – **9.4**


For Abbott Healthcare Pvt Ltd

Bonibir Singh
Customer Support Engineer
Abbott Diagnostics Division

**INSTALLATION QUALIFICATION
OPERATIONAL QUALIFICATION**

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PERFORMANCE QUALIFICATION

For the instrument Architect Plus

Model c4000

Serial No. C462206


VALIDATION REPORT

Equipment Name : Bio-chemistry Analyzer
:
Equipment Make : Architect Plus
Equipment Model No. : C4000SR
Equipment Serial No. : C462208
Supplier : Abbott Healthcare Pvt. Ltd.
Contact Name & Address : Abbott Diagnostics Pvt. Ltd.
405, Kirti Shikhar Bldg.
Janakpuri Distt. Centre,
New Delhi – 110 058.

I. Approval of IQ / OQ / PQ Procedure

Both S.M.H.S Hospital (GMC) Srinagar and Abbott Diagnostics Pvt. Ltd. are jointly responsible for the Installation of Architect Plus Vide Serial No. c462208 in the SMHS Hospital, Srinagar J&K.

Validation Team from Vendor

Name : Bonibir Singh
Designation : Technical Service Specialist.
Signature : 
Date : 31/08/2021
Company : Abbott Healthcare Pvt. Ltd.

Validation Team from LAB

Name :
Designation :
Signature :
Date : 31/08/2021
Department : LAB

Customer Authorization

Name :
Designation :
Signature :
Date : 31/08/2021
Site : Srinagar

II. Instructions

1. This document is to be completed at the time the system installation to its current location and setup for operation.
2. An authorized (Company) representative will check the system and enter the specific data related to installation, operation and performance qualification.
3. Employees of (Customer) will verify each result and sign the results. The member of the validation will carry this out.
4. All deviation from the normal specification to include any problems with installation will be noted under COMMENTS.

III. Scope

This Installation Qualification protocol is performed on the Architect Plus c4000 vide Serial No.c462208 in the G.M.C Srinagar..

This Protocol defines the documentation that is used to evaluate the instrument installation in accordance with the manufacturer's specification and intended use.

Successful completion of this protocol verifies that this instrument has been installed, operated in accordance with the intended usage.

Installation checks are performed to verify that the instrument has been installed with proper connection and utilities.

Operational qualifications will evaluate that the instrument have operational features available for the successful operation of instrument in accordance with the manufacturer's specifications.

Performance qualification will verify the actual functioning or performance of instrument.

IV. Equipment Description

Sr. No.	Instrument Identification		Verified by	Date
1	Equipment Name	Architect Plus	Bonibir Singh	31/08/2021
2	Model	C4000	Bonibir Singh	31/08/2021
3	Equipment ID	C4000	Bonibir Singh	31/08/2021
If two or more instruments of the same category are available, the first three characters of the ID should be same with different serial no. For ex. DEF01, DEF02.				
4	Serial No	C462208	Bonibir Singh	31/08/2021
5	Power	3 KVA	Bonibir Singh	31/08/2021

V. Utilities

Sr. No.	Instrument Identification		Verified by	Date
1	Environment Condition			
2	Free from Dust, electrical & Magnetic Interference	Yes	Bonibir Singh	31/08/2021
3	Temperature	23°C	Bonibir Singh	31/08/2021
4	Humidity		Bonibir Singh	31/08/2021
5	Adequate Space for installation	Yes	Bonibir Singh	31/08/2021
6	Electrical Outlets		Bonibir Singh	31/08/2021
7	Actual Voltage on site	230 V	Bonibir Singh	31/08/2021
8	Grounding	< 2V	Bonibir Singh	31/08/2021
9	Connected through UPS	Yes	Bonibir Singh	31/08/2021
10	Stabilizer	----N / A----		

IX. Operational Qualification

Following features / functions are available in the instrument as per manufacturer's specification and verified for ex. Self-Test, Washer Assays, Quality Control, Test Assay, Maintenance Checks.

Sr. No.	Description	Test Purpose	Verified by	Date
1	Self-Test / Diluent Test	System Performance	Bonibir Singh	31/08/2021
2	Quality Control	System Performance	Bonibir Singh	31/08/2021
3	Maintenance	Daily, weekly & Monthly	Bonibir Singh	31/08/2021
4	Calibration Feature	Yes	Bonibir Singh	31/08/2021
5	Test Assay	Biochemistry	Bonibir Singh	31/08/2021
6	Interfacing Facility	Bi-Directional	Bonibir Singh	31/08/2021
7	Any Other Assay	---N/A----		

X. Performance Qualification

Performance qualification validates the test procedure performed on the new instrument.

Performance qualification not only validates instrument performance but also test procedure.

Following are the steps required to validate your instrument and method.

1. Run all levels of QC sample and verify the values with acceptable range given in the insert of Quality Control Samples.
2. Run Five samples on new instrument and cross verify the results with other validated instruments or other reference Lab having validated instruments.
3. Run any one sample for one parameter ten times and check for the precision.

QC Results - Pass

Cross Verification Result - Pass

Precision Check - Pass


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31/05/2022



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Validation Procedure Performed by (Vendor)

Name : Bonibir Singh
Designation : Technical Service Specialist.
Signature : 
Date : 31/08/2021
Company : Abbott Healthcare Pvt. Ltd.

Validation Procedure performed by LAB

Name :
Designation :
Signature :
Date : 31/08/2021
Department : LAB

Validation Procedure Reviewed by LAB

Name :
Designation :
Signature :
Date : 31/08/2021