

400, 14711 SHAFTAR BUILDING, JANAKPURI DISTT CENTRE, NEW DELHI - 110 CSS TEL : +31 11 25613134 FAX: +31 11 25613332

Dated- 14<sup>th</sup> 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 23<sup>th</sup> August 2022. The next calibration is due on or before 22<sup>nd</sup> 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 Put I td

Bonibir Singh Customer Support Engineer Abbott Diagnostics Division

Abbott (Diagnostics Division)	5	SERVICE REPOR
405, KIRTI SHIKHAR BUILDING, UANAKPURI DISTIT CENTRE, NEW DELHI-110 058 JEL -130 FF 05819194, HAW 190 FF 05813392 MOB	REI	PORT NO
WARRANTY CONTRACT CHA	ARGE RAP	OTHERS (
CUSTOMER NAME AND ADDRESS  Biochemistry Diagnostic laboratory GMC  Srinagar, associated SMHS hospital	CALL STARTED	MODEL
Jammu & Kashmir	DATE: 21-08-2022 TIME: 10;00 am	C4000
SERVICE REQUESTED BY :	CALL FINISHED	SERIAL NUMBER
Mr. Javed Ji	DATE: 21-08-2022 TIME: 03:00 pm	C462206
PROBLEM:	OBSERVATIONS:	
PM need to be done		
SOLUTIONS:  Done the PM according to procedure  Calibrated the whole system.  Run QC, Daily maintenance, Weekly maintenance	nce.	
Machine is operational for further		

	- Y				FOR BIL	LING
PART NO	DESCRIPTION	D.C. NO.	QTY	REMARK	UNIT PRICE	VALU
	PM Kit		01			
					LABOUR	
STOMER'S RE					TOTAL	

TAMERSIGN AND STAMPS

Department

Department

Govt. Medical College

Total

Tot

ENGINEER'S SIGN



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

# INSTALLATION QUALIFICATION OPERATIONAL QUALIFICATION

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# PERFORMANCE QUALIFICATION

For the instrument Architect Plus

Model c4000

Serial No. C462206



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# 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.



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#### 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

: Godh

Date

: 31/08/2021

Company

: Abbott Healthcare Pvt. Ltd.

#### Validation Team from LAB

Name

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Designation

:

Signature

:

Date

31/08/2021

Department

LAB

#### **Customer Authorization**

Name

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Designation

:

Signature

:

Date

: 31/08/2021

Site

: Srinagar



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#### 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.



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### 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 i	more instruments of the same category are a same with different serial r		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	- Singn	31/30/2021



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# VI. List of Manuals and Certificates

Supplier provides the following with the instrument

No.	Description	Qty.
- 1	Operating Manual (Soft Copy)	Available – Yes
2	Purchase order (Reagent Rental Agreement)	Available – Yes Available – Yes
	Calibration Certificate	Available – Yes
5	Safety Instructions (Soft Copy)	Available

## VII. Installation Procedure

a) Installation of Hardware and Software

	allation of Hardware and Software  Description	Date	Remark
Sr. No.		31/08/2021	Done
1	Carrier Transport Calibration		Done
2	Pipettor Calibration	31/08/2021	
3	Crash Sensor Test	31/08/2021	Done
3		31/08/2021	Done
4	Sample Pipettor Calibration	31/08/2021	Done
5	R1 Pipettor Calibration	31/08/2021	Done
6	R2 Pipettor Calibration	31/08/2021	Done
7	Change water bath	31/08/2021	Done
8	Temperature Status	31/08/2021	Done
09	Flush Water Lines		Done
10	Bar Code Calibration	31/08/2021	
11	Pressure Monitoring Test	31/08/2021	Done
		31/08/2021	Done
12	LLS Test		Done
13	Optics Background	31/08/2021	Done



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# 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
<del></del>	Self-Test / Diluent Test	System Performance	Bonibir Singh	31/08/2021
2	Quality Control	System Performance	Bonibir Singh	31/08/2021
	Maintenance	Daily, weekly & Monthly	Bonibir Singh	31/08/2021
4	Calibration Feature	Yes	Bonibir Singh	31/08/2021
	Test Assay	Biochemistry	Bonibir Singh	31/08/2021
6	Interfacing Facility	Bi-Directional	Bonibir Singh	31/08/2021
<del></del>	Any Other Assay	N/A		



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# 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.

- Run all levels of QC sample and verify the values with acceptable range given in the insert of Quality Control Samples.
- 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

Send (05/202)



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# Validation Procedure Performed by (Vendor)

Name

: Bonibir Singh

Designation

: Technical Service Specialist.

Signature

: 50 // -

Date

: 31/08/2021

Company

: Abbott Healthcare Pvt. Ltd.

#### Validation Procedure performed by LAB

Name

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Designation

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Signature

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Date

: 31/08/2021

Department

: LAB

#### Validation Procedure Reviewed by LAB

Name

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Designation

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Signature

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Date

: 31/08/2021