FUJIFILM

INSTALLATION QUALIFICATION

OPERATIONAL QUALIFICATION

&

PERFORMANCE QUALIFICATION

For the Instrument FUJI DRI CHEMISTRY ANALYZER

Model: FDC NX 600i

Serial No.: 16621187

FUJIFILM INDIA PRIVATE LIMITED
Registered Office : C -1/114, Ground Floor, Janak Puri. New Delhi - 110058. Tel : +91-11-45509780 Telfax : +91-11-45793281

Vatika Business Park, 7th Floor, Block - One, Sohna Road, Sector - 49. Gurgaon - 122001, Haryana.
Telephone : +91-124-4325500, Fascimile : +91-124-4325555, E-mail : contact@fujifilmindia.com

FUJIFILM

VALIDATION REPORT

Equipment Name : Biochemistry Analyzer

Equipment Make : Fuji DRI-CHEM

Equipment Model No. : FDC NX 600i

Equipment Serial No. : **16621187**

Manufacturer : FUJIFILM

Supplier : Fujifilm India Pvt. Ltd

Contact Name & Address : Fujifilm India Pvt. Ltd

Unitech Cyber Park,

8th Floor, Unit No. 801-807,

Tower C, Sec-39,

Gurugram, Haryana-122001.

FUJIFILM

I. Approval of IQ/OQ Procedure

Both Atrea Healthcare., Bangalore and Fujifilm India Pvt. Ltd. are jointly responsible for the Installation of FDC NX 600i Serial No. 16621187 in the Biochemistry Laboratory.

Validation Team From Vendor

Name	**:**	**Mr. Sandeep**
Designation	**:**	Service Engineer
Signature	**:**	
Date	**:**	**03/01/2022**
Company	:	Fujifilm India Pvt. Ltd

Validation Team From Clinical Lab

Name	**:**	**Mr. K. Sanjay**
Designation	**:**	Lab incharge
Signature	**:**	
Date	**:**	**03/01/2022**
Department	**:**	Atrea Healthcare., Bangalore.

Customer Authorization

Name	**:**	**Dr. Deepak M Nadig**
Designation	**:**	Pathologist
Signature	**:**	
Date	**:**	**03/01/2022**
Company	**:**	Atrea Healthcare., Bangalore.

FUJIFILM

II. Instructions

1. This document is to be completed at the time the system is shifted to its current location (Clinical Laboratory) and setup for operation.

2. An authorized (Company) representative will check the entire system and enter specific data related to installation, operation and performance qualification.

3. Employees of (Customer) Clincial Laboratory will verify each result and sign the results. The member of Validation will carry this out.

4. All deviation from the normal specification to include any problems with installations will be noted under COMMENTS.

5. A Competent Authority (Customer) will supervise the the entire procedure and procvide the necessary Authorization of the procedure.

FUJIFILM INDIA PRIVATE LIMITED
Registered Office : C -1/114, Ground Floor, Janak Puri. New Delhi - 110058. Tel : +91-11-45509780 Telfax : +91-11-45793281

Vatika Business Park, 7th Floor, Block - One, Sohna Road, Sector - 49. Gurgaon - 122001, Haryana.
Telephone : +91-124-4325500, Fascimile : +91-124-4325555, E-mail : contact@fujifilmindia.com

FUJIFILM

III. Scope

This Installation Qualification Protocol is performed on the Fuji Dri Chem FDC NX 600i vide Serial No.16621187 located at Biochemistry Laboratory of Atrea Healthcare., Bangalore.

This Protocol defines the documentation that is used to evaluate the instrument installtaion 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 qualifiaction will verify the actual functioning or performance of instrument.

IV. Certificate of Purchase Order Compliance

I certify to the best of my knowledge. The instrument Fuji Dri Chem FDC NX 600i vide Serial No 16621187 installed on 03/01/2022 is in compliance with the specification of the purchase order.

FUJIFILM

V. Equipment Description

Sr. No.	Instrument Identification		Verified by	Date
1	Equipment Name	**Fuji Dri Chem**	Sandeep	03 JAN'2022
2	Model	**FDC NX 600i**	Sandeep	03 JAN'2022
3	Equipment ID.	**---**	Sandeep	03 JAN'2022
4	Serial No.	**16621187**	Sandeep	03 JAN'2022
5	Power, Voltage Limit	**200VA, 100 – 240 V**	Sandeep	03 JAN'2022
6	Electromagnetic Compatibility	**Class A (Confers to Part 15 of the FCC Rules)**	Sandeep	03 JAN'2022

VI. Utilities

Sr. No.	Instrument Identification		Verified by	Date
1	Environemnt Condition		Sandeep	03 JAN'2022
	Free from Dust, electrical & Magnetic Interference	**Yes**	Sandeep	03 JAN'2022
	Temperature	**15 -32^{0}C**	Sandeep	03 JAN'2022
	Humidity (RH)	**30 to 80%**	Sandeep	03 JAN'2022
	Illumination (no vapor condensation)	**<6000 lux**	Sandeep	03 JAN'2022
If Instrument is to be used with the sample barcode reader illumination should be below 3,000 cd/m^2 (lux)				
2	Adequate Space for Installation	**At least 10 cm on the back and both the sides.**	Sandeep	03 JAN'2022
3	Electrical Outlets			03 JAN'2022
	Actual Voltage on site	**240V**	Sandeep	03 JAN'2022

FUJIFILM INDIA PRIVATE LIMITED
Registered Office : C -1/114, Ground Floor, Janak Puri. New Delhi - 110058. Tel : +91-11-45509780 Telfax : +91-11-45793281

Vatika Business Park, 7th Floor, Block - One, Sohna Road, Sector - 49. Gurgaon - 122001, Haryana.
Telephone : +91-124-4325500, Fascimile : +91-124-4325555, E-mail : contact@fujifilmindia.com

FUJIFILM

	Grounding	**<2V**	Sandeep	03 JAN'2022
	Connected through UPS	**Yes**	Sandeep	03 JAN'2022
	Stabilizer	---N/A---		

VII. The Instrument Has Been Checked For The Following

Sr. No.	Verification		Verified by	Date
1	Instrument is identified	**Yes**	Sandeep	03 JAN'2022
2	Manufacturer's specification are included	**Yes**	Sandeep	03 JAN'2022
3	Accessories/Consumables are listed	**Yes**	Sandeep	03 JAN'2022
4	Equipment Manual from the Manufacturer	**Yes**	Sandeep	03 JAN'2022
5	Manufacturer certificate of compliance is attached	**Yes**	Sandeep	03 JAN'2022

VIII. Accessories / Consumables

The following accessories were supplied with the instrument. Check "Verified by" in case they are found to be in order. Separate list included.

Sr. No.	Description	Qty.	Verified by	Date
1	Accessory Box	1	Sandeep	03 JAN'2022

IX. List of Manuals and Certificates

Supplier provides the following with the instrument

Sr. No.	Description	Qty.
1	Instruction Manual	Available
2	Purchase order	Available
3	Calibration Certificate	Available
4	Instrument / Kit approval certificate	Available
5	Training Records	Available
6	Certificate of Authorization / Training of engineer	Available

FUJIFILM

X. Maintenance

The instrument listed within this document will be placed under the control of purchasing institution with respect to proper maintenance procedures as detailed in the operator's manual.

The Maintenance procedures will be filled separately.

A trained analyst using the manuals provided with the instrumentation can perform simple maintenance. Upon expiration of the warranty period vendor will offer several level of maintenance agreements and performance testing services to assist you in maintaining GLP / GMP compliance.

Contacting your local representative and requesting the additional service agreement can supply additional information.

XI. Installation Procedure

a) Installation of Incubator Chamber

Follow the instructions mentioned in the quick installation guide.

b) Installation of Instrument

Follow the instructions mentioned in the installation guide.

XII. Operational Qualification

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

Sr. No.	Description	Test Purpose	Verified by	Date
1	On Board Diluent Test	System Performance	Sandeep	03 JAN'2022
2	Maintenance	Daily, weekly & Monthly	Sandeep	03 JAN'2022
3	Test Assay	Biochemistry	Sandeep	03 JAN'2022
4	Audit Trail	Yes	Sandeep	03 JAN'2022
5	Interfacing Facility	Bi-Directional	Sandeep	03 JAN'2022

FUJIFILM

XIII. Performance Qualification

Performance qualification certificate is provided after checking five data points for Quality Control Level 1 and the complete PQ will be shared as a separate Addendum as per the customer's requirement.

QC Data : Biorad

QC: LEVEL 1

QC NAME	BIO-RAD	
QC LEVEL	L1	
LOT.NO	89731	
Parameter	Target	Range
T.Bil	1.1	0.8-1.4
SGOT	39	33-46
T.CHOL	209	187-231

Parameter	T.Bil	SGOT	T.CHOL
S.NO	L1	L1	L1
1	1.2	42.8	231
2	1.2	40.0	220
3	1.1	41.7	227
4	1.1	40.7	225
5	1.1	40.9	219
Mean	**1.14**	**41.50**	**226.00**
SD	**0.055**	**1.41**	**5.57**
CV%	**4.80**	**3.40**	**2.46**

FUJIFILM

Conclusion:

Performance Qualification of Fuji Dri Chem Analyser NX 600i installed at Atrea Healthcare, Bangalore was done on the basis of 3 QC results.

QC Check results show parameter within acceptable range.

CV % found within acceptable range.

QC Results - Pass

FUJIFILM INDIA PRIVATE LIMITED
Registered Office : C -1/114, Ground Floor, Janak Puri. New Delhi - 110058. Tel : +91-11-45509780 Telfax : +91-11-45793281

Vatika Business Park, 7th Floor, Block - One, Sohna Road, Sector - 49. Gurgaon - 122001, Haryana.
Telephone : +91-124-4325500, Fascimile : +91-124-4325555, E-mail : contact@fujifilmindia.com

FUJIFILM

Certificate of Training

1. Technician Training

This certifies that the technicians listed below have received basic user training for the System described.

Sr. No.	Training Program	Initials	Date
1	Instrument Setup	Sandeep	03 JAN'2022
2	System Operation	Sandeep	03 JAN'2022
3	Basic Troubleshooting	Sandeep	03 JAN'2022

Training Given by : Sandeep

Training Attended by :

1. **Dr. Deepak M Nadig**
2. **Mr.K.Sanjay**
3. **Mr.R.Chethan**

FUJIFILM INDIA PRIVATE LIMITED
Registered Office : C -1/114, Ground Floor, Janak Puri. New Delhi - 110058. Tel : +91-11-45509780 Telfax : +91-11-45793281

Vatika Business Park, 7th Floor, Block - One, Sohna Road, Sector - 49. Gurgaon - 122001, Haryana.
Telephone : +91-124-4325500, Fascimile : +91-124-4325555, E-mail : contact@fujifilmindia.com

FUJIFILM

Validation Team From Vendor

Name : **Mr. Sandeep**

Designation : Service Engineer

Signature :

Date : **03/01/2022**

Company : Fujifilm India Pvt. Ltd

Validation Team From Clinical Lab

Name : **Mr. K. Sanjay**

Designation : Lab incharge

Signature :

Date : **03/01/2022**

Department : Atrea Healthcare., Bangalore.

Customer Authorization

Name : **Dr. Deepak M Nadig**

Designation : Pathologist

Signature :

Date : **03/01/2022**

Company : Atrea Healthcare., Bangalore.

FUJIFILM ECN information

2014/10/29

FDC 2014-018

Subject : No Equipment Calibration Requirement for FDC 4000i, NX500i and FDC7000i

Design Change Reason	Action	Time frame
□ Specification/Function change □ Pro-active improvement □ Serviceability □ Part Replacement □ Corrective Action □ Preventive Action □ Regulatory Compliance ■ Other (information)	□ Mandatory □ Recommended □ Not required ( ) ■ Other (information only)	□ Immediately □ Next maintenance □ Upon trouble situation □ At your convenience ■ Not Applicable □ Other ( )

Date: 29/October/2014 Dept.: Medical Systems Business Div.

Originator: M.Jumawid Edited by: M. Jumawid Approved by: Y. Kashi

Affected Products: FUJI DRI-CHEM analyzers FDC 4000i, NX500i and FDC7000i

To whom it may concern:

This document certifies that FUJI DRI-CHEM analyzers FDC4000i, NX500i and FDC7000i do not require equipment calibration.

The quality of these analyzers is guaranteed through the following principle.

FUJI DRI-CHEM analyzers are equipped with reference white and black plates. The functions of these plates are 1) to adjust the gain for all the interference filters before every measurement, and 2) to assure that the analyzer is working within the manufacturer's quality standard. 2) is conducted after gain adjustment, where the optical densities of reflectance for these plates measured in a constant interval, are checked. If the values exceed the threshold, the machine will indicate an error and the analyzer will not give a measurement result for this abnormal case.

The reference white and black plates are made from ceramic material which do not degrade over time, thus the quality of the analyzers can be confirmed over a long period of time.

- Special tools / Instruments : □ Yes ■ No
- Supply of the articles : □ Yes ■ No
  If Yes, when :
  Name / Code :
- Old parts after replaced : □ Yes ■ No
- Report requirement after finished : □ Yes ■ No