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INSTALLATION QUALIFICATION

OPERATIONAL QUALIFICATION

&

PERFORMANCE QUALIFICATION

For the Instrument FUJI DRI CHEMISTRY ANALYZER

Model: FDC NX 600i

Serial No.: 27033449

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

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VALIDATION REPORT

Equipment Name	: Biochemistry Analyzer
Equipment Make	: Fuji DRI-CHEM
Equipment Model No.	: FDC NX 600i
Equipment Serial No.	: **27033449**
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.

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I. Approval of IQ/OQ Procedure

Both Lupin Healthcare Ltd., Latur and Fujifilm India Pvt. Ltd. are jointly responsible for the Installation of FDC NX 600i Serial No. 27033449 in the Biochemistry Laboratory.

Validation Team From Vendor

Name	:	**Mr. Chintan Shedge**
Designation	:	Service Engineer.
Signature	:	
Date	:	**07/02/2024**
Company	:	Unique Diagnostics & Scientific (FFIN Authorized Channel Partner)

Customer Authorization

Name	:	**Dr. Shaikh Mustkim**
Designation	:	Lab in-charge and Pathologist.
Signature	:	
Date	:	**07/02/2024**
Company	:	Lupin Healthcare Ltd., Latur

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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.

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III. Scope

This Installation Qualification Protocol is performed on the Fuji Dri Chem FDC NX 600i vide Serial No.27033449 located at Biochemistry Laboratory of Lupin Healthcare Ltd., Latur.

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 27033449 installed on 07/02/2024 is in compliance with the specification of the purchase order.

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V. Equipment Description

Sr. No.	Instrument Identification		Verified by	Date
1	Equipment Name	**Fuji Dri Chem**	Chintan	02 FEB'2024
2	Model	**FDC NX 600i**	Chintan	02 FEB'2024
3	Equipment ID.	**---**	Chintan	02 FEB'2024
4	Serial No.	**27033449**	Chintan	02 FEB'2024
5	Power, Voltage Limit	**200VA, 100 – 240 V**	Chintan	02 FEB'2024
6	Electromagnetic Compatibility	**Class A (Confers to Part 15 of the FCC Rules)**	Chintan	02 FEB'2024

VI. Utilities

Sr. No.	Instrument Identification		Verified by	Date
1	Environemnt Condition		Chintan	02 FEB'2024
	Free from Dust, electrical & Magnetic Interference	**Yes**	Chintan	02 FEB'2024
	Temperature	**15 -32^{0}C**	Chintan	02 FEB'2024
	Humidity (RH)	**30 to 80%**	Chintan	02 FEB'2024
	Illumination (no vapor condensation)	**<6000 lux**	Chintan	02 FEB'2024
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.**	Chintan	02 FEB'2024
3	Electrical Outlets			02 FEB'2024
	Actual Voltage on site	**240V**	Chintan	02 FEB'2024

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	Grounding	<2V	Chintan	02 FEB'2024
	Connected through UPS	Yes	Chintan	02 FEB'2024
	Stabilizer	---N/A---		

VII. The Instrument Has Been Checked For The Following

Sr. No.	Verification		Verified by	Date
1	Instrument is identified	Yes	Chintan	02 FEB'2024
2	Manufacturer's specification are included	Yes	Chintan	02 FEB'2024
3	Accessories/Consumables are listed	Yes	Chintan	02 FEB'2024
4	Equipment Manual from the Manufacturer	Yes	Chintan	02 FEB'2024
5	Manufacturer certificate of compliance is attached	Yes	Chintan	02 FEB'2024

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	Chintan	02 FEB'2024

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

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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	Chintan	02 FEB'2024
2	Maintenance	Daily, weekly & Monthly	Chintan	02 FEB'2024
3	Test Assay	Biochemistry	Chintan	02 FEB'2024
4	Audit Trail	Yes	Chintan	02 FEB'2024
5	Interfacing Facility	Bi-Directional	Chintan	02 FEB'2024

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XIII. Performance Qualification

Performance qualification certificate is provided after checking three 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 NAME	BIORAD		
QC LEVEL	L1		
Lot No	89731		
Parameters	Unit	Mean	Range
Albumin	g/dL	6.00	5.6–>6.00
ALT/SGPT (2)	U/L	19.0	13–26
AST/SGOT (2)	U/L	39.0	33–46
Bilirubin (Direct)	mg/dL	0.200	<0.100–0.4
Bilirubin (Total)	mg/dL	1.10	0.8–1.4
Cholesterol (HDL) (7)	mg/dL	93.0	75–>110
Cholesterol (Total)	mg/dL	240	218-262
Creatinine	mg/dL	1.30	0.9–1.7
Glucose	mg/dL	71.0	62–81
Protein Serum (Total)	g/dL	5.10	4.6–5.7
Triglycerides	mg/dL	104	86–123
Urea Nitrogen (BUN) (4)	mg/dL	34.2	29.8-38.2

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Result of QC

S.No	Name	Level	OV	OV	OV	OV	OV	Mean	SD	CV %
1	ALBUMIN	L1	6	6	6	6	6	6.00	0.00	0.00
2	ALT/SGPT	L1	18	17	17	17	17	17.20	0.45	2.60
3	AST/SGOT	L1	36	36	36	35	35	35.60	0.55	1.54
4	BILIRUBIN (DIRECT)	L1	0.1	0.1	0.1	0.1	0.1	0.10	0.00	0.00
5	BILITUBIN (TOTAL)	L1	1	1	1	1	1	1.00	0.00	0.00
6	CHOLESTEROL (TOTAL)	L1	219	217	220	227	223	221.20	3.90	1.76
7	CHOLESTEROL HDL	L1	99	94	94	90	91	93.60	3.51	3.75
8	CREATININE	L1	1.25	1.28	1.28	1.25	1.21	1.25	0.03	2.30
9	GLUCOSE	L1	63	66	66	66	66	65.40	1.34	2.05
10	PROTIEN SERUM (TOTAL)	L1	4.8	4.8	4.9	5	5	4.90	0.10	2.04
11	TRIGLYCERIDES	L1	105	111	112	114	113	111.00	3.54	3.19
12	UREA NITROGEN (BUN)	L1	16.3	16	16.3	16.2	16.3	16.22	0.13	0.80

*OV: Obtained Value

Conclusion:

Performance Qualification of Fuji Dri Chem Analyser NX 600i installed at Lupin Healthcare Ltd., Latur was done on the basis of 12 QC results.

QC Check results show parameter within acceptable range.

CV % found within acceptable range.

QC Results - Pass

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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	Chintan	02 FEB'2024
2	System Operation	Chintan	02 FEB'2024
3	Basic Troubleshooting	Chintan	02 FEB'2024

Training Given by : Chintan

Training Attended by :

1. **Mr. Shaikh Mustkim**
2. **Mr. Vivek Chafekarande**
3. **Mrs. Bhagirathi Sagar**
4. **Mr. Nandkumar Shinde**
5. **Mr. Mahesh Mitkari**
6. **Miss. Mayuri kolekar**

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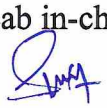
Validation Team From Vendor

Name	:	**Mr. Chintan Shedge**
Designation	:	Service Engineer.
Signature	:	
Date	:	**07/02/2024**
Company	:	Unique Diagnostics & Scientific (FFIN Authorized Channel Partner)

Customer Authorization

Name	:	**Dr. Shaikh Mustkim**
Designation	:	Lab in-charge and Pathologist.
Signature	:	
Date	:	**07/02/2024**
Company	:	Lupin Healthcare Ltd., Latur

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FUJIFILM ECN information 2021/04/15

Subject : No Equipment Calibration Requirement for FDC NX600, NX500 and NX700

		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: 15 - April - 2021 Dept.: Medical Systems Business Div.

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

Affected Products: FUJI DRI-CHEM analyzers FDC NX600, NX500 and NX700

To whom it may concern:

This document certifies that FUJI DRI-CHEM analyzers FDC NX600, NX500 and NX700 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