

FUJIFILM

**INSTALLATION QUALIFICATION
OPERATIONAL QUALIFICATION
&
PERFORMANCE QUALIFICATION**

For the Instrument FUJI DRI CHEMISTRY ANALYZER

Model: FDC NX600i

Serial No.: 16621193

FUJIFILM INDIA PRIVATE LIMITED

Registered Office : C -17114, Ground Floor, Janak Puri, New Delhi - 110058. Tel : +91-11-45609780 Telfax : +91-11-45793281

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

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VALIDATION REPORT

Equipment Name : Biochemistry Analyzer

Equipment Make : Fuji DRI-CHEM

Equipment Model No. : FDC NX600i

Equipment Serial No. : 16621193

Manufacturer : FUJIFILM

Supplier : Fujifilm India Pvt. Ltd

Contact Name & Address : Fujifilm India Pvt. Ltd

Vatika Business Park,

7th Floor, Block-One,

Sohna Road, Sec-49,

Gurgaon, Haryana-122001.

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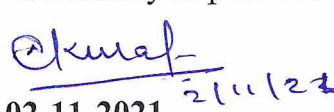
I. Approval of IQ/OO Procedure

Both Lupin Diagnostics, HLM Varad, Ahmednagar and Fujifilm India Pvt. Ltd. are jointly responsible for the Installation of FDC NX600i Serial No.16621193 in the Biochemistry Laboratory.

Validation Team From Vendor

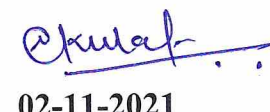
Name : Ms.Sana Mulani
Designation : Service Engineer
Signature : 
Date : 02-11-2021
Company : Lifetime Diagnostics (Channel Partner FFIN)

Validation Team From Clinical Lab

Name : Dr. Sagar Satish Kulat
Designation : Laboratory Supervisor
Signature : 
Date : 02-11-2021
Department : Biochemistry Laboratory, Lupin Diagnostics

LUPIN DIAGNOSTIC
Behind Zopadi Cantin,
Opp. Monica D.Ed. College
Savadi, Ahmednagar-414001

Customer Authorization

Name : Dr. Sagar Satish Kulat
Designation : Lab Head Operations
Signature : 
Date : 02-11-2021
Company : Lupin Diagnostics, HLM Varad, Ahmednagar

LUPIN DIAGNOSTIC
Behind Zopadi Cantin,
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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) Clinical 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 provide the necessary Authorization of the procedure.

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III. Scope

This Installation Qualification Protocol is performed on the Fuji Dri Chem FDC NX600i vide Serial No.16621193 located at Biochemistry Laboratory of Lupin Diagnostics, HLM Varad, Ahmednagar.

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. Certificate of Purchase Order Compliance

I certify to the best of my knowledge. The instrument Fuji Dri Chem FDC NX600i vide Serial No. 16621193 installed on 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	Sana	02 Nov 2021
2	Model	FDC NX600i	Sana	02 Nov 2021
3	Equipment ID.	---	Sana	02 Nov 2021
4	Serial No.	16621193	Sana	02 Nov 2021
5	Power, Voltage Limit	200VA, 100 – 240 V	Sana	02 Nov 2021
6	Electromagnetic Compatibility	Class A (Confers to Part 15 of the FCC Rules)	Sana	02 Nov 2021

VI. Utilities

Sr. No.	Instrument Identification		Verified by	Date
1	Environment Condition		Sana	02 Nov 2021
	Free from Dust, electrical & Magnetic Interference	Yes	Sana	02 Nov 2021
	Temperature	15 -32°C	Sana	02 Nov 2021
	Humidity (RH)	30 to 80%	Sana	02 Nov 2021
	Illumination (no vapor condensation)	<6000 lux	Sana	02 Nov 2021
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.	Sana	02 Nov 2021
3	Electrical Outlets			02 Nov 2021
	Actual Voltage on site	240V	Sana	02 Nov 2021
	Grounding	<2V	Sana	02 Nov 2021

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	Connected through UPS	Yes	Sana	02 Nov 2021
	Stabilizer	---N/A---		

VII. The Instrument Has Been Checked For The Following

Sr. No.	Verification		Verified by	Date
1	Instrument is identified	Yes	Sana	02 Nov 2021
2	Manufacturer's specification are included	Yes	Sana	02 Nov 2021
3	Accessories/Consumables are listed	Yes	Sana	02 Nov 2021
4	Equipment Manual from the Manufacturer	Yes	Sana	02 Nov 2021
5	Manufacturer certificate of compliance is attached	Yes	Sana	02 Nov 2021

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	Sana	02 Nov 2021

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 levels 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	Sana	02 Nov 2021
2	Maintenance	Daily, weekly & Monthly	Sana	02 Nov 2021
3	Test Assay	Biochemistry	Sana	02 Nov 2021
4	Audit Trail	Yes	Sana	02 Nov 2021
5	Interfacing Facility	Bi-Directional	Sana	02 Nov 2021

Certificate of Training

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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	Sana Mulani	02 Nov 2021
2	System Operation	Sana Mulani	02 Nov 2021
3	Basic Troubleshooting	Sana Mulani	02 Nov 2021

Training Given by : Ms.Sana Mulani

Training Attended by :

- Mahesh Bhalsing
- Sagar Malave
- Amol Satale
- Rohit Salave
- Jakir Shaikh
- Pooja Satpute
- Meghana Kalapurekal



ASatale
Rohit




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XIII. Performance Qualification

BIRAD QC LOT - 89711					
		CHOLESTEROL	TRIGLYCERIDES	HDL	URIC ACID
SR.NO	DATE	227-279	126-167	72-107	3.9-5.1
1	24-05-2023	246	155	91	4.7
2	25-05-2023	256	159	95	4.7
3	28-05-2023	254	149	94	4.7
4	29-05-2023	256	153	93	
5	07-06-2023	253	157	92	
6	12-06-2023	245	149	92	4.6
7	21-06-2023	260	156	88	4.8
Mean		252.86	154.00	92.14	4.70
SD		5.49	3.87	2.27	0.07
CV%		2.17	2.51	2.46	1.50

BIRAD QC LOT - 89712					
		CHOLESTEROL	TRIGLYCERIDES	HDL	URIC ACID
SR.NO	DATE	90-114	49-78	25-43	8.9-10.8
1	26-05-2023				10.4
2	27-05-2023	100	63	31	10.2
3	30-05-2023	97	63	31	10.1
4	02-06-2023				10.2
5	06-06-2023	97	71	32	10.1
6	10-06-2023	102	65	29	
7	16-06-2023	99	64	30	9.8
8	20-06-2023	99	65	27	10
9	22-06-2023	100	65	29	10
Mean		99.14	65.14	29.86	10.10
SD		1.77	2.73	1.68	0.18
CV%		1.79	4.20	5.61	1.76

Conclusion:

Performance Qualification of Fuji Dri Chem Analyser NX600i installed at Lupin Diagnostics, HLM Varad, Ahmednagar was completed successfully. QC Check results show parameter within acceptable range.

10 data points were taken for all parameters for two levels of control.

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CV % found within acceptable range.

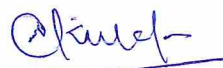
QC Results

- **Pass**

Validation Procedure Performed by FFIN


Name : Sana Mulani
Designation : Service Engineer
Signature : 
Date : 02 Nov 2021
Company : Lifetime Diagnostics (Channel Partner FFIN)

Validation Team From Clinical Lab

Name : Dr. Sagar Satish Kulat
Designation : Lab Supervisor
Signature : 
Date : 02 Nov 2021
Department : Biochemistry Laboratory, Lupin Diagnostics

LUPIN DIAGNOSTIC
Behind Zopadi Cantin,
Opp. Monica D.Ed. College
Savedi, Ahmednagar-414001

Customer Authorization

Name : Dr. Sagar Satish Kulat
Designation : Pathologist
Signature : 
Date : 02 Nov 2021
Company : Lupin Diagnostics, HLM Varad, Ahmednagar

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

<input type="checkbox"/> Specification/Function change <input type="checkbox"/> Pro-active improvement <input type="checkbox"/> Serviceability <input type="checkbox"/> Part Replacement <input type="checkbox"/> Corrective Action <input type="checkbox"/> Preventive Action <input type="checkbox"/> Regulatory Compliance <input checked="" type="checkbox"/> Other (information)	<input type="checkbox"/> Mandatory <input type="checkbox"/> Recommended <input type="checkbox"/> Not required () <input checked="" type="checkbox"/> Other (information only)	<p>Time frame</p> <input type="checkbox"/> Immediately <input type="checkbox"/> Next maintenance <input type="checkbox"/> Upon trouble situation <input type="checkbox"/> At your convenience <input checked="" type="checkbox"/> Not Applicable <input type="checkbox"/> Other ()
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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