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Corporote Office:
FUJIFILM INDIA PVT. LTD.
Unitech Cyber Park,
Unit No. 801-807, 8th Floor, Tower C,
Sector 39, Gurugram - 122001,

CUSTOMER NAME : Dr Aparna
CONTACT PERSON : Mr /Mrs. Dr. Shivam Mandhare
ADDRESS : Andheri
Phone : 8999688418
CITY : Mumbai
STATE : Maharashtra
REGION : Mumbai
☐ NORTH ☐ WEST ☑ EAST ☐ SOUTH
☑ FIELD SERVICE REPORT
☐ INSTALLATION REPORT

MEDICAL

PROBLEM DESCRIPTION & ERROR CODE : Preventive Maintenance

COMPLAINT DATE 30-11-2024
SFDC CASE NO:
START DATE / TIME 30-11-2024
END DATE / TIME 30-11-2024

ACTION TAKEN → System checked
→ Done preventive Maintenance as per the standard procedure
→ clean Incubator assembly, clean lamp Housing assembly, clean all filters, clean air filter, clean all boards and sensor clean ISE Unit
→ checked Refrence black plate level and lamp Hours ok.
→ Run dummy slide. Result ok
→ M/c working ok

ENGINEER NAME : Tanvi Sawant
DEALERS NAME : Unique diagnostic
EQUIPMENT TYPE : Dry chem
MODEL NO. Fuji NX500
SR. NO. 66655263
CONSOLE VERSION. V2.8
WORKSTATION : Laboratory

CONTRACT STATUS:

☐ **WARRANTY** ☐ **CMC**
☑ **AMC** ☐ **PER CALL**

JOB STATUS ☐ MACHINE UNDER OBSERVATION ☑ COMPLETED ☐ INCOMPLETE
REASON FOR INCOMPLETION :

JOB STATUS ☐ MACHINE UNDER OBSERVATION ☑ COMPLETED ☐ INCOMPLETE
REASON FOR INCOMEPLETION

CUSTOMER SIGNATURE

Dr. Shivam S. Mandhare
MVSc (Pathology)
MSVC-9865
8999688418

☐ PARTS USED / REQUIRED

PART NUMBER	DESCRIPTION	QTY

ENGINEER SIGNATURE

7738880665

CUSTOMER REMARKS :

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INSTALLATION QUALIFICATION

&

OPERATIONAL QUALIFICATION

For the Instrument FUJI DRI CHEMISTRY ANALYZER

Model: FDC NX 500i

Serial No.:- 66655263

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

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VALIDATION REPORT

Equipment Name : Biochemistry Analyzer

Equipment Make : Fuji DRI-CHEM

Equipment Model No. : FDC NX 500i

Equipment Serial No. : **66655263**

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/OQ Procedure

Both We Pathology Laboratory and Fujifilm India Pvt. Ltd. are jointly responsible for the Installation of FDC NX 500i Serial No. 66655263 in the Biochemistry Dept., ASAVLEE-Dr. Aparna's Lab, Andheri, Mumbai.

Validation Team From Vendor

Name	**:**	**Miss. Supriya**
Designation	**:**	Service Engineer
Date	**:**	18/04/2017
Company	**:**	Unique Diagnostics(FFIN Authorized Channel Partner)

Validation Team From Clinical Lab

Name	**:**	Dr.Aparna Jairam
Designation	**:**	Pathologist
Date	**:**	**18**/4/2017
Department	**:**	Biochemistry Dept., **ASAVLEE-Dr. Aparna's Lab**, **Andheri, Mumbai**

Customer Authorization

Name	**:**	Dr. Aparna Jairam
Designation	**:**	Pathologist
Date	**:**	18/4/2017
Company	**:**	**ASAVLEE-Dr. Aparna's Lab, Andheri, Mumbai.**

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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 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 Dry Chem FDC NX 500i vide Serial No.66655263 located at Biochemistry Dept., **ASAVLEE, Andheri, Mumbai , MS.**

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 Dry Chem FDC NX 500i vide Serial No 66655263 installed on 18/4/2017 is in compliance with the specification of the purchase order.

V. Equipment Description

Sr. No.	Instrument Identification		Verified by	Date
1	Equipment Name	**Fuji Dry Chem**	Miss Supriya	18 Apr 2017

2	Model FUJIFILM	**FDC NX 600i**	Miss Supriya	18 Apr 2017
3	Equipment ID.	---		
4	Serial No.	6655263	Miss Supriya	18 Apr 2017
5	Power, Voltage Limit	**200VA, 100 – 240 V**	Miss Supriya	18 Apr 2017
6	Electromagnetic Compatibility	**Class A (Confers to Part 15 of the FCC Rules)**	Miss Supriya	18 Apr 2017

VI. Utilities

Sr. No.	Instrument Identification		Verified by	Date
1	Environment Condition			
	Free from Dust, electrical & Magnetic Interference	**Yes**	Miss Supriya	18 Apr 2017
	Temperature	**15 -32^{0}C**	Miss Supriya	18 Apr 2017
	Humidity (RH)	**30 to 80%**	Miss Supriya	18 Apr 2017
	Illumination (no vapor condensation)	**<6000 lux**	Miss Supriya	18 Apr 2017
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.**	Miss Supriya	18 Apr 2017
3	Electrical Outlets			
	Actual Voltage on site	**240V**	Miss Supriya	18 Apr 2017
	Grounding	**<2V**	Miss Supriya	18 Apr 2017
	Connected through UPS	**Yes**	Miss Supriya	18 Apr 2017
	Stabilizer	---N/A---		

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VII. The Instrument Has Been Checked For The Following

Sr. No.	Verification		Verified by	Date
1	Instrument is identified	**Yes**	Miss Supriya	18 Apr 2017
2	Manufacturer's specification are included	**Yes**	Miss Supriya	18 Apr 2017
3	Accessories/Consumables are listed	**Yes**	Miss Supriya	18 Apr 2017
4	Equipment Manual from the Manufacturer	**Yes**	Miss Supriya	18 Apr 2017
5	Manufacturer certificate of compliance is attached	**Yes**	Miss Supriya	18 Apr 2017

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	Miss Supriya	18 Apr 2017

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	Miss Supriya	18 Apr 2017
2	Maintenance	Daily, weekly & Monthly	Miss Supriya	18 Apr 2017
3	Test Assay	Biochemistry	Miss Supriya	18 Apr 2017
4	Audit Trail	Yes	Miss Supriya	18 Apr 2017
5	Interfacing Facility	Bi-Directional	Miss Supriya	18 Apr 2017

Thank You

Pavan Shrivastav
Deputy Service Manager-IVD
Fujifilm India Pvt. Ltd.

PERFORMANCE QUALIFICATION

For the Instrument FUJI DRI CHEMISTRY ANALYZER

Model: FDC NX 500i

Serial No.: 66655263

FUJIFILM INDIA PRIVATE LIMITED

Registered Office: Unit No. 504 & 505, 5th Floor, 349 Business Point, Western Express Highway, Andheri (East), Mumbai – 400069, Telephone: +91-22-42364000 Fax: +91-22-42364001.
Corporate Office: Unitech Cyber Park, Unit No. 801-808, 8th Floor, Tower C, Sector 39, Gurugram -122001, Haryana Telephone : +91-124-4325500, Fax : +91-124-4325555, Website : www.fujifilm.com, Email : contact@fujifilm.com
CIN: U24233DL2008PTC171054.

Addendum-I

XIII. 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 QC inter day run to check the accuracy of parameters on Fuji Dri Chem.
2. Run 10 runs for precision check of all parameters.

Precesion & Accuracy Data:

ASAVLEE DR APARNA'S PATHOLOGY LABORATORY

CONTROL BIO-RAD

LEVEL 1

LOT NO 26461

EXPIRY 31-07-2022

MACHINE FUJI DRY CHEMISTRY

PARAMETER LEVEL 1

DATE	02-01-2022	02-03-2022	02-04-2022	02-07-2022	02-09-2022	02-11-2022	14/2/2022	16/2/2022	18/2/2022	21/2/2022	23/2/2022	25/2/2022	28/2/2022	Mean	SD	CV %
GLUCOSE	68.7	69	68.4	68.1	68.6	69	68.6	68.3	68	59.9	68.4	68.2	68.2	67.8	2.4	3.5
UREA (BUN)	15.3	15.2	15.6	15.8	15.5	16	16.2	15.9	15.6	15.8	16	15.6	15.8	15.7153	0.3	1.8
CREATININE	1.5	1.4	1.5	1.4	1.5	1.3	1.4	1.6	1.5	1.4	1.3	1.5	1.4	1.43846	0.1	6.0
TOTAL BILIRUBIN	0.81	0.8	0.9	0.8	0.85	0.81	0.79	0.83	0.86	0.83	0.8	0.82	0.81	0.82384	0.0	3.7
TOTAL PROTEIN	5.2	5.3	5.4	5.7	5.2	5.1	5.7	5.3	5	5.1	5.4	5.2	5.4	5.30769	0.2	4.0
ALBUMIN	5.9	5.8	5.8	6	5.7	5.9	6.2	6	5.7	5.9	5.8	5.8	5.9	5.87692	0.1	2.3
URIC ACID	4.1	4	4.3	4.1	4	3.9	4.3	4.2	4.6	4.3	4.1	4.4	4.2	4.19230	0.2	4.5
CHOLESTEROL	220	221	219	225	232	239	219	224	217	219	224	222	223	223.384	6.0	2.7
TRIGLYCERIDES	131	130	133	135	141	137	135	138	136	140	139	134	136	135.7692	3.3	2.4

Conclusion:

Performance Qualification of Fuji Dri Chem Analyser NX 500i installed at Asavlee Dr.Aparana's Pathology Laboratory was completed successfully. QC Check results show parameter within acceptable range.

FUJIFILM INDIA PRIVATE LIMITED

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Corporate Office: Unitech Cyber Park, Unit No. 801-808, 8th Floor, Tower C, Sector 39, Gurugram -122001, Haryana Telephone : +91-124-4325500, Fax : +91-124-4325555, Website : www.fujifilm.com, Email : contact@fujifilm.com

CIN: U24233DL2008PTC171054.

QC Results	**-**	**Pass**
Accuracy – Within Range	**-**	**Pass**
Precision	**-**	**Pass**

Validation Procedure Performed by (Vendor)

Name : **Ms. Trushi Sonavaria**

Designation : Deputy Manager – IVD Application

Signature : 

Date : **28-02-2022**

Company : Fujifilm India Pvt. Ltd.

Validation Team From Clinical Lab

Name : **Dr.Aparna Jairam**

Designation : Pathologist

Signature :

Date : **28-02-2022**

Department : Biochemistry Laboratory, Asavlee Dr.Aparana’s Pathology Laboratory

Customer Authorization

Name : **Dr.Aparna Jairam**

Designation : MD (Path)

Signature :

Date : **28-02-2022**

Company : Asavlee Dr.Aparana’s Pathology Laboratory