

FUJIFILM

**INSTALLATION QUALIFICATION
OPERATIONAL QUALIFICATION
&
PERFORMANCE QUALIFICATION**

For the Instrument FUJI DRI CHEMISTRY ANALYZER

Model: FDC NX 500i

Serial No.: 57153227

FUJIFILM INDIA PRIVATE LIMITED

Registered Office : C -1/114, Ground Floor, Janak Puri, New Delhi - 110058. Tel : +91-11-45509780 Teifax : +91-11-45793281

Vatika 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

VALIDATION REPORT

Equipment Name : Biochemistry Analyzer

Equipment Make : Fuji DRI-CHEM

Equipment Model No. : FDC NX 500i

Equipment Serial No. : 57153227

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 INDIA PRIVATE LIMITED

Registered Office : C -1/114, Ground Floor, Janak Puri, New Delhi - 110058. Tel. : +91-11-45509780 Teifax : +91-11-45793281

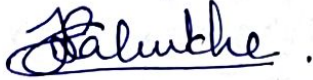
Vatika Business Park, 7th Floor, Block - One, Sohna Road, Sector - 49, Gurgaon - 122001, Haryana
Telephone : +91-124-4325500, Facsimile : +91-124-4325555. E-mail : contact@fujifilmindia.com

FUJIFILM


I. Approval of IQ/OQ Procedure

Both SRL Diagnostics, Vashi and Fujifilm India Pvt. Ltd. are jointly responsible for the Installation of FDC NX 500i Serial No. 57153227 in the Biochemistry Laboratory.

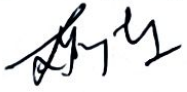
Validation Team From Vendor

Name : Ms. Jayshree Salunke
Designation : Service Engineer
Signature : 
Date : 03/03/2016
Company : United Diagnostics (FFIN Authorized Channel Partner)

Validation Team From Clinical Lab

Name : Mr. Rukaiya Sayyed
Designation : Technical Officer
Signature : 
Date : 03/03/2016
Department : Biochemistry Laboratory, SRL Vashi

Customer Authorization

Name : Dr. Monica Singhal
Designation : Pathologist (MD Path)
Signature : 
Date : 03/03/2016
Company : SRL Diagnostics, Vashi

FUJIFILM INDIA PRIVATE LIMITED

Registered Office : C -1/114, Ground Floor, Janak Puri, New Delhi - 110058. Tel : +91-11-45509780 Telex : +91-11-45793281

Vatika 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



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.

FUJIFILM INDIA PRIVATE LIMITED

Registered Office : C -1/114, Ground Floor, Janak Puri, New Delhi - 110058. Tel. : +91-11-45509780 Telex : +91-11-45793281

Vatika 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

III. Scope

This Installation Qualification Protocol is performed on the Fuji Dri Chem FDC NX 500i vide Serial No. 57153227 located at Biochemistry Laboratory of SRL Diagnostics, Vashi

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 NX 500i vide Serial No 57153227 installed on 03.03.2016 is in compliance with the specification of the purchase order.

FUJIFILM INDIA PRIVATE LIMITED

Registered Office : C -1/114, Ground Floor, Janak Puri, New Delhi - 110058, Tel : +91-11-45509780 Teifax : +91-11-45793281

Vatika 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

V. Equipment Description

Sr. No.	Instrument Identification		Verified by	Date
1	Equipment Name	Fuji Dri Chem	Jayshree Salunke	03 Mar'2016
2	Model	FDC NX 500i	Jayshree Salunke	03 Mar'2016
3	Equipment ID.	---	Jayshree Salunke	03 Mar'2016
4	Serial No.	57153227	Jayshree Salunke	03 Mar'2016
5	Power, Voltage Limit	200VA, 100 – 240 V	Jayshree Salunke	03 Mar'2016
6	Electromagnetic Compatibility	Class A (Confers to Part 15 of the FCC Rules)	Jayshree Salunke	03 Mar'2016

VI. Utilities

Sr. No.	Instrument Identification		Verified by	Date
1	Environemnt Condition		Jayshree Salunke	03 Mar'2016
	Free from Dust, electrical & Magnetic Interference	Yes	Jayshree Salunke	03 Mar'2016
	Temperature	15 -32⁰C	Jayshree Salunke	03 Mar'2016
	Humidity (RH)	30 to 80%	Jayshree Salunke	03 Mar'2016
	Illumination (no vapor condensation)	<6000 lux	Jayshree Salunke	03 Mar'2016
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.	Jayshree Salunke	03 Mar'2016
3	Electrical Outlets			03 Mar'2016
	Actual Voltage on site	240V	Jayshree Salunke	03 Mar'2016

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, Facsimile : +91-124-4325555, E-mail : contact@fujifilmindia.com

FUJIFILM

	Grounding	<2V	Jayshree Salunke	03 Mar'2016
	Connected through UPS	Yes	Jayshree Salunke	03 Mar'2016
	Stabilizer	---N/A---		

VII. The Instrument Has Been Checked For The Following

Sr. No.	Verification		Verified by	Date
1	Instrument is identified	Yes	Jayshree Salunke	03 Mar'2016
2	Manufacturer's specification are included	Yes	Jayshree Salunke	03 Mar'2016
3	Accessories/Consumables are listed	Yes	Jayshree Salunke	03 Mar'2016
4	Equipment Manual from the Manufacturer	Yes	Jayshree Salunke	03 Mar'2016
5	Manufacturer certificate of compliance is attached	Yes	Jayshree Salunke	03 Mar'2016

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	Jayshree Salunke	03 Mar'2016

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 INDIA PRIVATE LIMITED

Registered Office : C - 1/114, Ground Floor, Janak Puri, New Delhi - 110058, Tel : +91-11-45509780 Telex : +91-11-45793281

Vatika 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

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	Jayshree Salunke	03 Mar'2016
2	Maintenance	Daily, weekly & Monthly	Jayshree Salunke	03 Mar'2016
3	Test Assay	Biochemistry	Jayshree Salunke	03 Mar'2016
4	Audit Trail	Yes	Jayshree Salunke	03 Mar'2016
5	Interfacing Facility	Bi-Directional	Jayshree Salunke	03 Mar'2016

FUJIFILM INDIA PRIVATE LIMITED

Registered Office : C -1/114, Ground Floor, Janak Puri, New Delhi - 110058. Tel : +91-11-45509780 Telex : +91-11-45793281

Vatika 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

XIII. Performance Qualification

On Customer request, performance qualification certificate will be provided as an addendum after submitting twenty data points for Quality Control.

Inter Day Run: Normal Control 26411

PAR A	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	Mea n	SD	CV %
NA	151	149	145	148	155	152	153	149	153	151	150	153	148	150	147	150.27	2.69	1.79
K	4.1	4.3	3.7	3.8	3.7	3.9	4.1	4.1	3.8	3.9	4.1	4.2	4.4	3.9	3.8	3.9	0.1	2.0
CL	99	98	100	101	101	99	98	99	105	105	104	99	102	103	104	101.13	2.53	2.5
CRE	1.7	1.5	1.5	1.3	1.5	1.6	1.4	1.4	1.3	1.3	1.6	1.5	1.5	1.3	1.2	1.44	0.14	9.75
LIP	44	45	45	46	45	47	48	46	49	45	44	43	44	45	47	45.53	1.64	3.61
AML Y	76	75	74	73	75	76	80	79	77	79	78	77	77	78	79	76.87	2.03	2.64
ALP	169	176	160	165	162	158	161	152	155	159	160	152	153	159	160	160.07	6.41	4
TCH O	242	240	241	235	234	240	238	239	240	239	241	242	240	241	238	239.33	2.32	0.97
GLU	77	77	75	74	75	76	74	75	76	75	77	78	75	74	73	75.4	1.4	1.86
GGT	62	55.9	55.4	54	53.8	55	55.9	55	54.9	54.2	54	55.	54.	55.	55.	55.42	1.95	3.51
GPT	26	25	22	27	25	24	27	23	23	23	25	24	24	25	29	23.6	1.9	8.0
ALB	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6.0	0.0	0.0
CA	9.7	-	9	9.2	9.1	8.9	8.8	8.9	9	9	9.1	8.9	9	8.8	9.3	9.05	0.23	2.59
TP	5.3	5.2	4.9	5.3	5.2	5.0	4.7	5.6	4.9	5.1	5.2	5.3	5.2	5.2	5.3	5.19	0.21	4.13
BUN	15.9	15.4	15.6	14.3	14.8	13.9	15.	15.8	14.9	15.1	15.	13.	14.	14.	16.	15.03	0.74	4.89
TBIL	1	0.9	0.9	0.9	1	1.1	1.0	1.0	0.9	1.1	0.9	0.9	0.9	0.9	0.9	0.98	0.07	7.6

Inter Day Run: High Control 26412

PAR A	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	Mea n	SD	CV %
NA	132	129	127	132	130	135	129	130	128	129	132	128	136	134	132	130.87	2.7	2.06
K	6.1	5.8	5.9	5.7	5.6	5.6	5.9	6.2	6.3	6.2	5.9	6.3	5.8	5.9	6.2	5.96	0.24	4.05
CL	87	81	75	69	74	84	86	84	84	93	92	85	91	88	93	84.4	7.16	8.48
CRE	4.6	4.7	4.4	4	4.4	4.5	4.6	4.5	4.4	4.3	4.7	4.7	4.1	4.4	4	4.42	0.24	5.35
LIP	81	84	85	84	83	86	87	85	84	86	87	82	84	85	86	84.60	1.72	2.04
AMY	300	310	311	315	312	314	314	310	302	305	320	316	319	310	315	311.53	5.72	1.84

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, Facsimile : +91-124-4325555, E-mail : contact@fujifilmindia.com

FUJIFILM

ALP	746	784	750	752	769	749	770	776	749	756	751	752	748	760	761	758.2 0	11.5 6	1.53
TCH O	99	98	95	97	96	95	98	97	95	98	96	99	98	95	96	96.80	1.47	1.52
GLU	250	246	251	249	248	250	245	244	250	250	249	251	250	248	250	248.7 3	2.15	0.87
GGT	195	170	177	172	173	-	172	172	175	172	173	172	175	174	177	174.9 3	6.12	3.50
GPT	85	84	80	85	84	78	87	78	79	82	84	85	86	85	84	83.07	2.94	3.54
ALB	4.2	4	4.2	4.4	4.2	4.3	4.2	4.3	4.3	4.2	4.2	4.2	4.2	4.3	4.2	4.26	0.10	2.40
CA	14. 4	-	14	13. 9	14. 1	14	14. 2	14. 1	14	14. 3	14. 5	14. 2	14. 1	14. 2	14	14.14	0.17	1.20
TP	3.4	3.5	3.4 2	3.5	3.4 9	3.5 2	3.5 9	3.4 8	3.4 8	3.5 6	3.4 8	3.5 6	3.4 8	3	3.4 5	3.45	0.14	3.94
BUN	48. 3	46. 9	47. 2	44. 2	45. 9	42. 3	48. 5	47. 3	46. 2	47. 9	48. 8	42	44. 1	45. 5	48. 2	46.22	2.20	4.76
TBIL	3.7	-	3.6	3.5	3.5	3.6	3.7	3.8	3.9	3.8	3.8	3.7	3.6	3.7	3.5	3.67	0.13	3.45

Conclusion:

Performance Qualification of Fuji Dri Chem Analyser NX 500i installed at SRL Diagnostics, Vashi was completed successfully. QC Check results show parameter within acceptable range.

15 data points were taken for all parameters for both levels of controls.

CV % found within acceptable range.

QC Results - **Pass**
Cross Verification Result - **Pass**

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	Trushi Sonavaria	03 rd Mar' 2016
2	System Operation	Trushi Sonavaria	03 rd Mar' 2016
3	Basic Troubleshooting	Trushi Sonavaria	03 rd Mar' 2016

FUJIFILM INDIA PRIVATE LIMITED

Registered Office : C -1/114, Ground Floor, Janak Puri, New Delhi - 110058, Tel. +91-11-45509780 Teifax. +91-11-45793281

Vatika 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

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

Design Change Reason	Action	Time frame
<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)	<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 ()

Date: 06/May/2019 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