

**FUJIFILM**

**INSTALLATION QUALIFICATION  
OPERATIONAL QUALIFICATION  
&  
PERFORMANCE QUALIFICATION**

For the Instrument FUJI DRI CHEMISTRY ANALYZER

Model: FDC NX600i

Serial No.: 16621197

**FUJIFILM INDIA PRIVATE LIMITED**

Registered Office : C-1/114, Ground Floor, Janak Puri, New Delhi - 110058. Tel : +91-11-4509790 Telex : +91-11-45793261

Vatika Business Park - 7th Floor, Block - One, Sakra Road, Sector - 49, Gurgaon - 122001, Haryana  
Telephone : +91-124-4325503 Facsimile : +91-124-4325555 E-mail : [contact@fujifilmindia.com](mailto:contact@fujifilmindia.com)

## VALIDATION REPORT

**Equipment Name** : Biochemistry Analyzer

**Equipment Make** : Fuji DRI-CHEM

**Equipment Model No.** : FDC NX600i

**Equipment Serial No.** : 16621197

**Manufacturer** : FUJIFILM

**Supplier** : Fujifilm India Pvt. Ltd

**Contact Name & Address** : Fujifilm India Pvt. Ltd

Vatika Business Park,

7<sup>th</sup> Floor, Block-One,

Sohna Road, Sec-49,


Gurgaon, Haryana-122001.

# FUJIFILM


## I. Approval of IO/OO Procedure

Both Lupin Diagnostics, Solapur and Fujifilm India Pvt. Ltd. are jointly responsible for the Installation of FDC NX600i Serial No.16621197 in the Biochemistry Laboratory.

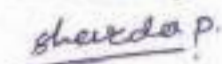
### Validation Team From Vendor

Name : Mr. Akash Daingade  
Designation : Service Engineer  
Signature :   
Date : 12-11-2021  
Company : Lifetime Diagnostics (Channel Partner FFIN)

### Validation Team From Clinical Lab

Name : Mr. Khemsing Rathod  
Designation : Laboratory Supervisor  
Signature :   
Date : 12-11-2021  
Department : Biochemistry Laboratory, Lupin Diagnostics

### Customer Authorization

Name : Dr. Sharada Patane  
Designation : Lab Head Operations  
Signature :   
Date : 12-11-2021  
Company : Lupin Diagnostics, Solapur

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10004 Business Park, 7th Floor, Brook + One, Solima Road, Sector - 48, Gurgaon - 122001, Haryana.  
Tel. : +91-124-4325611. Fax : +91-124-4325555. E-mail : [coms1@fujifilmindia.com](mailto:coms1@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.

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# FUJIFILM

## III. Scope

This Installation Qualification Protocol is performed on the Fuji Dri Chem FDC NX600i vide Serial No.16621197 located at Biochemistry Laboratory of Lupin Diagnostics, Solapur.

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. 16621197 installed on is in compliance with the specification of the purchase order.

### **FUJIFILM INDIA PRIVATE LIMITED**

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# FUJIFILM

## V. Equipment Description

Sr. No.	Instrument Identification		Verified by	Date
1	Equipment Name	<b>Fuji Dri Chem</b>	Akash	12 Nov 2021
2	Model	<b>FDC NX600i</b>	Akash	12 Nov 2021
3	Equipment ID.	---	Akash	12 Nov 2021
4	Serial No.	16621197	Akash	12 Nov 2021
5	Power, Voltage Limit	<b>200VA, 100 – 240 V</b>	Akash	12 Nov 2021
6	Electromagnetic Compatibility	<b>Class A (Confers to Part 15 of the FCC Rules)</b>	Akash	12 Nov 2021

## VI. Utilities

Sr. No.	Instrument Identification		Verified by	Date
1	Environment Condition		Akash	12 Nov 2021
	Free from Dust, electrical & Magnetic Interference	<b>Yes</b>	Akash	12 Nov 2021
	Temperature	<b>15 -32°C</b>	Akash	12 Nov 2021
	Humidity (RH)	<b>30 to 80%</b>	Akash	12 Nov 2021
	Illumination (no vapor condensation)	<b>&lt;6000 lux</b>	Akash	12 Nov 2021
If Instrument is to be used with the sample barcode reader illumination should be below 3,000 cd/m <sup>2</sup> (lux)				
2	Adequate Space for Installation	<b>At least 10 cm on the back and both the sides.</b>	Akash	12 Nov 2021
3	Electrical Outlets			12 Nov 2021
	Actual Voltage on site	<b>240V</b>	Akash	12 Nov 2021

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# FUJIFILM

	Grounding	<2V	Akash	12 Nov 2021
	Connected through UPS	Yes	Akash	12 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	Akash	12 Nov 2021
2	Manufacturer's specification are included	Yes	Akash	12 Nov 2021
3	Accessories/Consumables are listed	Yes	Akash	12 Nov 2021
4	Equipment Manual from the Manufacturer	Yes	Akash	12 Nov 2021
5	Manufacturer certificate of compliance is attached	Yes	Akash	12 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	Akash	12 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

### FUJIFILM INDIA PRIVATE LIMITED

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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	Akash	12 Nov 2021
2	Maintenance	Daily, weekly & Monthly	Akash	12 Nov 2021
3	Test Assay	Biochemistry	Akash	12 Nov 2021
4	Audit Trail	Yes	Akash	12 Nov 2021
5	Interfacing Facility	Bi-Directional	Akash	12 Nov 2021

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## XIII. Performance Qualification

Sr. No.	Parameter	Control Levels	Fujifilm QC Data points													Mean	SD	CV%
			Range		1	2	3	4	5	6	7	8	9	10				
			Min	Max														
1	GLUCOSE	Level 1	60	79	66	83	70	88	87	67	76	66	88	67	67.6	3.44	5.08	
		Level 2	214	258	237	245	249	220	290	251	252	242	245	229	240	10.70	4.46	
2	Creatinine	Level 1	0.9	1.7	1.38	1.81	1.45	1.47	1.47	1.53	1.57	1.44	1.52	1.41	1.47	0.88	5.84	
		Level 2	4	4.9	4.61	4.52	4.58	3.84	4.23	4.8	4.67	4.24	4.36	4.46	4.43	0.27	6.12	
3	Bilirubin Total	Level 1	0.5	1.5	0.8	0.7		0.8	0.7	0.8	0.8	0.8	0.9		0.79	0.04	8.14	
		Level 2	2.8	4.4	4	3.7	3.3	3.2	3.3	3.9	3.9	3.7	3.7	3.8	3.73	0.24	6.33	
4	Bilirubin Direct	Level 1	<0.1	0.3	0.1	0.1	0.1	0.1			0.1	0.1	0.1	0.1	0.1	0.00	0.00	
		Level 2	1.3	1.8	1.4	1.4	1.4	1.3	1.3	1.4	1.4	1.3	1.3	1.5	1.38	0.07	5.31	
5	SGOT	Level 1	29	41	31	36	34	35	34	35	38	34	31	31	34	3.54	7.47	
		Level 2	168	208	186	193	185	169	174	191	191	184	191	182	184.6	7.88	4.37	
6	SGPT	Level 1	16	28	17	20	18	18	21	19	17	18	17	18	18.4	1.35	7.34	
		Level 2	73	92	85	83	83	73	78	80	81	80	80	83	80.6	3.97	4.18	
7	ALP	Level 1	40	62	58		48	52	47	55	58	50	55	61	54.33	4.84	8.93	
		Level 2	234	308	249	247	290	294	293	292	288	294	299	281	275.7	22.00	7.98	
8	ALB	Level 1	5.6	>6	6	6	6	6	6	6	6	6	6	6	6	0.00	0.00	
		Level 2	2.6	4.8	4.4	4.5	4.3	4.7	4.8	4.7	4.6	4.8	4.7	4.8	4.64	0.17	3.68	
9	UA	Level 1	3.7	4.8	4.4	4.3	4.1	4	4.3	4.3	4.2	4.1	4.1	4.2	4.18	0.12	2.94	
		Level 2	8.9	10.4	10	10.7	10.3	10.1	10.6	10.3	10.4	10.5	10.8	10.3	10.38	0.21	2.17	
10	Ca	Level 1	7.8	10.4	9.4	9.5	10.3	9.7	9.4	9.1	9.2	9.6	9.1	9.4	9.47	0.35	3.73	
		Level 2	11.5	14.5	12.4	12.6	12.8	13.2	13	12.9	12.6	13.2	12.8	13	12.85	0.26	2.05	
11	BUN	Level 1	13.7	17.7	15.3	15.8	15.7	16.5	14.6	15.6		16.6	15.2	15	15.99	0.88	4.32	
		Level 2	41.3	49.9	48.4	46.5	47.5	46	49.8	48	49.3	48.1	48.5	49.1	48.03	1.10	2.29	
12	TP	Level 1	4.7	5.8	5.4	5.3	5.2	5.4	5.3	5.5	5.4	5.4	5.3	5	5.32	0.14	2.63	
		Level 2	8.1	8.1	8.8	8	7.7	8.6	8.9	8.8	8	7.7	8.8	8.7	8.78	0.19	3.90	
13	TC	Level 1	207	255	248	239	247	254	248	248	251	242	232	246	245.6	6.38	2.60	
		Level 2	89	113	105	110	107	105	113	107	110	114	109	107	108.7	5.09	2.85	
14	TG	Level 1	114	159	130	136	138	125	145	150	152	134	134	138	136.3	7.23	5.30	
		Level 2	54	82	69	74	69	69	76	71	68	71	67	70	69.8	1.93	2.77	
15	HDL	Level 1	75	>110	85	88	90	89		96	91	94	89	91	89.44	4.39	4.91	
		Level 2	27	46		31	30	31		34	31	33	31	34	31.88	1.55	4.87	
16	Na	Level 1	144	156	152	145	152	154	152	152	151	149	154	145	150.6	3.27	2.17	
		Level 2	126	137	129	130	132	135	130	135	127	135	131	132	131.4	2.55	1.94	
17	K	Level 1	3.6	4.4	4.1	3.7	4.1	4.2	4.1	4.1	4	3.9	4.1	4.4	4.07	0.18	4.49	
		Level 2	5.6	6.0	6.2	6.1	6	6.1	5.6	6.3	6.1	6	6.1	5.9	6.04	0.19	3.14	
18	Cl	Level 1	90	103	94	98	95	99	96	94	95	94	96	99	96	2.00	2.88	
		Level 2	81	83	87	86	85	90	88	88	85	85	82	91	84.8	2.62	3.01	

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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	Akash Daingade	12 Nov 2021
2	System Operation	Akash Daingade	12 Nov 2021
3	Basic Troubleshooting	Akash Daingade	12 Nov 2021

## Conclusion:

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

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




CV % found within acceptable range.

**QC Results**

- **Pass**

Training Given by : Mr. Akash Daingade

Training Attended by :

- Khemsing Rathod 
- Varsha Nakate 
- Lakul Bhalekar 

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## Conclusion:

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

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


CV % found within acceptable range.

**QC Results - Pass**

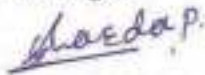
## Validation Procedure Performed by FFIN

Name : Akash Daingade  
Designation : Service Engineer  
Signature :   
Date : 12 Nov 2021  
Company : Lifetime Diagnostics (Channel Partner FFIN)

## Validation Team From Clinical Lab

Name : Mr. Khemsing Rathod  
Designation : Lab Supervisor  
Signature :   
Date : 12 Nov 2021  
Department : Biochemistry Laboratory, Lupin Diagnostics

## Customer Authorization

Name : Dr. Sharada Patane  
Designation : Pathologist  
Signature :   
Date : 12 Nov 2021  
Company : Lupin Diagnostics, Solapur

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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)	Time frame <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: 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

**CALIBRATION REPORT****STATUS : PASSED**DESCRIPTION : Single Channel Micropipette 2-20  $\mu$ l

DEVICE ID : 23204359

CALIBRATION DATE : 20/04/2023 4:50 PM

Method ID : VV/2-20

TERMINAL ID : 69

ULR No. : CC270523000194658F

Location : Lucknow (Permanent Lab)

**ENVIRONMENTAL FACTORS**TEMP : 25.00  $^{\circ}$ C Z FACTOR : 1.0026 mm<sup>3</sup>/mg BARO. PRESSURE : 80.00 KPa REL. HUMIDITY : 60.00%**CALIBRATION STATISTICS**

Vol ( $\mu$ l)	No	Cum Wt (mg)	Vol ( $\mu$ l)	Mean ( $\mu$ l)	SD ( $\mu$ l)	Inaccuracy E%		Imprecision CV%		Status
						Actual	Target	Actual	Target	
2.000	1	2.100	2.105	2.038	0.058	1.917	8.00	< 4.00	4.00	PASSED
	2	4.100	2.005							
	3	6.100	2.005							
10.000	1	10.100	10.126	10.059	0.115	0.593	1.60	< 0.80	0.80	PASSED
	2	20.000	9.926							
	3	30.100	10.126							
20.000	1	19.900	19.952	20.052	0.100	0.260	0.30	< 0.40	0.40	PASSED
	2	40.000	20.152							
	3	60.000	20.052							

Volume	Approx 10 $\mu$ l to 100 $\mu$ l	Approx 100 $\mu$ l to 5000 $\mu$ l	Approx 1 ml to 10 ml	Approx 10 ml to 100 ml
Uncertainty (k=2)	0.1 $\mu$ l	0.1 $\mu$ l	0.1 $\mu$ l	4 $\mu$ l

- Specifications conform to ISO 8655 standards
- Each instrument is individually calibrated on electronic balance
- 750 mmHg = 99.99 kPa
- Weight in mg or g
- Volume, Mean & S.D. in ml or  $\mu$ l

**Reference standard**

The instrument is calibrated using a standard electronic balance with calibration traceability to NPL.

The reported expanded uncertainty of measurement is calculated by multiplying the standard uncertainty of measurement by the coverage factor k=2, which for normal distribution corresponds to a coverage probability of approximately 95%.







ISO/IEC 17025:2017  
Certificate No.: CC-2788

**CALIBRATION REPORT****STATUS : PASSED**DESCRIPTION : Single Channel Micropipette 20-200  $\mu$ l

DEVICE ID : 23307520

CALIBRATION DATE : 18/08/2023 12:51 PM

Method ID : VV/20-200

TERMINAL ID : 52

ULR No. : CC270523000212325F

Location : Lucknow (Permanent Lab)

**ENVIRONMENTAL FACTORS**TEMP : 25.00  $^{\circ}$ C Z FACTOR : 1.0038 mm<sup>3</sup>/mg BARO. PRESSURE : 80.00 KPa REL. HUMIDITY : 60.00%**CALIBRATION STATISTICS**

Vol ( $\mu$ l)	No	Cum Wt (mg)	Vol ( $\mu$ l)	Mean ( $\mu$ l)	SD ( $\mu$ l)	Inaccuracy E%		Imprecision CV%		Status
						Actual	Target	Actual	Target	
20.000	1	20.100	20.176	20.176	0.101	0.882	6.00	< 2.00	2.00	PASSED
	2	40.100	20.076							
	3	60.300	20.277							
100.000	1	99.500	99.878	99.912	0.153	0.088	1.20	< 0.40	0.40	PASSED
	2	198.900	99.778							
	3	298.600	100.079							
200.000	1	198.900	199.656	199.656	0.402	0.172	0.60	< 0.20	0.20	PASSED
	2	397.400	199.254							
	3	596.700	200.057							

Volume	Above 10 $\mu$ l to 100 $\mu$ l	Above 100 $\mu$ l to 1000 $\mu$ l	Above 1 ml to 10 ml	Above 10 ml to 100 ml
Uncertainty (k=2)	0.1 $\mu$ l	0.1 $\mu$ l	0.1 $\mu$ l	4 $\mu$ l

- Specifications conform to ISO 8655 standards.
- Each instrument is individually calibrated on electronic balance.
- 750 mmHg = 99.98 kPa.
- Weight in mg or g.
- Volume, Mean & S.D. in ml or  $\mu$ l.

**Reference standard**

The instrument is calibrated using a standard electronic balance with calibration traceability to NPL.

The reported expanded uncertainty of measurement is calculated by multiplying the standard uncertainty of measurement by the coverage factor k=2, which for normal distribution corresponds to a coverage probability of approximately 95%.



**CALIBRATION REPORT****STATUS : PASSED**DESCRIPTION : Single Channel Micropipette 100-1000  $\mu$ l

DEVICE ID : 23217019

CALIBRATION DATE : 19/07/2023 9:43 AM

Method ID : VV/100-1000

TERMINAL ID : 20

ULR No. : CC270523000208539F

Location : Lucknow (Permanent Lab)

**ENVIRONMENTAL FACTORS**TEMP : 25.00  $^{\circ}$ C Z FACTOR : 1.0038 mm<sup>3</sup>/mg BARO. PRESSURE : 80.00 KPa REL. HUMIDITY : 60.00%**CALIBRATION STATISTICS**

Vol ( $\mu$ l)	No	Cum Wt (mg)	Vol ( $\mu$ l)	Mean ( $\mu$ l)	SD ( $\mu$ l)	Inaccuracy E%		Imprecision CV%		Status
						Actual	Target	Actual	Target	
100.000	1	99.800	100.179	99.878	0.362	0.122	6.00	< 2.00	2.00	PASSED
	2	196.900	99.477							
	3	298.500	99.978							
500.000	1	498.400	500.294	499.826	0.418	0.035	1.20	< 0.40	0.40	PASSED
	2	996.200	499.692							
	3	1493.800	499.491							
1000.000	1	997.600	1001.391	1000.822	1.163	0.082	0.60	< 0.20	0.20	PASSED
	2	1995.400	1001.592							
	3	2991.100	999.484							

Volume	About 10 $\mu$ l to 100 $\mu$ l	About 100 $\mu$ l to 1000 $\mu$ l	About 1 ml to 10 ml	About 10 ml to 100 ml
Uncertainty (k=2)	0.1 $\mu$ l	0.1 $\mu$ l	0.1 $\mu$ l	4 $\mu$ l

- Specifications conform to ISO 8655 standards.
- Each instrument is individually calibrated on electronic balance.
- TSD reading = 99.98 LPs.
- Weigh in mg or g.
- Volume, Mean & S.D. in ml or  $\mu$ l.

**Reference standard:**

The instrument is calibrated using a standard electronic balance with calibration traceability to NPL.

The reported expanded uncertainty of measurement is calculated by multiplying the standard uncertainty of measurement by the coverage factor k=2, which for normal distribution corresponds to a coverage probability of approximately 95%.

