

July - 2022

Lot. No. → 2022 0120

Urine analyser (Uriplus 200)

Exp. -

19/01/2023
Date

Parameter & Range	16 July	17 July	18 July	19 July	20 July	21 July	22 July	23 July	24 July	25 July	26 July	27 July
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Glucose (2+ To 4+)	2+	2+	2+	2+	2+	2+	2+	2+	3+	3+	2+	
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Bilirubin (1+ To 3+)	3+	3+	3+	3+	3+	3+	3+	3+	3+	3+	3+	
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Ketone (1+ To 3+)	1+	1+	1+	1+	1+	+-	1+	1+	1+	+-	1+	
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Blood (1+ To 3+)	3+	3+	3+	2+	2+	3+	2+	3+	3+	3+	2+	
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Protein (2+ To 3+)	2+	2+	3+	2+	2+	2+	2+	2+	2+	2+	2+	
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Urobilinogen (1+ To 3+)	2+	1+	1+	3+	3+	3+	3+	2+	2+	2+	3+	
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Sp. Gravity (1.015 To 1.030)	1.020	1.025	1.025	1.025	1.025	1.025	1.025	1.020	1.020	1.025	1.025	
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pH (5.5 To 7.5)	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	
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Leukocytes (1+ To 3+)	3+	3+	3+	3+	3+	3+	3+	3+	3+	3+	3+	
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Nitrite (Positive)	Positive	Positive	Positive	Positive	Pos.	Pos.	Pos.	Pos.	Pos.	Pos.	Pos.	
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GLOBAL TECHNICAL SERVICES

Sec. No.25, Plot No.49/3, L.I.G. Colony, Pradhikaran, Nigdi, Pune - 411044

Email : globaltechnical007@gmail.com

Mob : 9921239827 / 7276470703 / 9028888728

CALIBRATION CERTIFICATE

1) Customer

Name & Address SP HITECH PATHOLOGY LABORATORY Trimurti Plaza,Near Pavana Sahakari Bank, Somatane Phata Talegaon Dabhade Somatane Phata,	Calibration Certificate No . : GTS/220525/02- 015 Page No : 1 of 2 Date of Received : 25.05.2022 Date of Calibration : 25.05.2022 Calibration Due On : 24.05.2023 Location of Calibration : On Site
Amb. Temp. : 25±5 °C Relative Humidity : 50±20 %RH Condition of Item : ok	

2) Details of UUC

Name : Urine Analyzer	Make : Aspen
ID No : SPHL/EQ/URA/05	Model : uriplus 200
Sr No : 210010041629	
Location : Clinical Patholgy	

3) STANDARD USED FOR CALIBRATION

Name : Electrical Safety Analyzer
Certificate No : 2020001300
Certified By : Fluke Biomedical, USA
ID/Sr No : 4885027
Due Date : 12.02.2023

4) CALIBRATION RESULTS : EST TEST

VISUAL TEST

Sr No	Parameter	Result
1	Power Cords, Cables Checking	OK
2	Mains Socket Checking	OK
3	Equipment Type (B, BF, CF)	B
4	Equipment Class (I, II, III)	I

B-Body Type,BF-Body Float Type,CF-Cardiac Float Type
I-Properly Earthed ,II-Double Insulation,III-With Extra Low Safety Voltage

FUNCTIONAL TEST

Sr No	Parameter	Obsereved	Tolerance	Result
1	Voltage between Live and Neutral (Vln)	235.84	(210-240V)	Pass
2	Voltage between Live and Earth(Vle)	236.95	(210-240V)	Pass
3	Voltage between Neutral and and Earth (Vne)	1.13	(0-5V)	Pass
4	Enclosure Current	0.50	(0-10µA)	Pass
5	Leakage Current (IL)	125.62	(0-500µA)	Pass
6	Patient Leakage Current (PL)	0.75	(BF-0-100µA) (CF-0-10µA)	Pass



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Calibration Certificate No .

GTS/220525/02- 015

Page No 2 of 2

Note :

- 1)This certificate refers only to the particular item submitted for calibration. UUC stands for Unit Under Calibration.
- 2)This calibration results reported in the certificate are valid at the time of and the stated conditions of measurement.
- 3)Calibration Points were selected as per customer specification.
- 4)This certificate shall not be reproduced, except in full unless written permission for the publication of an approved abstract has been obtained from the Technical Manager of GTS,Pune.
- 5) Procedure used for calibration : MD-05

Calibrated By

S.C

Calibration Engineer
Mr Shafik Chorgaste

RN-21/0



Approved By

Technical Manager
Mr. Swapnil Bhagwat

End of the certificate



INSTALLATION REPORT

Customer Name : S P Hitech Pathology Laboratory

Place : Somatane Phata, Pune

Department : Laboratory

Contact Person : Anand Sir

Instrument Name : Uri-Plus 200

Serial Number : 2100100H1629

Date of Installation : 22 March 2022

The Analyzer was installed along with the necessary standard accessories. All basic requirements and adjustments were checked and are found to be satisfactory. The preliminary standardization of the analyzer and the training were provided to the complete satisfaction of the customer. The analyzer is found to be working satisfactorily.

For Aspen Diagnostics Pvt. Ltd

Authorized Signatory





INSTALLATION QUALIFICATION

IQ PROTOCOL

1. System Unpacking
2. System Checking For any Damages
3. All accessories as per check List verification
4. Space Requirement
5. Power Requirement
6. Reagents, Control, Calibrators verification.

1. SYSTEM UNPACKING & 2. SYSTEM CHECKING

Un packed Uri-Plus 200 instrument carefully and checked for any physical Damages.

3. ACCESSORIES CHECK-

Check all accessories as per check List

4. SPACE REQUIREMENT –

- Checked site for proper space allocation. At least 100 CM on each side and enough room for the below mentioned dimensions

DIMENSIONS	
Parameter	Analyzer OV
Width(mm)	376
Depth (mm)	316
Height (mm)	170
Weight (Kg)	3.6

5. POWER REQUIREMENT –

Requirement	Acceptable Range	Observed Ranged
Input Voltage	220 + / - 10 V	225 V
Line Frequency	50 HZ	50 HZ
Ambient Temperature	15 C – 30 C	23

6. STRIPS, CONTROL CHECK

Material	Expiry	Status
Strip Box		
Urinalysis Positive Control	2020 04 21	OK
Urinalysis Negative Control	2020 06 04	OK

PRE-INSTALLTION VERIFICATION REPORT :-

PRE-INSTALLATION VERIFICATION REPORT		
S/N	Parameter	Remark
1	Unpacking Instrument	OK
2	System Checking for damages	OK
3	Accessories check	OK
4	Space Check	OK
5	Power Check	OK
6	Reagents Check	OK



OPERATIONAL QUALIFICATION

The Operational Qualification procedure specifies the methodology for installation of specified system after successful installation qualification. Successful completion of procedure identifies that system is ready for operation and subsequent performance analysis.

OQ PROTOCOL

1. System Connections
2. Reagent & Waste Connections
3. Customizing the Analyzer Software
4. System Booting , Initialization & Check
5. Maintenance procedures.
6. Customer Training – Operation & Maintenance.

1. SYSTEM CONNECTION –

SYSTEM CONNECTIONS			
S/N	Name	Check	Remark
1	Input Power supply	Connected	Ok
2	Strip Moving Tray	Connected	Ok
3	Printer Paper	Inserted	Ok

2. REAGENT & WASTE CONNECTIONS -

Please refer to the User Manual and the Kit Literature of controls.

3. CUSTOMIZING ANALYZER SOFTWARE –

CUSTOMIZING ANALYZER SOFTWARE			
S/N	Parameters	Check	Remark
1	Date & Time	Operating Manual	Ok
2	QC Mode	Operating Manual	Ok
3	Reference Ranges	Operating Manual	Ok
4	Reference Units	Operating Manual	Ok
5	Printing format	Operating Manual	Ok
6	Creating New User	Operating Manual	Ok

4. SYSTEM BOOTING , INITIALIZATION & CHECK -

Installed Strip moving tray & Power ON System and check for successful initialization of the instrument.

5. MAINTENANCE PROCEDURES:-

MAINTENANCE			
S/N	Parameters	Check	Remark
1	Using Maintenance Protocol	Operator Manual	Ok

PERFORMANCE QUALIFICATION-

QC NAME: DIRUI Urinalysis Control

<u>Qc Name</u>	<u>Lot No</u>	<u>Expiry</u>
Positive Control	20211025	24.10.2022

<u>Item-Parameter</u>	<u>Range</u>	<u>Results Obtained</u>
Glucose	2+ to 4+	3+
Bilirubin	2+ to 3+	2+
Ketone	2+ to 3+	2+
Blood	1+ to 3+	2+
Protein	2+ to 3+	2+
Urobilinogen	1+ to 3+	2+
Leukocytes	1+ 3+	1+
Specific Gravity	1.015 to 1.030	1.020
pH	5.5 to 7.5	6.1
Nitrite	Positive	Positive

Date:26-07-2022 08:16

No. 0016

*UBG 3+ ≥ 135 $\mu\text{mol/L}$
*BIL 3+ ≥ 103 $\mu\text{mol/L}$
*KET 1+ 1.5 mmol/L
*BLD 2+ Ca80 Ery/uL
*PRO 2+ 1.0 g/L
*NIT Pos
*LEU 3+ $\geq \text{Ca}500\text{Leu/uL}$
*GLU 2+ 14 mmol/L
SG 1.025
pH 6.0

Date:25-07-2022 08:07

No. 0005

*UBG 2+ 68 $\mu\text{mol/L}$
*BIL 3+ ≥ 103 $\mu\text{mol/L}$
*KET +- 0.5 mmol/L
*BLD 3+ $\geq \text{Ca}200\text{Ery/uL}$
*PRO 2+ 1.0 g/L
*NIT Pos
*LEU 3+ $\geq \text{Ca}500\text{Leu/uL}$
*GLU 3+ 28 mmol/L
SG 1.025
pH 6.0

Date: 24-07-2022 08:28

No. 0006

*UBG	2+	68	umol/L
*BIL	3+	>=103	umol/L
*KET	1+	1.5	mmol/L
*BLD	3+	>=Ca200	Ery/uL
*PRO	2+	1.0	g/L
*NIT	Pos		
*LEU	3+	>=Ca500	Leu/uL
*GLU	3+	28	mmol/L
SG		1.020	
pH		6.0	

Date: 23-07-2022 08:11

No. 0007

*UBG	2+	68	umol/L
*BIL	3+	>=103	umol/L
*KET	1+	1.5	mmol/L
*BLD	3+	>=Ca200	Ery/uL
*PRO	2+	1.0	g/L
*NIT	Pos		
*LEU	3+	>=Ca500	Leu/uL
*GLU	2+	14	mmol/L
SG		1.020	
pH		6.0	

Date:21-07-2022 08:03

No. 0011

*UBG	3+	>=135	umol/L
*BIL	3+	>=103	umol/L
*KET	+-	0.5	mmol/L
*BLD	3+	>=Ca200	Ery/uL
*PRO	2+	1.0	g/L
*NIT	Pos		
*LEU	3+	>=Ca500	Leu/uL
*GLU	2+	14	mmol/L
SG		1.025	
pH		6.0	

Date:22-07-2022 08:03

No. 0015

*UBG	3+	>=135	umol/L
*BIL	3+	>=103	umol/L
*KET	1+	1.5	mmol/L
*BLD	2+	Ca80	Ery/uL
*PRO	2+	1.0	g/L
*NIT	Pos		
*LEU	3+	>=Ca500	Leu/uL
*GLU	2+	14	mmol/L
SG		1.025	
pH		6.0	

Date:19-07-2022 08:02

No. 0013

*UBG	3+	>=135	umol/L
*BIL	3+	>=103	umol/L
*KET	1+	1.5	mmol/L
*BLD	2+	Ca80	Ery/uL
*PRO	2+	1.0	g/L
*NIT	Pos		
*LEU	3+	>=Ca500	Leu/uL
*GLU	2+	14	mmol/L
SG		1.025	
pH		6.0	

Date:20-07-2022 08:11

No. 0014

*UBG	3+	>=135	umol/L
*BIL	3+	>=103	umol/L
*KET	1+	1.5	mmol/L
*BLD	2+	Ca80	Ery/uL
*PRO	2+	1.0	g/L
*NIT	Pos		
*LEU	3+	>=Ca500	Leu/uL
*GLU	2+	14	mmol/L
SG		1.025	
pH		6.0	