

CALIBRATION CERTIFICATE

Customer Name & Address:-	Date:- 02.09.2021
Likhithas Diagnostics and Speciality Lab, Zenrise, Plot No. 201, Mythrinagar, NH – 65, Madinaguda, Hyderabad, 500049	Instrument Name:- Urine analyzer
	Model:- DIRUI H-100
	Serial No:- N1900100H0713SE

Power Supply Check List

	Required Voltage	Observed Voltage
Point1	+5V	<input type="text" value="+5 V"/>
Point2	-12V	<input type="text" value="-12 V"/>
Point 3	+12V	<input type="text" value="+ 12 V"/>

Main Board Check List

	Required Voltage			Observed Voltage		
Pin JP 3	+5V	-12V	+12V	<input type="text" value="+5 V"/>	<input type="text" value="-12 V"/>	<input type="text" value="+ 12 V"/>
Pin JP 10	+12V			<input type="text" value="+ 12 V"/>		
Pin JP 8	+5V			<input type="text" value="+5 V"/>		
Pin JP 6	+12V all Pins			<input type="text" value="+ 12 V"/>		

A.D Board Check List

	Required Voltage	Observed Voltage
JP 1	+5V (First Pin)	+5 V

Calibration

Successful

Not Successful

For RAPHA DIAGNOSTICS PVT. LTD

Authorized Signatory



Next Calibration due on **01.09.2022**

Installation Qualification of the DIRUI H-100 Urine Analyzer

CERTIFICATION

Installation Qualification of the below mentioned Instrument

Instrument Name : Urine Analyzer

Model : DIRUI H-100

Serial No : N1900100H0713SE

Manufacturer: DIRUI INDUSTRIAL CO. LTD.

Customer: Likhitha's Diagnostics and Speciality Lab,
Zenrise, Plot No. 201, Mythrinagar, NH – 65, Madinaguda,
Hyderabad, 500049.

has been performed as per the manufacturer's protocols and was found to meet the requirements necessary
for the instrument to be installed in the customer's laboratory.

This installation qualification is valid from 02.09.2021

For RAPHA DIAGNOSTICS PVT. LTD



Authorized Signatory



Operational Qualification of the DIRUI H-100 Urine Analyzer

CERTIFICATION

Operational Qualification of the below mentioned Instrument

Instrument Name : Urine Analyzer

Model : DIRUI H-100

Serial No : N1900100H0713SE

Manufacturer: DIRUI INDUSTRIAL CO. LTD.

Customer: Likhithas Diagnostics and Speciality Lab,
Zenrise, Plot No. 201, Mythrinagar, NH – 65, Madinaguda,
Hyderabad, 500049

has been performed as per the manufacturer's protocols and was found to meet the requirements necessary
for the instrument to be used in the customer's laboratory.

This Operational Qualification is performed on 02.09.2021

For RAPHA DIAGNOSTICS PVT. LTD



Authorized Signatory



Performance Qualification of the DIRUI H-100 Urine Analyzer

CERTIFICATION

Performance Qualification of the below mentioned Instrument

Instrument Name : Urine Analyzer

Model : DIRUI H-100

Serial No : N1900100H0713SE

Manufacturer: DIRUI INDUSTRIAL CO. LTD.

Customer: Likhithas Diagnostics and Speciality Lab,
Zenrise, Plot No. 201, Mythrinagar, NH – 65, Madinaguda,
Hyderabad, 500049

has been performed as per the manufacturer's protocols and was found to meet the requirements necessary
for the instrument to be used in the customer's laboratory.

The validity of this Performance Verification is from 02.09.2021

For RAPHA DIAGNOSTICS PVT. LTD



Authorized Signatory



Likhitha's Diagnostics and Speciality Lab, ZenRise, Madinaguda, Hyderabad

URINE STRIP READER

Precision Check of DIRUI H100

Date: 02.09.2021

Equipment S.N.: N1900100H0713SE

Control : DIRUI Urinalysis Positive Control

Lot No. : 20210315 Expiry Date : 14.03.2022

S.N	Parameters									
	UBG	BIL	KET	BLD	PRO	NIT	LEU	GLU	SPG	pH
1	Normal	Neg	Neg	Neg	Neg	Neg	Neg	Neg	1.020	6.0
2	Normal	Neg	Neg	Neg	Neg	Neg	Neg	Neg	1.020	6.0
3	Normal	Neg	Neg	Neg	Neg	Neg	Neg	Neg	1.020	6.0
4	Normal	Neg	Neg	Neg	Neg	Neg	Neg	Neg	1.020	6.0
5	Normal	Neg	Neg	Neg	Neg	Neg	Neg	Neg	1.020	6.0
6	Normal	Neg	Neg	Neg	Neg	Neg	Neg	Neg	1.020	6.0
7	Normal	Neg	Neg	Neg	Neg	Neg	Neg	Neg	1.020	6.0
8	Normal	Neg	Neg	Neg	Neg	Neg	Neg	Neg	1.020	6.0
9	Normal	Neg	Neg	Neg	Neg	Neg	Neg	Neg	1.025	6.0
10	Normal	Neg	Neg	Neg	Neg	Neg	Neg	Neg	1.025	6.0

Comments : Satisfactory Performance

Processed By : Lab Technician
Kanishka

Verified By : Quality Manager
[Signature]
21/9/2021

Likhitha's Diagnostics and Speciality Lab, ZenRise, Madinaguda, Hyderabad

URINE STRIP READER

Precision Check of DIRUI H100

Date: 02.09.2021

Equipment S.N.: N1900100H0713SE

Control : DIRUI Urinalysis Positive Control

Lot No. : 20201116 Expiry Date : 15.11.2021

S.N	Parameters									
	UBG	BIL	KET	BLD	PRO	NIT	LEU	GLU	SPG	pH
1	1+	3+	2+	3+	2+	Pos	3+	3+	1.025	5.50
2	1+	3+	2+	3+	3+	Pos	3+	4+	1.025	6.00
3	1+	3+	2+	3+	3+	Pos	3+	3+	1.025	6.00
4	1+	3+	2+	3+	3+	Pos	3+	4+	1.025	6.00
5	1+	3+	2+	3+	2+	Pos	3+	4+	1.025	6.00
6	1+	3+	2+	3+	2+	Pos	3+	2+	1.025	6.00
7	1+	3+	2+	3+	3+	Pos	3+	4+	1.025	6.00
8	1+	3+	1+	2+	2+	Pos	3+	3+	1.025	5.50
9	1+	3+	2+	3+	3+	Pos	3+	2+	1.025	6.00
10	1+	3+	2+	3+	3+	Pos	3+	2+	1.025	6.00

Comments : Satisfactory Performance

Processed By : Lab Technician
Krushna

[Signature]
21/9/2021
Verified By : Quality Manager

DIRUI Urinalysis Control Neg
Lot No. - 20210315
Exp. Dt - 14/03/2022

DIRUI H100 Precision Study.
Equip S.N. N1900100H0713SE

Date
02/09/2021

Date:02-09-2021 08:19
No. 0001
ID:
UBG Normal
BIL Neg
KET Neg
BLD Neg
PRO Neg
NIT Neg
LEU Neg
GLU Neg
SG 1.020
pH 6.0
Color
Clarity

Stop
29/21

Date:02-09-2021 08:21
No. 0001
ID:
UBG Normal
BIL Neg
KET Neg
BLD Neg
PRO Neg
NIT Neg
LEU Neg
GLU Neg
SG 1.020
pH 6.0
Color
Clarity

Stop
29/21

Date:02-09-2021 08:22
No. 0001
ID:
UBG Normal
BIL Neg
KET Neg
BLD Neg
PRO Neg
NIT Neg
LEU Neg
GLU Neg
SG 1.020
pH 6.0
Color
Clarity

Stop
29/21

Date:02-09-2021 08:16
No. 0001
ID:
UBG Normal
BIL Neg
KET Neg
BLD Neg
PRO Neg
NIT Neg
LEU Neg
GLU Neg
SG 1.020
pH 6.0
Color
Clarity

Stop
29/21

Date:02-09-2021 08:15
No. 0001
ID:
UBG Normal
BIL Neg
KET Neg
BLD Neg
PRO Neg
NIT Neg
LEU Neg
GLU Neg
SG 1.020
pH 6.0
Color
Clarity

Stop
29/21

Date:02-09-2021 08:13
No. 0001
ID:
UBG Normal
BIL Neg
KET Neg
BLD Neg
PRO Neg
NIT Neg
LEU Neg
GLU Neg
SG 1.020
pH 6.0
Color
Clarity

Stop
29/21

Date:02-09-2021 08:12
No. 0001
ID:
UBG Normal
BIL Neg
KET Neg
BLD Neg
PRO Neg
NIT Neg
LEU Neg
GLU Neg
SG 1.020
pH 6.0
Color
Clarity

Stop
29/21

Date:02-09-2021 08:23
No. 0002
ID:
UBG Normal
BIL Neg
KET Neg
BLD Neg
PRO Neg
NIT Neg
LEU Neg
GLU Neg
SG 1.020
pH 6.0
Color
Clarity

Stop
29/21

Date:02-09-2021 08:36
No. 0001
ID:
UBG Normal
BIL Neg
KET Neg
BLD Neg
PRO Neg
NIT Neg
LEU Neg
GLU Neg
SG 1.025
pH 6.0
Color
Clarity

Stop
29/21

Date:02-09-2021 08:38
No. 0001
ID:
UBG Normal
BIL Neg
KET Neg
BLD Neg
PRO Neg
NIT Neg
LEU Neg
GLU Neg
SG 1.025
pH 6.0
Color
Clarity

Stop
29/21

DIRUI Urinalysis Control Pos
Lot No. 20201116
Exp. Dt - 15/11/2021

DIRUI H100 Precision Study
Equip SN. N1900100H0713SE

Date
02/09/2021

Date:02-09-2021 16:21
No. 0002
ID:
*UBG 1+
*BIL 3+
*KET 2+
*BLD 3+
*PRO 2+
*NIT Pos
*LEU 3+
*GLU 3+
SG 1.025
pH 5.5
Color
Clarity

Stop
29/21

Date:02-09-2021 16:23
No. 0002
ID:
*UBG 1+
*BIL 3+
*KET 2+
*BLD 3+
*PRO 3+
*NIT Pos
*LEU 3+
*GLU 3+
SG 1.025
pH 6.0
Color
Clarity

Stop
29/21

Date:02-09-2021 16:24
No. 0002
ID:
*UBG 1+
*BIL 3+
*KET 2+
*BLD 3+
*PRO 3+
*NIT Pos
*LEU 3+
*GLU 2+
SG 1.025
pH 6.0
Color
Clarity

Stop
29/21

Date:02-09-2021 16:26
No. 0002
ID:
*UBG 1+
*BIL 3+
*KET 2+
*BLD 3+
*PRO 3+
*NIT Pos
*LEU 3+
*GLU 2+
SG 1.025
pH 6.0
Color
Clarity

Stop
29/21

Date:02-09-2021 16:37
No. 0002
ID:
*UBG 1+
*BIL 3+
*KET 2+
*BLD 3+
*PRO 2+
*NIT Pos
*LEU 3+
*GLU 3+
SG 1.025
pH 6.0
Color
Clarity

Stop
29/21

Date:02-09-2021 16:37
No. 0002
ID:
*UBG 1+
*BIL 3+
*KET 2+
*BLD 3+
*PRO 2+
*NIT Pos
*LEU 3+
*GLU 3+
SG 1.025
pH 6.0
Color
Clarity

Stop
29/21

Date:02-09-2021 16:27
No. 0002
ID:
*UBG 1+
*BIL 3+
*KET 2+
*BLD 3+
*PRO 3+
*NIT Pos
*LEU 3+
*GLU 2+
SG 1.025
pH 6.0
Color
Clarity

Stop
29/21

Date:02-09-2021 16:29
No. 0002
ID:
*UBG 1+
*BIL 3+
*KET 2+
*BLD 2+
*PRO 2+
*NIT Pos
*LEU 3+
*GLU 3+
SG 1.025
pH 6.0
Color
Clarity

Stop
29/21

Date:02-09-2021 16:30
No. 0002
ID:
*UBG 1+
*BIL 3+
*KET 2+
*BLD 3+
*PRO 3+
*NIT Pos
*LEU 3+
*GLU 3+
SG 1.025
pH 6.0
Color
Clarity

Stop
29/21

Date:02-09-2021 16:32
No. 0002
ID:
*UBG 1+
*BIL 3+
*KET 2+
*BLD 3+
*PRO 3+
*NIT Pos
*LEU 3+
*GLU 3+
SG 1.025
pH 6.0
Color
Clarity

Stop
29/21