

CALIBRATION CERTIFICATE

Customer Name & Address:-

Date:- 02.09.2021

Likhitha's Diagnostics and Speciality Lab,
(A Unit of Pragnashree Health Care Private Limited)
H. No. 1-8-65/A, North Kamalanagar, Above Andhra Bank,
FCH, Hyderabad, Telangana State, Pin -500062

Instrument Name:- Urine analyzer

Model:- QDX Urilyzer

Serial No:- NI3001001H1172SE

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 QDX Urine Analyser

CERTIFICATION

Installation Qualification of the below mentioned Instrument

Instrument Name : Urine Analyzer

Model : QDX URILYZER

Serial No : N1300100H1172SE

Manufacturer: DIRUI INDUSTRIAL CO. LTD.

Customer: Likhitha's Diagnostics and Speciality Lab, (A unit of Pragnashree
Healthcare Pvt Ltd), H. No. 1-8-65/A , North Kamalanagar,
Above Andhra Bank, ECIL, Hyderabad -500062

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



Operation Qualification of the QDX Urine Analyser

CERTIFICATION

Operational Qualification of the below mentioned Instrument

Instrument Name : Urine Analyzer

Model : QDX URILYZER

Serial No : N1300100H1172SE

Manufacturer: DIRUI INDUSTRIAL CO. LTD,

Customer: Likhitha's Diagnostics and Speciality Lab, (A unit of
Pragnashree Healthcare Pvt Ltd), H. No. 1-8-65/A , North
Kamalanagar, Above Andhra Bank, ECIL, Hyderabad -
500062

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 QDX Urine Analyser

CERTIFICATION

Performance Qualification of the below mentioned Instrument

Instrument Name : Urine Analyzer

Model : QDX URILYZER

Serial No : N1300100H1172SE

Manufacturer: DIRUI INDUSTRIAL CO. LTD,

Customer: Likhitha's Diagnostics and Speciality Lab, (A unit of
Pragnashree Healthcare Pvt Ltd), H. No. 1-8-65/A ,
North Kamalanagar, Above Andhra Bank, ECIL,
Hyderabad -500062

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



QDX User,
 Calibration Report with. Std. Strip provided by
 the company.

Date:02-09-2021 10:05

Calibration OK



Am
2/9/2021.

URINE STRIP READER

Precision Check of QDX Urilyser

Date: 31.01.2022

Equipment S.N.: N1300100H1172SE

Control : DIRUI Urinalysis Negative Control

Equipment : QDX Urilyser

Lot No. : 20211019

Expiry Date : 18.10.2022

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

Comments : Satisfactory Performance

Processed By : *Naveen* Lab Technician

Verified By : *[Signature]* Quality Manager

URINE STRIP READER

Precision Check of QDX Urilyser

Date: 31.01.2022

Control : DIRUI Urinalysis Positive Control

Lot No. : 20211012 Expiry Date : 11.10.2022

Equipment S.N.: N1300100H1172SE

Equipment : QDX Urilyser

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

Comments : Satisfactory Performance

Processed By : Naveen
Lab Technician

Verified By : [Signature]
Quality Manager
30/1/2022

Date: 31-01-2022 16:32
 No. 0001
 *UBG 3+ >8 mg/dL
 *BIL 3+ >6 mg/dL
 *KET 2+ 40 mg/dL
 *BLD 2+ Ca80 Ery/uL
 *PRO 3+ >300 mg/dL
 *NIT Pos
 *LEU 2+ Ca125 Leu/uL
 *GLU 3+ 500 mg/dL
 SG 1.025
 pH 6.0

①

Date: 31-01-2022 16:34
 No. 0002
 *UBG 2+ 4 mg/dL
 *BIL 3+ >6 mg/dL
 *KET 3+ >80 mg/dL
 *BLD 2+ Ca80 Ery/uL
 *PRO 3+ >300 mg/dL
 *NIT Pos
 *LEU 2+ Ca125 Leu/uL
 *GLU 3+ 500 mg/dL
 SG 1.025
 pH 6.0

②

Date: 31-01-2022 16:36
 No. 0003
 *UBG 2+ 4 mg/dL
 *BIL 3+ >6 mg/dL
 *KET 3+ >80 mg/dL
 *BLD 2+ Ca80 Ery/uL
 *PRO 3+ >300 mg/dL
 *NIT Pos
 *LEU 2+ Ca125 Leu/uL
 *GLU 3+ 500 mg/dL
 SG 1.025
 pH 6.0

③

Date: 31-01-2022 16:37
 No. 0004
 *UBG 2+ 4 mg/dL
 *BIL 3+ >6 mg/dL
 *KET 2+ 40 mg/dL
 *BLD 2+ Ca80 Ery/uL
 *PRO 2+ 100 mg/dL
 *NIT Pos
 *LEU 2+ Ca125 Leu/uL
 *GLU 3+ 500 mg/dL
 SG 1.025
 pH 6.0

④

Date: 31-01-2022 16:38
 No. 0005
 *UBG 2+ 4 mg/dL
 *BIL 3+ >6 mg/dL
 *KET 2+ 40 mg/dL
 *BLD 2+ Ca80 Ery/uL
 *PRO 2+ 100 mg/dL
 *NIT Pos
 *LEU 2+ Ca125 Leu/uL
 *GLU 3+ 500 mg/dL
 SG 1.025
 pH 6.0

⑤

Date: 31-01-2022 16:39
 No. 0006
 *UBG 2+ 4 mg/dL
 *BIL 3+ >6 mg/dL
 *KET 2+ 40 mg/dL
 *BLD 2+ Ca80 Ery/uL
 *PRO 2+ 100 mg/dL
 *NIT Pos
 *LEU 2+ Ca125 Leu/uL
 *GLU 3+ 500 mg/dL
 SG 1.025
 pH 6.0

⑥

Date: 31-01-2022 16:40
 No. 0007
 *UBG 1+ 2 mg/dL
 *BIL 3+ >6 mg/dL
 *KET 2+ 40 mg/dL
 *BLD 2+ Ca80 Ery/uL
 *PRO 2+ 100 mg/dL
 *NIT Pos
 *LEU 2+ Ca125 Leu/uL
 *GLU 3+ 500 mg/dL
 SG 1.025
 pH 6.0

⑦

Date: 31-01-2022 16:43
 No. 0008
 *UBG 2+ 4 mg/dL
 *BIL 3+ >6 mg/dL
 *KET 3+ >80 mg/dL
 *BLD 3+ >Ca200 Ery/uL
 *PRO 3+ >300 mg/dL
 *NIT Pos
 *LEU 3+ >Ca500 Leu/uL
 *GLU 3+ 500 mg/dL
 SG 1.025
 pH 6.0

⑧

Date: 31-01-2022 16:45
 No. 0009
 *UBG 2+ 4 mg/dL
 *BIL 3+ >6 mg/dL
 *KET 3+ >80 mg/dL
 *BLD 3+ >Ca200 Ery/uL
 *PRO 3+ >300 mg/dL
 *NIT Pos
 *LEU 3+ >Ca500 Leu/uL
 *GLU 3+ 500 mg/dL
 SG 1.025
 pH 6.0

⑨

Date: 31-01-2022 16:46
 No. 0010
 *UBG 2+ 4 mg/dL
 *BIL 3+ >6 mg/dL
 *KET 3+ >80 mg/dL
 *BLD 3+ >Ca200 Ery/uL
 *PRO 3+ >300 mg/dL
 *NIT Pos
 *LEU 3+ >Ca500 Leu/uL
 *GLU 3+ 500 mg/dL
 SG 1.025
 pH 6.0

⑩

Control - DIRUI Urinalysis Control (Positive)
 Lot NO. 20211012 Exp Date - 11/10/2022
 Negative - Lot. 20211019
 Exp. 18/10/2022

JMP
 31/1/2022

Date:31-01-2022 17:22
No. 0011
UBG Normal 0.2 mg/dL
BIL Neg
KET Neg
BLD Neg
PRO Neg
NIT Neg
LEU Neg
GLU Neg
SG 1.025
pH 6.0

Date:31-01-2022 17:23
No. 0012
UBG Normal 0.2 mg/dL
BIL Neg
KET Neg
BLD Neg
PRO Neg
NIT Neg
LEU Neg
GLU Neg
SG 1.025
pH 6.0

Date:31-01-2022 17:24
No. 0013
UBG Normal 0.2 mg/dL
BIL Neg
KET Neg
BLD Neg
PRO Neg
NIT Neg
LEU Neg
GLU Neg
SG 1.025
pH 6.0

Date:31-01-2022 17:26
No. 0014
UBG Normal 0.2 mg/dL
BIL Neg
KET Neg
BLD Neg
PRO Neg
NIT Neg
LEU Neg
GLU Neg
SG 1.025
pH 6.0

Date:31-01-2022 17:27
No. 0015
UBG Normal 0.2 mg/dL
BIL Neg
KET Neg
BLD Neg
PRO Neg
NIT Neg
LEU Neg
GLU Neg
SG 1.025
pH 6.0

2100100H1443

Date:31-01-2022 17:28
No. 0016
UBG Normal 0.2 mg/dL
BIL Neg
KET Neg
BLD Neg
PRO Neg
NIT Neg
LEU Neg
GLU Neg
SG 1.025
pH 6.0

Date:31-01-2022 17:29
No. 0017
UBG Normal 0.2 mg/dL
BIL Neg
KET Neg
BLD Neg
PRO Neg
NIT Neg
LEU Neg
GLU Neg
SG 1.025
pH 6.0

Date:31-01-2022 17:30
No. 0018
UBG Normal 0.2 mg/dL
BIL Neg
KET Neg
BLD Neg
PRO Neg
NIT Neg
LEU Neg
GLU Neg
SG 1.025
pH 6.0

Date:31-01-2022 17:31
No. 0019
UBG Normal 0.2 mg/dL
BIL Neg
KET Neg
BLD Neg
PRO Neg
NIT Neg
LEU Neg
GLU Neg
SG 1.025
pH 6.0

Date:31-01-2022 17:33
No. 0020
UBG Normal 0.2 mg/dL
BIL Neg
KET Neg
BLD Neg
PRO Neg
NIT Neg
*LEU +- Ca15 Leu/uL
GLU Neg
SG 1.025
pH 6.0

Control - DRUI Urinalysis Control. (Negative) lot 20211019 Exp 18/10/22
lot No - 20211012, Exp Date - 11/10/2022 (Positive)

K. krishna

Jal
31/1/2022

Negative

01-02-2022

Date:2022-02-01 11:01
No. 0070
ID:
UBG Normal 0.2 mg/dL
BIL Neg
KET Neg
BLD Neg
PRO Neg
NIT Neg
LEU Neg
GLU Neg
SG 1.015
pH 6.0
Color
Clarity

2/2/22

Date:2022-02-02 12:12
No. 0030

ID:
UBG Normal 0.2 mg/dL
BIL Neg
KET Neg
BLD Neg
PRO Neg
*NIT Pos
LEU Neg
*GLU 2+ 250 mg/dL
SG 1.015
pH <=5.0
Color
Clarity

Negative

03-02-2022

Date:2022-02-03 11:04
No. 0072
ID:
UBG Normal 0.2 mg/dL
BIL Neg
KET Neg
BLD Neg
PRO Neg
NIT Neg
LEU Neg
GLU Neg
SG 1.020
pH 6.5
Color
Clarity

04-02-2022

Date:2022-02-04 08:34
No. 0033
ID:
UBG Normal 0.2 mg/dL
BIL Neg
KET Neg
BLD Neg
PRO Neg
NIT Neg
LEU Neg
*GLU 1+ 100 mg/dL
SG >=1.030
pH 6.0
Color
Clarity

Negative

05-02-2022

Date:2022-02-05 11:06
No. 0074
ID:
UBG Normal 0.2 mg/dL
BIL Neg
KET Neg
BLD Neg
PRO Neg
NIT Neg
LEU Neg
GLU Neg
SG 1.020
pH 6.0
Color
Clarity

Negative

06-02-2022

Date:2022-02-06 09:08
No. 0075
ID:
UBG Normal 0.2 mg/dL
BIL Neg
KET Neg
BLD Neg
PRO Neg
NIT Neg
LEU Neg
GLU Neg
SG 1.020
pH 6.0
Color
Clarity

7-02-2022

Negative

Date:2022-02-07 10:11
No. 0077
ID:
UBG Normal 0.2 mg/dL
BIL Neg
KET Neg
BLD Neg
PRO Neg
NIT Neg
LEU Neg
GLU Neg
SG 1.025
pH 6.0
Color
Clarity

08-02-2022

Negative

Date:2022-02-08 08:15
No. 0079
ID:
UBG Normal 0.2 mg/dL
BIL Neg
KET Neg
BLD Neg
PRO Neg
NIT Neg
LEU Neg
GLU Neg
SG 1.025
pH 6.0
Color
Clarity

09-02-
Negative

Date:2022-02-09 09:03
No. 0081
ID:
UBG Normal 0.2 mg/dL
BIL Neg
KET Neg
BLD Neg
PRO Neg
NIT Neg
LEU Neg
GLU Neg
SG 1.025
pH 6.0
Color
Clarity

Negative

10-02-2022

Date:2022-02-10 08:27
No. 0083
ID:
UBG Normal 0.2 mg/dL
BIL Neg
KET Neg
BLD Neg
PRO Neg
NIT Neg
LEU Neg
GLU Neg
SG 1.025
pH 6.0
Color
Clarity

Negative

11-02-2022

Date:2022-02-11 09:26
No. 0086
ID:
UBG Normal 0.2 mg/dL
BIL Neg
KET Neg
BLD Neg
PRO Neg
NIT Neg
LEU Neg
GLU Neg
SG ≥ 1.030
pH 6.0
Color
Clarity

Positive

01-02-2022

Date:2022-02-01 11:00
No. 0069

ID:
*UBG 2+ 4 mg/dL
*BIL 3+ >=6 mg/dL
*KET 2+ 40 mg/dL
*BLD 3+ >=Ca200Ery/uL
*PRO 2+ 100 mg/dL
*NIT Pos
*LEU 3+ >=Ca500Leu/uL
*GLU 3+ 500 mg/dL
SG 1.025
pH 6.0
Color
Clarity

Date:2022-02-02 12:14
No. 0031

ID:
*UBG 3+ >=8 mg/dL
*BIL 3+ >=6 mg/dL
*KET 2+ 40 mg/dL
*BLD 3+ >=Ca200Ery/uL
*PRO 2+ 100 mg/dL
*NIT Pos
*LEU 3+ >=Ca500Leu/uL
GLU Neg
SG 1.025
pH 6.5
Color
Clarity

Positive

03-02-2022

Date:2022-02-03 11:03
No. 0071

ID:
*UBG 2+ 4 mg/dL
*BIL 3+ >=6 mg/dL
*KET 2+ 40 mg/dL
*BLD 3+ >=Ca200Ery/uL
*PRO 2+ 100 mg/dL
*NIT Pos
*LEU 3+ >=Ca500Leu/uL
*GLU 2+ 250 mg/dL
SG 1.020
pH 6.0
Color
Clarity

Date:2022-02-04 08:36
No. 0034

ID:
*UBG 3+ >=8 mg/dL
*BIL 3+ >=6 mg/dL
*KET 2+ 40 mg/dL
*BLD 3+ >=Ca200Ery/uL
*PRO 2+ 100 mg/dL
*NIT Pos
*LEU 3+ >=Ca500Leu/uL
GLU Neg
SG 1.025
pH 6.0
Color
Clarity

Positive

05-02-2022

Date:2022-02-05 11:05
No. 0073

ID:
*UBG 2+ 4 mg/dL
*BIL 3+ >=6 mg/dL
*KET 2+ 40 mg/dL
*BLD 3+ >=Ca200Ery/uL
*PRO 2+ 100 mg/dL
*NIT Pos
*LEU 3+ >=Ca500Leu/uL
*GLU 2+ 250 mg/dL
SG 1.020
pH 6.5
Color
Clarity

Positive

06-02-2022

Date:2022-02-06 09:09
No. 0076

ID:
*UBG 1+ 2 mg/dL
*BIL 3+ >=6 mg/dL
*KET 2+ 40 mg/dL
*BLD 3+ >=Ca200Ery/uL
*PRO 2+ 100 mg/dL
*NIT Pos
*LEU 3+ >=Ca500Leu/uL
*GLU 2+ 250 mg/dL
SG 1.020
pH 6.5
Color
Clarity

7-02-2022

Positive

Date:2022-02-07 10:13
No. 0078

ID:
*UBG 1+ 2 mg/dL
*BIL 3+ >=6 mg/dL
*KET 1+ 15 mg/dL
*BLD 3+ >=Ca200Ery/uL
*PRO 2+ 100 mg/dL
*NIT Pos
*LEU 3+ >=Ca500Leu/uL
*GLU 2+ 250 mg/dL
SG 1.020
pH 6.0
Color
Clarity

08-02-2022

Positive

Date:2022-02-08 08:16
No. 0080

ID:
*UBG 1+ 2 mg/dL
*BIL 3+ >=6 mg/dL
*KET 1+ 15 mg/dL
*BLD 3+ >=Ca200Ery/uL
*PRO 2+ 100 mg/dL
*NIT Pos
*LEU 3+ >=Ca500Leu/uL
*GLU 2+ 250 mg/dL
SG 1.020
pH 6.0
Color
Clarity

09-02-2022

Positive

Date: 2022-02-09 09:05
 No. 0082
 ID:
 *UBG 1+ 2 mg/dL
 *BIL 3+ >=6 mg/dL
 *KET 1+ 15 mg/dL
 *BLD 3+ >=Ca200Ery/uL
 *PRO 2+ 100 mg/dL
 *NIT Pos
 *LEU 3+ >=Ca500Leu/uL
 *GLU 2+ 250 mg/dL
 SG 1.025
 pH 6.0
 Color
 Clarity

Date: 2022-02-10 08:30
 No. 0085
 ID:
 *UBG 1+ 2 mg/dL
 *BIL 3+ >=6 mg/dL
 *KET +- 5 mg/dL
 *BLD 3+ >=Ca200Ery/uL
 *PRO 2+ 100 mg/dL
 *NIT Pos
 *LEU 3+ >=Ca500Leu/uL
 *GLU 2+ *250 mg/dL
 SG 1.025
 pH 6.0
 Color
 Clarity

Positive

11-02-2022

Positive

Date: 2022-02-11 09:29
 No. 0087
 ID:
 UBG Normal 0.2 mg/dL
 BIL Neg
 *KET 3+ >=80 mg/dL
 *BLD 3+ >=Ca200Ery/uL
 *PRO 3+ >=300 mg/dL
 NIT Neg
 *LEU 3+ >=Ca500Leu/uL
 *GLU 4+ >=1000 mg/dL
 SG <=1.005
 pH >=9.0
 Color
 Clarity