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July 01, 2022

Calibration Certificate for Semi Automated Urine Analyser Model: Laura (Sl. No. 0846-1-202110)

This is to certify that the Semi Automated Urine Analyser, Model: Laura installed at Redcliffe Lifetech Pvt. Ltd., IGM Hospital Road, Rabindra Palli, Agartala, Tripura, PIN - 799001 has been calibrated. All parameters have been checked and found well within the limit.

This calibration is valid till June 30, 2023.

For Transasia Bio-Medicals Ltd.

Taraknath Chakraborty

Dy. Regional Service Manager



instrument Name

Automated Urine Analyzer

Instrument ID

0846-1-202110



Operational Qualification for Laura (Automated Urine Analyzer)

System Certification:

Study data has determined that the System described in this document either meets all criteria outlined in this Operational Protocol, or exceptional conditions have been identified and documentation included.

Exceptional conditions, if any, have been addressed.

The System is ready for specific usage.

Protocol Performed By:

TBM, Guwahati

Name: Prasenjit Das

Designation: Sr Service engineer

Customer Authorization:

Name: Samob Pand

Designation: Lab Lech

Company Representative Name & Sign

Customer Name & Sign

Date

30/6/202 AUMBAL12 C

Date: 01 - 07-2022

Instrument Name

Automated Urine Analyzer

Instrument ID

0846-1-202110



Installation Qualification for Laura (Automated Urine Analyzer)

Customer Name

: Redcliffe Life Tech PVT, LTD.

Address

: Agartala, Tripura

Instrument Name

: Laura (Automated Urine Analyzer)

Serial Number

: 0846-1-202110

Initial Inspection of the unit carried out and the details are as follows:

System Condition Report:

Found the System to have been delivered in satisfactory condition and no external physical damaged observed on the same. The Tilt-indicator and the Shock-indicators on the Packaging were found to be in Good Condition, indicating the System has not been subjected to mechanical shocks or stored in any manner, so as to cause any damage to the same.

Found all the required accessories as required.

Installation Procedure & Checklist Attached for records.

External Requirements for Installation:

1. Power Source

: Input 100-250V / 50-60 Hz

2. Temperature

: 10° - 30° C

3. Humidity

: ≤ 75%

5. Working Area

4. Atmospheric Pressure: 76 – 106kPa

: Free from intense light source, electromagnetic

interference

TRANSASIA BIOMEDICALS LIMITED	
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Instrument Name Automated Urine Analyzer Instrument ID 0846-1-202110	Bio-Medicals Ltd.

Installation Certificate for Laura (Automated urine Analyzer)

This is to certify that the Laura Instrument Serial No. 0846-1-202110 is successfully Installed and Commissioned at Redeliffe Lifetech Private LTD and the Installation Protocol / checklist has been successfully completed for the above instrument.

TBM, Technical Services Department

Name

: Prasenjit Das

Designation: Sr Service Engineer

Date

: 30.06.2022

instrument Name | Autom

Automated Urine Analyzer

Instrument ID

0846-1-202110



Installation Qualifications for Laura (Automated Urine Analyzer)

Carried out all the Installation Procedures as per the Installation Procedure & Checklists.

Carried out all the necessary checks and alignments.

Carried out all the necessary system checks and tests.

Carried out Priming and Cleaning Operations

Checked the counts by running the samples and found OK.

Performed all due maintenance activities.

Handed over the Instrument for Operators Training & Qualifications

For TBM, Technical Services Department

Name: Prasenjit Das

Designation: Sr Service Engineer

Date: 30.06.2022

astrument Name

Automated Urine Analyzer | Instrument ID

0846-1-202110

Installation Report for Laura (Automated Urine Analyzer)

Customer Name

: Redcliffe Life Tech PVT, LTD.

Department

: Laboratory

Contact Person

Instrument Model: Laura (Automated Urine Analyzer)

Serial Number

: 0846-1-202110

Date of Installation: 30.06.2022

The instrument was installed and was found to be working satisfactorily. Preliminary Customer Training was provided and standardization of some parameters were done. The results were found to be within the expected range and System found to be working satisfactorily.

TBM

Technical Services Department

Name

: Prasenjit Das

Designation: Sr Service Engineer

Signature

Date

CUSTOMER

Name: Saunab Paul

Contact Person: Sounds Paul

Designation: Lab Jech

Signature:

Sound Parl

Date: 01-07-2022



strument Name

Automated Urine Analyzer

Instrument ID

0846-1-202110

Instrument Setup

- 1. Assembled the instrument accessories.
- 2. Connect the Power cable to the plug on the backside of instrument
- 3. Mount Printer Paper roll

Operational Inspection

- 1. Switch ON the analyzer it will complete self test and complete self calibration.
- 2. Check the colour of blank/unreacted Strip with the Chart on bottle before Run.
- 3. Reagent Strip Should be immersed into urine for about 2 sec
- 4. Use fresh & well mixed Sample & ensure it for no Concentration or Dilution

TBM, Technical Services Department

Name

: Prasenjit Das

Designation: Sr Service E

Date: 30.06.2022

Instrument ID 0846-1-202110 Bio-Medicals Ltd.

Operations Qualifications for Laura (Automated Urine Analyser)

Automated Urine Analyzer

Sr. No. 0846-1-202110

Mument Name

Checked assemblies using Service password

Motor : Done
 Tray Sensor : Done
 Hand Sensor : Done
 Strip Sensor : Done
 Waste Bin Sensor : Done
 LCD : Done
 Printer : Done



ment Name

Automated Urine Analyzer | Instrument ID

0846-1-202110

Performance Qualifications for Laura (Automated Urine Analyzer)

Sr. No. 0846-1-202110

1. Calibration Parameters

a. Performance Qualification: Checked & found that Sensitivity of each Parameter is set as per %Value

Processed Sample and confirmed that the results are matching with the manual methods.

2. System Certification:

Study data has determined that the System described in this document either meets all criteria outlined in this Performance Qualification Protocol, or exceptional conditions have been identified and documentation included.

The System is ready for specific usage.

Protocol Performed By:

TBM Guwahati

DEKAPHAN LAURA

Seq.No: 0081

ID: LEVEL 1

2023.02.28

07:31

BLD	NEG
BIL	NEG
UBG	NORM
KET	NEG
GLU	NEG
PRO	NEG
рн	6
TIM	NEG
LEU	NEG
SG	1.030

28-02-23

DEKAPHAN LAURA

Seq.No: 0082

ID: LEVEL 2

2023.02.28 07:32

BLD	NEG			
*BIL	3	mg/d7	2+	
*UBG	1	mg/d7	1+	
*KET	52	mg/dl	2+	
*GLU	500	mg/dl	2+	
*PRO	100	mg/dl	2+	
рН	9	N		
*NIT	POS	1	\	3
*LEU	TRACE	\mathcal{Q}	100	レ
SG	1.000		8.02	
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