

Erba Lachema s.r.o.



Brno, 10.11.2016

To,
Redcliffe Lifetech Pvt Ltd.
Kolkata, West Bengal

Instrument Name: ERBA LAURA
Instrument Serial no: 0845-1-202110

We Erba Lachema SRO with registered office in Czech Republic, Karasek 2219/1D, 621 00 BMO, represented by its Production manager Veronika Pleskova here by confirm as Producer of LAURA instrument that this device is firmly calibrated by the manufacturer and does not require any regular calibration by the user, correct calibration of instrument is controlled by grey strips provided initially together with the instrument.

P.S.
A handwritten signature in blue ink, appearing to be "P.S.", followed by a large, stylized signature.

RNDr. Pavel Suchan Ph.D.

Global Product Manager, Urine Analysis

Erba Lachema s.r.o.

Karásek 1d, Brno 62100, Czech Republic



Installation Qualification for Laura (Automated Urine Analyzer)

Customer Name : REDCLIFFE LIFE TECH PVT LTD
Address : Kolkata
Instrument Name : Laura (Automated Urine Analyzer)
Serial Number : 0845-1-202110

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 (External Adapter) | : Input 200-240V / 50-60 Hz |
| 2. Power Consumption | : 35 W |
| 3. Temperature | : 15° - 30° C |
| 4. Humidity | : 20% - 80% |
| 5. Working Area | : Free from intense light source, |
| electromagnetic interference | |

Installation Certificate for Laura (Automated urine Analyzer)

This is to certify that the Laura V2 Instrument Serial No.: 0845-1-202110 is successfully Installed and Commissioned at TBM, Ahmedabad and the Installation Protocol / checklist has been successfully completed for the above instrument.

TBM, Technical Services Department

Name : Mr. Debraj Mondol

Designation : RSM.

Date :

01/07/2022

Debraj Mondol

Installation Qualifications for Laura (Automated Urine Analyzer)

Sr. No.: 0845-1-202110

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: Mr. Debraj Mondal

Debraj Mondal.

Designation: *R.S.M.*

Date: *01/07/2022*

Installation Report for Laura (Automated Urine Analyzer)

Sr. No. : 0845-1-202110

Customer Name : REDCLIFFE LIFE TECH PVT LTD

Department : CLINICAL PATHOLOGY.

Contact Person : SUVANKAR BHATTACHARJEE.

Instrument Model : Laura V2 (Automated Urine Analyzer)

Serial Number : 0845-1-202110

Date of Installation : 01/07/22.

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 : Mr. Debraj Mondal

Designation : RSM

Signature : *Debraj Mondal.*

Date : 01/07/2022.

CUSTOMER REDCLIFFE LIFE TECH
PVT LTD. (KOLKATA).

Name : SUVANKAR
BHATTACHARJEE.

Contact Person : SUVANKAR BHATTACHARJEE.

Designation : LAB ADMIN.

Signature : *S. Bhattacharjee*

Date : 01/07/2022.



Operational Qualification for Laura (Automated Urine Analyzer)

Sr. No. : 0845-1-202110

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: RSM

Name: Mr. Debraj Mondal

Designation: *RSM.*

Customer Authorization: Hospital: REDCLIFFE LIFE TECH PVT LTD

Name: *SUVANKAR BHATTACHARJEE*

Designation: *LAB ADMIN*

Debraj Mondal.
Company Representative Name & Sign

SUVANKAR BHATTACHARJEE
S. Bhattacharjee
Customer Name & Sign



Date: *01/07/2022.*

Date: *01/07/22.*

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 : MR. DEBRAJ MONDAL

Designation : RSM

Date: 01/07/2022.

Operations Qualifications for Laura (Automated Urine Analyser)

Sr. No.: 0845-1-202110

Checked assemblies

1. Motor : Done
2. Tray Sensor : Done
3. Hand Sensor : Done
4. Strip Sensor : Done
5. Waste Bin Sensor : Done
6. LCD : Done
7. Printer : Done

Performance Qualifications for Laura (Automated Urine Analyzer)

Sr. No. : 0845-1-202110

1. Calibration Parameters

- a. Performance Qualification:
Checked & found Grey QC strip within acceptable limit.

Run both level IQC and confirmed that the results are within range.

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:

BM

Technical Services Department

Name : MR . DEBRAJ MONDAL

Designation : RSM

Date: 01/07/2022.

Erba Urinalysis
Mediastem

LAURA

2023.02.15

11:51

DEKAPHAN LAURA

Seq.No: 0001

URINORM P

2023.02.15

11:55

.....
*BLD 10 Ery/u1
*BIL 3 mg/dl
*UBG 1 mg/dl
*KET 52 mg/dl
*GLU 1000 mg/dl
*PRO 500 mg/dl
PH 9
*NIT POS
*LEU 75 Leu/u1
SG 1.000

QC TEST: OK
<Admin>

DEKAPHAN LAURA

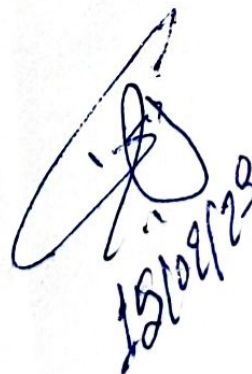
Seq.No: 0002

URINORM N

2023.02.15

11:56

.....
BLD NEG
BIL NEG
UBG NORM
KET NEG
GLU NEG
PRO NEG
PH 6
NIT NEG
LEU NEG
SG 1.025



QC TEST: OK
<Admin>