

Erba Lachema s.r.o.



Brno, 10.11.2016

To,
Redcliffe Lifetech Pvt Ltd.
Bilaspur, Chhattisgarh

Instrument Name: LAURA
Instrument Serial no: 0964-1-202201

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



Operational Qualification for Laura V2
(Automated Urine Analyzer)

Sr. No. 0964-1-202201

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

Aditya Kumar

Name: (Engineer's Name)

Designation: Sr. Service Engineer



ADITYA KUMAR

Customer Authorization: REDCLIFFE LIFETECH PVT LTD

Name: SAJAN KUMAR SONVANI

Designation: LAB ADMIN

Avi

Company Representative Name & Sign

AVINASH SONI

Date: 26/9/22



[Signature]

Customer Name & Sign

SAJAN KUMAR SONVANI

Date: 26/9/22

Installation Qualification for Laura M (Automated Urine Analyzer)

Sr. No. 0964-1-202201

Customer Name : REDCLIFFE LIFETECH PVT LTD

Address : BILASPUR

Instrument Name : Laura V2 (Automated Urine Analyzer)

Serial Number : 0964-1-202201

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 V2 (Automated urine Analyzer)

This is to certify that the Laura V2 Instrument Serial No. 0964-1-202201 is successfully Installed and Commissioned at TBM, Ahmedabad and the Installation Protocol / checklist has been successfully completed for the above instrument.

Avi

TBM, Technical Services Department

Name : AVINASH SONI

Designation : APPLICATION MANAGER

Date : 26/9/22



Installation Qualifications for Laura
V2(Automated Urine Analyzer)

Sr. No. 0964-1-202201

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: ADITYA KUMAR

Designation: Sr. Service Engineer

Date: 26/9/22



Installation Report for Laura V2 (Automated Urine Analyzer)

Sr. No. 0964-1-202201

Customer Name : REDCLIFFE LITETECH PVT LTD

Department : PATHOLOGY


Contact Person : SAJAN KUMAR SONVANI

Instrument Model : Laura V2 (Automated Urine Analyzer)

Serial Number : 0964-1-202201

Date of Installation :

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.

TRANSASIA BIOMEDICALS	CUSTOMER
NAME: AVINASH SONI	NAME: SAJAN KUMAR SONVANI
DESIGNATION APP MANAGER	DESIGNATION LAB ADMIN
SIGNATURE Avinash	SIGNATURE 
DATE 26/9/22	DATE 26/9/22

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

Avi

Technical Services Department

Name : AVINASH SONI

Designation : APPLICATION MANAGER

Date: 26/9/22



Operations Qualifications for Laura V2 (Automated Urine Analyzer)

Sr. No. Sr. No. 0964-1-202201

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 V2 (Automated Urine Analyzer)

Sr. No. 0964-1-202201

1. Calibration Parameters

a. Performance Qualification:

Checked & found Grey QC strip within acceptable limit.

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: Avinash Souj

TBM

Avi



DEKAPHAN LAURA

Seq.No: 0002

URINORM P

2023.02.16

10:38 AM

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*BLD	50	Ery/u1
*BIL	6	mg/dl
*UBG	1	mg/dl
*KET	52	mg/dl
*GLU	500	mg/dl
*PRO	100	mg/dl
PH	8	
*NIT	POS	
*LEU	500	Leu/u1
SG	1.000	

16/2

QC TEST: OK
<Admin>

DEKAPHAN LAURA

Seq.No: 0001

URINORM N

2023.02.16

10:35 AM

.....

BLD	NEG
BIL	NEG
UBG	NORM
KET	NEG
GLU	NEG
PRO	NEG
PH	5
NIT	NEG
LEU	NEG
SG	1.025

16/2

QC TEST: OK
<Admin>