

Erba Lachema s.r.o.



Brno, 10.11.2016

To,
Redcliffe Lifetech Pvt Ltd.
Bathinda, Punjab - 151001

Instrument Name: ERBA LAURA
Instrument Serial No: 1067-1-202209

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.

N.F.
A handwritten signature in black ink, appearing to be "P. Suchan", written over the printed name.

RNDr. Pavel Suchan Ph.D.

Global Product Manager, Urine Analysis

Erba Lachema s.r.o.

Karasek 1d, Brno 62100, Czech Republic

Erba Lachema s.r.o.

Karasek 1d, 621 00 Brno

DIC: CZ26918846 -10-



Erba Lachema s.r.o., Karasek 1d, 621 00 Brno, Czech Republic
Identification number: 269 18 846 Tax identification number: CZ26918846
Incorporated in the Commercial Register maintained by the Regional Court in Brno, Section C, insert 45458
Tel.: +420 517 077 111, fax: +420 517 077 077, e-mail: diagnostics@erbalachema.com www.erbalachema.com

Operational Qualification for Laura V2 (Automated Urine Analyzer)

Sr. No.-1067-1202209

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

Name: AMAN WALIA

Designation: SERVICE ENGINEER

Customer Authorization: Hospital:- Redcliffe Lab

Name: PARDEEP KUMAR

Designation: SENIOR OFFICER

Company Representative Name & Sign

Customer Name & Sign

Date: 02-07-2023

Date:02-07-2023

Installation Qualification for Laura M (Automated Urine Analyzer)

Sr.No. -0775-1-202109

Customer Name : Redcliffe Lab

Address : Bathinda

Instrument Name : Laura V2 (Automated Urine Analyzer)

Serial Number : **1067-1202209**

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
electromagnetic interference | : Free from intense light source, |

Installation Certificate for Laura V2 (Automated urine Analyzer)

This is to certify that the Laura V2 Instrument Serial No. 0775-1-202109 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 : AMAN WALIA

Designation : SERVICE ENGINEER

Date : 02-07-2023

Installation Qualifications for Laura V2(Automated Urine Analyzer)

Sr. No. 1067-1202209

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. AMAN WALIA

Designation: SERVICE ENGINEER

Date: 07-02-2023

Installation Report for Laura V2 (Automated Urine Analyzer)

Sr. No. 1067-1202209

Customer Name : Redcliffe Lab

Department : Laboratory

Contact Person : Pardeep kumar

Instrument Model : Laura V2 (Automated Urine Analyzer)

Serial Number : 1067-1202209

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.

TBM
Technical Services Department

Name : Mr. AMAN WALIA

Designation : SERVICE ENGINEER

Signature :

Date : 07-02-2023

CUSTOMER

Name : Redcliffe Lab

Contact Person : PARDEEP KUMAR

Designation : Senior officer

Signature :

Date :07-02-2023

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. AMAN WALIA

Designation : SERVICE ENGINEER

Date: 02-07-2023

Operations Qualifications for Laura V2(Automated Urine Analyser)

Sr. No. 1067-1202209

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 M (Automated Urine Analyzer)

Sr. No. 1067-1202209

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:

TBM

Mr. AMANDEEP KUMAR
Application Specialist



Urinalysis

LAIRA

2023.08.09

09:48

DEKAPHAN LAIRA

Seq.No: 000

URINORM P

2023.08.09

09:50

*B.D	240	Ery/u1
*BIL	6	mg/dl
*UBG	3	mg/dl
*KET	156	mg/dl
*GLU	500	mg/dl
*PRO	500	mg/dl
pH	9	
*NIT	POS	
*LEU	75	Leu/u1
SS	1.000	

DEKAPHAN LAIRA

Seq.No: 0001

URINORM N

2023.08.09

07:42 AM

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>