

Erba Lachema s.r.o.



Brno, 10.11.2016

To,
Redcliffe Lifetech Pvt Ltd.
Old Alwal, Secunderabad, Hyderabad

Instrument Name: ERBA LAURA
Instrument Serial no: 0840-1-202110

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 read "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 V2 (Automated Urine Analyzer)

Sr.No.0611-1-202106

Customer Name : Redcliffe Lifetech Pvt.Ltd.
Address : Old Alwal,Hyderabad
Instrument Name : Laura V2 (Automated Urine Analyzer)
Serial Number : 0840-1-202110

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 100-250V / 50-60 Hz
2. Power Consumption : 35W
3. Temperature : 10° - 30° C
4. Humidity :20% - 80%
5. Working Area : Free from intense light source, electromagnetic interference



UNMATCHED SERVICE
SINCE 1979...

Installation Certificate for Laura V2(Automated urine Analyzer)

This is to certify that the Laura V2 Instrument Serial No.0840-1-202110 is successfully Installed and Commissioned at TBM, Hyderabad and the Installation Protocol / checklist has been successfully completed for the above instrument.

TBM, Technical Services Department

Name : Kalyan Haldar

Kalyan Haldar

Designation : Sr.Application Manager

Date :07-06-2022



UNMATCHED SERVICE
SINCE 1979...

Installation Qualifications for Laura V2(Automated Urine Analyzer)

Sr. No.0840-1-202110

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

TBM, Technical Services Department

Name : Kalyan Haldar *Kalyan Haldar*

Designation :Sr. Application Manager

Date :07-06-2022



UNMATCHED SERVICE
SINCE 1979...

Installation Report for Laura V2 (Automated Urine Analyzer)

Sr. No.0840-1-202110

Customer Name : Redcliffe Lifetech Pvt.Ltd.

Contact Person : Dr.Namasani Yogitha

Instrument Model : Laura V2 (Automated Urine Analyzer)

Serial Number : 0840-1-202110

Date of Installation : 07-06-2022

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.

Protocol Performed By: TRANSASIA BIOMEDICAL LTD,MUMBAI

Name: Kalyan Haldar *KalyanHaldar*

Designation: Sr. Application Manager

Customer Authorization: Redcliffe Lifetech Pvt.Ltd.

Name: Dr.Namasani Yogitha

Designation: Pathologist





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 : Kalyan Haldar *KalyanHaldar*

Designation : Sr.Application Manager

Date :07-06-2022



Operational Qualification for Laura Version 2 (Automated Urine Analyzer)

Sr. No.0840-1-202110

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: TRANSASIA BIOMEDICAL LTD, MUMBAI

Name: Kalyan Haldar

Designation: Sr. Application Manager

Customer Authorization: Redcliffe Lifetech Pvt.Ltd.

Name: Dr.Namasani Yogitha

Designation: Pathologist

Company Representative Name & Signature

Kalyan Haldar

Date: 07-06-2022

Customer Name & Signature

Yogitha



Date: 07-06-2022



Operations Qualifications for Laura V2 (Automated Urine Analyser)

Sr. No.0840-1-202110

Checked assemblies using Service password

- | | |
|---------------------|--------|
| 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 |

Kalyan Chakraborty



Performance Qualifications for Laura V2 (Automated Urine Analyzer)

Sr. No.0840-1-202110

1. Calibration Parameters

a. Performance Qualification:

Checked & found Grey strip within acceptable limit

Processed Quality Control L1 ,L2 and result are with in the 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: TRANSASIA BIOMEDICAL LTD,MUMBAI

Name: Kalyan Haldar

Designation: Sr.Application Manager

Customer Authorization: Redcliffe Lifetech Pvt.Ltd.

Name: Dr.Namasani Yogitha

Designation: Pathologist

Company Representative Name & Signature

Kalyan Haldar

Date: 07-06-2022

Customer Name & Signature





LAURA
Redcliffe

12.07.2023 11:33 AM

DEKAPHAN LAURA
Seq.No: 0001
URINORM N
12.07.2023 11:33 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

DEKAPHAN LAURA
Seq.No: 0002
URINORM P
12.07.2023 11:35 AM

*BLD	2+
*BIL	2+
*UBG	1+
*KET	2+
*GLU	2+
*PRO	3+
pH	8
*NIT	POS
*LEU	2+
SG	1.000

QC TEST: OK