

Erba Lachema s.r.o.



Brno, 10.11.2016

To,
Redcliffe Lifetech Pvt Ltd.
Ahmedabad, Gujrat

Instrument Name: ERBA LAURA
Instrument Serial no: 0775-1-202109

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.

R.F.

Erba Lachema s.r.o.
Karásek 1d, 621 00 Brno
DIČ CZ26918846 -10-

RNDr. Pavel Suchan Ph.D.
Global Product Manager, Urine Analysis
Erba Lachema s.r.o.
Karásek 1d, Brno 62100, Czech Republic



ERBA- LAURA V2
AUTOMATED URINE ANALYZER

IQ, OQ, PQ

For

“ Redcliffe Lifetech Private Ltd.”

Marketed by:
Transasia Bio-Medicals Ltd.,
(ISO 9002 CERTIFIED)
Transasia House,
Chandivali Studio road,
Andheri (E),
MUMBAI - 400 072

Operational Qualification for Laura V2 (Automated Urine Analyzer)

Sr. No.-0775-1-202109

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: Mr. Shailesh Kumar

Designation: Area Service Manager



Customer Authorization: Hospital:- Redcliffe Lifetech Private Ltd.

Name: Dr. Hitesh Shah

Designation: Pathologist

Company Representative Name & Sign

Customer Name & Sign

Date:



Date:

Installation Qualification for Laura M (Automated Urine Analyzer)

Sr.No. -0775-1-202109

Customer Name : Redcliffe Lifetech Private Ltd.

Address : Ahmedabad

Instrument Name : Laura V2 (Automated Urine Analyzer)

Serial Number : 0775-1-202109

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 Qualification for Laura M (Automated Urine Analyzer)

Sr.No. -0775-1-202109

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Address : Ahmedabad

Instrument Name : Laura V2 (Automated Urine Analyzer)

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Installation Certificate for Laura V2 (Automated urine Analyzer)

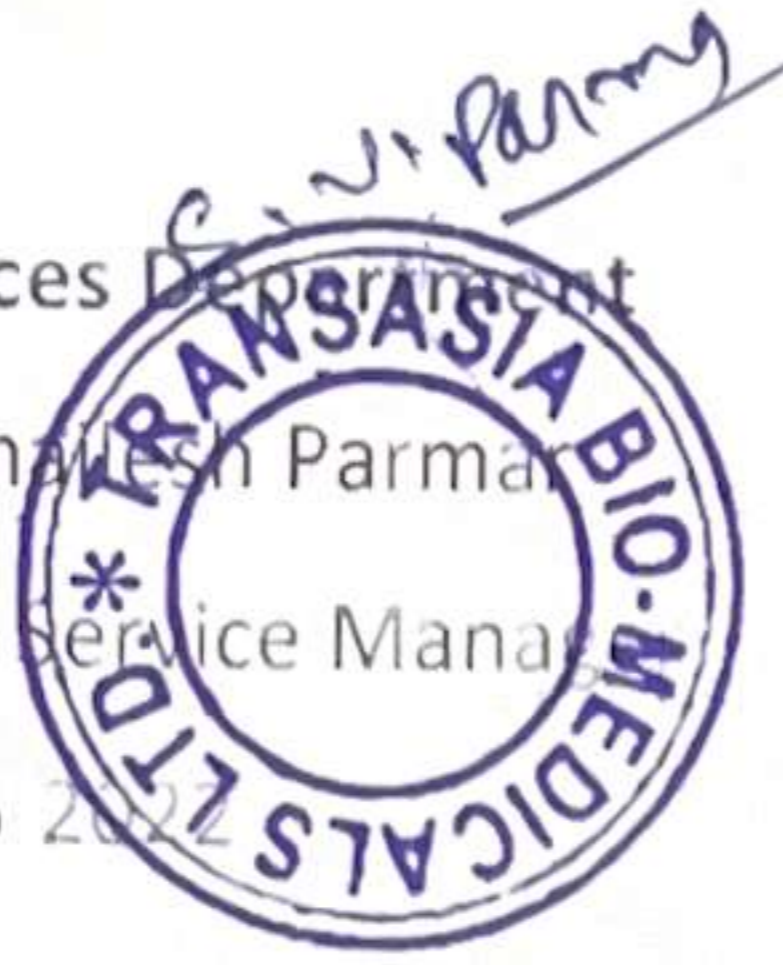
This is to certify that the Laura V2 Instrument Serial No. 0775-1-202109 is successfully Installed and Commissioned at TBM, Ahmedabad and the Installation Protocol / checklist has been successfully completed for the above instrument.

TBM, Technical Services Department

Name : Mr. Sharesh Parmar

Designation : Area Service Manager

Date : 16-06-2022



Installation Qualifications for Laura V2(Automated Urine Analyzer)

Sr. No. 0775-1-202109

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. Sharad P. Patil
Designation: Area Service Manager

Date: 16/06/2022



Installation Report for Laura V2 (Automated Urine Analyzer)

Sr. No. 0775-1-202109

Customer Name : Redcliffe Lifetech Private Ltd.

Department : Laboratory

Contact Person : Dr. Hitesh Shah

Instrument Model : Laura V2 (Automated Urine Analyzer)


Serial Number : 0775-1-202109

Date of Installation : 16/06/2022

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 :  Mr. Shailesh Parmar

Designation : Area Service Manager

Signature :

Date : 16/06/2022

CUSTOMER

Name : Redcliffe Lifetech Private Ltd.

Contact Person : Dr. Hitesh Shah

Designation : Pathologist

Signature :

Date :16/06/2022

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. Shailesh Patil

Designation : Area Service Manager

Date: 16/06/2022



Operations Qualifications for Laura V2(Automated Urine Analyser)

Sr. No. 0775-1-202109

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. 0775-1-202109

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. Brandra Yada
Application Specialist



DEKAPHAN LAURA
Seq.No: 0001
URINORM N
04.19.2023 08:44 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>

DEKAPHAN LAURA
Seq.No: 0001
URINORM N
04.19.2023 08:44 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>

DEKAPHAN LAURA
Seq.No: 0002
URINORM P
04.19.2023 08:46 AM

*BLD 10 Ery/u1 1+
*BIL 3 mg/dl
*UBG 1 mg/dl
*KET 52 mg/dl
*GLU 250 mg/dl
*PRO 100 mg/dl
pH 9
*NIT POS
*LEU 75 Leu/u1 1+
SG 1.000

QC TEST: OK
<Admin>

DEKAPHAN LAURA
Seq.No: 0002
URINORM P
04.19.2023 08:46 AM

*BLD 10 Ery/u1 1+
*BIL 3 mg/dl
*UBG 1 mg/dl
*KET 52 mg/dl
*GLU 250 mg/dl
*PRO 100 mg/dl
pH 9
*NIT POS
*LEU 75 Leu/u1 1+
SG 1.000

QC TEST: OK
<Admin>

Am
19/4/2023