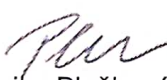


## LAURA: Calibration procedure

To,  
Redcliffe Lifetech Pvt. Limited.  
Shop 03 Rajeev Gandhi civic center  
New road Ratlam 457001

**Instrument Name : Laura**  
**Instrument Sr. No. :1018-1-202206**

We Erba Lachema s.r.o. with registered office in Czech Republic, Karásek 2219/1D, 621 00 Brno, represented by its Product Manager Veronika Plešková hereby confirm as producer of LAURA instrument that this device is firmly calibrated by manufacturer and does not require any regular calibration by the user. Correct calibration of the instrument is controlled by grey strips provided initially together with the instrument.

  
Veronika Plešková

  
Erba Corporate Services Ltd.  
GW1 Great West House  
Great West Road, London TW8 9DF

Product manager, Urine

Analysis Erba Corporate

Service Ltd.

GW1 Great West House

Great West Road, London TW8 9DF

**Erba**<sup>®</sup>  
Mannheim

Erba Corporate Services Ltd . Registered in England and Wales , Company No:  
11100097 Registered Office: c/o Erba Molecular, Unit 4 Bartholemews, Ely,  
Cambridgeshire, CB74EA, UK



**Operational Qualification for Laura V2 (Automated Urine Analyzer)**

**Sr. No. - 1018-1-202206**

**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: SANJAY TIWARI

Designation: ASM

Customer Authorization: DIGNOSTIC CENTER :- REDCLIFFE LIFE TECH

Name: NARENDRA SINGH JADAV

Designation: ADMIN

**Company Representative Name & Sign**

*Sanjay Tiwari*

Date: 15-10-2022

**Customer Name & Sign**

*Narendra Singh Jadav*

Date: 16-10-2022



**Installation Qualification for Laura M (Automated Urine Analyzer)**

**Sr.No. 1018-1-202206**

Customer Name : REDCLIFFE LIFE TECH  
Address : RATLAM  
Instrument Name : Laura V2 (Automated Urine Analyzer)  
Serial Number : **1018-1-202206**

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,<br>electromagnetic interference |

**Installation Certificate for Laura V2 (Automated urine Analyzer)**

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



**TRANSASIA**<sup>®</sup>  
No.1 Diagnostic Company in India

**TBM, Technical Services Department**

**Name : SANJAY TIWARI**

**Designation : ASM**

**Date : 15-10--2022**



**Installation Qualifications for Laura V2(Automated Urine Analyzer)**

**Sr. No. 1018-1-202206**

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: SANJAY TIWARI**

**Designation: ASM**

**Date: 15-10-2022**



**TRANSASIA**<sup>®</sup>  
No.1 Diagnostic Company in India

**Installation Report for Laura V2 (Automated Urine Analyzer)**

**Sr. No. : 1018-1-202206**

**Customer Name : REDCLIFFE LIFE TECH**

**Department : CLINICAL PATHOLOGY**

**Contact Person : NARENDRA SINGH JADAV**

**Instrument Model : Laura V2 (Automated Urine Analyzer )**

**Serial Number : 1018-1-202206**


**Date of Installation : 15-10-2022**

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 : SANJAY TIWARI**

**Designation : ASM**

**Signature : **

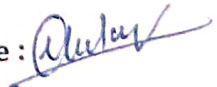
**Date : 15-10-2022**

**CUSTOMER**

**Name : RED CLIFFE LIFE TECH**

**Contact Person : NARENDRA**

**Designation : ADMIN**

**Signature : **

**Date : 16-10-2022**



### **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 : SANJAY TIWARI**

**Designation : ASM**

**Date: 15-10-2022**





**TRANSASIA**<sup>®</sup>  
No.1 Diagnostic Company in India

**Operations Qualifications for Laura M (Automated Urine Analyser)**

Sr. No. 1018-1-202206

**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. 1018-1-202206

**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 - JITENDRA PATIDAR

\*\*\*\*\*



Urinalysis

LAURA

\*\*\*\*\*

2023.06.26

08:47

DEKAPHAN LAURA

Seq.No: 0001

URINORM N

2023.06.26

08:54

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

DEKAPHAN LAURA

Seq.No: 0003

URINORM P

2023.06.26

09:05

*BLD	1+	
*BIL	3	mg/dl
*UBG	1+	
*KET	1+	
*GLU	3+	
*PRO	2+	
PH	9	
*NIT	POS	
*LEU	+ -	
SG	1.005	