

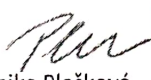


In London, 7.5.2019

LAURA: Calibration procedure

To Whom It May Concern:

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



Product manager, Urine Analysis

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



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

Installation Qualification for Laura M (Automated Urine Analyzer)

Sr.No. 0728-1-202107

Customer Name : REDCLIFFE LAB'S, JODHPUR, RAJASTHAN

Address : NEAR SHASTRI CIRCLE, JODHPUR, RAJASTHAN

Instrument Name : Laura V2 (Automated Urine Analyzer)

Serial Number : 0728-1-202107

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 interference | : Free from intense light source, electromagnetic |

H.O. address: Transasia House, 8 Chandivali Studio Road, Andheri (E), Mumbai – 440072 India
Tel. : +91 22 4030 9000

Installation Certificate for Laura V2 (Automated urine Analyzer)

This is to certify that the Laura V2 Instrument Serial No. **0728-1-202107** 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. GIRDHARI LAL SHARMA

Designation : SR. SERVICE ENGINEER

Date : 31-03-2022

H.O. address: Transasia House, 8 Chandivali Studio Road, Andheri (E), Mumbai – 440072 India
Tel. : +91 22 4030 9000

Installation Qualifications for Laura V2(Automated Urine Analyzer)

Sr. No. 0728-1-202107

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. GIRDHARI LAL SHARMA

Designation: SR. SERVICE ENGINEER

Date: 31-03-2022

H.O. address: Transasia House, 8 Chandivali Studio Road, Andheri (E), Mumbai – 440072 India
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Installation Report for Laura V2 (Automated Urine Analyzer)

Sr. No. 0728-1-202107

Customer Name : REDCLIFFE LAB'S

Department : CLINICAL PATHOLOGY

Contact Person : MR. KAPIL SHARMA

Instrument Model : Laura V2 (Automated Urine Analyzer)

Serial Number : 0728-1-202107

Date of Installation : 31-03-2022

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

CUSTOMER

Name : MR. GIRDHARI LAL SHARMA

Name : MR. KAPIL SHARMA

Designation : SR. SERVICE ENGINEER

Designation : LAB MANGEER

Signature :

Signature :

Date :

Date :

H.O. address: Transasia House, 8 Chandivali Studio Road, Andheri (E), Mumbai – 440072 India
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Operational Qualification for Laura V2 (Automated Urine Analyzer)

Sr. No. 0728-1-202107

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. GIRDHARI LAL SHRAM

Designation: SR. SERVICE ENGINEER

Customer Authorization:

REDCLIFFE LAB'S, JODHPUR

Name: MR. KAPIL SHARMA

Designation: LAB MANGEER

Company Representative Name & Sign

Customer Name & Sign

Date: 31-03-2022

Date: 31-03-2022

H.O. address: Transasia House, 8 Chandivali Studio Road, Andheri (E), Mumbai – 440072 India
Tel. : +91 22 4030 9000

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



For TBM, Technical Services Department

Name: MR. GIRDHARI LAL SHARMA

Designation: SR. SERVICE ENGINEER

Date: 31-03-2022

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Operations Qualifications for Laura M (Automated Urine Analyser)

Sr. No. 0728-1-202107

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 |

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Performance Qualifications for Laura M (Automated Urine Analyzer)

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:


For TBM, Technical Services Department

Name: MR. GIRDHARI LAL SHARMA

Designation: SR. SERVICE ENGINEER

Date: 31-03-2022

H.O. address: Transasia House, 8 Chandivali Studio Road, Andheri (E), Mumbai – 440072 India
Tel. : +91 22 4030 9000



LAURA

2023.07.11 11:09 AM

DEKAPHAN LAURA
Seq.No: 0001
URINORM N
2023.07.11 11:14 AM

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

QC TEST: OK
<Red Cliffe Labs>

DEKAPHAN LAURA
Seq.No: 0002
URINORM P
2023.07.11 11:15 AM

.....
*BLD 2+
*BIL 3+
*UBG 2+
*KET 1+
*GLU 3+
*PRO 3+
PH 9
*NIT POS
*LEU 3+
SG 1.000

QC TEST: OK
<Red Cliffe Labs>