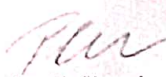


In London, 7.5.2019

LAURA: Calibration procedure

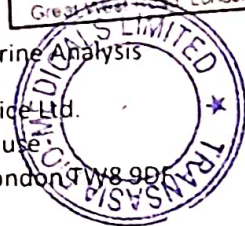
To Whom It May Concern:

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®

Operational Qualification for Laura V2 (Automated Urine Analyzer)

Sr. No.1136-1-202212

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: Pushpendra Singh
Designation: ASM
Customer Authorization: Redcliffe Lifetech Pvt Ltd.
Name:
Designation:

Company Representative Name & Sign

Date:



Customer Name & Sign

Date:

Installation Qualification for Laura M (Automated Urine Analyzer)

Sr.No. 1136-1-202212

Customer Name : Redcliffe Lifetech Pvt Ltd.

Address : Agra

Instrument Name : Laura V2 (Automated Urine Analyzer)

Serial Number : 1136-1-202212

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, |
| electromagnetic interference | |

Installation Certificate for Laura V2 (Automated urine Analyzer)

This is to certify that the Laura V2 Instrument Serial No. 1136-1-202212 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 : Pushendra Singh

Designation : ASM

Date



Installation Qualifications for Laura V2(Automated Urine Analyzer)

Sr. No. 1136-1-202212

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: Pushpendra Singh

Designation: ASM

Date:



Installation Report for Laura V2 (Automated Urine Analyzer)

Sr. No. 1136-1-202212

Customer Name : Redcliffe Lifetech Pvt Ltd

Department : Pathology

Contact Person : Mr pawan

Instrument Model : Laura V2 (Automated Urine Analyzer)

Serial Number : 1136-1-202212

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 : Pushpendra Singh

Designation : ASM

Signature :

Date



CUSTOMER

Name :

Contact Person :

Designation :

Signature :

Date :

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 : Pushpendra Singh

Designation : ASM

Date:



Operations Qualifications for Laura M (Automated Urine Analyser)

Sr. No. 1136-1-202212

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. 1136-1-202212

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

25.05.2024 00:00
DEKAPHAN LAURA

Seq.No: 0001

URINORM N

25.05.2024

10:30

.....

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

25.05.2024

10:33

.....

*BLD	250	Ery/u1
*BIL	6	mg/dl
*UBG	12	mg/dl
*KET	16	mg/dl
*GLU	500	mg/dl
*PRO	100	mg/dl
pH	9	
*NIT	POS	
*LEU	500	Leu/u1
SG	1.000	

QC TEST: OK

<Admin>