

Date: 15/09/2020

Laura Calibration Certificate

To whomsoever it may concern :

We Erba Lachema,s.r.o ,with registered office in Czech Republic, Karasek, 2219/D,621 00 Brno, Known in India as Erba group(Transasia biomedicals Ltd)hereby confirm as a manufacturer & service provider of Laura instrument that this device is firmly calibrated by manufacture & does not require any regular calibration by the user.

Regards,

Vinayak Lad

For Transasia biomedicals Ltd



Installation Qualification for Laura SMART (Automated Urine Analyzer)

Sr.No. : 271705
Customer Name : MICROCRAFT PATHOLOGY LLP
Address : NAVJIVAN CO.OP.HSG.LTD,MUMBAI CENTRAL,400008
Instrument Name : Laura M (Automated Urine Analyzer)
Serial Number : 271705

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 : Input 100-250V / 50-60 Hz
2. Temperature : 10° - 30° C
3. Humidity : $\leq 75\%$
4. Atmospheric Pressure: 76 – 106kPa
5. Working Area : Free from intense light source, electromagnetic interference

Installation Certificate for Laura SMART(Automated urine Analyzer)

This is to certify that the Laura M Instrument Serial No. **271705** is successfully Installed and Commissioned at Microcraft pathology laboratory and the Installation Protocol / checklist has been successfully completed for the above instrument.





TBM, Technical Services Department

Name : MR VINAYAK LAD

Designation : SERVICE ENGINEER

Date : 15/09/2020



Installation Qualifications for Laura SMART(Automated Urine Analyzer)

Sr. No. 271705

Carried out all the Installation Procedures as per the Installation Procedure.

Carried out all the necessary checks and alignments.

Carried out all the necessary system checks and tests.

Checked the counts by running the samples and found OK.

Handed over the Instrument for Operators Training & Qualifications



For TBM, Technical Services Department

Name: MR VINAYAK LAD

Designation: SERVICE ENGINEER

Date: 15/09/2020



Installation Report for Laura SMART (Automated Urine Analyzer)

Sr. No. : 271705

Customer Name : MICROCRAFT PATHOLOGY LLP

Department : PATHOLOGY

Instrument Model : Laura SMART (Automated Urine Analyzer)

Serial Number : 271705

Date of Installation : 15/09/2020

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 VINAYAK LAD

Designation : SERVICE ENGINEER

Signature :

Date : 15/09/2020

CUSTOMER

Name : MS KARUNA JADHAV

Contact Person : MS KARUNA JADHAV

Designation : SR LAB TECHNICIAN /QM

Signature :

Date : 15/09/2020



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 VINAYAK LAD

Designation : SERVICE ENGINEER

Date : 15/09/2020



Operational Qualification for Laura SMART (Automated Urine Analyzer)

Sr. No.271705

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.

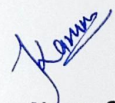
Protocol Performed By: TBM, Mumbai
Name: Vinayak lad
Designation: Service engineer
Customer Authorization: Hospital:- Microcraft Pathology LLP
Name: Ms Karuna Jadhav
Designation: Sr Lab Technician/QM



Company Representative Name & Sign

MR VINAYAK LAD

Date: 16/09/2020



Customer Name & Sign

MS KARUNA JADHAV

Date: 16/09/2020



Operations Qualifications for Laura M (Automated Urine Analyser)

Sr. No. 271705

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



Performance Qualifications for Laura SMART (Automated Urine Analyzer)

Sr. No. 271705

1. Calibration Parameters

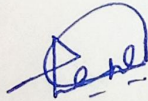
- a. Performance Qualification:
Checked & found that Urinorm Normal and Urinorm Abnormal QC results are found to be satisfactory and passes the test.

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: MS RAHAT SHAIKH
16/09/2020



DekaPHAN LAURA
ID: URINORM-N
16.09.2020 16:32

BLD NEG
LEU NEG
BIL NEG
UBG NORM
KET NEG
GLU NEG
PRO NEG
pH 6
NIT NEG
SG 1.030

QC TEST OK

DekaPHAN LAURA **P**
ID: URINORM-P
16.09.2020 16:35

*BLD 250 Ery/ μ l 3
*LEU 500 Leu/ μ l 3
*BIL 3 mg/dl 2
*UBG 1 mg/dl 1
*KET 156 mg/dl 3
*GLU 300 mg/dl 3
*PRO 100 mg/dl 2
pH 9
*NIT POS
SG 1.005

QC TEST OK

DekaPHAN LAURA
ID: URINORM-N
16.09.2020 16:32

BLD NEG
LEU NEG
BIL NEG
UBG NORM
KET NEG
GLU NEG
PRO NEG
pH 6
NIT NEG
SG 1.030

QC TEST OK

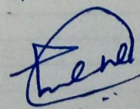
DekaPHAN LAURA **P**
ID: URINORM-P
16.09.2020 16:35

*BLD 250 Ery/ μ l 3
*LEU 500 Leu/ μ l 3
*BIL 3 mg/dl 2
*UBG 1 mg/dl 1
*KET 156 mg/dl 3
*GLU 300 mg/dl 3
*PRO 100 mg/dl 2
pH 9
*NIT POS
SG 1.005

QC TEST OK

PERFORMED BY:

MS RAHAT SHAIKH
16/09/2020



CHECKED BY ?

MS KARUNA JADHAV
16/09/2020

