

Erba Lachema s.r.o.

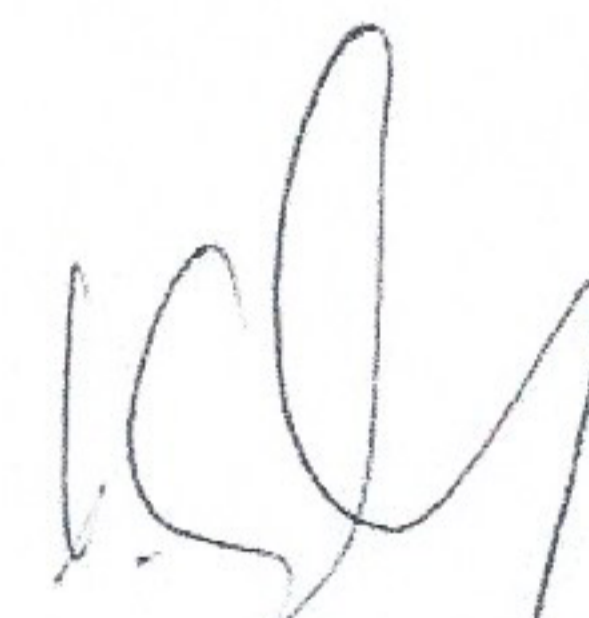


Brno, 10.11.2016

To,
Redcliffe Lifetech Pvt Ltd.
Jabalpur, Madhya Pradesh.

Instrument Name: ERBA LAURA
Instrument Serial no: 1003-1-202206

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.

P. F.

RNDr. Pavel Suchan Ph.D.

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

Global Product Manager, Urine Analysis
Erba Lachema s.r.o.
Karásek 1d, Brno 62100, Czech Republic



TRANSASIA BIOMEDICALS LIMITED				
PERFORMANCE QUALIFICATION				
Laura Smart	Automated Urine Analyzer	Instrument ID	1003-1-202206	

Operational Qualification for Laura SMART (Automated Urine Analyzer)

Sr. No. - 1023-1-202206

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: Transasia Bio Medicals Ltd

Name : Mr.Abhishek Choudhary

Designation : Service Engineer

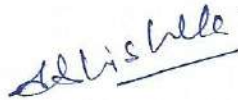
Customer Authorization: Pathology : Redcliffe Life Tech Pvt Ltd,Jabalpur M.P.


Name : Dr. Amogh Tiwari

Designation : M.D.Pathologist

Company Representative Name & Sign

Customer Name & Sign


Mr.Abhishek Choudhary


Dr.Amogh Tiwari
M.D.Pathologist

Date: 27/11/2022

Date: 27/11/2022

TRANSASIA BIOMEDICALS LIMITED**PERFORMANCE QUALIFICATION**

Laura Smart

Automated Urine Analyzer

Instrument ID

1003-1-202206

Installation Qualification for Laura SMART (Automated Urine Analyzer)**Sr. No. - 1023-1-202206****Customer Name** : Redcliffe Life Tech Pvt Ltd ,Jabalpur M.P.**Address** :New 639,Old 295,Napier Town
1st Floor,Opposite Bhanwartal Garden
Jabalpur 482001**Instrument Name** : LAURA (Automated Urine Analyzer)**Serial Number** : 1023-1-202206**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 : Input 100-250V / 50-60 Hz
2. Temperature : 10° - 30° C
3. Humidity : ≤ 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 SMART Instrument **Serial No. 35981-201701** is successfully Installed and Commissioned at TBM and the Installation Protocol / checklist has been successfully completed for the above instrument.

TBM, Technical Services Department**Name** : Mr. Abhishek Choudhary**Designation** : Service Engineer**Date** : 27/11/2022

TRANSASIA BIOMEDICALS LIMITED**PERFORMANCE QUALIFICATION****Laura Smart****Automated Urine Analyzer****Instrument ID****1003-1-202206****Installation Qualifications for Laura SMART(Automated Urine Analyzer)****Sr. No. - 1023-1-202206**

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** : Mr.  Abhishek Choudhary**Designation** : Service Engineer**Date** : 27/11/2022

TRANSASIA BIOMEDICALS LIMITED**PERFORMANCE QUALIFICATION****TRANSASIA****Laura Smart****Automated Urine Analyzer****Instrument ID****1003-1-202206****Installation Report for Laura SMART (Automated Urine Analyzer)****Sr. No. - 1023-1-202206****Customer Name** : Redcliffe Life Tech Pvt Ltd Jabalpur M.P.**Department** : Laboratory**Contact Person** : Mr.Arvind Maurya**Instrument Model** : LAURA (Automated Urine Analyzer)**Serial Number** : **1023-1-202206****Date of Installation** : 27/11/2022

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.Abhishek Choudhary****Designation** : Service Engineer**Signature** :**Date** : 27/11/2022**CUSTOMER****Name** : Redcliffe Life Tech Pvt Ltd**Contact Person** : Mr.Arvind Maurya**Designation** : Lab Admin**Signature** :**Date** : 27/11/2022

TRANSASIA BIOMEDICALS LIMITED**PERFORMANCE QUALIFICATION****TRANSASIA**
BIOMEDICALS**Laura Smart****Automated Urine Analyzer****Instrument ID****1003-1-202206****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

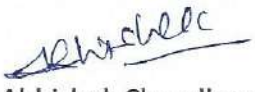
TBM**Technical Services Department****Name** : Mr. Abhishek Choudhary**Designation** : Service Engineer**Date** : 27/11/2022

TRANSASIA BIOMEDICALS LIMITED**PERFORMANCE QUALIFICATION****TRANSASIA**
BIOMEDICALS**Laura Smart****Automated Urine Analyzer****Instrument ID****1003-1-202206****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. Abhishek Choudhary**Designation** : Service Engineer**Date** : 27/11/2022

TRANSASIA BIOMEDICALS LIMITED				
PERFORMANCE QUALIFICATION				
Laura Smart	Automated Urine Analyzer	Instrument ID	1003-1-202206	

Performance Qualifications for Laura SMART (Automated Urine Analyzer)

Sr. No. - 1023-1-202206

1. Calibration Parameters

a. Performance Qualification:

Checked & found that Sensitivity of each Parameter is set as per %Value

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 
Technical Services Department

CUSTOMER

Name : Mr. Abhishek Choudhary

Name : Redcliffe Life Tech Pvt Ltd

Designation : Service Engineer

Contact Person : Mr. Arvind Maurya

Signature :

Designation : Lab Admin

Date : 27/11/2022

Signature : 

Date : 27/11/2022

DEKAPHAN LAURA
Seq.No: 0002
URINORM P
2023.06.20 05:57

.....
*BLD 250 Ery/u1 3+
*BIL 6 mg/dl 3+
*UBG 3 mg/dl 2+
*KET 52 mg/dl 2+
*GLU 500 mg/dl 2+
*PRO 500 mg/dl 3+
PH 9
*NIT POS
*LEU 500 Leu/u1 3+
SG 1.000

QC TEST: OK
<Admin>

DEKAPHAN LAURA
Seq.No: 0001
URINORM N
2023.06.20 05:54

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

[Handwritten signature]
2023/06/20

QC TEST: OK
<Admin>