

Erba Lachema s.r.o.




Brno, 10.11.2016

To,  
Redcliffe Lifetech Pvt Ltd.  
Lucknow, U.P

Instrument Name: ERBA LAURA  
Instrument Serial no: 0644-1-202106

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.

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

  
RNDr. Pavel Suchan Ph.D.

Global Product Manager, Urine Analysis

Erba Lachema s.r.o.

Karásek 1d, Brno 62100, Czech Republic



<Admin>

DEKAPHAN LAURA  
Seq.No: 0005  
URINORM H  
2022.12.24 09:25

BID	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: 0006  
URINORM P  
2022.12.24 09:27

*BID	10	Ery/u1
*BIL	6	mg/dl
*UBG	3	mg/dl
*KET	16	mg/dl
*GLU	1000	mg/dl
*PRO	500	mg/dl
pH	9	
*NIT	POS	
*LEU	75	Leu/u1
SG	1.000	

QC TEST: OK



<b>TRANSASIA BIOMEDICALS LIMITED</b>			
<b>PERFORMANCE QUALIFICATION</b>			
<b>Laura V2</b>	<b>Automated Urine Analyzer</b>	<b>Instrument ID</b>	<b>0644-1-202106</b>

**TRANSASIA<sup>®</sup>**  
Bio-Medicals Ltd.

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

**Sr. No. 0644-1-202106**

**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. Bharat Gupta  
Designation : Service Engineer

Customer Authorization: Lab : Redcliffe Lifetech Pvt Ltd.  
Name : Dr.Upama Singh  
Designation : M.D.Pathologist

**Company Representative Name & Sign**

**Customer Name & Sign**

Mr. Bharat Gupta

Dr. Upama Singh  
M.D. Pathologist

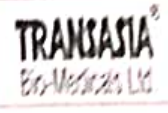
Date: 15/12/2021

Date: 15/12/2021



*Bharat*

TRANSASIA BIOMEDICALS LIMITED			
PERFORMANCE QUALIFICATION			
Laura V2	Automated Urine Analyzer	Instrument ID	0644-1-202106



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

**Sr.No. 0644-1-202106**

**Customer Name** : Redcliffe Lifetech Pvt Ltd.  
**Address** : 6A-F01 R.B.Road Telibagh Near CNG Gas Station Lucknow U.P  
**Instrument Name** : Laura V2 (Automated Urine Analyzer)  
**Serial Number** : 0644-1-202106

**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:**

**Power Source** : Input 100-250V / 50-60 Hz  
**Temperature** : 10°- 30° C  
**Humidity** : ≤ 75%  
**Atmospheric Pressure:** 76 – 106kPa  
**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.Bharat Gupta  
**Designation** : Service Engineer  
**Date** : 15/15/2021



TRANSASIA BIOMEDICALS LIMITED  
PERFORMANCE QUALIFICATION

TRANSASIA®  
Bio-Medicals Ltd.

Laura V2

Automated Urine Analyzer

Instrument ID

0644-1-202106

Installation Qualifications for Laura SMART(Automated Urine Analyzer)

Sr. No. 0644-1-202106

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. Bharat Gupta

Designation : Service Engineer

Date : 15/12/2021

*B. Gupta*



## TRANSASIA BIOMEDICALS LIMITED

## PERFORMANCE QUALIFICATION

TRANSASIA  
Bio-Medicals Ltd.

Laura V2

Automated Urine Analyzer

Instrument ID

0644-1-202106

Installation Report for Laura SMART (Automated Urine Analyzer)Sr. No.0644-1-202106

Customer Name : Redcliffe Lifetech Pvt Ltd.

Department : Laboratory

Contact Person : Ms.Bushra Sarwar

Instrument Model : Laura V2 (Automated Urine Analyzer )

Serial Number : 0644-1-202106

Date of Installation : 15/12/2021

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.Bharat Gupta

Designation : Service Engineer

Signature :

Date

: 15/12/2021



## CUSTOMER

Name : Redcliffe Lifetech Pvt Ltd.

Contact Person : Dr.Upama

Designation : Lab In-charge

Signature :

Date : 15/12/2021

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Bio-Medicals Ltd.

Laura V2

Automated Urine Analyzer

Instrument ID

0644-1-202106

**Instrument Setup**

Assembled the instrument accessories.

Connect the Power cable to the plug on the backside of instrument

Mount Printer Paper roll

**Operational Inspection**

Switch ON the analyzer it will complete self test and complete self calibration.

Check the colour of blank/unreacted Strip with the Chart on bottle before Run.

Reagent Strip Should be immersed into urine for about 2 sec

Use fresh & well mixed Sample & ensure it for no Concentration or Dilution

TBM

Technical Services Department



Name : Mr. Bharat Gupta

*Bharat*

Designation : Service Engineer

Date : 15/12/2021

TRANSASIA BIOMEDICALS LIMITED

PERFORMANCE QUALIFICATION

TRANSASIA<sup>®</sup>  
Bio-Medicals Ltd

Laura V2	Automated Urine Analyzer	Instrument ID	0644-1-202106
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Operations Qualifications for Laura SMART (Automated Urine Analyser)

Sr. No. 0644-1-202106

Checked assemblies using Service password

Motor : Done  
Tray Sensor : Done  
Hand Sensor : Done  
Strip Sensor : Done  
Waste Bin Sensor : Done  
LCD : Done  
Printer : Done



Laura V2

Automated Urine Analyzer

Instrument ID

0644-1-202106

Performance Qualifications for Laura SMART (Automated Urine Analyzer)

Sr. No. 0644-1-202106

**Calibration Parameters**

## Performance Qualification:

Checked &amp; 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,

Name : Mr. Abhay Dixit

Designation : Application Specialist

Signature :  Mr. Abhay Dixit  
Sr. App. Specialist  
Transasia Biomedical

Date : 15/12/2021

CUSTOMER

Name : Redcliffe Lifetech Pvt Ltd

Contact Person : Dr. Upama Singh

Designation : Lab In-charge

v Signature :

Date : 15/12/2021