

Erba Lachema s.r.o.



Brno, 10.11.2016

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

Instrument Name: ERBA LAURA  
Instrument Serial no: 1023-1-202206

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.

*1.7. 10.11.2016*

**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



<b>TRANSASIA BIOMEDICALS LIMITED</b>				<b>TRANSASIA®</b> Bio-Medicals Ltd.
<b>PERFORMANCE QUALIFICATION</b>				
<b>Laura Smart</b>	<b>Automated Urine Analyzer</b>	<b>Instrument ID</b>	<b>4974-1-201709</b>	

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

**Sr. No. - 1023-1-202206**

**Customer Name** : Redcliffe Life Tech Pvt Ltd (Redcliffe Labs Bhopal)

**Address** : Ground Floor, E-7/137, Ward 0049, Zone -09  
HIG, Arera Colony, Bhopal 462016

**Instrument Name** : Laura SMART (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. Sudhir Ahirwar

**Designation** : Service Engineer

**Date** : 27/11/2022

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**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. Sudhir Ahirwar

**Designation** : Service Engineer

**Date** : 27/11/2022

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**Installation Report for Laura SMART (Automated Urine Analyzer)**

**Sr. No. - 1023-1-202206**

**Customer Name** : Redcliffe Life Tech Pvt Ltd (Redcliffe Labs Bhopal)

**Department** : Laboratory

**Contact Person** : Mr.Brijesh Raikwar

**Instrument Model** : Laura SMART (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

**CUSTOMER**

**Name** : Mr.Sudhir Ahirwar

**Name** : Redcliffe Life Tech Pvt Ltd

**Designation** : Service Engineer

**Contact Person** : Mr.Brijesh Raikwar

**Signature** : 

**Designation** : Lab Admin

**Date** : 27/11/2022

**Signature** : 

**Date** : 27/11/2022

**TRANSASIA BIOMEDICALS LIMITED****PERFORMANCE QUALIFICATION****TRANSASIA**<sup>®</sup>  
Bio-Medicals Ltd.

Laura Smart

Automated Urine Analyzer

Instrument ID

4974-1-201709

**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. Sudhir Ahirwar**Designation** : Service Engineer**Date** : 27/11/2022

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<b>Laura Smart</b>	<b>Automated Urine Analyzer</b>	<b>Instrument ID</b>	<b>4974-1-201709</b>	

**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.Sudhir Ahirwar

Designation                 : Service Engineer

Customer Authorization:    Pathology                    : Redcliffe Life Tech Pvt Ltd (Redcliffe Labs Bhopal)

Name                            : Dr.Sakar Saxena

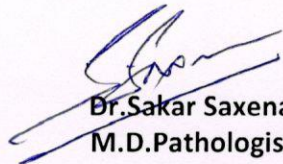
Designation                 : M.D.Pathologist

**Company Representative Name & Sign**

**Customer Name & Sign**



**Mr.Sudhir Ahirwar**



**Dr.Sakar Saxena**  
**M.D.Pathologist**

**Date: 27/11/2022**

**Date: 27/11/2022**

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**Operations Qualifications for Laura SMART (Automated Urine Analyser)**

**Serial Number : 1023-1-202206**

**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**

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**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.Sudhir Ahirwar

Name : Redcliffe Life Tech Pvt Ltd

Designation : Service Engineer

Contact Person : Mr.Brijesh Raikwar

Signature : 

Designation : Lab Admin

Date : 27/11/2022

Signature : 

Date : 27/11/2022



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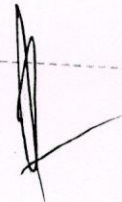
**Erba** Mannheim Urinalysis

LAURA  
\*\*\*\*\*  
23.06.2023 07:55 AM

DEKAPHAN LAURA  
Seq.No: 0001  
URINORM N  
23.06.2023 08:05 AM  
.....

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>



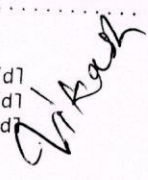
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**Erba** Mannheim Urinalysis

LAURA  
\*\*\*\*\*  
23.06.2023 08:35 AM

DEKAPHAN LAURA  
Seq.No: 0001  
URINORM P  
23.06.2023 08:35 AM  
.....

\*BLD 2+  
\*BIL 3 mg/dl  
\*UBG 1 mg/dl  
\*KET 52 mg/dl  
\*GLU 2+  
\*PRO 2+  
pH 9  
\*NIT POS  
\*LEU 125 Leu [u] 2+  
SG 1.000



QC TEST: OK  
<Admin>

