

Erba Lachema s.r.o.



Brno, 10.11.2016

To,
Redcliffe Lifetech Pvt Ltd.
Yusuf Sarai, New Delhi.

Instrument Name: ERBA LAURA
Instrument Serial no: 0994-1-202206

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.

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

6.7. 
RNDr. Pavel Suchan Ph.D.

Global Product Manager, Urine Analysis

Erba Lachema s.r.o.

Karásek 1d, Brno 62100, Czech Republic



Erba Lachema s.r.o., Karásek 1d, 621 00 Brno, Czech Republic
Identification number: 269 18 846. Tax identification number: CZ26918846
Incorporated in the Commercial Register maintained by the Regional Court in Brno, Section C, insert 45458
www.erbalachema.com

TRANSASIA BIOMEDICALS LIMITED			TRANSASIA[®] Bio-Medicals Ltd.
OPERATIONAL QUALIFICATION CHECKLIST			
Instrument Name Laura	Clinical Chemistry Analyzer Redcliffe Labs	Instrument ID 0994-1-202206	

Operational Qualification for Laura M (Automated Urine Analyzer)

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, New Delhi
 Name: Anubhav Sharma
 Designation: Dy.R.S.M. Service

Customer Authorization: Redcliffe Labs New Delhi
 Name: Dr.Param Prakash
 Designation: Pathologist

Company Representative Name & Sign

Date:

Anubhav Sharma

Customer Name & Sign

Date:

[Signature]

TRANSASIA BIOMEDICALS LIMITED			
OPERATIONAL QUALIFICATION CHECKLIST			
Instrument Name Laura	Clinical Chemistry Analyzer Redcliffe Labs	Instrument ID 0994-1-202206	TRANSASIA [®] Bio-Medicals Ltd.

Installation Qualification for Laura (Automated Urine Analyzer)

Customer Name : Redcliffe Labs New Delhi

Address : Redcliffe Labs, Yusuf Sarai Market New Delhi

Initial Inspection of the unit carried out and the details are as follows:

Instrument Name : Laura (Automated Urine Analyzer)

Serial Number : 0994-1-202206

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. TEMPERATURE:-

Ambient Conditions (10~37° C)RH ≤ 80 % (Optimum)


Utmost Conditions (0~40° C)RH ≤ 85 %

with Relative Humidity 30-85% and Atmospheric Pressure 70-106 kPa.

2 POWER SUPPLY:-

Input :100-250V
Out put DC12 V,3A



TRANSASIA BIOMEDICALS LIMITED			
OPERATIONAL QUALIFICATION CHECKLIST			
Instrument Name Laura	Clinical Chemistry Analyzer Redcliffe Labs	Instrument ID 0994-1-202206	

Installation Certificate for Laura (Automated urine Analyzer)

This is to certify that the Laura Instrument Serial No. 0994-1-202206 is successfully Installed and Commissioned at TBM, New Delhi and the Installation Protocol / checklist has been successfully completed for the above instrument.

TBM, Technical Services Department

Name : Anubhav Sharma
Designation : Regional Service Manager
Date : Anush

TRANSASIA BIOMEDICALS LIMITED			TRANSASIA [®] Bio-Medicals Ltd.
OPERATIONAL QUALIFICATION CHECKLIST			
Instrument Name Laura	Clinical Chemistry Analyzer Redcliffe Labs	Instrument ID 0994-1-202206	

Installation Qualifications for Laura M(Automated Urine Analyzer)

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

protocol Performed By: **TBM, New Delhi**
 Name: Anubhav Sharma
 Designation: Dy.R.S.M. Service

Customer Authorization: **Redcliffe Labs New Delhi**
 Name: Dr.Param Prakash
 Designation: Pathologist

Company Representative Name & Sign

Date:

Anubhav Sharma

Customer Name & Sign

Date:

[Signature]

TRANSASIA BIOMEDICALS LIMITED			
OPERATIONAL QUALIFICATION CHECKLIST			
Instrument Name Laura	Clinical Chemistry Analyzer Redcliffe Labs	Instrument ID 0994-1-202206	TRANSASIA [®] Bio-Medicals Ltd.

Instrument Setup

1. Assembled the instrument accessories.
2. Slide and fix the plate into the middle of the instrument
3. Connect the AC adapter to the port on the backside of instrument
4. Connect the Key board in such a way that 2 USB Signal should coincide
5. Mount Printer Paper roll

Operational Inspection

1. Calibrate the analyzer before Sample Run
2. To Check Optics of System run the Calibration Strip, it should be 333(+/-10)
3. Check the mode of Analyzer, when not using Switch to Stand by Mode.
4. Check the colour of blank/underacted Strip with the Chart on bottle before Run.
5. Reagent Strip Should be immersed into urine for about 2 sec
6. Use fresh & well mixed Sample & ensure it for no Concentration or Dilution

TBM, Technical Services Department

Name : Anubhav Sharma

Designation : Dy.R.S.M. Service

Date: *Anush*



TRANSASIA BIOMEDICALS LIMITED			TRANSASIA [®] Bio-Medicals Ltd.
OPERATIONAL QUALIFICATION CHECKLIST			
Instrument Name Laura	Clinical Chemistry Analyzer Redcliffe Labs	Instrument ID 0994-1-202206	

Operations Qualifications for Laura M Sr. No. 10241060317

1. Verified Motor function : Done
2. Verified Plate Sensor & Lamp : Done
3. Verified LCD & Printer : Done
4. Verified Optics of System : Done
5. Verified Functional Key board : Done



TRANSASIA BIOMEDICALS LIMITED			
OPERATIONAL QUALIFICATION CHECKLIST			
Instrument Name Laura	Clinical Chemistry Analyzer Redcliffe Labs	Instrument ID 0994-1-202206	
			TRANSASIA Bio-Medicals Ltd.

**Performance Qualifications for Laura (Automated Urine Analyzer)
Sr. No. 0994-1-202206**

1. Calibration Parameters

a. Calibrated 12 parameters

Checked and found that reflectance of all test parameters are within the acceptable range

b. Performance Qualification:

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

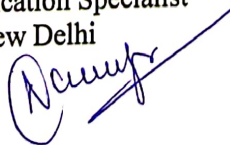
Data Sheet Attached

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: Naveen Kumar Jain
Sr.Application Specialist
TBM New Delhi



DEKAPHAN LAURA

Seq.No: 0140

URINORM N

2023.05.29

06:06 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>

DEKAPHAN LAURA

Seq.No: 0141

URINORM P

2023.05.29

08:56 AM

.....
*BLD 2+
*BIL 3+
*UBG 2+
*KET 1+
*GLU 2+
*PRO 3+
pH 9
*NIT POS
*LEU 2+
SG 1.000

Meara B.L.
29/05/23

QC TEST: OK
<Admin>

