

Erba Lachema s.r.o.



Brno, 10.11.2016

To,  
Redcliffe Lifetech Pvt Ltd.  
Bareilly, Uttar Pradesh

Instrument Name: ERBA LAURAv2  
Instrument Serial no: 1033-1-202207

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



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

**Sr. No. :- 1033-1-202207**

**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**

**Name: Dinesh Singh**

**Designation: Sr.Service Engineer**

**Customer Authorization: REDCLIFFE LIFETECH PVT LTD "BAREILY"**

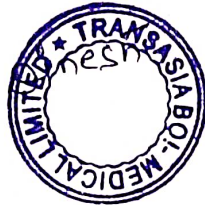
**Name: DR. ANNU JHANJHI**

**Designation: LAB INCHARGE**

**Company Representative Name & Sign**

**Dinesh Singh  
Sr.Service Engineer**

**Date: 29/11/2022**



**Customer Name & Sign**

**DR. ANNU JHANJHI  
LAB INCHARGE**

**Date:29/11/2022**

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

**Sr. No. 1033-1-202207**

**Checked assemblies**

- |    |                         |               |
|----|-------------------------|---------------|
| 1. | <b>Motor</b>            | <b>: Done</b> |
| 2. | <b>Tray Sensor</b>      | <b>: Done</b> |
| 3. | <b>Hand Sensor</b>      | <b>: Done</b> |
| 4. | <b>Strip Sensor</b>     | <b>: Done</b> |
| 5. | <b>Waste Bin Sensor</b> | <b>: Done</b> |
| 6. | <b>LCD</b>              | <b>: Done</b> |
| 7. | <b>Printer</b>          | <b>: Done</b> |

### 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

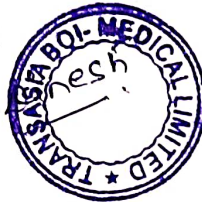
1. Switch ON the analyzer it will complete self test and complete self calibration.
2. Check the colour of blank/unreacted Strip with the Chart on bottle before Run.
3. Reagent Strip Should be immersed into urine for about 2 sec
4. Use fresh & well mixed Sample & ensure it for no Concentration or Dilution

TBM, Technical Services Department

Name : Dinesh Singh

Designation : Sr.Service Engineer

Date : 29/11/2022



**Performance Qualifications for Laura (Automated Urine Analyzer )**

**Sr. No. 1033-1-202207**

**1. Calibration Parameters**

a. Performance Qualification:  
Checked & found Grey QC strip within acceptable limit.

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 : Abhay Dixit**  
**Designation : Sr.Application Specialist**  
**Date : 29/11/2022**

  
**Mr. Abhay Dixit**  
**Sr.App. Specialist**  
**Transasia Biomedical**

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LAURA  
\*\*\*\*\*  
2023.09.28 08:18 AM

DEKAPHAN LAURA  
Seq.No: 0001  
URINORM N 09:00 AM  
2023.09.28  
.....

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: 0002  
URINORM P 09:02 AM  
2023.09.28  
.....

*BLD	50	Ery/u1	2+
*BIL	6	mg/dl	3+
*UBG	1	mg/dl	1+
*KET	52	mg/dl	2+
*GLU	250	mg/dl	1+
*PRO	500	mg/dl	3+
pH	9		
*NIT	POS		
*LEU	TRACE		
SG	1.000		

QC TEST: OK  
<Admin>

*Abhishek*  
28/9/23