

Brno, 10.11.2016

Laura Smart: Calibration procedure

To Whom It May Concern:

We Erba Lachema s.r.o. with registered office in Czech Republic, Karásek 1d, 621 00 Brno, represented by its Global Product Manager Pavel Suchan hereby confirm as producer of the Laura Smart instrument that this device is firmly calibrated by manufacturer and does not require any regular calibration by the user. Correct calibration of the instrument is controlled by grey strips provided initially together with the instrument.

A handwritten signature in blue ink, appearing to be "P. Suchan", written over a vertical line that extends down the page.

RNDr. Pavel Suchan Ph.D.

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	7043-1-202105

TRANSASIA[®]
Bio-Medicals Ltd.

Operational Qualification for Laura SMART (Automated Urine Analyzer)

Sr. No. 7043-1-202105

Customer Name : Vyas Super Speciality Hospital, Jodhpur

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. Girdhari Sharma

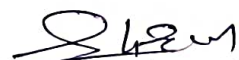
Designation : Service Engineer

Customer Authorization: Hospital : Vyas Super Speciality Hospital, Jodhpur

Name : Mr. Sharwan

Designation : Lab Technician


Company Representative Name & Sign


Customer Name & Sign

TRANSASIA BIOMEDICALS LIMITED			TRANSASIA[®] Bio-Medicals Ltd.
PERFORMANCE QUALIFICATION			
Laura Smart	Automated Urine Analyzer	Instrument ID	

Installation Qualification for Laura SMART (Automated Urine Analyzer)

Sr.No. 7043-1-202105

Customer Name : Vyas Super Speciality Hospital, Jodhpur

Address : Pali Road, Jodhpur

Instrument Name : Laura SMART (Automated Urine Analyzer)

Serial Number : 7043-1-202105

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. 7043-1-202105** 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. Girdhari Sharma

Designation : Service Engineer

Installation Qualifications for Laura SMART(Automated Urine Analyzer)Sr. No. 7043-1-202105

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

TBM, Technical Services Department

Name : Mr. Girdhari Sharma

Designation : Service Engineer

TRANSASIA BIOMEDICALS LIMITED			
PERFORMANCE QUALIFICATION			
Laura Smart	Automated Urine Analyzer	Instrument ID	7043-1-202105



Installation Report for Laura SMART (Automated Urine Analyzer)

Sr. No. 7043-1-202105

Customer Name : Vyas Super Speciality Hospital, Jodhpur

Department : Laboratory

Contact Person : Mr. Sharwan

Instrument Model : Laura SMART (Automated Urine Analyzer)

Serial Number : 7043-1-202105

Date of Installation : 25-02-2023

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. Girdhari Sharma

Name : Vyas Super Speciality Hospital

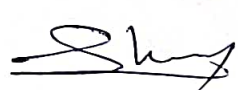
Designation : Service Engineer

Contact Person : Mr. Sharwan

Signature : 

Designation : Lab Technician

Date : 25-02-2023

Signature : 

TRANSASIA BIOMEDICALS LIMITED**PERFORMANCE QUALIFICATION****TRANSASIA**[®]
Bio-Medicals Ltd.**Laura Smart****Automated Urine Analyzer****Instrument ID****7043-1-202105****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**TBM, Technical Services Department****Name** : Mr. Girdhari Sharma**Designation** : Service Engineer

TRANSASIA BIOMEDICALS LIMITED			
PERFORMANCE QUALIFICATION			
Laura Smart	Automated Urine Analyzer	Instrument ID	7043-1-202105



Operations Qualifications for Laura SMART (Automated Urine Analyser)

Sr. No. 7043-1-202105

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

Performance Qualifications for Laura SMART (Automated Urine Analyzer)

TRANSASIA BIOMEDICALS LIMITED**PERFORMANCE QUALIFICATION**

Laura Smart

Automated Urine Analyzer

Instrument ID

7043-1-202105

TRANSASIA[®]
Bio-Medicals Ltd.Sr. No. 7043-1-202105**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**

Name : Mr. Girdhari Sharma

Designation : Service Engineer

Signature : 

Date : 25-02-2023

CUSTOMER

Name : Vyas Super Speciality Hospital

Contact Person : Mr. Sharwan

Designation : Lab Technician

Signature : 

LAURA[®]
S M A R T

CHECK MODE

25.01.2024

10:10

.....
1: 686 674
2: 323 312
3: 135 130

QC TEST: OK

LAURA[®]
S M A R T

CHECK MODE

Check strip

URINORM-N

URINORM-P

X
ESC