

LAURA<sup>®</sup>  
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<sup>®</sup>  
S M A R T

CHECK MODE

Check strip

URINORM-N

URINORM-P

X  
ESC



## Certificate of Conformity and Calibration

TO WHOMSOEVER IT MAY CONCERN

### ISO 15189:2012 REQUIREMENTS REGARDING,"CALIBRATION AND VERIFICATION PROCEDURE"

All Transasia Bio-Medicals Ltd diagnostics products which are distributed and for which a certificates is issued are CE Marked. Transasia Bio-Medicals Ltd , Mumbai ,manufacturers of diagnostic devices with company quality management system in compliance with standard ISO13485:2016 ;ISO9001:2015 .This means that all the processes in development and manufacturing of TBM products are guided by quality management system.

TBM declares and assure following

- The mentioned regulations require that production system and measuring devices are qualified and manufacturing and test procedures are validated as per ISO 13485:2016 and ISO 9001:2015 standard and it is assured through schedule maintenance and by regular qualification.
- TBM declares to have established procedure and to maintain it in order to assure the post marketing surveillance according to directive of 98/79/EC.
- All physical quantities, calibrators and controls used in TBM system are fully traceable to certified standards or reference materials.
- All TBM products are factory calibrated and final qc passed at the time of release.
- The performance of TBM system at customer site is assured if regular QC measurements, cleaning and maintenance procedure as described in the instruction for use or service documentation are performed
- Additional calibration or verification procedure is not required in order to assure the specified performances of every TBM system. Only if user deviates from the manufactures recommendation does he have to establish site specific calibration and verification procedure as part of his accreditation process.

Date:-26/04/2021

Manish Airan

Head Of Quality Department & Regulatory

## INSTALLATION & TRAINING REPORT

Customer Name : Vyash super specialty Hospital  
 Department : Hospital Laboratory  
 Address : Near Kudi Mod, pali Road, Jodhpur  
 City : Jodhpur Pin : 342005 State : Rajasthan  
 Territory : Jodhpur Zone : CL1  
 Telephone & Fax : \_\_\_\_\_ email : \_\_\_\_\_  
 Contact Person : Mr. Krishna Mobile No. : 9044862424  
 Instrument Model : Laura Smart Sr. No. : 7043-1-202105  
 Installation Date : 25/02/2023

The above mentioned Instrument has been satisfactorily installed by Service Engineer / Product Specialist of Transasia Bio-Medicals Ltd. Operational Training & User Maintenance of the Instrument was provided to the following staff members on date (s) : 25.02.2023

Name (s)	Designation/ Dept.
1. <u>Mr. Charwan</u>	<u>Sr. L.T</u>
2. <u>Mr. Sanderjeed</u>	<u>L.T</u>
3. <u>Ms. Divya</u>	<u>L.T</u>

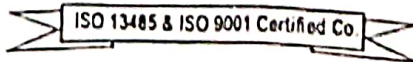
Test/ Parameters Demonstrated : \_\_\_\_\_  
 Customer Comments (If any) : \_\_\_\_\_

Engineer / Product Specialist : Upendra Customer Signature : \_\_\_\_\_  
 Signature : [Signature] Customer Name : \_\_\_\_\_  
 Name : Girdharilal Designation : \_\_\_\_\_  
 Date : 25/02/2023 Customer Seal : \_\_\_\_\_



**Arbitration Clause**  
 All disputes, Differences, controversies and questions directly or indirectly arising at any time under, out of, in connection with or in relation to the payment of this Instrument / reagents / service shall be referred to the sole arbitrator to be appointed by Transasia Bio-Medicals Limited under the Arbitration and Conciliation Act 1996. The venue and seat of arbitration shall be at Mumbai. The award rendered by the arbitrator(s) shall be final and binding upon both Parties.

www.transasia.co.in



**TRANSASIA BIO-MEDICALS LTD.**

H. O. COPY

TRANSASIA HOUSE, 8 CHANDIVALI STUDIO ROAD, ANDHERI (E), MUMBAI - 400 072 TEL : 4030 9000 FAX : (022) 4030 9090 / 2857 3030 Email : transasia@transasia.co.in

DELHI (011) 25732223 CHENNAI (044) 28227149 KOLKATA (033) 22157839 BANGALORE (080) 25568044 AHMEDABAD (079) 26407030

Doc No. 5COO-430/ISS-4

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 :  $\leq 75\%$
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

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

<b>Laura Smart</b>	<b>Automated Urine Analyzer</b>	<b>Instrument ID</b>	<b>7043-1-202105</b>
--------------------	---------------------------------	----------------------	----------------------

**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****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** : 

<b>TRANSASIA BIOMEDICALS LIMITED</b>			<b>TRANSASIA<sup>®</sup></b> Bio-Medicals Ltd.
<b>PERFORMANCE QUALIFICATION</b>			
<b>Laura Smart</b>	<b>Automated Urine Analyzer</b>	<b>Instrument ID</b> <b>7043-1-202105</b>	

**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

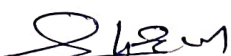
Designation                        : Service Engineer

Customer Authorization:        Hospital                                : Vyas Super Speciality Hospital, Jodhpur

Name                                 : Mr. Sharwan

Designation                         : Lab Technician

  
**Company Representative Name & Sign**

  
**Customer Name & Sign**

Laura Smart	Automated Urine Analyzer	Instrument ID	7043-1-202105
-------------	--------------------------	---------------	---------------

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**

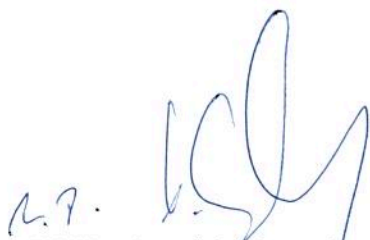
**Signature : **

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.



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  
DIČ: CZ26918846 -10-





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

**TRANSASIA**<sup>®</sup>  
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

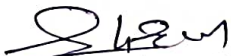
Designation : Service Engineer

Customer Authorization: Hospital : Vyas Super Speciality Hospital, Jodhpur

Name : Mr. Sharwan

Designation : Lab Technician

  
Company Representative Name & Sign

  
Customer Name & Sign

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

**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

TRANSASIA BIOMEDICALS LIMITED

PERFORMANCE QUALIFICATION

Laura Smart

Automated Urine Analyzer

Instrument ID

7043-1-202105

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

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

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



**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

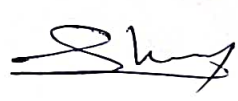
**Designation** : Service Engineer

**Contact Person** : Mr. Sharwan

**Signature** : 

**Designation** : Lab Technician

**Date** : 25-02-2023

**Signature** : 

**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

<b>TRANSASIA BIOMEDICALS LIMITED</b>			
<b>PERFORMANCE QUALIFICATION</b>			
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<sup>®</sup>**  
Bio-Medicals Ltd.Sr. No. 7043-1-202105**1. Calibration Parameters**

## a. 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. Girdhari Sharma

Designation : Service Engineer

Signature : 

Date : 25-02-2023

**CUSTOMER**

Name : Vyas Super Speciality Hospital

Contact Person : Mr. Sharwan

Designation : Lab Technician

Signature : 