

**TRANSASIA BIOMEDICALS LIMITED**  
**PERFORMANCE QUALIFICATION**



Laura Smart Automated Urine Analyzer Instrument ID 1015-1-202206

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

**Sr. No. 1015-1-202206**

**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. Sunil Giri

Designation : Service Engineer

Customer Authorization: Hospital : P H Medical Centre –Sanatacruz

Name : Mr. Rajesh Nambiar

Designation : HOD

**Company Representative Name & Sign**

**Customer Name & Sign**

Mr. Sunil Giri

Service Engineer

Date: 25-10-2022

Mr. Rajesh Nambiar

HOD

Date: 25-10-2022

**TRANSASIA BIOMEDICALS LIMITED****PERFORMANCE QUALIFICATION****TRANSASIA**

Laura Smart

Automated Urine Analyzer

Instrument ID

1015-1-202206

**Installation Qualification for Laura SMART (Automated Urine Analyzer)****Sr.No.** 1015-1-202206**Customer Name** : P H Medical Centre – Santacruz west**Address** : P.H.Medical centre,juhu road Near Santacruz (w)  
Mumbai - 400054**Instrument Name** : Laura SMART (Automated Urine Analyzer)**Serial Number** : 1015-1-202206**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. 5919-1-201909 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. Sunil**Designation** : Service Engineer**Date** : 25-10-2022

Laura Smart

Automated Urine Analyzer

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**Installation Qualifications for Laura SMART(Automated Urine Analyzer)****Sr. No. 1015-1-202206**

Carried out all the Installation Procedures as per the Installation Procedure &amp; 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 &amp; Qualifications

**For TBM, Technical Services Department****Name** : Mr. Vikrant Bargude**Designation** : Service Engineer**Date** : 25-10-2022

Laura Smart

Automated Urine Analyzer

Instrument ID

1015-1-202206

**Installation Report for Laura SMART (Automated Urine Analyzer)****Sr. No.** 1015-1-202206**Customer Name** : P. H. Medical Centre Santacruz**Department** : Laboratory**Contact Person** : Mr.Rajesh Nambiar**Instrument Model** : Laura SMART (Automated Urine Analyzer )**Serial Number** : 1015-1-202206**Date of Installation** : 25-10-2022

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****Name** : Mr. Sunil Giri**Designation** : Service Engineer**Signature** :**Date** : 25-10-2022**CUSTOMER****P. H. Medical Centre Sanataacruz****Name** : Mr.Rajesh Nambiar**Designation** : HOD**Signature** :**Date** : 25-10-2022

Laura Smart

Automated Urine Analyzer

Instrument ID

1015-1-202206

**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.Sunil Giri**Designation** : Service Engineer**Date** : 25-10-2022

Laura Smart

Automated Urine Analyzer

Instrument ID

1015-1-202206

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

Sr. No. 1015-1-202206

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

Laura Smart

Automated Urine Analyzer

Instrument ID

1015-1-202206

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

Sr. No. 1015-1-202206

**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. Vikrant Bargude**Designation** : Application Specialist**Signature** :**Date** : 25-10-2022**CUSTOMER****P. H. Medical Centre Sanataacruz****Name** : Mr. Rajesh Nambiar**Designation** : HOD**Signature** :**Date** : 25-10-2022