

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA[®] Bio-Medicals Ltd.
PERFORMANCE QUALIFICATION				
Laura Smart	Automated Urine Analyzer	Instrument ID	5919-1-201909	

Operational Qualification for Laura SMART (Automated Urine Analyzer)

Sr. No. 5919-1-201909

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 – Kandivali

Name : Dr. Sheetal Mane

Designation : HOD


Company Representative Name & Sign



Mr. Sunil Giri
Service Engineer

Date: 08-10-2022

Customer Name & Sign



Dr. Sheetal Mane
HOD

Date: 08-10-2022

Installation Qualification for Laura SMART (Automated Urine Analyzer)

TRANSASIA BIOMEDICALS LIMITED			
PERFORMANCE QUALIFICATION			
Laura Smart	Automated Urine Analyzer	Instrument ID	5919-1-201909

Laura Smart
Installation
Sr. N

Sr.No. 5919-1-201909

Customer Name : P H Medical Centre – Kandivali East

Address : Shree Ganesh Aangan Society,
Next to thakur mall , Thakur Village,
Kandivali East. Mumbai - 400101

Instrument Name : Laura SMART (Automated Urine Analyzer)

Serial Number : 5919-1-201909

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 : 08-10-2022

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Installation Qualifications for Laura SMART(Automated Urine Analyzer)

Sr. No. 5919-1-201909

- 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

For TBM, Technical Services Department

Name : Mr. Vikrant Bargude

Designation : Service Engineer

Date : 08-10-2022

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TRANSASIA
Bio-Medicals

Laura Smart
Instru

Installation Report for Laura SMART (Automated Urine Analyzer)

Sr. No. 5919-1-201909

Customer Name : P. H. Medical Centre Kandivali

Department : Laboratory

Contact Person : Dr. Sheetal Mane.

Instrument Model : Laura SMART (Automated Urine Analyzer)

Serial Number : 5919-1-201909

Date of Installation : 08-10-2022

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

CUSTOMER
P. H. Medical Centre Kandivali

Name : Mr. Sunil Giri

Name : Dr. Sheetal Mane..

Designation : Service Engineer

Designation : HOD

Signature :

Signature :

Date : 08-10-2022

Date : 08-10-2022



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Laura Smart	Automated Urine Analyzer	Instrument ID	5919-1-201909
			TRANSASIA[®] Bio-Medicals Ltd.

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 : 08-10-2022

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Laura Smart	Automated Urine Analyzer	Instrument ID	5919-1-201909

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Operations Qualifications for Laura SMART (Automated Urine Analyser)

Sr. No. 5919-1-201909

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**

TRANSASIA BIOMEDICALS LIMITED

PERFORMANCE QUALIFICATION

TRANSASIA[®]
Bio-Medicals Ltd.

Laura Smart

Automated Urine Analyzer

Instrument ID

5919-1-201909

Performance Qualifications for Laura SMART (Automated Urine Analyzer)

Sr. No. 5919-1-201909

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.

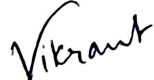
Protocol Performed By:

TBM

Technical Services Department

Name : Mr. Vikrant Bargude

Designation : Application Specialist

Signature : 

Date : 08-10-2022

CUSTOMER

P. H. Medical Centre Kandivali

Name : Dr. Sheetal Mane..

Designation : HOD

Signature : 

Date : 08-10-2022

TECHNICAL SERVICE REPORT

No. **1482755W**

DATE: **13/4/23**

CUSTOMER DETAILS		INSTRUMENT DETAILS		SERVICE STATUS	
NAME: P. M. M. B. G.		MODEL: Laura Smart		<input checked="" type="checkbox"/> WARRANTY <input type="checkbox"/> R&R <input type="checkbox"/> AMC <input type="checkbox"/> CMC <input type="checkbox"/> CHARGED CALL	
ADDRESS: Kandivali (E)		SR. NO.: 5919-1-201909		TYPE OF CALL <input type="checkbox"/> INSTALLATION <input checked="" type="checkbox"/> P.M. VISIT <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> APPLICATION SUPPORT <input type="checkbox"/> BREAKDOWN	
TEL NO:		COMPLAINT RECD.		DOWN TIME:	
NAME OF THE OPERATOR:		RESPONSE		COUNTER READING:	
PROBLEM REPORTED: PM VISIT		JOB COMPLETED			
OBSERVATIONS:		RESPONSE TIME			
ACTION TAKEN: Carried out the preventive maintenance weekly OK. Protein Results were (High value coming).		TRAVEL TIME			
SITE CONDITION: LINE-NEUTRAL VOLT.: 230V		NEUTRAL-EARTH VOLT.: 0V		LINE-EARTH VOLT.: 230V	
BRAND OF REAGENT USED:		TO BE FILLED IN BY CUSTOMER <input type="checkbox"/> PREVENTIVE MAINTENANCE CARRIED OUT SATISFACTORILY. <input type="checkbox"/> FAULT RECTIFIED & INSTRUMENT IS WORKING SATISFACTORILY. <input type="checkbox"/> WE HEREBY APPROVE RS. _____ FOR PARTS <input type="checkbox"/> COMMENTS (IF ANY):			
<input checked="" type="checkbox"/> FOLLOWING PARTS HAVE BEEN REPLACED <input type="checkbox"/> FOLLOWING PARTS NEED TO BE REPLACED. PLEASE APPROVE		SEAL DATE CUSTOMER'S SIGNATURE NAME: Amal			
NO.	DESCRIPTION	QTY.	COST	TOTAL	
TOTAL Rs.					
INVOICE NO.:		DATE:		BRANCH H. O.	
FOLLOW-UP ACTION (Required if any):		RECEIVED ON:		CHECKED BY:	
ENGINEER'S/APPLICATION SPECIALIST'S SIGNATURE:		JOB CARD NO.:			
TIME:	NAME: Amal				

NOTE: Parts replaced are chargeable except during warranty period. Consumables like printer head, lamp, tubing, paper rolls etc. & breakable parts are not covered by warranty and hence are chargeable. Parts replaced due to negligence in operation will also be charged in every case.

AT TRANSASIA, CUSTOMER SATISFACTION IS OUR PRIME CONCERN. IN CASE YOU HAVE ANY SUGGESTIONS PLEASE CONTACT: GENERAL MANAGER (TECHNICAL SERVICE), MUMBAI. TEL.: 4030 9000

TRANSASIA BIO-MEDICALS LTD.

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