



Calibration Certificate

Date 30th Mar 2022

To,
MAEER's Vishwaraj Hospital Laboratory, Pune.

Dear Sir,
As desired by you please find enclosed herewith Technical calibration report for your Urine Analyzer Model: Laura M Sr. No. 8381160315.

1. Date of Calibration - : 30th Mar 2022
2. Next Calibration date- : 29th Mar 2023

Calibration status:

Ref	R=335	G=336	B=338
LEU	R=335	G=336	B=338
NIT	R=335	G=336	B=338
URO	R=335	G=336	B=338
PRO	R=335	G=336	B=338
pH	R=335	G=336	B=338
BLD	R=335	G=336	B=338
S.G.	R=335	G=336	B=338
KET	R=335	G=336	B=338
BIL	R=335	G=336	B=338
GLU	R=335	G=336	B=338
VTC	R=335	G=336	B=338

Calibration value Range 333+/- 10 (323 -343)

Calibration of instrument is ok.
Thanking you and assuring of our prompt attention at all times.

Yours faithfully,

For TRANSASIA BIO-MEDICALS LTD.

Mr. Swapnil Kamarikar
Service Engineer





Calibration Certificate

Date 01st Apr 2021

To,
MAEER's Vishwaraj Hospital Laboratory, Pune.

Dear Sir,
As desired by you please find enclosed herewith Technical calibration report for your Urine Analyzer Model: Laura M Sr. No. 8381160315.

1. Date of Calibration - : 01st Apr 2021
2. Next Calibration date- : 31st Mar 2022

Calibration status:

Ref	R=335	G=336	B=338
LEU	R=335	G=336	B=338
NIT	R=335	G=336	B=338
URO	R=335	G=336	B=338
PRO	R=335	G=336	B=338
pH	R=335	G=336	B=338
BLD	R=335	G=336	B=338
S.G.	R=335	G=336	B=338
KET	R=335	G=336	B=338
BIL	R=335	G=336	B=338
GLU	R=335	G=336	B=338
VTC	R=335	G=336	B=338

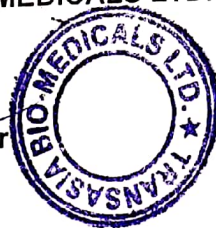
Calibration value Range 333+/- 10 (323 -343)

Calibration of instrument is ok.
Thanking you and assuring of our prompt attention at all times.

Yours faithfully,

For TRANSASIA BIO-MEDICALS LTD.

Mr. Swapnil Kamarikar
Service Engineer





Installation Report for

Customer Name : MAEER'S VISHWARAJ HOSPITAL LABORATORY, PUNE

Department : Sample collection

Contact Person :

Instrument Model : Laura M(Automated Urine Analyzer)

Serial Number : 8381160315

Date of Installation :

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 : Swapnil Kamarikar

Designation : Service Engineer


Signature : 

CUSTOMER

Name : Dr. Anindita Ganesh

Contact Person :

Designation : HOD - Laboratory

Signature : 

Date : 01/01/21



L-①



Instrument Setup

1. Assembled the instrument accessories.
2. Slide and fix the plate into the middle of the instrument
3. Connect the AC adapter to the port on the backside of instrument
4. Connect the Key board in such a way that 2 USB Signal should coincide
5. Mount Printer Paper roll

Operational Inspection

1. Calibrate the analyzer before Sample Run
2. To Check Optics of System run the Calibration Strip, it should be 333(+/-10)
3. Check the mode of Analyzer, when not using Switch to Stand by Mode.
4. Check the colour of blank/unreacted Strip with the Chart on bottle before Run.
5. Reagent Strip Should be immersed into urine for about 2 sec
6. Use fresh & well mixed Sample & ensure it for no Concentration or Dilution

TBM, Technical Services Department

Name : Vijay Shahu

Designation : Application Specialist

Date: 01/01/21

Vijay



Installation Qualification for Laura M (Automated Urine Analyzer)

Customer Name : MAEER'S VISHWARAJ HOSPITAL LABORATORY, PUNE
Address : Pune
Instrument Name : Laura M (Automated Urine Analyzer)
Serial Number : 8381160315

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:

- TEMPERATURE:-**
Ambient Conditions (10~37 °C) RH ≤ 80 % (Optimum)
Utmost Conditions (0~40 °C) RH ≤ 85 %
with Relative Humidity 30-85% and Atmospheric Pressure 70-106 kPa.
- POWER SUPPLY:-** Input : 100-250V
Out put DC12 V,3A

Installation Certificate for Laura M (Automated urine Analyzer)

This is to certify that the Laura M Instrument Serial No. 8381160315 is successfully Installed and Commissioned at TBM, Pune and the Installation Protocol / checklist has been successfully completed for the above instrument.



TBM, Technical Services Department

Name : Swapnil Kamarikar

Designation : Service Enginner

Date : 01/01/21

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Installation Qualifications for Laura M (Automated Urine Analyzer)

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: Swapnil Kamarikar

Designation: Service Engineer

Date: 01/01/21



Operations Qualifications for Laura M Sr. No.8381160315

1. Verified Motor function : Done
2. Verified Plate Sensor & Lamp : Done
3. Verified LCD & Printer : Done
4. Verified Optics of System : Done
5. Verified Functional Key board : Done

L-G



Operational Qualification:

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, Pune
Name: Swapnil Kamarikar
Designation: Service Engineer



Customer Authorization: Hospital:- MAEER'S VISHWARAJ HOSPITAL
LABORATORY, PUNE

Name: *Dr. Aninreddha Ganesh*
Designation: *HOD - Laboratory*

Company Representative Name & Sign
Swapnil Kamarikar *[Signature]*

[Signature]
Customer Name & Sign

Date: *01/01/21*

Date:

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Performance Qualifications for Laura M (Automated Urine Analyzer) Sr. No. 8381160315

1. Calibration Parameters

- a. Calibrated 12 parameters

Checked and found that reflectance of all test parameters are within the acceptable range

- b. Performance Qualification:

Checked & found that Sensitivity of each Parameter is set as per %Value Change Method

Data Sheet Attached

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: Vijay Shahu
Application Specialist
TBM Pune



Date: 01/01/2021

Time: 13:18:00

No. 000007

Colour: yellow

BLD	neg.
BIL	neg.
URO	norm.
KET	neg.
GLU	neg.
PRO	neg.
PH	≤ 6
NIT	neg.
LEU	neg.
SG	1.030

neg.

1.030

Date: 01/01/2021

Time: 13:13:59

No. 000006

Colour: yellow

BLD neg.

BIL neg.

URO norm.

KET neg.

GLU neg.

PRO neg.

PH ≤ 6

NIT neg.

LEU neg.

SG 1.030

Date: 01/01/2021

Time: 13:18:37

No. 000011

Colour: yellow

BLD neg.

BIL neg.

URO norm.

KET neg.

GLU neg.

PRO neg.

PH ≤ 6

NIT neg.

LEU neg.

SG 1.030

Date: 29/03/2022

Time: 09:25:56

No. 000002

Colour: yellow

BLD	neg.
BIL	neg.
URO	norm.
KET	neg.
GLU	neg.
PRO	neg.
PH	≤ 6
NIT	neg.
LEU	neg.
SG	1.030

Date: 01/01/2021

Time: 13:23:26

No. 000016

Colour: yellow

BLD	neg.
BIL	neg.
URO	norm.
KET	neg.
GLU	neg.
PRO	neg.
PH	≤ 6
NIT	neg.
LEU	neg.
SG	1.030

Date: 01/01/2021

Time: 13:13:34

No. 000002

Colour: yellow

BLD neg.

BIL neg.

URO norm.

KET neg.

GLU neg.

PRO neg.

PH ≤ 6

NIT neg.

LEU neg.

SG 1.030

Date: 01/01/2021

Time: 13:13:40

No. 000003

Colour: yellow

BLD	neg.
BIL	neg.
URO	norm.
KET	neg.
GLU	neg.
PRO	neg.
PH	≤ 6
NIT	neg.
LEU	neg.
SG	1.030

Date: 01/01/2021

Time: 13:18:12

No. 000008

Colour: yellow

BLD	neg.
BIL	neg.
URO	norm.
KET	neg.
GLU	neg.
PRO	neg.
PH	≤ 6
NIT	neg.
LEU	neg.
SG	1.030

Date: 01/01/2021

Time: 13:13:46

No. 000004

Colour: yellow

BLD	neg.
BIL	neg.
URO	norm.
KET	neg.
GLU	neg.
PRO	neg.
PH	≤ 6
NIT	neg.
LEU	neg.
SG	1.030

Date: 01/01/2021

Time: 13:13:53

No. 000005

Colour: yellow

BLD	neg.
BIL	neg.
URO	norm.
KET	neg.
GLU	neg.
PRO	neg.
PH	≤ 6
NIT	neg.
LEU	neg.
SG	1.030

Date: 01/01/2021

Time: 13:43:21

No. 000006

Colour: yellow

BLD	neg.
BIL	neg.
URO	norm.
KET	neg.
GLU	4+
PRO	2+
PH	7
NIT	neg.
LEU	neg.
SG	1.015

Date: 01/01/2021

Time: 13:44:29

No. 000009

Colour: yellow

BLD	neg.
BIL	neg.
URO	norm.
KET	neg.
GLU	4+
PRO	2+
PH	7
NIT	neg.
LEU	neg.
SG	1.015

Date: 01/01/2021

Time: 13:42:38

No. 000004

Colour: yellow

BLD	neg.
BIL	neg.
URO	norm.
KET	neg.
GLU	4+
PRO	2+
PH	7
NIT	neg.
LEU	neg.
SG	1.015

Date: 01/01/2021

Time: 13:43:09

No. 000005

Colour: yellow

BLD neg.

BIL neg.

URO norm.

KET neg.

GLU 4+

PRO 2+

PH 7

NIT neg.

LEU neg.

SG 1.015

Date: 01/01/2021

Time: 13:42:19

No. 000003

Colour: yellow

BLD	neg.
BIL	neg.
URO	norm.
KET	neg.
GLU	4+
PRO	2+
PH	7
NIT	neg.
LEU	neg.
SG	1.015

Date: 01/01/2021

Time: 13:43:47

Colour: yellow

BLD	neg.
BIL	neg.
URO	norm.
KET	neg.
GLU	4+
PRO	2+
PH	7
NIT	neg.
LEU	neg.
SG	1.015

Date: 01/01/2021

Time: 13:40:47

Colour: yellow

BLD	neg.
BIL	neg.
URO	norm.
KET	neg.
GLU	4+
PRO	2+
PH	7
NIT	neg.
LEU	neg.
SG	1.015

Date: 01/01/2021

Time: 13:38:10

ID: 1

Colour: yellow

BLD	neg.
BIL	neg.
URO	norm.
KET	neg.
GLU	4+
PRO	2+
PH	7
NIT	neg.
LEU	neg.
SG	1.015

Date: 01/01/2021

Time: 13:41:49

Colour: yellow

BLD	neg.
BIL	neg.
URO	norm.
KET	neg.
GLU	4+
PRO	1+
PH	7
NIT	neg.
LEU	neg.
SG	1.010