

CALIBRATION CERTIFICATE

Date: 5TH MARCH 2021

To,
NEYVELI DIAGNOSTIC CENTRE,
Dr. RADHAKRISHNAN SALAI,
BLOCK 11, NEYVELI-607803

Dear Sir/Madam,

As desired by you please find enclosed herewith the calibration report

1. M/C Detail : M/C Name : EM 200 SR NO B150406
2. Range of the instrument : optical density Linear from 0-3.5 A
3. Calibration done Date : 27TH FEB 2021
4. Next Calibration due Date : 26TH FEB 2022

Pressure	Ideal	Actual
	1 bar	0.98bar
Lamp voltage	12 V	11.7 V
Temperature	37 °C	37 °C
Photometer calibration check	ok	
Cuvette blank check	ok	
Wavelength	Off set	Gain
340	255	105
376	255	111
415	255	101
450	255	106
480	255	102
505	255	111
546	255	115
570	255	116
600	255	107
660	255	118

The instrument does photometer check before each batch of tests is run. It will give an error message if

The photometer test fails and it will not run any samples.

Thanking you and assuring of our prompt attention at all times.

Your faithfully,

For TRANSASIA BIO-MEDICALS LTD.



S. GANESH
Regional Service Manager



Photometer Calibration Check	Ok
Cuvette Blank Check	Ok

Wavelength	Off Set	Gain
340	255	387
376	255	327
415	255	443
450	255	367
480	255	351
505	255	467
546	255	521
570	255	389
600	255	357
660	255	443

The Calibrator used: Multical
Lot No: 2005093D
Expiry Date: December 2021

The Control used : Bio-Rad (level 1, level 2)
Lot No : 20470, 20470
Expiry date : DEC 2022

The instrument does photometer check before each batch of tests is run. It will give an error message if the photometer test fails and it will not run any samples.

Thanking you and assuring of our prompt attention at all times.

Yours faithfully,
For TRANSASIA **BIO-MEDICALS LTD.**

For


REGIONAL SERVICE MANAGER

TRANSASIA BIO MEDICALS LTD.
New No. 19, Dr. Ranga Road,
Jupiter Complex, 3rd Floor,
Mylapore, Chennai - 600 004



Accuracy study with Potassium Dichromate ($K_2Cr_2O_7$) in comparison with EM - 200

Wavelengths scan on Referral Spectrophotometer for Potassium Dichromate ($K_2Cr_2O_7$)

Wavelength	Spectrophotometer OD	
	Low	High
335	0.1874	1.7437
367	0.1902	1.7803
423	0.1936	1.8217
353	0.1976	1.8629
468	0.2021	1.9055
527	0.2009	1.9479
653	0.2115	1.9875
486	0.2163	2.0226
568	0.2212	2.0588
594	0.2255	2.0845

Test of Potassium Dichromate ($K_2Cr_2O_7$) on XL-600

Pipetted / Measured by XL-300		Manually Pipettes XL		Manually pipetted & read in Autospan	
Low	High	Low	High	Low	High
0.2005	1.9785	0.2010	1.9795	0.2009	1.9788

This instrument is manufactured in accordance with the European law in force, in particular to "Electricity Safety" EN 610101 and "Electromagnetic Compatibility" EN 61326 Standards.

Pressure	Ideal	Actual
	1.0 bar	0.95 bar
Lamp Voltage	12 VDC	12.07V
Temperature	37 ⁰ C	37 ⁰ C



Ref No : TSD/NEYD/2041

Date : 08 SEPTEMBER 2021

**NEYVELI DIAGNOSTICS CENTRE,
DR. RADHAKRISHNAN SALAI,
BLOCKII, NEYVELI-607803**

Dear Sir/ Madam,

As desired by you please find herewith the Calibration report

Manufacturer detail : EM 200 S.R NO: B150406
Range of the instrument : Optical density Linear form 0-3.5 A
Date of calibration : 27 FEB 2021
Next calibration due date : 26 FEB 2022

Precision with Potassium Dichromate ($K_2Cr_2O_7$),

Reagent / Sample ratio :-

Cup Position	Replicates	Absorbance (X)	SD	CV
Cup 1	20	1.5438 OD	0.0054	0.40%
Cup 2	20	1.5438 OD	0.0052	0.42 %
Cup 3	20	1.5449 OD	0.0047	0.38%

TRANSASIA[®]

Transasia Bio - Medicals Ltd., No: 8/3, Unique Sterling, 3rd Cross Street, Sterling Road, Nungambakkam,
Chennai - 600034 Tel: +91 44 3297 7703/ 2822 7149 Fax: +91 44 2825 9435 Email: sz1@transasia.co.in
CIN: U33110MH1985PLC036198



TRANSASIA BIO-MEDICAL LTD.

EM-200

SR. NO : B150406

IQ, OQ AND PQ

For

**NEYVELI DIAGNOSTICS CENTER,
NEYVELI - 605006**

**Marketed by:
Transasia Bio-Medicals Ltd.,
Transasia House,
Chandivali Studio road,
Andheri (E),
MUMBAI - 400 072**



Installation Qualification for EM200, Sr. No.: B150406

Customer Name : NEYVELI DIAGNOSTICS CENTER
Address : Dr. Ambedkar road, Block – 12, Neyveli – 605006
Instrument Name : EM-200
Serial Number : B150406

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. Package was kept in Good Condition as per the directional indicators like not tilt, 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. Input voltage of 220V-240V / 50Hz or 60Hz.
2. Recommended Operating Temperature is 15-30 °C, with Relative Humidity 30-85% and Atmospheric Pressure 70-106 kPa.





Installation Certificate for EM-200, Sr. No.:- B150406

This is to certify that the instrument **EM-200 Sr. No.:- B150406** is successfully Installed and Commissioned at **NEYVELI DIAGNOSTICS CENTER, Neyveli**, and the Installation Protocol / checklist has been successfully completed for the Above instrument.

Date of Installation: 15/06/2015

Protocol Performed By:

Transasia Bio-Medical Ltd., Technical Services Department

Name : Mr. Shaik Ajmeer

Designation : Service Engineer

Signature : For
M. Shankar

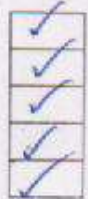




Installation Qualifications for EM-200, Sr. No.:- B150406

Performed/Verified

Installation Procedures as per Checklists.
Necessary checks and alignments.
Priming and Cleaning Operations
Check the results by running the controls.
Hand over the Instrument for Operators Training & Qualifications



Protocol Performed By:

For TBM, Technical Services Department

Name : Mr. Shaik Ajmeer

Designation : Service Engineer

Signature :





Installation Qualification for EM-200, Sr. No.:- B150406

Customer Name : NEYVELI DIAGNOSTICS CENTER,
Address : Dr. Ambedkar road, Block - 12, Neyveli - 605006
Contact Person : Mrs. J. Umarani
Instrument Model : EM-200
Serial Number : B150406
Date of Installation : 15-06-2015

The instrument was installed and was found to be working satisfactorily. Preliminary Customer Training was provided and standardization of the parameters were done. The results were found to be within the expected range and System found to be working satisfactorily.

Protocol Performed By:

**TBM, Technical Services Department
CENTER**

Name : Mr. Shaik Ajmeer

Designation : Service Engineer

Signature : *Ferd*

CUSTOMER : NEYVELI DIAGNOSTICS

Contact Person : Mrs. J. Umarani

Designation : Lab in charge

Signature :



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: **Transasia Bio-Medical Ltd.**

Name: Mr. M. Sankar

Designation: Sr.Application Specialist

Customer Authorization: **NEYVELI DIAGNOSTICS CENTER**

Name: Mrs. J. Umarani

Designation: Lab in charge

Company Representative Name & Sign

Date: 23/06/2015

Customer Name & Sign

Date: 23/06/2015





Instrument Setup

1. Assembled the instrument accessories.
2. Removed the Shipping Clamps
3. Connected the Sampler
4. Set the Reagent tubings
5. Connected the Reagents
6. Connected the waste Tank
7. Connected the Waste Tubings
8. Connected the Power Cord and Connection Cord.
9. Connected the External Printer
10. Perform the setting sequence

Result/Checks

✓
✓
✓
✓
✓
✓
✓
✓
✓
✓

Operational Inspection

1. Mechanical Movements.
2. Hydraulics.
3. Electricals.
4. Controls and samples, Results.

Result/Checks

✓
✓
✓
✓

Protocol Performed By:

TBM, Technical Services Department

Name : Mr. Shaik Ajmeer

Designation : Service Engineer

Signature :





Performance Qualifications for EM-200, Sr. No.:-

Operations Qualifications for EM-200, Sr. No.:- B150406

- 1) Mechanical Movements : Verified
- 2) Hydraulics : Verified
- 3) Electrical Systems : Verified
- 4) Controls : Verified

Protocol Performed By:

TBM, Technical Services Department

Name : Mr. Shaik Ajmeer

Designation : Service Engineer

Date : 23-06-2015

Signature :





Performance Qualifications for EM-200, Sr. No.:-

Operations Qualifications for EM-200, Sr. No.:- B150406

- 1) Mechanical Movements : Verified
- 2) Hydraulics : Verified
- 3) Electrical Systems : Verified
- 4) Controls : Verified

Protocol Performed By:

TBM, Technical Services Department

Name : Mr. Shaik Ajmeer

Designation : Service Engineer

Date : 23-06-2015

Signature :

Mr. Shaik Ajmeer





Performance Qualifications for EM-200, Sr. No.:- B150406

1. **CONTROLS:** - Run QC Erba Normal and High of all the parameters, found within acceptable limit.
2. **PRECISION CHECK:** - Run the precision of all the parameters, calculate mean, and SD, found within range.

System Certification:

Study data has determined that the System described in this document either meets the necessary 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:

Name : Mr. Shaik Ajmeer

Designation : Service Engineer

Signature : *M. Shaik Ajmeer*

Date : 23/06/2015

PERFORMANCE QUALIFICATION DONE BY

Name : Mr. M. Sankar

Designation: Sr. Application Specialist

Signature : *M. Sankar*

Date : 23/06/2015



CERTIFICATE OF CALIBRATION

CUSTOMER DETAILS:

NEYVELI DIAGONSTIC CENTRE
NO.2, Dr.Radhakrishanan salai,block 11
Neyveli-T.s,Cuddalore.

Calibrated at : Lab
Date of Receipt :14.11.21
Cond. On Receipt:Satisfactory
Date of issue :14.11.21
Date Of calibration : 14.11.21
Recom. Due Date:13.11.22

Certificate No : NDC/2021-22/CAL/3
Asset No: NDC/2021-22/AN/3

DETAILS OF UUC:

Description : Digital temperature
Range : 0 °c to 10 °c
Resolution :-0.1°c
Location : - LAB
Cal-reference:- SC-CP-ET-01

Identification No : TL-01
Make : waves
Serial No: -
Accuary: As per manual
Reference :-EURAMET

Environmental Details : Temperature 30±5°C Relative Humidity : 40-70%RH

STANDARDS/MASTER USED FOR CALIBRATION AND TRACEABILITY

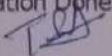
INSTRUMENT NAME	MAKE	SERIAL NO	REPORT NO	DUE NO
TEMPERATURE CALIBRATOR	METRAVI	183150543	21-22/5884-2	10-NOV-2022

MECHANICAL CALIBRATION

RANGE	STD INPUT	DUC READING	ERROR OBSERVED	MEASUREMENT UNCERTAINTY
TEMPERATURE 0°C to 10 °c	2.0°C	2.1°C	0.1°C	0.58°C
	4.0°C	4.2°C	0.2°C	0.58°C
	6.0°C	6.2°C	0.2°C	0.58°C
	8.0°C	8.2°C	0.2°C	0.58°C
	10.0°C	10.3°C	0.3°C	0.58°C

The above mentioned instrument has been calibrated using standards manufacturer recommended protocols, using equipments having traceability to National/International Standards. Devices for which there are no National / International Standards calibration standards are measured against in-house performance standard using accepted test procedure. Partial reproduction of the certificate is not permitted.

Calibration Done by



Approved By

