



**TRANSASIA**<sup>®</sup>  
No.1 Diagnostic Company in India

TRANSASIA

EM- 200

SR. NO 2002796

FULLY AUTOMATIC BIOCHEMISTRY ANALYZER

IQ&OQ

For

PASTURE INSTITUTE, SHILLONG

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



**H.O. address:** Transasia House, 8 Chandivali Studio Road, Andheri (E), Mumbai – 440072 India  
Tel. : +91 22 4030 9000

## 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, Guwahati

Name: Mr. Taraknath Chakraborty

Designation: Regional Service Manager

Customer Authorization: Pasteur Institute, Shillong

Name:

Designation:

Company Representative Name & Sign

Customer Name & Sign

Mr. Taraknath Chakraborty

Regional Service Manager

Date: 4-03-2022

Date: 4-03-2022



**Installation Qualification for EM-200, Sr. No.:- 2002796**

**Customer Name** : Pasteur Institute, Shillong  
**Address** : Near Polobazar, East Khasihills.Shillong,  
Meghalaya - 793001  
**Instrument Name** : EM-200  
**Serial Number** : 2002796

**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.

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**Installation Certificate for EM-200, Sr. No.:- 2002796**

This is to certify that the instrument **EM-200 Sr. No.:- 2002796** is successfully Installed and Commissioned at Pacific Health Diagnostic Centre, Worli, Mumbai and the Installation Protocol / checklist has been successfully completed for the above instrument.

Date of Installation: 03-03-2022

**TBM, Technical Services Department**

**Name** : Mr. Taraknath Chakraborty

**Designation** : Regional service Manager



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**Installation Qualifications for EM-200, Sr. No.:- 2002796**

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 results by running the controls and found OK.

Handed over the Instrument for Operators Training & Qualifications

**For TBM, Technical Services Department**

**Name** : Mr. Taraknath Chakraborty  
**Designation** : Regional Service Manager



**Installation Qualification for EM-200, Sr. No.:- 2002796**

**Customer Name** : Pasteur Institute, Shillong  
**Address** : Near Polobazar, East Khasihills. Shillong,  
Meghalaya – 793001  
**Contact Person** :  
**Instrument Model** : EM-200  
**Serial Number** : 2002796  
**Date of Installation** : 3-03-2022

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.

Technical Services Department  
Centre, Guwahati

CUSTOMER : **Pasteur Institute, Shillong**

Name : Taraknath Chakraborty

Contact Person :

Designation : Regional Service Manager

Designation :

Signature :

Signature :



## 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

## Operational Inspection

1. Checked and found Mechanical Movements OK
2. Checked and found Hydraulics OK.
3. Checked and found Electricals OK.
4. Checked with controls and samples ,results are found OK.

### **TBM, Technical Services Department**

**Name** : Mr. Taraknath Chakraborty

**Designation** : Regional Service Manager



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**Operations Qualifications for EM-200, Sr. No.:- 2002796**

1. Verified all the Mechanical Movements : Done
2. Verified Hydraulics. : Done
3. Verified Electrical Systems : Done
4. Verified with Controls : Done

**TBM, Technical Services Department**

**Name** : Mr. Taraknath Chakraborty

**Designation** : Regional Service Manager

**Date** : 4-03-2022





**Performance Qualifications for EM-200, Sr. No.:- 2002796**

1. **CONTROLS:** - Run QC Erba Normal and High of all the parameters, found within acceptable limit.
2. **PRECISION CHECK:** - Run the precision of three the parameters, calculate mean, CV% 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.Taraknath Chakraborty

**Designation** : Regional Service Manager

PERFORMANCE QUALIFICATION DONE BY

**Name** :

**Designation** :

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