

February 13, 2024

***Calibration Certificate for Fully Automated Random Access
Biochemistry Analyser, Model: EM-200 (Sl. No. v200782)***

This is to certify that Fully Automated Random Access Biochemistry Analyser, Model: EM-200 installed at Diagnostics, 190B, Rash Behari Ave, Golpark, Hindustan Park, Gariahat, Kolkata, West Bengal 700029 has been calibrated and the calibration value of filter gains and all other values has been checked and found well within the limit.

This calibration is valid till February 12, 2025.

For Transasia Bio-Medicals Ltd.



Arijit Dey
Sr. Area Service Manager


TRANSASIA BIOMEDICALS LIMITED			
INSTALLATION QUALIFICATION			
INSTRUMENT NAME	EM-200	Instrument ID	V200182


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TRANSASIA BIOMEDICALS LIMITED			TRANSASIA[®] Bio-Medicals Ltd.
INSTALLATION QUALIFICATION			
INSTRUMENT NAME	EM-200	Instrument ID	

1.0 PRE APPROVAL

1.1 Prepared By

Name	Designation	Signature	Date
MR.ARIJIT DEY	Engineer		

1.2 Checked By

Name	Designation	Signature	Date

1.3 Approved By

Name	Designation	Signature	Date

Note: After the Pre-Approval, this document is effective for the execution.

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INSTALLATION QUALIFICATION			
INSTRUMENT NAME	EM-200	Instrument ID	

2.0 OBJECTIVE

The objective of this document is to provide an outline for the inspection of EM 200 (Bio-Chemistry Random Analyzer) and to verify that the following boundaries:

- Each Installed subcomponent complies with the engineering design and instrument data sheet / design specifications & manufacturer's recommendations.
- To ensure that all the safety features are defined before the start up of operational qualification exercise.
- The system meets the current regulatory requirements.
- To identify the Standard operating procedures for Operational Qualification.

3.0 SCOPE

The scope of this protocol is to outline procedure for Installation qualification of the subjected instrument within the following boundaries:

- Identification and verification of its Major components / Accessories
- Identification, Classification and Verification of Process Control Instruments / Gauges / Devices
- Identification and verification of Material of Construction
- Identification and verification of Supporting Utilities
- Identification of Standard Operating Procedures
- Identification and Verification of Documents

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INSTRUMENT NAME	EM-200	Instrument ID	V200182

4.0 EXECUTION TEAM

Name	Department	Designation	Signature

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INSTRUMENT NAME	EM-200	Instrument ID	V200182

5.0 INSTRUMENT DESCRIPTION

The Clinical Chemistry Analyzer is an open, full automated, discrete, patient prioritized, random access, computerized analyzer.

Technical Specifications:

System Type	Open, Automated, Discrete, Random Access, Patient Prioritized, Clinical Chemistry Analyzer
Analysis Speed	200 Biochemistry tests per hour.
Display resolution	800 x 600
Analyzer Dimensions	840 (W) x 610 (D) x 1100 (H) mm
Number of tests on board	Unlimited
Assay Modes	1-point, 2-point, Rate-A and Rate -B
Calibration	Linear (two point and multi point), Factorized and Non-linear multipoint
Sample (Tubes / Cups)	Primary tubes of 5, 7 or 10mL & sample cups
Photometric Optics	Mono and Bi-chromatic measurement using holographic diffraction grating and 12 wavelengths
Absorbance Range	0 – 2.5
Auxiliary Data	Unlimited
Interface	USB for Bi-directional Communication
Stat Sampling	Total 39 position

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INSTRUMENT NAME	EM-200	Instrument ID	V200782	

Purpose:

The purpose of this instrument is to analyze the bio-chemical parameters, such as Sugar, Cholesterol, Tri-glycerides, Proteins, etc.

The working unit of the analyzer comprises the following:

- Basic operating unit with an intelligent photometer
- Sophisticated robotics combined with an operating console and a central processing unit (CPU).

Operating Unit:

The operating unit of the analyzer includes the sample and reagent handling systems. The sample handling system consists of a sample tray, sample arm, sample syringe and a wash station for the sample probe.

Photometric System:

The photometric system consists of 45 hard glass cuvettes, a high-resolution diffraction grating (with 8 user selectable wavelengths) and a halogen lamp.

Operating Console:

The operating console consists of a touch screen (optional) color monitor, a key board and a mouse.


CPU (Central Processing Unit):

CPU consists of Pentium – IV 1.7 GHz processor (or Higher) with a 48 x CD Drive, and minimum 256 MB memory. The application software can be installed on computers with operating systems of Windows XP.

Besides the above mentioned, this analyzer has got the unique Software and Hardware features.


6.0 IDENTIFICATION OF MAJOR COMPONENTS / ACCESSORIES

Details of each major component identified in this section, is recorded in a data sheet under the section 08.0.

Name of Component / Accessories	Present	Verified by Signature	Observations
	Yes / No		
Sample Tray / Disk	YES		
Sample Syringe	YES		
Sample Probe	YES		
Wash Station for Sample Probe	YES		
Reagent Tray / Disk	YES		
Reagent Bottles	YES		
5 ml tube adaptor (10 nos)	YES		
40 ml & 20 ml reagent bottles	YES		
Stirrer	YES		
Permanent Reaction Cuvette	YES		
7 Stage Laundry System	YES		
Light Source	YES		
Sample Cups	YES		
Software of EM 200	YES		

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INSTALLATION QUALIFICATION			
INSTRUMENT NAME	EM-200	Instrument ID	V200782

7.0 INSTALLATION CHECK / REVIEW

S. No.	Statement	Yes / No	Verified by Signature
1.	Verify that the "as built" drawings are complete and represent the design concept	YES VERIFIED	
2.	Verify that major components / accessories are securely anchored and shock proof.		
3.	Verify that there is no observable physical damage.		
4.	Verify that there is sufficient room of servicing provided		
5.	Verify that all utilities and electrical connections have been done according to the drawings.		
6.	Walking access to ground mounted instrument provided.		
7.	Required electric connections are tight, weather proof and earthed.		
8.	Instrument identification nameplate visible.		
9.	Units installed on foundation and secure in place as per manufacturer's recommendations.		
10.	Verify that the instruments installed and leveled properly on the floor.		
11.	Verify that the Material of Construction is proper and meeting the requirements.		

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INSTALLATION QUALIFICATION				
INSTRUMENT NAME	EM-200	Instrument ID	V200182	

8.0 INSPECTION CHECK / REVIEW

Instructions for completing the check / review


1. For each **data sheet**, record the required information with pen. Wherever required record "Yes" for acceptance, "No" for non-compliance and "NA" for not applicable.

"No" replies must be explained / justified.
2. When more than one component of same specification/type exists in the same equipment, individual data sheets should be filled for each component.
3. When a list of acceptable options is presented, tick (✓) the option that is actually present.
4. In the "**Method of Verification**" column indicate that item is installed and inspected according to manufacturer's specifications, such as by Visual / Physical, SOP, Test Certificate, Manual, etc.

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INSTALLATION QUALIFICATION			
INSTRUMENT NAME	EM-200	Instrument ID	V200782

Instrument/ Component Name: Sample Tray / Disk


Date :

Description	Specified	Actual	Method of Verification	Verified by Signature
No. of patient cups / samples	39 positions	YES	VISUAL	
Standards / Stat	Any place	YES	VISUAL	
Blank	Any place	YES	VISUAL	
Control	Any place	YES	VISUAL	

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INSTRUMENT NAME	EM-200	Instrument ID	V200782	

Instrument/ Component Name: Sample Reagent Syringe for Sample

Date :


Description	Specified	Actual	Method of Verification	Verified by Signature
Dispensing Volume	3 – 70 µL	YES	TECHNICAL	
Installed Location	Behind the Front panel of the Analyzer	YES	TECHNICAL	
Quantity	01 No.	YES	TECHNICAL	
Increase in dispensing volume	0.1 µL	YES	TECHNICAL	

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INSTALLATION QUALIFICATION			
INSTRUMENT NAME	EM-200	Instrument ID	V200782

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Instrument/ Component Name: Sample Reagent Probe for sample


Date :

Description	Specified	Actual	Method of Verification	Verified by Signature
Aspiration Volume	2 – 60 µL	YES	TECHNICAL	
MOC	Teflon coated	YES	TECHNICAL	
Quantity	01 No.	YES	TECHNICAL	
Increase in aspiration volume	0.1 µL	YES	TECHNICAL	

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INSTRUMENT NAME	EM-200	Instrument ID	V2007182	

Instrument/ Component Name: Wash Station for Sample Probe


Date :

Description	Specified	Actual	Method of Verification	Verified by Signature
No. of position	02 Nos'	YES	TECHNICAL	
Type of positions	i) Drain ii) Trough	YES	TECHNICAL	

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INSTALLATION QUALIFICATION			
INSTRUMENT NAME	EM-200	Instrument ID	V200182

Instrument/ Component Name: Reagent Tray / Disk


Date :

Description	Specified	Actual	Method of Verification	Verified by Signature
Cool reagent disk	50 positions	YES	VISUAL	
Outer Rings	25 positions	YES	VISUAL	
Inner Rings	25 positions	YES	VISUAL	
Adaptors of 5mL	50 positions	YES	VISUAL	
Maintenance of Temperature	4-12°C ± 2°C	YES	VISUAL	
Rotation of disk	Counter-Clockwise	YES	VISUAL	
Time for Rotation of one Cuvette	Every 18 seconds	YES	VISUAL	

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INSTALLATION QUALIFICATION			
INSTRUMENT NAME	EM-200	Instrument ID	

Instrument/ Component Name: Reagent Bottles

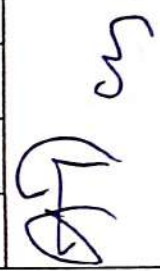
Date :

Description	Specified	Actual	Method of Verification	Verified by Signature
Minimum Capacity	5 mL	YES	VISUAL	
Maximum Capacity	40 mL	YES	VISUAL	
Quantity (Large)	25 Nos'	YES	VISUAL	
Quantity (Smaller)	25 Nos'	YES	VISUAL	
Type	Screw Capped	YES	VISUAL	
Outer ring position	20 mL bottles & 5ml adaptors	YES	VISUAL	
Inner ring position	20 mL & 50 mL bottles & 5ml adaptors	YES	VISUAL	
MOC	Plastic	YES	VISUAL	
Adaptor	50 Nos'	YES	VISUAL	
Adaptor Capacity	5 mL	YES	VISUAL	
Identification of Reagents	Barcode labels on the reagent containers	YES	VISUAL	

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INSTALLATION QUALIFICATION				
INSTRUMENT NAME	EM-200	Instrument ID	V200782	

Instrument/ Component Name: Sample Reagent Probe for Reagent

Date :

Description	Specified	Actual	Method of Verification	Verified by Signature
Aspiration Volume	R1: 75 – 300 μ L	YES	TECHNICAL	
	R2: 0 or 10 – 300 μ L	YES	TECHNICAL	
MOC	Teflon coated	YES	TECHNICAL	
Quantity	01 Nos.	YES	TECHNICAL	
Increase in aspiration volume	1 μ L	YES	TECHNICAL	


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INSTALLATION QUALIFICATION

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INSTRUMENT NAME	EM-200	Instrument ID	V200782
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Instrument/ Component Name: Sample Reagent Syringes for Reagent

Date :


Description	Specified	Actual	Method of Verification	Verified by Signature
Maximum capacity	500 µL	YES	TECHNICAL	
Installed Location	Beside the sample syringe	YES	TECHNICAL	
Quantity	01 Nos'	YES	TECHNICAL	
Increase in dispensing volume	0.1 µL	YES	TECHNICAL	

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INSTRUMENT NAME	EM-200	Instrument ID	V200182

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Instrument/ Component Name: Stirrer

Date :

Description	Specified	Actual	Method of Verification	Verified by Signature
Type	Stirrer	YES	VISUAL	
No. of paddles	01 Nos'	YES	VISUAL	

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INSTALLATION QUALIFICATION


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INSTRUMENT NAME | EM-200 | **Instrument ID** | V200182

Instrument/ Component Name: Permanent Reaction Cuvette

Tag/Identification No.:


Date :

Description	Specified	Actual	Method of Verification	Verified by Signature
Quantity	45 Nos'	YES	VISUAL	
MOC	Hard Glass	YES	VISUAL	
Capacity	770 µL	YES	TECHNICAL	

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INSTRUMENT NAME	EM-200	Instrument ID	V200782	

Instrument/ Component Name: 7 Stage Laundry System


Date :

Description	Specified	Actual	Method of Verification	Verified by Signature
Nozzles	Nozzle - 1	yes	VISUAL	
	Nozzle - 2	yes	VISUAL	
	Nozzle - 3	yes	VISUAL	
	Nozzle - 4	yes	VISUAL	
	Nozzle - 5	yes	VISUAL	
	Nozzle - 6	yes	VISUAL	
	Nozzle - 7	yes	VISUAL	

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INSTRUMENT NAME	EM-200	Instrument ID	V200182	

Instrument/ Component Name: Light Source

Date :

Description	Specified	Actual	Method of Verification	Verified by Signature
Watts	12 W	YES	TECHNICAL	
Volts	12 V	YES	TECHNICAL	
MOC	Halogen	YES	TECHNICAL	
Quantity	01 No	YES	TECHNICAL	


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INSTRUMENT NAME | EM-200 | Instrument ID | V2007182

Instrument/ Component Name: Sample Cups

Date :

Description	Specified	Actual	Method of Verification	Verified by Signature
Quantity	39 Nos'	YES	VISUAL	
MOC	Plastic	YES	VISUAL	
Capacity	2 mL	YES	VISUAL	

TRANSASIA BIOMEDICALS LIMITED

INSTALLATION QUALIFICATION



INSTRUMENT NAME	EM-200	Instrument ID	V200182
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Instrument/ Component Name: Software of EM 200


Date :

Description	Specified	Actual	Method of Verification	Verified by <i>Signature</i>
Version				
CD number				
Product	EM-200			
Make	Erba Transasia			

9.0 IDENTIFICATION AND VERIFICATION OF MATERIAL OF CONSTRUCTION

Identify and list down all components of the equipment for its material of construction.


Method of Test may be Molybdenum Test, Test Certificate, Manual, etc.

Component (s)	Material of Construction	Actual	Method of Verification	Verified by Sign & Date
Sample Reagent Probe	Teflon coated			
Permanent Reaction Cuvette	Hard Glass			
Light Source	Halogen			
Reagent Bottle	Plastic			
Sample Cups	Plastic			

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INSTALLATION QUALIFICATION			
INSTRUMENT NAME	EM-200	Instrument ID	V200782

10.0 IDENTIFICATION AND VERIFICATION OF SUPPORTING UTILITIES

List the supporting utilities and record whether or not they are properly connected and identified.

Utilities	Observation / Result	Verified by Sign & Date
Power		
Distilled Water		
Wash Solution		
UPS		

TRANSASIA BIOMEDICALS LIMITED**INSTALLATION QUALIFICATION****TRANSASIA**[®]
Bio-Medicals Ltd.**INSTRUMENT NAME****EM-200****Instrument ID****V2007182****11.0 IDENTIFICATION OF STANDARD OPERATING PROCEDURE**

SOP No.	Title
Operation	Operation of Bio-Chemistry Random Analyzer
Calibration	Calibration of Parameters
Controls	Checking of Controls for Parameters
Maintenance	Maintenance / Checking of Distilled water, Waste, Wash solution, Cuvette rinse, Sample probe wash and Water save
Cleaning	Cleaning of Instrument surface

TRANSASIA BIOMEDICALS LIMITED

INSTALLATION QUALIFICATION



INSTRUMENT NAME	EM-200	Instrument ID	V200182
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12.0 IDENTIFICATION AND VERIFICATION OF DOCUMENTS

12.1 DRAWINGS

Title	Drawing No.	Verified by Sign & Date
As-built Drawing		
Computer Trolley Assembly		

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INSTALLATION QUALIFICATION			
INSTRUMENT NAME	EM-200	Instrument ID	

12.2 GENERAL DOCUMENTS

Title	Document No.	Verified by Sign & Date
General		
Purchase Order No.		
Warranty Certificate		
Invoice		
Test Certificates		
Material of Construction		
Electrical Motor		

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INSTALLATION QUALIFICATION



INSTRUMENT NAME	EM-200	Instrument ID	V2007182
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13.0 DEFICIENCIES / DEVIATIONS:

No deviation

Reviewed by:

Name	Signature	Date

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INSTRUMENT NAME	EM-200	Instrument ID	V200782

14.0 SUMMARY AND EVALUATION:

All ok.

Reviewed by:

Name	Signature	Date

TRANSASIA BIOMEDICALS LIMITED			TRANSASIA Bio-Medicals Ltd.
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INSTRUMENT NAME	EM-200	Instrument ID	

15.0 ABBREVIATIONS

SOP	Standard Operating Procedure
MOC	Material of Construction
IQ	Installation Qualification

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INSTRUMENT NAME	EM-200	Instrument ID	

16.0 POST APPROVAL:

16.1 Checked by

Name	Designation	Signature	Date

16.2 Approved by

Name	Designation	Signature	Date

Note: This report is effective from the date of approval.

OPERATIONAL QUALIFICATION

Instrument Name	EM-200	Instrument ID	V200182
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As part of Operational qualification, the following checks shall be done and each test shall be recorded:

Instrument Start-up

To check and establish the standard sequence to be followed, during start-up of the subjected instrument in Auto / Manual mode, to propose for correct operation and to avoid any damage to the instrument and personnel.

Functional Checks

To check and ensure that different functions (such as switching devices, indication / monitoring / recording devices, feedback system, etc.) for correct operation of the subjected instrument are working as expected.

Interlocks and Alarms Check

To check and ensure that the interlocks and alarms (such as status indication system, negative feed back system, control loops, sound alarms, etc.) for correct control and monitoring of the operation cycle are working as expected.

Safety / Security Checks

To check and ensure that the safety / security functions (such as program logging, process control, personnel safety systems, password check, etc.) to protect the instrument and personnel are working as expected.

Instrument Shut-down

To check and establish the standard sequence to be followed, during shut-down of the subjected instrument in Auto / Manual mode, to propose for correct operation and to avoid any damage to the instrument and personnel.

TRANSASIA BIOMEDICALS LIMITED			TRANSASIA Bio-Medicals Ltd.
OPERATIONAL QUALIFICATION			
Instrument Name	EM-200	Instrument ID	

As part of Operational qualification, the following checks shall be done and each test shall be recorded:

Instrument Start-up

To check and establish the standard sequence to be followed, during start-up of the subjected instrument in Auto / Manual mode, to propose for correct operation and to avoid any damage to the instrument and personnel.

Functional Checks

To check and ensure that different functions (such as switching devices, indication / monitoring / recording devices, feedback system, etc.) for correct operation of the subjected instrument are working as expected.

Interlocks and Alarms Check

To check and ensure that the interlocks and alarms (such as status indication system, negative feed back system, control loops, sound alarms, etc.) for correct control and monitoring of the operation cycle are working as expected.

Safety / Security Checks

To check and ensure that the safety / security functions (such as program logging, process control, personnel safety systems, password check, etc.) to protect the instrument and personnel are working as expected.

Instrument Shut-down

To check and establish the standard sequence to be followed, during shut-down of the subjected instrument in Auto / Manual mode, to propose for correct operation and to avoid any damage to the instrument and personnel.







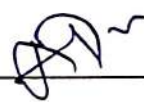

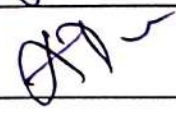
OPERATIONAL QUALIFICATION

Instrument Name | EM-200

Instrument ID | V200782

1.0 INSTRUMENT START-UP:

Refer the Operator's Manual for the procedures, for the following activities:

Action	Observation	Verified by (Sign & Date)	Remarks
Ensure that all the required electrical connections are properly connected.	Properly Connected		
Ensure the proper filling of double distilled / de-ionized water and Cleaning solution in the respective cans.	Properly Filled		
Ensure the availability of XL Wash.	Available		
Ensure the availability of Biohazard Waste.	OK		
Ensure the availability of Normal Waste.	OK		
Switch ON the rear switch of the analyzer.	WORKING		
Switch ON the side switch of the analyzer.	WORKING		
Switch ON the computer and start the analyzer application software.	WORKING		
Initialization	Properly Initialized		

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OPERATIONAL QUALIFICATION

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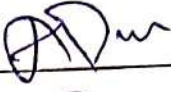

Instrument Name | **EM-200**

Instrument ID | **V200782**

2.0 FUNCTIONAL CHECKS:

2.1 Maintenance:

Refer the Operator's Manual for the procedures, for the following activities:

Activity	Observation	Verified by (Sign & Date)	Remarks
Photometer functioning	OK		
Cuvette Rinse	OK		

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OPERATIONAL QUALIFICATION

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Instrument Name EM-200

Instrument ID V200182

2.2 Loading of Reagents:

Refer the Operator's Manual for the procedures, for the following activities:

Action	Observation	Verified by (Sign & Date)	Remarks
Reagent Level Scan, Dead Volume Check & 2 Reagent Chemistry	OK		

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OPERATIONAL QUALIFICATION

Instrument Name EM-200

Instrument ID V200182

2.3 Calibration:

Refer the Operator's Manual for the procedures, for the following activities:

Action	Observation	Verified by (Sign & Date)	Remarks
Blank (Distilled Water)	OK		
Standard , Calibrator	OK		

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OPERATIONAL QUALIFICATION

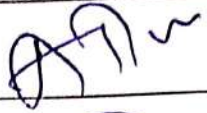
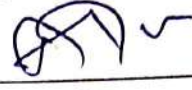


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Instrument Name EM-200

Instrument ID V200T82

3.0 INTERLOCKS AND ALARMS CHECK:

Refer the Operator's Manual for the procedures, for the following activities:

Action	Observation	Verified by (Sign & Date)	Remarks
Less volume of Distilled Water	Sensor is working properly		
Less volume of Wash Solution	Sensor is working properly		
More volume of Bio-Hazard waste	Sensor is working properly		
More volume of Normal / General waste	Sensor is working properly		



TRANSASIA BIOMEDICALS LIMITED**OPERATIONAL QUALIFICATION****TRANSASIA**
Bio-Medicals Ltd.

Instrument Name | EM-200

Instrument ID | V200782

4.0 SAFETY / SECURITY CHECKS:

Refer the Operator's Manual for the procedures, for the following activities:

Action	Observation	Verified by (Sign & Date)	Remarks
Password Check for Test Parameters	NO	 ✓	
Password Check for QC Mode	NO	 ✓	

TRANSASIA BIOMEDICALS LIMITED

OPERATIONAL QUALIFICATION






Instrument Name | EM-200

Instrument ID | V200782



5.0 INSTRUMENT SHUT-DOWN:

Refer the Operator's Manual for the procedures, for the following activities:

Action	Observation	Verified by (Sign & Date)	Remarks
Sample Probe Wash	Working Properly		
Water Save	Working Properly		
Switch OFF the computer.	Working Properly		
Switch OFF the side switch of the analyzer.	Working Properly		
Switch OFF the rear switch of the analyzer.	Working Properly		

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Carryover worksheet.

Instrument ID: EM 200 SN V200182

Date performed: 05-04-2023

Carryover calculation:

Carryover % = $(L1-L3) / (H3-L3) * 100$.

Interpretation of results. :

1) If $(L1-L3)$ is equal to a negative number or zero then stop as there is no evidence of carryover.

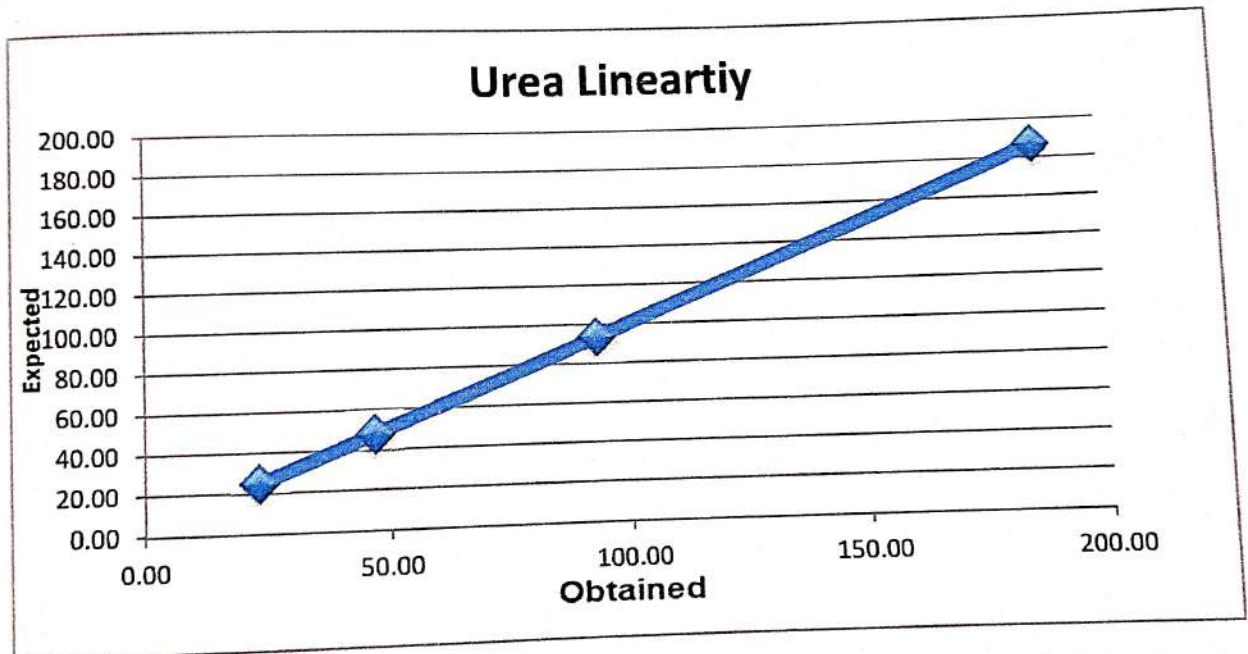
Instrument	Analytes	
	GLUCOSE	UREA
H1	361.2	187.8
H2	359.7	187.3
H3	361.8	187.8
L1	24.0	13.5
L2	24.0	13.5
L3	24.0	13.6
% age Carryover	0.00	-0.06
Acceptable Range	1.0	1.0
Status	PASS	PASS

THE DIAGNOSTICS

Instrument Name:

EM 200, SN: S2007182

UREA	Expected	Obtained
Neat	186.80	186.80
1:2	93.40	93.60
1:4	46.70	47.70
1:8	23.35	24.80
1:16	11.68	13.30



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PERFORMANCE QUALIFICATION

TRANSASIA[®]
Bio-Medicals Ltd.

Instrument Name

EM-200

Instrument Serial Number

V200182

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TRANSASIA BIOMEDICALS LIMITED			TRANSASIA[®] Bio-Medicals Ltd.
PERFORMANCE QUALIFICATION			
Instrument Name	EM-200	Instrument Serial Number	V200782

1.0 PRE APPROVAL

1.1 Prepared By

Name	Designation	Signature	Date
ATANU BISWAS	APPLICATION MANAGER	<i>Atanu Biswas</i>	13/2/23

1.2 Checked By

Name	Designation	Signature	Date

1.3 Approved By

Name	Designation	Signature	Date

TRANSASIA BIOMEDICALS LIMITED

PERFORMANCE QUALIFICATION

TRANSASIA
Bio-Medicals Ltd.

Instrument Name	EM-200	Instrument Serial Number	V200782
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2.0 OBJECTIVE

The objective of this protocol is to establish documented evidence for the Performance Qualification of EM 200 (Bio-Chemistry Random Analyzer) and to ensure that the results obtained are within the pre-determined Acceptance Criteria.

3.0 SCOPE

The Scope of this protocol is applicable to EM 200 (Bio-Chemistry Random Analyzer).

4.0 PRE-REQUISITES:

Following Pre-requisites are required before the execution of Performance Qualification.

- Completion of Installation Qualification prior to PQ.
- Completion of Operational Qualification prior to PQ.

5.0 EXECUTION TEAM

Name	Department	Designation	Signature

TRANSASIA BIOMEDICALS LIMITED

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7.0 EXECUTION OF TEST PLAN

- A. PRECISION CHECK FOR GLUCOSE & UREA → REPORT ATTACHED
- B. CARRYOVER TEST FOR GLUCOSE & UREA → REPORT ATTACHED
- C. LINEARITY TEST FOR GLUCOSE & UREA → REPORT ATTACHED
- D. QC DATA FOR ALL PARAMETERS → REPORT ATTACHED

Reviewed by:

Name	Signature	Date

TRANSASIA BIOMEDICALS LIMITED

PERFORMANCE QUALIFICATION

TRANSASIA[®]
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Instrument Name | EM-200

Instrument Serial Number |

V200782

8.0 DEFICIENCIES / DEVIATIONS:

Reviewed by:

Name	Signature	Date

TRANSASIA BIOMEDICALS LIMITED

PERFORMANCE QUALIFICATION

TRANSASIA[®]
Bio-Medicals Ltd.

Instrument Name

EM-200

Instrument Serial Number

V200782

9.0 SUMMARY AND EVALUATION:

All Ok

Reviewed by:

Name	Signature	Date

TRANSASIA BIOMEDICALS LIMITED

PERFORMANCE QUALIFICATION

Instrument Name	EM-200	Instrument Serial Number	V200782
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10.0 ABBREVIATIONS

SOP	Standard Operating Procedure
MOC	Material of Construction
PQ	Performance Qualification

Instrument Name | EM-200

Instrument Serial Number | V200782

11.0 POST APPROVAL

11.1 Checked by

Name	Designation	Signature	Date

11.2 Approved by

Name	Designation	Signature	Date

Note: This report is effective from the date of approval.

Test Statistics

UREA	Report Type	Patients
05-Apr-2023	Date To	05-Apr-2023

Computed Ranges And Statistical Values

Reference Range	0
Upper Reference Range	20
Lower Reference Range	0
Default Range	0
Total Test(s)	20

Sr# From 1 To 20

N	20
Mean	187.7
SD	1.95
%CV	1.04
Range	8.7

Test Statistics

UREA

Report Type

Patienta

05-Apr-2023

Date To

05-Apr-2023

Re ID	Precision		Patient Name	Result Date	Curve #	Used Calibration
	Result	Unit				
1	188.0	mg/dL	H	05-Apr-2023 13:11:48	5913	14-Feb-2023 15:48:12
2	184.8	mg/dL	H	05-Apr-2023 13:11:28	5912	14-Feb-2023 15:48:12
3	187.4	mg/dL	H	05-Apr-2023 13:11:10	5911	14-Feb-2023 15:48:12
4	188.0	mg/dL	H	05-Apr-2023 13:10:52	5910	14-Feb-2023 15:48:12
5	185.5	mg/dL	H	05-Apr-2023 13:10:34	5909	14-Feb-2023 15:48:12
6	183.4	mg/dL	H	05-Apr-2023 13:10:16	5908	14-Feb-2023 15:48:12
7	189.6	mg/dL	H	05-Apr-2023 13:09:58	5907	14-Feb-2023 15:48:12
8	188.0	mg/dL	H	05-Apr-2023 13:09:40	5906	14-Feb-2023 15:48:12
9	188.5	mg/dL	H	05-Apr-2023 13:09:21	5905	14-Feb-2023 15:48:12
0	190.0	mg/dL	H	05-Apr-2023 13:09:03	5904	14-Feb-2023 15:48:12
1	188.1	mg/dL	H	05-Apr-2023 13:08:45	5903	14-Feb-2023 15:48:12
2	185.1	mg/dL	H	05-Apr-2023 13:08:27	5902	14-Feb-2023 15:48:12
3	188.3	mg/dL	H	05-Apr-2023 13:08:09	5901	14-Feb-2023 15:48:12
4	187.5	mg/dL	H	05-Apr-2023 13:07:51	5900	14-Feb-2023 15:48:12
5	187.3	mg/dL	H	05-Apr-2023 13:07:33	5899	14-Feb-2023 15:48:12
6	187.0	mg/dL	H	05-Apr-2023 13:07:15	5898	14-Feb-2023 15:48:12
7	188.5	mg/dL	H	05-Apr-2023 13:06:57	5897	14-Feb-2023 15:48:12
8	188.3	mg/dL	H	05-Apr-2023 13:06:39	5896	14-Feb-2023 15:48:12
9	189.1	mg/dL	H	05-Apr-2023 13:06:21	5895	14-Feb-2023 15:48:12
0	192.1	mg/dL	H	05-Apr-2023 13:06:03	5894	14-Feb-2023 15:48:12

Test Statistics

	GLU	Report Type	Patients
From	05-Apr-2023	Date To	05-Apr-2023

Computed Ranges And Statistical Values

Reference Range	0
Above Reference Range	20
Below Reference Range	0
Default Range	0
Total Test(s)	20

Sr# From 1 To 20

N	20
Mean	361.2
SD	1.09
%CV	0.30
Range	3.8

Test Statistics

From **GLU** **05-Apr-2023** **Report Type** **Patients**
Date To **05-Apr-2023**

Sample ID	Precision	Patient Name	Age	Curve #	Used Calibration
Curr. #	Result Unit	Flag	Result Date		
1	362.5 mg/dL	H	05-Apr-2023 13:17:47	5933	14-Feb-2023 16:59:11
2	361.5 mg/dL	H	05-Apr-2023 13:17:29	5932	14-Feb-2023 16:59:11
3	360.2 mg/dL	H	05-Apr-2023 13:17:11	5931	14-Feb-2023 16:59:11
4	360.7 mg/dL	H	05-Apr-2023 13:16:53	5930	14-Feb-2023 16:59:11
5	361.3 mg/dL	H	05-Apr-2023 13:16:35	5929	14-Feb-2023 16:59:11
6	361.7 mg/dL	H	05-Apr-2023 13:16:17	5928	14-Feb-2023 16:59:11
7	360.7 mg/dL	H	05-Apr-2023 13:15:59	5927	14-Feb-2023 16:59:11
8	359.8 mg/dL	H	05-Apr-2023 13:15:40	5926	14-Feb-2023 16:59:11
9	359.3 mg/dL	H	05-Apr-2023 13:15:23	5925	14-Feb-2023 16:59:11
10	363.1 mg/dL	H	05-Apr-2023 13:15:04	5924	14-Feb-2023 16:59:11
11	361.5 mg/dL	H	05-Apr-2023 13:14:46	5923	14-Feb-2023 16:59:11
12	361.0 mg/dL	H	05-Apr-2023 13:14:28	5922	14-Feb-2023 16:59:11
13	362.8 mg/dL	H	05-Apr-2023 13:14:10	5921	14-Feb-2023 16:59:11
14	360.4 mg/dL	H	05-Apr-2023 13:13:52	5920	14-Feb-2023 16:59:11
15	360.7 mg/dL	H	05-Apr-2023 13:13:34	5919	14-Feb-2023 16:59:11
16	361.6 mg/dL	H	05-Apr-2023 13:13:16	5918	14-Feb-2023 16:59:11
17	360.0 mg/dL	H	05-Apr-2023 13:12:58	5917	14-Feb-2023 16:59:11
18	361.8 mg/dL	H	05-Apr-2023 13:12:40	5916	14-Feb-2023 16:59:11
19	362.7 mg/dL	H	05-Apr-2023 13:12:22	5915	14-Feb-2023 16:59:11
20	359.7 mg/dL	H	05-Apr-2023 13:12:04	5914	14-Feb-2023 16:59:11

Result Reprint

ort Type :Patients

Test: GLU

Sr #	Sample ID	Test	Result Unit	Flag	Curvo #	Result Date
1	Carry Over High	GLU	361.2 mg/dL	H	5937	05-Apr-2023 13:18:59
2	Carry Over High	GLU	359.7 mg/dL	H	5938	05-Apr-2023 13:19:17
3	Carry Over High	GLU	361.8 mg/dL	H	5939	05-Apr-2023 13:19:35
4	Carry Over Low	GLU	24.0 mg/dL	L	5943	05-Apr-2023 13:20:47
5	Carry Over Low	GLU	24.0 mg/dL	L	5944	05-Apr-2023 13:21:05
6	Carry Over Low	GLU	24.0 mg/dL	L	5945	05-Apr-2023 13:21:24

Result Reprint

Type :Patients

Test: UREA

#	Sample ID	Test	Result Unit	Flag	Curve #	Result Date
1	Carry Over High	UREA	187.8 mg/dL	H	5934	05-Apr-2023 13:18:05
2	Carry Over High	UREA	187.3 mg/dL	H	5935	05-Apr-2023 13:18:23
3	Carry Over High	UREA	187.8 mg/dL	H	5936	05-Apr-2023 13:18:41
4	Carry Over Low	UREA	13.5 mg/dL	L	5940	05-Apr-2023 13:19:53
5	Carry Over Low	UREA	13.5 mg/dL	L	5941	05-Apr-2023 13:20:11
6	Carry Over Low	UREA	13.6 mg/dL	L	5942	05-Apr-2023 13:20:29

Result Reprint

Report Type :Patients

Test: GLU

#	Sample ID	Test	Result Unit	Flag	Curve #	Result Date
	Linearity Raw	GLU	359.1 mg/dL	H	5885	05-Apr-2023 13:03:20
	Linearity 1-2	GLU	175.3 mg/dL	H	5887	05-Apr-2023 13:03:57
	Linearity 1-4	GLU	88.4 mg/dL		5889	05-Apr-2023 13:04:33
	Linearity 1- 8	GLU	45.9 mg/dL	L	5891	05-Apr-2023 13:05:09
	Linearity 1- 16	GLU	23.8 mg/dL	L	5893	05-Apr-2023 13:05:45

Result Reprint

Report Type :Patients

05-Apr-2023

Test: UREA

#	Sample ID	Test	Result Unit	Flag	Curve #	Result Date
	Linearity Raw	UREA	186.8 mg/dL	H	5884	05-Apr-2023 13:03:03
	Linearity 1-2	UREA	93.6 mg/dL	H	5886	05-Apr-2023 13:03:38
	Linearity 1-4	UREA	47.7 mg/dL		5888	05-Apr-2023 13:04:15
	Linearity 1- 8	UREA	24.8 mg/dL		5890	05-Apr-2023 13:04:51
	Linearity 1- 16	UREA	13.3 mg/dL	L	5892	05-Apr-2023 13:05:27