

TRANSASIA®

Transasia Bio-Medicals Ltd., 518, Kamalalaya Centre, 156A, Lenin Sarani, Kolkata - 700013
Tel: 033-22153898/22157839 Fax: 033-22158035 Email : ez@transasia.co.in
CIN : U33110MH1985PLC036198



EM-200
AUTOMATED BIOCHEMISTRY ANALYZER

INSTALLATION
QUALIFICATION

For

“GOODDAYS DIAGNOSTIC”
CHINSURAH

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

www.transasia.co.in



HO : Transasia House, 8 Chandivali Studio Road, Andheri (E), Mumbai - 400 072 Tel: +91 22 4030 9000 Fax: +91 22 2857 3030

TRANSASIA BIOMEDICALS LIMITED			TRANSASIA® Bio-Medicals Ltd.
INSTALLATION QUALIFICATION			
INSTRUMENT NAME	EM-200	Instrument ID	V200262


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TRANSASIA BIOMEDICALS LIMITED			TRANSASIA Bio-Medicals Ltd
INSTALLATION QUALIFICATION			
INSTRUMENT NAME	EM-200	Instrument ID	V200262

1.0 PRE APPROVAL

1.1 Prepared By

Name	Designation	Signature	Date
Atanu Halder	Service Engineer		

1.2 Checked By

Name	Designation	Signature	Date
Uma Bhattacharya.	Sr. Lab Tech		
Dolon Malo	Lab Tech	Dolon Malo	Dolon Malo
Abhrajit Das.	Sr. Lab Tech		

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	V200262	

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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INSTALLATION QUALIFICATION				
INSTRUMENT NAME	EM-200	Instrument ID	V200262	

5.0 INSTRUMENTDESCRIPTION

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
AbsorbanceRange	0 – 2.5
Auxiliary Data	Unlimited
Interface	USB for Bi-directional Communication
Stat Sampling	Total 39 position

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INSTALLATION QUALIFICATION				
INSTRUMENT NAME	EM-200	Instrument ID	V200262	

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		

TRANSASIA BIOMEDICALS LIMITED			
INSTALLATION QUALIFICATION			
INSTRUMENT NAME	EM-200	Instrument ID	V200262
			TRANSASIA[®] Bio-Medicals Ltd.

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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INSTRUMENT NAME	EM-200	Instrument ID	V200262	

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.

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

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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INSTALLATION QUALIFICATION				
INSTRUMENT NAME	EM-200	Instrument ID	V200262	

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	V200262	

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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INSTALLATION QUALIFICATION				
INSTRUMENT NAME	EM-200	Instrument ID	V200262	

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	V200262

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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	V200262	

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	V200262	

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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INSTRUMENT NAME	EM-200	Instrument ID	V200262	

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	01Nos'	YES	TECHNICAL	
Increase in dispensing volume	0.1 µL	YES	TECHNICAL	

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INSTRUMENT NAME	EM-200	Instrument ID	V200262

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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	01Nos'	YES	VISUAL	

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INSTRUMENT NAME	EM-200	Instrument ID	V200262	

Instrument/ Component Name: Permanent Reaction Cuvette

Tag/Identification No.:


Date :

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

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INSTRUMENT NAME	EM-200	Instrument ID	V200262

Instrument/ Component Name: 7 Stage Laundry System


Date :

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

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INSTALLATION QUALIFICATION			
INSTRUMENT NAME	EM-200	Instrument ID	V200262

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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INSTALLATION QUALIFICATION			
INSTRUMENT NAME	EM-200	Instrument ID	V200262

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Instrument/ Component Name: Sample Cups


Date :

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

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INSTALLATION QUALIFICATION			
INSTRUMENT NAME	EM-200	Instrument ID	V200262

Instrument/ Component Name: Software of EM 200

Date :


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

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INSTALLATION QUALIFICATION			
INSTRUMENT NAME	EM-200	Instrument ID	V200262

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	V200262
			TRANSASIA® Bio-Medicals Ltd.

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		

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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

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INSTALLATION QUALIFICATION				
INSTRUMENT NAME	EM-200	Instrument ID	V200262	

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	V200262

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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OPERATIONAL QUALIFICATION				
Instrument Name	EM-200	Instrument ID	V200262	

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.

Instrument Name: POC 200

Instrument No: 120043

1.0 INSTRUMENT SET 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.	Property Connected		
Ensure the proper filling of waste bottles. Is-vented water and Cleaning solution in the respective cans.	Property Filled		
Ensure the availability of H. Waste	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	Property Initialized		

TRANSASIA BIOMEDICALS LIMITED

OPERATIONAL QUALIFICATION



Instrument Name	EM-200	Instrument ID	V200262
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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		

TRANSASA HOME MEDICAL ASSOCIATED

OPERATIONAL MANUAL



Instrument Name: EDA-200

Instrument ID: 123456

2.2 Handling of Kits/containers:

Refer to the Operation Manual for the procedures for the following services:

Action	Description	Performed by (Name & Date)	Remarks
Reagent Level Check Reagent Volume Check & Reagent Chemistry	OK		



TRANSASIA BIOMEDICALS LIMITED

OPERATIONAL QUALIFICATION



Instrument Name EM-200 Instrument ID V200262

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		

TRANSASIA BIOMEDICALS LIMITED
OPERATIONAL QUALIFICATION



Instrument Name EM-200

Instrument ID V200262

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


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Instrument Name EM-200

Instrument ID V200262

4.1 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		


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OPERATIONAL QUALIFICATION

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Instrument Name	EM-200	Instrument ID	V200262
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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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TRANSASIA BIOMEDICALS LIMITED
PERFORMANCE QUALIFICATION



Instrument Name EM-200 Instrument Serial Number V200262

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PERFORMANCE QUALIFICATION

TRANSASIA
BIOMEDICALS

Instrument Name: EVO-200 Instrument Serial Number: N200262

1.0 PRE APPROVAL

1.1 Prepared By

Name	Designation	Signature	Date
SUDIPTAJANA	APPLICATION MANAGER		



1.2 Checked By

Name	Designation	Signature	Date

1.3 Approved By

Name	Designation	Signature	Date

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
Uma Bhattacharya	Biochemistry	Sr. Lab Tech.	
Dolon Malo	Microbiology	Lab Tech	Dolon Malo
Ahrijit Das	Haematology & Biochemistry	Sr. Lab Tech.	

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PERFORMANCE QUALIFICATION

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Instrument Name	EM-200	Instrument Serial Number	V200262
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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

TRANASIA BIOMEDICALS LIMITED
PERFORMANCE QUALIFICATION

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Instrument Name EM-200 Instrument Serial Number V200262

11.0 POST APPROVAL

11.1 Checked by

Name	Designation	Signature	Date
Uma Khetkar	Gr. Lab Tech.		
Dolon Male	Lab Tech	- Dolon Male	
Mohanjit Dc.	Sr. Lab Tech.		

11.2 Approved by

Name	Designation	Signature	Date

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

GOODDAYS DIAGNOSTIC CENTRE

CHINSURAH, FIRM SIDE ROAD

Test Statistics

Test	GLU	Report Type	Patients
Date From	12-Oct-2023	Date To	12-Oct-2023

Sample ID	PRECISION	Patient Name	Age		
Sr#	Result Unit	Flag	Result Date	Curve #	Used Calibration
1	76.4 mg/dL	-	12-Oct-2023 13:52:07	34575	06-Oct-2023 13:44:06
2	76.7 mg/dL	-	12-Oct-2023 13:51:49	34574	06-Oct-2023 13:44:06
3	75.7 mg/dL	-	12-Oct-2023 13:51:30	34573	06-Oct-2023 13:44:06
4	76.5 mg/dL	-	12-Oct-2023 13:51:12	34572	06-Oct-2023 13:44:06
5	75.9 mg/dL	-	12-Oct-2023 13:50:54	34571	06-Oct-2023 13:44:06
6	74.7 mg/dL	-	12-Oct-2023 13:50:36	34570	06-Oct-2023 13:44:06
7	75.5 mg/dL	-	12-Oct-2023 13:50:18	34569	06-Oct-2023 13:44:06
8	76.4 mg/dL	-	12-Oct-2023 13:50:00	34568	06-Oct-2023 13:44:06
9	76.1 mg/dL	-	12-Oct-2023 13:49:42	34567	06-Oct-2023 13:44:06
10	76.3 mg/dL	-	12-Oct-2023 13:49:24	34566	06-Oct-2023 13:44:06
11	76.8 mg/dL	-	12-Oct-2023 13:49:06	34565	06-Oct-2023 13:44:06
12	76.2 mg/dL	-	12-Oct-2023 13:48:48	34564	06-Oct-2023 13:44:06
13	76.7 mg/dL	-	12-Oct-2023 13:48:30	34563	06-Oct-2023 13:44:06
14	76.1 mg/dL	-	12-Oct-2023 13:48:12	34562	06-Oct-2023 13:44:06
15	76.1 mg/dL	-	12-Oct-2023 13:47:54	34561	06-Oct-2023 13:44:06
16	76.0 mg/dL	-	12-Oct-2023 13:47:36	34560	06-Oct-2023 13:44:06
17	75.9 mg/dL	-	12-Oct-2023 13:47:18	34559	06-Oct-2023 13:44:06
18	75.7 mg/dL	-	12-Oct-2023 13:47:00	34558	06-Oct-2023 13:44:06
19	76.7 mg/dL	-	12-Oct-2023 13:46:42	34557	06-Oct-2023 13:44:06
20	76.0 mg/dL	-	12-Oct-2023 13:46:23	34556	06-Oct-2023 13:44:06



GOODDAYS DIAGNOSTIC CENTRE

CHINSURAH, FIRM SIDE ROAD

Test Statistics

Test	GLU	Report Type	Patients
Date From	12-Oct-2023	Date To	12-Oct-2023

Computed Ranges And Statistical Values

Reference Range	21
Above Reference Range	0
Below Reference Range	0
Default Range	0
Total Test(s)	21

Sr# From - To -

N	20
Mean	76.1
SD	0.50
%CV	0.65
Range	2.1



GOODDAYS DIAGNOSTIC CENTRE

CHINSURAH, FIRM SIDE ROAD

Test Statistics

Test	UREA	Report Type	Patients
Date From	12-Oct-2023	Date To	12-Oct-2023

Sample ID	PRECISION1	Patient Name	Age	Result Date	Curve #	Used Calibration
Srl	Result	Unit	Flag			
1	98.6	mg/dL	H	12-Oct-2023 13:58:25	34596	11-Oct-2023 13:02:46
2	97.7	mg/dL	H	12-Oct-2023 13:58:07	34595	11-Oct-2023 13:02:46
3	97.5	mg/dL	H	12-Oct-2023 13:57:50	34594	11-Oct-2023 13:02:46
4	99.0	mg/dL	H	12-Oct-2023 13:57:31	34593	11-Oct-2023 13:02:46
5	98.0	mg/dL	H	12-Oct-2023 13:57:13	34592	11-Oct-2023 13:02:46
6	97.8	mg/dL	H	12-Oct-2023 13:56:55	34591	11-Oct-2023 13:02:46
7	96.3	mg/dL	H	12-Oct-2023 13:56:37	34590	11-Oct-2023 13:02:46
8	97.7	mg/dL	H	12-Oct-2023 13:56:19	34589	11-Oct-2023 13:02:46
9	96.7	mg/dL	H	12-Oct-2023 13:56:01	34588	11-Oct-2023 13:02:46
10	96.5	mg/dL	H	12-Oct-2023 13:55:43	34587	11-Oct-2023 13:02:46
11	96.4	mg/dL	H	12-Oct-2023 13:55:25	34586	11-Oct-2023 13:02:46
12	96.2	mg/dL	H	12-Oct-2023 13:55:07	34585	11-Oct-2023 13:02:46
13	96.3	mg/dL	H	12-Oct-2023 13:54:49	34584	11-Oct-2023 13:02:46
14	96.0	mg/dL	H	12-Oct-2023 13:54:31	34583	11-Oct-2023 13:02:46
15	97.0	mg/dL	H	12-Oct-2023 13:54:13	34582	11-Oct-2023 13:02:46
16	96.6	mg/dL	H	12-Oct-2023 13:53:55	34581	11-Oct-2023 13:02:46
17	97.6	mg/dL	H	12-Oct-2023 13:53:37	34580	11-Oct-2023 13:02:46
18	97.4	mg/dL	H	12-Oct-2023 13:53:19	34579	11-Oct-2023 13:02:46
19	96.7	mg/dL	H	12-Oct-2023 13:53:01	34578	11-Oct-2023 13:02:46
20	97.1	mg/dL	H	12-Oct-2023 13:52:43	34577	11-Oct-2023 13:02:46



GOODDAYS DIAGNOSTIC CENTRE

CHINSURAH, FIRM SIDE ROAD

Test Statistics

Test	UREA	Report Type	Patients
Date From	12-Oct-2023	Date To	12-Oct-2023

Computed Ranges And Statistical Values

Reference Range	0
Above Reference Range	21
Below Reference Range	0
Default Range	0
Total Test(s)	21

Stat From - To -

N	20
Mean	97.8
SD	0.86
%CV	0.88
Range	3.2



GOODDAYS DIAGNOSTIC

Carryover worksheet.

Instrument ID: EM 200 SN= V200262

Date performed: 10/12/2023

Carryover calculation:

$$\text{Carryover \%} = (L1-L3) / (H3-L3) * 100.$$

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	284.5	99.4
H2	288.4	97.3
H3	288.5	97.5
L1	17.7	13.1
L2	17.9	13.1
L3	17.8	12.8
% age Carryover	-0.04	0.35
Acceptble Range	1.0	1.0
Status	PASS	PASS



GOODDAYS DIAGNOSTIC CENTRE

CHINSURAH, FIRM SIDE ROAD

Result Reprint

Report Type	Patients	Test UREA				
Sr #	Sample ID	Test	Result Unit	Flag	Curve #	Result Date
1	HS	UREA	88.4 mg/dL	H	34633	12-Oct-2023 16:27:50
2	HS	UREA	87.5 mg/dL	H	34634	12-Oct-2023 16:28:08
3	HS	UREA	87.5 mg/dL	H	34635	12-Oct-2023 16:28:26
4	LS -	UREA	13.1 mg/dL	L	34636	12-Oct-2023 16:28:44
5	LS -	UREA	13.1 mg/dL	L	34637	12-Oct-2023 16:29:02
6	LS -	UREA	12.8 mg/dL	L	34638	12-Oct-2023 16:29:20



GOODDAYS DIAGNOSTIC CENTRE

CHINSURAH, FIRM SIDE ROAD

Result Reprint

Report Type	Patients	Test	GLU			
Sr #	Sample ID	Test	Result Unit	Flag	Curve #	Result Date
1	HIGH	GLU	284.5 mg/dL	H	34626	12-Oct-2023 15:23:55
2	HIGH	GLU	288.4 mg/dL	H	34627	12-Oct-2023 15:24:13
3	HIGH	GLU	288.5 mg/dL	H	34628	12-Oct-2023 15:24:31
4	LOW	GLU	17.7 mg/dL	L	34629	12-Oct-2023 15:24:49
5	LOW	GLU	17.9 mg/dL	L	34630	12-Oct-2023 15:25:07
6	LOW	GLU	17.8 mg/dL	L	34631	12-Oct-2023 15:25:25



GOODDAYS DIAGNOSTIC

Instrument Id:

Date performed:

Linearity Parameter:

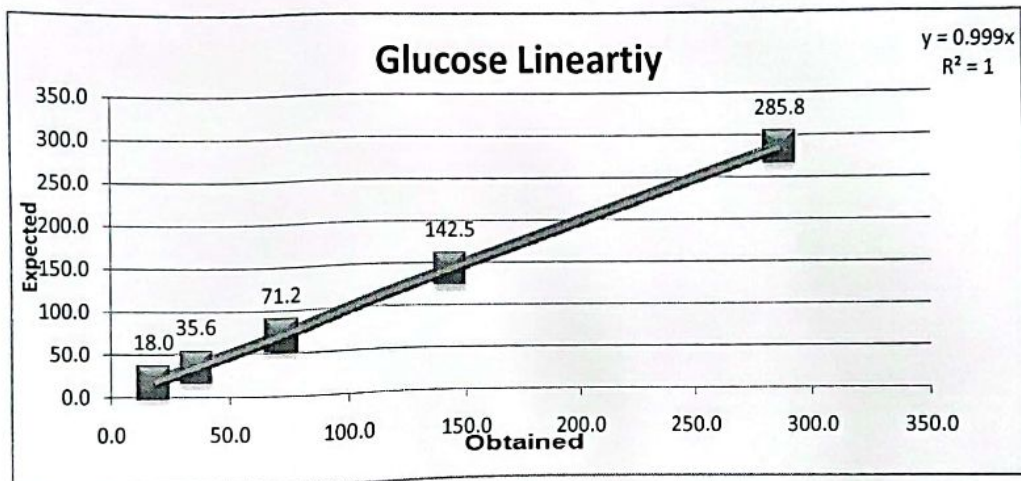
12-Oct-23

Glucose

Instrument Name:

EM 200, SN:V200262

GLUCOSE	Expected	Obtained
Neat	285.8	285.8
1:2	142.9	142.5
1:4	71.5	71.2
1:8	35.7	35.6
1:16	17.9	18.0



GOODDAYS DIAGNOSTIC CENTRE

CHINSURAH, FIRM SIDE ROAD

Result Reprint

Report Type	Patients	Test: GLU					
Sr #	Sample ID	Test	Result	Unit	Flag	Curve #	Result Date
1	NEAT	GLU	255.8	mg/dL	H	34507	12-Oct-2023 15:05:52
2	1-2	GLU	142.5	mg/dL	H	34511	12-Oct-2023 15:07:04
3	1-4	GLU	71.2	mg/dL	L	34516	12-Oct-2023 15:08:34
4	1-8	GLU	35.6	mg/dL	L	34520	12-Oct-2023 15:09:47
5	1-15	GLU	18.0	mg/dL	L	34521	12-Oct-2023 15:10:05

Print Date

12-Oct-2023

1/1



GOODDAYS DIAGNOSTIC

Instrument Id:

Date performed:

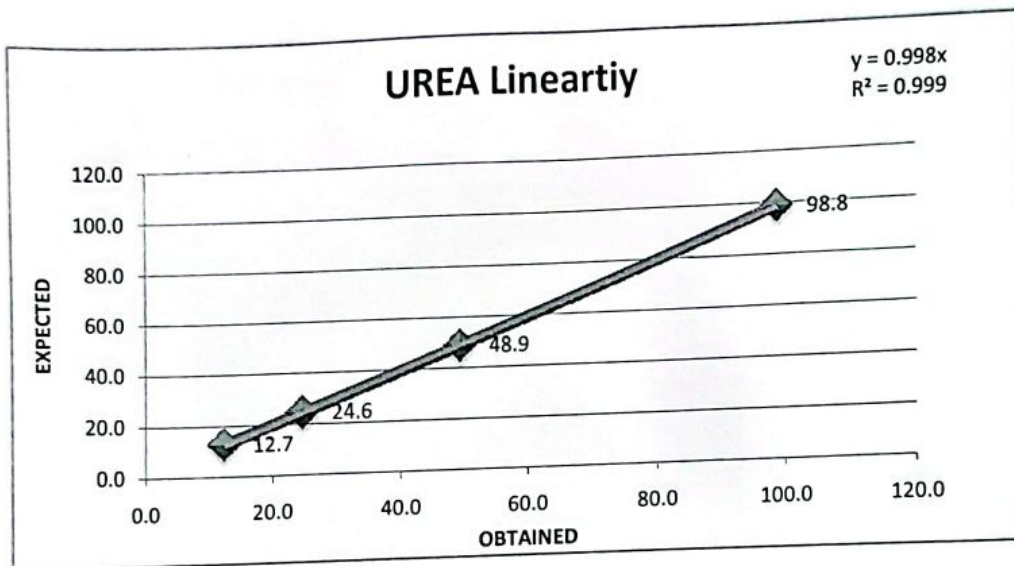
12-Oct-23

Linearity Parameter:

UREA

EM 200, SN:V200262

Instrument Name:		Expected	Obtained
UREA		98.8	98.8
Neat		49.4	48.9
1:2		24.7	24.6
1:4		12.4	12.7
1:8			



GOODDAYS DIAGNOSTIC CENTRE

CHINSURAH, FIRM SIDE ROAD

Result Reprint

Report Type	Patients	Test	UREA
Sr #	Sample ID	Test	Result Unit Flag Curve # Result Date
1	NEAT	UREA	98.8 mg/dL H 34805 12-Oct-2023 15:05:16
2	1-2	UREA	48.9 mg/dL 34810 12-Oct-2023 15:06:46
3	1-4	UREA	24.6 mg/dL 34813 12-Oct-2023 15:07:40
4	1-8	UREA	12.7 mg/dL L 34818 12-Oct-2023 15:08:10

