Date:29/07/2021

CALIBRATION REPORT

Customer Name: HARSHIT MEDICAL AND RESEARCH CENTRE,JAUNPUR

Model: Fully Automated Bio-Chemistry Analyzer EM-200

Serial No.: S200350

Calibration done date: 29/07/2021

Next Calibration due Date: 29/07/2022

Lab In charge: Dr.D.C.KOTHARI

This is to certify that above mentioned product has been verified of calibration By
Checking Lamp Voltage 11.8V

Checking gain of Photo meter for all wavelength values obtained are as under:

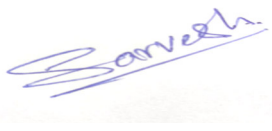
Filter	340	405	505	546	578	600	660	700
Gain	788	722	644	629	566	587	551	513

Checked calibration of probe on all locations.

Checked temperature at Reagent tray at 8.0 degree (Range 4 to 11 degree) and reaction tray 37.2 degree (Range 36.5 to 37.5 Degree)

Followed by QC run with satisfactory values of QC

Calibration at site performed by Mr.Sarvesh Singh



Authorized Signatory
(Mr.Sarvesh Singh)
Service Engineer
For Transasia Bio-Medicals Ltd.

Result Reprint

Report Type : Controls 29-Jul-2021

Sr #	Lot #	Consumable	Test	Result Unit	Flag	Curve #	Result Date	Mean	SD	Interval (3SD)
1	S052024A	ERBA NORM	SGPTD	40.4 U/L	-1SD	33288	29-Jul-2021 10:39:22	43.400	2.890	34.73 - 52.07
2	S052024A	ERBA NORM	SGOTD	42.8 U/L		33289	29-Jul-2021 10:39:39	44.750	2.980	35.81 - 53.69
3	S052024A	ERBA NORM	ALPU	111 U/L	-2SD	33290	29-Jul-2021 10:39:57	135.590	9.040	108.47 - 162.71
4	S052024A	ERBA NORM	BIDD	0.60 mg/dl		33292	29-Jul-2021 10:40:34	0.590	0.050	0.44 - 0.74
5	S052024A	ERBA NORM	BTDCA	1.59 mg/dl		33293	29-Jul-2021 10:40:52	1.520	0.130	1.13 - 1.91
6	S052024A	ERBA NORM	CRENZ	1.05 mg/dl		33295	29-Jul-2021 10:41:28	1.100	0.060	0.92 - 1.28
7	S052024A	ERBA NORM	GLUR	87.7 mg/dl		33296	29-Jul-2021 10:41:46	85.960	4.300	73.06 - 98.86
8	S052024A	ERBA NORM	TRIG	117.5 mg/dl	+1SD	33297	29-Jul-2021 10:42:04	109.190	5.460	92.81 - 125.57
9	S052024A	ERBA NORM	CHOL	147.7 mg/dl		33298	29-Jul-2021 10:42:22	140.730	7.040	119.61 - 161.85
10	S052024A	ERBA NORM	HDLC	40.0 mg/dl	-2SD	33299	29-Jul-2021 10:42:40	46.750	3.120	37.39 - 56.11
11	S052024A	ERBA NORM	UA	6.4 mg/dl		33300	29-Jul-2021 10:42:58	6.120	0.310	5.19 - 7.05
12	S052024A	ERBA NORM	CA	8.8 mg/dl	+1SD	33301	29-Jul-2021 10:43:16	8.190	0.410	6.96 - 9.42
13	S052024A	ERBA NORM	ALBD	3.65 g/dl		33302	29-Jul-2021 10:43:34	3.520	0.180	2.98 - 4.06
14	S052024A	ERBA NORM	PRO	5.32 g/dl	-1SD	33303	29-Jul-2021 10:43:52	5.900	0.300	5 - 6.8
15	S052024A	ERBA NORM	ALPU	154 U/L	+2SD	33315	29-Jul-2021 11:38:15	135.590	9.040	108.47 - 162.71
16	S052024A	ERBA NORM	PHOS	4.00 mg/dl	-2SD	33322	29-Jul-2021 11:40:22	4.510	0.230	3.82 - 5.2
17	S052024A	ERBA NORM	UREA	32.4 mg/dl	-2SD	33329	29-Jul-2021 11:42:28	36.780	1.840	31.26 - 42.3

Result Reprint

Report Type : Controls 29-Jul-2021

Sr #	Lot #	Consumable	Test	Result	Unit	Flag	Curve #	Result Date	Mean	SD	Interval (3SD)
18	S052024A	ERBA NORM	ALPU	160	U/L	+2SD	33336	29-Jul-2021 12:16:43	135.590	9.040	108.47 - 162.71
19	S052024A	ERBA NORM	UREA	33.2	mg/dl	-1SD	33343	29-Jul-2021 12:18:49	36.780	1.840	31.26 - 42.3

TRANSASIA BIOMEDICALS LIMITED IQOQPQ HARSHIT MEDICAL & RESEARCH CENTRE				TRANSASIA® Bio-Medicals Ltd.
Instrument Name	**EM200**	**Instrument SN**	**S200350**	

INSTALLATION QUALIFICATION

S. No	Title
1	Pre Approval
2	Objective
3	Scope
4	Instrument description
5	Identification of Major components / accessories
6	Installation check / review
7	Inspection check / review
8	Identification and verification of material of construction
9	Identification and verification of supporting utilities
10	Identification of standard operating procedure
11	Abbreviations
12	Post Approval

1.0 APPROVAL

I. Approval of the IQ procedure:

Charak Diagnostic Centre and Transasia are jointly responsible for the installation of the system ERBA Clinical Chemistry Analyzer, Model: EM200, Serial No. S200350 in the clinical lab of Charak Diagnostic Centre as per the attached protocol.

Protocol Performed By: Transasia Representative

Name	:	Sarvesh Singh	Signature:	Sarvesh
Title	:	**INSTALLATION-QUALIFICATION**		
Company	:	**TRANSASIA BIO-MEDICALS LTD.**	Date:	29/7/21

Customer Authorizations:

Name	:	Dr.D.C.Kothari	Signature :	Dr.D.C.Kothari
Title	:	**INSTALLATION QUALIFICATION**		
Site	:	Jaunpur	Date :	29/7/21

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'srecommendations.
- 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

4.0 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, 1/2Reageants
Analysis Speed	200 Biochemistry tests per hour 400 tests per hour (with ISE) for a cycle time of 18 seconds
Display resolution	1024 X 768
Analyzer Dimensions	810 (W) x 800 (D) x 600 (H) mm
Number of tests on board	Maximum: 50
Assay Modes	1-point, 2-point,Rate-A and Rate –B, ISE optional
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 8 wavelengths
Absorbance Range	0 – 2.5
Auxiliary Data	10,000 results
Interface	RS-232 C port for Bi-directional Communication
Stat Sampling	Total 30 positions

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

The working unit of the analyzer comprises the following:

- Basic operating unit with an intelligentphotometer
- 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, multi wavelength diffracting photometer and a halogen lamp.

Operating Console:
The operating console consists of a touch screen (optional) color TFT 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.

5.0 IDENTIFICATION OF MAJOR COMPONENTS /ACCESSORIES

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

Name of Component / Accessories	Present Yes / No	Verified by Signature	Observations
Sample Tray / Disk	Yes		
Sample Syringe	Yes		
Sample Probe	Yes		
Wash Station for Sample Probe	Yes		
Reagent Tray / Disk	Yes		
Reagent Bottles	Yes		
Reagent Probe	Yes		
Stirrer	Yes		
Permanent Reaction Cuvette	Yes		
9 Stage Laundry System	Yes		
Light Source	Yes		
Sample Cups	Yes		
Software of EM 200	Yes		

6.0 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	
2.	Verify that major components / accessories are securely anchored and shock proof.	Yes	
3.	Verify that there is no observable physical damage.	Yes	
4.	Verify that there is sufficient room of servicing provided	Yes	
5.	Verify that all utilities and electrical connections have been done according to the drawings.	Yes	
6.	Walking access to ground mounted instrument provided.	Yes	Sawesh
7.	Required electric connections are tight, weather proof and earthed.	Yes	
8.	Instrument identification nameplate visible.	Yes	
9.	Units installed on foundation and secure in place as per manufacturer's recommendations.	Yes	
10.	Verify that the instruments installed and leveled properly on the floor.	Yes	
11.	Verify that the Material of Construction is proper and meeting the requirements.	Yes	

7.0 INSPECTION CHECK / REVIEW

Instructions for completing the check / review

1. For each **data sheet,** record the required information withpen. Wherever required record "Yes" for acceptance, "No" for non-compliance and "NA" for notapplicable.

   "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.

Instrument/ Component Name: Sample Tray / Disk

Description	Specified	Actual	Method of Verification	Verified by Signature
No. of patient cups / samples	30 positions	OK	Physical/Practical	Sawan
Standards / Stat	30 positions	OK	Physical/Practical	
Blank	Can be put on any position	OK	Physical/Practical	
Controls	Can be programmed on any positions	OK	Physical/Practical	

Instrument/ Component Name: Sample Syringe

Description	Specified	Actual	Method of Verification	Verified by Signature
Dispensing Volume	2 – 70 µL	OK	Physical/Practical	Sawan
Installed Location	Behind the instrument on the right side	OK	Physical/Practical	
Quantity	01 No.	OK	Physical/Practical	
Increase in dispensing volume	0.2 µL	OK	Physical/Practical	

Instrument/ Component Name: Sample Probe

Description	Specified	Actual	Method of Verification	Verified by Signature
Aspiration Volume	2 – 70 µL	OK	Physical/Practical	
MOC	Teflon coated	OK	Physical/Practical	
Quantity	01 No.	OK	Physical/Practical	
Increase in aspiration volume	0.2 µL	OK	Physical/Practical	

Instrument/ Component Name: Wash Station for Sample Probe

Description	Specified	Actual	Method of Verification	Verified by Signature
No. of position	01 No	OK	Physical/Practical	
Type of positions	i) Drain ii) Trough	OK	Physical/Practical	

TRANSASIA BIOMEDICALS LIMITED IQOQPQ HARSHIT MEDICAL & RESEARCH CENTRE				TRANSASIA® Bio-Medicals Ltd.
Instrument Name	**EM200**	**Instrument SN**	**S200350**	

Instrument/ Component Name: Reagent Tray / Disk

Description	Specified	Actual	Method of Verification	Verified by Signature
Cool reagent disk	50 positions	OK	Physical/Practical	
Outer Rings	25 positions	OK	Physical/Practical	
Inner Rings	25 positions	OK	Physical/Practical	
Adaptors of 5mL	50 positions	OK	Physical/Practical	
Maintenance of Temperature	8-12°C ± 2°C	OK	Physical/Practical	
Rotation of disk	Counter-Clockwise	OK	Physical/Practical	
Time for Rotation of one Cuvette	Every 18 seconds	OK	Physical/Practical	

TRANSASIA BIOMEDICALS LIMITED IQOQPQ HARSHIT MEDICAL & RESEARCH CENTRE				TRANSASIA® Bio-Medicals Ltd.
Instrument Name	**EM200**	**Instrument SN**	**S200350**	

Instrument/ Component Name: Reagent Bottles

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

Instrument/ Component Name: Reagent Probe

Description	Specified	Actual	Method of Verification	Verified by Signature
Aspiration/Dispensing Volume	R1: 50 – 300 µL	OK	Physical/Practical	Sawan
	R2: 0 or10 – 300 µL	OK	Physical/Practical	
MOC	Teflon coated	OK	Physical/Practical	
Quantity	02 Nos'.	OK	Physical/Practical	
Increase in aspiration/dispensing volume	1 µL	OK	Physical/Practical	

Instrument/ Component Name: Reagent Syringe

Description	Specified	Actual	Method of Verification	Verified by Signature
Maximum capacity	500 µL	OK	Physical/Practical	Sawan
Installed Location	At the back of the instrument on the right side	OK	Physical/Practical	
Quantity	01 No.	OK	Physical/Practical	
Increase in dispensing volume	1 µL	OK	Physical/Practical	

Instrument/ Component Name: Stirrer

Description	Specified	Actual	Method of Verification	Verified by Signature
Type	Single Stirrer	OK	Physical/Practical	Sawan
No. of paddles	01 No.	OK	Physical/Practical	

Instrument/ Component Name: Permanent Reaction Cuvette

Description	Specified	Actual	Method of Verification	Verified by Signature
Quantity	45 Nos'	OK	Physical/Practical	Santosh
MOC	Hard Glass	OK	Physical/Practical	
Capacity	770 µL	OK	Physical/Practical	

Instrument/ Component Name: 7 Stage Laundry System

Description	Specified	Actual	Method of Verification	Verified by Signature
Nozzles	Nozzle - 1	OK	Physical/Practical	Santosh
	Nozzle – 2	OK	Physical/Practical	
	Nozzle – 3	OK	Physical/Practical	
	Nozzle – 4	OK	Physical/Practical	
	Nozzle – 5	OK	Physical/Practical	
	Nozzle – 6	OK	Physical/Practical	
	Nozzle - 7	OK	Physical/Practical	

Instrument/ Component Name: LightSource

Description	Specified	Actual	Method of Verification	Verified by Signature
Watts	12 W	OK	Physical/Practical	
Volts	12 V	OK	Physical/Practical	
MOC	Halogen	OK	Physical/Practical	
Quantity	01 No	OK	Physical/Practical	

Instrument/ Component Name: SampleCups

Description	Specified	Actual	Method of Verification	Verified by Signature
Quantity	500 Nos'	OK	Physical/Practical	
MOC	Plastic	OK	Physical/Practical	
Capacity	2 mL	OK	Physical/Practical	

Instrument/ Component Name: Software of EM 200

Description	Specified	Actual	Method of Verification	Verified by Signature
Version	2019	OK	Physical/Practical	
CD number		OK	Physical/Practical	
Product	EM- 200	OK	Physical/Practical	
Make	Erba Transasia	OK	Physical/Practical	

8.0 IDENTIFICATION AND VERIFICATION OF MATERIAL OFCONSTRUCTION

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 Probe	Teflon coated	OK	Physical/Practical	Sanwan 29/7/21
Reagent Probe	Teflon coated	OK	Physical/Practical	
Permanent Reaction Cuvette	Hard Glass	OK	Physical/Practical	
Light Source	Halogen	OK	Physical/Practical	
Reagent Bottle	Plastic	OK	Physical/Practical	
Sample Cups	Plastic	OK	Physical/Practical	

9.0 IDENTIFICATION AND VERIFICATION OF SUPPORTINGUTILITIES

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

Utilities	Observation / Result	Verified by Sign & Date
Power	OK	Sanwan 29/7/21
Distilled Water	OK	
Wash Solution	OK	
UPS	OK	

10.0 IDENTIFICATION OF STANDARD OPERATINGPROCEDURE

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

11.0 ABBREVIATIONS

SOP	**Standard Operating Procedure**
MOC	Material of Construction
IQ	Installation Qualification

12.0 POSTAPPROVAL:

12.1 Checkedby

Name	Designation	Signature	Date
Sarvesh Singh	Service Engineer	Sarvesh	29/7/21
Dheeraj Gupta	Application Specialist	Dheeraj Gupta	29/7/21

12.2 CustomerAuthorization:

Name	Designation	Signature	Date
Dr.D.C.Kothari	HOD	Damchand	29/7/21

OPERATIONAL QUALIFICATION

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.

1.0 INSTRUMENT START-UP:

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

Action	Observation	Verified by	Remarks
Ensure that all the required electrical connections are properly connected.	OK	Sarvesh Singh	NA
Ensure the proper filling of double distilled / de-ionized water and Cleaning solution in the respective cans.	OK	Sarvesh Singh	NA
Ensure the availability of XL Wash.	OK	Sarvesh Singh	NA
Ensure the availability of Biohazard Waste.	OK	Sarvesh Singh	NA
Ensure the availability of Normal Waste.	OK	Sarvesh Singh	NA
Switch ON the rear switch of the analyzer.	OK	Sarvesh Singh	NA
Switch ON the side switch of the analyzer.	OK	Sarvesh Singh	NA
Switch ON the computer and start the analyzer application software.	OK	Sarvesh Singh	NA
Initialization	OK	Sarvesh Singh	NA

2.0 FUNCTIONALCHECKS:

2.1 Maintenance:

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

Activity	Observation	Verified by	Remarks
Photometer functioning	OK	Sarvesh Singh	NA
Cuvette Rinse	OK	Sarvesh Singh	NA

2.2 Loading of Reagents:

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

Action	Observation	Verified by	Remarks
Reagent Level Scan, Dead Volume Check & 2 Reagent Chemistry	OK	Sarvesh Singh	NA

2.3 Calibration:

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

Action	Observation	Verified by	Remarks
Blank (Distilled Water)	OK	Dheeraj Gupta	NA
Standard (Multical)	OK	Dheeraj Gupta	NA

3.0 INTERLOCKS AND ALARMS CHECK:

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

Action	Observation	Verified by	Remarks
Less volume of Distilled Water	OK	Dheeraj Gupta	NA
Less volume of Wash Solution	OK	Dheeraj Gupta	NA
More volume of Bio-Hazard waste	OK	Dheeraj Gupta	NA
More volume of Normal / General waste	OK	Dheeraj Gupta	NA

4.0 SAFETY / SECURITY CHECKS:

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

Action	Observation	Verified by	Remarks
Password Check for Test Parameters	OK	Dheeraj Gupta	NA
Password Check for QC Mode	OK	Dheeraj Gupta	NA

5.0 INSTRUMENT SHUT-DOWN:

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

Action	Observation	Verified by	Remarks
Sample Probe Wash	OK	Dheeraj Gupta	NA
Water Save	OK	Dheeraj Gupta	NA
Switch OFF the computer.	OK	Dheeraj Gupta	NA
Switch OFF the side switch of the analyzer.	OK	Dheeraj Gupta	NA
Switch OFF the rear switch of the analyzer.	OK	Dheeraj Gupta	NA

Protocol Performed By:

Name	Designation	Signature	Date
Sarvesh Singh	Service Engineer	Sawesh	29/7/21
Dheeraj Gupta	Application Specialist	Dheeraj Gupta	29/7/21

Customer Authorization:

Name	Designation	Signature	Date
Dr. D.C.Kothari	HOD	Ramchand	29/7/21

Performance Qualification

S. No	Title
1.0	Pre approval
2.0	Objective
3.0	Scope
4.0	Pre- Requisites
5.0	Test Plan
6.0	Execution of Test Plan
7.0	Post Approval

1.0 PRE APPROVAL

I. Approval of the PQ procedure

Both Charak Diagnostic Centre and Transasia are jointly responsible for conducting the Performance Check of the Clinical Chemistry Analyzer, Model: ERBA – EM200, Serial No. S200350 in the clinical lab of Charak Diagnostic Centre as per the attached protocol.

Protocol Performed By: Transasia Representative

Name : Dheeraj Gupta Signature: Dheeraj Gupta
Title : PERFORMANCE-QUALIFICATION
Company : TRANSASIA BIO-MEDICALS LTD. Date:29-7-2021

Customer Authorizations:

Name : Dr. D.C.Kothari Signature : Dr. D.C. Kothari
Title : PERFORMANCE-QUALIFICATION
Site : Jaunpur Date : 29/7/21

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 toPQ.
- Completion of Operational Qualification prior toPQ.

5.0 TEST PLAN

The following tests shall be followed, during the Performance Qualification of EM200 (Bio-Chemistry Random Analyzer).

1. **Glucose**
2. **Chol**
3. **SGOT**

- **Data Analysis of PQ attachedseparately.**

Conclusion:-

The study data has been determined, The system describes all Criteria outlined in its protocol
The system is ready for specific uses

6.0 ABBREVIATIONS

SOP	Standard Operating Procedure
MOC	Material of Construction
PQ	Performance Qualification

7.0 POSTAPPROVAL

7.1 Protocol doneby

Name	Designation	Signature	Date
Dheeraj Gupta	Application Specialist	Dheeraj Gupta	29/7/21

7.2 CustomerAuthorization:

Name	Designation	Signature	Date
Dr:D.C.Kothari	HOD	Harmchand	29/7/21