

<b>TRANSASIA BIOMEDICALS LIMITED</b>				<b>TRANSASIA</b> <sup>®</sup> Bio-Medicals Ltd.
<b>IQOQPQ for EM200 (Omega Path Lab)</b>				
<b>Instrument Name</b>	<b>EM200</b>	<b>Instrument SN</b>	<b>2002941</b>	

## **INSTALLATION QUALIFICATION**

<b>S. No</b>	<b>Title</b>
1	Pre Approval
2	Objective
3	Scope
4	Instrument description
5	Identification of Major components / accessories
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## 2.0 OBJECTIVE

The objective of this document is to provide an outline for the inspection of EM 200 (Fully Auto Bio- Chemistry 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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#### 4.0 INSTRUMENT DESCRIPTION

The Fully Auto Bio- 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, 1/2 Reagents
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

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**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, 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):**

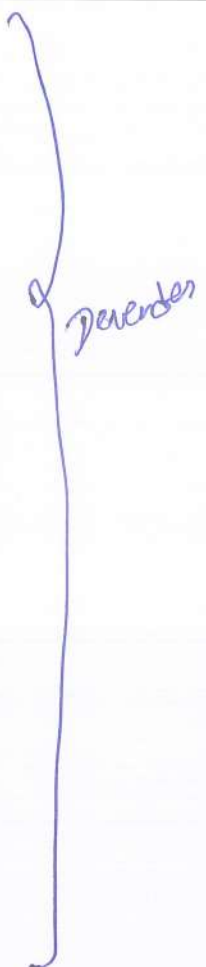
CPU consists of Pentium – IV 1.7 GHz processor (or Higher) with a 48 x CD Drive, and minimum 256 MB memory. The application software can be installed on computers with operating systems of Windows XP.

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

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### 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	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		
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		

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**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	
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	

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## 7.0 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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**Instrument/ Component Name: Sample Tray / Disk**

<b>Description</b>	<b>Specified</b>	<b>Actual</b>	<b>Method of Verification</b>	<b>Verified by Signature</b>
No. of patient cups / samples	30 positions	OK	Physical/Practical	<i>Devender</i>
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**

<b>Description</b>	<b>Specified</b>	<b>Actual</b>	<b>Method of Verification</b>	<b>Verified by Signature</b>
Dispensing Volume	2 – 70 µL	OK	Physical/Practical	<i>Devender</i>
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	

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**Instrument/ Component Name: Sample Probe**

<b>Description</b>	<b>Specified</b>	<b>Actual</b>	<b>Method of Verification</b>	<b>Verified by Signature</b>
Aspiration Volume	2 – 70 µL	OK	Physical/Practical	<i>Devender</i>
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**

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

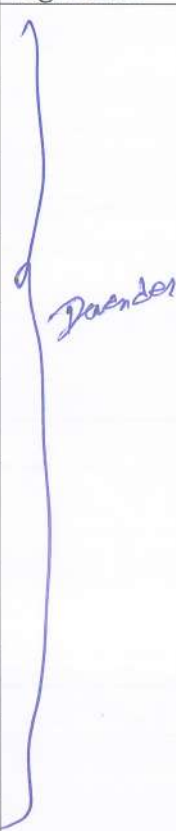
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**Instrument/ Component Name: Reagent Tray / Disk**

<b>Description</b>	<b>Specified</b>	<b>Actual</b>	<b>Method of Verification</b>	<b>Verified by Signature</b>
Cool reagent disk	50 positions	OK	Physical/Practical	<i>Detinder</i>
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	

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**Instrument/ Component Name: Reagent Bottles**

<b>Description</b>	<b>Specified</b>	<b>Actual</b>	<b>Method of Verification</b>	<b>Verified by Signature</b>
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	

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**Instrument/ Component Name: Reagent Probe**

Description	Specified	Actual	Method of Verification	Verified by Signature
Aspiration/Dispensing Volume	R1: 50 – 300 $\mu$ L	OK	Physical/Practical	} <i>Deventer</i>
	R2: 0 or 10 – 300 $\mu$ L	OK	Physical/Practical	
MOC	Teflon coated	OK	Physical/Practical	
Quantity	02 Nos.	OK	Physical/Practical	
Increase in aspiration/dispensing volume	1 $\mu$ L	OK	Physical/Practical	

**Instrument/ Component Name: Reagent Syringe**


Description	Specified	Actual	Method of Verification	Verified by Signature
Maximum capacity	500 $\mu$ L	OK	Physical/Practical	} <i>Deventer</i>
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 $\mu$ L	OK	Physical/Practical	

**Instrument/ Component Name: Stirrer**


Description	Specified	Actual	Method of Verification	Verified by Signature
Type	Single Stirrer	OK	Physical/Practical	} <i>Deventer</i>
No. of paddles	01 No.	OK	Physical/Practical	

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**Instrument/ Component Name: Permanent Reaction Cuvette**

<b>Description</b>	<b>Specified</b>	<b>Actual</b>	<b>Method of Verification</b>	<b>Verified by Signature</b>
Quantity	45 Nos <sup>7</sup>	OK	Physical/Practical	
MOC	Hard Glass	OK	Physical/Practical	
Capacity	770 µL	OK	Physical/Practical	

**Instrument/ Component Name: 7 Stage Laundry System**

<b>Description</b>	<b>Specified</b>	<b>Actual</b>	<b>Method of Verification</b>	<b>Verified by Signature</b>
Nozzles	Nozzle - 1	OK	Physical/Practical	
	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	

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**Instrument/ Component Name: Light Source**

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

**Instrument/ Component Name: Sample Cups**

Description	Specified	Actual	Method of Verification	Verified by Signature
Quantity	500 Nos'	OK	Physical/Practical	} <i>Davender</i>
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	} <i>Davender</i>
CD number		OK	Physical/Practical	
Product	EM- 200	OK	Physical/Practical	
Make	Erba Transasia	OK	Physical/Practical	

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**8.0 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 Probe	Teflon coated	OK	Physical/Practical	} <i>Devedes</i>
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 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	OK	} <i>Devedes</i>
Distilled Water	OK	
Wash Solution	OK	
UPS	OK	



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#### 10.0 IDENTIFICATION OF STANDARD OPERATING PROCEDURE

<b>SOP No.</b>	<b>Title</b>
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

<b>SOP</b>	<b>Standard Operating Procedure</b>
<b>MOC</b>	Material of Construction
<b>IQ</b>	Installation Qualification

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**12.0 POST APPROVAL:**

**12.1 Checked by**

Name	Designation	Signature	Date
Devender Singh	Service Engineer	<i>Devender</i>	30/8/22
Ankit Gupta	Application Specialist	<i>Ankit</i>	30/8/22

**12.2 Customer Authorization:**

Name	Designation	Signature	Date
Dr Jyoti Goel	HOD		30/8/22

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## **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.

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### 1.0 INSTRUMENT START-UP:

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

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

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**2.0 FUNCTIONAL CHECKS:**

**2.1 Maintenance:**

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

<b>Activity</b>	<b>Observation</b>	<b>Verified by</b>	<b>Remarks</b>
Photometer functioning	OK	Devender Singh	NA
Cuvette Rinse	OK	Devender Singh	NA

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### 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	Devender 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	Ankit Gupta	NA
Standard (Multical)	OK	Ankit 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	Ankit Gupta	NA
Less volume of Wash Solution	OK	Ankit Gupta	NA
More volume of Bio-Hazard waste	OK	Ankit Gupta	NA
More volume of Normal / General waste	OK	Ankit Gupta	NA

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#### 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	Ankit Gupta	NA
Password Check for QC Mode	OK	Ankit 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	Ankit Gupta	NA
Water Save	OK	Ankit Gupta	NA
Switch OFF the computer.	OK	Ankit Gupta	NA
Switch OFF the side switch of the analyzer.	OK	Ankit Gupta	NA
Switch OFF the rear switch of the analyzer.	OK	Ankit Gupta	NA

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**Protocol Performed By:**

<b>Name</b>	<b>Designation</b>	<b>Signature</b>	<b>Date</b>
Devender Singh	Service Engineer	<i>Devender</i>	30/8/22
Ankit Gupta	Application Specialist	<i>Ankit</i>	30/8/22

**Customer Authorization:**

<b>Name</b>	<b>Designation</b>	<b>Signature</b>	<b>Date</b>
Dr. Jyoti Goel	HOD		30/8/22



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## 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

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**1.0 PRE APPROVAL**

**I. Approval of the PO procedure**

Both Omega Path Lab and Transasia are jointly responsible for conducting the Performance Check of the Fully Auto Bio-Chemistry Analyzer, Model: ERBA – EM200, Serial No. 2002941 in the clinical lab of Omega Path Lab Faridabad as per the attached protocol.

**Protocol Performed By: Transasia Representative**

Name : Ankit Gupta  
 Title : PERFORMANCE-QUALIFICATION  
 Company : TRANSASIA BIO-MEDICALS LTD.

Signature: 

Date:30/8/2022

**Customer Authorizations:**

Name : Dr.Jyoti Goel  
 Title : PERFORMANCE-QUALIFICATION  
 Site : Delhi

Signature :

Date :30/8/2022

<b>TRANSASIA BIOMEDICALS LIMITED</b>				<b>TRANSASIA</b> <sup>®</sup> Bio-Medicals Ltd.
<b>IQQPQ for EM200 (Omega Path Lab)</b>				
<b>Instrument Name</b>	<b>EM200</b>	<b>Instrument SN</b>	<b>2002941</b>	

## 2.0 OBJECTIVE

The objective of this protocol is to establish documented evidence for the Performance Qualification of EM 200 (Fully Auto Bio-Chemistry 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 (Fully Auto Bio-Chemistry 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.

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<b>IQQPQ for EM200 (Omega Path Lab)</b>				
<b>Instrument Name</b>	<b>EM200</b>	<b>Instrument SN</b>	<b>2002941</b>	

## 5.0 TEST PLAN

The following tests shall be followed, during the Performance Qualification of EM200 (Fully Auto Bio- Chemistry Analyzer). Precision Study & QC has been run.

1. Glucose
2. Chol
3. SGPT

- **Data Analysis of PQ attached separately.**

### **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

<b>SOP</b>	Standard Operating Procedure
<b>MOC</b>	Material of Construction
<b>PQ</b>	Performance Qualification

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<b>IQQPQ for EM200 (Omega Path Lab)</b>				
<b>Instrument Name</b>	<b>EM200</b>	<b>Instrument SN</b>	<b>2002941</b>	

## 7.0 POST APPROVAL

### 7.1 Protocol done by

Name	Designation	Signature	Date
Ankit Gupta	Application Specialist		

### 7.2 Customer Authorization:

Name	Designation	Signature	Date
Dr. Jyoti Goel	HOD		

## Test Statistics

t	UREA	Report Type	Patients
e From	10-Sep-2022	Date To	10-Sep-2022

Sample ID	PRE2	Patient Name	Age		
Result	Unit	Flag	Result Date	Curve #	Used Calibration
20.6	mg/dL	-	10-Sep-2022 16:48:48	295	10-Sep-2022 13:57:38
20.5	mg/dL	-	10-Sep-2022 16:48:29	294	10-Sep-2022 13:57:38
20.6	mg/dL	-	10-Sep-2022 16:48:11	293	10-Sep-2022 13:57:38
20.5	mg/dL	-	10-Sep-2022 16:47:53	292	10-Sep-2022 13:57:38
21.0	mg/dL	-	10-Sep-2022 16:47:35	291	10-Sep-2022 13:57:38
20.3	mg/dL	-	10-Sep-2022 16:47:17	290	10-Sep-2022 13:57:38
20.4	mg/dL	-	10-Sep-2022 16:46:59	289	10-Sep-2022 13:57:38
20.4	mg/dL	-	10-Sep-2022 16:46:41	288	10-Sep-2022 13:57:38
20.6	mg/dL	-	10-Sep-2022 16:46:23	287	10-Sep-2022 13:57:38
20.9	mg/dL	-	10-Sep-2022 16:46:05	286	10-Sep-2022 13:57:38

### Computed Ranges And Statistical Values

Reference Range	12
Above Reference Range	0
Below Reference Range	0
Default Range	0
Total Test(s)	12

### Sr# From - To -

Count	10
Mean	20.6
SD	0.22
CV	1.07
Range	0.7

## Test Statistics

Test	UA	Report Type	Patients
Date From	10-Sep-2022	Date To	10-Sep-2022

Sample ID	PRE2	Patient Name	Age		
#	Result Unit	Flag	Result Date	Curve #	Used Calibration
1	6.4 mg/dL	-	10-Sep-2022 16:56:01	319	10-Sep-2022 14:03:39
2	6.3 mg/dL	-	10-Sep-2022 16:55:25	317	10-Sep-2022 14:03:39
3	6.3 mg/dL	-	10-Sep-2022 16:54:48	315	10-Sep-2022 14:03:39
4	6.4 mg/dL	-	10-Sep-2022 16:54:30	314	10-Sep-2022 14:03:39
5	6.8 mg/dL	-	10-Sep-2022 16:54:12	313	10-Sep-2022 14:03:39
6	6.8 mg/dL	-	10-Sep-2022 16:53:54	312	10-Sep-2022 14:03:39
7	6.9 mg/dL	-	10-Sep-2022 16:53:36	311	10-Sep-2022 14:03:39
8	6.7 mg/dL	-	10-Sep-2022 16:53:18	310	10-Sep-2022 14:03:39
9	6.8 mg/dL	-	10-Sep-2022 16:53:00	309	10-Sep-2022 14:03:39
10	6.9 mg/dL	-	10-Sep-2022 16:52:42	308	10-Sep-2022 14:03:39

### Computed Ranges And Statistical Values

Reference Range	12
Above Reference Range	0
Below Reference Range	0
Default Range	0
Total Test(s)	12

#### Sr# From - To -

N	10
Mean	6.6
SD	0.25
%CV	3.77
Range	0.6

## Test Statistics

Test	TRIG	Report Type	Patients
Date From	10-Sep-2022	Date To	10-Sep-2022

Sample ID	PRE2	Patient Name	Age	Result	Unit	Flag	Result Date	Curve #	Used Calibration
1				140.4	mg/dL	-	10-Sep-2022 16:52:24	307	10-Sep-2022 14:01:15
2				137.6	mg/dL	-	10-Sep-2022 16:52:06	306	10-Sep-2022 14:01:15
3				136.0	mg/dL	-	10-Sep-2022 16:51:48	305	10-Sep-2022 14:01:15
4				139.2	mg/dL	-	10-Sep-2022 16:51:30	304	10-Sep-2022 14:01:15
5				152.9	mg/dL	-	10-Sep-2022 16:51:12	303	10-Sep-2022 14:01:15
6				139.4	mg/dL	-	10-Sep-2022 16:50:54	302	10-Sep-2022 14:01:15
7				139.0	mg/dL	-	10-Sep-2022 16:50:36	301	10-Sep-2022 14:01:15
8				152.6	mg/dL	-	10-Sep-2022 16:50:18	300	10-Sep-2022 14:01:15
9				153.8	mg/dL	-	10-Sep-2022 16:50:00	299	10-Sep-2022 14:01:15
0				134.8	mg/dL	-	10-Sep-2022 16:49:05	296	10-Sep-2022 14:01:15

### Computed Ranges And Statistical Values

Reference Range	12
Above Reference Range	0
Below Reference Range	0
Default Range	0
Total Test(s)	12

Sr# From - To -

N	10
Mean	142.6
SD	7.46
%CV	5.23
Range	19.0



## Test Statistics

Test	SGPTD	Report Type	Patients
Date From	10-Sep-2022	Date To	10-Sep-2022

Sample ID	PRE2	Patient Name	Age
#	Result Unit	Flag	Result Date
1	31.7 U/L	-	10-Sep-2022 16:34:39
2	31.4 U/L	-	10-Sep-2022 16:34:21
3	31.2 U/L	-	10-Sep-2022 16:34:03
4	31.4 U/L	-	10-Sep-2022 16:33:45
5	31.7 U/L	-	10-Sep-2022 16:33:09
6	31.4 U/L	-	10-Sep-2022 16:32:51
7	31.4 U/L	-	10-Sep-2022 16:32:33
8	31.9 U/L	-	10-Sep-2022 16:32:14
9	31.4 U/L	-	10-Sep-2022 16:31:39
10	31.7 U/L	-	10-Sep-2022 16:31:21

### Computed Ranges And Statistical Values

Reference Range	12
Above Reference Range	0
Below Reference Range	0
Default Range	0
Total Test(s)	12

Sr# From - To -

N	10
Mean	31.5
SD	0.21
%CV	0.68
Range	0.7

## Test Statistics

Test	SGOTD	Report Type	Patients
Date From	10-Sep-2022	Date To	10-Sep-2022

Sample ID	PRE2	Patient Name	Age
#	Result Unit	Flag	Result Date
1	28.7 U/L	-	10-Sep-2022 16:45:11
2	28.9 U/L	-	10-Sep-2022 16:44:53
3	29.5 U/L	-	10-Sep-2022 16:44:35
4	29.5 U/L	-	10-Sep-2022 16:44:17
5	28.1 U/L	-	10-Sep-2022 16:43:59
6	28.4 U/L	-	10-Sep-2022 16:43:41
7	28.7 U/L	-	10-Sep-2022 16:43:23
8	28.7 U/L	-	10-Sep-2022 16:43:05
9	28.9 U/L	-	10-Sep-2022 16:35:15
10	29.2 U/L	-	10-Sep-2022 16:34:57

### Computed Ranges And Statistical Values

Reference Range	12
Above Reference Range	0
Below Reference Range	0
Default Range	0
Total Test(s)	12

Sr# From - To -

N	10
Mean	28.9
SD	0.45
%CV	1.55
Range	1.4

## Test Statistics

Test	PRO	Report Type	Patients
Date From	10-Sep-2022	Date To	10-Sep-2022

Sample ID	PRE1	Patient Name	Age		
#	Result Unit	Flag	Result Date	Curve #	Used Calibration
1	7.30 g/dL	-	10-Sep-2022 16:31:02	259	10-Sep-2022 14:07:16
2	7.36 g/dL	-	10-Sep-2022 16:30:44	258	10-Sep-2022 14:07:16
3	7.30 g/dL	-	10-Sep-2022 16:30:08	256	10-Sep-2022 14:07:16
4	7.45 g/dL	-	10-Sep-2022 16:29:50	255	10-Sep-2022 14:07:16
5	7.35 g/dL	-	10-Sep-2022 16:29:32	254	10-Sep-2022 14:07:16
6	7.31 g/dL	-	10-Sep-2022 16:29:14	253	10-Sep-2022 14:07:16
7	7.34 g/dL	-	10-Sep-2022 16:28:56	252	10-Sep-2022 14:07:16
8	7.44 g/dL	-	10-Sep-2022 16:28:20	250	10-Sep-2022 14:07:16
9	7.28 g/dL	-	10-Sep-2022 16:28:02	249	10-Sep-2022 14:07:16
10	7.39 g/dL	-	10-Sep-2022 16:27:44	248	10-Sep-2022 14:07:16

### Computed Ranges And Statistical Values

Reference Range	12
Above Reference Range	0
Below Reference Range	0
Default Range	0
Total Test(s)	12

Sr# From - To -

N	10
Mean	7.35
SD	0.06
%CV	0.80
Range	0.17

## Test Statistics

Test	PHOS	Report Type	Patients
Date From	10-Sep-2022	Date To	10-Sep-2022

Sample ID	PRE1	Patient Name	Age	Result Date	Curve #	Used Calibration
#	Result Unit	Flag				
1	3.41 mg/dL	-		10-Sep-2022 16:20:13	223	10-Sep-2022 13:54:02
2	3.30 mg/dL	-		10-Sep-2022 16:19:55	222	10-Sep-2022 13:54:02
3	3.41 mg/dL	-		10-Sep-2022 16:19:37	221	10-Sep-2022 13:54:02
4	3.39 mg/dL	-		10-Sep-2022 16:19:18	220	10-Sep-2022 13:54:02
5	3.40 mg/dL	-		10-Sep-2022 16:19:00	219	10-Sep-2022 13:54:02
6	3.36 mg/dL	-		10-Sep-2022 16:18:42	218	10-Sep-2022 13:54:02
7	3.42 mg/dL	-		10-Sep-2022 16:18:24	217	10-Sep-2022 13:54:02
8	3.43 mg/dL	-		10-Sep-2022 16:18:06	216	10-Sep-2022 13:54:02
9	3.36 mg/dL	-		10-Sep-2022 16:17:48	215	10-Sep-2022 13:54:02
10	3.31 mg/dL	-		10-Sep-2022 16:17:30	214	10-Sep-2022 13:54:02

### Computed Ranges And Statistical Values

Reference Range	12
Above Reference Range	0
Below Reference Range	0
Default Range	0
Total Test(s)	12

Sr# From - To -

N	10
Mean	3.38
SD	0.05
%CV	1.34
Range	0.13

## Test Statistics

Test	GLU	Report Type	Patients
Date From	10-Sep-2022	Date To	10-Sep-2022

Sample ID	PRE1	Patient Name	Age		
#	Result Unit	Flag	Result Date	Curve #	Used Calibration
1	83.5 mg/dL	-	10-Sep-2022 16:27:26	247	10-Sep-2022 14:00:03
2	82.8 mg/dL	-	10-Sep-2022 16:27:08	246	10-Sep-2022 14:00:03
3	84.9 mg/dL	-	10-Sep-2022 16:26:50	245	10-Sep-2022 14:00:03
4	86.3 mg/dL	-	10-Sep-2022 16:26:31	244	10-Sep-2022 14:00:03
5	84.9 mg/dL	-	10-Sep-2022 16:26:14	243	10-Sep-2022 14:00:03
6	83.2 mg/dL	-	10-Sep-2022 16:25:56	242	10-Sep-2022 14:00:03
7	84.5 mg/dL	-	10-Sep-2022 16:25:38	241	10-Sep-2022 14:00:03
8	85.6 mg/dL	-	10-Sep-2022 16:25:20	240	10-Sep-2022 14:00:03
9	84.0 mg/dL	-	10-Sep-2022 16:24:43	238	10-Sep-2022 14:00:03
10	83.9 mg/dL	-	10-Sep-2022 16:24:25	237	10-Sep-2022 14:00:03

### Computed Ranges And Statistical Values

Reference Range	12
Above Reference Range	0
Below Reference Range	0
Default Range	0
Total Test(s)	12

*Sr# From - To -*

N	10
Mean	84.4
SD	1.09
%CV	1.30
Range	3.5

## Test Statistics

Test	GGT	Report Type	Patients
Date From	10-Sep-2022	Date To	10-Sep-2022

Sample ID	PRE1	Patient Name	Age
#	Result Unit	Flag	Result Date
1	26.3 U/L	-	10-Sep-2022 16:16:18
2	25.7 U/L	-	10-Sep-2022 16:16:00
3	25.7 U/L	-	10-Sep-2022 16:15:42
4	25.2 U/L	-	10-Sep-2022 16:15:06
5	26.1 U/L	-	10-Sep-2022 16:14:48
6	25.6 U/L	-	10-Sep-2022 16:14:30
7	25.4 U/L	-	10-Sep-2022 16:14:11
8	25.7 U/L	-	10-Sep-2022 16:13:54
9	26.3 U/L	-	10-Sep-2022 16:13:35
0	25.2 U/L	-	10-Sep-2022 16:13:17

### Computed Ranges And Statistical Values

Reference Range	12
Above Reference Range	0
Below Reference Range	0
Default Range	0
Total Test(s)	12

*Sr# From - To -*

N	10
Mean	25.7
SD	0.40
%CV	1.57
Range	1.1

## Test Statistics

Test	CRENZ	Report Type	Patients
Date From	10-Sep-2022	Date To	10-Sep-2022

Sample ID	PRE1	Patient Name	Age		
#	Result Unit	Flag	Result Date	Curve #	Used Calibration
1	0.89 mg/dL	-	10-Sep-2022 16:23:49	235	10-Sep-2022 13:58:51
2	0.89 mg/dL	-	10-Sep-2022 16:23:31	234	10-Sep-2022 13:58:51
3	0.89 mg/dL	-	10-Sep-2022 16:23:13	233	10-Sep-2022 13:58:51
4	0.88 mg/dL	-	10-Sep-2022 16:22:55	232	10-Sep-2022 13:58:51
5	0.86 mg/dL	-	10-Sep-2022 16:22:19	230	10-Sep-2022 13:58:51
6	0.86 mg/dL	-	10-Sep-2022 16:22:01	229	10-Sep-2022 13:58:51
7	0.87 mg/dL	-	10-Sep-2022 16:21:43	228	10-Sep-2022 13:58:51
8	0.87 mg/dL	-	10-Sep-2022 16:21:25	227	10-Sep-2022 13:58:51
9	0.88 mg/dL	-	10-Sep-2022 16:20:49	225	10-Sep-2022 13:58:51
10	0.87 mg/dL	-	10-Sep-2022 16:20:31	224	10-Sep-2022 13:58:51

### Computed Ranges And Statistical Values

Reference Range	12
Above Reference Range	0
Below Reference Range	0
Default Range	0
Total Test(s)	12

*Sr# From - To -*

N	10
Mean	0.88
SD	0.01
%CV	1.34
Range	0.03

## Test Statistics

Test	CHOL	Report Type	Patients
Date From	10-Sep-2022	Date To	10-Sep-2022

Sample ID	PRE	Patient Name	Age			
r#	Result	Unit	Flag	Result Date	Curve #	Used Calibration
1	130	mg/dL	-	10-Sep-2022 16:09:23	187	10-Sep-2022 14:02:27
2	131	mg/dL	-	10-Sep-2022 16:08:47	185	10-Sep-2022 14:02:27
3	147	mg/dL	-	10-Sep-2022 16:08:28	184	10-Sep-2022 14:02:27
4	128	mg/dL	-	10-Sep-2022 16:08:11	183	10-Sep-2022 14:02:27
5	128	mg/dL	-	10-Sep-2022 16:07:52	182	10-Sep-2022 14:02:27
6	134	mg/dL	-	10-Sep-2022 16:07:34	181	10-Sep-2022 14:02:27
7	131	mg/dL	-	10-Sep-2022 16:07:16	180	10-Sep-2022 14:02:27
8	132	mg/dL	-	10-Sep-2022 16:06:58	179	10-Sep-2022 14:02:27
9	145	mg/dL	-	10-Sep-2022 16:06:40	178	10-Sep-2022 14:02:27
10	130	mg/dL	-	10-Sep-2022 16:06:22	177	10-Sep-2022 14:02:27

### Computed Ranges And Statistical Values

Reference Range	12
Above Reference Range	0
Below Reference Range	0
Default Range	0
Total Test(s)	12

#### Sr# From - To -

N	10
Mean	134
SD	6.79
%CV	5.08
Range	19



## Test Statistics

Test	BIT	Report Type	Patients
Date From	10-Sep-2022	Date To	10-Sep-2022

Sample ID	PRE	Patient Name	Age
#	Result Unit	Flag	Result Date
			Curve # Used Calibration
1	0.59 mg/dL	-	10-Sep-2022 16:05:46 175 10-Sep-2022 13:56:26
2	0.59 mg/dL	-	10-Sep-2022 16:05:10 173 10-Sep-2022 13:56:26
3	0.58 mg/dL	-	10-Sep-2022 16:04:52 172 10-Sep-2022 13:56:26
4	0.59 mg/dL	-	10-Sep-2022 16:04:34 171 10-Sep-2022 13:56:26
5	0.58 mg/dL	-	10-Sep-2022 16:04:16 170 10-Sep-2022 13:56:26
6	0.59 mg/dL	-	10-Sep-2022 16:03:58 169 10-Sep-2022 13:56:26
7	0.58 mg/dL	-	10-Sep-2022 16:03:40 168 10-Sep-2022 13:56:26
8	0.59 mg/dL	-	10-Sep-2022 16:03:22 167 10-Sep-2022 13:56:26
9	0.58 mg/dL	-	10-Sep-2022 16:03:04 166 10-Sep-2022 13:56:26
10	0.59 mg/dL	-	10-Sep-2022 16:02:46 165 10-Sep-2022 13:56:26

### Computed Ranges And Statistical Values

Reference Range	12
Above Reference Range	0
Below Reference Range	0
Default Range	0
Total Test(s)	12

*Sr# From - To -*

N	10
Mean	0.59
SD	0.01
%CV	0.88
Range	0.01

## Test Statistics

Test	BIT	Report Type	Patients
Date From	10-Sep-2022	Date To	10-Sep-2022

Sample ID	PRE	Patient Name	Age			
r#	Result	Unit	Flag	Result Date	Curve #	Used Calibration
1	0.59	mg/dL	-	10-Sep-2022 16:05:46	175	10-Sep-2022 13:56:26
2	0.59	mg/dL	-	10-Sep-2022 16:05:10	173	10-Sep-2022 13:56:26
3	0.58	mg/dL	-	10-Sep-2022 16:04:52	172	10-Sep-2022 13:56:26
4	0.59	mg/dL	-	10-Sep-2022 16:04:34	171	10-Sep-2022 13:56:26
5	0.58	mg/dL	-	10-Sep-2022 16:04:16	170	10-Sep-2022 13:56:26
6	0.59	mg/dL	-	10-Sep-2022 16:03:58	169	10-Sep-2022 13:56:26
7	0.58	mg/dL	-	10-Sep-2022 16:03:40	168	10-Sep-2022 13:56:26
8	0.59	mg/dL	-	10-Sep-2022 16:03:22	167	10-Sep-2022 13:56:26
9	0.58	mg/dL	-	10-Sep-2022 16:03:04	166	10-Sep-2022 13:56:26
10	0.59	mg/dL	-	10-Sep-2022 16:02:46	165	10-Sep-2022 13:56:26

### Computed Ranges And Statistical Values

Reference Range	12
Above Reference Range	0
Below Reference Range	0
Default Range	0
Total Test(s)	12

#### Sr# From - To -

N	10
Mean	0.59
SD	0.01
%CV	0.88
Range	0.01

## Test Statistics

Test	BIDD	Report Type	Patients
Date From	10-Sep-2022	Date To	10-Sep-2022

Sample ID	PRE	Patient Name	Age	Result Date	Curve #	Used Calibration
1	0.27	mg/dL	-	10-Sep-2022 16:01:51	162	10-Sep-2022 13:55:14
2	0.27	mg/dL	-	10-Sep-2022 16:01:33	161	10-Sep-2022 13:55:14
3	0.28	mg/dL	-	10-Sep-2022 16:01:15	160	10-Sep-2022 13:55:14
4	0.28	mg/dL	-	10-Sep-2022 16:00:39	158	10-Sep-2022 13:55:14
5	0.28	mg/dL	-	10-Sep-2022 16:00:21	157	10-Sep-2022 13:55:14
6	0.28	mg/dL	-	10-Sep-2022 16:00:03	156	10-Sep-2022 13:55:14
7	0.28	mg/dL	-	10-Sep-2022 15:59:45	155	10-Sep-2022 13:55:14
8	0.28	mg/dL	-	10-Sep-2022 15:59:27	154	10-Sep-2022 13:55:14
9	0.28	mg/dL	-	10-Sep-2022 15:59:09	153	10-Sep-2022 13:55:14
0	0.28	mg/dL	-	10-Sep-2022 15:58:51	152	10-Sep-2022 13:55:14

### Computed Ranges And Statistical Values

Reference Range	12
Above Reference Range	0
Below Reference Range	0
Default Range	0
Total Test(s)	12

*Sr# From - To -*

N	10
Mean	0.28
SD	0.00
%CV	1.52
Range	0.01



Date: 1-09-2022

## Calibration Certificate

Customer Name : Omega Path Lab NIT 5 Faridabad

Model : EM200

Serial No. : 2002941

Calibration Date : 1-09-2022

Calibration Due Date : 30-8-2023

*This is to certify that we have calibrated the Fully Automated Biochemistry Analyser , Model : EM 200 bearing Sr. No. 2002941 and on inspection of the instrument it is observed that the results are well within the range and instrument is working fine **Instrument is properly calibrated***

Thanking you,  
For Transasia Bio-Medicals Ltd.

  
**Devender Singh**  
Sr. Service Engineer



### Calibration Data

<b>Diffraction Grating Data:</b>				
Sr. No.	Filter	Gain Range	Measured Value	Ok Yes/No
	340	340-900	458	OK
	405	340-900	448	OK
	505	340-900	420	OK
	546	340-900	483	OK
	578	340-900	491	OK
	600	340-900	519	OK
	660	340-900	483	OK
	700	340-900	478	OK
<b>Reagent Tray Temperature:</b>				
		Range	Measured Value	Ok Yes/No
		4 -12 ° C	11°C	OK
<b>Reaction Cuvette Tray Temperature:</b>				
		Range	Measured Value	Ok Yes/No
		36.9 -37.1 °C	37.0	OK
<b>Water Pressure:</b>				
		Range	Measured Value	Ok Yes/No
		0.9 – 1.1 bar	1.0 bar	OK
<b>Lamp Voltage:</b>				
		Range	Measured Value	Ok Yes/No
		11.9 – 12.1 v	11.95 v	OK
<b>Cuvette Blank:</b>				
		Range	Measured Value	Ok Yes/No
		0.01 – 0.10	All in Range	OK

### Calibration Data

<b>Sample Syringe :</b>				
		Dispensed	Measured Value	Ok Yes/No
Dispense Volume	2µl	2µl	2µl	Ok
Dispense Volume	70µl	70 µl	70µl	Ok
<b>Reagent Syringe :</b>				
		Dispensed	Measured Value	Ok Yes/No
Dispense Volume	50µl	60µl	60µl	Ok
Dispense Volume	300µl	300µl	300µl	Ok

For Transasia Biomedicals Ltd



Devender Singh  
Sr. Service Engineer