



CERTIFICATE OF CALIBRATION/ VERIFICATION

Customer Name: SANJEEVANI LABORATORY
Model: Fully Automated Bio-Chemistry Analyzer-EM 200
Serial No: B2001058
Calibration Date: 10-11-2022
Next Calibration due on before : 09-11-2023
Calibrator Used: Multical Lot Number:2110192
Quality Control Used: Erba Norm Lot Number:S052024A

This is to certify that the above mentioned instrument has been verified of calibration according to the procedures provided by the manufacturer -

General Parameters:

Parameter	Measured Value	Acceptable Range	
Line Voltage	230V	230 V +/- 5%	Pass
Logic Voltage	5.0 V	4.9 V to 5.1 V	Pass
Lamp Voltage	12.0 V	11.8 V to 12.2 V	Pass
Flow cell Temperature	37.0 deg	37 +/- 0.5	Pass
45 Cuvette blank value for all filter	Enclose valuesheet for all cuvette	Abs 0.02-0.2	Pass



Photometer Filter Gain Levels:

s.no	Filter Value in nm	Filter Gain in mv	Acceptable Range of gain
	340	578	50 mv to 200 mv
	405	517	50 mv to 200 mv
	505	528	50 mv to 200 mv
	546	516	50 mv to 200 mv
	578	495	50 mv to 200 mv
	600	498	50 mv to 200 mv
	660	478	50 mv to 200 mv
	700	460	50 mv to 200 mv

*D.V.V.
Adam*

Technical Service Department

Transasia Bio-medical Limited



TRANSASIA BIOMEDICALS LIMITED			
INSTALLATION QUALIFICATION			
EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058

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TRANSASIA BIOMEDICALS LIMITED			
INSTALLATION QUALIFICATION			
EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058

1.0 PRE APPROVAL

1.1 Prepared By

Name	Designation	Signature	Date
Mr. Vaibhav Kadam	Senior Service Engineer	<i>V. Kadam</i>	01/12/22

1.2 Checked By

Name	Designation	Signature	Date
Mr. Sagar Sawant	Lab Incharge	<i>Sawant</i>	01/12/22
Sawant			

1.3 Approved By

Name	Designation	Signature	Date
Sagar Sawant	Lab Incharge	<i>Sawant</i>	01/12/22

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



TRANSASIA BIOMEDICALS LIMITED			
INSTALLATION QUALIFICATION			
EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058

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 startup 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



TRANSASIA BIOMEDICALS LIMITED			
INSTALLATION QUALIFICATION			
EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058

4.0 EXECUTION TEAM

Name	Department	Designation	Signature
Mr. Vaibhav Kadam	TBM	Senior Service Engineer	



TRANSASIA BIOMEDICALS LIMITED			
INSTALLATION QUALIFICATION			
EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058

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, 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



TRANSASIA BIOMEDICALS LIMITED			
INSTALLATION QUALIFICATION			
EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058

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.



TRANSASIA BIOMEDICALS LIMITED			
INSTALLATION QUALIFICATION			
EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058

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	<i>D.V.V. Custom</i>	<i>Nil</i>
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		
8 Stage Laundry System	Yes		
Light Source	Yes		
Sample Cups	Yes		
Software of EM 200	Yes		



TRANSASIA BIOMEDICALS LIMITED			
INSTALLATION QUALIFICATION			
EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058

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	
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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INSTALLATION QUALIFICATION			
EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058

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			
INSTALLATION QUALIFICATION			
EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058

Instrument/ Component Name: Sample Tray / Disk

Date :

Description	Specified	Actual	Method of Verification	Verified by Signature
No. of patient cups / samples	30 positions	30	Manually	
Standards / Stat	30 positions	30	Manually	
Blank	Can be put on any position	Yes	Manually	
ISE positions (Optional)	Can be programmed on any positions	Yes	Manually	
Controls	Can be programmed on any positions	Yes	Manually	



TRANSASIA BIOMEDICALS LIMITED			
INSTALLATION QUALIFICATION			
EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058

Instrument/ Component Name: Sample Syringe

Date :

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



TRANSASIA BIOMEDICALS LIMITED			
INSTALLATION QUALIFICATION			
EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058

Instrument/ Component Name: Sample Probe

Date :

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



TRANSASIA BIOMEDICALS LIMITED			
INSTALLATION QUALIFICATION			
EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058

Instrument/ Component Name: Wash Station for Sample Probe

Date :

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



TRANSASIA BIOMEDICALS LIMITED			
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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	50 positions	Manually	
Outer Rings	25 positions	25 positions	Manually	
Inner Rings	25 positions	25 positions	Manually	
Adaptors of 5mL	50 positions	50 positions	Manually	
Maintenance of Temperature	8-12°C ± 2°C	8-12°C ± 2°C	Manually	
Rotation of disk	Counter-Clockwise	Counter-Clockwise	Manually	
Time for Rotation of one Cuvette	Every 18 seconds	Every 18 seconds	Manually	



TRANSASIA BIOMEDICALS LIMITED			
INSTALLATION QUALIFICATION			
EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058

Instrument/ Component Name: Reagent Bottles

Date :

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



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INSTALLATION QUALIFICATION			
EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058

Instrument/ Component Name: Reagent Probe

Date :

Description	Specified	Actual	Method of Verification	Verified by Signature
Aspiration/Dispensing Volume	R1: 50 – 300 μ L	R1: 50 – 300 μ L	Manually	
	R2: 0 or 10 – 300 μ L	R2: 0 or 10 – 300 μ L	Manually	
MOC	Teflon coated	Teflon coated	Manually	
Quantity	02 Nos'.	02 Nos'.	Manually	
Increase in aspiration/dispensing volume	1 μ L	1 μ L	Manually	



TRANSASIA BIOMEDICALS LIMITED			
INSTALLATION QUALIFICATION			
EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058

Instrument/ Component Name: Reagent Syringe

Date :

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



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EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058

Instrument/ Component Name: Stirrer

Date :

Description	Specified	Actual	Method of Verification	Verified by Signature
Type	Single Stirrer	Single Stirrer	Manually	<i>D. V. V. Vadav</i>
No. of paddles	01 No.	01 No.	Manually	



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INSTALLATION QUALIFICATION			
EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058

Instrument/ Component Name: Permanent Reaction Cuvette

Tag/Identification No.:

Date :

Description	Specified	Actual	Method of Verification	Verified by Signature
Quantity	45 Nos'	45 Nos'	Manually	<i>D.V.V. Dabkin</i>
MOC	Hard Glass	Hard Glass	Manually	
Capacity	770 µL	770 µL	Manually	



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EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058

Instrument/ Component Name: 7 Stage Laundry System

Date : 26/08/2021

Description	Specified	Actual	Method of Verification	Verified by Signature
Nozzles	Nozzle - 1	Nozzle - 1	Manually	<i>D. V. V. Dastgiri</i>
	Nozzle - 2	Nozzle - 2	Manually	
	Nozzle - 3	Nozzle - 3	Manually	
	Nozzle - 4	Nozzle - 4	Manually	
	Nozzle - 5	Nozzle - 5	Manually	
	Nozzle - 6	Nozzle - 6	Manually	
	Nozzle - 7	Nozzle - 7	Manually	
	Nozzle - 8	Nozzle - 8	Manually	



TRANSASIA BIOMEDICALS LIMITED			
INSTALLATION QUALIFICATION			
EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058

Instrument/ Component Name: Light Source

Date : 26/08/2021

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



TRANSASIA BIOMEDICALS LIMITED			
INSTALLATION QUALIFICATION			
EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058

Instrument/ Component Name: Sample Cups

Date : 26/08/2021

Description	Specified	Actual	Method of Verification	Verified by Signature
Quantity	500 Nos'	500 Nos'	Manually	
MOC	Plastic	Plastic	Manually	
Capacity	2 mL	2 mL	Manually	



TRANSASIA BIOMEDICALS LIMITED			
INSTALLATION QUALIFICATION			
EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058

Instrument/ Component Name: Software of EM 200

Date :

Description	Specified	Actual	Method of Verification	Verified by Signature
Version	V2019.07A (EM200)TLS	V2019.07A (EM200)TLS	Manually	
CD number			Manually	
Product	EM- 200	EM- 200	Manually	
Make	Erba Transasia	Erba Transasia	Manually	



TRANSASIA BIOMEDICALS LIMITED			
INSTALLATION QUALIFICATION			
EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058

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 Probe	Teflon coated	Yes	Manually	
Reagent Probe	Teflon coated	Yes	Manually	
Permanent Reaction Cuvette	Hard Glass	Yes	Manually	
Light Source	Halogen	Yes	Manually	
Reagent Bottle	Plastic	Yes	Manually	
Sample Cups	Plastic	Yes	Manually	



TRANSASIA BIOMEDICALS LIMITED			
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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	Connected and identified	
Distilled Water	Connected and identified	
Wash Solution	Connected and identified	
UPS	Connected and identified	



TRANSASIA BIOMEDICALS LIMITED			
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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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12.0 IDENTIFICATION AND VERIFICATION OF DOCUMENTS

12.1 DRAWINGS

Title	Drawing No.	Verified by Sign & Date
As-built Drawing	NA	<i>D.V.V. Coctum</i>



TRANSASIA BIOMEDICALS LIMITED			
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12.2 GENERAL DOCUMENTS

Title	Document No.	Verified by Sign & Date
General		
Purchase Order No.		<i>Don V. Eckert</i>
Warranty Certificate		
Invoice		
Test Certificates		
Material of Construction		<i>Don V. Eckert</i>
Electrical Motor		



TRANSASIA BIOMEDICALS LIMITED			
INSTALLATION QUALIFICATION			
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13.0 DEFICIENCIES / DEVIATIONS:

No Deficiencies or deviations found.

Reviewed by:

Name	Signature	Date
Mr. Vaibhav Kadam		11/12/22



TRANSASIA BIOMEDICALS LIMITED			
INSTALLATION QUALIFICATION			
EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058



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INSTALLATION QUALIFICATION			
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14.0 SUMMARY AND EVALUATION:

Reviewed by:

Name	Signature	Date
Mr.Vaibhav Kadam		01/12/22



TRANSASIA BIOMEDICALS LIMITED			
INSTALLATION QUALIFICATION			
EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058



TRANSASIA BIOMEDICALS LIMITED			
INSTALLATION QUALIFICATION			
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15.0 ABBREVIATIONS

SOP	Standard Operating Procedure
MOC	Material of Construction
IQ	Installation Qualification

Transasia Bio-Medicals Ltd., Transasia House, 8 Chandivali Studio Road, Andheri (East), Mumbai - 400 072
 Tel: +91 22 40301930 Fax: +91 22 2857 3030 Email: @transasia.co.in



Name	Designation	Signature	Date
TRANSASIA BIOMEDICALS LIMITED			
INSTALLATION QUALIFICATION			
EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058
16.0 POST APPROVAL:			

16.1 Checked by

Mr. Sagar Sawant
 Lab Incharge

Sawant
 11/12/22

16.2 Approved by

Mr. Sagar Sawant
 Lab Incharge

Sawant
 11/12/22

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



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OPERATIONAL QUALIFICATION CHECKLIST			
EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058

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 feedback 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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OPERATIONAL QUALIFICATION CHECKLIST			
EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058

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 feedback 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			
OPERATIONAL QUALIFICATION CHECKLIST			
EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058



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.	Yes	<i>D.V.V. Cadam</i>	NA
Ensure the proper filling of double distilled / de-ionized water and Cleaning solution in the respective cans.	Yes	<i>D.V.V. Cadam</i>	NA
Ensure the availability of XL Wash.	Yes	<i>D.V.V. Cadam</i>	NA
Ensure the availability of Biohazard Waste.	Yes	<i>D.V.V. Cadam</i>	NA
Ensure the availability of Normal Waste.	Yes	<i>D.V.V. Cadam</i>	NA
Switch ON the rear switch of the analyser.	Yes	<i>D.V.V. Cadam</i>	NA
Switch ON the side switch of the analyser.	Yes	<i>D.V.V. Cadam</i>	NA
Switch ON the computer and start the analyzer application software.	Yes	<i>D.V.V. Cadam</i>	NA
Initialization	Yes	<i>D.V.V. Cadam</i>	NA



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OPERATIONAL QUALIFICATION CHECKLIST			
EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058

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	Yes	<i>M. Vaibhav Kadam</i>	NA
Cuvette Rinse	Yes	<i>M. Vaibhav Kadam</i>	NA

Name	Designation	Signature	Date
Mr. Vaibhav Kadam	Senior Service Engineer	<i>M. Vaibhav Kadam</i>	01/12/22

Checked By

Name	Designation	Signature	Date
<i>Sagar Sawant</i>	<i>Lab Incharge</i>	<i>Sawant</i>	<i>01/12/22</i>



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OPERATIONAL QUALIFICATION CHECKLIST			
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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 (Sign & Date)	Remarks
Reagent Level Scan, Dead Volume Check & 2 Reagent Chemistry	Yes	<i>Dr. V. V. Kadam</i>	NA

Name	Designation	Signature	Date
Mr. Vaibhav Kadam	Senior Service Engineer	<i>Dr. V. V. Kadam</i>	11/12/22

Checked By

Name	Designation	Signature	Date
<i>Sagar Sawant</i>	<i>Lab Incharge</i>	<i>Sawant</i>	11/12/22



TRANSASIA BIOMEDICALS LIMITED			
OPERATIONAL QUALIFICATION CHECKLIST			
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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)	Yes	<i>Dev V. Kadam</i>	NA
Standard (Multical)	Yes	<i>Dev V. Kadam</i>	NA

Name	Designation	Signature	Date
Mr. Vaibhav Kadam	Senior Service Engineer	<i>Dev V. Kadam</i>	01/12/22

Checked By

Name	Designation	Signature	Date
Sagar Sawant	Lab Incharge	<i>Sawant</i>	01/12/22



TRANSASIA BIOMEDICALS LIMITED			
OPERATIONAL QUALIFICATION CHECKLIST			
EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058



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	Yes	<i>D.V.V. Kadam</i>	NA
Less volume of Wash Solution	Yes	<i>D.V.V. Kadam</i>	NA
More volume of Bio-Hazard waste	Yes	<i>D.V.V. Kadam</i>	NA
More volume of Normal / General waste	Yes	<i>D.V.V. Kadam</i>	NA

Name	Designation	Signature	Date
Mr. Vaibhav Kadam	Senior Service Engineer	<i>D.V.V. Kadam</i>	01/12/22

Checked By

Name	Designation	Signature	Date
<i>Sagar Sawant</i>	<i>Lab Incharge</i>	<i>Sawant</i>	<i>01/12/22</i>



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TRANSASIA BIOMEDICALS LIMITED			
OPERATIONAL QUALIFICATION CHECKLIST			
EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058

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	Yes	<i>Dev V Kadam</i>	NA
Password Check for QC Mode	Yes	<i>Dev V Kadam</i>	NA

Name	Designation	Signature	Date
Mr. Vaibhav Kadam	Senior Service Engineer	<i>Dev V Kadam</i>	01/12/22

Checked By

Name	Designation	Signature	Date
<i>Sagar Sawant</i>	<i>Lab Incharge</i>	<i>Sawant</i>	01/12/22



TRANSASIA BIOMEDICALS LIMITED			
OPERATIONAL QUALIFICATION CHECKLIST			
EM200	Clinical Chemistry Analyzer	Instrument ID B2001058	

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	Yes	<i>Dev. V. Kadam</i>	NA
Water Save	Yes	<i>Dev. V. Kadam</i>	NA
Switch OFF the computer.	Yes	<i>Dev. V. Kadam</i>	NA
Switch OFF the side switch of the analyzer.	Yes	<i>Dev. V. Kadam</i>	NA
Switch OFF the rear switch of the analyzer.	Yes	<i>Dev. V. Kadam</i>	NA

Name	Designation	Signature	Date
Mr. Vaibhav Kadam	Senior Service Engineer	<i>Dev. V. Kadam</i>	01/12/22

Checked By

Name	Designation	Signature	Date
<i>Sagar Sawant</i>	<i>Lab Incharge</i>	<i>Sawant</i>	01/12/22



TRANSASIA BIOMEDICALS LIMITED			
PERFORMANCE QUALIFICATION			
EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058

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TRANSASIA BIOMEDICALS LIMITED			
PERFORMANCE QUALIFICATION			
EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058

1.0 PRE APPROVAL

1.1 Prepared By

Name	Designation	Signature	Date
Mr.Krishnakant Seegarla	Application Specialist		01/12/22

1.2 Checked By

Name	Designation	Signature	Date
Sagar Sawant	Lab Incharge		01/12/22

1.3 Approved By

Name	Designation	Signature	Date
Sagar Sawant	Lab Incharge		01/12/22



TRANSASIA BIOMEDICALS LIMITED			
PERFORMANCE QUALIFICATION			
EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058

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
Mr.Krishnakant Seegarla	TBM	Application Specialist	



TRANSASIA BIOMEDICALS LIMITED			
PERFORMANCE QUALIFICATION			
EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058

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7.0 EXECUTION OF TEST PLAN

- 1) Glucose
- 2) Cholesterol
- 3) Triglyceride
- 4) Urea
- 5) S/CPT

Reviewed by:

Name	Signature	Date
Mr.Krishnakant Seegarla		01/12/22



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PERFORMANCE QUALIFICATION			
EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058

NA



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EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058

8.0 DEFICIENCIES / DEVIATIONS:

No Deviations found

Reviewed by:

Name	Signature	Date
Mr.Krishnakant Seegarla		01/12/22



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PERFORMANCE QUALIFICATION			
EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058

Handwritten signature



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PERFORMANCE QUALIFICATION			
EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058

9.0 SUMMARY AND EVALUATION:

Attached the raw data.

Reviewed by:

Name	Signature	Date
Mr.Krishnakant Seegarla		01/12/22



TRANSASIA BIOMEDICALS LIMITED			
PERFORMANCE QUALIFICATION			
EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058

10.0 ABBREVIATIONS

SOP	Standard Operating Procedure
MOC	Material of Construction
PQ	Performance Qualification



TRANSASIA BIOMEDICALS LIMITED			
PERFORMANCE QUALIFICATION			
EM200	Clinical Chemistry Analyzer	Instrument ID	B2001058

11.0 POST APPROVAL

11.1 Checked by

Name	Designation	Signature	Date
Mr.Krishnakant Seegarla	Application Specialist		01/12/22

11.2 Approved by

Name	Designation	Signature	Date
Sagar Sawant	Sagar Sawant		01/12/22

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

Photometric ISE ReCalculated All Abnormal Result Deleted Test
 Calculated Items Offline Rerun Rerun Result Undo Selection
 Show Sample Remark Show Patient Remark (X)

Result Date	Sample ID	Sample Type	Patient Name	Age	Category	Test	Result	Unit	Flag	Normal Range
11-Nov-2022	Precision ...	SERUM	Precision Check 2	-	Default	BIT	2.98	mg/dl	H	0.00 - 2.00 mg/dl
11-Nov-2022	Precision ...	SERUM	Precision Check 2	-	Default	BIT	2.97	mg/dl	H	0.00 - 2.00 mg/dl
11-Nov-2022	Precision ...	SERUM	Precision Check 2	-	Default	BIT	3.00	mg/dl	H	0.00 - 2.00 mg/dl
11-Nov-2022	Precision ...	SERUM	Precision Check 2	-	Default	BIT	2.98	mg/dl	H	0.00 - 2.00 mg/dl
11-Nov-2022	Precision ...	SERUM	Precision Check 2	-	Default	UREA	46.3	mg/dl		18.0 - 55.0 mg/dl
11-Nov-2022	Precision ...	SERUM	Precision Check 2	-	Default	UREA	49.2	mg/dl		18.0 - 55.0 mg/dl
11-Nov-2022	Precision ...	SERUM	Precision Check 2	-	Default	UREA	45.4	mg/dl		18.0 - 55.0 mg/dl
11-Nov-2022	Precision ...	SERUM	Precision Check 2	-	Default	UREA	47.0	mg/dl		18.0 - 55.0 mg/dl
11-Nov-2022	Precision ...	SERUM	Precision Check 2	-	Default	UREA	46.6	mg/dl		18.0 - 55.0 mg/dl
11-Nov-2022	Precision ...	SERUM	Precision Check 2	-	Default	UREA	47.6	mg/dl		18.0 - 55.0 mg/dl
11-Nov-2022	Precision ...	SERUM	Precision Check 2	-	Default	UREA	46.8	mg/dl		18.0 - 55.0 mg/dl
11-Nov-2022	Precision ...	SERUM	Precision Check 2	-	Default	UREA	49.4	mg/dl		18.0 - 55.0 mg/dl
11-Nov-2022	Precision ...	SERUM	Precision Check 2	-	Default	UREA	50.0	mg/dl		18.0 - 55.0 mg/dl
11-Nov-2022	Precision ...	SERUM	Precision Check 2	-	Default	UREA	46.4	mg/dl		18.0 - 55.0 mg/dl
11-Nov-2022	Precision ...	SERUM	Precision Check 2	-	Default	CHOL	144	mg/dl		0 - 200 mg/dl
11-Nov-2022	Precision ...	SERUM	Precision Check 2	-	Default	CHOL	141	mg/dl		0 - 200 mg/dl
11-Nov-2022	Precision ...	SERUM	Precision Check 2	-	Default	CHOL	142	mg/dl		0 - 200 mg/dl
11-Nov-2022	Precision ...	SERUM	Precision Check 2	-	Default	CHOL	139	mg/dl		0 - 200 mg/dl
11-Nov-2022	Precision ...	SERUM	Precision Check 2	-	Default	CHOL	141	mg/dl		0 - 200 mg/dl
11-Nov-2022	Precision ...	SERUM	Precision Check 2	-	Default	CHOL	141	mg/dl		0 - 200 mg/dl
11-Nov-2022	Precision ...	SERUM	Precision Check 2	-	Default	CHOL	143	mg/dl		0 - 200 mg/dl
11-Nov-2022	Precision ...	SERUM	Precision Check 2	-	Default	CHOL	150	mg/dl		0 - 200 mg/dl
11-Nov-2022	Precision ...	SERUM	Precision Check 2	-	Default	CHOL	143	mg/dl		0 - 200 mg/dl
11-Nov-2022	Precision ...	SERUM	Precision Check 2	-	Default	CHOL	143	mg/dl		0 - 200 mg/dl

Indication : Please select data to Print.

<input checked="" type="radio"/> Photometric <input type="radio"/> ISE <input type="radio"/> ReCalculated <input type="radio"/> All <input type="radio"/> Calculated Items <input type="radio"/> Offline		<input type="checkbox"/> Abnormal Result <input checked="" type="checkbox"/> Deleted Test <input type="checkbox"/> Rerun Result <input checked="" type="checkbox"/> Deleted Test								
Result Date	Sample ID	Sample Type	Patient Name	Age	Category	Test	Result	Unit	Flag	Normal Range
<input type="checkbox"/>	11-Nov-2022	Precision ...	Precision Check 2	-	Default	SGPTD	54.3	U/L	H	0.0 - 45.0 U/L
<input type="checkbox"/>	11-Nov-2022	Precision ...	Precision Check 2	-	Default	SGPTD	57.0	U/L	H	0.0 - 45.0 U/L
<input type="checkbox"/>	11-Nov-2022	Precision ...	Precision Check 2	-	Default	BIT	3.04	mg/dl	H	0.00 - 2.00 mg/dl
<input type="checkbox"/>	11-Nov-2022	Precision ...	Precision Check 2	-	Default	BIT	3.00	mg/dl	H	0.00 - 2.00 mg/dl
<input type="checkbox"/>	11-Nov-2022	Precision ...	Precision Check 2	-	Default	BIT	2.97	mg/dl	H	0.00 - 2.00 mg/dl
<input type="checkbox"/>	11-Nov-2022	Precision ...	Precision Check 2	-	Default	BIT	2.97	mg/dl	H	0.00 - 2.00 mg/dl
<input type="checkbox"/>	11-Nov-2022	Precision ...	Precision Check 2	-	Default	BIT	2.97	mg/dl	H	0.00 - 2.00 mg/dl
<input type="checkbox"/>	11-Nov-2022	Precision ...	Precision Check 2	-	Default	BIT	2.98	mg/dl	H	0.00 - 2.00 mg/dl
<input type="checkbox"/>	11-Nov-2022	Precision ...	Precision Check 2	-	Default	BIT	2.98	mg/dl	H	0.00 - 2.00 mg/dl
<input type="checkbox"/>	11-Nov-2022	Precision ...	Precision Check 2	-	Default	BIT	2.97	mg/dl	H	0.00 - 2.00 mg/dl
<input type="checkbox"/>	11-Nov-2022	Precision ...	Precision Check 2	-	Default	BIT	2.97	mg/dl	H	0.00 - 2.00 mg/dl
<input type="checkbox"/>	11-Nov-2022	Precision ...	Precision Check 2	-	Default	BIT	3.00	mg/dl	H	0.00 - 2.00 mg/dl
<input type="checkbox"/>	11-Nov-2022	Precision ...	Precision Check 2	-	Default	BIT	2.98	mg/dl	H	0.00 - 2.00 mg/dl
<input type="checkbox"/>	11-Nov-2022	Precision ...	Precision Check 2	-	Default	UREA	46.3	mg/dl	H	18.0 - 55.0 mg/dl
<input type="checkbox"/>	11-Nov-2022	Precision ...	Precision Check 2	-	Default	UREA	49.2	mg/dl	H	18.0 - 55.0 mg/dl
<input type="checkbox"/>	11-Nov-2022	Precision ...	Precision Check 2	-	Default	UREA	45.4	mg/dl	H	18.0 - 55.0 mg/dl
<input type="checkbox"/>	11-Nov-2022	Precision ...	Precision Check 2	-	Default	UREA	47.0	mg/dl	H	18.0 - 55.0 mg/dl
<input type="checkbox"/>	11-Nov-2022	Precision ...	Precision Check 2	-	Default	UREA	46.6	mg/dl	H	18.0 - 55.0 mg/dl
<input type="checkbox"/>	11-Nov-2022	Precision ...	Precision Check 2	-	Default	UREA	47.6	mg/dl	H	18.0 - 55.0 mg/dl
<input type="checkbox"/>	11-Nov-2022	Precision ...	Precision Check 2	-	Default	UREA	46.8	mg/dl	H	18.0 - 55.0 mg/dl
<input type="checkbox"/>	11-Nov-2022	Precision ...	Precision Check 2	-	Default	UREA	49.4	mg/dl	H	18.0 - 55.0 mg/dl
<input type="checkbox"/>	11-Nov-2022	Precision ...	Precision Check 2	-	Default	UREA	50.0	mg/dl	H	18.0 - 55.0 mg/dl
<input type="checkbox"/>	11-Nov-2022	Precision ...	Precision Check 2	-	Default	UREA	46.4	mg/dl	H	18.0 - 55.0 mg/dl
<input type="checkbox"/>	11-Nov-2022	Precision ...	Precision Check 2	-	Default	CHOL	144	mg/dl	H	0 - 200 mg/dl
<input type="checkbox"/>	11-Nov-2022	Precision ...	Precision Check 2	-	Default	CHOL	141	mg/dl	H	0 - 200 mg/dl

Indication : Please select data to Print.



Result Date	Sample ID	Sample Type	Patient Name	Age	Category	Test	Result	Unit	Flag	Normal Range
11-Nov-2022	9 Nathuram	SERUM		-	Default	BIT	2.44	mg/dl	H	0.00 - 2.00 mg/dl
11-Nov-2022	9 Nathuram	SERUM		-	Default	CRENZ	0.70	mg/dl		0.70 - 1.30 mg/dl
11-Nov-2022	9 Nathuram	SERUM		-	Default	GLU1	109.8	mg/dl	H	74.0 - 100.0 mg/dl
11-Nov-2022	Precision ...	SERUM	Precision Check 1	-	Default	GLU1	291.0	mg/dl	H	74.0 - 100.0 mg/dl
11-Nov-2022	Precision ...	SERUM	Precision Check 1	-	Default	GLU1	288.3	mg/dl	H	74.0 - 100.0 mg/dl
11-Nov-2022	Precision ...	SERUM	Precision Check 1	-	Default	GLU1	293.0	mg/dl	H	74.0 - 100.0 mg/dl
11-Nov-2022	Precision ...	SERUM	Precision Check 1	-	Default	GLU1	284.4	mg/dl	H	74.0 - 100.0 mg/dl
11-Nov-2022	Precision ...	SERUM	Precision Check 1	-	Default	GLU1	284.1	mg/dl	H	74.0 - 100.0 mg/dl
11-Nov-2022	Precision ...	SERUM	Precision Check 1	-	Default	GLU1	284.1	mg/dl	H	74.0 - 100.0 mg/dl
11-Nov-2022	Precision ...	SERUM	Precision Check 1	-	Default	GLU1	286.5	mg/dl	H	74.0 - 100.0 mg/dl
11-Nov-2022	Precision ...	SERUM	Precision Check 1	-	Default	GLU1	286.3	mg/dl	H	74.0 - 100.0 mg/dl
11-Nov-2022	Precision ...	SERUM	Precision Check 1	-	Default	GLU1	285.9	mg/dl	H	74.0 - 100.0 mg/dl
11-Nov-2022	Precision ...	SERUM	Precision Check 1	-	Default	GLU1	285.7	mg/dl	H	74.0 - 100.0 mg/dl
11-Nov-2022	Precision ...	SERUM	Precision Check 2	-	Default	SGPTD	54.0	U/L	H	0.0 - 45.0 U/L
11-Nov-2022	Precision ...	SERUM	Precision Check 2	-	Default	SGPTD	54.3	U/L	H	0.0 - 45.0 U/L
11-Nov-2022	Precision ...	SERUM	Precision Check 2	-	Default	SGPTD	55.8	U/L	H	0.0 - 45.0 U/L
11-Nov-2022	Precision ...	SERUM	Precision Check 2	-	Default	SGPTD	56.4	U/L	H	0.0 - 45.0 U/L
11-Nov-2022	Precision ...	SERUM	Precision Check 2	-	Default	SGPTD	57.0	U/L	H	0.0 - 45.0 U/L
11-Nov-2022	Precision ...	SERUM	Precision Check 2	-	Default	SGPTD	54.6	U/L	H	0.0 - 45.0 U/L
11-Nov-2022	Precision ...	SERUM	Precision Check 2	-	Default	SGPTD	55.5	U/L	H	0.0 - 45.0 U/L
11-Nov-2022	Precision ...	SERUM	Precision Check 2	-	Default	SGPTD	54.6	U/L	H	0.0 - 45.0 U/L
11-Nov-2022	Precision ...	SERUM	Precision Check 2	-	Default	SGPTD	54.3	U/L	H	0.0 - 45.0 U/L
11-Nov-2022	Precision ...	SERUM	Precision Check 2	-	Default	SGPTD	57.0	U/L	H	0.0 - 45.0 U/L
11-Nov-2022	Precision ...	SERUM	Precision Check 2	-	Default	BIT	3.04	mg/dl	H	0.00 - 2.00 mg/dl

Indication : Please select data to Print.

