



Calibration Certificate


This is to certify that the Fully Automatic Biochemistry Analyser Erba **EM-200**
Sr. No.-2002400 Installed at :

SUNSHINE LAB & DIAGNOSTICS
(A UNIT OF AMAR GREENGRASS HEALTHCARE & DIAGNOSTICS PVT. LTD.)

ADD: RZ A-1/7, PIPAL WALI GALI, MAHAVIR ENCLAVE, NEW DELHI- 110045

Has been fully calibrated and Qc has been run and found to be in range.
The calibration data is enclosed.

For Transasia Biomedicals Ltd


19/10/2021
krishan kumar
Sr. Service Engineer
Delhi.

Calibration Data




Diffraction Grating Data:				
Sr. No.	Filter	Gain Range	Measured Value	Ok Yes/No
	340	350-900	626	OK
	405	350-900	506	OK
	505	350-900	505	OK
	546	350-900	457	OK
	578	350-900	476	OK
	600	350-900	445	OK
	660	350-900	515	OK
	700	350-900	442	OK
Reagent Tray Temperature:				
		Range	Measured Value	Ok Yes/No
		4 -12 ° C	8°C	OK
Reaction Cuvette Tray Temperature:				
		Range	Measured Value	Ok Yes/No
		36.9 -37.1 °C	37.0	OK
Water Pressure:				
		Range	Measured Value	Ok Yes/No
		0.9 – 1.1 bar	1.0 bar	OK
Lamp Voltage:				
		Range	Measured Value	Ok Yes/No
		11.9 – 12.1 v	12.0 v	OK
Cuvette Blank:				
		Range	Measured Value	Ok Yes/No
		0.01 – 0.10	All in Range	OK

For Transasia Biomedicals Ltd

19/10/2021


KRISHAN KUMAR
 Sr. Service Engineer
 Delhi.

TRANSASIA BIOMEDICALS LIMITED				
TRAINING CERTIFICATE				
Instrument Name EM200	CLINICAL BIOCHEMISTRY ANALYZER	Instrument ID	2002400	

7th May 2021

TRAINING CERTIFICATE

TO WHOMSOEVER IT MAY CONCERN

This is to Certify that Mr./MS ABHINAV KUMAR THAKUR Technical Staff Team of Sunshine Lab and Diagnostics, Mahaveer Enclave, Delhi, 110045 have successfully completed training on operation and maintenance, under supervision of our Application Specialist Amit Pal. Training held on:- Fully Automated Analyzer, Model: EM200



Amit Pal
Sr. Application Specialist

For Transasia Bio-Medicals Ltd.



Calibration Certificate


This is to certify that the Fully Automatic Biochemistry Analyser Erba **EM-200**
Sr. No.-2002400 Installed at :

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For Transasia Biomedicals Ltd


19/10/2021
krishan kumar
Sr. Service Engineer
Delhi.

Calibration Data



UNMATCHED SERVICE
SINCE 1979...

Diffraction Grating Data:				
Sr. No.	Filter	Gain Range	Measured Value	Ok Yes/No
	340	350-900	626	OK
	405	350-900	506	OK
	505	350-900	505	OK
	546	350-900	457	OK
	578	350-900	476	OK
	600	350-900	445	OK
	660	350-900	515	OK
	700	350-900	442	OK
Reagent Tray Temperature:				
		Range	Measured Value	Ok Yes/No
		4 -12 ° C	8°C	OK
Reaction Cuvette Tray Temperature:				
		Range	Measured Value	Ok Yes/No
		36.9 -37.1 ° C	37.0	OK
Water Pressure:				
		Range	Measured Value	Ok Yes/No
		0.9 – 1.1 bar	1.0 bar	OK
Lamp Voltage:				
		Range	Measured Value	Ok Yes/No
		11.9 – 12.1 v	12.0 v	OK
Cuvette Blank:				
		Range	Measured Value	Ok Yes/No
		0.01 – 0.10	All in Range	OK

For Transasia Biomedicals Ltd

19/10/2021


KRISHAN KUMAR
Sr. Service Engineer
Delhi.

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA[®] Bio-Medicals Ltd.
INSTALLATION QUALIFICATION for SUNSHINE LAB & DIAGNOSTICS				
Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400	


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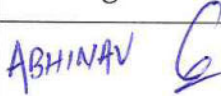
TRANSASIA BIOMEDICALS LIMITED				TRANSASIA® Bio-Medicals Ltd.
INSTALLATION QUALIFICATION for SUNSHINE LAB & DIAGNOSTICS				
Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400	

1.0 PRE APPROVAL

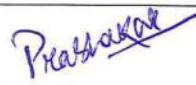
1.1 Prepared By

Name	Designation	Signature	Date
Amit Pal	Sr. Application Specialist		19-10-2021

1.2 Checked By

Name	Designation	Signature	Date
Mr. Abhinav Thakur	Lab Technologist		19-10-2021

1.3 Approved By

Name	Designation	Signature	Date
Dr. P A Kumar	HOD		19-10-2021

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

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA® Bio-Medicals Ltd.
INSTALLATION QUALIFICATION for SUNSHINE LAB & DIAGNOSTICS				
Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400	

2.0 OBJECTIVE

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

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


3.0 SCOPE

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

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

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INSTALLATION QUALIFICATION for SUNSHINE LAB & DIAGNOSTICS				
Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400	

4.0 EXECUTION TEAM

Name	Department	Designation	Signature
Amit Pal	TSD	Sr. Application Specialist	

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INSTALLATION QUALIFICATION for SUNSHINE LAB & DIAGNOSTICS				
Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400	

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

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INSTALLATION QUALIFICATION for SUNSHINE LAB & DIAGNOSTICS				
Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400	

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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Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400


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	Anil	Ok
Sample Syringe			
Sample Probe			
Wash Station for Sample Probe			
Reagent Tray / Disk			
Reagent Bottles			
Reagent Probe			
Stirrer			
Permanent Reaction Cuvette			
9 Stage Laundry System			
Light Source			
Sample Cups			
Software of EM 200			

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INSTALLATION QUALIFICATION for SUNSHINE LAB & DIAGNOSTICS				
Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400	

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

TRANSASIA BIOMEDICALS LIMITED				
INSTALLATION QUALIFICATION for SUNSHINE LAB & DIAGNOSTICS				
Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400	

8.0 INSPECTION CHECK / REVIEW

Instructions for completing the check / review

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

"No" replies must be explained / justified.

2. When more than one component of same specification/type exists in the same equipment, individual data sheets should be filled for each component.
3. When a list of acceptable options is presented, tick (✓) the option that is actually present.
4. In the "**Method of Verification**" column indicate that item is installed and inspected according to manufacturer's specifications, such as by Visual / Physical, SOP, Test Certificate, Manual, etc.

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA® Bio-Medicals Ltd.
INSTALLATION QUALIFICATION for SUNSHINE LAB & DIAGNOSTICS				
Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400	

Instrument/ Component Name: Sample Tray / Disk

Date : 19-10-2021

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

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INSTALLATION QUALIFICATION for SUNSHINE LAB & DIAGNOSTICS				
Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400	

Instrument/ Component Name: Sample Syringe


Date : 19-10-2021

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

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INSTALLATION QUALIFICATION for SUNSHINE LAB & DIAGNOSTICS				
Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400	

Instrument/ Component Name: Sample Probe

Date : 19-10-2021

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

TRANSASIA BIOMEDICALS LIMITED

INSTALLATION QUALIFICATION for SUNSHINE LAB & DIAGNOSTICS



Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400
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Instrument/ Component Name: Wash Station for Sample Probe

Date : 19-10-2021

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

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INSTALLATION QUALIFICATION for SUNSHINE LAB & DIAGNOSTICS				
Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400	

Instrument/ Component Name: Reagent Tray / Disk

Date :19-10-2021

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

TRANSASIA BIOMEDICALS LIMITED

INSTALLATION QUALIFICATION for SUNSHINE LAB & DIAGNOSTICS



Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400
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Instrument/ Component Name: Reagent Bottles

Date : 19-10-2021

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

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INSTALLATION QUALIFICATION for SUNSHINE LAB & DIAGNOSTICS				
Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400	

Instrument/ Component Name: Reagent Probe

Date : 19-10-2021

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

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INSTALLATION QUALIFICATION for SUNSHINE LAB & DIAGNOSTICS				
Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400	

Instrument/ Component Name: Reagent Syringe


Date : 19-10-2021

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

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INSTALLATION QUALIFICATION for SUNSHINE LAB & DIAGNOSTICS				
Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400	

Instrument/ Component Name: Stirrer

Date : 19-10-2021

Description	Specified	Actual	Method of Verification	Verified by Signature
Type	Single Stirrer	OK	physical	
No. of paddles	01 No.			

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INSTALLATION QUALIFICATION for SUNSHINE LAB & DIAGNOSTICS				
Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400	

Instrument/ Component Name: Permanent Reaction Cuvette

Date : 19-10-2021

Description	Specified	Actual	Method of Verification	Verified by Signature
Quantity	45 Nos'	OK	physical	Anish
MOC	Hard Glass			
Capacity	770 µL			

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INSTALLATION QUALIFICATION for SUNSHINE LAB & DIAGNOSTICS				
Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400	

Instrument/ Component Name: 7 Stage Laundry System

Date : 19-10-2021

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

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INSTALLATION QUALIFICATION for SUNSHINE LAB & DIAGNOSTICS				
Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400	

Instrument/ Component Name: Light Source

Date : 19-10-2021

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

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INSTALLATION QUALIFICATION for SUNSHINE LAB & DIAGNOSTICS				
Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400	

Instrument/ Component Name: Sample Cups

Date : 19-10-2021

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

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA® Bio-Medicals Ltd.
INSTALLATION QUALIFICATION for SUNSHINE LAB & DIAGNOSTICS				
Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400	

Instrument/ Component Name: Software of EM 200

Date : 19-10-2021

Description	Specified	Actual	Method of Verification	Verified by Signature
Version	2019.07A	for	Physical	Anib
CD number	N/A			
Product	EM- 200			
Make	Erba Transasia			

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA® Bio-Medicals Ltd.
INSTALLATION QUALIFICATION for SUNSHINE LAB & DIAGNOSTICS				
Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400	

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	} OK	Physical	Anish
Reagent Probe	Teflon coated			
Permanent Reaction Cuvette	Hard Glass			
Light Source	Halogen			
Reagent Bottle	Plastic			
Sample Cups	Plastic			

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INSTALLATION QUALIFICATION for SUNSHINE LAB & DIAGNOSTICS			
Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400

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	} ok	 19/10/21
Distilled Water		
Wash Solution		
UPS		

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INSTALLATION QUALIFICATION for SUNSHINE LAB & DIAGNOSTICS				
Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400	

11.0 IDENTIFICATION OF STANDARD OPERATING PROCEDURE

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

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INSTALLATION QUALIFICATION for SUNSHINE LAB & DIAGNOSTICS			
Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400

12.0 IDENTIFICATION AND VERIFICATION OF DOCUMENTS

12.1 DRAWINGS

Title	Drawing No.	Verified by Sign & Date
As-built Drawing	N/A	<i>Amik</i> 19/10/14

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INSTALLATION QUALIFICATION for SUNSHINE LAB & DIAGNOSTICS			
Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400

12.2 GENERAL DOCUMENTS


Title	Document No.	Verified by Sign & Date
General		
Purchase Order No.	N/A	<i>Amk</i> 19/10/21
Warranty Certificate	N/A	
Invoice	N/A	
Test Certificates		
Material of Construction	N/A	<i>Amk</i> 17/10/21
Electrical Motor	OK	

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INSTALLATION QUALIFICATION for SUNSHINE LAB & DIAGNOSTICS				
Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400	

13.0 DEFICIENCIES / DEVIATIONS:

NO DEVIATION

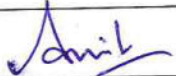
Reviewed by:

Name	Signature	Date
Amit Pal		19-10-2021

TRANSASIA BIOMEDICALS LIMITED			TRANSASIA[®] Bio-Medicals Ltd.
INSTALLATION QUALIFICATION for SUNSHINE LAB & DIAGNOSTICS			
Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400

14.0 SUMMARY AND EVALUATION:

Reviewed by:

Name	Signature	Date
Amit Pal		19-10-2021

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA[®] Bio-Medicals Ltd.
INSTALLATION QUALIFICATION for SUNSHINE LAB & DIAGNOSTICS				
Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400	

15.0 ABBREVIATIONS

SOP	Standard Operating Procedure
MOC	Material of Construction
IQ	Installation Qualification

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INSTALLATION QUALIFICATION for SUNSHINE LAB & DIAGNOSTICS				
Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400	

16.0 POST APPROVAL:

16.1 Checked by

Name	Designation	Signature	Date
Mr. Abhinav	Lab Technician	ABHINAV G	19-10-2021

16.2 Approved by

Name	Designation	Signature	Date
Dr. P A Kumar	HOD	P. A. Kumar	19-10-2021

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

Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400
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As part of Operational qualification, the following checks shall be done and each test shall be recorded:

Instrument Start-up

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

Functional Checks

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

Interlocks and Alarms Check

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

Safety / Security Checks

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

Instrument Shut-down

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

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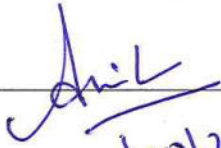
OPERATIONAL QUALIFICATION CHECKLIST for SUNSHINE LAB & DIAGNOSTICS



Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400
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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.	} OK	 19/10/21	
Ensure the proper filling of double distilled / de-ionized water and Cleaning solution in the respective cans.			
Ensure the availability of XL Wash.			
Ensure the availability of Biohazard Waste.			
Ensure the availability of Normal Waste.			
Switch ON the rear switch of the analyzer.			
Switch ON the side switch of the analyzer.			
Switch ON the computer and start the analyzer application software.			
Initialization			

TRANSASIA BIOMEDICALS LIMITED

OPERATIONAL QUALIFICATION CHECKLIST for SUNSHINE LAB & DIAGNOSTICS



Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400
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2.0 FUNCTIONAL CHECKS:

2.1 Maintenance:

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

Activity	Observation	Verified by (Sign & Date)	Remarks
Photometer functioning	OK	<i>Amish</i> 19/10/24	
Cuvette Rinse			

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OPERATIONAL QUALIFICATION CHECKLIST for SUNSHINE LAB & DIAGNOSTICS

Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400
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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	OK	<i>Anil</i> 19/10/24	

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OPERATIONAL QUALIFICATION CHECKLIST for SUNSHINE LAB & DIAGNOSTICS

Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400
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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)	} ok	<i>Amik</i>	
Standard (Multical)			

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OPERATIONAL QUALIFICATION CHECKLIST for SUNSHINE LAB & DIAGNOSTICS

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Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400
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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	} OK	Anil 19/10/21	
Less volume of Wash Solution			
More volume of Bio-Hazard waste			
More volume of Normal / General waste			

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OPERATIONAL QUALIFICATION CHECKLIST for SUNSHINE LAB & DIAGNOSTICS

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Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400
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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 (Sign & Date)	Remarks
Password Check for Test Parameters	OK	Anil 19/10/24	
Password Check for QC Mode			

OPERATIONAL QUALIFICATION CHECKLIST for SUNSHINE LAB & DIAGNOSTICS

Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400
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5.0 INSTRUMENT SHUT-DOWN:

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

Action	Observation	Verified by (Sign & Date)	Remarks
Sample Probe Wash	} OK	<i>Amik</i> 19/10/24	
Water Save			
Switch OFF the computer.			
Switch OFF the side switch of the analyzer.			
Switch OFF the rear switch of the analyzer.			

Instrument Name
EM200

Clinical Chemistry Analyzer

Instrument ID

2002400

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PERFORMANCE QUALIFICATION for SUNSHINE LAB & DIAGNOSTICS



Instrument Name
EM200

Clinical Chemistry Analyzer

Instrument ID

2002400

1.0 PRE APPROVAL

1.1 Prepared By

Name	Designation	Signature	Date
Amit Pal	Sr. Application Specialist		16-11-2021

1.2 Checked By

Name	Designation	Signature	Date
Mr. Abhinav	Lab Technician		16-11-2021

1.3 Approved By

Name	Designation	Signature	Date
Dr. P A Kumar	HOD		16-11-2021

TRANSASIA BIOMEDICALS LIMITED

PERFORMANCE QUALIFICATION for SUNSHINE LAB & DIAGNOSTICS



Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400
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2.0 OBJECTIVE

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

3.0 SCOPE

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

4.0 PRE-REQUISITES:

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

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

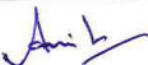
5.0 EXECUTION TEAM

Name	Department	Designation	Signature
Amit Pal	TSD	Sr. Application Specialist	

TRANSASIA BIOMEDICALS LIMITED**PERFORMANCE QUALIFICATION for SUNSHINE LAB & DIAGNOSTICS****TRANSASIA**[®]
Bio-Medicals Ltd.**Instrument Name**
EM200**Clinical Chemistry Analyzer****Instrument ID****2002400****7.0 EXECUTION OF TEST PLAN**

Run QC 5 times and Calculated Parameters CV%

Reviewed by:

Name	Signature	Date
Amit Pal		16-11-2021

TRANSASIA BIOMEDICALS LIMITED

PERFORMANCE QUALIFICATION for SUNSHINE LAB & DIAGNOSTICS



Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400
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8.0 DEFICIENCIES / DEVIATIONS:

No Deviations


Reviewed by:

Name	Signature	Date
Amit Pal		16-11-2021

TRANSASIA BIOMEDICALS LIMITED**PERFORMANCE QUALIFICATION for SUNSHINE LAB & DIAGNOSTICS****TRANSASIA**[®]
Bio-Medicals Ltd.**Instrument Name**
EM200**Clinical Chemistry Analyzer****Instrument ID****2002400****9.0 SUMMARY AND EVALUATION:**

All results are within acceptable range. (Data Attached).

Reviewed by:

Name	Signature	Date
Amit Pal		16-11-2021

Instrument Name EM200	Clinical Chemistry Analyzer	Instrument ID	2002400
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10.0 ABBREVIATIONS

SOP	Standard Operating Procedure
MOC	Material of Construction
PQ	Performance Qualification

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PERFORMANCE QUALIFICATION for SUNSHINE LAB & DIAGNOSTICS



Instrument Name
EM200

Clinical Chemistry Analyzer

Instrument ID

2002400

11.0 POST APPROVAL

11.1 Checked by

Name	Designation	Signature	Date
Mr. Abhinav	Lab Technician	ABHINAV G	16-11-2021

11.2 Approved by

Name	Designation	Signature	Date
Dr . P A Kumar	HOD	P. Ashokan	16-11-2021

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

Test CHOL Report Type Controls

Date From 16-Nov-2021

Date To 16-Nov-2021

Lot # S062125 Consumable ERBANORM

Sr#	Result	Unit	Flag	Result Date	Curve #	Used Calibration
1	133	mg/dl	-	16-Nov-2021 16:19:38	2026	19-Oct-2021 17:39:50
2	134	mg/dl	-	16-Nov-2021 16:19:20	2025	19-Oct-2021 17:39:50
3	133	mg/dl	-	16-Nov-2021 16:19:01	2024	19-Oct-2021 17:39:50
4	135	mg/dl	-	16-Nov-2021 16:18:43	2023	19-Oct-2021 17:39:50
5	134	mg/dl	-	16-Nov-2021 16:18:25	2022	19-Oct-2021 17:39:50

Computed Ranges And Statistical Values

Reference Range 0
 Above Reference Range 0
 Below Reference Range 0
 Ref Range Not Defined 0
 Total Test(s) 7

SI#From - To =

N 5
 Mean 134
 SD 0.84
 %CV 0.63
 Range 2

Test Statistics

Test: CRE Report Type: Controls

Date From: 16-Nov-2021

Date To: 16-Nov-2021

Lot #: S062125 Consumable: ERBANORM

Sr#	Result	Unit	Flag	Result Date	Curve #	Used Calibration
1	1.23	mg/dl	-1SD	16-Nov-2021 16:16:01	2014	16-Nov-2021 14:00:12
2	1.25	mg/dl	-1SD	16-Nov-2021 16:15:43	2013	16-Nov-2021 14:00:12
3	1.25	mg/dl	-1SD	16-Nov-2021 16:15:25	2012	16-Nov-2021 14:00:12
4	1.25	mg/dl	-1SD	16-Nov-2021 16:14:49	2010	16-Nov-2021 14:00:12
5	1.23	mg/dl	-1SD	16-Nov-2021 16:14:31	2009	16-Nov-2021 14:00:12

Computed Ranges And Statistical Values

Reference Range: 0

Above Reference Range: 0

Below Reference Range: 0

Ref Range Not Defined: 0

Total Test(s): 7

StatFrom - To -

N: 5

Mean: 1.24

SD: 0.01

%CV: 0.88

Range: 0.02

Test Statistics

Test: GLU

Report Type

Controls

Date From: 16-Nov-2021

Date To: 16-Nov-2021

Lot #: S062125

Consumable

ERBANORM

Sr#	Result	Unit	Fbg	Result Date	Curve #	Used Calibration
1	89.5	mg/dl	-1SD	16-Nov-2021 16:17:49	2020	25-Oct-2021 16:23:21
2	88.8	mg/dl	-1SD	16-Nov-2021 16:17:31	2019	25-Oct-2021 16:23:21
3	89.1	mg/dl	-1SD	16-Nov-2021 16:17:13	2018	25-Oct-2021 16:23:21
4	89.6	mg/dl	-1SD	16-Nov-2021 16:16:55	2017	25-Oct-2021 16:23:21
5	87.5	mg/dl	-1SD	16-Nov-2021 16:16:37	2016	25-Oct-2021 16:23:21

Computed Ranges And Statistical Values

Reference Range: 0

Above Reference Range: 0

Below Reference Range: 0

Ref Range Not Defined: 0

Total Test(s): 7

SI#From - To -

N: 5

Mean: 00.9

SD: 0.85

%CV: 0.95

Range: 2.1

Report Type

Controls

Test SGPTD
 Date From 16-Nov-2021
 Date To 16-Nov-2021

Lot # S062125

Consumable

ERBANORM

Sr#	Result	Unit	Flag	Result Date	Curve #	Used Calibration
1	37.2	U/L	-	16-Nov-2021 16:14:13	2008	23-Oct-2021 15:15:54
2	37.2	U/L	-	16-Nov-2021 16:13:54	2007	23-Oct-2021 15:15:54
3	36.7	U/L	-	16-Nov-2021 16:13:36	2006	23-Oct-2021 15:15:54
4	37.5	U/L	-	16-Nov-2021 16:13:18	2005	23-Oct-2021 15:15:54
5	37.5	U/L	-	16-Nov-2021 16:13:00	2004	23-Oct-2021 15:15:54

Computed Ranges And Statistical Values

Reference Range 0
 Above Reference Range 0
 Below Reference Range 0
 Ref Range Not Defined 0
 Total Test(s) 7

Sr#From - To -

N 5
 Mean 37.2
 SD 0.33
 %CV 0.88
 Range 0.8

Test UA

Report Type

Controls

Date From 16-Nov-2021

Date To 16-Nov-2021

Lot # S062125

Consumable

ERBANORM

Sl#	Result	Unit	Flag	Result Date	Curve #	Used Calibration
1	6.1	mg/dl	-	16-Nov-2021 16:21:26	2032	20-Oct-2021 14:34:30
2	6.1	mg/dl	-	16-Nov-2021 16:21:08	2031	20-Oct-2021 14:34:30
3	6.1	mg/dl	-	16-Nov-2021 16:20:50	2030	20-Oct-2021 14:34:30
4	6.1	mg/dl	-	16-Nov-2021 16:20:32	2029	20-Oct-2021 14:34:30
5	6.1	mg/dl	-	16-Nov-2021 16:20:14	2028	20-Oct-2021 14:34:30

Computed Ranges And Statistical Values

Reference Range 0

Above Reference Range 0

Below Reference Range 0

Ref Range Not Defined 0

Total Test(s) 7

Sl#From - To -

N 5

Mean 6.1

SD 0.00

%CV 0.00

Range 0.0

Report Type Controls

Test HDLD
Date From 16-Nov-2021
Date To 16-Nov-2021

Lot # S062125 Consumable ERBANORM

Sr#	Result	Unit	Flag	Result Date	Curve #	Used Calibration
1	43.0	mg/dl	-	16-Nov-2021 16:23:14	2038	19-Oct-2021 17:50:21
2	43.4	mg/dl	-	16-Nov-2021 16:22:56	2037	19-Oct-2021 17:50:21
3	42.4	mg/dl	-	16-Nov-2021 16:22:38	2036	19-Oct-2021 17:50:21
4	42.7	mg/dl	-	16-Nov-2021 16:22:20	2035	19-Oct-2021 17:50:21
5	43.0	mg/dl	-	16-Nov-2021 16:22:02	2034	19-Oct-2021 17:50:21

Computed Ranges And Statistical Values

Reference Range 0
 Above Reference Range 0
 Below Reference Range 0
 Ref Range Not Defined 0
 Total Test(s) 7

Sr#From - To -

N 5
 Mean 42.9
 SD 0.37
 %CV 0.87
 Range 1.0