TRANSASIA

Erba EM-200

AUTOMATED BIOCHEMISTRY ANALYZER

IQ, OQ, PQ Documents

For

SR Diagnostics Center, Sewa-Rural, Jhagadia

Marketed by:
Transasia Bio-Medicals Ltd.,
(ISO 9001:2008 & ISO 13485:2003 CERTIFIED)
Transasia House,
Chandivali Studio road,
Andheri (E),
MUMBAI – 400 072

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1.0 PRE APPROVAL

1.1 Prepared By

Name	Designation	Signature	Date
Mr. Jitesh Gandhi	Service Manager		19/03/2021

1.2 Checked By

Name	Designation	Signature	Date
Dr. Gayatri Desai	Lab Incharge	Desai	19/03/2021
Mr. Rajendra Kachhia	Lab Tech		19/03/2021

1.3 Approved By

Name	Designation	Signature	Date
Dr. Gayatri Desai	Lab Incharge	Desai	19/03/2021

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

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

4.0 EXECUTION TEAM

Name	Department	Designation	Signature
Dr. Gayatri Desai	Laboratory	Lab Incharge	Desai
Mr. Rajendra Kachhia	Laboratory	Lab Tech.	

5.0 INSTRUMENT DESCRIPTION

The Clinical Chemistry Analyzer is a close, fully automated, discrete, patient prioritized, random access, computerized analyzer.

Technical Specifications:

System Type	Close, Automated, Discrete, Random Access, Patient Prioritized, 1/2 Reageants
Analysis Speed	200 Biochemistry tests per hour 400 tests per hour (with ISE) for a cycle time of 18 seconds
Display resolution	1024 X 768
Analyzer Dimensions	810 (W) x 800 (D) x 600 (H) mm
Number of tests on board	Maximum: 50
Assay Modes	1-point, 2-point,Rate-A and Rate –B, ISE optional
Calibration	Linear (two point and multi point), Factorized and Non-linear multipoint
Sample (Tubes / Cups)	Primary tubes of 5, 7 or 10mL & sample cups
Photometric Optics	Mono and Bi-chromatic measurement using 8 wavelengths
Absorbance Range	0 – 2.5
Auxiliary Data	10,000 results
Interface	RS-232 C port for Bi-directional Communication
Stat Sampling	Total 30 positions

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

The working unit of the analyzer comprises the following:

- Basic operating unit with an 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.

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

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.		

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			
Instrument Name	**Clinical Chemistry Analyzer**	**Instrument ID**	**2002286**

Instrument/ Component Name: Sample Tray / Disk

Date : 19/03/2021

Description	**Specified**	**Actual**	**Method of Verification**	**Verified by Signature**
No. of patient cups / samples	30 positions	30	Visual	
Standards / Stat	30 positions	30	"	
Blank	Can be put on any position	Same as specified	"	
Controls	Can be programmed on any positions	Same as specified	"	

Instrument/ Component Name: Sample Syringe

Date : 19/03/2021

Description	**Specified**	**Actual**	**Method of Verification**	**Verified by Signature**
Dispensing Volume	2 – 70 µL	2 - 70	Physical	
Installed Location	Behind the instrument on the right side	Same as Specified	"	
Quantity	01 No	1	"	
Increase in dispensing volume	0.2 µl	0.2 µL	"	

Instrument/ Component Name: Sample Probe

Date : 19/03/2021

Description	**Specified**	**Actual**	**Method of Verification**	**Verified by Signature**
Aspiration Volume	2 – 70 µL	2 - 70 µL	Physical	
MOC	Teflon coated	Same as specified	Manual	
Quantity	01 No.	1	physical	
Increase in aspiration volume	0.2 µL	0.2 µL	physical	

Instrument/ Component Name: Wash Station for Sample Probe

Date : 19/03/2021

Description	**Specified**	**Actual**	**Method of Verification**	**Verified by Signature**
No. of position	01 No	1	Visual	
Type of positions	i) Drain ii) Trough	Same as specified	Visual	

Instrument/ Component Name: Reagent Tray / Disk

Date : 19/03/2021

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

Instrument/ Component Name: Reagent Bottles

Date : 19/03/2021

Description	**Specified**	**Actual**	**Method of Verification**	**Verified by Signature**
Minimum Capacity	20 mL	20 ml	Physical	
Maximum Capacity	50 mL	50 ml	"	
Quantity (Large)	25 Nos'	25 Nos	Visual	
Quantity (Smaller)	25 Nos'	25 Nos	"	
Type	Screw Capped	Screw Cap	"	
Outer ring position	20 mL bottles & 5ml adaptors	Same as specified	"	
Inner ring position	20 mL & 50 mL bottles & 5ml adaptors	Same as specified	"	
MOC	Plastic	plastic	"	
Adaptor	50 Nos'	50 Nos.	physical	
Adaptor Capacity	5 mL	5 ml	"	
Identification of Reagents	Barcode labels on the reagent containers	Same as specified	"	

Instrument/ Component Name: Reagent Probe

Date : 19/03/2021

Description	**Specified**	**Actual**	**Method of Verification**	**Verified by Signature**
Aspiration/Dispensing Volume	R1: 50 – 300 µL	50-300 µL	Physical	
	R2: 0 or10 – 300 µL	0-10 µL	"	
MOC	Teflon coated	Teflon	"	
Quantity	01 Nos'.	1.	"	
Increase in aspiration/dispensing volume	1 µL	1 µL	"	

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA Bio-Medicals Ltd.
INSTALLATION QUALIFICATION				
Instrument Name	**Clinical Chemistry Analyzer**	**Instrument ID**	**2002286**	

Instrument/ Component Name: Reagent Syringe

Date : 19/03/2021

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

Instrument/ Component Name: Stirrer

Date : 19/03/2021

Description	Specified	Actual	Method of Verification	Verified by Signature
Type	Single Stirrer	Single	Visual	
No. of paddles	01 No.	1 No.	"	

Instrument/ Component Name: Permanent Reaction Cuvette

Tag/Identification No.:

Date : 19/03/2021

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

Instrument/ Component Name: 7 Stage Laundry System

Date : 19/03/2021

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

Instrument/ Component Name: Light Source

Date : 19/03/2021

Description	Specified	Actual	Method of Verification	Verified by Signature
Watts	12 W	12 W	Physical	
Volts	12 V	12 V	"	
MOC	Halogen	Halogen	Manual	
Quantity	01 No	1 No.	Physical	

Instrument/ Component Name: Sample Cups

Date : 19/03/2021

Description	Specified	Actual	Method of Verification	Verified by Signature
Quantity	300 Nos'	300 Nos.	Certificate	
MOC	Plastic	Plastic	Visual	
Capacity	2 mL	2 ml	Physical	

Instrument/ Component Name: Software of EM 200

Date : 19/03/2021

Description	**Specified**	**Actual**	**Method of Verification**	**Verified by Signature**
Version		2019-07 A		
CD number				
Product	EM- 200	EM-200		
Make	Erba Transasia	TBM		

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	Same as MOC	Certificate	
Reagent Probe	Teflon coated	"	"	
Permanent Reaction Cuvette	Hard Glass	"	"	
Light Source	Halogen	"	"	
Reagent Bottle	Plastic	"	Visual	
Sample Cups	Plastic	"	"	

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	Yes	
Distilled Water	Yes	
Wash Solution	Yes	
UPS	Yes	

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

12.0 IDENTIFICATION AND VERIFICATION OF DOCUMENTS

12.1 DRAWINGS

Title	Drawing No.	Verified by Sign & Date
As-built Drawing		

12.2 GENERAL DOCUMENTS

Title	Document No.	Verified by Sign & Date
General		
Purchase Order No.		
Warranty Certificate		
Invoice		
Test Certificates		
Material of Construction		
Electrical Motor		

13.0 DEFICIENCIES / DEVIATIONS:

- No deficiencies / deviations observed.
- Installation done successfully.

Reviewed by:

Name	Signature	Date
Mr. Rajendra Kachhia		19/03/2021

14.0 SUMMARY AND EVALUATION:

- Installation done successfully.

Reviewed by:

Name	Signature	Date
Mr. Rajendra Kachhia		19/03/2021

15.0 ABBREVIATIONS

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

16.0 POST APPROVAL:

16.1 Checked by

Name	Designation	Signature	Date
Mr. Jitesh Gandhi	Service Manager	for	19/03/2021

16.2 Approved by

Name	Designation	Signature	Date
Dr. Gayatri Desai	Lab Incharge	Desai	19/03/2021

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

TRANSASIA BIOMEDICALS LIMITED			
OPERATIONAL QUALIFICATION CHECKLIST			
Name	Clinical Chemistry Analyzer	Instrument ID	2002286

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perational qualification, the following checks shall be done and each test shall be recorded:

Start-up

d establish the standard sequence to be followed, during start-up of the subjected instrument anual mode, to propose for correct operation and to avoid any damage to the instrument and

Checks

nd ensure that different functions (such as switching devices, indication / monitoring / evices, feedback system, etc.) for correct operation of the subjected instrument are working as

and Alarms Check

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

curity Checks

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

t Shut-down

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

TRANSASIA BIOMEDICALS LIMITED			
OPERATIONAL QUALIFICATION CHECKLIST			
nstrument Name	Clinical Chemistry Analyzer	Instrument ID	2002286

.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		-
Ensure the proper filling of double distilled / de-ionized water and Cleaning solution in the respective cans.	Yes		-
Ensure the availability of XL Wash.	Yes	19/03/21	-
Ensure the availability of Biohazard Waste.	Yes		-
Ensure the availability of Normal Waste.	Yes		-
Switch ON the rear switch of the analyzer.	Yes / O.K		-
Switch ON the side switch of the analyzer.	O.K.		-
Switch ON the computer and start the analyzer application software.	O.K.		-
Initialization .	O.K.		-

FUNCTIONAL CHECKS:

Maintenance:

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

tivity	Observation	Verified by (Sign & Date)	Remarks
otometer functioning	O K		–
vette Rinse	O K.		–

oading of Reagents:

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

n	Observation	Verified by (Sign & Date)	Remarks
nt Level Scan, Volume Check & gent Chemistry	O K		–

ument Name	Clinical Chemistry Analyzer	Instrument ID	2002286

alibration:

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

n	Observation	Verified by (Sign & Date)	Remarks
(Distilled Water)	O.K		-
ard (Multical)	O.K		-

INTERLOCKS AND ALARMS CHECK:

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

tion	Observation	Verified by (Sign & Date)	Remarks
ss volume of stilled Water	O.K.		-
ss volume of Wash ution	O.K.		-
re volume of Bio-zard waste	O.K.		-
re volume of rmal / General waste	O.K.		-

AFETY / SECURITY CHECKS:

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

on	Observation	Verified by (Sign & Date)	Remarks
vord Check for Parameters	O. K		-
vord Check for QC	O. K		-

nstrument Name	Clinical Chemistry Analyzer	Instrument ID	2002286

.0 INSTRUMENT SHUT-DOWN:

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

ction	Observation	Verified by (Sign & Date)	Remarks
ample Probe Wash	O. K		-
laintenance & Shut own	O. K		-
vitch OFF the mputer.	O. K		-
vitch OFF the side vitch of the analyzer.	O. K		-
vitch OFF the rear vitch of the analyzer.	O. K		-

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RE APPROVAL

.1 Prepared By

Name	Designation	Signature	Date
Mr. Siddharth Pancholi	Sr. Application Specialist		29/03/22

2 Checked By

Name	Designation	Signature	Date
Dr. Gayatri Desai	Lab Incharge	Desai	29/03/22
Mr. Rajendra Kachhia	Lab Tech.		29/03/22

Approved By

Name	Designation	Signature	Date
Dr. Gayatri Desai	Lab Incharge	Desai	29/03/22

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
Dr. Gayatri Desai	Laboratory	Lab Incharge	
Mr. Rajendra Kachhia	Laboratory	Lab Tech.	

.0 TEST PLAN

The following tests shall be followed, during the Performance Qualification of EM-200 (Bio-Chemistry Random Analyzer).

Test Parameter	Acceptance Criteria	Test Procedure / Reference
Albumin	< 5%	5 Replicates/ Manufacture Reference
Alkline Phosphatase	< 5%	5 Replicates/ Manufacture Reference
Bilirubin Direct	< 5%	5 Replicates/ Manufacture Reference
Bilirubin Total	< 5%	5 Replicates/ Manufacture Reference
Cholesterol	< 5%	5 Replicates/ Manufacture Reference
Createnine Enzymatic	< 5%	5 Replicates/ Manufacture Reference
Glucose	< 5%	5 Replicates/ Manufacture Reference
HDL Cholesterol	< 5%	5 Replicates/ Manufacture Reference
SGPT	< 5%	5 Replicates/ Manufacture Reference
Total Protein	< 5%	5 Replicates/ Manufacture Reference
Triglyceride	< 5%	5 Replicates/ Manufacture Reference
Uric Acid	< 5%	5 Replicates/ Manufacture Reference
Urea	< 5%	5 Replicates/ Manufacture Reference

7.0 EXECUTION OF TEST PLAN

To be check out all parameters are within acceptable CV %.

viewed by:

Name	Signature	Date
Mr. Rajendra Kachhia		29/03/22

0 **DEFICIENCIES / DEVIATIONS:**

No deviation found during precision check. All parameters are within accepted CV%

Row data attached.

No Deficiencies found during accuracy. All parameters are within acceptable manufacturer reference range.

Row data attached.

iewed by:

Name	Signature	Date
Mr. Rajendra Kachhia		29/03/22

rument Name	Clinical Chemistry Analyzer	Instrument ID	2002286

TRANSASIA Bio-Medicals Ltd

SUMMARY AND EVALUATION:

Precision and accuracy of instrument is ok.

ewed by:

Name	Signature	Date
Mr. Rajendra Kachhia		29/03/22

0.0 ABBREVIATIONS

SOP	Standard Operating Procedure
MOC	Material of Construction
PQ	Performance Qualification

0 POST APPROVAL

11.1 Checked by

Name	Designation	Signature	Date
Mr. Siddharth Pancholi	Sr. Application Specialist		29/03/22

11.2 Approved by

Name	Designation	Signature	Date
Dr. ~~Priyanka~~ Gayatri Desai	Lab Incharge	Desai	29/03/22

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

A to Z Biomedical Services

426, 4th Floor, pramukh TANGENT, KH-0, Sargasan Circle, KH-0 to GIFT City Road, Gandhinagar-382421, Gujarat
Mo: +91 - 7874807758 | e-mail: atoz_bm@yahoo.com

CALIBRATION CERTIFICATE

Details of Device Under Calibration :

Date:05-03-2022

Customer Name & Address: SR DIAGNOSTIC CENTRE,SEWA RURAL JHAGADIA	Certificate ID : AZ/21-22/ 1207
Name of Equipment:BLOOD MIXED Manufacturer :TRANSASIA BIOMEDICAL Model :SR 20A Serial No :NS	Calibration Date : **22-02-2022** Calibration Due Date : **21-02-2023** Location of equipment : LAB Ambient Temperature : 27 °C

Test Equipment Used:

sr no	Test equipment	Company	Model	Sr no.	Cali. date	Cali. due date
1	Electrical safety Analyzer	Fluke Biomedical	ESA 620	1685037	01-03-2021	01-03-2022

Electrical Safety Test:

(A) Visual Test:

Sr No	Test	Remarks
1	Power Cords , Cable Checking	OK
2	Mains Socket Checking	OK

(B) Safety Analyzer Test

Sr No.	Parameters	Measured Values(Limits)		Remarks
1	Voltage Between live & neutral (Vln)	**230.8**	(210 -240 V)	Pass
2	Voltage Between live & earth (Vle)	**229.8**		Pass
3	Voltage Between neutral & earth(Vne)	**1.6**	(1 - 5 V)	Pass
4	Load current(Ia)	**0.22**	(0 -0.5 A)	Pass
5	Leakage Current (IL)	**145**	(0 -500 micro A)	Pass
6	Enclosure Current	**3.8**	(0 -10 micro A)	Pass
7	Patient Leackage current(PL)	**25**	(0 -100microA)	Pass

Note:

(1) Results reported are valid at the time of and under the stated conditions of measurement.
(2)Calibration has been done as per customer's requirment.
(3) Measurements are tracable to the National Standard
(4) NS means Not Specified and DUC means Device Under Calibration
(5)This document shall not reproduced, except in full,without the written approval of " A to Z Biomedical Services"

Calibrated By: Gaurang Jansari	Approved By: Gaurav Desai

A to Z Biomedical Services Gandhinagar