TRANSASIA®

TECHNICAL SERVICE REPORT

No. 1358239 DATE : 15-12-2021

CUSTOMER DETAILS	INSTRUMENT DETAILS	SERVICE STATUS
NAME : POLO LABS	MODEL : CM-200	☐ WARRANTY ☑ R&R ☐ AMC ☐ CMC ☐ CHARGED CALL
ADDRESS : KHANNA	SR. NO. : 13140713	TYPE OF CALL ☐ INSTALLATION ☑ P.M. VISIT ☐ I ☐ II ☐ III ☑ IV ☐ APPLICATION SUPPORT ☐ BREAKDOWN
TEL NO :	CALL DETAILS	
NAME OF THE OPERATOR :		DOWN TIME :
		COUNTER READING :

CALL DETAILS	DATE	TIME
COMPLAINT RECD.		
RESPONSE		
JOB COMPLETED		
RESPONSE TIME		
TRAVEL TIME		

PROBLEM REPORTED : P.M. Visit

OBSERVATIONS : Do

ACTION TAKEN : PM carried out. Cleaned probe, Landing pads, Cuvettes, manifold, trough, Stirrer unit Pumps. Performed calibration and QC results found OK.

SITE CONDITION : LINE-NEUTRAL VOLT. : 240 NEUTRAL-EARTH VOLT. : 0 LINE-EARTH VOLT. :

BRAND OF REAGENT USED :

☐ FOLLOWING PARTS HAVE BEEN REPLACED
☐ FOLLOWING PARTS NEED TO BE REPLACED. PLEASE APPROVE

NO.	DESCRIPTION	QTY.	COST	TOTAL

TOTAL Rs.

TO BE FILLED IN BY CUSTOMER

☐ PREVENTIVE MAINTENANCE CARRIED OUT SATISFACTORILY.
☐ FAULT RECTIFIED & INSTRUMENT IS WORKING SATISFACTORILY.
☐ WE HEREBY APPROVE RS. _____ FOR PARTS
☐ COMMENTS (IF ANY) :

SEAL DATE CUSTOMER'S SIGNATURE
NAME :

INVOICE NO. : DATE :

FOLLOW-UP ACTION (Required if any) :

BRANCH H. O.

RECEIVED ON :

CHECKED BY :

ENGINEER'S/PRODUCT SPECIALIST'S SIGNATURE :

TIME : NAME : RAKHOOL SINGH ROHA

JOB CARD NO. :

NOTE : Parts replaced are chargeable except during warranty Period. Consumables like printer head, lamp, tubing, paper rolls etc. & breakable parts are not covered by warranty and hence are chargeable. Parts replaced due to negligence in operation will also be charged in every case.

AT TRANSASIA, CUSTOMER SATISFACTION IS OUR PRIME CONCERN. IN CASE YOU HAVE ANY SUGGESTIONS PLEASE CONTACT : GENERAL MANAGER (TECHNICAL SERVICE), MUMBAI. TEL. : 4030 9000 FAX : (022) 4030 9090

TRANSASIA BIO-MEDICALS LTD.

Head Office : Transasia House, 8, Chandivali Studio Road, Andheri (E), Mumbai - 400 072. Tel. : (022) 4030 9000 Fax : (022) 2857 3030

Mumbai	: Toll Free 1800 103 8226				
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Chandigarh	: Tel. : (0172) 464 3837	Hyderabad	: Tel. : (040) 4430 9000	Ahmedabad	: Tel./Fax : (079) 02640 7030/4032 1903
Jaipur	: Tel. : 93092 63147	Guwahati	: Tel. : 91369 50480	Bangalore	: Tel./Fax : (080) 2556 8044
Patna	: Tel. : 77669 00553	Chuttack	: Tel. : (0671) 232 4555		
Kochi	: Tel. : (0484) 402 0511	Hubli	: Tel. : (0836) 485 0900		

CUSTOMER COPY

Erba® Mannheim

DOC NO : SC00-406 / ISS - 5

ISO 13485 & ISO 9001 Certified Co.

www.transasia.co.in

Transasia Bio Medicals Ltd., SCO No. 95, 1st Floor Sector 44C, Chandigarh 160047
Tele Fax: 0172-4643837 Email : nz3@transasia.co.in
CIN : U33110MH1985PLC036198

TRANSASIA

UNMATCHED SERVICE
SINCE 1979

Date : 14th April '2021

Polo Labs Pvt. Ltd.,
Khanna.

Dear Sir

As desired by you please find enclosed herewith the Calibration report

1. Instrument & Serial No.: **Erba EM-200-Serial No. B140713.**
2. Range of the instrument: Optical density Linear form 0-3.5 A
3. Precison & Accuracy study on EM-200 done on 14-04-2021 & valid upto 13-04-2022.

Precison with Potassium Dichromate ($K_2Cr_2O_7$)

Reagent / Sample ratio -

Cup Position	Replicates	Absorbance (X)	SD	CV
Cup 1	20	1.5633 OD	0.0054	0.47%
Cup 2	20	1.5861 OD	0.0069	0.53%
Cup 3	20	1.5982 OD	0.073	0.51%

Accuracy study with Potassium Dichromate ($K_2Cr_2O_7$) In comparision with EM-200

Wavelengths scan on Referral Spectrophotometer for Potassium Dichromate ($K_2Cr_2O_7$)

TRANSASIA BIO-MEDICALS LTD. CHANDIGARH

Contd..2

Erba

Transasia Bio Medicals Ltd. SCO No. 95, 1st Floor, Sector 44C, Chandigarh - 160047
Telefax: 0172 4643837 Email: tbc3@transasia.co.in
CIN : U51109PB1985PLC036198

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Wavelength	Spectrophotometer OD	
	Low	High
335	0.1882	1.7351
336	0.1958	1.7429
337	0.1979	1.7830
338	0.2011	1.8123
339	0.2038	1.8320
340	0.2079	1.8731
341	0.2153	1.9021
342	0.2179	1.9356
343	0.2205	1.9761
344	0.2303	2.0124
345	0.2352	2.0520

Contd...3

SCO No. 95, 1st Floor, Sector 44C, Chandigarh - 160047
Email : cz3@transasia.co.in

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Test of Potassium Dichromate ($K_2Cr_2O_7$) on EM-200

Pipetted/Measured by EM 200		Manually Pipettes EM		Manually pipetted & read in Autospan	
Low	High	Low	High	Low	High
0.2031	1.8205	0.1858	1.8690	0.2112	1.9532

This instrument is manufactured in accordance with the European law in force, in particular to "Electricity Safety" EN 610101 and "Electromagnetic Compatibility " EN 61326 Standards.

Pressure	Ideal	Actual
	0.9 bar	0.92bar
Lamp Voltage	12 V	12.01 V
Temperature	37° C	37 ° C

Photometer Calibraion Check	Ok
Cuvette Blank Check	Ok

Wavelength	Off Set	Gain
340	NA	680
405	NA	481
505	NA	563
546	NA	479
578	NA	539
600	NA	435
660	NA	381
700	NA	432

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Erba

Transasia Bio-Medicals Ltd. SCO No. 85, 1st Floor, Sector 44C, Chandigarh - 160047
Tele/fax: 0172-4643837 Email : rnz@transasia.co.in
CIN : U33110MH1985PLC036198

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The instrument does photometer check before each batch of tests is run. It will give an error message if the photometer test fails and it will not run any samples

Thanking you and assuring of our prompt attention at all times.

Yours faithfully,

For TRANSASIA BIO-MEDICALS LTD.

Rashpal Singh Rana
Sr. Regional Service Manager
M: +91-9316004670
E mail: r.rana@transasia.co.in

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TRANSASIA BIO-MEDICALS LTD. CHANDIGARH

1.0 PRE APPROVAL

1.1 Prepared By

Name	Designation	Signature	Date
Sukhwinder kumar	SERVICE ENGINEER		18-09-2014

1.2 Checked By

Name	Designation	Signature	Date
Dr Parashant			
TR Working	Quality Head		

1.3 Approved By

Name	Designation	Signature	Date
Dr Parashant			

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

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 200 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	Verified by Signature	Observations
	Yes / No		
Sample Tray / Disk	YES		
Sample Syringe	YES		
Sample Probe	YES		
Wash Station for Sample Probe	YES		
Reagent Tray / Disk	YES		
Reagent Bottles	YES		
Reagent Probe	YES		
Test Loader	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

Instrument/ Component Name: Sample Tray / Disk

Date :

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

Instrument/ Component Name: Sample Syringe

Date :

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

Instrument/ Component Name: Sample Probe

Date :

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

Instrument/ Component Name: Wash Station for Sample Probe

Date :

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

Instrument/ Component Name: Reagent Tray / Disk

Date :

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

Instrument/ Component Name: Reagent Bottles

Date :

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

Instrument/ Component Name: Reagent Probe

Date :

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

Instrument/ Component Name: Reagent Syringe

Date :

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

Instrument/ Component Name: Stirrer

Date :

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

Instrument/ Component Name: Permanent Reaction Cuvette

Tag/Identification No.:

Date :

Description	Specified	Actual	Method of Verification	Verified by Signature
Quantity	45 No's	✓	VISUAL	
MOC	Hard Glass	✓	VISUAL	
Capacity	770 µL	✓	TEST CERTIFICATE	

Instrument/ Component Name: 7 Stage Laundry System

Date :

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

Instrument/ Component Name: 7 Stage Laundry System

Date :

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

Instrument/ Component Name: Light Source

Date :

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

Instrument/ Component Name: Sample Cups

Date :

Description	Specified	Actual	Method of Verification	Verified by Signature
Quantity	500 No's	✓	VISUAL	
MOC	Plastic	✓	VISUAL	
Capacity	2 mL	✓	TEST CERTIFICATE	

Instrument/ Component Name: Software of EM 200

Date :

Description	Specified	Actual	Method of Verification	Verified by Signature
Version		✓	VISUAL	
CD number		✓	VISUAL	
Product	EM- 200	✓	VISUAL	
Make	Erba Transasia	✓	VISUAL	

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

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	230 V	
Distilled Water	1 TDS	
Wash Solution	PRESENT	
UPS	PRESENT	

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	M08.81.00.00.00.091	

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TRANSASIA BIOMEDICALS LIMITED				TRANSASIA Bio-Medicals Ltd.
OPERATIONAL QUALIFICATION CHECKLIST				
Em200	**Clinical Chemistry Analyzer**	**Instrument ID**	**B140713**	

As part of Operational qualification, the following checks shall be done and each test shall be recorded:

Instrument Start-up

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

Functional Checks

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

Interlocks and Alarms Check

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

Safety / Security Checks

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

Instrument Shut-down

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

1.0 INSTRUMENT START-UP:

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

Action	Observation	Verified by (Sign & Date)	Remarks
Ensure that all the required electrical connections are properly connected.	Working fine	Dr Parashant	Satisfactory
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	,,	,,	,,

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	properly	Dr Parashant	satisfactory
Cuvette Rinse	properly	Dr Parashant	satisfactory

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	properly	Dr Parashant	Satisfactory

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)	checked	Dr Parashant	Satisfactory
Standard (Multical)	Checked	Dr Parashant	Satisfactory

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	checked	Dr Parashant	Satisfactory
Less volume of Wash Solution	checked	Dr Parashant	Satisfactory
More volume of Bio-Hazard waste	checked	Dr Parashant	Satisfactory
More volume of Normal / General waste	checked	Dr Parashant	Satisfactory

TRANSASIA BIOMEDICALS LIMITED			
OPERATIONAL QUALIFICATION CHECKLIST			
Em200	Clinical Chemistry Analyzer	Instrument ID	B140713

TRANSASIA Bio-Medicals Ltd.

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	checked	Dr Parashant	Satisfactory
Password Check for QC Mode	checked	Dr Parashant	Satisfactory

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	checked	Dr Parashant	Satisfactory
Water Save	checked	Dr Parashant	Satisfactory
Switch OFF the computer.	checked	Dr Parashant	Satisfactory
Switch OFF the side switch of the analyzer.	checked	Dr Parashant	Satisfactory
Switch OFF the rear switch of the analyzer.	checked	Dr Parashant	Satisfactory

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1.0 PRE APPROVAL

1.1 Prepared By

Name	Designation	Signature	Date
Rashpal Singh	Application Specialist		11-2-2022

1.2 Checked By

Name	Designation	Signature	Date
Jaswinder	Lab Supervisor		11-2-2022

1.3 Approved By

Name	Designation	Signature	Date
Dr Parashant			11-02-2022

6.0 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
CRE	CV% Should be less than 5%	As per lab requirement
URIC	CV% Should be less than 5%	As per lab requirement
AMY	CV% Should be less than 5%	As per lab requirement
SGOTD	CV% Should be less than 5%	As per lab requirement

7.0 EXECUTION OF TEST PLAN

S.NO	SGOTD	AMY	URIC	CRE
1	143.6	147	11.7	2.45
2	141	145	11.7	2.52
3	143.3	142	11.9	2.44
4	142.2	140	12	2.53
5	142.4	143	11.9	2.53
6	141.6	142	11.9	2.50
7	142.4	143	11.8	2.50
8	141	145	11.8	2.37
9	144	142	12	2.40
10	142.4	140	12.9	2.29
MEAN	142.5	143	12	2.45
SD	1.18	2.27	0.35	0.06
CV%	0.83	1.60	2.90	3.25
Acceptable	<5%	<5%	<5%	<5%

QC detail attached.

Reviewed by:

Name	Signature	Date
Dr Parashant		14-2-2022