Dear Sir/Madam,

Kindly exclude Hematology from the Scope and issue approval.

The calibration document of Biochemistry analyser is attached below.

Kindly do the needful.

Regards

Transasia Bio - Medicals Ltd., Transasia House, 8 Chandivali Studio Road, Andheri (E) Mumbai - 400 072
Tel: +91 22 4030 9000 **Fax:** +91 22 2857 3030 **Email:** transasia@transasia.co.in **CIN:** U33110MH1985PLC036198

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Certificate of Conformity and Calibration

TO WHOMSOEVER IT MAY CONCERN

ISO 15189:2012 REQUIREMENTS REGARDING,"CALIBRATION AND VERIFICATION PROCEDURE"

All Transasia Bio-Medicals Ltd diagnostics products which are distributed and for which a certificates is issued are CE Marked. Transasia Bio-Medicals Ltd , Mumbai ,manufacturers of diagnostic devices with company quality management system in compliance with standard ISO13485:2016 ;ISO9001:2015 .This means that all the processes in development and manufacturing of TBM products are guided by quality management system.

TBM declares and assure following

- **The mentioned regulations require that production system and measuring devices are qualified and manufacturing and test procedures are validated as per ISO 13485:2016 and ISO 9001:2015 standard and it is assured through schedule maintenance and by regular qualification.**
- **TBM declares to have established procedure and to maintain it in order to assure the post marketing surveillance according to directive of 98/79/EC.**
- **All physical quantities, calibrators and controls used in TBM system are fully traceable to certified standards or reference materials.**
- **All TBM products are factory calibrated and final qc passed at the time of release.**
- **The performance of TBM system at customer site is assured if regular QC measurements, cleaning and maintenance procedure as described in the instruction for use or service documentation are performed**
- **Additional calibration or verification procedure is not required in order to assure the specified performances of every TBM system. Only if user deviates from the manufactures recommendation does he have to establish site specific calibration and verification procedure as part of his accreditation process.**

Date:-26/04/2021

Manish Airan

Head Of Quality Department & Regulatory

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Transasia Bio-Medicals Ltd., No. 43, Castle Street, Richmond Road, Opp. Empire Suites, Asholnagar Bengaluru - 560025
Tel: 080 4430 9000 / 2556 8044 Email : sz2@transasia-bio-medicals.com

ERBA – EM 200
FULLY AUTOMATED BIOCHEMISTRY ANALYZER
SerialNo. V200050

INSTALLATION QUALIFICATION

For

Customer Name: H CLOUD HEALTH CARE #161B 6TH MAIN 3RDCROSS ROAD 3RD PHASE JP NAGAR BANGALORE-560078

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1.0 PRE APPROVAL

1.1 Prepared By

Name	Designation	Signature	Date
ESHWAR	SERVICE ENGINEER		19/3/22

1.2 Checked By

Name	Designation	Signature	Date
ESHWAR	SERVICE ENGINEER		19/3/22

1.3 Approved By

Name	Designation	Signature	Date
MR. RAVINDRA BABU	RSM		19/3/22

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 instrumentdata 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 instrumentwithin the following boundaries:

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

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4.0 EXECUTION TEAM

Name	Department	Designation	Signature

Transasia Bio-Medicals Ltd., No. 43, Castle Street, Richmond Road, Opp. Empire Suites, Ashoknagar Bengaluru - 560025
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5.0 INSTRUMENTDESCRIPTION

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 hour400 tests per hour (with ISE) for a cycle time of 18 seconds
Display resolution	1024 X 768
Analyzer Dimensions	810 (W) x 800 (D) x 600 (H) mm
Number of tests on board	Maximum: 50
Assay Modes	1-point, 2-point,Rate-A and Rate –B, ISE optional
Calibration	Linear (two point and multi point), Factorized and Non-linear multipoint
Sample (Tubes / Cups)	Primary tubes of 5, 7 or 10mL & sample cups
Photometric Optics	Mono and Bi-chromatic measurement using 8 wavelengths
Absorbance Range	0 – 2.5
Auxiliary Data	10,000 results
Interface	RS-232 C port for Bi-directional Communication
Stat Sampling	Total 30 positions

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Purpose:

The purpose of this instrument is to analyze the bio-chemical parameters, such as Sugar, 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.

5.0 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		
Stirrer	Yes		
Permanent Reaction Cuvette	Yes		
9 Stage Laundry System	Yes		
Light Source	Yes		
Sample Cups	Yes		
Software of EM 200	Yes		

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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.		

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INSPECTION CHECK / REVIEW

Instructions for completing the check / review

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

   "No" replies must be explained / justified.

2. When more than one component of same specification/type exists in the same equipment, individual data sheets should be filled for each component.

3. When a list of acceptable options is presented, tick (✓) the option that is actually present.

4. In the "**Method of Verification**" column indicate that item is installed and inspected according to manufacturer's specifications, such as by Visual / Physical, SOP, Test Certificate, Manual, etc.

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Instrument/ Component Name: Sample Tray / Disk

Date :19-03-2022

Description	Specified	Actual	Method of Verification	Verified by Signature
No. of patient cups / samples	30 positions	30	MANUAL	
Standards / Stat	30 positions	30+9	MANUAL	
Blank	Can be put on any position		YES	
ISE positions (Optional)	Can be programmed on any positions	NA	NA	
Controls	Can be programmed on any positions		YES	

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Instrument/ Component Name: Sample Syringe

Date :19-03-2022

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

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Instrument/ Component Name: Sample Probe

Date :19-03-2022

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

Instrument/ Component Name: Wash Station for Sample Probe

Date :19-03-2022

Description	Specified	Actual	Method of Verification	Verified by Signature
No. of position	01 No	1	MANUAL	
Type of positions	i) Drain ii) Trough		MANUAL	

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Instrument/ Component Name: Reagent Tray / Disk

Date :19-03-2022

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

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Instrument/ Component Name: Reagent Bottles

Date :19-03-2022

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

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Instrument/ Component Name: Reagent Probe

Date :19-03-2022

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

Instrument/ Component Name: Reagent Syringe

Date :19-03-2022

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

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Instrument/ Component Name: Stirrer

Date :19-03-2022

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

Instrument/ Component Name: Permanent Reaction Cuvette

Tag/Identification No.:

Date :19-03-2022

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

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Instrument/ Component Name: 7 Stage Laundry System

Date :19-03-2022

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

Instrument/ Component Name: Light Source

Date :19-03-2022

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

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Tel: 080 4430 9000 / 2556 8044 Email : sz2@transasia.co.in CIN : U33110MH1985PLC036198

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Instrument/ Component Name: Sample Cups

Date :19-03-2022

Description	Specified	Actual	Method of Verification	Verified by Signature
Quantity	500 No's		MANUAL	
MOC	Plastic		MANUAL	
Capacity	2 mL		MANUAL	

Instrument/ Component Name: Software of EM 200

Date :19-03-2022

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

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

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	MANUAL	
Distilled Water	MANUAL	
Wash Solution	MANUAL	
UPS	MANUAL	

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12.0 IDENTIFICATION AND VERIFICATION OF DOCUMENTS

12.1 DRAWINGS

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

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

12.2 GENERAL DOCUMENTS

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

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
MS.ANITHA			

16.2 Approved by

Name	Designation	Signature	Date
DR.VENUS KUMAR	Lab HEAD		

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

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ERBA– EM 200
FULLY AUTOMATED BIOCHEMISTRY ANALYZER
Serial No. V200050

OPERATIONAL QUALIFICATION

For

Customer Name: H CLOUD HEALTH CARE #161B 6TH MAIN 3RDCROSS ROAD 3RDPHASE JP NAGAR BANGALORE-560078

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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Tel: 080 4430 9000 / 2556 8044 Email : sz2@transasia.co.in CIN : U33110MH1985PLC036198

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		
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		
Ensure the availability of Biohazard Waste.	yes		
Ensure the availability of Normal Waste.	yes		
Switch ON the rear switch of the analyzer.	yes		
Switch ON the side switch of the analyzer.	yes		
Switch ON the computer and start the analyzer application software.	yes		
Initialization	yes		

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		
Cuvette Rinse	yes		

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		

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		
Standard (Multical)	yes		

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		
Less volume of Wash Solution	yes		
More volume of Bio-Hazard waste	yes		
More volume of Normal / General waste	yes		

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	NA		
Password Check for QC Mode	NA		

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		
Water Save	yes		
Switch OFF the computer.	yes		
Switch OFF the side switch of the analyzer.	yes		
Switch OFF the rear switch of the analyzer.	yes		

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TRANSASIA BIOMEDICALS LIMITED
PERFORMANCE QUALIFICATION

Customer Name: H CLOUD HEALTH CARE CENTER #161B 6TH MAIN 3RDCROSS ROAD 3RDPHASE JP NAGAR BANGALORE-560078	Model: EM-200	Serial Number:	V2000 9...

ANNEXURE-A

TABLE OF CONTENTS

1. **APPROVAL:**

Prepared By:

Name	Designation	Signature	Date
RUPESH N	APPLICATION MANAGER		6/2/12

Checked By:

Name	Designation	Signature	Date
MS.ANITHA	LAB TECHNICIAN		

Approved By:

Name	Designation	Signature	Date
DR.VENUS KUMAR	LAB HEAD		

TRANSASIA BIOMEDICALS LIMITED
PERFORMANCE QUALIFICATION

Customer Name: H CLOUD HEALTH CARE CENTER #161B 6TH MAIN 3RD CROSS ROAD 3RDPHASE JP NAGAR BANGALORE-560078	Model: EM-200	Serial Number:	V2000 9...

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2. OBJECTIVE:

The objective of this protocol is to establish documented evidence for the Performance Qualification of Fully Automated Biochemistry Analyzer and to Ensure that the results obtained are within the pre-determined Acceptance Criteria.

3. PRE-REQUISITES:

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

- Completion of Installation Qualification (IQ) prior to PQ.
- Completion of Operational Qualification (OQ) prior to PQ.

4. TEST PLAN:

Following any of 3 available test parameters precision shall be performed (N=10 *for each parameter each level*) on Mono-Level &/or Bi-Level controls and check the CV% during the Performance Qualification of Fully Automated Bio-chemistry Analyzer.

Sr.No.	Test Parameter
1.	ALBUMIN
2.	CHOLESTEROL
3.	GAMMA GT
4.	GLUCOSE
5.	SGPT
6.	PROTEIN
7.	UREA

5. ACCEPTANCE CRITERIA:

Acceptance criteria are based on the precision studies conducted as per *CLSI Guideline EP 05-A3*

6. SUMMARY:

Test Name	ALBUMIN		SGPT		GLUCOSE	
Level	ERBA NORM	ERBA PATH	ERBA NORM	ERBA PATH	ERBA NORM	ERBA PATH
Mean	3.54	5.14	39.7	80.2	91.9	273.4
SD	0.02	0.03	0.94	1.27	0.87	1.14
CV%	0.59	0.65	2.36	1.58	0.94	0.42
Acceptable Criteria (Max.value)						
Status	PASS	PASS	PASS	PASS	PASS	PASS

Traceability: Instrument Raw Data from Test Statistics Menu.
Note: This report is effective from the date of approval.

Erba Mannheim

Transasia Bio-Medicals Ltd., No. 43, C... - 560025
Tel: 080 4430 9000 / 2556 8044 ... CIN: U24231KA1996PLC036198

TRANSASIA BIOMEDICALS LIMITED
PERFORMANCE QUALIFICATION

Customer Name: H CLOUD HEALTH CARE CENTER #161B 6TH MAIN 3RD CROSS ROAD 3RDPHASE JP NAGAR BANGALORE-560078	Model: EM-200	Serial Number:	V20005...

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Annexure-B

Instrument Raw Data from Test Statistics Menu to be attached as printout attachments in Annexure-B.

Erba Mannheim