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TRANSASIA BIOMEDICALS LIMITED			
INSTALLATION QUALIFICATION			
Instrument Name	Clinical Chemistry Analyzer	Instrument ID	

1.0 PRE APPROVAL


1.1 Prepared By

Name	Designation	Signature	Date
Bign. N. m	St. ASM		12/4/21

1.2 Checked By

Name	Designation	Signature	Date
Bign. N. m	St. ASM		12/4/21

1.3 Approved By

Name	Designation	Signature	Date
Bign. N. m	St. ASM		12/4/21

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



UNMATCHED SERVICE
SINCE 1979...

13/4/21

CALIBRATION CERTIFICATE

THIS IS TO CERTIFY THAT THE FULLY AUTOMATED BIO CHEMISTRY ANALYSER EM 200 HAVING SR.NO.2002360 INSTALLED AT CPC LAB; CALICUT IS CALIBERATED ON 13/4/21 AND THE NEXT CALIBRATION DATE WILL BE ON 13/4/22.

CALIBRATOR: MULTICALIBRATOR

EXPIRY: 15/6/21

TRANSASIA BIO MEDICALS LTD

SR. A S M

CALICUT.

TRANSASIA BIOMEDICALS LIMITED
OPERATIONAL QUALIFICATION CHECKLIST

TRANSASIA
Bio-Medicals Ltd.

Instrument Name	Clinical Chemistry Analyzer	Instrument ID	
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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.

TRANSASIA BIOMEDICALS LIMITED
OPERATIONAL QUALIFICATION CHECKLIST



Instrument Name	Clinical Chemistry Analyzer	Instrument ID	
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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.	✓		
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



Instrument Name | Clinical Chemistry Analyzer | Instrument ID

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		
Cuvette Rinse	OK		


TRANSASIA BIOMEDICALS LIMITED
OPERATIONAL QUALIFICATION CHECKLIST



Instrument Name	Clinical Chemistry Analyzer	Instrument ID	
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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		

TRANSASIA BIOMEDICALS LIMITED
OPERATIONAL QUALIFICATION CHECKLIST



Instrument Name | Clinical Chemistry Analyzer | Instrument ID

2.3 Calibration:

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



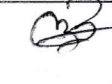
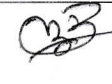
Action	Observation	Verified by (Sign & Date)	Remarks
Blank (Distilled Water)	OK		
Standard (Multical)	OK		

OPERATIONAL QUALIFICATION CHECKLIST

Instrument Name	Clinical Chemistry Analyzer	Instrument ID	
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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		
Less volume of Wash Solution	ok		
More volume of Bio-Hazard waste	ok		
More volume of Normal / General waste	ok		

TRANSASIA BIOMEDICALS LIMITED
OPERATIONAL QUALIFICATION CHECKLIST



Instrument Name | Clinical Chemistry Analyzer | Instrument ID

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		
Password Check for QC Mode	ok		

TRANSASIA BIOMEDICALS LIMITED
OPERATIONAL QUALIFICATION CHECKLIST



Instrument Name	Clinical Chemistry Analyzer	Instrument ID	
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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		
Water Save	ok		
Switch OFF the computer.	ok		
Switch OFF the side switch of the analyzer.	ok		
Switch OFF the rear switch of the analyzer.	ok		

Instrument Name

Clinical Chemistry Analyzer

Instrument ID

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TRANSASIA BIOMEDICALS LIMITED



PERFORMANCE QUALIFICATION

Instrument Name	Clinical Chemistry Analyzer	Instrument ID
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1.0 PRE APPROVAL

1.1 Prepared By

Name	Designation	Signature	Date
Bigm N.m	Sr. ASM		12/4/21

1.2 Checked By

Name	Designation	Signature	Date
Bigm N.m	Sr. ASM		12/4/21

1.3 Approved By

Name	Designation	Signature	Date
Jincy R Chandran	BIOCHEMIST		12/4/21

PERFORMANCE QUALIFICATION

Instrument Name	Clinical Chemistry Analyzer	Instrument ID	
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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
Bijan Arora			

Instrument Name

Clinical Chemistry Analyzer

Instrument ID

7.0 EXECUTION OF TEST PLAN

Reviewed by:

Name	Signature	Date

TRANSASIA BIOMEDICALS LIMITED

PERFORMANCE QUALIFICATION

TRANSASIA[®]
Bio-Medicals Ltd.

Instrument Name

Clinical Chemistry Analyzer

Instrument ID

8.0 DEFICIENCIES / DEVIATIONS:

Reviewed by:

Name	Signature	Date

TRANSASIA BIOMEDICALS LIMITED

PERFORMANCE QUALIFICATION

TRANSASIA[®]
Bio-Medicals Ltd.

Instrument Name

Clinical Chemistry Analyzer

Instrument ID

9.0 SUMMARY AND EVALUATION:

Reviewed by:

Name	Signature	Date

10.0 ABBREVIATIONS

SOP	Standard Operating Procedure
MOC	Material of Construction
PQ	Performance Qualification