### TRANSASIA BIOMEDICALS LIMITED INSTALLATION QUALIFICATION Instrument ID

Clinical Chemistry Analyzer **Instrument Name** 

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	TRANSASIA BIOMEDICALS	LIMITED		TD AMCACIA <sup>®</sup>
	INSTALLATION QUALIFIC	CATION		IKANANA
Instrument Name	Clinical Chemistry Analyzer	Instrument ID	e e	Bio-Medicals Ltd.

### 1.0 PRE APPROVAL

### 1.1 Prepared By

Name	Designation	Signature	Date
1317m. N.m	56. Asm	033	12/4/21

### 1.2 Checked By

Name	Designation	Signature	Date
Bim. N.D	578. Asm	CAB .	12/4/21
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		b	

# 1.3 Approved By

Name	Designation	Signature	Date
BIMINIO	50. Asn	(1) (1) (1) (1) (1) (1) (1) (1) (1) (1)	12/4/21

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



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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.

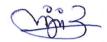
CALIBRATOR: MULTICALIBRATOR

EXPIRY:15/6/21

TRANSASIA BIO MEDICALS LTD

SR. ASM

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



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	C Die Medicale 144
Instrument Name   Clinical Chemistry Analyzer   Instrument ID	DIO-IVIBUICAIS LIU.

# 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.		023	
Ensure the proper filling of double distilled / de-ionized water and Cleaning solution in the respective cans.		03	
Ensure the availability of XL Wash.		200	
Ensure the availability of Biohazard Waste.		<b>3</b>	
Ensure the availability of Normal Waste.		03	
Switch ON the rear switch of the analyzer.		3	
Switch ON the side switch of the analyzer.			
Switch ON the computer and start the analyzer application software.		23	
Initialization			

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<b>OPERA</b>	ANSASIA BIOMEDICA TIONAL QUALIFICAT nical Chemistry Analyzer	ION CHECKLIST	TRANSASIA® Bio-Medicals Ltd.		
2.0 FUNCTIONAL CH	ECKS:				
2.1 Maintenance:					
Refer the Operator's Manual for the procedures, for the following activities:					
Activity	Observation	Verified by (Sign & Date)	Remarks		
Photometer functioning	o K	033			
Cuvette Rinse	04	3			
		4			

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Instrument Name	<b>Clinical Chemistry Analyzer</b>	Instrument ID	DIU-IVIKUIKAIS LIU.

# 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	01	000		

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OPERATIONAL QUALIFICATION CHECKLIST  Instrument Name   Clinical Chemistry Analyzer   Instrument ID				
2.3 Calibration:				
Refer the Operator's	Manual for the procedures,	for the following activit	ies:	
Action	Observation	Verified by (Sign & Date)	Remarks	
Blank (Distilled Water)	ok	03		
Standard (Multical)	0 +	03		

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OPERATIONAL QUALIFICATION CHECKLIST				Dia Madiana Ita
Instrument Name	Clinical Chemistry Analyzer	Instrument ID		DIU-WKUIGAS LIU.

# 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	03	
Less volume of Wash Solution	ok	033	
More volume of Bio- Hazard waste	0 (	23	
More volume of Normal / General waste	ok	03	

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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	93	
Password Check for QC Mode	ok	99	

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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	0 <	(2)	
Water Save	ok	<b>3</b>	
Switch OFF the computer.	ok	03	
Switch OFF the side switch of the analyzer.	OC	8	
Switch OFF the rear switch of the analyzer.	or	3	

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	PERFORMANCE QUALIFI	CATION	IKAWANA
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	PERFORMANCE QUALIFICATION		
Instrument Name	Clinical Chemistry Analyzer	Instrument ID	Bio-Medicals Ltd.

# 1.0 PRE APPROVAL

# 1.1 Prepared By

Name	Designation	Signature	Date
Bion No	5-6- A5m	03	12/4/21

# 1.2 Checked By

Name	Designation	Signature	Date
Bim N.m	56. Asm	03	12/4/21

# 1.3 Approved By

	Name	Designation	Signature	Date
Janey	R chandran	BLOCHEMIST	min	12/4/21

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Instrument Name	Clinical Chemistry Analyzer	Bio-Medicals Ltd.	

### 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
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	PERFORMANCE QUALIFI	CATION	IKANANA
<b>Instrument Name</b>	Clinical Chemistry Analyzer	<b>Instrument ID</b>	Bio-Medicals Ltd.

### 6.0 TEST PLAN

The following tests shall be followed, during the Performance Qualification of XL 640 (Bio-Chemistry Random Analyzer).

Test Parameter	Acceptance Criteria	Test Procedure / Reference
Glucose	±4.30	GOD POD
cholesterol Calcism		CHOD- PAP
Calcierm	± 0.41	Arsen 9 30 111
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7.0 EXECUTION	ON OF TEST PLA		Instrument ID	
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Instrument Name	<b>Clinical Chemistry</b>			Bio-Medicals Ltd.
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.0 SUMMAR	Y AND EVALUATION:	
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Reviewed by:	***	
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Instru	ıment Name	TRANSASIA BIOMEDICALS LIMITED PERFORMANCE QUALIFICATION Clinical Chemistry Analyzer   Instrument ID		TRANSASIA® Bio-Medicals Ltd.
	ABBREVIA			-
	SOP	Standard Operating Procedure		
	мос	Material of Construction		
	PQ	Performance Qualification		
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