TRANSASIA BIOMEDICALS LIMITED				TRALIA ALI
INSTALLATION QUALIFICATION				TRANSASIA
Instrument Name	Clinical Chemistry Analyzer	Instrument ID	v200403	Bio-Medicals Ltd.

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		TRANSASIA BIOMEDICALS	LIMITED		YM ANICACIA®
	INSTALLATION QUALIFICATION				TRANSASIA
ĺ	Instrument Name	Clinical Chemistry Analyzer	Instrument ID	v200403	Bio-Medicals Ltd.

# 1.0 PRE APPROVAL

## 1.1 Prepared By

Name .	Designation	Signature Date	
Siddharth Pandey	Sr. Application Specialist	8	

## 1.2 Checked By

Name	Designation	Signature	Date
Kuldeep	Manager	4	
		and An and an	ya gara (Algiri Malaka ka Malaka Malaka Malaka mara mamba maraya ya kenenga 1981 ang kang dapan gishara sishar

## 1.3 Approved By

Name	Designation	Signature	Date
mary t	Manager	Mer	

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



TRANSASIA BIOMEDICALS LIMITED				PRANCACIA®
INSTALLATION QUALIFICATION			TRANSASIA	
Instrument Name	Clinical Chemistry Analyzer	Instrument ID	v200403	Bio-Medicals Ltd.

## 4.0 EXECUTION TEAM

Name	Department	<b>Designation</b>	Signature
•			
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INSTALLATION QUALIFICATION			TRANSASIA	
Instrument Name	Clinical Chemistry Analyzer	Instrument ID	v200403	Bio-Medicals Ltd.

#### 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:

- o Each Installed subcomponent complies with the engineering design and instrument data sheet / design specifications & manufacturer's recommendations.
- o To ensure that all the safety features are defined before the start up of operational qualification exercise.
- o The system meets the current regulatory requirements.
- o 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:

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



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Instrument Name	Clinical Chemistry Analyzer	Instrument ID	v200403	Bio-Medicals Ltd.

#### 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 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



урга у на камерические поческой просторительной простительной простительной простительной простительной прости	TRANSASIA BIOMEDICALS	LIMITED	TRANCASIA <sup>®</sup>
INSTALLATION QUALIFICATION			Nia Hadinsla Lide
Instrument Name	Clinical Chemistry Analyzer	Instrument ID v200	0403 Bio-Medicals Ltd.

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.



TRANSASIA BIOMEDICALS LIMITED			
INSTALLATION QUALIFICATION			
Instrument Name   Clinical Chemistry Analyzer   Instrument ID   v200403	Bio-Medicals Ltd.		

## 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.

NATE OF MANY OF A FAMILY OF	Present		Verified by	Observations	
Name of Component / Accessories	Yes / N	0	Signature	Onservations	
Sample Tray / Disk	X es			,	
Sample Syringe	accessed and accessible developing the second secon	1			
Sample Probe ·	alan magini di mandala di diginggi nga a malilah na di manara di dina di dina di manara di dina di dina di din ,		energe (in		
Wash Station for Sample Probe					
Reagent Tray / Disk			The second secon	NIL	
Reagent Bottles					
Reagent Probe		gga i gaga a gang a	***************************************		
Stirrer		gapah gapan garan paganan paganan kanan kata in manan paganan kanan ka	and the second s		
Permanent Reaction Cuvette	-	annaman e chilitish e da			
9 Stage Laundry System			all market and a second a second and a second a second and a second a second and a second and a second and a second and a		
Light Source	and the state of t	angganinakan anggandak malaing bawahtinu akhi ka ang ali 1970. N	American di distanta		
Sample Cups			manip parlate rates to	,	
Software of EM 200		1 es			



	TRANSASIA BIOMEDICALS I	LIMITED		TRANSASIA®
INSTALLATION QUALIFICATION				
Instrument Name	Clinical Chemistry Analyzer	Instrument ID	v200403	Bio-Medicals Ltd.
Instrument Name	Chinear Chemistry Analyzer	REPORT WHICH IN	TAVVTVU	L

## 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	Jes .	
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.	40	



	TRANSASIA BIOMEDICALS	LIMITED		WALLEL MA®
	INSTALLATION QUALIFIC	ATION	,	IKANDAJIA -
Instrument Name	Clinical Chemistry Analyzer	Instrument ID	v200403	Bio-Medicals Ltd.

#### 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®			
INSTALLATION QUALIFICATION				A A SA ME MAN MAN ME IN THE
Instrument Name	Clinical Chemistry Analyzer	Instrument ID	v200403	Bio-Medicals Ltd.

Instrument/ Component Name: Sample Tray / Disk

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



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INSTALLATION QUALIFICATION				TRANSASIA"
Instrument Name	Clinical Chemistry Analyzer	Instrument ID	v200403	Bio-Medicals Ltd.

Instrument/ Component Name: Sample Syringe

Description	Specified	Actual	Method of Verification	Verified by Signature
Dispensing Volume	$2-70~\mu L$	Cont	ok	,
Installed Location	Behind the instrument on the right side		012	8
Quantity	01 No.	8	οK	
Increase in dispensing volume	0.2 μL	0.2 m	OIL	



TRANSASIA BIOMEDICALS LIMITED	*DANIFACIA®
INSTALLATION QUALIFICATION.	TRANSASIA
Instrument Name   Clinical Chemistry Analyzer   Instrument ID   v200403	Bio-Medicals Ltd.

Instrument/ Component Name: Sample Probe

Description	Specified	Actual	Method of Verification	Verified by Signature
Aspiration Volume	2 – 70 μL	Completis	ok	
MOC	Teflon coated	Complis	614	8
Quantity	01 No.	Complex	or.	** 
Increase in aspiration volume	0.2 μL	Compl.	n~	



	TRANSASIA BIOMEDICALS LIMITED INSTALLATION QUALIFICATION TRANSAGE  TRANSAGE  **RANSAGE**				
INSTALLATION QUALIFICATION					
Instrument Name	Clinical Chemistry Analyzer	Instrument ID	v200403	Bio-Medicals Ltd.	

Instrument/ Component Name: Wash Station for Sample Probe

Description	Specified	Actual	Method of Verification	Verified by Signature
No. of position	01 No		~	, D
Type of positions	i) Drain		<i>\</i>	
	ii) Trough			



TRANSASIA BIOMEDICALS LIMITED				PRANCE CIS
	INSTALLATION QUALIFIC	ATION		TRANSASIA
Instrument Name	Clinical Chemistry Analyzer	Instrument ID	v200403	Bio-Medicals Ltd.

Instrument/ Component Name: Reagent Tray / Disk

Description	Specified	Actual	Method of Verification	Verified by Signature
Cool reagent disk	50 positions	4		
Outer Rings	25 positions	~	V	
Inner Rings	25 positions	~		l k
Adaptors of 5mL	50 positions	<b>✓</b>	. /	
Maintenance of Temperature	8-12°C ± 2°C		·	
Rotation of disk	Counter-Clockwise	✓ ·	V	
Time for Rotation of one Cuvette	Every 18 seconds	✓	<b>/</b>	



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	INSTALLATION QUALIFIC	ATION		TRANSASIA®
Instrument Name	Clinical Chemistry Analyzer	Instrument ID	v200403	Bio-Medicals Ltd.

Instrument/ Component Name: Reagent Bottles

Description	Specified	Actual	Method of Verification	Verified by Signature
Minimum Capacity	20 mL			
Maximum Capacity	50 mL	<b></b>	· ·	
Quantity (Large)	25 Nos	. /	~	
Quantity (Smaller)	25 Nos	<b>/</b>		
Туре	Screw Capped	/		1
Outer ring position	20 mL bottles & 5ml adaptors			V
Inner ring position	20 mL & 50 mL bottles & 5ml adaptors	V	✓ .	
MOC	Plastic	/		
Adaptor	50 Nos	V		
Adaptor Capacity	5 mL			
Identification of Reagents	Barcode labels on the reagent containers			



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INSTALLATION QUALIFICATION	TRANTASIA
Instrument Name   Clinical Chemistry Analyzer   Instrument ID   v200403	Bio-Medicals Ltd.

Instrument/ Component Name: Reagent Probe

Description	Specified	Actual	Method of Verification	Verified by Signature
Aspiration/Dispensing Volume	R1: 50 – 300 μL		V	
	R2: 0 or10 – 300 μL		✓ ···	8
MOC	Teflon coated		~	
Quantity	02 Nos		~	
Increase in aspiration/dispensing volume	1 μL			



TRANSASIA BIOMEDICALS LIMITED				TRANSASIA®
	INSTALLATION QUALIFIC	ATION		,
Instrument Name	Clinical Chemistry Analyzer	Instrument ID	v200403	Bio-Medicals Ltd.

Instrument/ Component Name: Reagent Syringe

Description	Specified	Actual	Method of Verification	Verified by Signature
Maximum capacity	500,μL	~		
Installed Location	At the back of the instrument on the right side			8
Quantity	01 No.	V		
Increase in dispensing volume	1 μL			



	TRANSASIA BIOMEDICALS I	LIMITED		TRANSASIA®
INSTALLATION QUALIFICATION				
Instrument Name	Clinical Chemistry Analyzer	Instrument ID	v200403	Bio-Medicals Ltd.

Instrument/ Component Name: Stirrer

Description	Specified	Actual	Method of Verification	Verified by Signature	
Type .	Single Stirrer				
No. of paddles	01 No.		~	<i>\mathcal{k}</i>	



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ļ	TRANSASIA BIOMEDICALS LIMITED	Bran 1112 1 4100
	INSTALLATION QUALIFICATION	transasia"
	Instrument Name   Clinical Chemistry Analyzer   Instrument ID   v200403	Bio-Medicals Ltd.

Instrument/ Component Name: Permanent Reaction Cuvette

Description	Specified	Actual	Method of Verification	Verified by Signature
Quantity	45 Nos		<i>Y</i>	
MOC	Hard Glass			2
Capacity	770 μL	/		- 



TRANSASIA BIOMEDICALS LIMITED				
	INSTALLATION QUALIFIC	ATION		TRANSASIA
Instrument Name	Clinical Chemistry Analyzer	Instrument ID	v200403	Bío-Medicals Ltd.

Instrument/ Component Name: 7 Stage Laundry System

Description	Specified	Actual	Method of Verification	Verified by Signature
Nozzles	Nozzle - 1 ·			
•	Nozzle – 2			
	Nozzle – 3			
	Nozzle – 4			1
	Nozzle – 5			
	Nozzle – 6			
	Nozzle - 7		and and the second of the second and	



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INSTALLATION QUALIFICATION .	"RANVASIA"
Instrument Name   Clinical Chemistry Analyzer   Instrument ID   v200403	Bio-Medicals Ltd.

Instrument/ Component Name: Light Source

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



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	TRANSASIA BIOMEDICALS LIMITED	
	INSTALLATION QUALIFICATION	TRANSASIA"
-	Instrument Name   Clinical Chemistry Analyzer   Instrument ID   v200403	Bio-Medicals Ltd.
		ALD ILLOWINKIN PIR.

Instrument/ Component Name: Sample Cups

Date:

Description	Specified	Actual	Method of Verification	Verified by
Quantity	500 Nos'		· · · · · · · · · · · · · · · · · · ·	Signature
MOC	Plastic			
Capacity	2 mL			



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INSTALLATION OTHER VIDEO	Philippais 0
Clinical Chemistry A 1	TRANSASIA"
v200403	Bio-Medicals Ltd.

Instrument/ Component Name: Software of EM 360

Description	Specified	Actual	Method of Verification	Verified by
Version ·				Signature
	*			
CD number				• • • • • • • • • • • • • • • • • • • •
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Instrument Name Clinical Chamistry And	TRANSASIA
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v200403	Bio-Medicals Lid

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
Sample Probe	Teflon coated			Sign & Date
Reagent Probe	Teflon coated			
Permanent Reaction Cuvette	Hard Glass			
Light Source	Halogen			A -
Reagent Bottle	Plastic			8
Sample Cups	Plastic			
	Tasuc			



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	TRANSASIA BIOMEDICALS LIMITED	
		A LIGHT ALS
L	Chemistry Analyzou	TRANSASIA®
	v200403	Bio-Medicals Ltd.
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# 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
Power		Sign & Date
Distilled Water		
Wash Solution		8
UPS		-



TRANSASIA BIOMEDICALS LIMITED	And the state of t
INSTALLATION QUALIFICATION	TRANSASIA®
Clinical Chemistry Analyza:	Dia Madianta Lid
instrument ID   v200403	Bio-Medicals Ltd.

# 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



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TRANSASIA BIOMEDICALS LIMITED	•
INSTALLATION OF THE PROPERTY O	
Instrument Name   Clinical Chemistry A   Instrument Name   Clinical Chemistry	TRANSASIA®
The state of the s	
rustrument ID v200403	Bio-Medicals Ltd.
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# 12.0 IDENTIFICATION AND VERIFICATION OF DOCUMENTS

# 12.1 DRAWINGS

Title	Drawing No.	Verified by
As-built Drawing		Verified by Sign & Date
		8
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TRANSASIA BIOMEDICALS LIMITED	
INSTALLATION OTTAL TRUE	No. 41224
Instrument Name Clinical Chamistan August 1987	TRANSASIA®
Instrument Name   Clinical Chemistry Analyzer   Instrument ID   v200403	Bio-Medicals Ltd.
YZUVYUJ	OKO-IMEDICAIS LIQ.

# 12.2 GENERAL DOCUMENTS

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



Printed Annual Control	•
TRANSASIA BIOMEDICALS LIMITED	
INSTALLATION QUALIFICATION	PALLIAL AL O
Land Camera Camera	TRANSAJIA"
v200403	Bio-Medicals Ltd.
	The second second

# 13.0 DEFICIENCIES / DEVIATIONS:

NIC

# Reviewed by:

Name	Signature	and the second s
	o-gratute	Date
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And the state of t	•
TRANSASIA BIOMEDICALS LIMITED	
INSTALLATION QUALIFICATION	
Instrument Name Clinical Chemistry A. J.	TRANJASIA®
Instrument Name   Clinical Chemistry Analyzer   Instrument ID   v200	
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# 14.0 SUMMARY AND EVALUATION:

# Reviewed by:

Name	The state of the s	
	Signature	Date
Kuldan		
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and the second s		



TRANSASIA BIOMEDICALS LIMITED	
INSTALLATION QUALIFICATION	TRANSASIA®
Chnical Chemistry Analyzer Lead	
v200403	Bio-Medicals Ltd.

# 15.0 ABBREVIATIONS

SOP	Standard Operating Procedure
МОС	Material of Construction
IQ	Installation Qualification
	The state of the s



Annual particular of the selection of th		•
	TRANSASIA BIOMEDICALS LIMITED	
T	INSTALLATION QUALIFICATION Clinical Chemistry Applyone V	TRANSASIA®
	instrument ID v200403	· Biq-Medicals Ltd.

# 16.0 POST APPROVAL:

# 16.1 Checked by

Name	Designation	Signature	Date
Kuldeep	Manage	k.	
		•	

# 16.2 Approved by

Name			
	Designation	Signature	Date
Manif	Mange	W	
	The state of the s		

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



#### TRANSASIA BIOMEDICALS LIMITED OPERATIONAL QUALIFICATION CHECKLIST



Instrument Name | Clinical Chemistry Analyzer | Instrument ID | v200403

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

TRANSASIA Bio-Medicals Ltd.

Instrument Name | Clinical Chemistry Analyzer | Instrument ID | v200403

## 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.		6	
Ensure the proper filling of double distilled / de-ionized water and Cleaning solution in the respective cans.		L.	
Ensure the availability of XL Wash.		*	And the second s
Ensure the availability of Biohazard Waste.		<i>(</i> +)	
Ensure the availability of Normal Waste.		8	
Switch ON the rear switch of the analyzer.		6	
Switch ON the side switch of the analyzer.		. 6	
Switch ON the computer and start the analyzer application software.		<b>\</b>	
Initialization		P	



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TRANSASIA BIOMEDICALS LIMITED	PMANIA PIA
OPERATIONAL QUALIFICATION CHECKLIST	TRANSASIA"
Instrument Name   Clinical Chemistry Analyzer   Instrument ID   v200403	Bio-Medicals Ltd.

#### 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		6	
Cuvette Rinse		B	



TRANSASIA BIOMEDICALS LIMITED	TRANSASIA"	
OPERATIONAL QUALIFICATION CHECKLIST		
Instrument Name   Clinical Chemistry Analyzer   Instrument ID   v200403	Bio-Medicals Ed.	

## 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		6	



TRANSASIA BIOMEDICALS LIMITED		
OPERATIONAL QUALIFICATION CHECKLIST		
Instrument Name   Clinical Chemistry Analyzer   Instrument ID   v200403	Blo-M::dicals Ltd.	

## 2.3 Calibration:

Action	Observation	Verified by (Sign & Date)	Remarks
Blank (Distilled Water)	<b>V</b>	B	
Standard (Multical)		H	



# TRANSASIA BIOMEDICALS LIMITED OPERATIONAL QUALIFICATION CHECKLIST Instrument Name | Clinical Chemistry Analyzer | Instrument ID | v200403

TRANSASIA® Bio-Afedicals Ltd.

#### 3.0 INTERLOCKS AND ALARMS CHECK:

Action	Observation	Verified by (Sign & Date)	Remarks
Less volume of Distilled Water			The same of the sa
Less volume of Wash Solution		~	
More volume of Bio- Hazard waste			
More volume of Normal / General waste			



TRANSASIA BIOMEDICALS LIMITED	TRANSASIA
OPERATIONAL QUALIFICATION CHECKLIST	
Instrument Name   Clinical Chemistry Analyzer   Instrument ID   v200403	Bio-Medicals Lld.

## 4.0 SAFETY / SECURITY CHECKS:

Action	Observation	Verified by (Sign & Date)	Remarks
Password Check for Test Parameters			
Password Check for QC Mode	/		



TRANSASIA BIOMEDICALS LIMITED	TRANSASIA"
OPERATIONAL QUALIFICATION CHECKLIST	- Bio-Medicals Ltd.
Instrument Name   Clinical Chemistry Analyzer   Instrument ID   v200403	Oto modivido kiu.

### 5.0 INSTRUMENT SHUT-DOWN:

Action	Observation	Verified by (Sign & Date)	Remarks
Sample Probe Wash			
Water Save			And the second s
Switch OFF the computer.			
Switch OFF the side switch of the analyzer.			
Switch OFF the rear switch of the analyzer.			



# TRANSASIA BIOMEDICALS LIMITED PERFORMANCE QUALIFICATION Clinical Chemistry Analyzer | Instrument ID | v200403

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Instrument Name

**TRANSATIA®** Bio-Medicals Ltd.

TRANSASIA BIOMEDICALS LIMITED .				
•	PERFORMANCE QUALIFICATION			
Instrument Name	Clinical Chemistry Analyzer	Instrument ID v200403	Bio-Medicals Ltd.	

## 1.0 PRE APPROVAL

## 1.1 Prepared By

Name	Designation	Signature	Date .
Siddharth Pandey	Sr. Application Specialist	· •	1/2/20-3.

# 1.2 Checked By

Name	Designation	Signature	Date
Kyldup	Manager	Led deal	1/2/2023
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# 1.3 Approved By

Name	Designation	Signature	Date
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# TRANSASIA BIOMEDICALS LIMITED PERFORMANCE QUALIFICATION Instrument Name | Clinical Chemistry Analyzer | Instrument ID | v200403 | 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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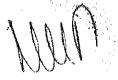


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	TRANSASIA BIOMEDICALS LIMITED	54
	PERFORMANCE QUALIFICATION	"RANSASIA"
	Instrument Name   Clinical Chemistry Analyzer   Instrument ID   v200403	Bio-Medicals Ltd,

### 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
SGOT	CV% less than 5%	As Manufacturer Guidelines
Chol	CV% less than 5%	As Manufacturer Guidelines
BIT	CV% less than 5%	As Manufacturer Guidelines
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PERFORMANCE QUALIFICATION	TRANSASIA®
Instrument Name   Clinical Chemistry Analyzer   Instrument ID   v200403	Bio•Medicals Ltd.

# 8.0 DEFICIENCIES / DEVIATIONS:



# Reviewed by:

Name	Signature	Date
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Page 6 of 9

	TRANSASIA BIOMEDICALS	LIMITED	-	*MALIPA ME®
	PERFORMANCE QUALIFIC	CATION	•	TRANSASIA®
Instrument Name	Clinical Chemistry Analyzer	Instrument ID	v200403	Bio:Medicals Ltd.

## 7.0 EXECUTION OF TEST PLAN



# Reviewed by:

Name .	Signature	Date

TRANSASIA BIOMEDICALS LIMITED	Burn 4 1 1 4 4 1 1 0
PERFORMANCE QUALIFICATION	"RANSASIA"
Instrument Name   Clinical Chemistry Analyzer   Instrument ID   v200403	Bio-Medicals Ltd.

# Reviewed by:

Name	Signature	Date
Kulderp	5	01/02/2027

# 10.0 ABBREVIATIONS

SOP	Standard Operating Procedure
MOC	Material of Construction
PQ	Performance Qualification



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PR	ERFORMANCE QUALIFIC	CATION	TRANSASIA"
Instrument Name   Cli	nical Chemistry Analyzer	Instrument ID v200403	Bio-Medicals Ltd.

## 9.0 SUMMARY AND EVALUATION:

S.NO	SGOT	Chol	BIT
1	139.0	252	4.96
2	141.4	250	4.95
3	142.3	249	4.98
4	142.3	231	4,96
5	141.4	250	4.96 .
6	145.7	248	4.93
7 .	144.1	252	4.96
8	139.9	247	4.93
9	. 141.7	247	4.90
10	140.5	249	4.94
SD	1.96	6.06	0.02
CV%	1.38	2.45	0.46
Acceptable	Less than 5%	Less than 5%	Less Than 5%



TRANSASIA BIOMEDICALS LIMITED	"RANSASIA"	
PERFORMANCE QUALIFICATION		
Instrument Name   Clinical Chemistry Analyzer   Instrument ID   v200403	Bio-Medicals Ltd.	

## 11.0 POST APPROVAL

## 11.1 Checked by

Designation	Signature	Date .
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# 11.2 Approved by

Name	Designation	Signature	Date
Mauit	Many 18m	V	8/10/2019

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



