

TRANSASIA BIOMEDICALS LIMITED			TRANSASIA Bio-Medicals Ltd.
INSTALLATION QUALIFICATION			
Instrument Name EM200	Clinical Chemistry Analyzer Dr.Dass Path Lab	Instrument ID B200537	

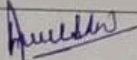
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TRANSASIA BIOMEDICALS LIMITED			
INSTALLATION QUALIFICATION			
Instrument Name EM200	Clinical Chemistry Analyzer Dr.Dass Path Lab	Instrument ID B200537	TRANSASIA Bio-Medicals Ltd.

1.0 PRE APPROVAL

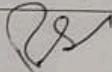
1.1 Prepared By

Name	Designation	Signature	Date
Anubhav Sharma	DY.R.S.M Service		01-11-2017

1.2 Checked By

Name	Designation	Signature	Date

1.3 Approved By

Name	Designation	Signature	Date
Dr.R.Srivastva	Pathologist		01-11-2017

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

TRANSASIA BIOMEDICALS LIMITED
INSTALLATION QUALIFICATION

Instrument Name
EM200

Clinical Chemistry Analyzer
Dr.Dass Path Lab

Instrument ID
B200537

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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


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Instrument Name EM200	Clinical Chemistry Analyzer Dr.Dass Path Lab	Instrument ID B200537	

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 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

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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.

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INSTALLATION QUALIFICATION

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EM200

Clinical Chemistry Analyzer
Dr.Dass Path Lab

Instrument ID
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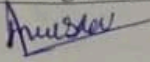
6.0 IDENTIFICATION OF MAJOR COMPONENTS / ACCESSORIES

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	<i>[Signature]</i>	<i>All are found ✓</i>
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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INSTALLATION QUALIFICATION			
Instrument Name EM200	Clinical Chemistry Analyzer Dr.Dass Path Lab	Instrument ID B200537	

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.	Yes	
3.	Verify that there is no observable physical damage.	Yes	
4.	Verify that there is sufficient room of servicing provided	Yes	
5.	Verify that all utilities and electrical connections have been done according to the drawings.	Yes	
6.	Walking access to ground mounted instrument provided.	Yes	
7.	Required electric connections are tight, weather proof and earthed.	Yes	
8.	Instrument identification nameplate visible.	Yes	
9.	Units installed on foundation and secure in place as per manufacturer's recommendations.	Yes	
10.	Verify that the instruments installed and leveled properly on the floor.	Yes	
11.	Verify that the Material of Construction is proper and meeting the requirements.	Yes	

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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.

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Instrument Name EM200	Clinical Chemistry Analyzer Dr.Dass Path Lab	Instrument ID B200537	

Instrument/ Component Name: Sample Tray / Disk

Date : 01-11-2017

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

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Instrument/ Component Name: Sample Tray / Disk

Date :01-11-2017

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

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 INSTALLATION QUALIFICATION

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Instrument Name EM200	Clinical Chemistry Analyzer Dr.Dass Path Lab	Instrument ID B200537
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Instrument/ Component Name: Sample Syringe

Date :

Description	Specified	Actual	Method of Verification	Verified by Signature
Dispensing Volume	2 – 70 µL	2 – 70 µL		<i>[Signature]</i>
Installed Location	Behind the instrument on the right side	Ok		
Quantity	01 No.	01		
Increase in dispensing volume	0.2 µL	0.2		

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Instrument Name
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Instrument/ Component Name: Sample Probe

Date : 01-11-2017

Description	Specified	Actual	Method of Verification	Verified by Signature
Aspiration Volume	2 – 70 µL	2 – 70 µL		<i>[Signature]</i>
MOC	Teflon coated	Teflon coated		
Quantity	01 No.	01		
Increase in aspiration volume	0.2 µL	0.2		

TRANSASIA BIOMEDICALS LIMITED
INSTALLATION QUALIFICATION



Instrument Name EM200	Clinical Chemistry Analyzer Dr.Dass Path Lab	Instrument ID B200537
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Instrument/ Component Name: Wash Station for Sample Probe

Date : 01-11-2017

Description	Specified	Actual	Method of Verification	Verified by Signature
No. of position	01 No	01		<i>[Signature]</i>
Type of positions	i) Drain ii) Trough	Drain Trough		

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 INSTALLATION QUALIFICATION

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Instrument Name EM200	Clinical Chemistry Analyzer Dr.Dass Path Lab	Instrument ID B200537
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Instrument/ Component Name: Reagent Tray / Disk

Date : 01-11-2017

Description	Specified	Actual	Method of Verification	Verified by Signature
Cool reagent disk	50 positions	50		<i>Auskar</i>
Outer Rings	25 positions	25		
Inner Rings	25 positions	25		
Adaptors of 5mL	50 positions	50		
Maintenance of Temperature	8-12°C ± 2°C	01-11-2017		
Rotation of disk	Counter-Clockwise	Counter-Clockwise		
Time for Rotation of one Cuvette	Every 18 seconds	Every 18 seconds		

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Instrument Name
EM200Clinical Chemistry Analyzer
Dr.Dass Path LabInstrument ID
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Instrument/ Component Name: Reagent Bottles

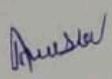
Date : 01-11-2017

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

TRANSASIA BIOMEDICALS LIMITED			
INSTALLATION QUALIFICATION			
Instrument Name EM200	Clinical Chemistry Analyzer Dr.Dass Path Lab	Instrument ID B200537	

Instrument/ Component Name: Reagent Probe

Date : 01-11-2017

Description	Specified	Actual	Method of Verification	Verified by Signature
Aspiration/Dispensing Volume	R1: 50 – 300 μ L	R1: 50 – 300 μ L		
	R2: 0 or 10 – 300 μ L	R2: 0 or 10 – 300 μ L		
MOC	Teflon coated	Teflon coated		
Quantity	02 Nos ^r .	02 Nos ^r .		
Increase in aspiration/dispensing volume	1 μ L	1 μ L		

TRANSASIA BIOMEDICALS LIMITED

INSTALLATION QUALIFICATION



Instrument Name EM200	Clinical Chemistry Analyzer Dr.Dass Path Lab	Instrument ID B200537
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Instrument/ Component Name: Reagent Syringe

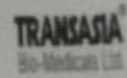
Date : 01-11-2017

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

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INSTALLATION QUALIFICATION

Instrument Name FM200	Clinical Chemistry Analyzer Dr.Dass Path Lab	Instrument ID B200537
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Instrument/ Component Name: Stirrer

Date : 01-11-2017

Description	Specified	Actual	Method of Verification	Verified by Signature
Type	Single Stirrer	Single Stirrer		<i>[Signature]</i>
No. of paddles	01 No.	01 No.		

TRANSASIA BIOMEDICALS LIMITED
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Instrument Name
 EM200

Clinical Chemistry Analyzer
 Dr.Dass Path Lab

Instrument ID
 B200537

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Instrument/ Component Name: Permanent Reaction Cuvette

Tag/Identification No.:

Date : 01-11-2017

Description	Specified	Actual	Method of Verification	Verified by Signature
Quantity	45 Nos'	45 Nos'		<i>[Signature]</i>
MOC	Hard Glass	Hard Glass		
Capacity	770 µL	770 µL		

**TRANSASIA BIOMEDICALS LIMITED
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Instrument Name
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Clinical Chemistry Analyzer
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Instrument/ Component Name: 7 Stage Laundry System

Date : 01-11-2017

Description	Specified	Actual	Method of Verification	Verified by Signature
Nozzles	Nozzle - 1	Nozzle - 1		<i>Anusha</i>
	Nozzle - 2	Nozzle - 2		
	Nozzle - 3	Nozzle - 3		
	Nozzle - 4	Nozzle - 4		
	Nozzle - 5	Nozzle - 5		
	Nozzle - 6	Nozzle - 6		
	Nozzle - 7	Nozzle - 7		

TRANSASIA BIOMEDICALS LIMITED
OPERATIONAL QUALIFICATION CHECKLIST

Instrument Name EM1200	Clinical Chemistry Analyzer Dr-Bass Path Lab	Instrument ID B200537	TRANSASIA Bio-Medicals Ltd
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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	<i>Amudat</i> 11/11/12	
Water Save	Ok	<i>Amudat</i> 11/11/12	
Switch OFF the computer.	Ok	<i>Amudat</i> 11/11/12	
Switch OFF the side switch of the analyzer.	Ok	<i>Amudat</i> 11/11/12	
Switch OFF the rear switch of the analyzer.	Ok	<i>Amudat</i> 11/11/12	

Transasia Bio-Medicals Ltd. -109-110, 1st floor, 8, Deep Shikha Building, Rajendra Place, New Delhi - 110 008
Tel: 011 - 25732223 Fax: 011 - 25789451 Email: tr@transasia.co.in CIN: U33110MH1985PLCO08198



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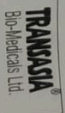
Date: 1 NOV 2018

CALIBRATION CERTIFICATE

Name of Customer : DR. DAS PATHLAB
Instrument Name : BIO CHEMISTRY ANALYSER EM1200
Instrument Sr. No. : B 200537

This is to certify that the above mentioned product does not require any instrument calibration.

For **Transasia Biomedicals Ltd**
Prashant kumar
Prashant Kumar
Service Engineer.



TRANSASIA BIOMEDICALS LIMITED
OPERATIONAL QUALIFICATION CHECKLIST
Instrument Name: Clinical Chemistry Analyzer
Dr. Dass Path Lab
EM200
Instrument ID: B200537

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	<i>Praveen</i> 11/1/19	
Password Check for QC Mode	OK	<i>Praveen</i> 11/1/19	

TRANSASIA BIOMEDICALS LIMITED

OPERATIONAL QUALIFICATION CHECKLIST

Instrument Name EM200	Clinical Chemistry Analyzer Dr.Dass Path Lab	Instrument ID B200537	
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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	<i>Prudhvi</i> 11/11/12	
Less volume of Wash Solution	Ok	<i>Prudhvi</i> 11/11/12	
More volume of Bio-Hazard waste	Ok	<i>Prudhvi</i> 11/11/12	
More volume of Normal / General waste	Ok	<i>Prudhvi</i> 11/11/12	

TRANSASIA BIOMEDICALS LIMITED			
OPERATIONAL QUALIFICATION CHECKLIST			
Instrument Name	Clinical Chemistry Analyzer	Instrument ID	
EM200	Dr. Dass Path Lab	B200537	



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	<i>Arun Kumar</i>	
Standard (Multical)	OK	<i>Arun Kumar</i>	

TRANSASIA BIOMEDICALS LIMITED			
OPERATIONAL QUALIFICATION CHECKLIST			
Instrument Name	Clinical Chemistry Analyzer	Instrument ID	
E/M200	Dr. Pass Path Lab	B200537	
			TRANSASIA Bio-Medics Ltd.

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.	OK	<i>Ausdal</i> 11/11/12	
Ensure the proper filling of double distilled / de-ionized water and Cleaning solution in the respective cans.	OK	<i>Ausdal</i> 11/11/12	
Ensure the availability of XL Wash.	OK	<i>Ausdal</i> 11/11/12	
Ensure the availability of Biohazard Waste.	OK	<i>Ausdal</i> 11/11/12	
Ensure the availability of Normal Waste.	OK	<i>Ausdal</i> 11/11/12	
Switch ON the rear switch of the analyzer.	OK	<i>Ausdal</i> 11/11/12	
Switch ON the side switch of the analyzer.	OK	<i>Ausdal</i> 11/11/12	
Switch ON the computer and start the analyzer application software.	OK	<i>Ausdal</i> 11/11/12	
Initialization	OK	<i>Ausdal</i> 11/11/12	

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	<i>Approved</i> 11/11/12	
Cuvette Rinse	Ok	<i>Approved</i> 11/11/12	

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	<i>Ausley</i> (10/11/17)	

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Tel: 011-25723224 Fax: 011-25785451 Email: nzt@transasia.co.in CIN: U33110MH1989PLCO38198

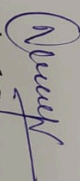


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Certificate of Training

*This is to certify that Mr. Suraj Singh working in Dr. D.ass Path
Lab New Delhi has undergone training on the operation and
user maintenance of the instrument fully Automated
Biochemistry analyzer Erba EM200.*

For Transasia Bio-Medicals Ltd.,

*
Authorized Signatory*



TRANSASIA BIOMEDICALS LIMITED
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Instrument Name EM200	Clinical Chemistry Analyzer Dr.Dass Path Lab	Instrument ID B200537
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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	Teflon coated		<i>Aravind</i>
Reagent Probe	Teflon coated	Teflon coated		
Permanent Reaction Cuvette	Hard Glass	Hard Glass		
Light Source	Halogen	Halogen		
Reagent Bottle	Plastic	Plastic		
Sample Cups	Plastic	Plastic		

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Instrument Name
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Clinical Chemistry Analyzer
Dr.Dass Path Lab

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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 Sign & Date
Power	Power	<i>Amesha</i>
Distilled Water	Distilled Water	
Wash Solution	Wash Solution	
UPS	UPS	

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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

16.0 POST APPROVAL:

16.1 Checked by

Name	Designation	Signature	Date
Anubhav Sharma	Dy.R.S.M.Service	<i>Anubhav</i>	01-11-2017

16.2 Approved by

Name	Designation	Signature	Date
Dr.R.Srivastva	Pathologist	<i>RS</i>	01-11-2017

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

TRANSASIA BIOMEDICALS LIMITED
INSTALLATION QUALIFICATION

Instrument Name
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Clinical Chemistry Analyzer
Dr.Dass Path Lab

Instrument ID
B200537

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Instrument/ Component Name: Light Source

Date : 01-11-2017

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