



Date: 27/11/2020

Calibration Certificate

Customer Name : Rainbow Diagnostics (Unit of Viraj Diagnostics Pvt Ltd)

Address of Customer: Sahibabad

Model : XL640

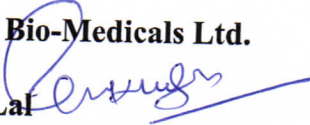
Serial No. : 640189

Calibration Done Date : 27/11/2020

Calibration Due Date : On or Before 26/11/2021

This is to certify that we have calibrated the Biochemistry Analyzer Model: XL640 bearing Sr. No. 640189 by Multi Cal Lot No B2005093A and on inspection of the instrument it is observed that the results are well within the range and instrument is working fine

Thanking you,
For
Transasia Bio-Medicals Ltd.

Lavkush Lal 

Application Specialist



TRANSASIA BIOMEDICALS LIMITED			
INSTALLATION QUALIFICATION			
Instrument Name	Clinical Chemistry Analyzer XL640	Instrument ID 640189	

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INSTALLATION QUALIFICATION				
Instrument Name	Clinical Chemistry Analyzer XL640	Instrument ID	640189	

Instructions

1. This document is to be completed at the time the system is shifted to its current location and set up for operation.
2. An authorized TRANSASIA representative will check the system and enter the specific data as outlined in the appropriate Installation Qualification. Each result will be noted and dated

1.0 PRE APPROVAL

Rainbow Diagnostics (Unit of Viraj Diagnostics Pvt Ltd) and Transasia are jointly responsible for the installation of the system ERBA CLINICAL CHEMISTRY Analyzer, Model: XL640, Serial No. 640189 in the clinical lab of Rainbow Diagnostics as per the below protocol.

Protocol Performed By: Transasia Representative

Name : Vivek Yadav
 Designation : Service Engineer
 Title : INSTALLATION-QUALIFICATION
 Company : TRANSASIA BIO-MEDICALS LTD.

Signature: *Vivek*

Date: *27/11/20*

Customer Authorizations:

Name : Mr Vijay Kumar
 Designation : Lab Director
 Title : INSTALLATION QUALIFICATION
 Site : Sahibabad

Signature :

Date :

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INSTALLATION QUALIFICATION				
Instrument Name	Clinical Chemistry Analyzer XL640	Instrument ID	640189	

2.0 OBJECTIVE

The objective of this document is to provide an outline for the inspection of XL640 (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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INSTALLATION QUALIFICATION				
Instrument Name	Clinical Chemistry Analyzer XL640	Instrument ID	640189	

4.0 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, Clinical Chemistry Analyzer
Analysis Speed	390-400 Biochemistry tests per hour 640 tests(with ISE)
Display resolution	800 x 600
Analyzer Dimensions	887 (W) x 655 (D) x 1170 (H) mm
Number of tests on board	Maximum: 56
Assay Modes	1-point, 2-point, Rate-A and Rate -B
Calibration	K-factor, Linear (1-point, two point and multi point), Logit-log, Spline , Exponential, Polynomial (second, third and fourth order) Multi-point upto 10 points. One point correction to multi-point calibration line is provided.
Sample (Tubes / Cups)	Primary tubes of 5ml(13x 75mm), 7ml(14.5x 84 mm) or 10mL(16x100mm) & sample cups 2ml.
Photometric Optics	Mono and Bi-chromatic measurement using holographic diffraction grating and 12 wavelengths.
Absorbance Range	0 – 2.5 Light path calculated as 10mm
Auxiliary Data	100,000 results Reaction curve: 9999 curves
Interface	RS-232 C port for Bi-directional Communication

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Instrument Name	Clinical Chemistry Analyzer XL640	Instrument ID	640189	

Purpose:

The purpose of this instrument is to analyze the bio-chemical parameters, such as Sugar, Cholesterol, Triglycerides, 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 60 hard glass cuvettes, a high-resolution diffraction grating (with 12 user selectable wavelengths) and a halogen lamp.

Operating Console:

The operating console consists of a touch screen (optional) color 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 512 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				
Instrument Name	Clinical Chemistry Analyzer XL640	Instrument ID	640189	

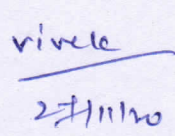
5.0 IDENTIFICATION OF MAJOR COMPONENTS / ACCESSORIES

Details of each major component identified in this section, is recorded in a data sheet.

Name of Component / Accessories	Present	Verified by Signature	Observations
	Yes / No		
Sample Tray / Disk	Yes	<i>Winele</i> <hr/> <i>27/11/20</i>	OK
Sample Syringe	Yes		
Sample Probe	Yes		
Wash Station for Sample Probe	Yes		
Reagent Tray / Disk	Yes		
Reagent Bottles	Yes		
Reagent Probe	Yes		
Reagent Syringe	Yes		
Stirrer	Yes		
Permanent Reaction Cuvette	Yes		
7 Stage Laundry System	Yes		
Light Source	Yes		
Sample Cups	Yes		
Software of XL 640	Yes		

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INSTALLATION QUALIFICATION			
Instrument Name	Clinical Chemistry Analyzer XL640	Instrument ID	

6.0 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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INSTALLATION QUALIFICATION				
Instrument Name	Clinical Chemistry Analyzer XL640	Instrument ID	640189	

8.0 INSPECTION CHECK / REVIEW

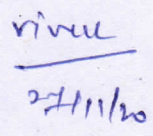
Instructions for completing the check / review

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.

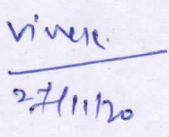
"No" replies must be explained / justified.
2. When more than one component of same specification/type exists in the same equipment, individual data sheets should be filled for each component.
3. When a list of acceptable options is presented, tick (✓) the option that is actually present.
4. In the "**Method 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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INSTALLATION QUALIFICATION				
Instrument Name	Clinical Chemistry Analyzer XL640	Instrument ID	640189	

Instrument/ Component Name: Sample Tray / Disk

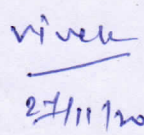
Description	Specified	Actual	Method of Verification	Verified by Signature
No. of patient cups / samples	56 positions	✓	Physical	
Standards / Stat	20 positions/20 positions on standard tray & 5 positions on sample tary.	✓	Physical	
Blank	02 Nos'	✓	Physical	
ISE positions (Optional)	02 Nos'	✓	Physical	
Controls	08 Nos'	✓	Physical	

Instrument/ Component Name: Sample Syringe

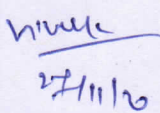
Description	Specified	Actual	Method of Verification	Verified by Signature
Dispensing Volume	2 – 70 µL	✓	Physical	
Installed Location	Behind the Front panel of the Analyzer	✓	Physical	
Quantity	01 No.	✓	Physical	
Increase in dispensing volume	0.2 µL	✓	Physical	

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Instrument Name	Clinical Chemistry Analyzer XL640	Instrument ID	640189	

Instrument/ Component Name: Sample Probe

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

Instrument/ Component Name: Wash Station for Sample Probe

Description	Specified	Actual	Method of Verification	Verified by Signature
No. of position	02 Nos'	✓	Physical	
Type of positions	i) Drain ii) Trough	✓	Physical	

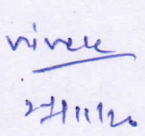
TRANSASIA BIOMEDICALS LIMITED				TRANSASIA [®] Bio-Medicals Ltd.
INSTALLATION QUALIFICATION				
Instrument Name	Clinical Chemistry Analyzer XL640	Instrument ID	640189	

Instrument/ Component Name: Reagent Tray / Disk

Description	Specified	Actual	Method of Verification	Verified by Signature
Cool reagent disk	56 positions	✓	Physical	<i>W. Vell</i> <hr style="width: 50px; margin: 0 auto;"/> <i>27/11/12</i>
Outer Rings	28 positions	✓	Physical	
Inner Rings	28 positions	✓	Physical	
Adaptors of 5mL	56 positions	✓	Physical	
Maintenance of Temperature	8-12°C ± 2°C	✓	Physical	
Rotation of disk	Counter-Clockwise	✓	Physical	
Time for Rotation of one Cuvette	Every 9 seconds	✓	Physical	

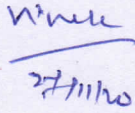
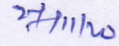
TRANSASIA BIOMEDICALS LIMITED				TRANSASIA [®] Bio-Medicals Ltd.
INSTALLATION QUALIFICATION				
Instrument Name	Clinical Chemistry Analyzer XL640	Instrument ID	640189	

Instrument/ Component Name: Reagent Bottles

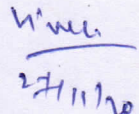
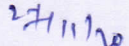
Description	Specified	Actual	Method of Verification	Verified by Signature
Minimum Capacity	20 mL	✓	Physical	
Maximum Capacity	50 mL	✓	Physical	
Quantity (Large)	25 Nos'	✓	Physical	
Quantity (Smaller)	25 Nos'	✓	Physical	
Type	Screw Capped	✓	Physical	
Outer ring position	20 mL bottles & 5ml adaptors	✓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

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA Bio-Medicals Ltd.
INSTALLATION QUALIFICATION				
Instrument Name	Clinical Chemistry Analyzer XL640	Instrument ID	640189	

Instrument/ Component Name: Reagent Probe

Description	Specified	Actual	Method of Verification	Verified by Signature
Aspiration Volume	R1: 60 – 300 μ L	✓	Physical	 
	R2: 0 or 10 – 300 μ L	✓	Physical	
MOC	Teflon coated	✓	Physical	
Quantity	02 Nos.	✓	Physical	
Increase in aspiration volume	1 μ L	✓	Physical	

Instrument/ Component Name: Reagent Syringes (R1 & R2)

Description	Specified	Actual	Method of Verification	Verified by Signature
Maximum capacity	500 μ L	✓	Physical	 
Installed Location	Beside the sample syringe	✓	Physical	
Quantity	02 Nos' (R1 & R2)	✓	Physical	
Increase in dispensing volume	0.1 μ L	✓	Physical	

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INSTALLATION QUALIFICATION				
Instrument Name	Clinical Chemistry Analyzer XL640	Instrument ID	640189	

Instrument/ Component Name: Stirrer

Description	Specified	Actual	Method of Verification	Verified by Signature
Type	Dual Stirrer	✓	Physical	<u>W. V. S.</u> 27/11/20
No. of paddles	02 Nos'	✓	Physical	

Instrument/ Component Name: Permanent Reaction Cuvette

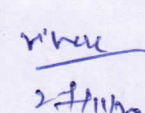
Description	Specified	Actual	Method of Verification	Verified by Signature
Quantity	72 Nos'	✓	Physical	<u>W. V. S.</u> 27/11/20
MOC	Hard Glass	✓	Physical	
Capacity	700 µL	✓	Physical	

Instrument/ Component Name: 7 Stage Laundry System

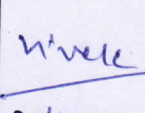
Description	Specified	Actual	Method of Verification	Verified by Signature
Nozzles	Nozzle - 1	✓	Physical	<u>W. V. S.</u> 27/11/20
	Nozzle - 2	✓	Physical	
	Nozzle - 3	✓	Physical	
	Nozzle - 4	✓	Physical	
	Nozzle - 5	✓	Physical	
	Nozzle - 6	✓	Physical	
	Nozzle - 7	✓	Physical	

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INSTALLATION QUALIFICATION				
Instrument Name	Clinical Chemistry Analyzer XL640	Instrument ID	640189	

Instrument/ Component Name: Light Source

Description	Specified	Actual	Method of Verification	Verified by Signature
Watts	12 W	✓	Physical	 27/11/20
Volts	12 V	✓	Physical	
MOC	Halogen	✓	Physical	
Quantity	01 No	✓	Physical	

Instrument/ Component Name: Software of XL640

Description	Specified	Actual	Method of Verification	Verified by Signature
Version	2017	✓	Physical	 27/11/20
CD number	NA	✓	Physical	
Product	XL 640	✓	Physical	
Make	Erba Transasia	✓	Physical	

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Instrument Name	Clinical Chemistry Analyzer XL640	Instrument ID	640189	

8.0 IDENTIFICATION AND VERIFICATION OF MATERIAL OF CONSTRUCTION

Identify and list down all components of the equipment for its material of construction.

Component (s)	Material of Construction	Actual	Method of Verification	Verified by Sign & Date
Sample Probe	Teflon coated	✓	Physical	<i>n'vella</i> <hr style="width: 50%; margin: 0 auto;"/> 27/11/20
Reagent Probe	Teflon coated	✓	Physical	
Permanent Reaction Cuvette	Hard Glass	✓	Physical	
Light Source	Halogen	✓	Physical	
Reagent Bottle	Plastic	✓	Physical	
Sample Cups	Plastic	✓	Physical	

9.0 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	OK	<i>n'vella</i> <hr style="width: 50%; margin: 0 auto;"/> 27/11/20
Distilled Water	OK	
Wash Solution	OK	
UPS	OK	

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INSTALLATION QUALIFICATION				
Instrument Name	Clinical Chemistry Analyzer XL640	Instrument ID	640189	

10.0 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

11.0 ABBREVIATIONS

SOP	Standard Operating Procedure
MOC	Material of Construction
IQ	Installation Qualification

TRANSASIA BIOMEDICALS LIMITED			TRANSASIA Bio-Medicals Ltd.
INSTALLATION QUALIFICATION			
Instrument Name	Clinical Chemistry Analyzer XL640	Instrument ID	640189

System Certification

Study data has determined that the system described in this document either meets all criteria outlined in this independently Installation Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been addressed. The system is ready for specified usage.

Protocol Performed By: Transasia Representative

Name : Vivek Yadav
 Designation : Service Engineer
 Title : INSTALLATION-QUALIFICATION
 Company : TRANSASIA BIO-MEDICALS LTD.

Signature: *Vivek*

Date: *27/11/20*

Customer Authorizations:

Name : Mr Vijay Kumar
 Designation : Lab Director
 Title : INSTALLATION QUALIFICATION
 Site : Sahibabad

Signature :

Date :



TRANSASIA BIOMEDICALS LIMITED			
OPERATIONAL QUALIFICATION			
Instrument Name	Clinical Chemistry Analyzer XL640	Instrument ID	640189

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			
Instrument Name	Clinical Chemistry Analyzer XL640	Instrument ID	

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>vivek</i> <u>27/11/20</u>	NA
Ensure the proper filling of double distilled / de-ionized water and Cleaning solution in the respective cans.	OK	<i>vivek</i> <u>27/11/20</u>	NA
Ensure the availability of XL Wash.	OK	<i>vivek</i> <u>27/11/20</u>	NA
Ensure the availability of Biohazard Waste.	OK	<i>vivek</i> <u>27/11/20</u>	NA
Ensure the availability of Normal Waste.	OK	<i>vivek</i> <u>27/11/20</u>	NA
Switch ON the rear switch of the analyzer.	OK	<i>vivek</i> <u>27/11/20</u>	NA
Switch ON the side switch of the analyzer.	OK	<i>vivek</i> <u>27/11/20</u>	NA
Switch ON the computer and start the analyzer application software.	OK	<i>vivek</i> <u>27/11/20</u>	NA
Initialization	OK	<i>vivek</i> <u>27/11/20</u>	NA

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA Bio-Medicals Ltd.
OPERATIONAL QUALIFICATION CHECKLIST				
Instrument Name	Clinical Chemistry Analyzer XL640	Instrument ID	640189	

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>Walec</i> <i>27/11/20</i>	NA
Cuvette Rinse	OK	<i>Walec</i> <i>27/11/20</i>	NA

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>Walec</i> <i>27/11/20</i>	NA

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>Walec</i> <i>27/11/20</i>	NA
Standard (Multical)	OK	<i>Walec</i> <i>27/11/20</i>	NA

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OPERATIONAL QUALIFICATION CHECKLIST			
Instrument Name	Clinical Chemistry Analyzer XL640	Instrument ID	

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>vivek</i> <u>27/11/20</u>	NA
Less volume of Wash Solution	OK	<i>vivek</i> <u>27/11/20</u>	NA
More volume of Bio-Hazard waste	OK	<i>vivek</i> <u>27/11/20</u>	NA
More volume of Normal / General waste	OK	<i>vivek</i> <u>27/11/20</u>	NA

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>vivek</i> <u>27/11/20</u>	NA
Password Check for QC Mode	OK	<i>vivek</i> <u>27/11/20</u>	NA

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA Bio-Medicals Ltd.
OPERATIONAL QUALIFICATION CHECKLIST				
Instrument Name	Clinical Chemistry Analyzer XL640	Instrument ID	640189	

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>Nivelle</i> <i>27/11/20</i>	NA
Water Save	OK	<i>Nivelle</i> <i>27/11/20</i>	NA
Switch OFF the computer.	OK	<i>Nivelle</i> <i>27/11/20</i>	NA
Switch OFF the side switch of the analyzer.	OK	<i>Nivelle</i> <i>27/11/20</i>	NA
Switch OFF the rear switch of the analyzer.	OK	<i>Nivelle</i> <i>27/11/20</i>	NA

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OPERATIONAL QUALIFICATION CHECKLIST			
Instrument Name	Clinical Chemistry Analyzer XL640	Instrument ID	640189

System Certification

Study data has determined that the system described in this document either meets all criteria outlined in this independently Operational Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been addressed. The system is ready for specified usage.

Protocol Performed By: Transasia Representative

Name	:	Vivek Yadav	Signature: <i>vivek</i>
Designation	:	Service Engineer	
Title	:	OPERATIONAL-QUALIFICATION	
Company	:	TRANSASIA BIO-MEDICALS LTD.	Date: <i>27/11/20</i>

Customer Authorizations:

Name	:	Mr Vijay Kumar	Signature: <i>vijay</i>
Designation	:	Lab Director	<i>27/11/20</i>
Title	:	INSTALLATION QUALIFICATION	
Site	:	Sahibabad	Date :



TRANSASIA BIOMEDICALS LIMITED			
PERFORMANCE QUALIFICATION			
Instrument Name	Clinical Chemistry Analyzer XL640	Instrument ID	640189

Table of Contents:

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I	Approval of the PQ procedure
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III	Scope
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I. Approval of the PQ procedure

Rainbow Diagnostics (Unit of Viraj Diagnostics Pvt Ltd) and Transasia are jointly responsible for the performance check of the system ERBA CLINICAL CHEMISTRY Analyzer, Model: XL640, Serial No. 640189 in the clinical lab of Rainbow Diagnostics as per the below protocol.

Protocol Performed By: Transasia Representative

Name : Lavkush Lal
Designation : Application Specialist
Title : PERFORMANCE-QUALIFICATION
Company : TRANSASIA BIO-MEDICALS LTD.

Signature:

Date: 27/11/20

Customer Authorizations:

Name : Mr Vijay Kumar
Designation : Lab Director
Title : PERFORMANCE QUALIFICATION
Site : Sahibabad

Signature :

Date :

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA[®] Bio-Medicals Ltd.
PERFORMANCE QUALIFICATION				
Instrument Name	Clinical Chemistry Analyzer XL640	Instrument ID	640189	

II. OBJECTIVE

The objective of this protocol is to establish documented evidence for the Performance Qualification of XL 640 (Bio-Chemistry Random Analyzer) and to ensure that the results obtained are within the pre-determined Acceptance Criteria.

III SCOPE

The Scope of this protocol is applicable to XL 640 (Bio-Chemistry Random Analyzer).

IV. 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.

V. Performance Qualification

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

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PERFORMANCE QUALIFICATION				
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6.0 TEST PLAN

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

1. Cholesterol
2. Alkaline Phosphatase
3. Uric Acid

Precision Study			
Sr. No.	Chol	ALPU	Uric Acid
1	154	257	7.8
2	163	257	7.9
3	158	259	7.9
4	158	261	8
5	160	259	8.1
6	161	258	8
7	159	257	8.3
8	164	263	8.1
9	163	256	8.1
10	165	255	8
11	161	259	8.9
12	162	260	8.1
Mean	161.27	258.55	8.13
SD	2.37	2.30	0.28
CV %	1.47	0.89	3.44

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PERFORMANCE QUALIFICATION				
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IQC Data After Calibration								
QC Lot No.	Level	Tests	Results	Unit	Mean	SD	Low Range	High Range
S052024A	Erba Norm	HDLC	46.1	mg/dl	44.43	2.96	38.51	47.39
S052025	Erba Path	HDLC	83.7	mg/dl	85.57	5.5	74.57	91.07
S052024A	Erba Norm	PRO	6.21	g/dl	5.91	0.3	5.31	6.21
S052025	Erba Path	PRO	9.27	g/dl	9.17	0.46	8.25	9.63
S052024A	Erba Norm	LIP	57.6	U/L	48.68	5	38.68	53.68
S052025	Erba Path	LIP	66.4	U/L	66.44	5.54	55.36	71.98
S052024A	Erba Norm	PHOS	3.69	mg/dl	4.23	0.21	3.81	4.44
S052025	Erba Path	PHOS	6.12	mg/dl	6.7	0.34	6.02	7.04
S052024A	Erba Norm	CHOL	113	mg/dl	110	7.15	95.7	117.15
S052025	Erba Path	CHOL	197	mg/dl	210	13.04	183.92	223.04
S052024A	Erba Norm	LDH	300	U/L	346.46	25	296.46	371.46
S052025	Erba Path	LDH	628	U/L	707.98	47.2	613.58	755.18
S052024A	Erba Norm	UA	5.6	mg/dl	5.94	0.3	5.34	6.24
S052025	Erba Path	UA	10.7	mg/dl	11.36	0.57	10.22	11.93
S052024A	Erba Norm	ALPU	114	U/L	125.95	8.4	109.15	134.35
S052025	Erba Path	ALPU	400	U/L	438.17	30	378.17	468.17
S052024A	Erba Norm	BID	0.57	mg/dl	0.62	0.1	0.42	0.72
S052025	Erba Path	BID	1.46	mg/dl	1.67	0.14	1.39	1.81
S052024A	Erba Norm	CRENZ	1.04	mg/dl	1.1	0.1	0.9	1.2
S052025	Erba Path	CRENZ	3.29	mg/dl	3.55	0.25	3.05	3.8
S052024A	Erba Norm	GLU	79.6	mg/dl	84.45	4.22	76.01	88.67
S052025	Erba Path	GLU	233.5	mg/dl	253.21	13.66	225.89	266.87
S052024A	Erba Norm	TRIG	108.7	mg/dl	110.36	5.52	99.32	115.88
S052025	Erba Path	TRIG	155.1	mg/dl	167.97	8.4	151.17	176.37
S052024A	Erba Norm	AMY	53	U/L	58.39	3.89	50.61	62.28
S052025	Erba Path	AMY	142	U/L	163.76	11	141.76	174.76
S052024A	Erba Norm	PHOS	4.36	mg/dl	4.23	0.21	3.81	4.44
S052025	Erba Path	PHOS	6.72	mg/dl	6.7	0.34	6.02	7.04
S052024A	Erba Norm	ALB	3.21	g/dl	3.53	0.18	3.17	3.71
S052025	Erba Path	ALB	4.8	g/dl	5.01	0.25	4.51	5.26

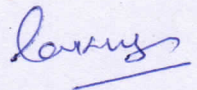
TRANSASIA BIOMEDICALS LIMITED				TRANSASIA[®] Bio-Medicals Ltd.
PERFORMANCE QUALIFICATION				
Instrument Name	Clinical Chemistry Analyzer XL640	Instrument ID	640189	

System Certification

Study data has determined that the system described in this document either meets all criteria outlined in this independently Performance Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been addressed. The system is ready for specified usage.

Protocol Performed By: Transasia Representative

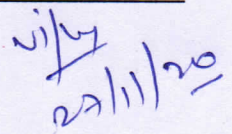
Name : Lavkush Lal
 Designation : Application Specialist
 Title : INSTALLATION-QUALIFICATION
 Company : TRANSASIA BIO-MEDICALS LTD.

Signature: 

Date: 27/11/20

Customer Authorizations:

Name : Mr Vijay Kumar
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Signature : 

Date :