



CERTIFICATE OF CALIBRATION/ VERIFICATION

Customer Name : Likhitha Diagnostics and Speciality LAB
Department : BIOCHEMISTRY
Model : Fully Automated Bio-chemistry Analyzer-EM 200
Serial Number : 2002005
Calibration Date : 23-10-2021
Next Calibration due on or before : 22.10.2022

Calibrator Used: Multical Lot : 2105079,HDL CAL-Lot :45698

Quality Control Used: Biorad L1:26491 ,Biorad L2:26492

This is to certify that the above mentioned instrument has been verified of calibration according to the procedures provided by the manufacturer in the reference manual.

The reference instruments used for value assignment are managed by the traceability systems with the manufacturer and these are traceable to international standards.

General Parameters:

Parameter	Measured Value	Acceptable Range	
Line Voltage	231 V	230 V +/- 5%	Pass
Logic Voltage	5.0 V	4.9 V to 5.1 V	Pass
Lamp Voltage	11.9 V	11.8 V to 12.2 V	Pass
Flow cell Temperature	37.0 deg	37 +/- 0.5	Pass
45 Cuvette blank value for all filter	Enclose valuesheet for all cuvette	Abs 0.03-0.2	Pass



Photometer Filter Gain Levels: Attached Instrument Print

s.no	Filter Value in nm	Filter Gain in mv	Acceptable Range of gain
1	340	469	200 mv to 800 mv
2	405	430	200 mv to 800 mv
3	505	460	200 mv to 800 mv
4	546	469	200 mv to 800 mv
5	578	497	200 mv to 800 mv
6	600	460	200 mv to 800 mv
7	660	464	200 mv to 800 mv
8	700	464	200 mv to 800 mv

Kalyanhalder

Technical Service Department

Transasia Bio-medical Limited

TRANSASIA[®]

Transasia Bio-Medicals Ltd., 1st Floor, 1-10-27/1, Street No. 3, Ashok Nagar, Hyderabad - 500 020
Tel: 040-40159005/44309000 Fax: 040-44309000 Email : sz4@transasia.co.in
CIN : U33110MH1985PLC036198



Installation Qualification –EM200

Likhitha Diagnostics and Speciality Lab

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA[®] Bio-Medicals Ltd.
INSTALLATION QUALIFICATION				
Likhitha Diagnostics and Speciality LAB	Model : EM 200	Sr No:	2002005	

TABLE OF CONTENTS

S. No	Title	Page No.
1.0	Pre Approval	2
2.0	Objective	3
3.0	Scope	3
4.0	Execution team	4
5.0	Instrument description	5 – 6
6.0	Identification of Major components / accessories	7
7.0	Installation check / review	8
8.0	Inspection check / review	9 – 23
9.0	Identification and verification of material of construction	24
10.0	Identification and verification of supporting utilities	25
11.0	Identification of standard operating procedure	26
12.0	Identification and verification of documents	27 – 28
13.0	Deficiencies / Deviations	29
14.0	Summary and Evaluation	30
15.0	Abbreviations	31
16.0	Post Approval	32

TRANSASIA BIOMEDICALS LIMITED			TRANSASIA[®] Bio-Medicals Ltd.
INSTALLATION QUALIFICATION			
Likhitha Diagnostics and Speciality LAB	Model : EM 200	Sr No: 2002005	

1.0 PRE APPROVAL

1.1 Prepared By

Name	Designation	Signature	Date
Kalyan Haldar	Application Manager	<i>Kalyan Haldar</i>	02.11.2020

1.2 Checked By

Name	Designation	Signature	Date
Ms Srija	Lab Technician	<i>Srija</i>	02.11.2020
Mr. Naveen K	Lab Technician	<i>Naveen</i>	02.11.2020

1.3 Approved By

Name	Designation	Signature	Date
Mr. Hanmant Jadhav	Quality Manager	<i>Hanjadhav</i>	02.11.2020

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

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA® Bio-Medicals Ltd.
INSTALLATION QUALIFICATION				
Likhitha Diagnostics and Speciality LAB	Model : EM 200	Sr No:	2002005	

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

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA[®] Bio-Medicals Ltd.
INSTALLATION QUALIFICATION				
Likhitha Diagnostics and Speciality LAB	Model : EM 200	Sr No:	2002005	

4.0 EXECUTION TEAM

Name	Department	Designation	Signature
Kalyan Haldar	Technical Service	Application Manager	<i>KalyanHaldar</i>
Ms Srija	Lab Technician	Lab Technician	<i>Srija</i>
Mr. Naveen K	Lab Technician	Lab Technician	<i>Naveen</i>

TRANSASIA BIOMEDICALS LIMITED**INSTALLATION QUALIFICATION****TRANSASIA**[®]
Bio-Medicals Ltd.

Likhitha Diagnostics and Speciality LAB

Model : EM 200

Sr No:

2002005

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, Clinical Chemistry Analyzer
Analysis Speed	200 Biochemistry tests per hour
Display resolution	800 x 600
Analyzer Dimensions	810 mm (W) x 700 mm (D) x 600 mm (H) mm
Number of reagent on board	Maximum: 50
Assay Modes	1-point, 2-point, Rate-A and Rate -B
Calibration	Linear, 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 holographic diffraction grating and 08 wavelengths
Absorbance Range	0 - 3.0
Auxiliary Data	10,000 results
Interface	RS-232 C port for Bi-directional Communication

TRANSASIA BIOMEDICALS LIMITED			TRANSASIA® Bio-Medicals Ltd.
INSTALLATION QUALIFICATION			
Likhitha Diagnostics and Speciality LAB	Model : EM 200	Sr No:	2002005

Purpose:

The purpose of this instrument is to analyze the bio-chemical parameters, such as Sugar, Cholesterol, 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, 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 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			TRANSASIA® Bio-Medicals Ltd.
INSTALLATION QUALIFICATION			
Likhitha Diagnostics and Speciality LAB	Model : EM 200	Sr No: 2002005	

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>Kalyan Chaudary</i>	
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 EM 200	YES		

TRANSASIA BIOMEDICALS LIMITED			
INSTALLATION QUALIFICATION			
Likhitha Diagnostics and Speciality LAB	Model : EM 200	Sr No:	2002005
			TRANSASIA® Bio-Medicals Ltd.

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	<i>Kalyan-haldar</i>
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	

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA[®] Bio-Medicals Ltd.
INSTALLATION QUALIFICATION				
Likhitha Diagnostics and Speciality LAB	Model : EM 200	Sr No:	2002005	

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 BIOMEDICALS LIMITED				TRANSASIA® Bio-Medicals Ltd.
INSTALLATION QUALIFICATION				
Likhitha Diagnostics and Speciality LAB	Model : EM 200	Sr No:	2002005	

Instrument/ Component Name: Sample Tray / Disk

Date :02.11.2020

Description	Specified	Actual	Method of Verification	Verified by Signature
No. of patient cups / samples	30 positions	30	Physical	<i>Kavya Kulkarni</i>
Standards/Blank/Control	09 positions	9	Physical	

TRANSASIA BIOMEDICALS LIMITED**INSTALLATION QUALIFICATION****TRANSASIA**[®]
Bio-Medicals Ltd.

Likhitha Diagnostics and Speciality LAB

Model : EM 200

Sr No:

2002005

Instrument/ Component Name: Sample Syringe**Date :02.11.2020**

Description	Specified	Actual	Method of Verification	Verified by Signature
Dispensing Volume	2 – 70 μ L	Same	Physical	<i>Kalyanbabu</i>
Installed Location	Behind the Front panel of the Analyzer	Same	Physical	
Quantity	01 No.	Same	Physical	
Increase in dispensing volume	0.1 μ L	Same	Physical	

TRANSASIA BIOMEDICALS LIMITED**INSTALLATION QUALIFICATION****TRANSASIA[®]**
Bio-Medicals Ltd.

Likhitha Diagnostics and Speciality LAB

Model : EM 200

Sr No:

2002005

Instrument/ Component Name: Sample Probe**Date : 02.11.2020**

Description	Specified	Actual	Method of Verification	Verified by Signature
Type of Probe	Capacitance	Same	Physical	<i>Kalyanabhai</i>
MOC	Teflon coated	Same	Physical	
Quantity	01 No.	Same	Physical	

TRANSASIA BIOMEDICALS LIMITED**INSTALLATION QUALIFICATION****TRANSASIA**[®]
Bio-Medicals Ltd.

Likhitha Diagnostics and Speciality LAB

Model : EM 200

Sr No:

2002005

Instrument/ Component Name: Wash Station for Sample Probe**Date : 02.11.2020**

Description	Specified	Actual	Method of Verification	Verified by Signature
No. of position	02 Nos'	Same	Physical	<i>Kalyan Chabbu</i>
Type of positions	i) Drain ii) Trough	Same	Physical	

TRANSASIA BIOMEDICALS LIMITED**INSTALLATION QUALIFICATION****TRANSASIA®**
Bio-Medicals Ltd.

Likhitha Diagnostics and Speciality LAB

Model : EM 200

Sr No:

2002005

Instrument/ Component Name: Reagent Tray / Disk**Date :02.11.2020**

Description	Specified	Actual	Method of Verification	Verified by Signature
Cool reagent disk	50 positions	Same	Physical	<i>Kalyan Kalyan</i>
Outer Rings	25 positions	Same	Physical	
Inner Rings	25 positions	Same	Physical	
Adaptors of 5mL	50 positions	Same	Physical	
RCT Maintenance of Temperature	37 ± 0.2°C	Same	Physical	
Rotation of disk	Both Directions	Same	Physical	
Time for Rotation of RCT Cuvette	Every 18 seconds	Same	Physical	

TRANSASIA BIOMEDICALS LIMITED**INSTALLATION QUALIFICATION****TRANSASIA®**
Bio-Medicals Ltd.

Likhitha Diagnostics and Speciality LAB

Model : EM 200

Sr No:

2002005

Instrument/ Component Name: Reagent Bottles**Date : 02.11.2020**

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

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA [®] Bio-Medicals Ltd.
INSTALLATION QUALIFICATION				
Likhitha Diagnostics and Speciality LAB	Model : EM 200	Sr No:	2002005	

Instrument/ Component Name: Sample/Reagent Probe

Date : 02.11.2020

Description	Specified	Actual	Method of Verification	Verified by Signature
Aspiration Volume	R1: 50 – 300 µL	Same	Physical	<i>Kalyanbalay</i>
	R2: 0 – 200 µL	Same	Physical	
MOC	Teflon coated	Same	Physical	
Quantity	01 Nos'.	Same	Physical	
Increase in aspiration volume	1 µL	Same	Physical	

TRANSASIA BIOMEDICALS LIMITED**INSTALLATION QUALIFICATION****TRANSASIA[®]**
Bio-Medicals Ltd.

Likhitha Diagnostics and Speciality LAB

Model : EM 200

Sr No:

2002005

Instrument/ Component Name: Sample/Reagent Syringe**Date : 02.11.2020**

Description	Specified	Actual	Method of Verification	Verified by Signature
Maximum capacity	500 µL	Same	Physical	<i>Kalyanhalay</i>
Installed Location	Beside the sample syringe	Same	Physical	
Quantity	01 Nos' (R1 & R2/Sample)	Same	Physical	
Increase in dispensing volume	0.1 µL	Same	Physical	

TRANSASIA BIOMEDICALS LIMITED**INSTALLATION QUALIFICATION****TRANSASIA®**
Bio-Medicals Ltd.

Likhitha Diagnostics and Speciality LAB

Model : EM 200

Sr No:

2002005

Instrument/ Component Name: Stirrer**Date : 02.11.2020**

Description	Specified	Actual	Method of Verification	Verified by Signature
Type	Single Stirrer	Same	Physical	<i>Kalyanrao</i>
No. of paddles	01 Nos'	Same	Physical	

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA® Bio-Medicals Ltd.
INSTALLATION QUALIFICATION				
Likhitha Diagnostics and Speciality LAB	Model : EM 200	Sr No:	2002005	

Instrument/ Component Name: Permanent Reaction Cuvette

Tag/Identification No.:

Date : 02.11.2020

Description	Specified	Actual	Method of Verification	Verified by Signature
Quantity	45 Nos'	Same	Physical	<i>Kalyanbabu</i>
MOC	Hard Glass	Same	Physical	
Capacity	700 µL	Same	Physical	

TRANSASIA BIOMEDICALS LIMITED**INSTALLATION QUALIFICATION****TRANSASIA®**
Bio-Medicals Ltd.

Likhitha Diagnostics and Speciality LAB

Model : EM 200

Sr No:

2002005

Instrument/ Component Name: 8 Stage Laundry System**Date : 02.11.2020**

Description	Specified	Actual	Method of Verification	Verified by Signature
Nozzles	Nozzle - 1	Same	Physical	<i>Kayantaday</i>
	Nozzle - 2	Same	Physical	
	Nozzle - 3	Same	Physical	
	Nozzle - 4	Same	Physical	
	Nozzle - 5	Same	Physical	
	Nozzle - 6	Same	Physical	
	Nozzle - 7,8	Same	Physical	

TRANSASIA BIOMEDICALS LIMITED			TRANSASIA® Bio-Medicals Ltd.
INSTALLATION QUALIFICATION			
Likhitha Diagnostics and Speciality LAB	Model : EM 200	Sr No: 2002005	

Instrument/ Component Name: Light Source

Date :02.11.2020

Description	Specified	Actual	Method of Verification	Verified by Signature
Watts	20W	Same	Physical	<i>Kayalab</i>
Volts	12 V	Same	Physical	
MOC	Halogen	Same	Physical	
Quantity	01 No	Same	Physical	

TRANSASIA BIOMEDICALS LIMITED**INSTALLATION QUALIFICATION****TRANSASIA**[®]
Bio-Medicals Ltd.

Likhitha Diagnostics and Speciality LAB

Model : EM 200

Sr No:

2002005

Instrument/ Component Name: Sample Cups**Date :02.11.2020**

Description	Specified	Actual	Method of Verification	Verified by Signature
Quantity	30 Nos'	Same	Physical	<i>Kalyanbabu</i>
MOC	Plastic	Same	Physical	
Capacity	2 mL	Same	Physical	

TRANSASIA BIOMEDICALS LIMITED**INSTALLATION QUALIFICATION****TRANSASIA[®]**
Bio-Medicals Ltd.

Likhitha Diagnostics and Speciality LAB

Model : EM 200

Sr No:

2002005

Instrument/ Component Name: Software of EM 200**Date : 02.11.2020**

Description	Specified	Actual	Method of Verification	Verified by Signature
Version	Multi XL V2019.07A(EM2 00 CS-T)	Same	Physical	<i>Kayalabhar</i>
Product	EM 200	Same	Physical	
Make	Erba Transasia	Same	Physical	

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA® Bio-Medicals Ltd.
INSTALLATION QUALIFICATION				
Likhitha Diagnostics and Speciality LAB	Model : EM 200	Sr No:	2002005	

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	Same	Physical	<i>Kalyanbalaji</i>
Reagent Probe	Teflon coated	Same	Physical	
Permanent Reaction Cuvette	Hard Glass	Same	Physical	
Light Source	Halogen	Same	Physical	
Reagent Bottle	Plastic	Same	Physical	
Sample Cups	Plastic	Same	Physical	

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA® Bio-Medicals Ltd.
INSTALLATION QUALIFICATION				
Likhitha Diagnostics and Speciality LAB	Model : EM 200	Sr No:	2002005	

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	Physical	<i>Kayantaban</i>
Distilled Water	Physical	
Wash Solution	Physical	
UPS	Physical	

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA® Bio-Medicals Ltd.
INSTALLATION QUALIFICATION				
Likhitha Diagnostics and Speciality LAB	Model : EM 200	Sr No:	2002005	

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

TRANSASIA BIOMEDICALS LIMITED			TRANSASIA® Bio-Medicals Ltd.
INSTALLATION QUALIFICATION			
Likhitha Diagnostics and Speciality LAB	Model : EM 200	Sr No:	2002005

12.0 IDENTIFICATION AND VERIFICATION OF DOCUMENTS

12.1 DRAWINGS

Title	Drawing No.	Verified by Sign & Date
As-built Drawing	Annexure – 01	<i>Kalyanbatar</i> 02.11.20

TRANSASIA BIOMEDICALS LIMITED

INSTALLATION QUALIFICATION

TRANSASIA[®]
Bio-Medicals Ltd.

Likhitha Diagnostics and Speciality LAB

Model : EM 200

Sr No:

2002005

12.2 GENERAL DOCUMENTS

Title	Document No.	Verified by Sign & Date
General		
Invoice		<i>Kalyanrao</i> 02.11.20

TRANSASIA BIOMEDICALS LIMITED

INSTALLATION QUALIFICATION

TRANSASIA[®]
Bio-Medicals Ltd.

Likhitha Diagnostics and Speciality LAB


Model : EM 200

Sr No:

2002005

13.0 DEFICIENCIES / DEVIATIONS:


Reviewed by:

Name	Signature	Date
Mr.Hanmant Jadhav	Quality Manager 	02.11.2020

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA® Bio-Medicals Ltd.
INSTALLATION QUALIFICATION				
Likhitha Diagnostics and Speciality LAB	Model : EM 200	Sr No:	2002005	

14.0 SUMMARY AND EVALUATION:

Reviewed by:

Name	Signature	Date
Mr.Hanmant Jadhav	Quality Manager 	02.11.2020

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA[®] Bio-Medicals Ltd.
INSTALLATION QUALIFICATION				
Likhitha Diagnostics and Speciality LAB	Model : EM 200	Sr No:	2002005	

15.0 ABBREVIATIONS

SOP	Standard Operating Procedure
MOC	Material of Construction
IQ	Installation Qualification
Same	As Per Specified
Physical	Verified Visible


TRANSASIA BIOMEDICALS LIMITED				TRANSASIA® Bio-Medicals Ltd.
INSTALLATION QUALIFICATION				
Likhitha Diagnostics and Speciality LAB	Model : EM 200	Sr No:	2002005	

16.0 POST APPROVAL:

16.1 Checked by

Name	Designation	Signature	Date
Ms Srija	Lab Technician	Ms. Srija	02.11.2020
Mr. Naveen K	Lab Technician	Mr. Naveen	02.11.2020

16.2 Approved by

Name	Designation	Signature	Date
Mr. Hanmant Jadhav	Quality Manager		02.11.2020

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

Operation Qualification –EM200

Likhitha Diagnostics and Speciality Lab

TRANSASIA BIOMEDICALS LIMITED**OPERATIONAL QUALIFICATION****TRANSASIA**[®]
Bio-Medicals Ltd.

Likhitha Diagnostics and Speciality Lab

Model: EM 200

Sr No:

2002005

TABLE OF CONTENTS

S. No	Title	Page No.
1.0	Pre Approval	2
2.0	Objective	3
3.0	Scope	3
4.0	Pre- Requisites	3
5.0	Execution Team	3
6.0	Operational Qualification List	4
7.0	Instrument Start Up	5
8.0	Functional Checks	6
9.0	Loading of Reagents	7
10.0	Calibration	8
11.0	Interlocks and Alarm Checks	9
12.0	Safety/Security Checks	10
13.0	Instrument Shut Down	11
14.0	Abbreviations	12
15.0	Post Approval	13

TRANSASIA BIOMEDICALS LIMITED**OPERATIONAL QUALIFICATION****TRANSASIA**[®]
Bio-Medicals Ltd.

Likhitha Diagnostics and Speciality Lab

Model: EM 200

Sr No:

2002005

1.0 PRE APPROVAL**1.1 Prepared By**

Name	Designation	Signature	Date
Kalyan Haldar	Application Manager	<i>Kalyan Haldar</i>	02.11.20

1.2 Checked By

Name	Designation	Signature	Date
Ms Srija	Lab Technician	<i>Srija</i>	02-11-20
Mr. Naveen K	Lab Technician	<i>Naveen</i>	02-11-20

1.3 Approved By

Name	Designation	Signature	Date
Mr. Hanmant Jadhav	Quality Manager	<i>Hanjadhav</i>	02.11.2020

TRANSASIA BIOMEDICALS LIMITED**OPERATIONAL QUALIFICATION****TRANSASIA**[®]
Bio-Medicals Ltd.

Likhitha Diagnostics and Speciality Lab

Model: EM 200

Sr No: 2002005

2.0 OBJECTIVE

The objective of this protocol is to establish documented evidence for the Operational 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 Operational Qualification.

- Completion of Installation Qualification prior to OQ

5.0 EXECUTION TEAM

Name	Department	Designation	Signature
Kalyan Haldar	Technical Service	Application Manager	<i>Kalyan Haldar</i>
Ms Srija	Laboratory	Lab Technician	<i>Srija</i>
Mr. Naveen K	Laboratory	Lab Technician	<i>Naveen</i>

TRANSASIA BIOMEDICALS LIMITED

OPERATIONAL QUALIFICATION



Likhitha Diagnostics and Speciality Lab

Model: EM 200

Sr No:

2002005

6.0 OPERATIONAL QUALIFICATION LIST

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

TRANSASIA[®]
Bio-Medicals Ltd.

Likhitha Diagnostics and Speciality Lab

Model: EM 200

Sr No:

2002005

7.0 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.	Physical	<i>Kalyan</i> 02.11.20	
Ensure the proper filling of double distilled / de-ionized water and Cleaning solution in the respective cans.	Physical	<i>Kalyan</i> 02.11.20	
Ensure the availability of XL Wash.	Physical	<i>Kalyan</i> 02.11.20	
Ensure the availability of Biohazard Waste.	Physical	<i>Kalyan</i> 02.11.20	
Ensure the availability of Normal Waste.	Physical	<i>Kalyan</i> 02.11.20	
Switch ON the rear switch of the analyzer.	Physical	<i>Kalyan</i> 02.11.20	
Switch ON the side switch of the analyzer.	Physical	<i>Kalyan</i> 02.11.20	
Switch ON the computer and start the analyzer application software.	Physical	<i>Kalyan</i> 02.11.20	
Initialization	Physical	<i>Kalyan</i> 02.11.20	

Likhitha Diagnostics and Speciality Lab

Model: EM 200

Sr No:

2002005

8.0 FUNCTIONAL CHECKS:**Maintenance:**

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

Activity	Observation	Verified by (Sign & Date)	Remarks
Photometer functioning	Physical	<i>Kalyanababu</i> 02.11.20	
Cuvette Rinse	Physical	<i>Kalyanababu</i> 02.11.20	

TRANSASIA BIOMEDICALS LIMITED**OPERATIONAL QUALIFICATION****TRANSASIA**[®]
Bio-Medicals Ltd.

Likhitha Diagnostics and Speciality Lab

Model: EM 200

Sr No: 2002005

9.0 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	Physical	<i>Kalyanbabbar</i> 02.11.20	

TRANSASIA BIOMEDICALS LIMITED**OPERATIONAL QUALIFICATION**

Likhitha Diagnostics and Speciality Lab

Model: EM 200

Sr No:

2002005

TRANSASIA
Bio-Medicals Ltd.**10.0 Calibration:**

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

Action	Observation	Verified by (Sign & Date)	Remarks
Blank (Distilled Water)	Physical	<i>Kalyanharan</i> 02.11.20	
Standard (Multical)	Physical	<i>Kalyanharan</i> 02.11.20	

TRANSASIA BIOMEDICALS LIMITED

OPERATIONAL QUALIFICATION

TRANSASIA[®]
Bio-Medicals Ltd.

Likhitha Diagnostics and Speciality Lab

Model: EM 200

Sr No:

2002005

11. 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	Physical	<i>Kalyan</i> 02.11.20	
Less volume of Wash Solution	Physical	<i>Kalyan</i> 02.11.20	
More volume of Bio-Hazard waste	Physical	<i>Kalyan</i> 02.11.20	
More volume of Normal / General waste	Physical	<i>Kalyan</i> 02.11.20	

TRANSASIA BIOMEDICALS LIMITED**OPERATIONAL QUALIFICATION****TRANSASIA**[®]
Bio-Medicals Ltd.

Likhitha Diagnostics and Speciality Lab

Model: EM 200

Sr No:

2002005

12.0 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	Physical	<i>Kalyan</i> 02.11.20	
Password Check for QC Mode	Physical	<i>Kalyan</i> 02.11.20	

TRANSASIA BIOMEDICALS LIMITED

OPERATIONAL QUALIFICATION

TRANSASIA[®]
Bio-Medicals Ltd.

Likhitha Diagnostics and Speciality Lab

Model: EM 200

Sr No: 2002005

13.0 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	Physical	<i>Kalyan</i> 02.11.20	
Water Save	Physical	<i>Kalyan</i> 02.11.20	
Switch OFF the computer.	Physical	<i>Kalyan</i> 02.11.20	
Switch OFF the side switch of the analyzer.	Physical	<i>Kalyan</i> 02.11.20	
Switch OFF the rear switch of the analyzer.	Physical	<i>Kalyan</i> 02.11.20	

15.0 ABBREVIATIONS

SOP	Standard Operating Procedure
MOC	Material of Construction
OQ	Operation Qualification
Physical	Verified Visible

TRANSASIA BIOMEDICALS LIMITED**OPERATIONAL QUALIFICATION****TRANSASIA**[®]
Bio-Medicals Ltd.

Likhitha Diagnostics and Speciality Lab

Model: EM 200

Sr No:

2002005

15.0 POST APPROVAL**15.1 Checked by**

Name	Designation	Signature	Date
Kalyan Haldar	Application Manager		<i>Kalyan</i> 02.11.20
Ms Srija	Laboratory	Lab Technician	02.11.2020
Mr. Naveen K	Laboratory	Lab Technician	02.11.2020

15.2 Approved by

Name	Designation	Signature	Date
Mr. Hanmant Jadhav	Quality Manager	<i>Hanj</i>	02.11.2020

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



UNMATCHED SERVICE
SINCE 1979...

Performance Qualification –EM200

Likhitha Diagnostics and Speciality Lab

TRANSASIA BIOMEDICALS LIMITED**PERFORMANCE QUALIFICATION**

Likhitha Diagnostics and Speciality Lab

Model: EM 200

Sr No:

2002005

TRANSASIA[®]
Bio-Medicals Ltd.**TABLE OF CONTENTS**

S. No	Title	Page No.
1.0	Pre approval	02
2.0	Objective	03
3.0	Scope	03
4.0	Pre- Requisites	03
5.0	Execution Team	03
6.0	Test Plan	04 - 07
7.0	Execution of Test Plan	08
8.0	Deficiencies / Deviations	09
9.0	Summary and Evaluation	10
10.0	Abbreviations	11
11.0	Post Approval	12

TRANSASIA BIOMEDICALS LIMITED			
PERFORMANCE QUALIFICATION			
Likhitha Diagnostics and Speciality Lab	Model: EM 200	Sr No: 2002005	TRANSASIA Bio-Medicals Ltd.

1.0 PRE APPROVAL

1.1 Prepared By

Name	Designation	Signature	Date
Kalyan Haldar	Application Manager	<i>Kalyan Haldar</i>	04.11.20

1.2 Checked By

Name	Designation	Signature	Date
Ms Srija	Lab Technician	<i>Srija</i>	04-11-21
Mr. Naveen K	Lab Technician	<i>Naveen</i>	04-11-20

1.3 Approved By

Name	Designation	Signature	Date
Mr. Hanmant Jadhav	Quality Manager	<i>Hanjadhav</i>	04.11.2020

TRANSASIA BIOMEDICALS LIMITED**PERFORMANCE QUALIFICATION**

Likhitha Diagnostics and Speciality Lab

Model: EM 200

Sr No:

2002005

TRANSASIA[®]
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
	Laboratory	Lab Technician	
A.V.Subbarao	Technical Services	RSM	
Kalyan Haldar	Technical Services	Application Manager	

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA [®] Bio-Medicals Ltd.
PERFORMANCE QUALIFICATION				
Likhitha Diagnostics and Speciality Lab	Model: EM 200	Sr No:	2002005	

6.0 TEST PLAN

The following tests shall be followed, during the Performance Qualification of EM 200(Bio-Chemistry Random Analyzer).

6.1 Calibration:

Calibrator Name: XL Multi Cal-Done Calibration of all parameter.

TRANSASIA BIOMEDICALS LIMITED

PERFORMANCE QUALIFICATION



Likhitha Diagnostics and Speciality Lab

Model: EM 200

Sr No:

2002005

6.2. Control Data:

Quality Control L1 ,L2 all parameter Result Came with in the range

TRANSASIA BIOMEDICALS LIMITED

PERFORMANCE QUALIFICATION



Likhitha Diagnostics and Speciality Lab


Model: EM 200

Sr No:

2002005

7.0 EXECUTION OF TEST PLAN


Reviewed by:

Name	Signature	Date
Mr.Hanmant Jadhav		04.11.2020

TRANSASIA BIOMEDICALS LIMITED			
PERFORMANCE QUALIFICATION			
Likhitha Diagnostics and Speciality Lab	Model: EM 200	Sr No:	2002005
			TRANSASIA[®] Bio-Medicals Ltd.

8.0 DEFICIENCIES / DEVIATIONS:

Reviewed by:

Name	Signature	Date
Mr.Hanmant Jadhav		04.11.2020

TRANSASIA BIOMEDICALS LIMITED**PERFORMANCE QUALIFICATION****TRANSASIA**[®]
Bio-Medicals Ltd.


Likhitha Diagnostics and Speciality Lab

Model: EM 200

Sr No:

2002005

9.0 SUMMARY AND EVALUATION:**Reviewed by:**

Name	Signature	Date
Mr.Hanmant Jadhav		04.11.2020

TRANSASIA BIOMEDICALS LIMITED			
PERFORMANCE QUALIFICATION			
Likhitha Diagnostics and Speciality Lab	Model: EM 200	Sr No:	2002005
			TRANSASIA [®] Bio-Medicals Ltd.

10.0 ABBREVIATIONS

SOP	Standard Operating Procedure
MOC	Material of Construction
PQ	Performance Qualification

TRANSASIA BIOMEDICALS LIMITED

PERFORMANCE QUALIFICATION



Likhitha Diagnostics and Speciality Lab	Model: EM 200	Sr No:	2002005
---	---------------	--------	---------

11.0 POST APPROVAL

11.1 Checked by

Name	Designation	Signature	Date
Kalyan Haldar	Application Manager	<i>Kalyan Haldar</i>	01.11.20
Ms Sristi	Lab Technician	<i>Sristi</i>	04.11.20
Mr. Naveen K	Lab Technician	<i>Naveen</i>	04-11-20

11.2 Approved by

Name	Designation	Signature	Date
Mr. Hanmant Jadhav	Quality Manager	<i>Hanjadhav</i>	04.11.2020

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

Calibration - EM 200

Test : GLU

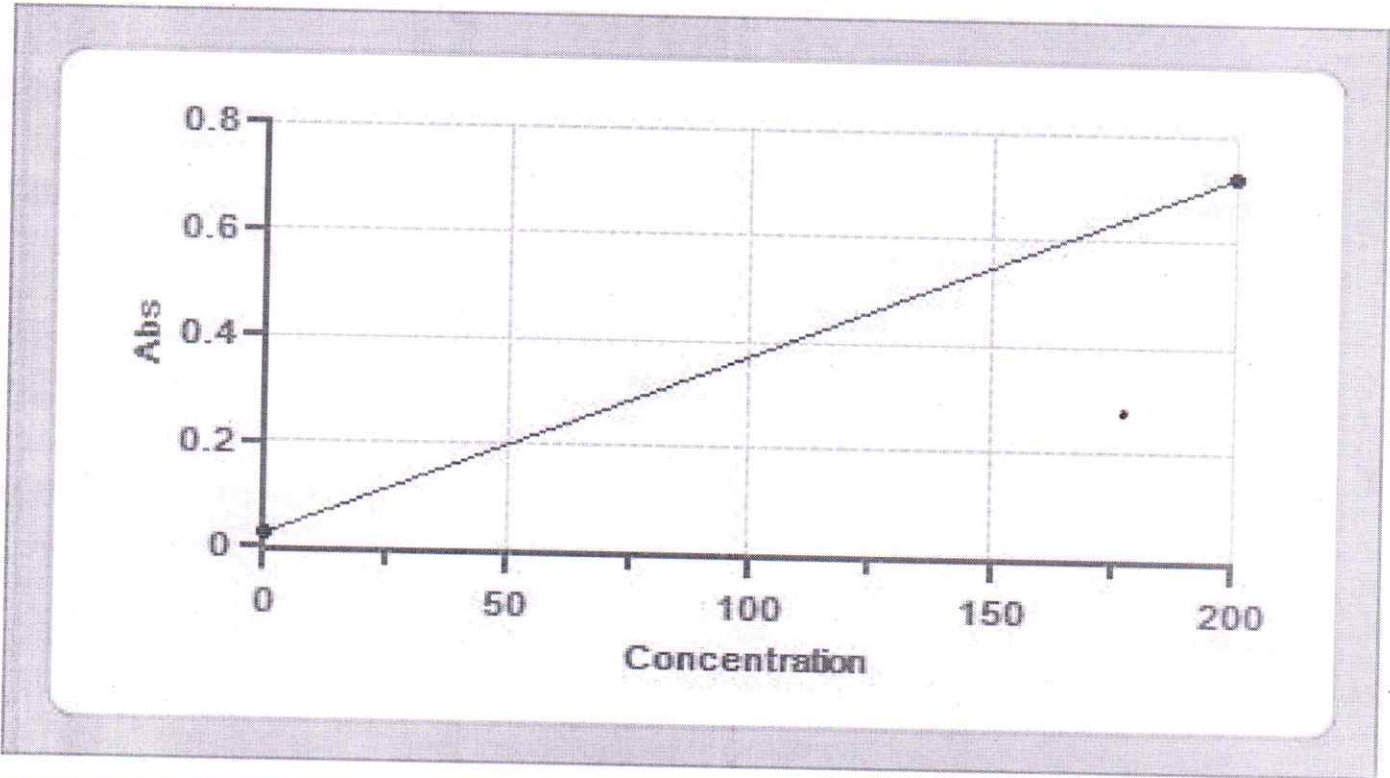
Curve Type : Linear

R1 Lot No : B062139-125

Calibration Date : 12-Feb-2022 19:14:59

R2 Lot No : ---

Last Calibration Date : 12-Feb-2022 19:14:59



Pos	Consumable	LotNo.	Conc	Abs	Factor
I-1	DI WATER	45698	0.000	0.0270	0.0000
I-5	XL MULTICAL	2105079B	200.000	0.7214	288.0184

Calibration - EM 200

Test : UREA

Revision : <A-200-UREA-2 01.03.2016>

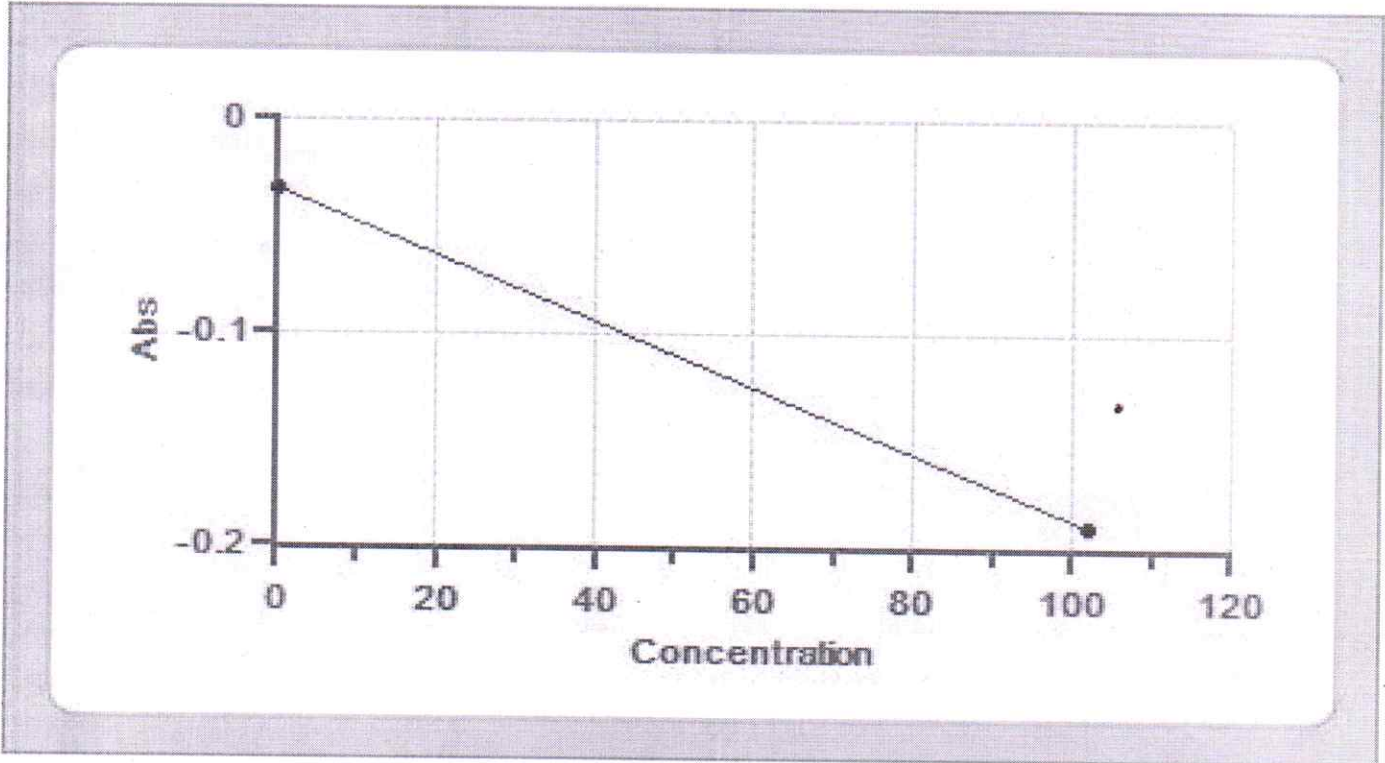
Curve Type : Linear

R1 Lot No : S052146-120

Calibration Date : 12-Feb-2022 19:11:22

R2 Lot No : S052146-120

Last Calibration Date : 12-Feb-2022 19:11:22



Pos	Consumable	LotNo.	Conc	Delta Abs/Min	Factor
I-1	DI WATER	45698	0.000	-0.0323	0.0000
I-5	XL MULTICAL	2105079B	102.000	-0.1900	-647.0029

Calibration - EM 200

Test : CRENZ

Revision : <A-200-CRENZ-1 01.08.2014>

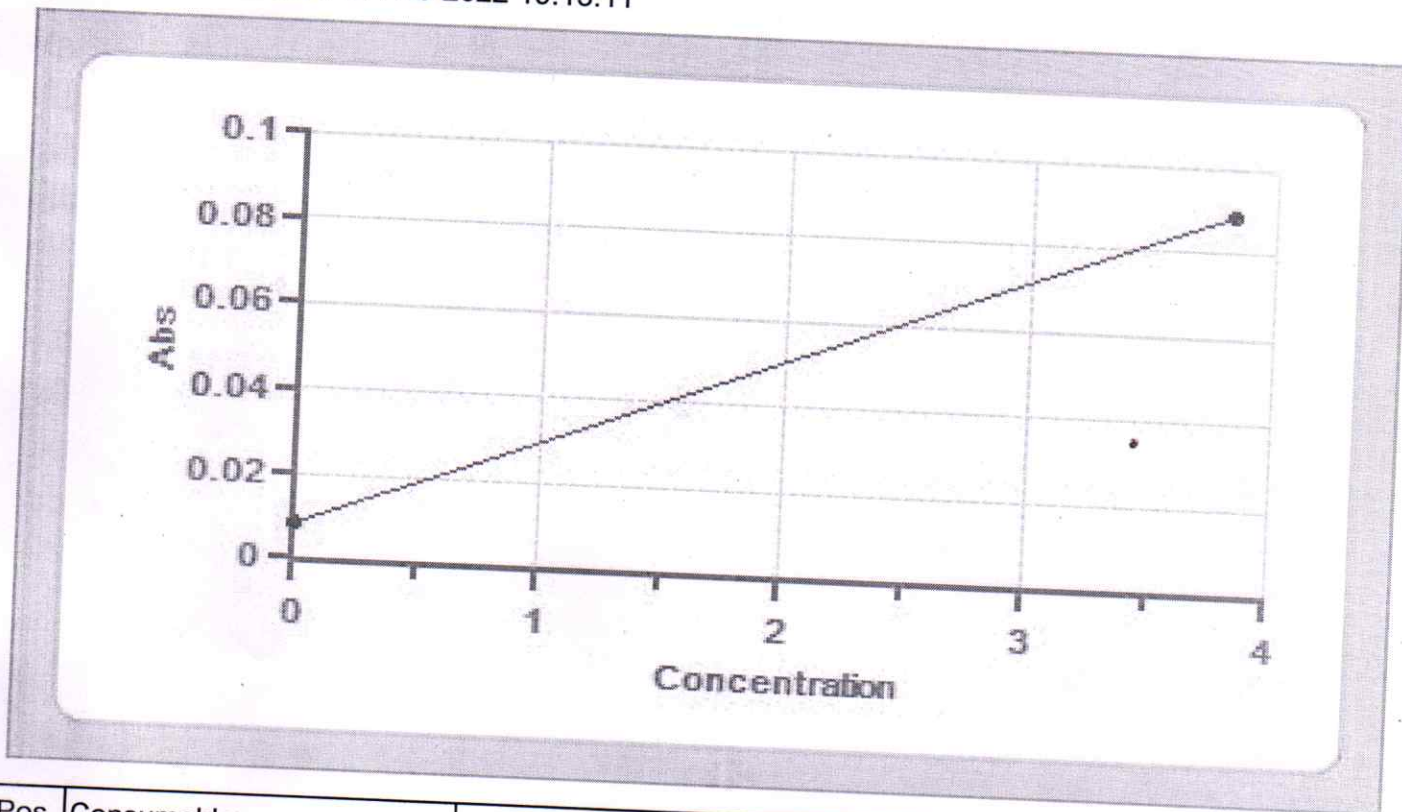
Curve Type : Linear

R1 Lot No : S112140-148

Calibration Date : 12-Feb-2022 19:13:11

R2 Lot No : S112140-148

Last Calibration Date : 12-Feb-2022 19:13:11



Pos	Consumable	LotNo.	Conc	Abs	Factor
I-1	DI WATER	45698	0.000	0.0083	0.0000
I-5	XL MULTICAL	2105079B	3.830	0.0889	47.5186

Calibration - EM 200

Test : BIT

Revision : <A-200-BIT-2 26.09.2013>

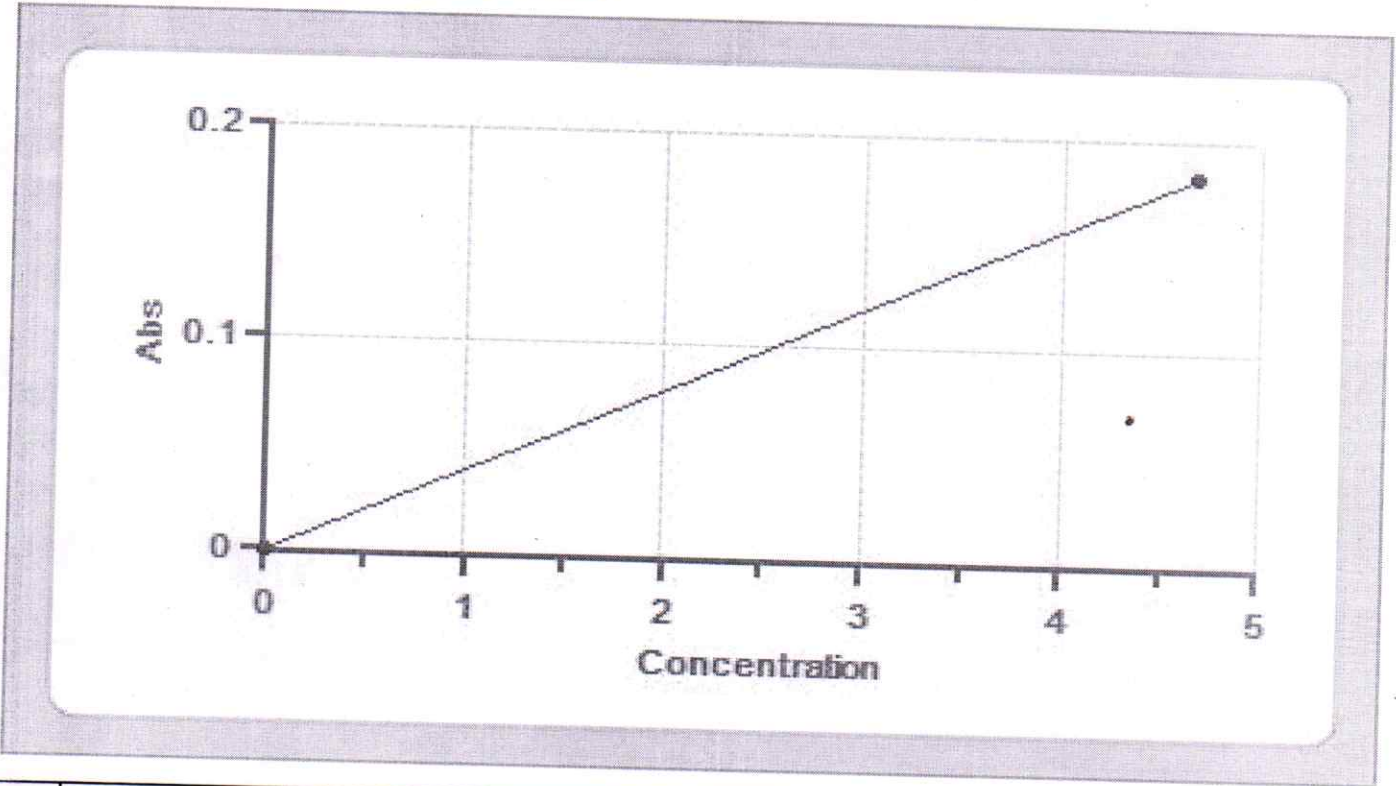
Curve Type : Linear

R1 Lot No : S102146-143

Calibration Date : 12-Feb-2022 19:09:34

R2 Lot No : S102146-143

Last Calibration Date : 12-Feb-2022 19:09:34



Pos	Consumable	LotNo.	Conc	Abs	Factor
I-1	DI WATER	45698	0.000	0.0001	0.0000
I-5	XL MULTICAL	2105079B	4.680	0.1829	25.6088

Calibration - EM 200

Test : BIDD

Revision : <A-200-BIDD-4 10.04.2018>

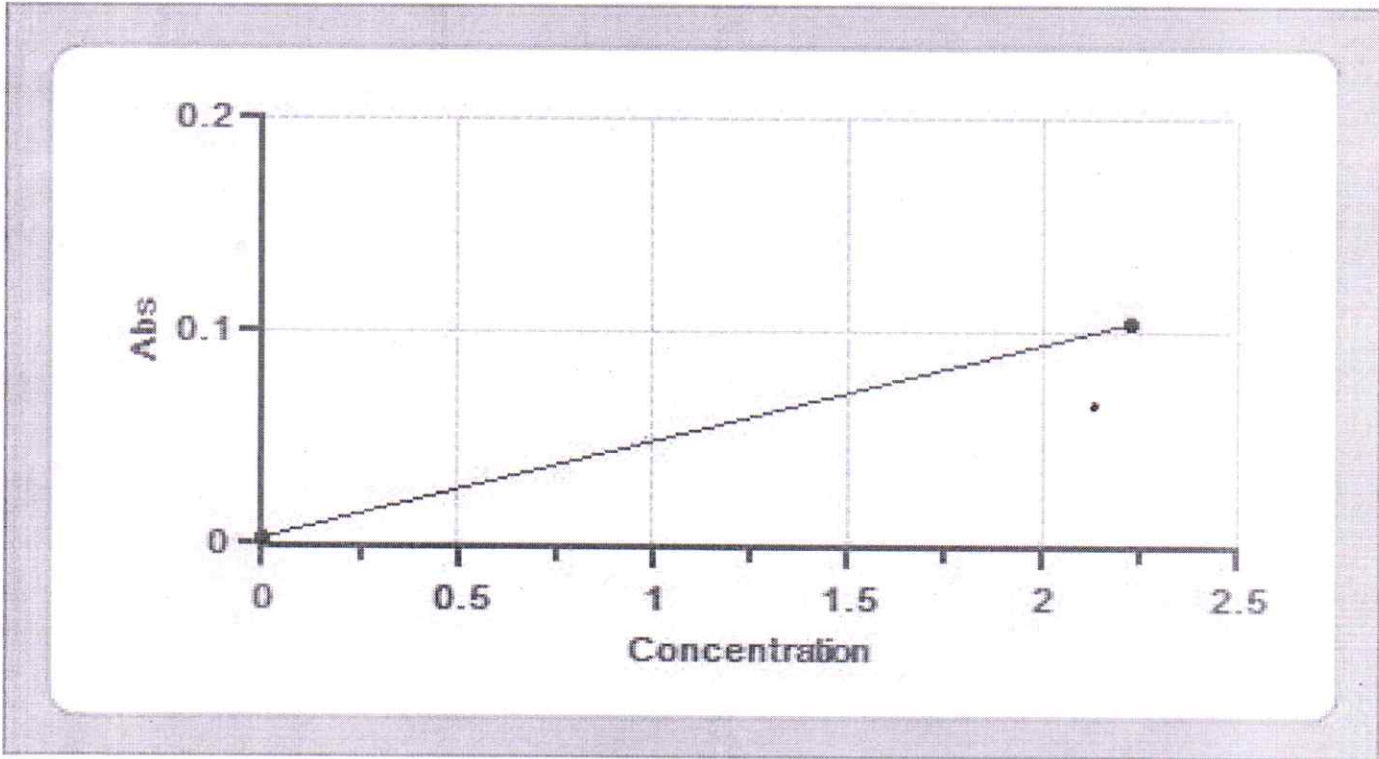
Curve Type : Linear

R1 Lot No : S072102-126

Calibration Date : 12-Feb-2022 19:07:46

R2 Lot No : S072102-126

Last Calibration Date : 12-Feb-2022 19:07:46



Pos	Consumable	LotNo.	Conc	Abs	Factor
I-1	DI WATER	45698	0.000	0.0030	0.0000
I-5	XL MULTICAL	2105079B	2.230	0.1046	21.9704

Calibration - EM 200

Test : SGOTD

Curve Type : Linear

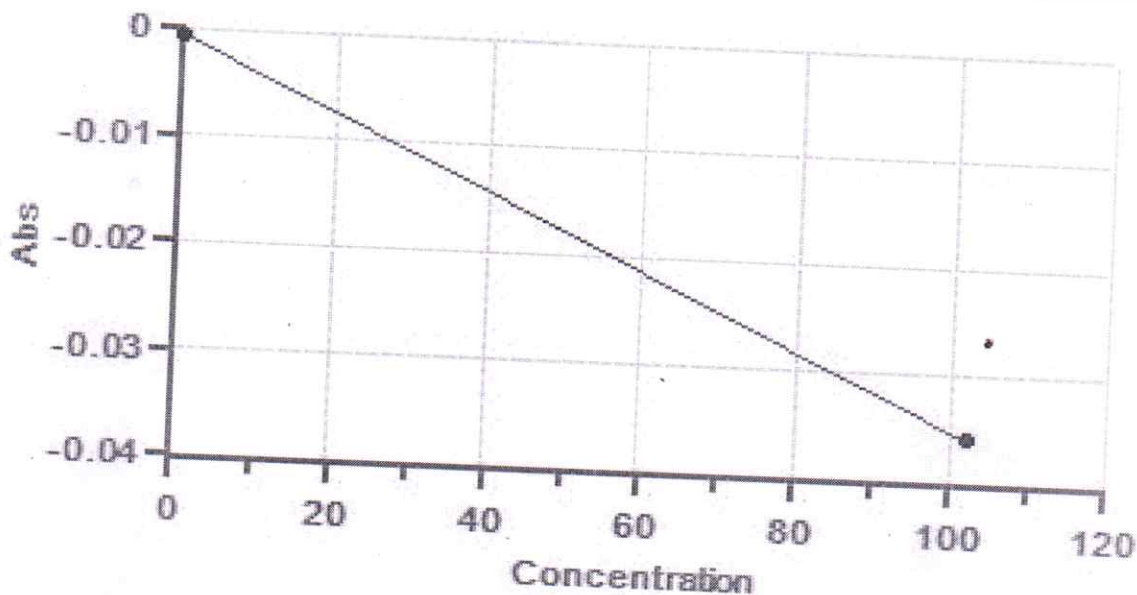
Calibration Date : 12-Feb-2022 18:58:44

Last Calibration Date : 12-Feb-2022 18:58:44

Revision : <A-200-SGOTD-3 21.06.2017>

R1 Lot No : S092153-140

R2 Lot No : S092153-140



Pos	Consumable	LotNo.	Conc	Delta Abs/Min	Factor
I-1	DI WATER	45698	0.000	-0.0005	0.0000
I-5	XL MULTICAL	2105079B	102.000	-0.0359	-2,885.4312

Calibration - EM 200

Test : SGPTD

Revision : <A-200-SGPTD-3 21.06.2017>

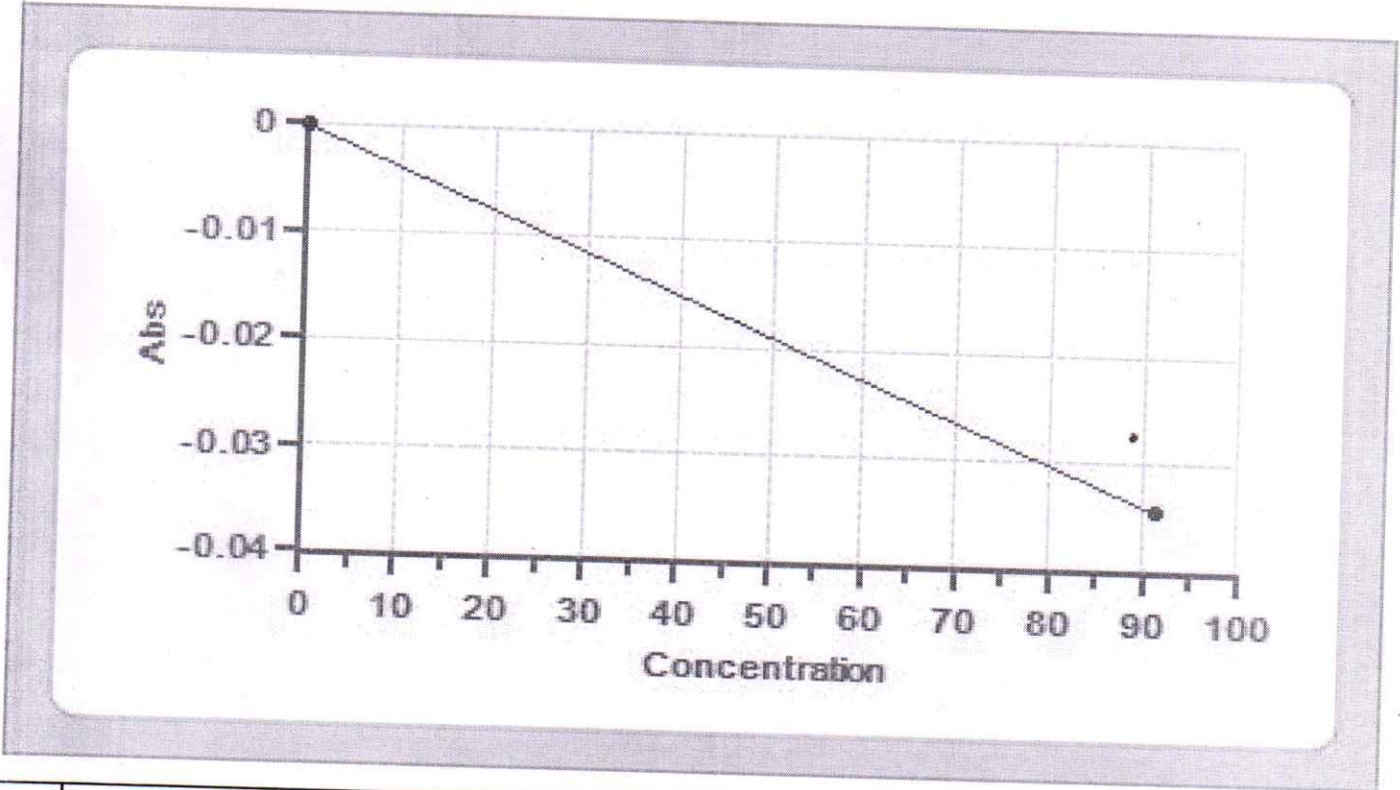
Curve Type : Linear

R1 Lot No : S102117-141

Calibration Date : 12-Feb-2022 18:56:56

R2 Lot No : S102117-141

Last Calibration Date : 12-Feb-2022 18:56:56



Pos	Consumable	LotNo.	Conc	Delta Abs/Min	Factor
I-1	DI WATER	45698	0.000	-0.0001	0.0000
I-5	XL MULTICAL	2105079B	91.300	-0.0345	-2,650.2180

Calibration - EM 200

Test : ALPU

Revision : <A-200-ALPU-3 01.03.2016>

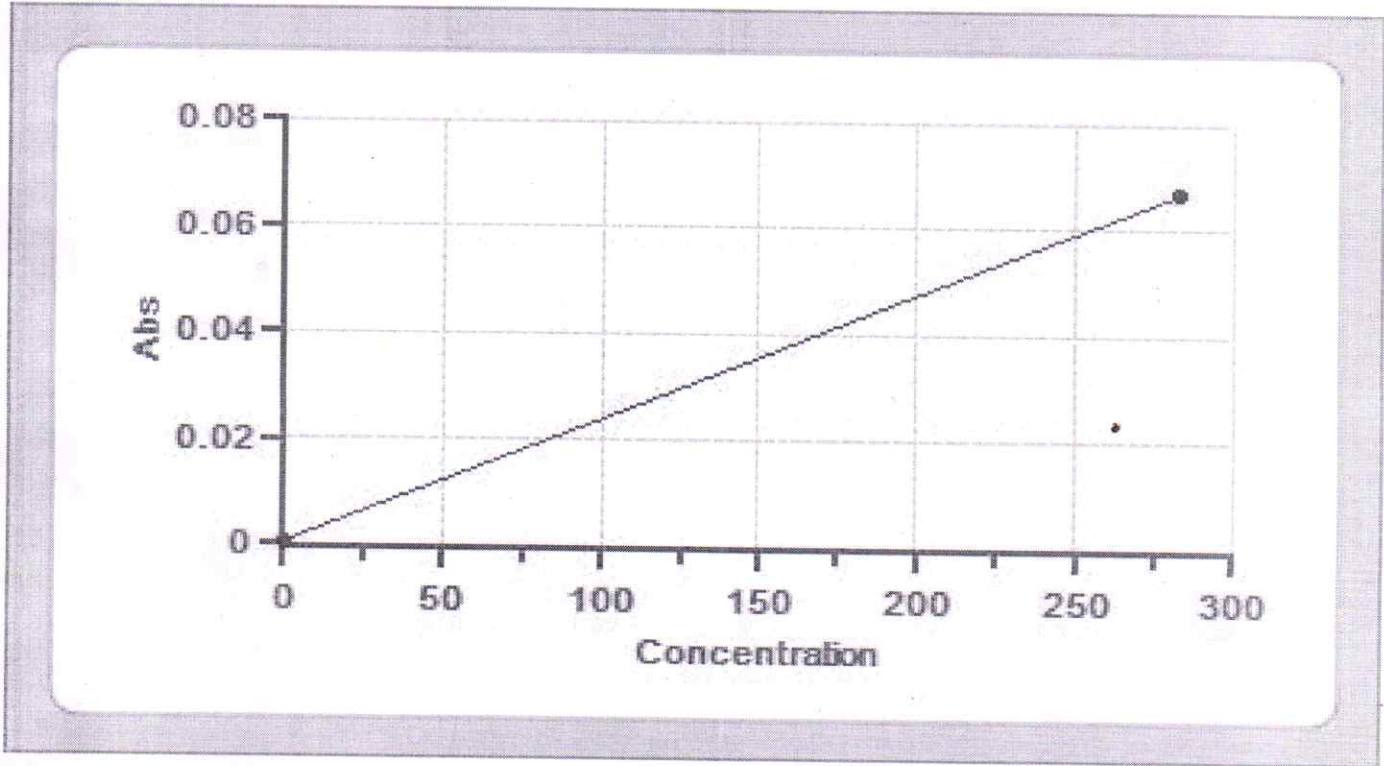
Curve Type : Linear

R1 Lot No : B092118-138

Calibration Date : 12-Feb-2022 19:02:21

R2 Lot No : B082112-132

Last Calibration Date : 12-Feb-2022 19:02:21



Pos	Consumable	LotNo.	Conc	Delta Abs/Min	Factor
I-1	DI WATER	45698	0.000	0.0007	0.0000
I-5	XL MULTICAL	2105079B	283.000	0.0670	4,268.4766

Calibration - EM 200

Test : PRO

Revision : <A-200-PRO-2 26.09.2013>

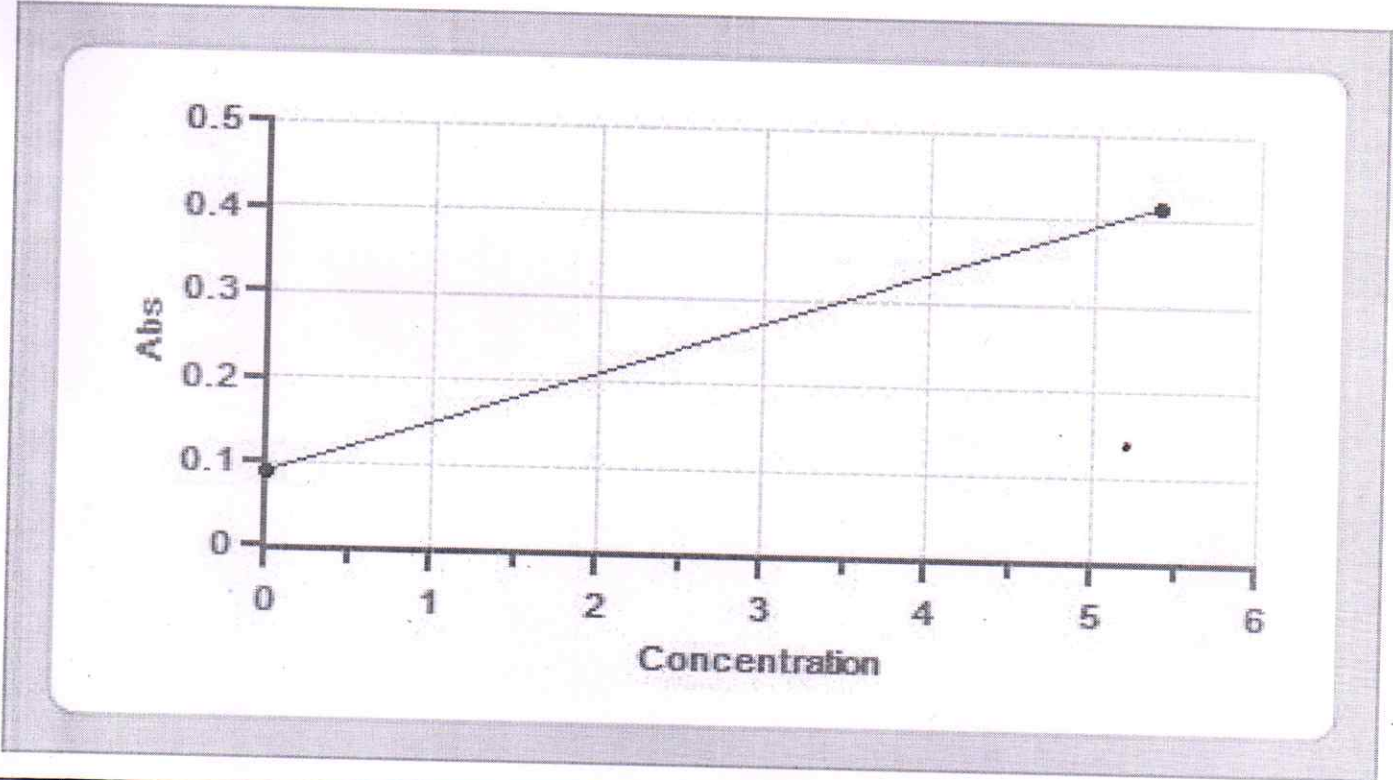
Curve Type : Linear

R1 Lot No : S032108-109

Calibration Date : 12-Feb-2022 19:27:19

R2 Lot No : ---

Last Calibration Date : 12-Feb-2022 19:27:19



Pos	Consumable	LotNo.	Conc	Abs	Factor
I-1	DI WATER	45698	0.000	0.0887	0.0000
I-5	XL MULTICAL	2105079B	5.390	0.4164	16.4430

Calibration - EM 200

Test : ALBD

Revision : <A-200-ALBD-1 07.11.2017>

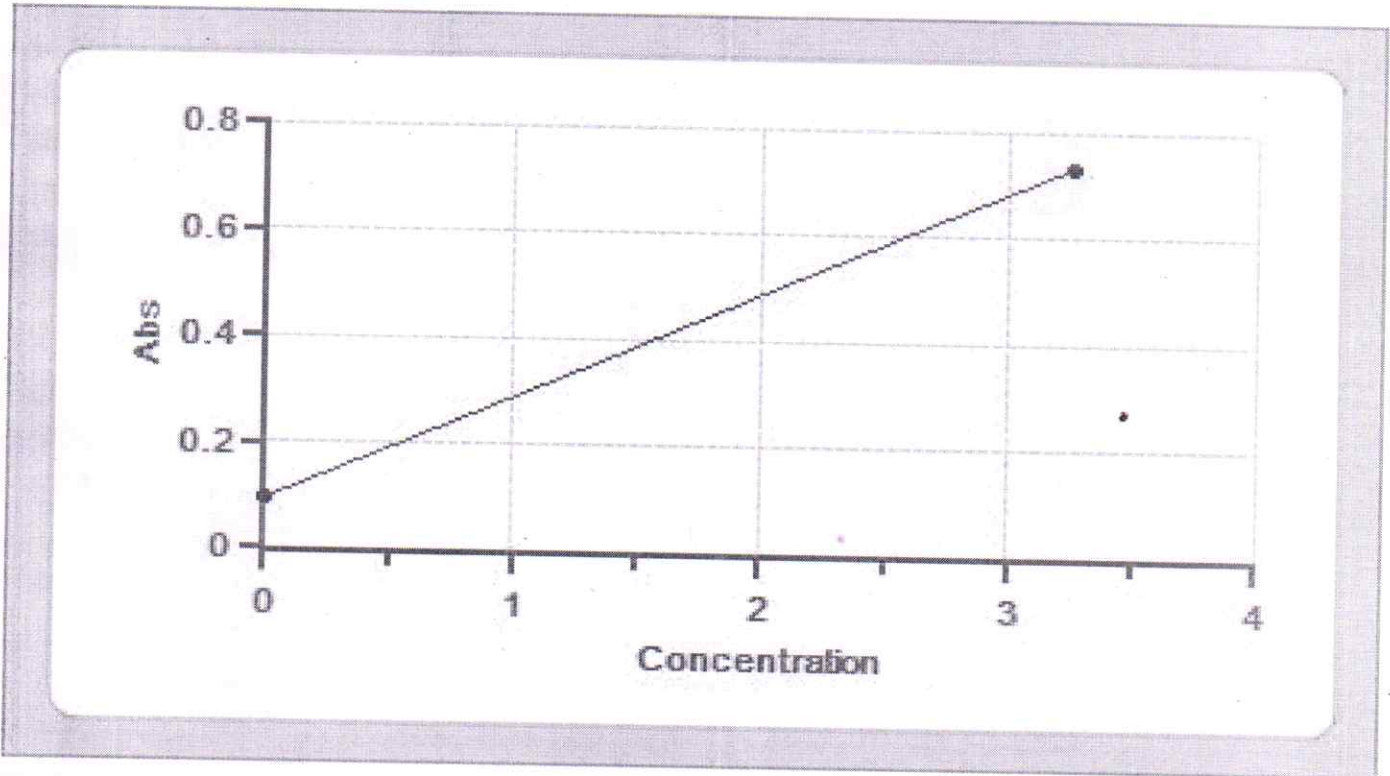
Curve Type : Linear

R1 Lot No : B062164-125

Calibration Date : 12-Feb-2022 19:25:31

R2 Lot No : ---

Last Calibration Date : 12-Feb-2022 19:25:31



Pos	Consumable	LotNo.	Conc	Abs	Factor
I-1	DI WATER	45698	0.000	0.0949	0.0000
I-5	XL MULTICAL	2105079B	3.250	0.7331	5.0924

Calibration - EM 200

Test : CHOL

Revision : <A-200-CHOL-1 20.08.2013>

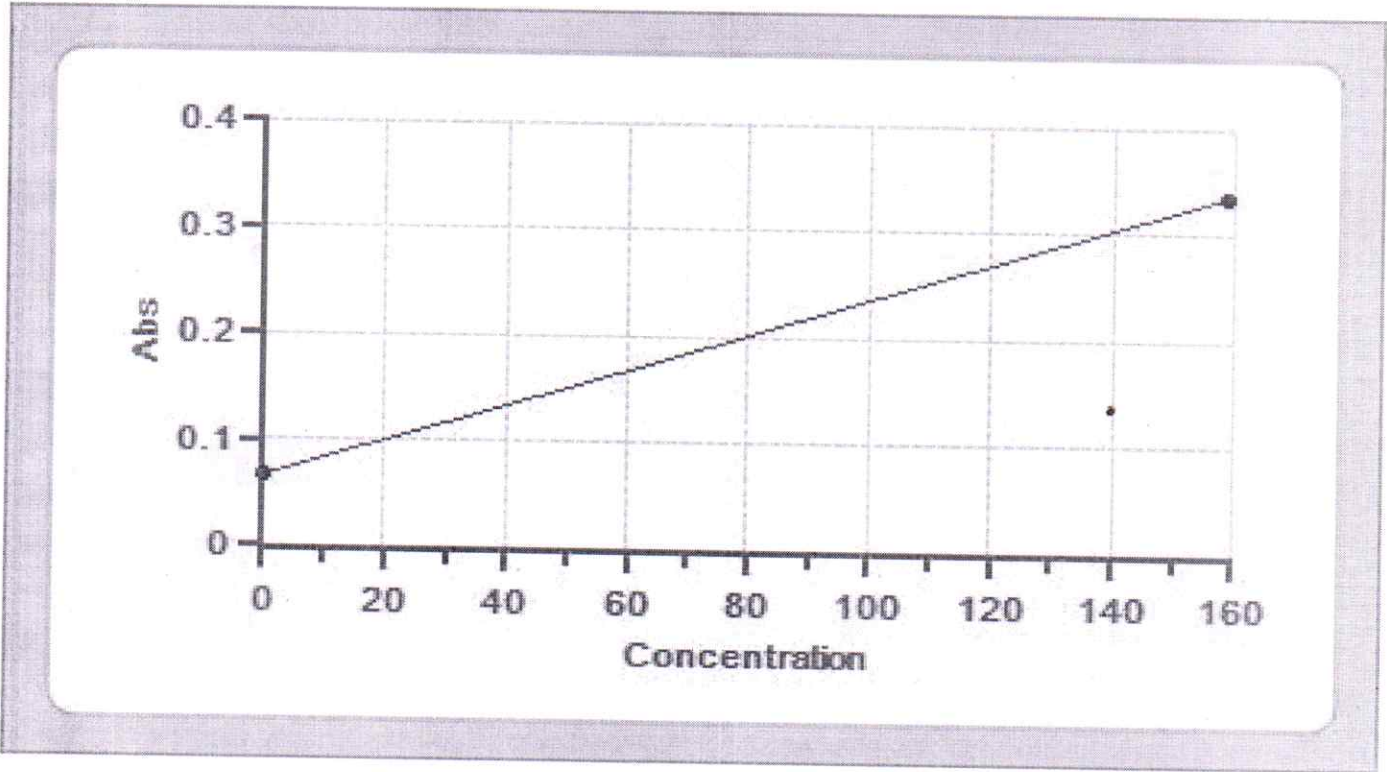
Curve Type : Linear

R1 Lot No : S072103-129

Calibration Date : 12-Feb-2022 19:18:35

R2 Lot No : ---

Last Calibration Date : 12-Feb-2022 19:18:35



Pos	Consumable	LotNo.	Conc	Abs	Factor
I-1	DI WATER	45698	0.000	0.0674	0.0000
I-5	XL MULTICAL	2105079B	159.000	0.3360	592.0685

Calibration - EM 200

Test : TRIG

Revision : <A-200-TRIG-1 20.08.2013>

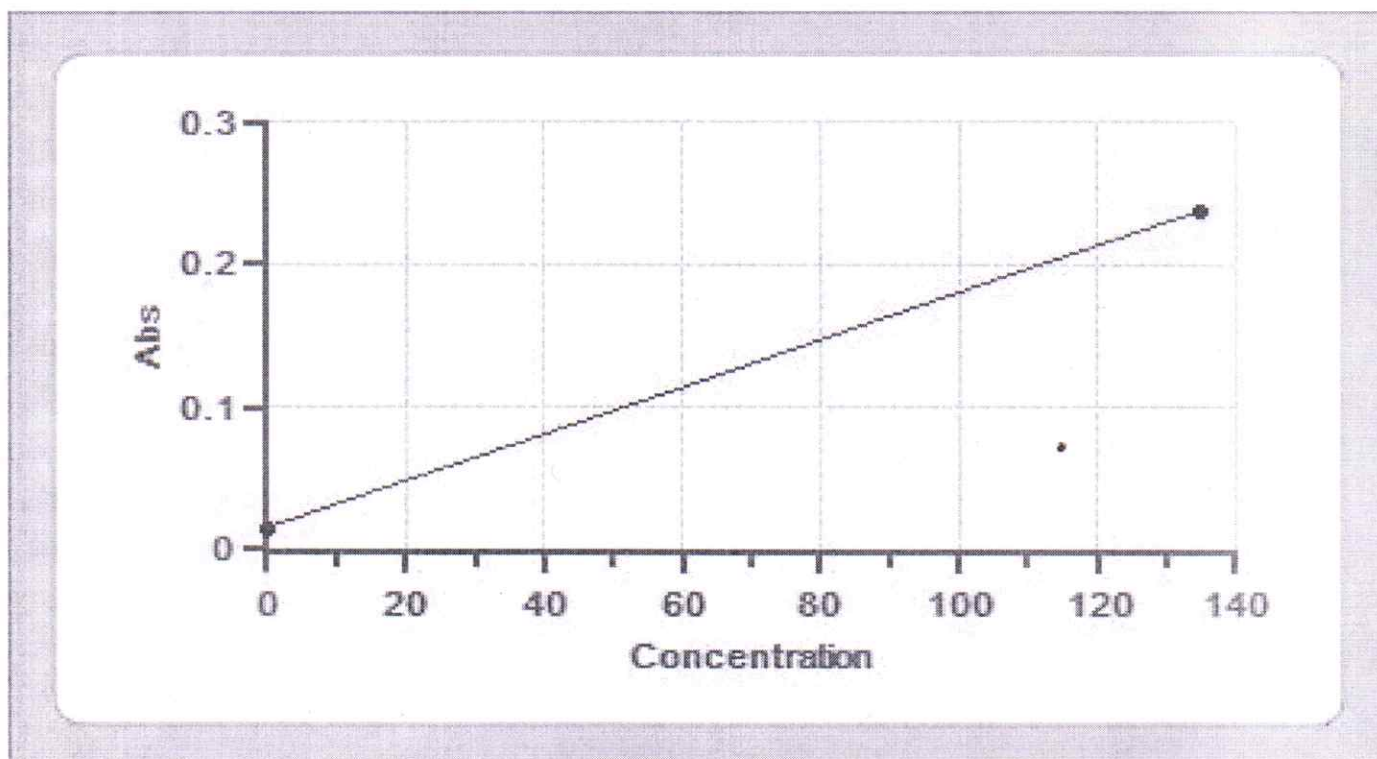
Curve Type : Linear

R1 Lot No : B012168-103

Calibration Date : 12-Feb-2022 19:16:47

R2 Lot No : B012168-103

Last Calibration Date : 12-Feb-2022 19:16:47



Pos	Consumable	LotNo.	Conc	Abs	Factor
I-1	DI WATER	45698	0.000	0.0157	0.0000
I-5	XL MULTICAL	2105079B	135.000	0.2381	606.8780

Calibration - EM 200

Test : HDLC

Revision : <A-200-HDLC-1 20.08.2013>

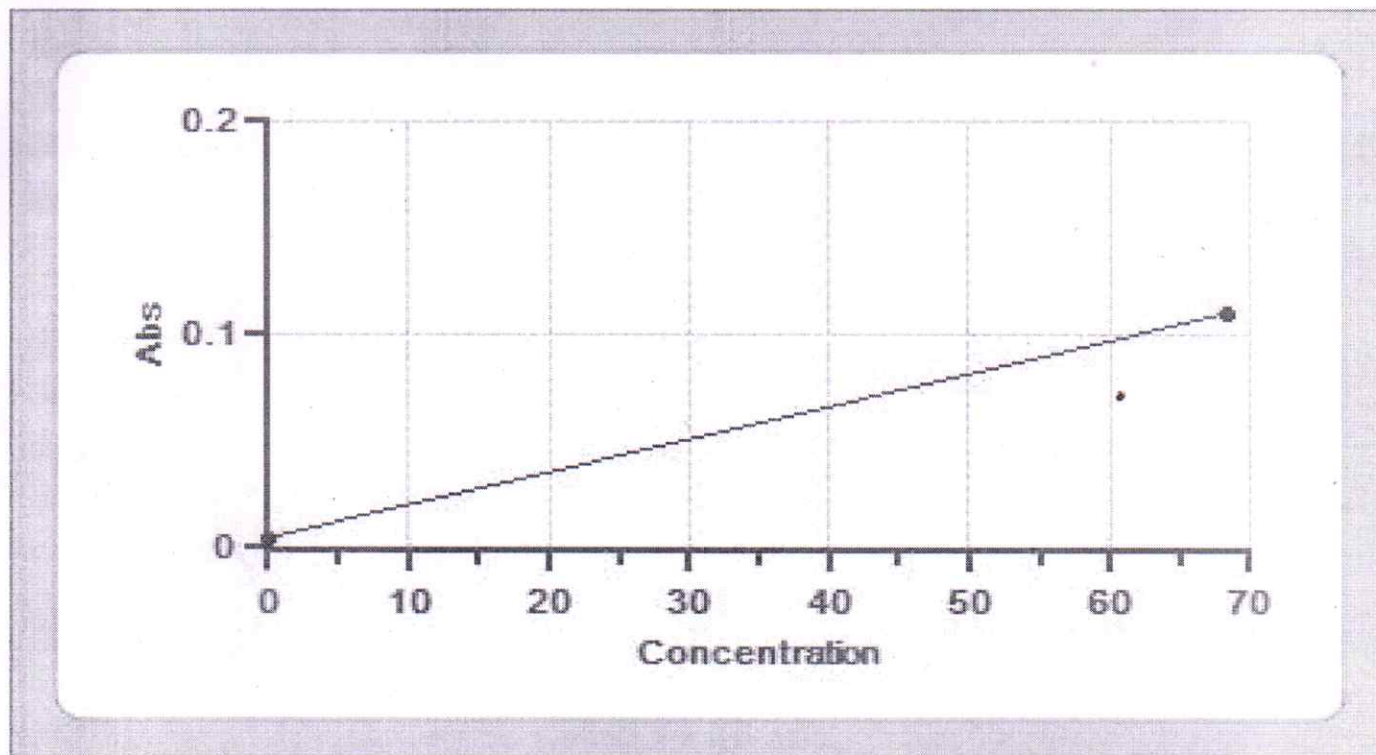
Curve Type : Linear

R1 Lot No : B082122-132

Calibration Date : 23-Oct-2021 15:46:22

R2 Lot No : B082122-132

Last Calibration Date : 23-Oct-2021 15:46:22



Pos	Consumable	LotNo.	Conc	Abs	Factor
-	DI WATER	45698	0.000	0.0049	0.0000
-	HDL CAL	B082122	68.400	0.1104	648.3412

Calibration - EM 200

Test : UA

Revision : <A-200-UA-1 01.06.2015>

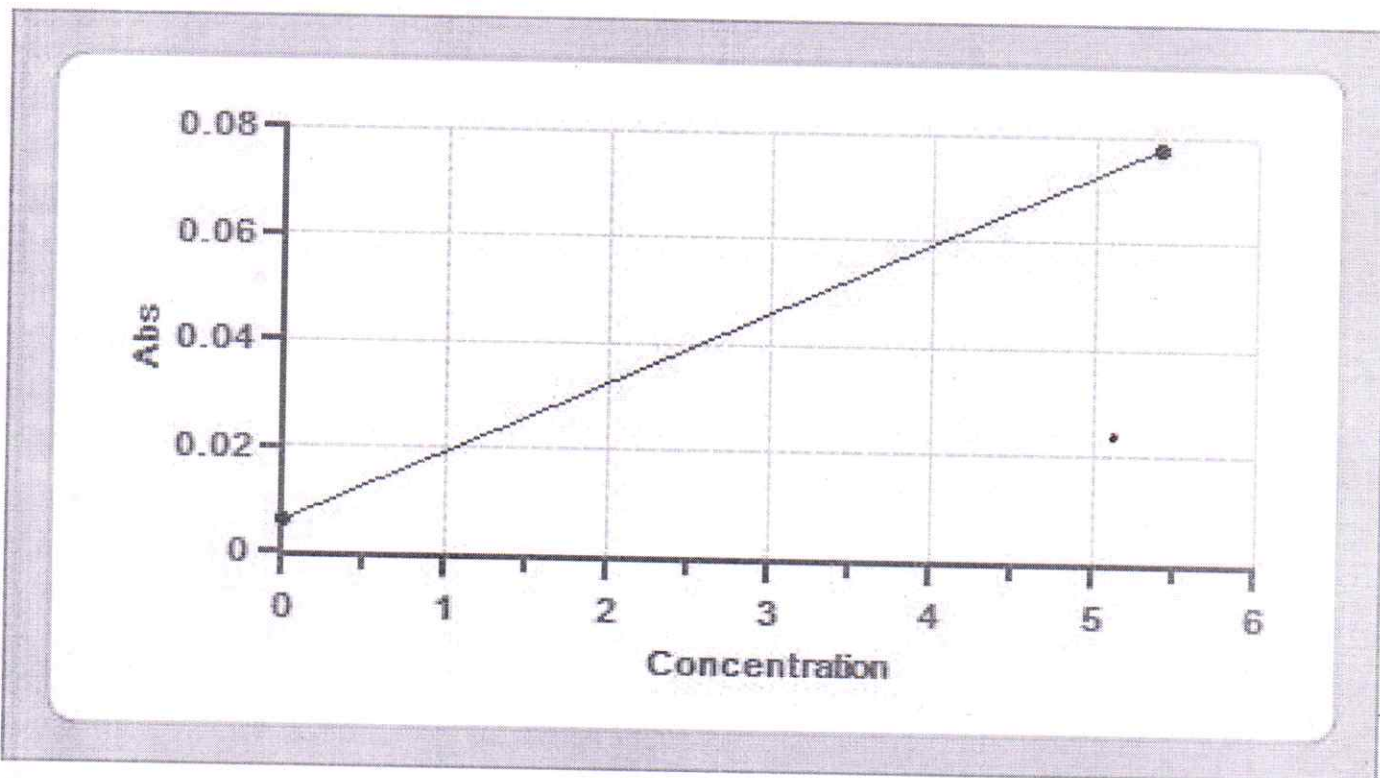
Curve Type : Linear

R1 Lot No : S092116-137

Calibration Date : 12-Feb-2022 19:20:24

R2 Lot No : S092116-137

Last Calibration Date : 12-Feb-2022 19:20:24



Pos	Consumable	LotNo.	Conc	Abs	Factor
I-1	DI WATER	45698	0.000	0.0061	0.0000
I-5	XL MULTICAL	2105079B	5.390	0.0778	75.1219

Calibration - EM 200

Test : CA

Revision : <A-200-CA-1 20.08.2013>

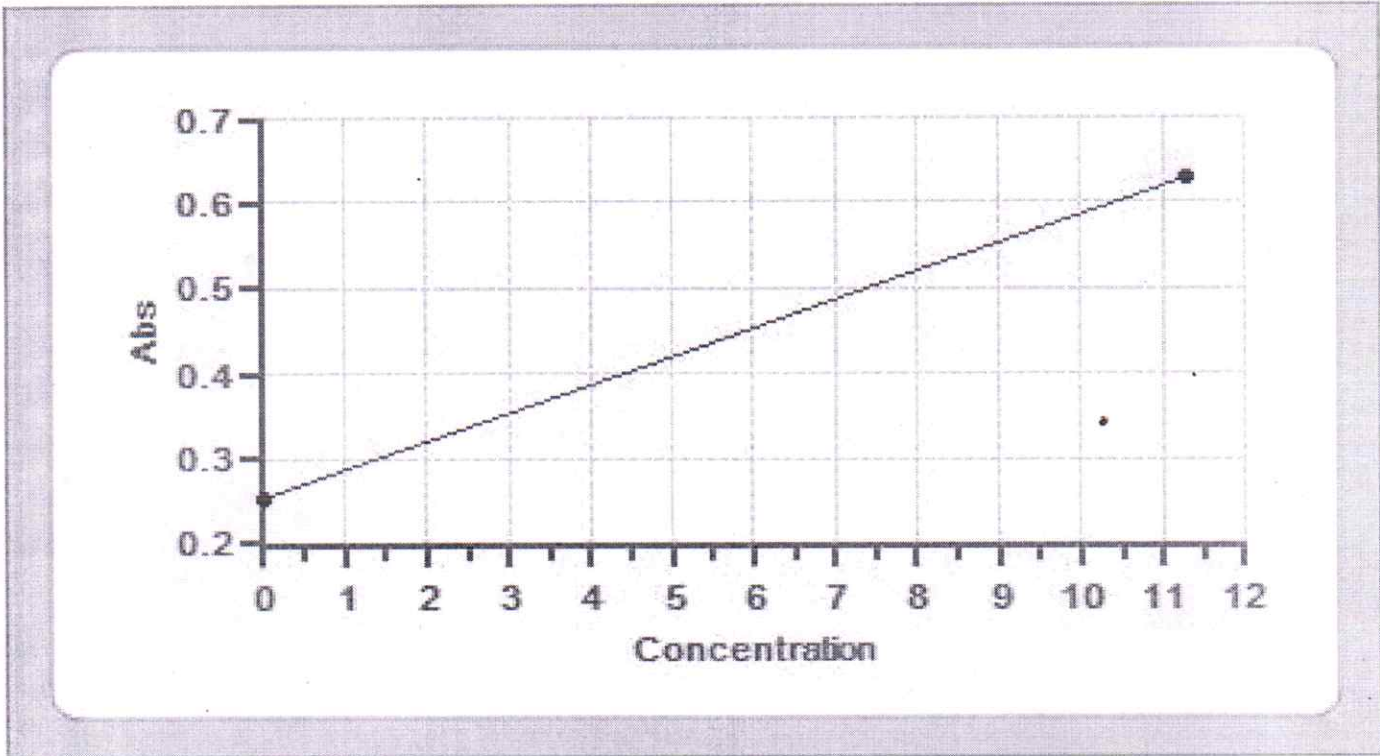
Curve Type : Linear

R1 Lot No : B052153-122

Calibration Date : 12-Feb-2022 19:23:42

R2 Lot No : ---

Last Calibration Date : 12-Feb-2022 19:23:42



Pos	Consumable	LotNo.	Conc	Abs	Factor
I-1	DI WATER	45698	0.000	0.2539	0.0000
I-5	XL MULTICAL	2105079B	11.300	0.6295	30.0812

Calibration - EM 200

Test : FE

Revision : <A-200-FE-1 20.08.2013>

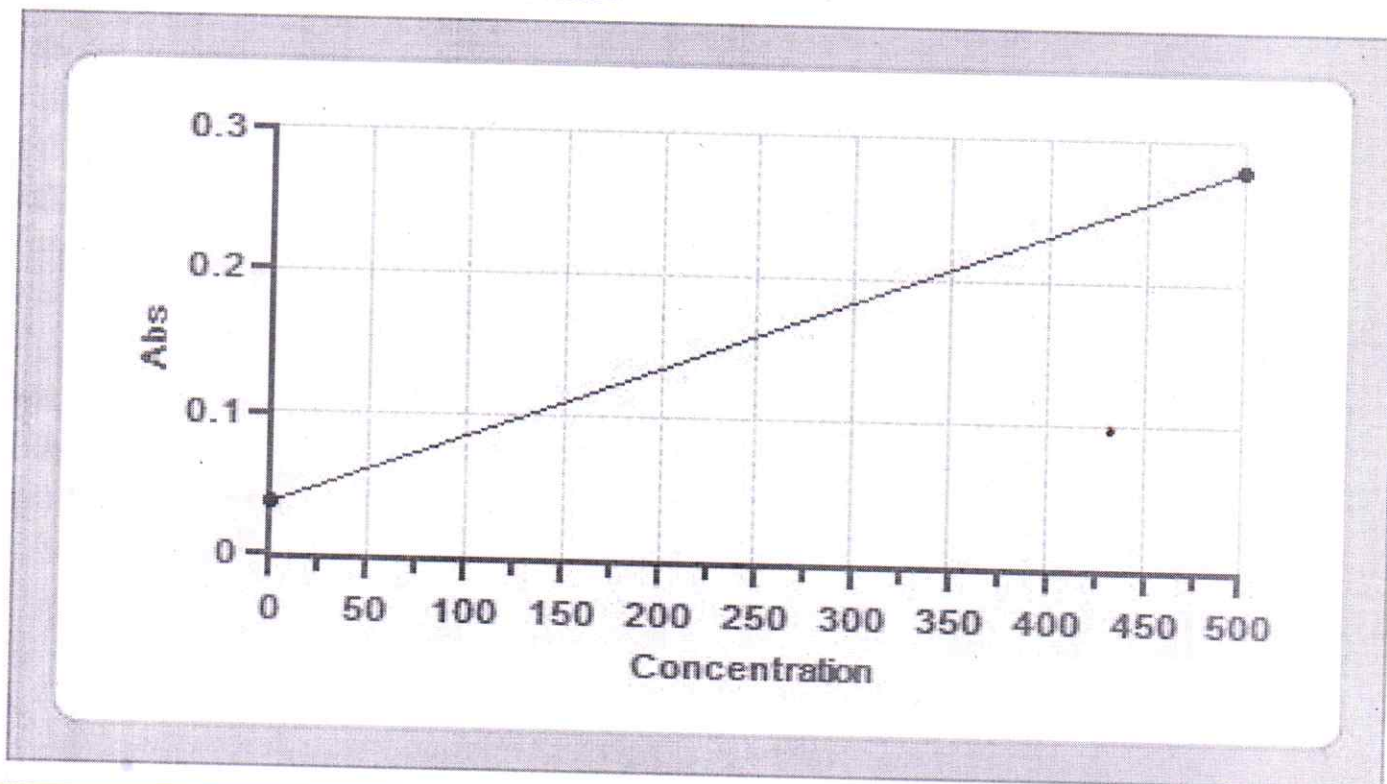
Curve Type : Linear

R1 Lot No : 2105003-118

Calibration Date : 14-Nov-2021 09:46:30

R2 Lot No : 2105003-118

Last Calibration Date : 14-Nov-2021 09:46:30



Pos	Consumable	LotNo.	Conc	Abs	Factor
-	SALINE	89653	0.000	0.0372	0.0000
-	FE	2105003	500.000	0.2797	2,061.0059

Result Reprint

Report Type : Calibration 12-Feb-2022

Consumable: XL MULTICAL

Sr #	Lot #	Consumable	Test	Result Unit	Flag	Curve #	Result Date
1	2105079B	XL MULTICAL	LDH	-0.0620	-	63080	12-Feb-2022 18:55:26
2	2105079B	XL MULTICAL	LDH	-0.0618	-	63081	12-Feb-2022 18:55:43
3	2105079B	XL MULTICAL	LDH	-0.0625	-	63082	12-Feb-2022 18:56:02
4	2105079B	XL MULTICAL	SGPTD	-0.0346	-	63086	12-Feb-2022 18:57:14
5	2105079B	XL MULTICAL	SGPTD	-0.0350	-	63087	12-Feb-2022 18:57:32
6	2105079B	XL MULTICAL	SGPTD	-0.0345	-	63088	12-Feb-2022 18:57:50
7	2105079B	XL MULTICAL	SGOTD	-0.0362	-	63092	12-Feb-2022 18:59:02
8	2105079B	XL MULTICAL	SGOTD	-0.0359	-	63093	12-Feb-2022 18:59:20
9	2105079B	XL MULTICAL	SGOTD	-0.0359	-	63094	12-Feb-2022 19:01:26
10	2105079B	XL MULTICAL	ALPU	0.0670	-	63098	12-Feb-2022 19:02:39
11	2105079B	XL MULTICAL	ALPU	0.0671	-	63099	12-Feb-2022 19:02:57
12	2105079B	XL MULTICAL	ALPU	0.0669	-	63100	12-Feb-2022 19:03:15
13	2105079B	XL MULTICAL	AMY	0.0731	-	63104	12-Feb-2022 19:04:27
14	2105079B	XL MULTICAL	AMY	0.0730	-	63105	12-Feb-2022 19:04:45
15	2105079B	XL MULTICAL	AMY	0.0734	-	63106	12-Feb-2022 19:05:03
16	2105079B	XL MULTICAL	PHOS	0.9403	-	63110	12-Feb-2022 19:06:15
17	2105079B	XL MULTICAL	PHOS	0.9323	-	63111	12-Feb-2022 19:06:33

Print Date 13-Feb-2022

Result Reprint

Consumable: XL MULTICAL

Report Type : Calibration 12-Feb-2022

Sr #	Lot #	Consumable	Test	Result Unit	Flag	Curve #	Result Date
18	2105079B	XL MULTICAL	PHOS	0.9536 -		63112	12-Feb-2022 19:06:51
19	2105079B	XL MULTICAL	BIDD	0.1050 -		63116	12-Feb-2022 19:08:04
20	2105079B	XL MULTICAL	BIDD	0.1046 -		63117	12-Feb-2022 19:08:22
21	2105079B	XL MULTICAL	BIDD	0.1045 -		63118	12-Feb-2022 19:08:40
22	2105079B	XL MULTICAL	BIT	0.1831 -		63122	12-Feb-2022 19:09:52
23	2105079B	XL MULTICAL	BIT	0.1835 -		63123	12-Feb-2022 19:10:10
24	2105079B	XL MULTICAL	BIT	0.1827 -		63124	12-Feb-2022 19:10:28
25	2105079B	XL MULTICAL	UREA	-0.1898 -		63128	12-Feb-2022 19:11:40
26	2105079B	XL MULTICAL	UREA	-0.1902 -		63129	12-Feb-2022 19:11:58
27	2105079B	XL MULTICAL	UREA	-0.1911 -		63130	12-Feb-2022 19:12:16
28	2105079B	XL MULTICAL	CRENZ	0.0889 -		63134	12-Feb-2022 19:13:29
29	2105079B	XL MULTICAL	CRENZ	0.0889 -		63135	12-Feb-2022 19:13:47
30	2105079B	XL MULTICAL	CRENZ	0.0886 -		63136	12-Feb-2022 19:14:05
31	2105079B	XL MULTICAL	GLU	0.7234 -		63140	12-Feb-2022 19:15:17
32	2105079B	XL MULTICAL	GLU	0.7210 -		63141	12-Feb-2022 19:15:35
33	2105079B	XL MULTICAL	GLU	0.7217 -		63142	12-Feb-2022 19:15:53
34	2105079B	XL MULTICAL	TRIG	0.2393 -		63146	12-Feb-2022 19:17:05

Result Reprint

Report Type : Calibration 12-Feb-2022

Consumable: XL MULTICAL

Sr #	Lot #	Consumable	Test	Result Unit	Flag	Curve #	Result Date
35	2105079B	XL MULTICAL	TRIG	0.2378 -		63147	12-Feb-2022 19:17:23
36	2105079B	XL MULTICAL	TRIG	0.2384 -		63148	12-Feb-2022 19:17:41
37	2105079B	XL MULTICAL	CHOL	0.3313 -		63152	12-Feb-2022 19:18:53
38	2105079B	XL MULTICAL	CHOL	0.3358 -		63153	12-Feb-2022 19:19:12
39	2105079B	XL MULTICAL	CHOL	0.3361 -		63154	12-Feb-2022 19:19:30
40	2105079B	XL MULTICAL	UA	0.0779 -		63158	12-Feb-2022 19:20:42
41	2105079B	XL MULTICAL	UA	0.0783 -		63159	12-Feb-2022 19:21:00
42	2105079B	XL MULTICAL	UA	0.0778 -		63160	12-Feb-2022 19:21:18
43	2105079B	XL MULTICAL	CA	0.6339 -		63164	12-Feb-2022 19:24:01
44	2105079B	XL MULTICAL	CA	0.6282 -		63165	12-Feb-2022 19:24:18
45	2105079B	XL MULTICAL	CA	0.6309 -		63166	12-Feb-2022 19:24:36
46	2105079B	XL MULTICAL	ALBD	0.7370 -		63170	12-Feb-2022 19:25:49
47	2105079B	XL MULTICAL	ALBD	0.7328 -		63171 *	12-Feb-2022 19:26:07
48	2105079B	XL MULTICAL	ALBD	0.7334 -		63172	12-Feb-2022 19:26:25
49	2105079B	XL MULTICAL	PRO	0.4157 -		63176	12-Feb-2022 19:27:37
50	2105079B	XL MULTICAL	PRO	0.4130 -		63177	12-Feb-2022 19:27:55
51	2105079B	XL MULTICAL	PRO	0.4172 -		63178	12-Feb-2022 19:28:13



Likhitha Diagnostics and Speciality LAB

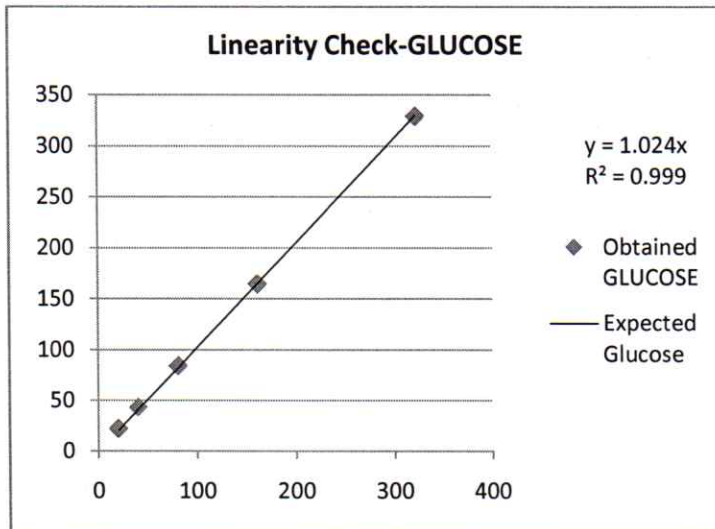
Instrument Name:EM 200

Instrument Serial Number:2002005

Glucose Linearity Study

Date performed:26-10-2021

Dilution Factor	Expected GLUCOSE	Obtained GLUCOSE
Original Sample	322.3	329.4
1:2 dil	161.2	164.6
1:4 dil	80.5	84.5
1:8 dil	40.3	43.6
1:16 dil	20.2	22.2



Company Representative

Signature: *Kalyanhalder*

Date: *26.10.21*

Customer Authorization

Signature: *V. S. ...*

Date: *26/10/21*



Likhitha Diagnostics and Speciality LAB

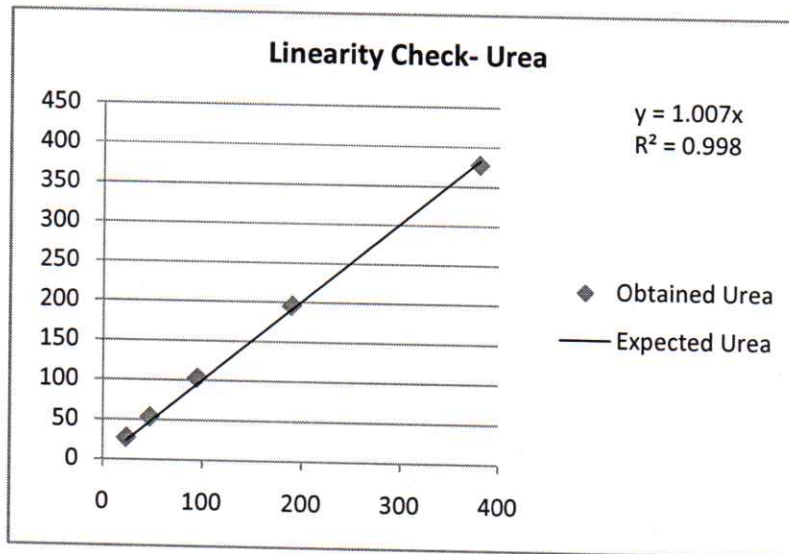
Instrument Name:EM 200

Instrument Serial Number:2002005

Urea Linearity Study

Date performed:23-10-2021

Dilution Factor	Expected Urea	Obtained Urea
Original Sample	380	377.9
1:2 dil	190	196.2
1:4 dil	95	103
1:8 dil	47.5	53.4
1:16 dil	23.8	27.5
1:32 dil	11.9	15.1



Company Representative

Signature: *Kalyan Kaldon*

Date: *23.10.21*

Customer Authorization

Signature: *V.S...*

Date: *23/10/21*



UNMATCHED SERVICE
SINCE 1979...

Likhitha Diagnostics and Speciality LAB

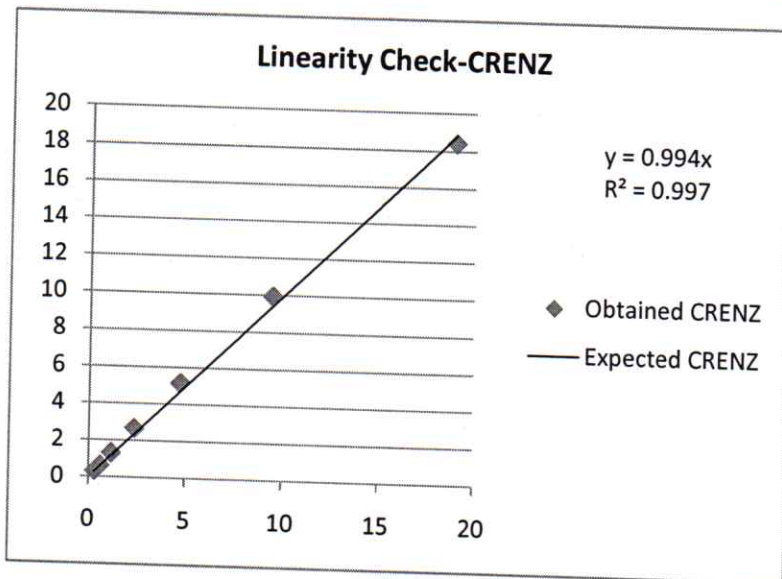
Instrument Name:EM 200

Instrument Serial Number:2002005

Creatinine Linearity Study

Date performed:23-10-2021

Dilution Factor	Expected CRENZ	Obtained CRENZ
Original Sample	18.94	18.4
1:2 dil	9.47	9.94
1:4 dil	4.72	5.16
1:8 dil	2.37	2.66
1:16 dil	1.19	1.32
1:32 dil	0.6	0.64
1:64 dil	0.3	0.34



Company Representative

Customer Authorization

Signature: *Kalyanhalder*

Signature: *V.K.*

Date: *23.10.21*

Date: *23/10/21*



UNMATCHED SERVICE
SINCE 1979...

Likhitha Diagnostics and Speciality LAB

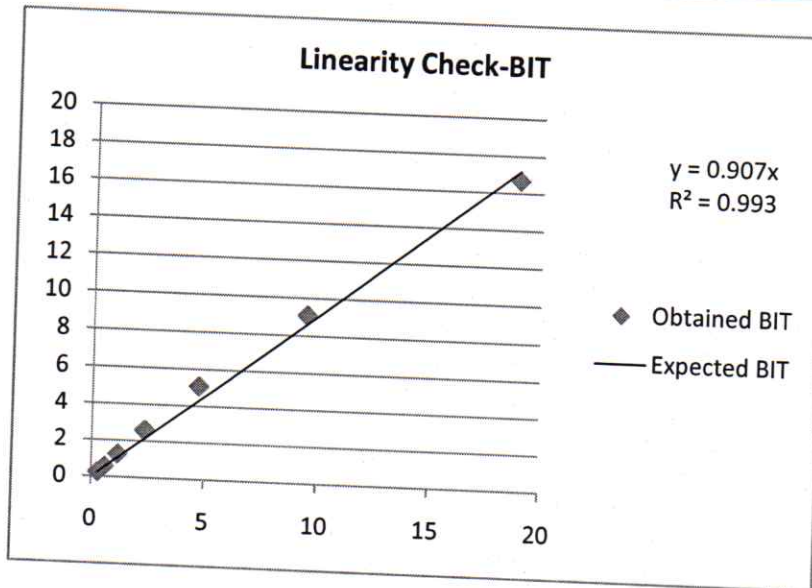
Instrument Name:EM 200

Instrument Serial Number:2002005

BIT Linearity Study

Date performed:23-10-2021

Dilution Factor	Expected BIT	Obtained BIT
Original Sample	18.93	16.66
1:2 dil	9.47	9.09
1:4 dil	4.73	5.08
1:8 dil	2.36	2.6
1:16 dil	1.18	1.26
1:32 dil	0.59	0.57
1:64 dil	0.29	0.27



Company Representative

Customer Authorization

Signature: *Kalyanbabay*

Signature: *V. S. ...*

Date: *23.10.21*

Date: *23/10/21*



Likhitha Diagnostics and Speciality LAB

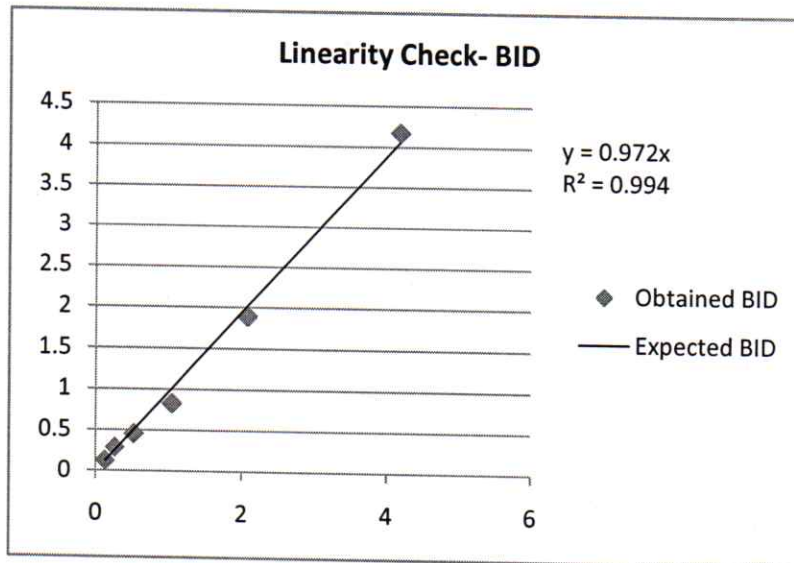
Instrument Name:EM 200

Instrument Serial Number:2002005

BID Linearity Study

Date performed:23-10-2021

Dilution Factor	Expected BID	Obtained BID
Original Sample	4.17	4.17
1:2 dil	2.08	1.89
1:4 dil	1.04	0.83
1:8 dil	0.52	0.46
1:16 dil	0.26	0.29
1:32 dil	0.13	0.13



Company Representative

Customer Authorization

Signature: *Kalyanbabu*

Signature: *V.P.*

Date: *23.10.21*

Date: *23/10/21*



Likhitha Diagnostics and Speciality LAB

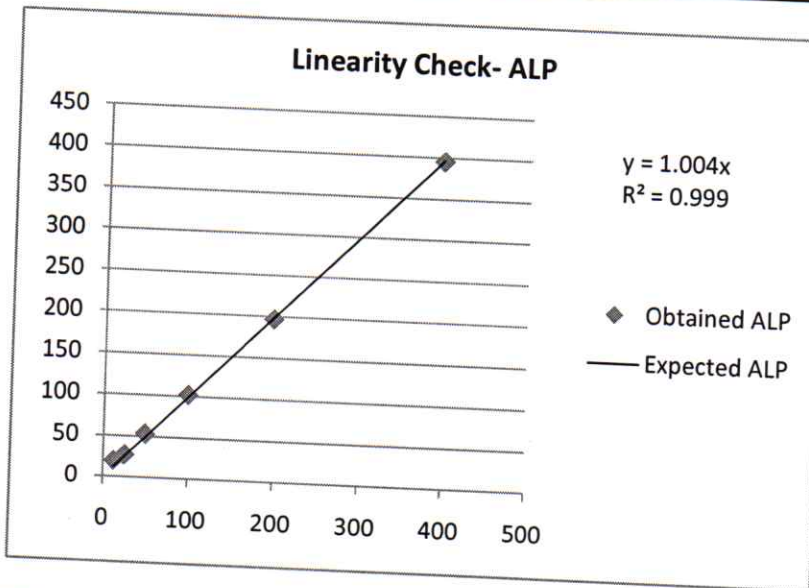
Instrument Name:EM 200

Instrument Serial Number:2002005

ALP Linearity Study

Date performed:26-10-2021

Dilution Factor	Expected ALP	Obtained ALP
Original Sample	395	396
1:2 dil	197.5	197
1:4 dil	99	102
1:8 dil	49.3	53
1:16 dil	25	27
1:32 dil	12.3	20



Company Representative

Signature: *Kalyanhalbor*

Date: *26.10.21*

Customer Authorization

Signature: *[Signature]*

Date: *26/10/21*



Likhitha Diagnostics and Speciality LAB

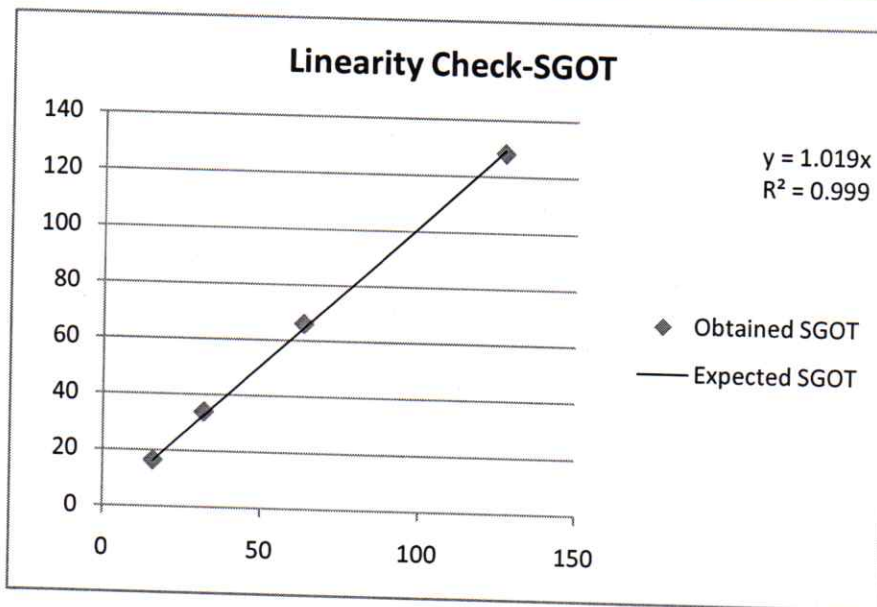
Instrument Name:EM 200

Instrument Serial Number:2002005

SGOT Linearity Study

Date performed:23-10-2021

Dilution Factor	Expected SGOT	Obtained SGOT
Original Sample	126.7	128.1
1:2 dil	63.35	66.1
1:4 dil	32	33.9
1:8 dil	16	16.5



Company Representative

Signature: *Kalyanhalday*

Date: 23.10.21

Customer Authorization

Signature: *V.S.*

Date: 23/10/21



UNMATCHED SERVICE
SINCE 1979...

Likhitha Diagnostics and Speciality LAB

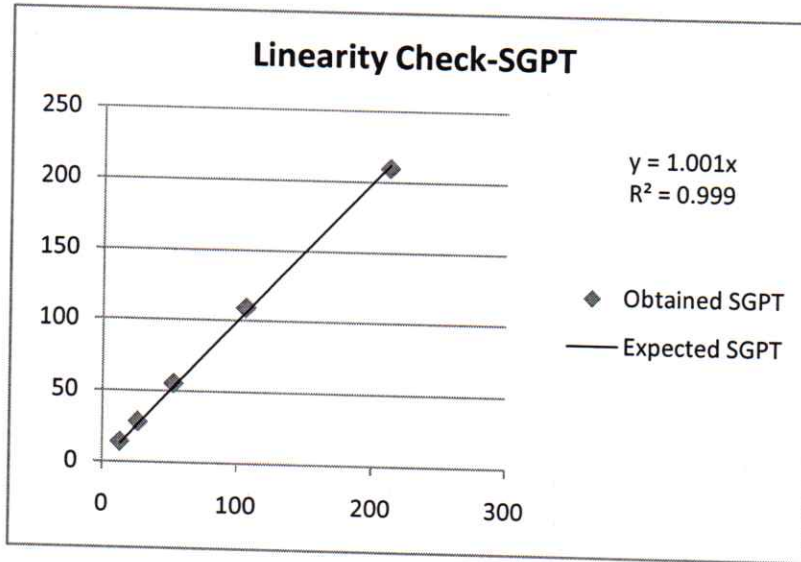
Instrument Name:EM 200

Instrument Serial Number:2002005

SGPT Linearity Study

Date performed:21-10-2021

Dilution Factor	Expected SGPT	Obtained SGPT
Original Sample	211.9	210
1:2 dil	106	109.1
1:4 dil	53	55.1
1:8 dil	26.5	28.2
1:16 dil	13.2	14.3



Company Representative

Customer Authorization

Signature: *Kalyanbabu*

Signature: *Vig*

Date: *21.10.21*

Date: *21/10/21*



UNMATCHED SERVICE
SINCE 1979...

Likhitha Diagnostics and Speciality LAB

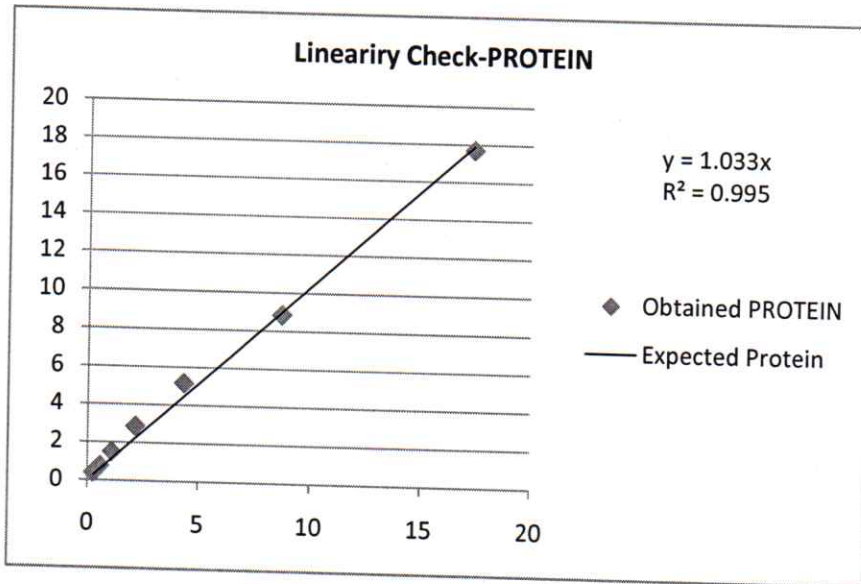
Instrument Name:EM 200

Instrument Serial Number:2002005

Protein Linearity Study

Date performed:23-10-2021

Dilution Factor	Expected PROTEIN	Obtained PROTEIN
Original Sample	17.33	17.7
1:2 dil	8.7	8.86
1:4 dil	4.33	5.18
1:8 dil	2.16	2.86
1:16 dil	1.1	1.49
1:32 dil	0.55	0.75
1:64 dil	0.27	0.4



Company Representative

Customer Authorization

Signature: *Kalyanbaldan*

Signature: *V.S...*

Date: *23.10.21*

Date: *23/10/21*



Likhitha Diagnostics and Speciality LAB

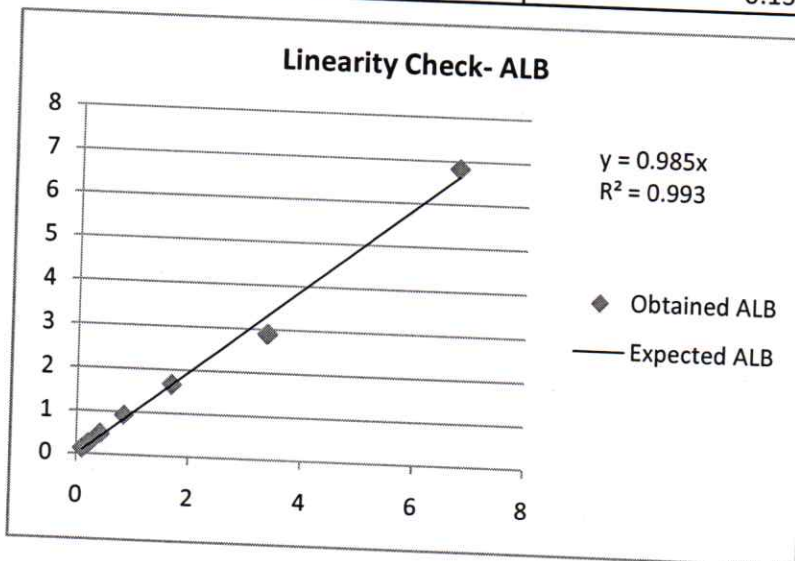
Instrument Name: EM 200

Instrument Serial Number: 2002005

Albumin Linearity Study

Date performed: 23-10-2021

Dilution Factor	Expected ALB	Obtained ALB
Original Sample	6.74	6.83
1:2 dil	3.37	2.9
1:4 dil	1.68	1.67
1:8 dil	0.84	0.92
1:16 dil	0.42	0.49
1:32 dil	0.21	0.26
1:64 dil	0.1	0.13



Company Representative

Customer Authorization

Signature: *Kalyanhalbo*

Signature: *V.P.*

Date: *23-10-21*

Date: *23/10/21*



Likhitha Diagnostics and Speciality LAB

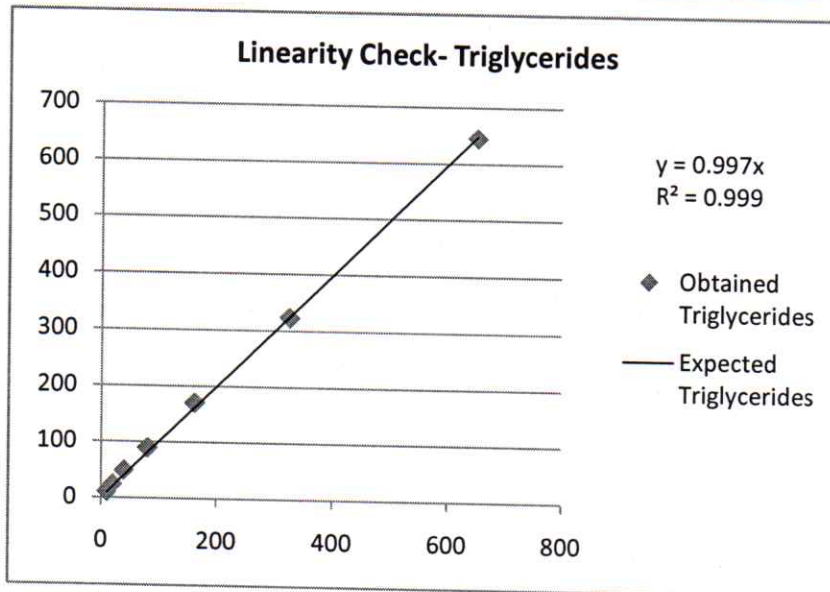
Instrument Name:EM 200

Instrument Serial Number:2002005

Triglycerides Linearity Study

Date performed:23-10-2021

Dilution Factor	Expected Triglycerides	Obtained Triglycerides
Original Sample	650	645
1:2 dil	325	323
1:4 dil	162	170
1:8 dil	81	89
1:16 dil	40	49
1:32 dil	20	24
1:64 dil	10	11



Company Representative

Customer Authorization

Signature: *Kalyanbabu*

Signature: *V. J. ...*

Date: *23.10.21*

Date: *23/10/21*



Likhitha Diagnostics and Speciality LAB

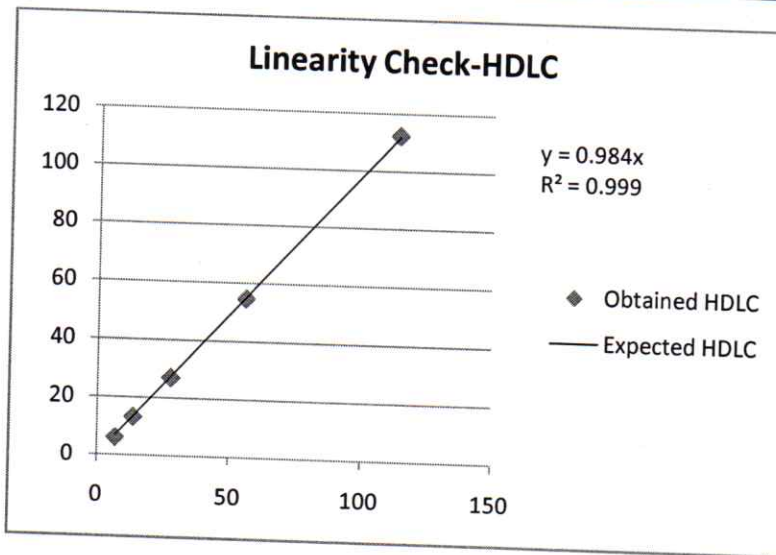
Instrument Name:EM 200

Instrument Serial Number:2002005

HDL Linearity Study

Date performed:23-10-2021

Dilution Factor	Expected HDLC	Obtained HDLC
Original Sample	113.7	112.4
1:2 dil	56	54.7
1:4 dil	28	27.2
1:8 dil	14	13.4
1:16 dil	7	6



Company Representative

Customer Authorization

Signature: *Kalyanbabu*

Signature: *V. J. ...*

Date: 23.10.21

Date: 23/10/21



UNMATCHED SERVICE
SINCE 1979...

Likhitha Diagnostics and Speciality LAB

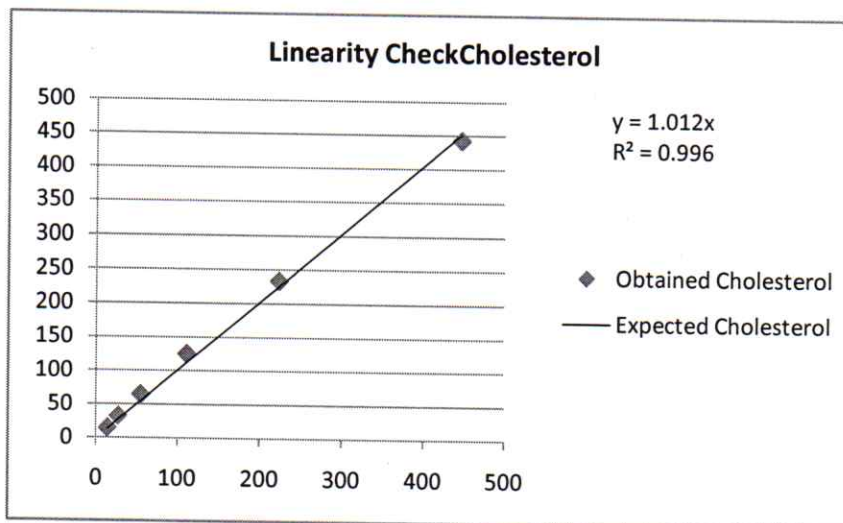
Instrument Name:EM 200

Instrument Serial Number:2002005

Cholesterol Linearity Study

Date performed:21-10-2021

Dilution Factor	Expected Cholesterol	Obtained Cholesterol
Original Sample	446	443
1:2 dil	223	234
1:4 dil	111	125
1:8 dil	55	65
1:16 dil	27	33
1:32 dil	14	15



Company Representative

Signature: *Kalyanbabu*

Date: 21.10.21

Customer Authorization

Signature: *V.g.*

Date: 21/10/21

Result Reprint

Report Type : Controls 12-Feb-2022

Consumable: BIORAD L1

Sr #	Lot #	Consumable	Test	Result Unit	Flag	Curve #	Result Date	Mean	SD	Interval (3SD)
1	26491	BIORAD L1	LDH	319 U/L		63179	12-Feb-2022 19:49:44	333.000	33.000	234 - 432
2	26491	BIORAD L1	SGPTD	29.3 U/L		63181	12-Feb-2022 19:50:20	27.600	2.700	19.5 - 35.7
3	26491	BIORAD L1	SGOTD	35.9 U/L		63183	12-Feb-2022 19:50:56	38.200	3.750	26.95 - 49.45
4	26491	BIORAD L1	ALPU	118 U/L		63185	12-Feb-2022 19:51:32	115.000	11.470	80.59 - 149.41
5	26491	BIORAD L1	PHOS	3.67 mg/dl		63187	12-Feb-2022 19:52:09	3.870	0.280	3.03 - 4.71
6	26491	BIORAD L1	BIT	0.87 mg/dl		63191	12-Feb-2022 19:53:21	0.990	0.120	0.63 - 1.35
7	26491	BIORAD L1	UREA	34.3 mg/dl		63193	12-Feb-2022 19:53:57	33.800	2.550	26.15 - 41.45
8	26491	BIORAD L1	CRENZ	1.82 mg/dl		63195	12-Feb-2022 19:54:33	1.800	0.180	1.26 - 2.34
9	26491	BIORAD L1	GLU	85.3 mg/dl		63197	12-Feb-2022 19:55:09	91.700	7.020	70.64 - 112.76
10	26491	BIORAD L1	TRIG	182.4 mg/dl		63199	12-Feb-2022 19:55:45	186.000	13.500	145.5 - 226.5
11	26491	BIORAD L1	CHOL	238 mg/dl		63201	12-Feb-2022 19:56:21	251.000	19.500	192.5 - 309.5
12	26491	BIORAD L1	HDLC	59.7 mg/dl		63203	12-Feb-2022 19:56:57	67.200	14.250	24.45 - 109.95
13	26491	BIORAD L1	UA	5.2 mg/dl		63205	12-Feb-2022 19:57:33	5.380	0.400	4.18 - 6.58
14	26491	BIORAD L1	CA	10.1 mg/dl		63207	12-Feb-2022 19:58:10	9.940	0.740	7.72 - 12.16
15	26491	BIORAD L1	ALBD	3.82 g/dl		63208	12-Feb-2022 19:58:28	3.900	0.300	3 - 4.8
16	26491	BIORAD L1	PRO	6.85 g/dl		63210	12-Feb-2022 19:59:04	6.940	0.520	5.38 - 8.5

Print Date 13-Feb-2022

Result Reprint

Report Type : Controls

Sr #	Lot #	Consumable	Test *	Result Unit	Flag	Curve #	Result Date	Mean	SD	Interval (3
1	26492	BIORAD L2	LDH	856 U/L		63214	13-Feb-2022 07:39:54	888.000	88.500	622.5 - 11
2	26492	BIORAD L2	SGPTD	98.2 U/L		63215	13-Feb-2022 07:40:12	104.000	10.370	72.89 - 13
3	26492	BIORAD L2	SGOTD	190.0 U/L		63216	13-Feb-2022 07:40:30	204.000	21.000	141 - 267
4	26492	BIORAD L2	ALPU	478 U/L		63217	13-Feb-2022 07:40:48	487.000	48.000	343 - 631
5	26492	BIORAD L2	BIDD	1.27 mg/dl		63218	13-Feb-2022 07:41:06	1.310	0.160	0.83 - 1.79
6	26492	BIORAD L2	BIT	4.36 mg/dl		63219	13-Feb-2022 07:41:24	4.770	0.600	2.97 - 6.57
7	26492	BIORAD L2	UREA	100.8 mg/dl		63220	13-Feb-2022 07:41:42	103.000	7.500	80.5 - 125.1
8	26492	BIORAD L2	CRENZ	5.07 mg/dl		63221	13-Feb-2022 07:42:00	5.210	0.520	3.65 - 6.77
9	26492	BIORAD L2	GLU	283.5 mg/dl		63222	13-Feb-2022 07:42:18	304.000	22.500	236.5 - 371
10	26492	BIORAD L2	CHOL	97 mg/dl		63224	13-Feb-2022 07:42:54	104.000	7.750	80.75 - 127
11	26492	BIORAD L2	HDLC	21.7 mg/dl		63225	13-Feb-2022 07:43:13	23.900	2.400	16.7 - 31.1
12	26492	BIORAD L2	CA	13.5 mg/dl		63226	13-Feb-2022 07:43:31	13.400	1.050	10.25 - 16.5
13	26492	BIORAD L2	ALBD	2.54 g/dl		63227	13-Feb-2022 07:43:49	2.700	0.210	2.07 - 3.33
14	26492	BIORAD L2	PRO	4.77 g/dl		63228	13-Feb-2022 07:44:07	4.750	0.360	3.67 - 5.83