

Instrument Name

Clinical Chemistry Analyzer

Instrument ID

S20015-91

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TRANSASIA BIOMEDICALS LIMITED  
 INSTALLATION QUALIFICATION



Instrument Name	Clinical Chemistry Analyzer	Instrument ID	32001581
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1.0 PRE APPROVAL

1.1 Prepared By

Name	Designation	Signature	Date
Vinayak Lal	Sr. Asm		15/09/2020.

1.2 Checked By

Name	Designation	Signature	Date
Ms Naruna J.	Sr. Lab Technician		15/09/2020
Ms.			

1.3 Approved By

Name	Designation	Signature	Date
Dr. Rakesh Kumar	Lab Director.		15/09/20

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



## INSTALLATION QUALIFICATION

Instrument Name	Clinical Chemistry Analyzer	Instrument ID	B2001581
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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






Instrument Name

Clinical Chemistry Analyzer

Instrument ID

B2001541

4.0 EXECUTION TEAM

Name	Department	Designation	Signature
Vinayak Lal	TSD	Sr. Asm	



Instrument Name	Clinical Chemistry Analyzer	Instrument ID	B200571
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## 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



## INSTALLATION QUALIFICATION

Instrument Name	Clinical Chemistry Analyzer	Instrument ID	82001571
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**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, 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.






INSTALLATION QUALIFICATION

Instrument Name	Clinical Chemistry Analyzer	Instrument ID	B2001521
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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	Y		NA
Sample Syringe	Y		
Sample Probe	Y		
Wash Station for Sample Probe	Y		
Reagent Tray / Disk	Y		
Reagent Bottles	Y		
Reagent Probe	Y		
Stirrer	Y		
Permanent Reaction Cuvette	Y		
9 Stage Laundry System	Y		
Light Source	Y		
Sample Cups	Y		
Software of EM 200	Y		



INSTALLATION QUALIFICATION

Instrument Name	Clinical Chemistry Analyzer	Instrument ID	B2001531
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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	X	
2.	Verify that major components / accessories are securely anchored and shock proof.	Y	
3.	Verify that there is no observable physical damage.	Y	
4.	Verify that there is sufficient room of servicing provided	Y	
5.	Verify that all utilities and electrical connections have been done according to the drawings.	Y	
6.	Walking access to ground mounted instrument provided.	Y	
7.	Required electric connections are tight, weather proof and earthed.	Y	
8.	Instrument identification nameplate visible.	Y	
9.	Units installed on foundation and secure in place as per manufacturer's recommendations.	Y	
10.	Verify that the instruments installed and leveled properly on the floor.	Y	
11.	Verify that the Material of Construction is proper and meeting the requirements.	Y	





Instrument Name	Clinical Chemistry Analyzer	Instrument ID	B2001581
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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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## INSTALLATION QUALIFICATION

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Instrument Name Clinical Chemistry Analyzer Instrument ID 82001591

Instrument/ Component Name: Sample Tray / Disk

Date : 15/09/2020

Description	Specified	Actual	Method of Verification	Verified by Signature
No. of patient cups / samples	30 positions	30	Physical	
Standards / Stat	30 positions	30	— — —	
Blank	Can be put on any position	30	— — —	
ISE positions (Optional)	Can be programmed on any positions	NA	—	
Controls	Can be programmed on any positions	4	Physical.	




## INSTALLATION QUALIFICATION

Instrument Name	Clinical Chemistry Analyzer	Instrument ID	B200157
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Instrument/ Component Name: Sample Syringe

Date : 15/09/2020

Description	Specified	Actual	Method of Verification	Verified by Signature
Dispensing Volume	2 – 70 $\mu$ L	4	S/W	
Installed Location	Behind the instrument on the right side	4	-	
Quantity	01 No.	4	S/W	
Increase in dispensing volume	0.2 $\mu$ L	4	S/W	





Instrument Name


Clinical Chemistry Analyzer

Instrument ID

B2001591

Instrument/ Component Name: Sample Probe

Date : 15/09/2020

Description	Specified	Actual	Method of Verification	Verified by Signature
Aspiration Volume	2 – 70 $\mu$ L	Y	S/W	
MOC	Teflon coated	Y	—	
Quantity	01 No.	Y	01	
Increase in aspiration volume	0.2 $\mu$ L	Y	S/W	



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## INSTALLATION QUALIFICATION

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Instrument Name Clinical Chemistry Analyzer Instrument ID 82001521

Instrument/ Component Name: Wash Station for Sample Probe

Date : 15/09/2020

Description	Specified	Actual	Method of Verification	Verified by Signature
No. of position	01 No	01	SN	
Type of positions	i) Drain	01	SN	
	ii) Trough	01		



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## INSTALLATION QUALIFICATION

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Instrument Name | Clinical Chemistry Analyzer | Instrument ID | B2001591

Instrument/ Component Name: Reagent Tray / Disk

Date : 15/09/2020

Description	Specified	Actual	Method of Verification	Verified by Signature
Cool reagent disk	50 positions	Y	S/w	
Outer Rings	25 positions	Y	Physical.	
Inner Rings	25 positions	Y	Physical.	
Adaptors of 5ml.	50 positions	Y	Physical.	
Maintenance of Temperature	8-12°C ± 2°C	Y	S/w	
Rotation of disk	Counter-Clockwise	Y	S/w	
Time for Rotation of one Cuvette	Every 18 seconds	Y	S/w	






Instrument Name	Clinical Chemistry Analyzer	Instrument ID	B 2001521
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Instrument/ Component Name: Reagent Bottles

Date: 15/09/2020

Description	Specified	Actual	Method of Verification	Verified by Signature
Minimum Capacity	20 mL	4	Physical	
Maximum Capacity	50 mL	4	---	
Quantity (Large)	25 Nos'	4	---	
Quantity (Smaller)	25 Nos'	4	---	
Type	Screw Capped	4	---	
Outer ring position	20 mL bottles & 5ml adaptors	4	---	
Inner ring position	20 mL & 50 mL bottles & 5ml adaptors	4	---	
MOC	Plastic	4	---	
Adaptor	50 Nos'	4	---	
Adaptor Capacity	5 mL	4	---	
Identification of Reagents	Barcode labels on the reagent containers	4	---	



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## INSTALLATION QUALIFICATION

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Instrument Name	Clinical Chemistry Analyzer	Instrument ID	B2001541
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Instrument/ Component Name: Reagent Probe

Date : 15/09/2020


Description	Specified	Actual	Method of Verification	Verified by Signature
Aspiration/Dispensing Volume	R1: 50 – 300 $\mu$ L	4	S/W	
	R2: 0 or 10 – 300 $\mu$ L		S/W	
MOC	Teflon coated	4	S/W	
Quantity	02 Nos.	4	@S/W	
Increase in aspiration/dispensing volume	1 $\mu$ L	4	S/W	



Instrument Name	Clinical Chemistry Analyzer	Instrument ID	B2001531
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Instrument/ Component Name: Reagent Syringe

Date : 15/09/2020

Description	Specified	Actual	Method of Verification	Verified by Signature
Maximum capacity	500 $\mu$ L	4	Physical.	
Installed Location	At the back of the instrument on the right side	4	-11-	
Quantity	01 No.	4	-1-	
Increase in dispensing volume	1 $\mu$ L	4	S/w.	





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INSTALLATION QUALIFICATION



Instrument Name	Clinical Chemistry Analyzer	Instrument ID	32001571
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Instrument/ Component Name: Stirrer

Date: 15/09/2020

Description	Specified	Actual	Method of Verification	Verified by Signature
Type	Single Stirrer	4	Physical	
No. of paddles	01 No.	4	Physical	



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## INSTALLATION QUALIFICATION


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Instrument Name	Clinical Chemistry Analyzer	Instrument ID	B2001591
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Instrument/ Component Name: Permanent Reaction Cuvette

Tag/Identification No.:

Date : 15/09/2020

Description	Specified	Actual	Method of Verification	Verified by Signature
Quantity	45 Nos <sup>*</sup>	4	Physical	
MOC	Hard Glass	4	—	
Capacity	770 µL	4	—	




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 INSTALLATION QUALIFICATION

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Instrument Name    Clinical Chemistry Analyzer    Instrument ID    B 2001531

Instrument/ Component Name: 7 Stage Laundry System

Date : 15/09/2020

Description	Specified	Actual	Method of Verification	Verified by Signature
Nozzles	Nozzle - 1	4	Physical	
	Nozzle - 2	4	- - -	
	Nozzle - 3	4	- - -	
	Nozzle - 4	4	- - -	
	Nozzle - 5	4	- - -	
	Nozzle - 6	4	- - -	
	Nozzle - 7	4	- - -	





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## INSTALLATION QUALIFICATION

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Instrument Name	Clinical Chemistry Analyzer	Instrument ID	B2001591
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Instrument/ Component Name: Light Source

Date : 15/09/2020

Description	Specified	Actual	Method of Verification	Verified by Signature
Watts	12 W	4	Physical.	
Volts	12 V	4	Physical by Multimeter	
MOC	Halogen	4	4	
Quantity	01 No	4	4	



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Instrument Name	Clinical Chemistry Analyzer	Instrument ID	B 2001581
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Instrument/ Component Name: Sample Cups

Date : 15/09/2020

Description	Specified	Actual	Method of Verification	Verified by Signature
Quantity	500 Nos	4	Physical	
MOC	Plastic	4	--	
Capacity	2 mL	4	--	



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## INSTALLATION QUALIFICATION

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Instrument Name


Clinical Chemistry Analyzer

Instrument ID

B200571

Instrument/ Component Name: Software of EM ~~200~~ 200

Date : 15/09/2020

Description	Specified	Actual	Method of Verification	Verified by Signature
Version	Multix L v2019.02A	Y	Physical	
CD number	—	Y	—	
Product	EM- 200	Y	—	
Make	Erba Transasia	Y	—	






Instrument Name	Clinical Chemistry Analyzer	Instrument ID	B2001571
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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	4	Physical.	
Reagent Probe	Teflon coated	4	—	
Permanent Reaction Cuvette	Hard Glass	4	—	
Light Source	Halogen	4	—	
Reagent Bottle	Plastic	4	—	
Sample Cups	Plastic	4	—	



Instrument Name	Clinical Chemistry Analyzer	Instrument ID	0200 (58)
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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	✓	
Distilled Water	✓	
Wash Solution	✓	
UPS	YVA.	



Instrument Name

Clinical Chemistry Analyzer

Instrument ID

B2001581

## 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





Instrument Name	Clinical Chemistry Analyzer	Instrument ID	B2001581
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12.0 IDENTIFICATION AND VERIFICATION OF DOCUMENTS

12.1 DRAWINGS

Title	Drawing No.	Verified by Sign & Date
As-built Drawing	—	—
	—	





Instrument Name

Clinical Chemistry Analyzer

Instrument ID

B2001581

12.2 GENERAL DOCUMENTS

Title	Document No.	Verified by Sign & Date
<b>General</b>		
Purchase Order No.	—	
Warranty Certificate	—	
Invoice	—	
<b>Test Certificates</b>		
Material of Construction	—	
Electrical Motor	—	



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INSTALLATION QUALIFICATION

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Instrument Name

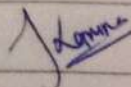
Clinical Chemistry Analyzer

Instrument ID

8200581

13.0 DEFICIENCIES / DEVIATIONS:

Reviewed by:

Name	Signature	Date
MS KARUNA JADHAV		15/09/2020





Instrument Name

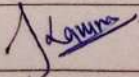
Clinical Chemistry Analyzer

Instrument ID

B2001591

14.0 SUMMARY AND EVALUATION:

Reviewed by:

Name	Signature	Date
Ms KARUNA JADHAV		15/9/2020



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INSTALLATION QUALIFICATION

**TRANSASIA**<sup>®</sup>  
Bio-Medicals Ltd.

Instrument Name

Clinical Chemistry Analyzer

Instrument ID

B2001571

### 15.0 ABBREVIATIONS

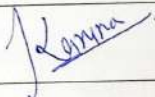
SOP	Standard Operating Procedure
MOC	Material of Construction
IQ	Installation Qualification




Instrument Name	Clinical Chemistry Analyzer	Instrument ID	B2001591
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## 16.0 POST APPROVAL:

## 16.1 Checked by

Name	Designation	Signature	Date
MskARUNA J	Dr TECHNICAL GRT		15/9/2020

## 16.2 Approved by

Name	Designation	Signature	Date
Dr RAJESH PATEA	LAB DIRECTOR		15/9/2020

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





TRANSASIA BIOMEDICALS LIMITED  
OPERATIONAL QUALIFICATION CHECKLIST

TRANSASIA<sup>®</sup>  
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Instrument Name	Clinical Chemistry Analyzer	Instrument ID	B2001591
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As part of Operational qualification, the following checks shall be done and each test shall be recorded:

### Instrument Start-up

To check and establish the standard sequence to be followed, during start-up of the subjected instrument in Auto / Manual mode, to propose for correct operation and to avoid any damage to the instrument and personnel.

### Functional Checks

To check and ensure that different functions (such as switching devices, indication / monitoring / recording devices, feedback system, etc.) for correct operation of the subjected instrument are working as expected.

### Interlocks and Alarms Check

To check and ensure that the interlocks and alarms (such as status indication system, negative feed back system, control loops, sound alarms, etc.) for correct control and monitoring of the operation cycle are working as expected.

### Safety / Security Checks

To check and ensure that the safety / security functions (such as program logging, process control, personnel safety systems, password check, etc.) to protect the instrument and personnel are working as expected.

### Instrument Shut-down

To check and establish the standard sequence to be followed, during shut-down of the subjected instrument in Auto / Manual mode, to propose for correct operation and to avoid any damage to the instrument and personnel.



**TRANSASIA BIOMEDICALS LIMITED**  
**OPERATIONAL QUALIFICATION CHECKLIST**

**TRANSASIA**  
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**Instrument Name** | Clinical Chemistry Analyzer | **Instrument ID** | 02001591

**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.	y			
Ensure the proper filling of double distilled / de-ionized water and Cleaning solution in the respective cans.	y		 (15/09/2020)	
Ensure the availability of XL Wash.	y			
Ensure the availability of Biohazard Waste.	y			
Ensure the availability of Normal Waste.	y			
Switch ON the rear switch of the analyzer.	y			
Switch ON the side switch of the analyzer.	y			
Switch ON the computer and start the analyzer application software.	y			
Initialization	y			



**TRANSASIA BIOMEDICALS LIMITED**  
**OPERATIONAL QUALIFICATION CHECKLIST**



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Instrument Name | Clinical Chemistry Analyzer | Instrument ID | **B 2001581**

**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	4		
Cuvette Rinse	4	 15/09/2024	





**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	4	 15/09/2020	





**TRANSASIA BIOMEDICALS LIMITED**  
**OPERATIONAL QUALIFICATION CHECKLIST**



<b>Instrument Name</b>	Clinical Chemistry Analyzer	<b>Instrument ID</b>	B2001591
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**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)	4	 15/09/2020	
Standard (Multical)	4	 15/09/2020	



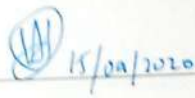
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**OPERATIONAL QUALIFICATION CHECKLIST**

**TRANSASIA**  
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Instrument Name    Clinical Chemistry Analyzer    Instrument ID    **B2001581**

**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	4		
Less volume of Wash Solution	4		
More volume of Bio-Hazard waste	4		
More volume of Normal / General waste	4		






**TRANSASIA BIOMEDICALS LIMITED**  
**OPERATIONAL QUALIFICATION CHECKLIST**



Instrument Name	Clinical Chemistry Analyzer	Instrument ID	B2001591
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**4.0 SAFETY / SECURITY CHECKS:**

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

Action	Observation	Verified by (Sign & Date)	Remarks
Password Check for Test Parameters	4	 15/09/2020	-
Password Check for QC Mode	NA	-	-



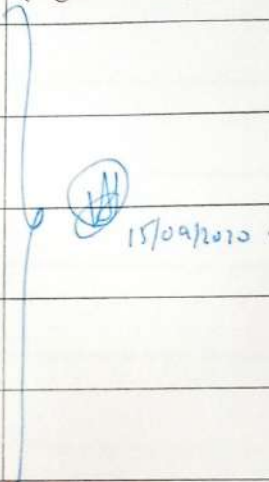
**TRANSASIA BIOMEDICALS LIMITED**  
**OPERATIONAL QUALIFICATION CHECKLIST**

**TRANSASIA**  
 Bio-Medicals Ltd.

Instrument Name    Clinical Chemistry Analyzer    Instrument ID    **B2001581**

**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	4		
Water Save	4		
Switch OFF the computer.	4		15/09/2020
Switch OFF the side switch of the analyzer.	4		
Switch OFF the rear switch of the analyzer.	4		



Instrument Name

Clinical Chemistry Analyzer

Instrument ID

B2001581

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## TRANSASIA BIOMEDICALS LIMITED

## PERFORMANCE QUALIFICATION

TRANSASIA<sup>®</sup>  
Bio-Medicals Ltd.

Instrument Name

Clinical Chemistry Analyzer

Instrument ID

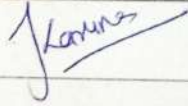
B2001581

## 1.0 PRE APPROVAL

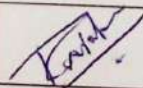
## 1.1 Prepared By

Name	Designation	Signature	Date
Rahat Shaikh	Appl. Manager		16-09-2020

## 1.2 Checked By

Name	Designation	Signature	Date
Karuna Jadhav	Sr. Technician Q.M.		16-09-2020

## 1.3 Approved By

Name	Designation	Signature	Date
Dr. Rakesh Patkar	Lab. Director		16-09-2020



**TRANSASIA BIOMEDICALS LIMITED**

**PERFORMANCE QUALIFICATION**

**TRANSASIA®**  
Bio-Medicals Ltd.

<b>Instrument Name</b>	<b>Clinical Chemistry Analyzer</b>	<b>Instrument ID</b>	<b>B2001581</b>
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**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**


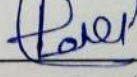
The Scope of this protocol is applicable to EM 200 (Bio-Chemistry Random Analyzer).

**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**

<b>Name</b>	<b>Department</b>	<b>Designation</b>	<b>Signature</b>
Winayak Lad	TSD	Service Engineer	
Rahat Shaikh	TSD	Application Manager	







Instrument Name	Clinical Chemistry Analyzer	Instrument ID	B2001581
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## 7.0 EXECUTION OF TEST PLAN

① Precision

- ① Three methods used for the precision check.
- ② Any normal sample to be run 10 times for one endpt., one kinetic and one fixed Time method.
- ③ The CV% of the above precision should be within  $\pm 5\%$  limits.

② Accuracy

- ① Level 2 and Level 3 control run for all parameters.
- ② The controls should be within  $\pm 1SD$  of the target value.



Reviewed by:

Name	Signature	Date
Karuna Jadhav	<i>Karuna</i>	16-09-2020

**TRANSASIA BIOMEDICALS LIMITED**

**PERFORMANCE QUALIFICATION**

**TRANSASIA<sup>®</sup>**  
Bio-Medicals Ltd

Instrument Name	Clinical Chemistry Analyzer	Instrument ID	B2001581
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**8.0 DEFICIENCIES / DEVIATIONS:**



**Reviewed by:**

Name	Signature	Date
Karana Jadhav	<i>Karana</i>	16-09-2020

## TRANSASIA BIOMEDICALS LIMITED

## PERFORMANCE QUALIFICATION

TRANSASIA<sup>®</sup>  
Bio-Medicals Ltd.

Instrument Name

Clinical Chemistry Analyzer

Instrument ID

B2001581

## 9.0 SUMMARY AND EVALUATION:

- ① IQ, OQ and PQ found satisfactory.
- ② Accuracy and Precision found satisfactory.

Reviewed by:



Name

Signature

Date

Karuna Jadhav

16-09-2020



**TRANSASIA BIOMEDICALS LIMITED****PERFORMANCE QUALIFICATION****TRANSASIA<sup>®</sup>**  
Bio-Medicals Ltd

Instrument Name

Clinical Chemistry Analyzer

Instrument ID

B2001581

## 10.0 ABBREVIATIONS

SOP	Standard Operating Procedure
MOC	Material of Construction
PQ	Performance Qualification





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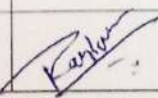
Instrument Name	Clinical Chemistry Analyzer	Instrument ID	B2001581
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**11.0 POST APPROVAL**

**11.1 Checked by**

Name	Designation	Signature	Date
Ankita Nalawade	Lab Technician		16-09-2020
Karuna Jadhav	Sr. Lab Technician/ QM.		16-09-2020

**11.2 Approved by**

Name	Designation	Signature	Date
Sr. Rakesh Patkar	LAB DIRECTOR		16-09-2020

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



Sample ID	1	Patient ID	
Name	PRECISION	Sample Type	SERUM
Category	-	Collection Date	16-Sep-2020
Age	-	Reg. Date	16-Sep-2020
Ref. Dr		Analyst	
Sample Remark		Location	

Sr.No.	Test	Result	Flag	Normal Range
1	Glucose	113.8 mg/dl	H	↑ 74.0 - 100.0 mg/dl
2	Glucose	113.6 mg/dl	H	↑ 74.0 - 100.0 mg/dl
3	Glucose	114.6 mg/dl	H	↑ 74.0 - 100.0 mg/dl
4	Glucose	113.5 mg/dl	H	↑ 74.0 - 100.0 mg/dl
5	Glucose	113.1 mg/dl	H	↑ 74.0 - 100.0 mg/dl
6	Glucose	112.9 mg/dl	H	↑ 74.0 - 100.0 mg/dl
7	Glucose	113.9 mg/dl	H	↑ 74.0 - 100.0 mg/dl
8	Glucose	116.0 mg/dl	H	↑ 74.0 - 100.0 mg/dl
9	Glucose	112.3 mg/dl	H	↑ 74.0 - 100.0 mg/dl
10	Glucose	112.7 mg/dl	H	↑ 74.0 - 100.0 mg/dl

Patient Remark

Completion Date 16-Sep-2020 11:16

Note : Tests have been performed on fully automated analyzer:- EM 200

Print Date 16-Sep-2020 11:25 Page 1 of 1

PERFORMED BY: ANKITA NALWADE  
LAB TECHNICIAN

CHECKED BY: KARUNA JADNAV  
SR LAB TECHNICIAN / GM

AN

Karuna



Sample ID	1	Patient ID	
Name	PRECISION	Sample Type	SERUM
Category	-	Collection Date	16-Sep-2020
Age	-	Reg. Date	16-Sep-2020
Ref. Dr		Analyst	
Sample Remark		Location	

Sr.No.	Test	Result	Flag	Normal Range
1	ALT/GPT	15.3 U/L		0.0 - 45.0 U/L
2	ALT/GPT	14.5 U/L		0.0 - 45.0 U/L
3	ALT/GPT	14.0 U/L		0.0 - 45.0 U/L
4	ALT/GPT	14.0 U/L		0.0 - 45.0 U/L
5	ALT/GPT	14.3 U/L		0.0 - 45.0 U/L
6	ALT/GPT	13.5 U/L		0.0 - 45.0 U/L
7	ALT/GPT	14.0 U/L		0.0 - 45.0 U/L
8	ALT/GPT	14.5 U/L		0.0 - 45.0 U/L
9	ALT/GPT	14.5 U/L		0.0 - 45.0 U/L
10	ALT/GPT	14.0 U/L		0.0 - 45.0 U/L

Patient Remark

Completion Date 16-Sep-2020 11:10

Note : Tests have been performed on fully automated analyzer:- EM 200

Print Date 16-Sep-2020 11:25 Page 1 of 1

PERFORMED BY : ANKITA NAWARDE  
LAB TECHNICIAN

CHECKED BY : FARUNA JADHAN  
SR LAB TECHNICIAN / BM

*(Signature)*

*(Signature)*

Sample ID	1	Patient ID	
Name	PRECISION	Sample Type	SERUM
Category	-	Collection Date	16-Sep-2020
Age	-	Reg. Date	16-Sep-2020
Ref. Dr		Analyst	
Sample Remark		Location	

Sr.No.	Test	Result	Flag	Normal Range
1	Creatinine	1.16 mg/dl		0.70 - 1.30 mg/dl
2	Creatinine	1.10 mg/dl		0.70 - 1.30 mg/dl
3	Creatinine	1.08 mg/dl		0.70 - 1.30 mg/dl
4	Creatinine	1.05 mg/dl		0.70 - 1.30 mg/dl
5	Creatinine	1.07 mg/dl		0.70 - 1.30 mg/dl
6	Creatinine	1.08 mg/dl		0.70 - 1.30 mg/dl
7	Creatinine	1.07 mg/dl		0.70 - 1.30 mg/dl
8	Creatinine	1.10 mg/dl		0.70 - 1.30 mg/dl
9	Creatinine	1.06 mg/dl		0.70 - 1.30 mg/dl
10	Creatinine	1.08 mg/dl		0.70 - 1.30 mg/dl

Patient Remark

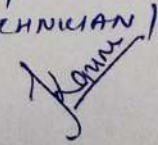
Completion Date 16-Sep-2020 11:19

Note : Tests have been performed on fully automated analyzer:- EM 200

Print Date 16-Sep-2020 11:26 Page 1 of 1

PERFORMED BY : ANKITA NALWADE  
LAB TECHNICIAN

CHECKED BY : KARUNA JADHAV  
Sr LAB TECHNICIAN / QM.



## Certificate of Conformity and Calibration

TO WHOMSOEVER IT MAY CONCERN

ISO 15189:2012 REQUIREMENTS REGARDING, "CALIBRATION AND VERIFICATION PROCEDURE"

All Transasia Bio-Medicals Ltd diagnostics products which are distributed and for which a certificates is issued are CE Marked. Transasia Bio-Medicals Ltd , Mumbai ,manufacturers of diagnostic devices with company quality management system in compliance with standard ISO13485:2016 ;ISO9001:2015 .This means that all the processes in development and manufacturing of TBM products are guided by quality management system.

TBM declares and assure following

- The mentioned regulations require that production system and measuring devices are qualified and manufacturing and test procedures are validated as per ISO 13485:2016 and ISO 9001:2015 standard and it is assured through schedule maintenance and by regular qualification.
- TBM declares to have established procedure and to maintain it in order to assure the post marketing surveillance according to directive of 98/79/EC.
- All physical quantities, calibrators and controls used in TBM system are fully traceable to certified standards or reference materials.
- All TBM products are factory calibrated and final qc passed at the time of release.
- The performance of TBM system at customer site is assured if regular QC measurements, cleaning and maintenance procedure as described in the instruction for use or service documentation are performed
- Additional calibration or verification procedure is not required in order to assure the specified performances of every TBM system. Only if user deviates from the manufactures recommendation does he have to establish site specific calibration and verification procedure as part of his accreditation process.

Date:-26/04/2021

Manish Airan

Head Of Quality Department & Regulatory



# Calibration - EM 200

Test : SGOTD

Revision : <A-200-SGOTD-1 01.06.2016>

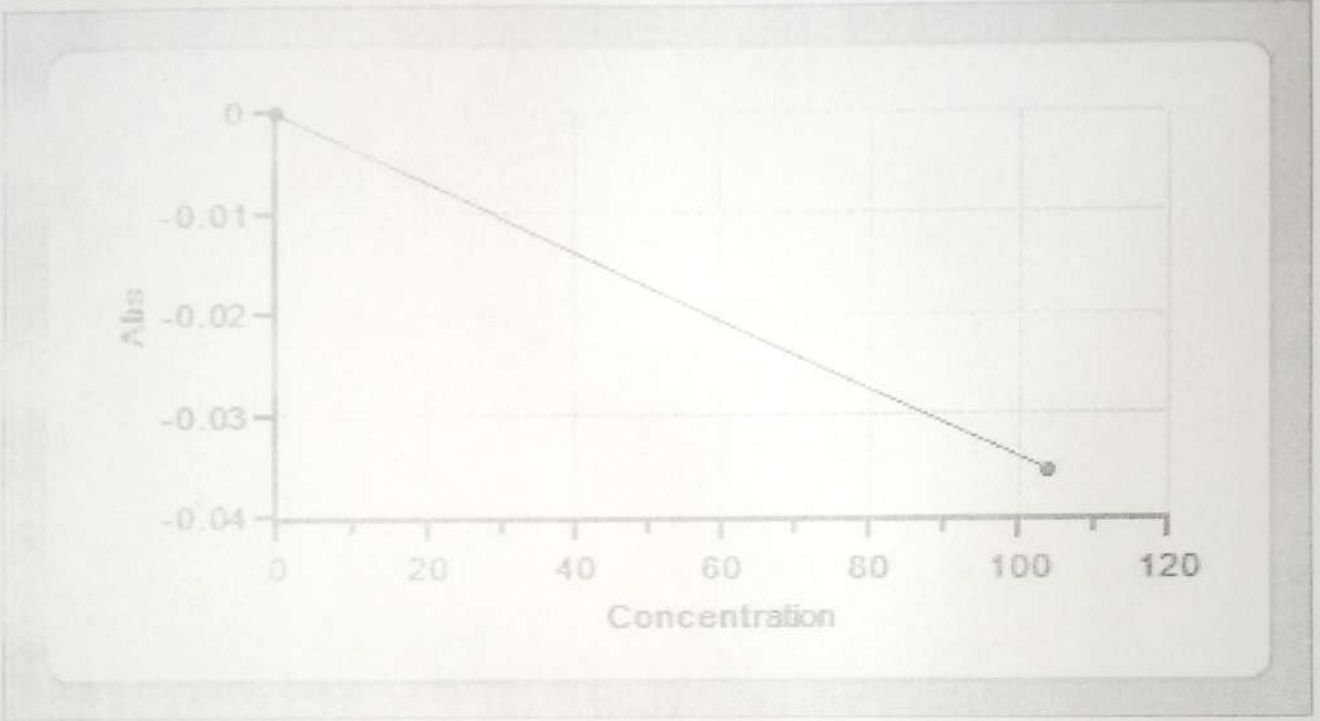
Curve Type : Linear

R1 Lot No : S062147-124

Calibration Date : 13-Oct-2021 11:23:48

R2 Lot No : S062147-124

Last Calibration Date : 13-Oct-2021 11:23:48



Pos	Consumable	LotNo.	Conc	Delta Abs/Min	Factor
-	Blank	4567	0.000	-0.0001	0.0000
-	MULTICAL1907088F	1907088F	104.000	-0.0355	-2,933.7095

PERFORMED BY: ANKITA NAHAJDE

AN  
13/10/2021

CHECKED BY: KARUNA JADHA

Karuna  
13/10/2021

# Calibration - EM 200

Test : SGPTD

Revision : <A-200-SGPTD-1 01.06.2016>

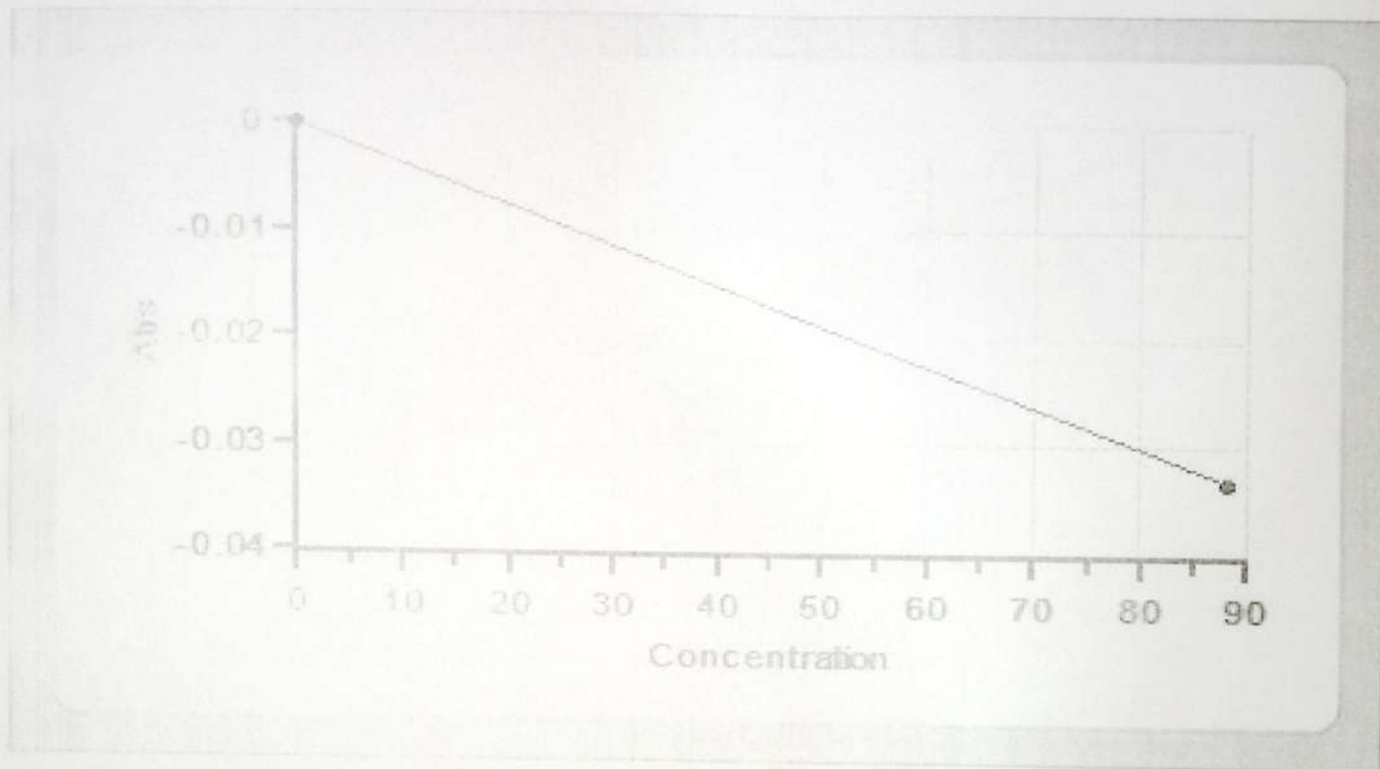
Curve Type : Linear

R1 Lot No : S062150-125

Calibration Date : 13-Oct-2021 11:21:42

R2 Lot No : S062150-125

Last Calibration Date : 13-Oct-2021 11:21:42



Pos	Consumable	LotNo.	Conc	Delta Abs/Min	Factor
-	Blank	4567	0.000	0.0000	0.0000
-	MULTICAL1907088F	1907088F	88.200	-0.0331	-2,664.6523

PERFORMED BY : ANKITA MALAODE

CHECKED BY : KARUNA JADHAV

AN  
13/10/2021

Karuna  
13/10/21

# Calibration - EM 200

Test : PHOS

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

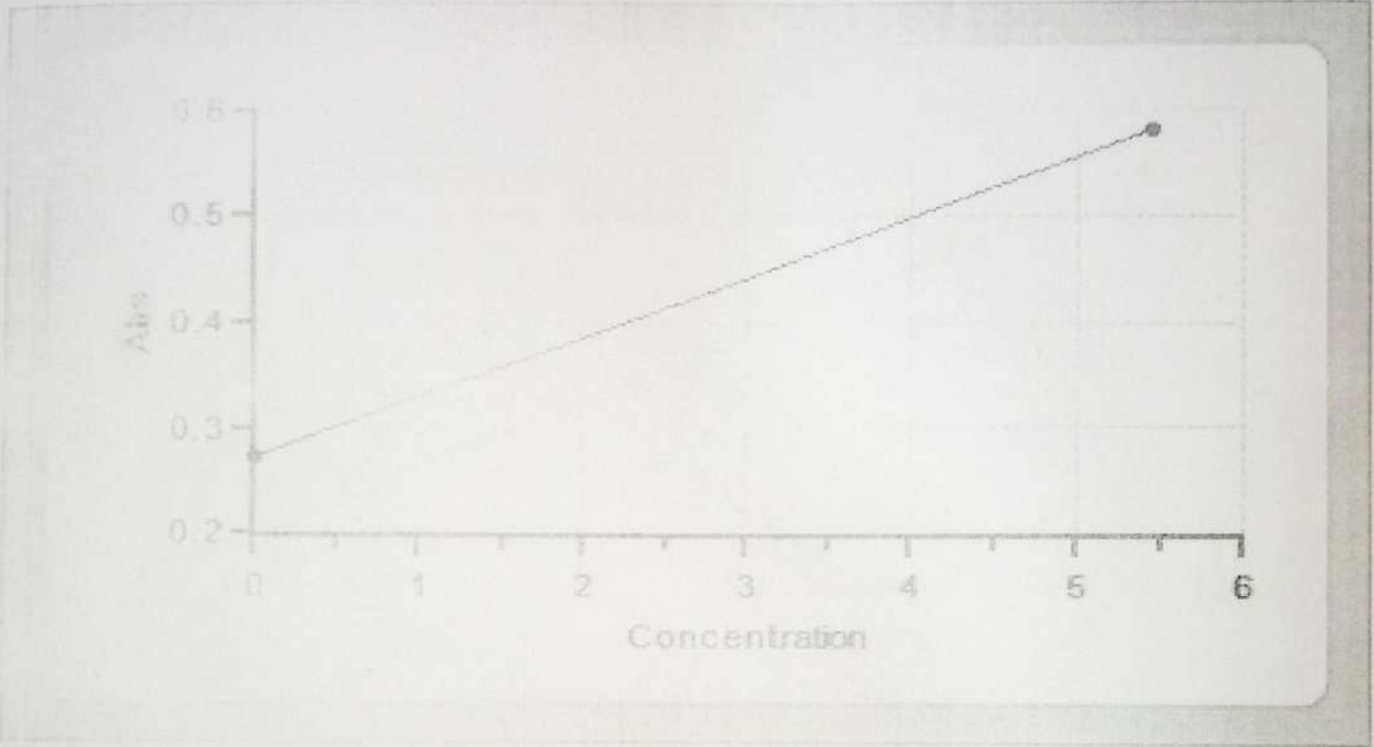
Curve Type : Linear

R1 Lot No : S012131-103

Calibration Date : 13-Oct-2021 11:28:01

R2 Lot No : ---

Last Calibration Date : 13-Oct-2021 11:28:01



Pos	Consumable	LotNo.	Conc	Abs	Factor
-	Blank	4567	0.000	0.2722	0.0000
-	MULTICAL1907088F	1907088F	5.460	0.5809	17.6871

PERFORMED BY: ANHITA NARAYAN

CHECKED BY: KARUNA JADAVAN

AN  
13/10/2021

Karuna  
13/10/21



# Calibration - EM 200

Test : GGT

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

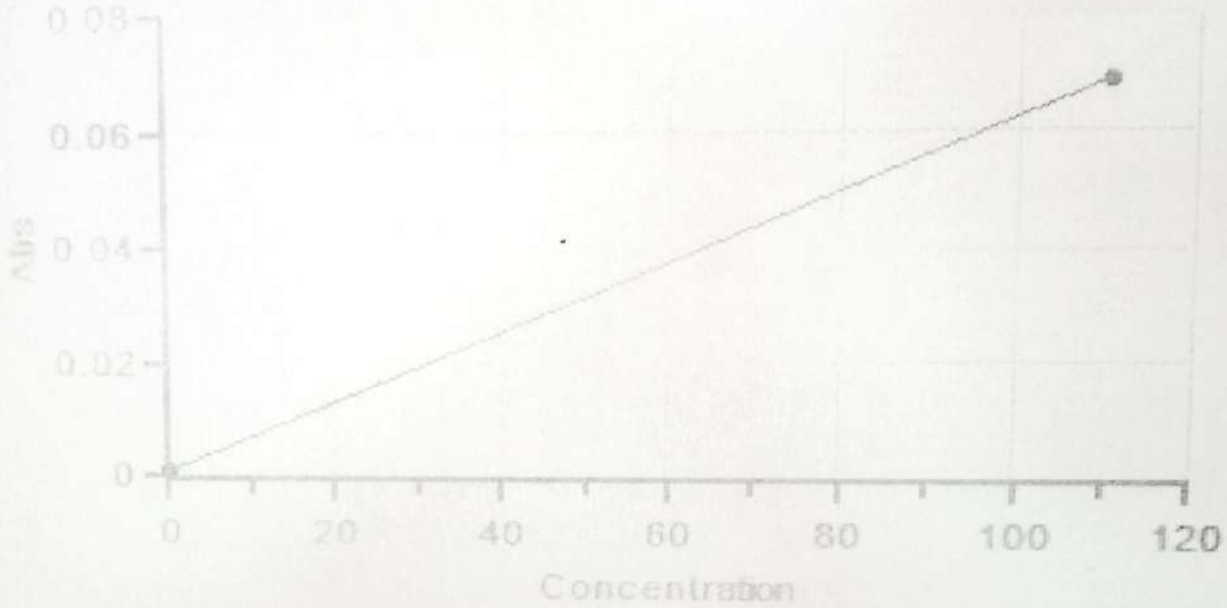
Curve Type : Linear

R1 Lot No : S062109-122

Calibration Date : 20-Oct-2021 11:44:14

R2 Lot No : S062109-122

Last Calibration Date : 20-Oct-2021 11:44:14



Pos	Consumable	LotNo.	Conc	Delta Abs/Min	Factor
-	Blank	4567	0.000	0.0010	0.0000
-	MULTICAL 1907088F	1907088F	110.000	0.0689	1,618.8374

PERFORMER BY : ANKITA NALWADE

CHECKED BY : KARUNA SADHAN

RN  
13/10/2021

J Lemmas  
13/10/21

# Calibration - EM 200

Test : BIT

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

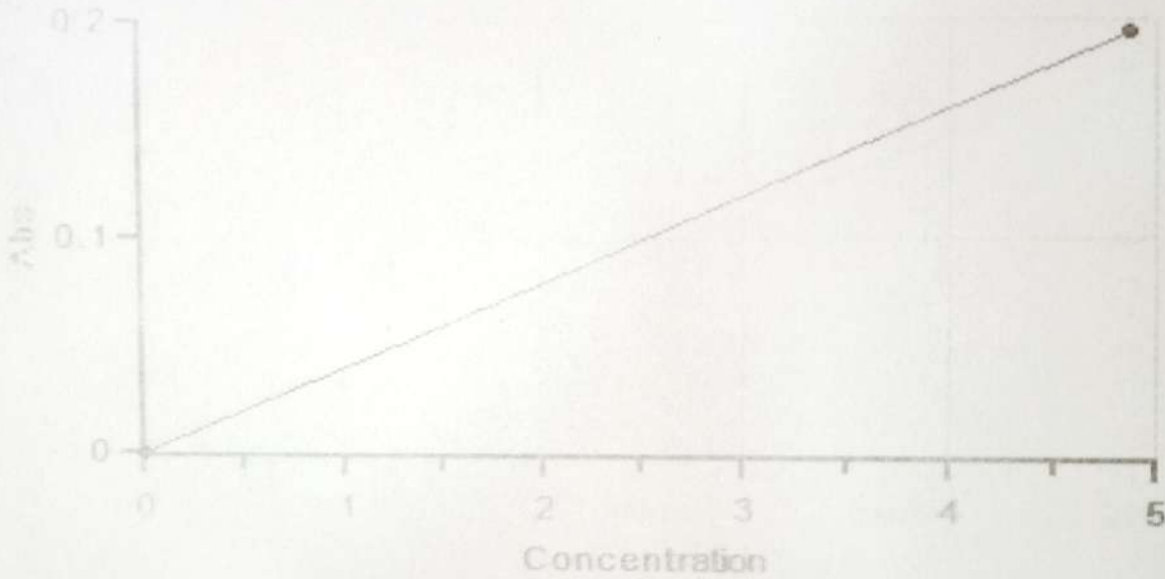
Curve Type : Linear

R1 Lot No : B012106-101

Calibration Date : 13-Oct-2021 11:32:14

R2 Lot No : B012106-101

Last Calibration Date : 13-Oct-2021 11:32:14



Pos	Consumable	LotNo.	Conc	Abs	Factor
-	Blank	4567	0.000	0.0000	0.0000
-	MULTICAL1907088F	1907088F	4.870	0.1938	25.1355

PERFORMED BY: ANKITA NAUWDE

CHECKED BY: KARANJ  
JADHAV

AN  
13/10/2021

Karanj  
13/10/21

# Calibration - EM 200

Test : GLU

Curve Type : Linear

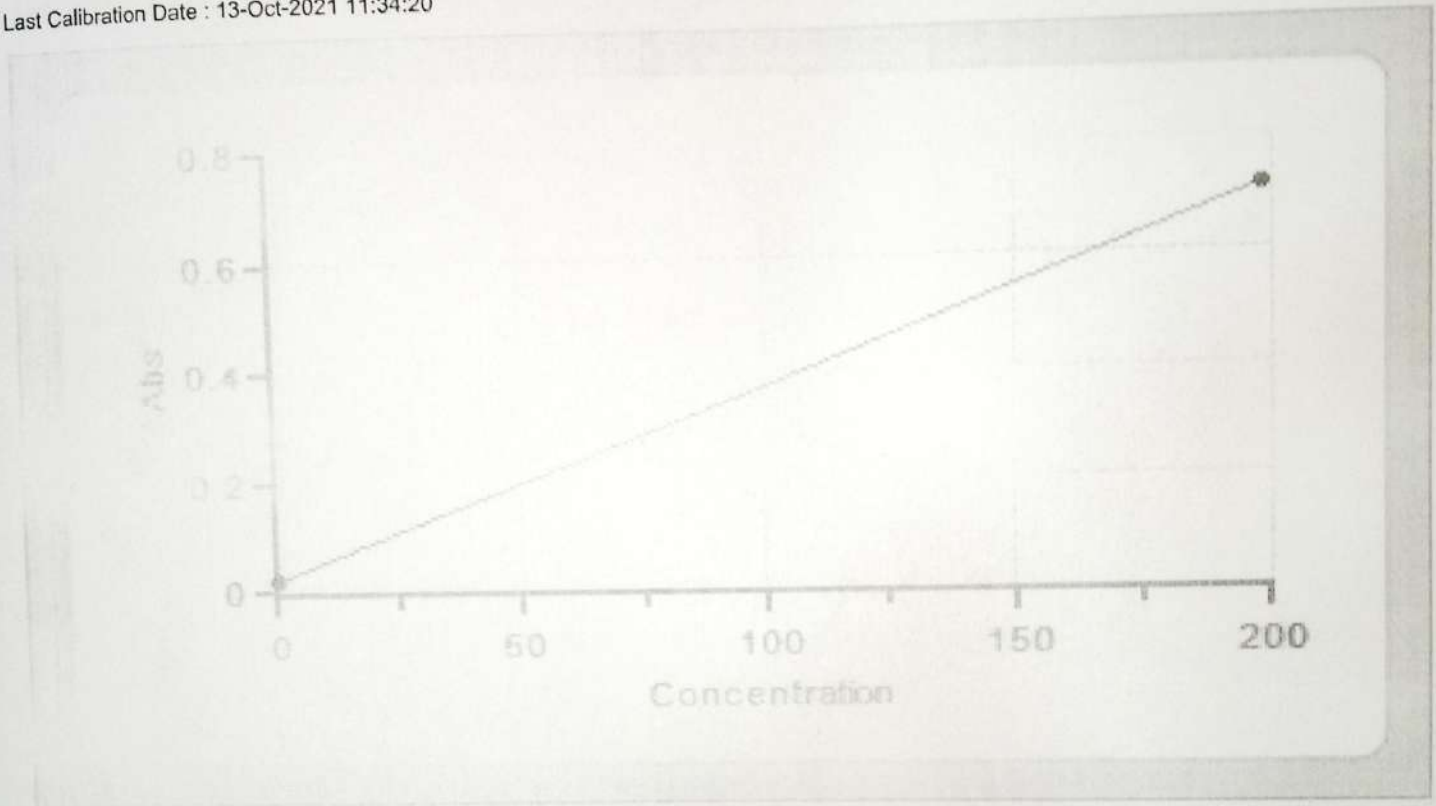
Calibration Date : 13-Oct-2021 11:34:20

Last Calibration Date : 13-Oct-2021 11:34:20

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

R1 Lot No : B062172-126

R2 Lot No : ---



Pos	Consumable	LotNo.	Conc	Abs	Factor
-	Blank	4567	0.000	0.0214	0.0000
-	MULTICAL1907088F	1907088F	198.000	0.7158	285.1588

PERFORMED BY: ANKITA NALAWDE

CHECKED BY: KAPUNIA

AN  
13/10/2021

JADHAV

Jadhav  
13/10/21



# Calibration - EM 200

Test : TRIG

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

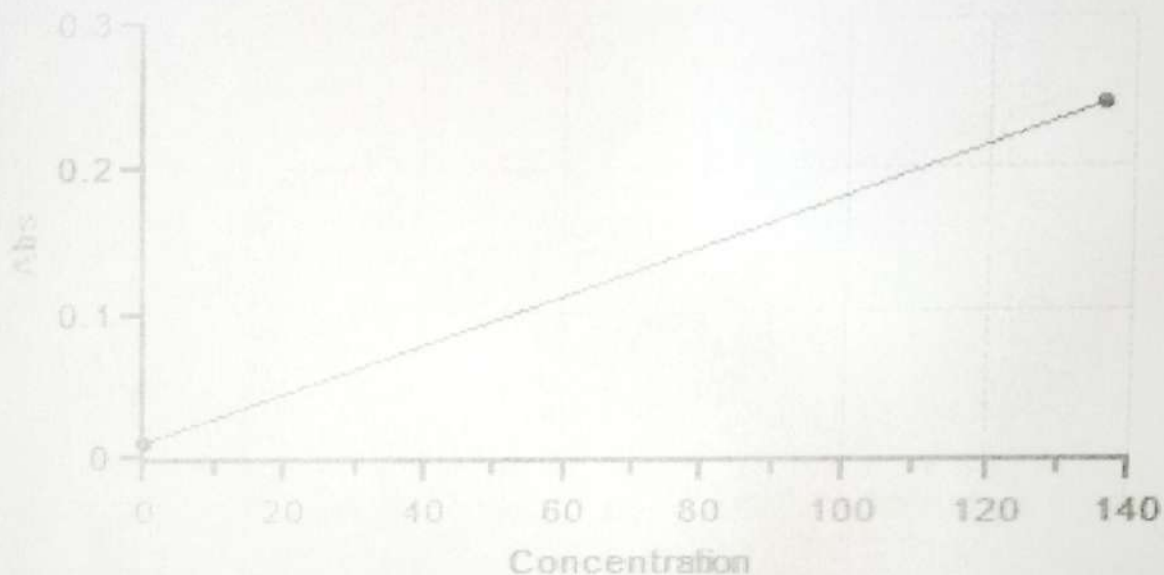
Curve Type : Linear

R1 Lot No : S052110-119

Calibration Date : 13-Oct-2021 11:36:26

R2 Lot No : S052110-119

Last Calibration Date : 13-Oct-2021 11:36:26



os	Consumable	LotNo.	Conc	Abs	Factor
	Blank	4567	0.000	0.0106	0.0000
	MULTICAL 1907088F	1907088F	136.000	0.2415	589.2548

PERFORMED BY : ANKITA NALAWADE

AN  
13/10/2021

CHECKED BY : KARUNA

JAOHAN  
Karuna  
13/10/21

# Calibration - EM 200

Test : CHOL

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

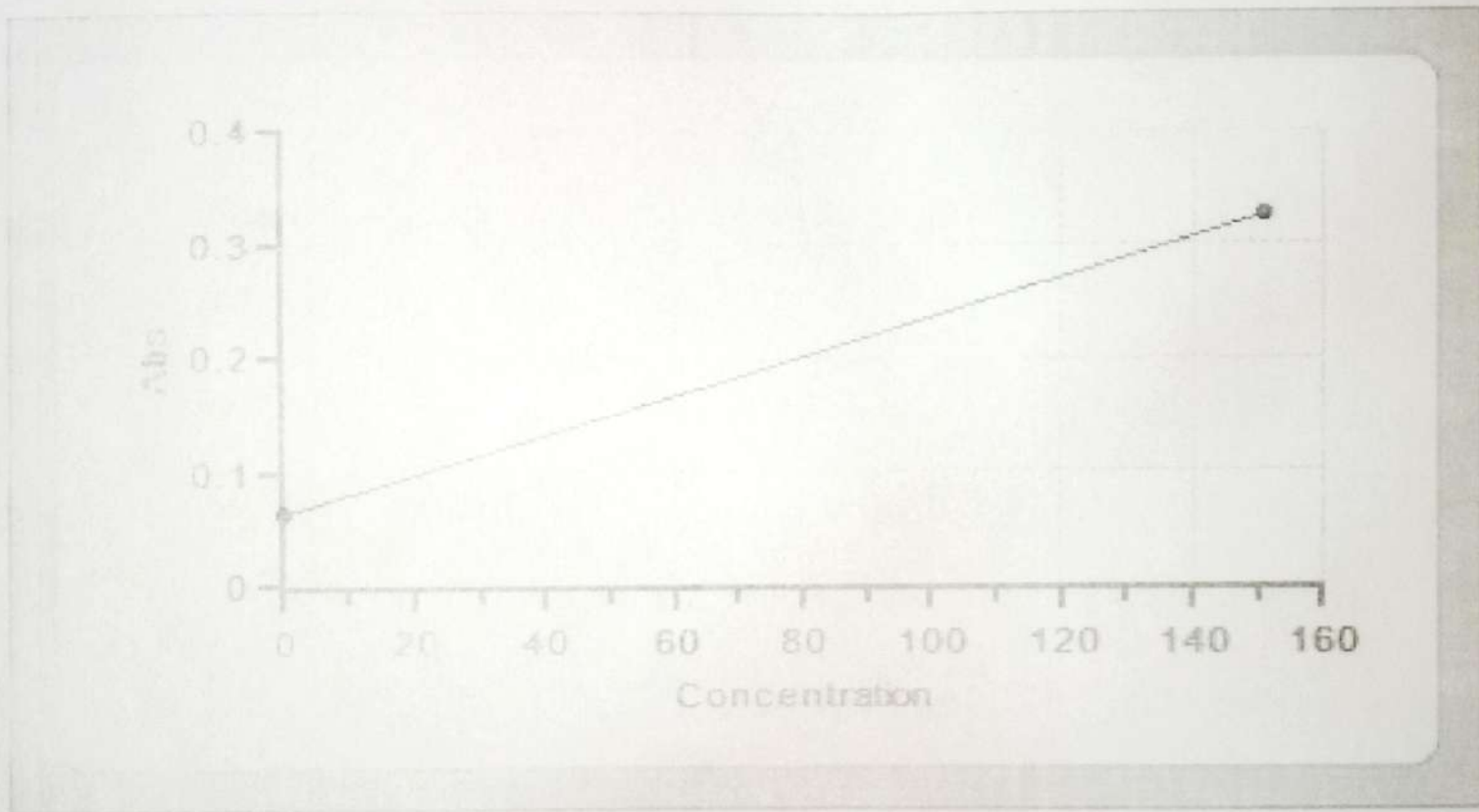
Curve Type : Linear

R1 Lot No : S032113-109

Calibration Date : 13-Oct-2021 11:38:33

R2 Lot No : —

Last Calibration Date : 13-Oct-2021 11:38:33



Pos	Consumable	LotNo.	Conc	Abs	Factor
-	Blank	4567	0.000	0.0637	0.0000
-	MULTICAL1907088F	1907088F	151.000	0.3259	576.1160

PERFORMED BY: ANKITA  
NAYAK

AN  
13/10/2021

CHECKED BY: KARUNA  
JADHAV

Karuna  
13/10/21

# Calibration - EM 200

Test : UA

Curve Type : Linear

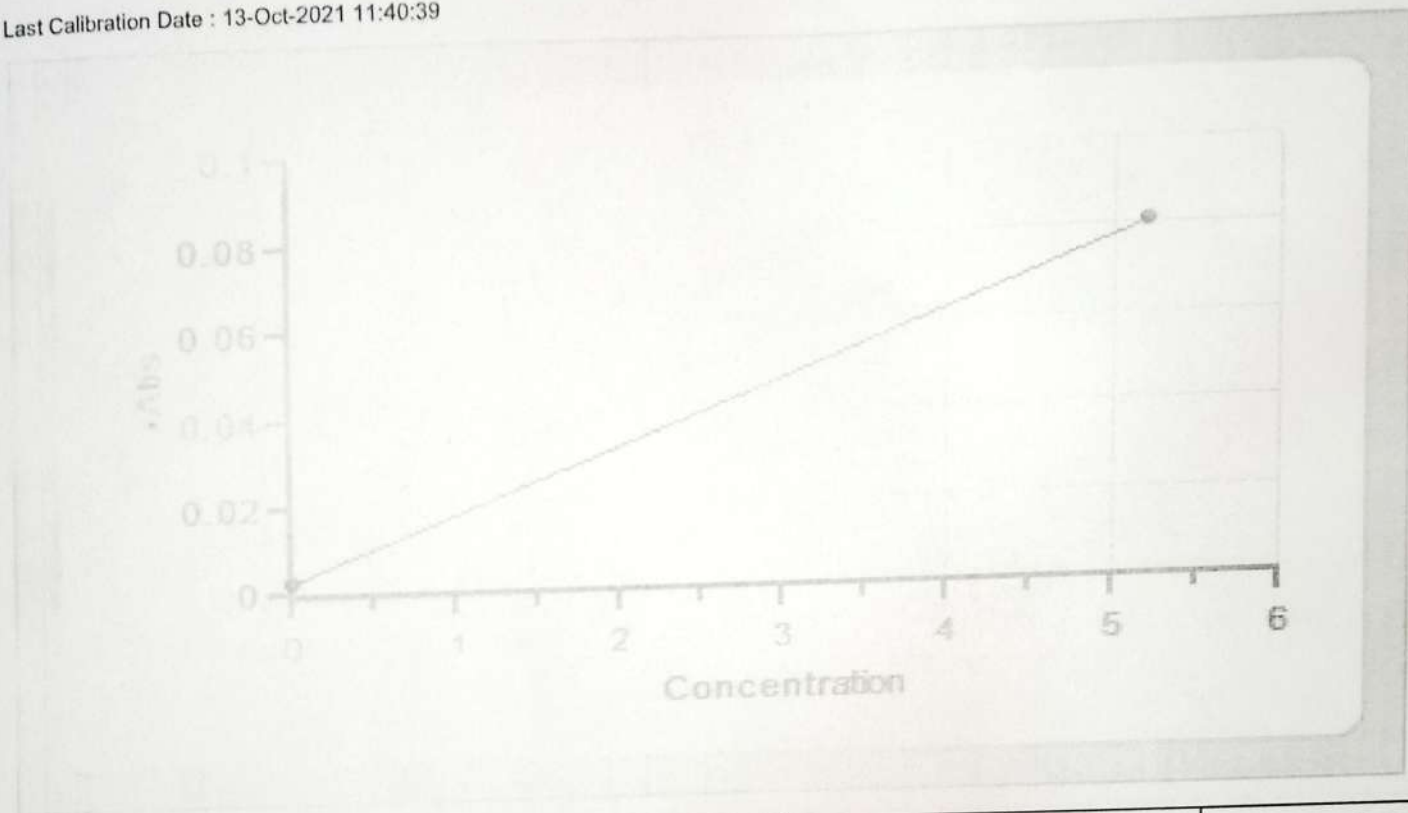
Calibration Date : 13-Oct-2021 11:40:39

Last Calibration Date : 13-Oct-2021 11:40:39

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

R1 Lot No : B122069-052

R2 Lot No : B122069-052



Pos	Consumable	LotNo.	Conc	Abs	Factor
-	Blank	4567	0.000	0.0026	0.0000
-	MULTICAL 1907088F	1907088F	5.210	0.0808	66.5815

PERFORMED BY: ANKITA MALAWADE

AN  
13/10/2021

CHECKED BY: KATKUMD  
JADHAV

Katku  
13/10/21



# Calibration - EM 200

Test : ALB

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

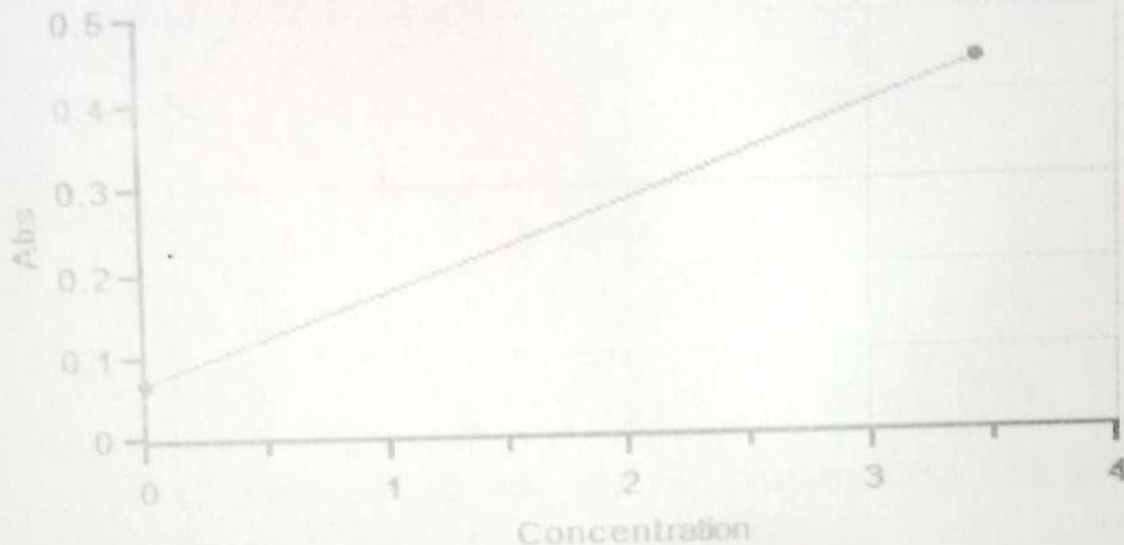
Curve Type : Linear

R1 Lot No : B072013-028

Calibration Date : 13-Oct-2021 11:42:46

R2 Lot No : ---

Last Calibration Date : 13-Oct-2021 11:42:46



Pos	Consumable	LotNo.	Conc	Abs	Factor
-	Blank	4567	0.000	0.0676	0.0000
-	MULTICAL 1907088F	1907088F	3.430	0.4398	9.2167

PERFORMED BY: ANKITA NALAWADE

AN  
13/10/2021

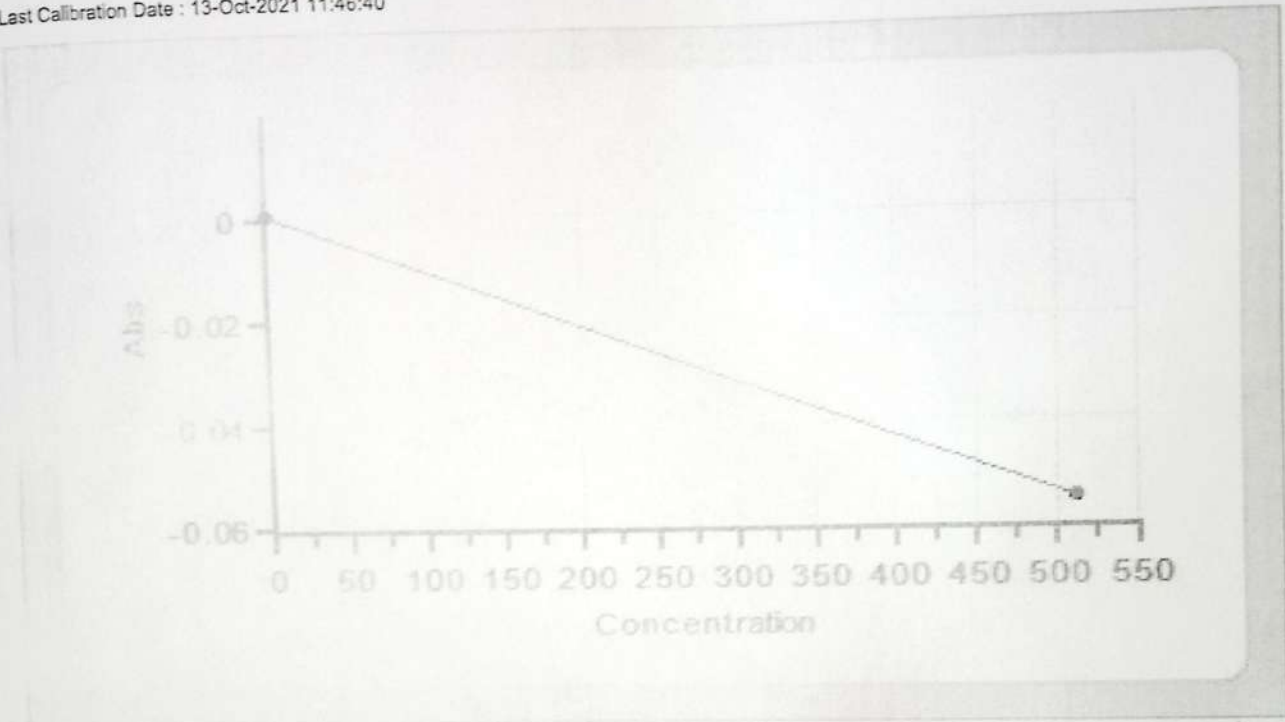
CHECKED BY: KAPUNA

JADHAV  
Kapuna  
13/10/21

# Calibration - EM 200

Test : LDHE  
 Curve Type : Linear  
 Calibration Date : 13-Oct-2021 11:46:40  
 Last Calibration Date : 13-Oct-2021 11:46:40

R1 Lot No : B081902  
 R2 Lot No : B081902



Pos	Consumable	LotNo.	Conc	Delta Abs/Min	Factor
-	Blank	4567	0.000	0.0007	0.0000
-	MULTICAL1907088F	1907088F	511.000	-0.0547	-9,215.5098

PERFORMED BY: ANJANA NAUADOL

CHECKED BY: KARUNA SARDHAN

AN  
13/10/2021

Karuna  
13/10/21

# Calibration - EM 200

Test : UREA

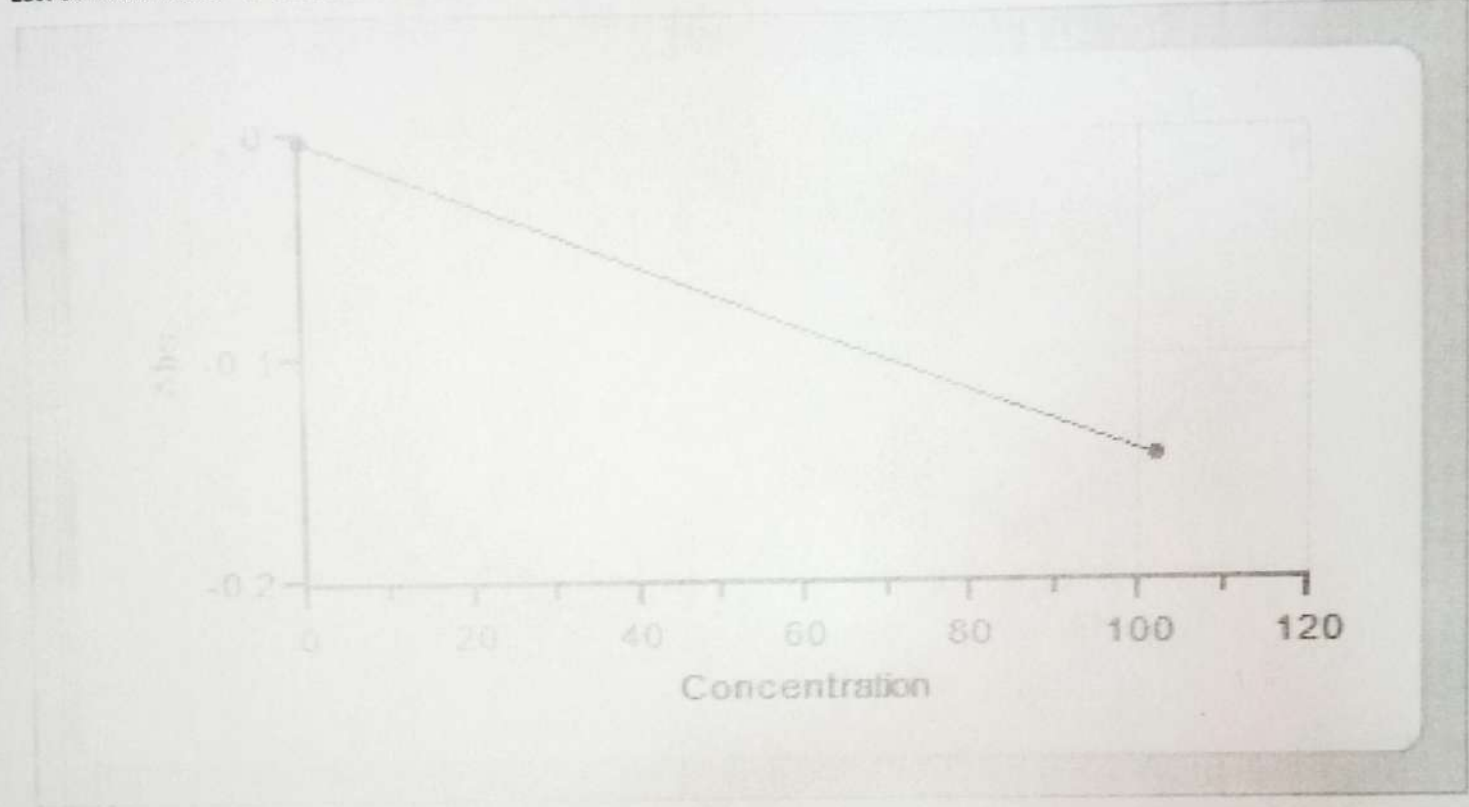
Curve Type : Linear

R1 Lot No : B101955

Calibration Date : 13-Oct-2021 11:48:47

R2 Lot No : B101955

Last Calibration Date : 13-Oct-2021 11:48:47



Pos	Consumable	LotNo.	Conc	Delta Abs/Min	Factor
-	Blank	4567	0.000	-0.0031	0.0000
-	MULTICAL1907088F	1907088F	102.000	-0.1456	-715.5384

PERFORMED BY: ANIKITA NAVALADE

CHECKED BY: KARUNA

AN  
13/10/2021

JADHAV  
Karuna  
13/10/21



# Calibration - EM 200

Test : CREE

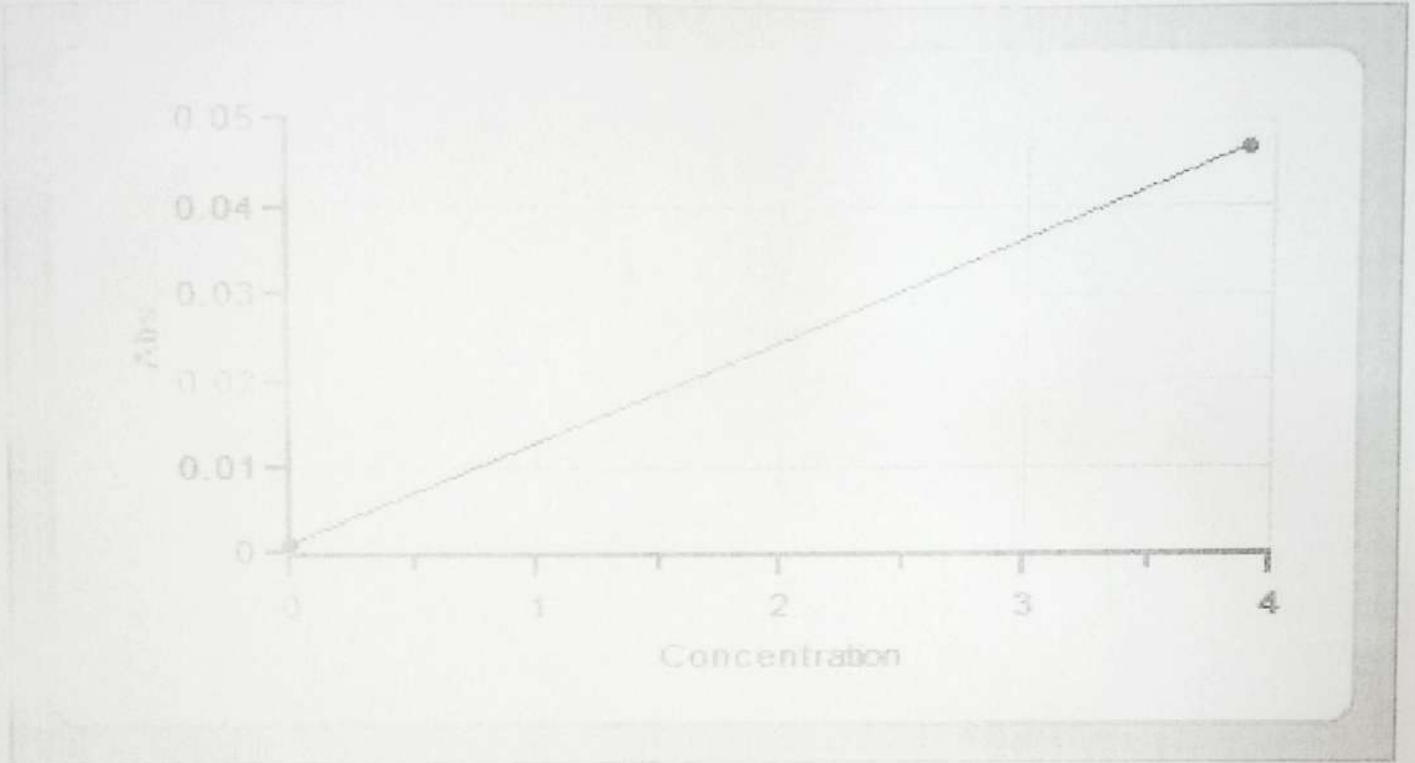
Curve Type : Linear

Calibration Date : 13-Oct-2021 11:52:59

Last Calibration Date : 13-Oct-2021 11:52:59

R1 Lot No : ---

R2 Lot No : ---



Pos	Consumable	LotNo.	Conc	Delta Abs/Min	Factor
-	Blank	4567	0.000	0.0011	0.0000
-	MULTICAL1907088F	1907088F	3.890	0.0470	84.6572

PERFORMED BY : ANKITA NALAWADE

CHECKED BY: KAPUNTA  
JADHAN

AN  
13/10/2021

Kapunta  
13/10/21

# Calibration - EM 200

Test : PROE

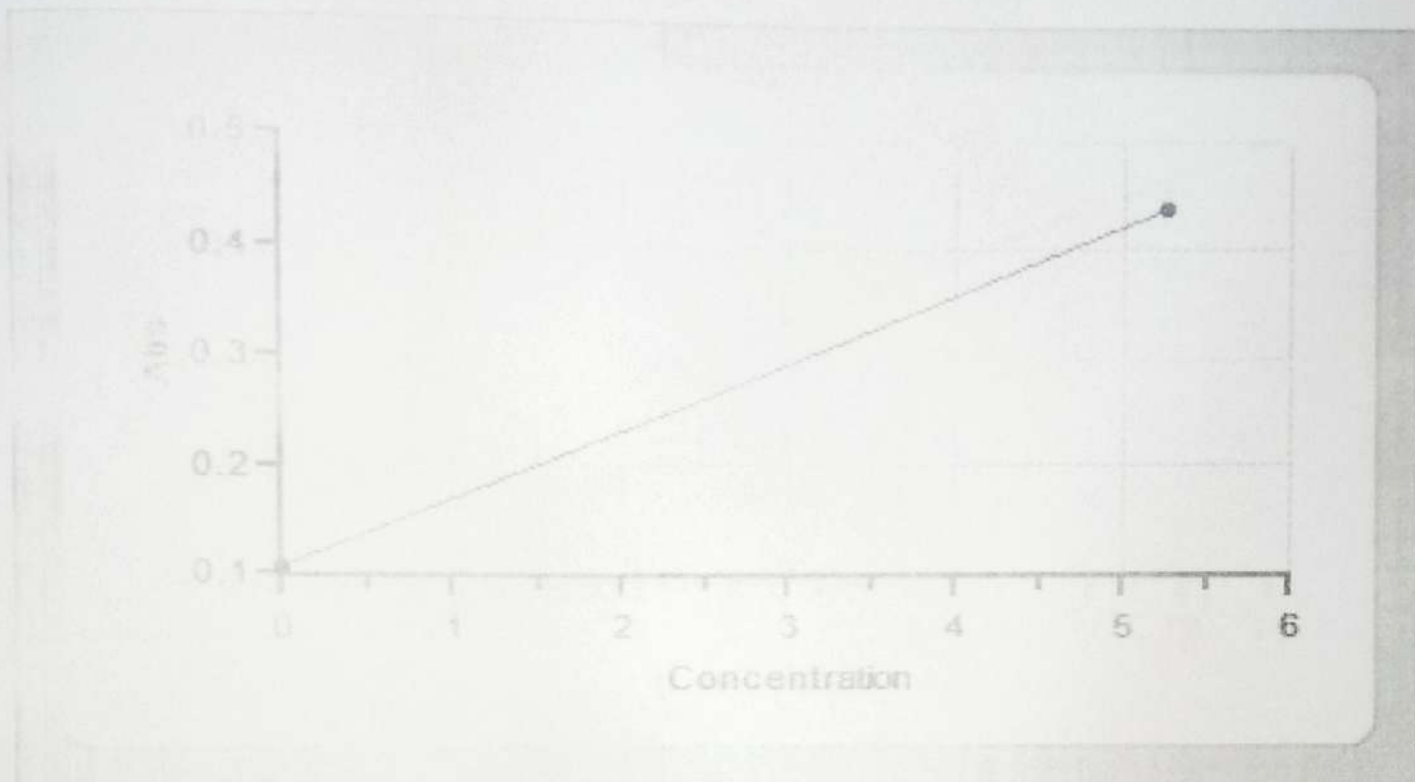
Curve Type : Linear

Calibration Date : 13-Oct-2021 11:55:24

Last Calibration Date : 13-Oct-2021 11:55:24

R1 Lot No : —

R2 Lot No : —



Pos	Consumable	LotNo.	Conc	Abs	Factor
-	Blank	4567	0.000	0.1062	0.0000
-	MULTICAL1907088F	1907088F	5.260	0.4385	15.8267

PERFORMED BY: ANKITA NALAWADE

CHECKED BY: KARUNA

JADHAN

AN  
13/10/2021

Karuna  
13/10/21

# Calibration - EM 200

Test : CAL1

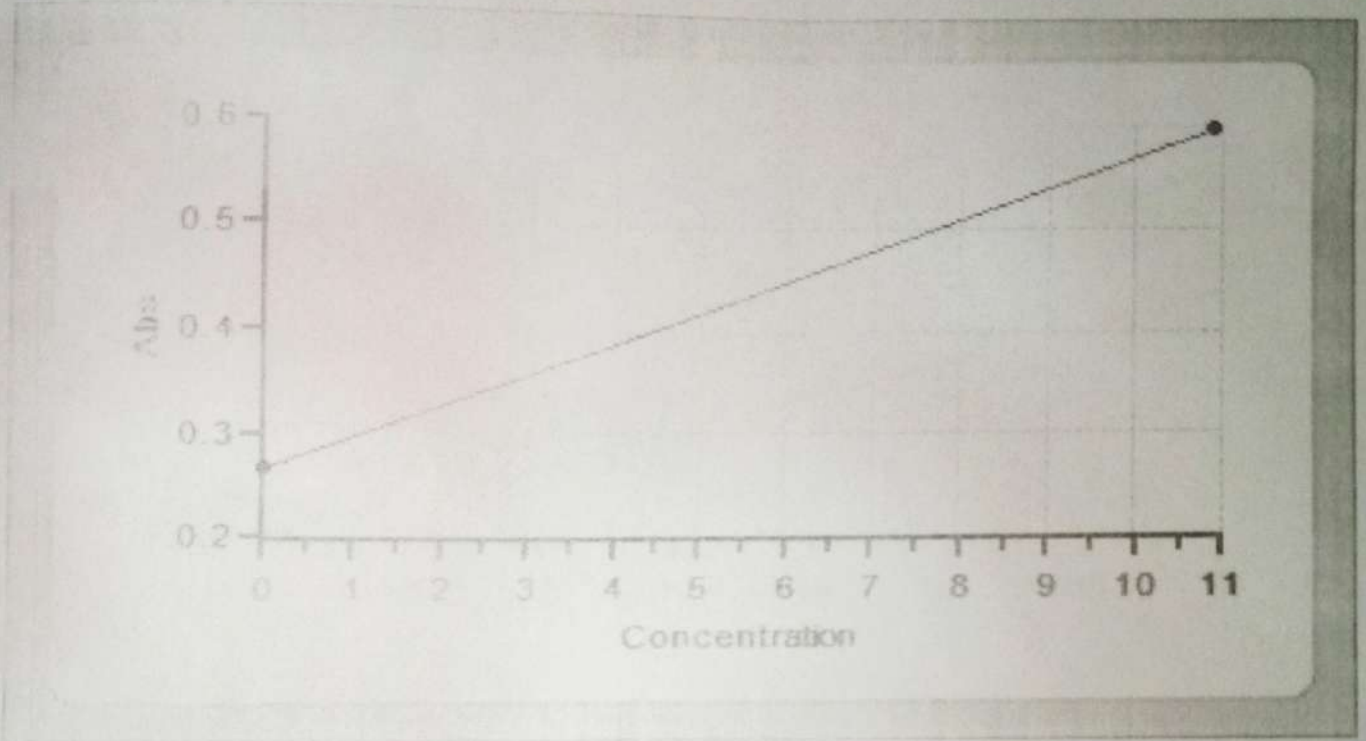
Curve Type : Linear

Calibration Date : 29-Oct-2021 11:46:36

Last Calibration Date : 29-Oct-2021 11:46:36

R1 Lot No : b072067

R2 Lot No : —



Pos	Consumable	LotNo.	Conc	Abs	Factor
I-1	Blank	4567	0.000	0.2661	0.0000
I-2	MULTICAL1907088F	1907088F	10.900	0.5959	33.0553

PERFORMED BY: ANKITA NALAWADE

CHECKED BY: KARUNA JADHAV

AN  
13/10/2021

Karuna  
13/10/21



# Calibration - EM 200

Test : HDLC1

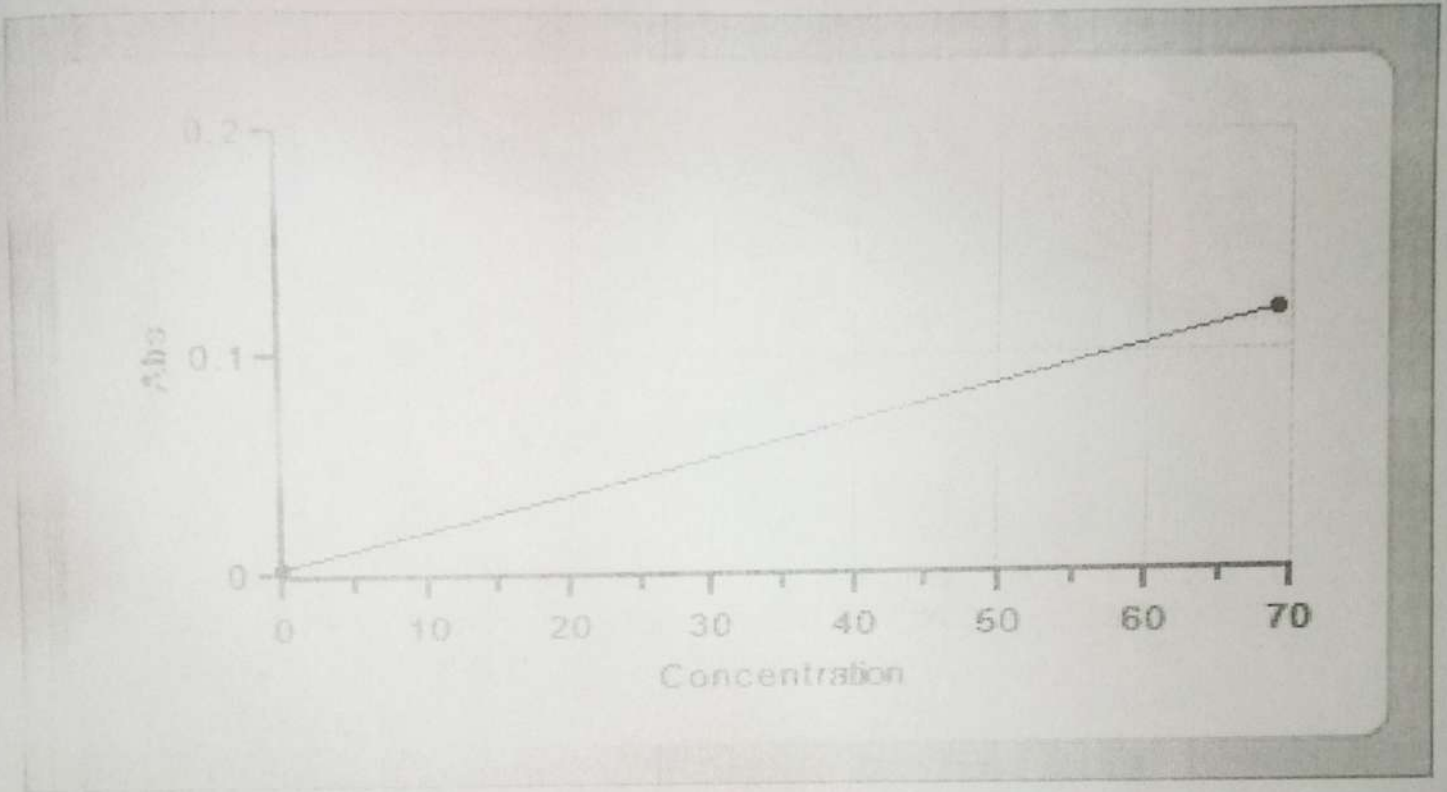
Curve Type : Linear

R1 Lot No : 1234

Calibration Date : 13-Oct-2021 13:46:34

R2 Lot No : 1234

Last Calibration Date : 13-Oct-2021 13:46:34



Pos	Consumable	LotNo.	Conc	Abs	Factor
-	Blank	4567	0.000	0.0030	0.0000
I-8	Hdl std--HDLC1	B072183	69.100	0.1186	597.4924

PERFORMED BY: ANKITA NAWTWADE

CHECKED BY: KARUNA  
JADHAV

AN  
13/10/2021

Karuna  
13/10/21

# Calibration - EM 200

Test : ALPUE

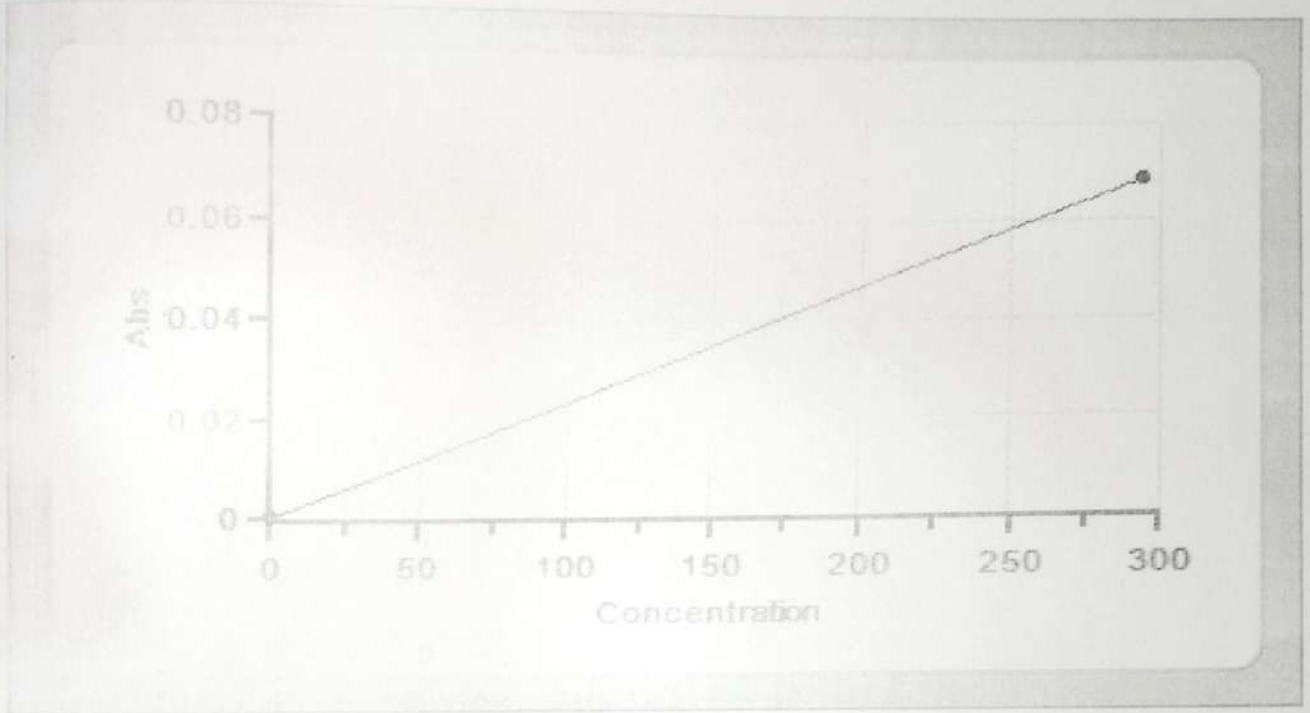
Curve Type : Linear

Calibration Date : 13-Oct-2021 11:50:53

Last Calibration Date : 13-Oct-2021 11:50:53

R1 Lot No : B022034

R2 Lot No : B022034



Pos	Consumable	LotNo.	Conc	Delta Abs/Min	Factor
-	Blank	4567	0.000	0.0003	0.0000
-	MULTICAL1907088F	1907088F	294.000	0.0686	4,304.5386

PERFORMED BY: ANKITA NALAWADE

AN  
13/10/2021

CHECKED BY: KARUNA

JASHAN

Jashan  
13/10/21

# Result Reprint

Report Type : Controls      13-Oct-2021

Sr #	Lot #	Consumable	Test	Result Unit	Flag	Curve #	Result Date	Mean	SD	Interval (3SD)
1	1104UE	RANDOX 3	SGPTD	122.0 U/L	-1SD	91226	13-Oct-2021 11:22:54	139.000	13.500	98.5 - 179.5
2	1104UE	RANDOX 3	SGOTD	152.7 U/L		91233	13-Oct-2021 11:25:00	157.000	16.000	109 - 205
3	1104UE	RANDOX 3	GGT	137.9 U/L		91240	13-Oct-2021 11:27:07	169.000	12.500	131.5 - 206.5
4	1104UE	RANDOX 3	PHOS	6.98 mg/dl		91247	13-Oct-2021 11:29:13	6.760	0.500	5.26 - 8.26
5	1104UE	RANDOX 3	BID	1.61 mg/dl		91254	13-Oct-2021 11:31:20	1.730	0.190	1.16 - 2.3
6	1104UE	RANDOX 3	BIT	4.72 mg/dl		91261	13-Oct-2021 11:33:26	5.210	0.550	3.56 - 6.86
7	1104UE	RANDOX 3	GLU	282.3 mg/dl		91268	13-Oct-2021 11:35:32	279.000	21.500	214.5 - 343.5
8	1104UE	RANDOX 3	TRIG	256.4 mg/dl		91275	13-Oct-2021 11:37:39	255.000	20.500	193.5 - 316.5
9	1104UE	RANDOX 3	CHOL	260 mg/dl		91282	13-Oct-2021 11:39:45	271.000	18.000	217 - 325
10	1104UE	RANDOX 3	UA	9.4 mg/dl		91289	13-Oct-2021 11:41:51	9.320	0.610	7.49 - 11.15
11	1104UE	RANDOX 3	ALB	3.07 g/dl		91296	13-Oct-2021 11:43:58	2.890	0.220	2.23 - 3.55
12	1104UE	RANDOX 3	LDHE	708 U/L		91303	13-Oct-2021 11:47:52	698.000	52.500	540.5 - 855.5
13	BOZ2020A	ERBA PATH	ALPUE	432 U/L	-1SD	95106	13-Oct-2021 11:48:38	495.270	33.020	396.21 - 594.33
14	1104UE	RANDOX 3	UREAE	123.1 mg/dl		91316	13-Oct-2021 11:49:59	120.000	9.000	93 - 147
15	1104UE	RANDOX 3	CREE	4.12 mg/dl		91330	13-Oct-2021 11:54:12	4.270	0.430	2.98 - 5.56
16	1104UE	RANDOX 3	PROE	5.21 g/dl	+1SD	91338	13-Oct-2021 11:56:36	4.990	0.440	3.07 - 5.71
17	1104UE	RANDOX 3	CAL1	13.0 mg/dl	+1SD	91345	13-Oct-2021 11:58:42	12.300	0.600	10.5 - 14.1

Print Date      01-Nov-2021

PERFORMED BY: ANKITA NARWANE

AN  
13/10/2021

CHECKED BY: FARUKH SAJJAD

12/10/21