



May 21, 2024

Calibration Certificate for Fully Automated Random Access Biochemistry Analyser, Model: XL-200 (Sl. No.20P0092)

*This is to certify that Fully Automated Random Access Biochemistry Analyser, Model: XL-200 installed at **global ultrascan & diagnostic centre, 200 n.s.c bose road, narendrapur, Kolkata 700103, West Bengal**, has been calibrated and the calibration value of filter gains and all other values has been checked and found well within the limit.*

This calibration is valid till May 20, 2025

For Transasia Bio-Medicals Ltd.


Subhasish De Sarkar
Area Service Manager



XL-200 AUTOMATED BIOCHEMISTRY ANALYZER

OPERATIONAL QUALIFICATION For

**“GLOBAL ULTRA SCAN & DIAGNOSTIC CENTRE”
NARENDRAPUR, KOLKATA**

Marketed by:
Transasia Bio-Medicals Ltd.,
Transasia House,
Chandivali Studio road,
Andheri (E),
MUMBAI – 400 072

OQ

Operational Qualification

Operational Inspection

1. Checked Temperature of all RCT and RGT found OK.
2. Checked all mechanical alignment found OK.
3. Reagents loaded on the system.
4. Maintenance (Cuvette Rinse followed by Auto Span) performed 3 times, to achieve pressure, filling of tubes and cleaning of probe.
5. Initial Performance of test in replicate found OK.

Operational Report for XL 200

Customer Name : GLOBAL ULTRASCAN & DIAGNOSTIC CENTRE
Address : 200 N. S.C Bose Road, Narendrapur, Kolkata 700103

Instrument Name : XL 200, Fully Automated Coagulation Analyzer
Serial Number : 20P0092

The instrument was operationalised and was found to be working satisfactorily. Preliminary working with test some parameters was done. The results were found to be within the expected range and System found to be working satisfactorily.



Operational Certificate of XL 200

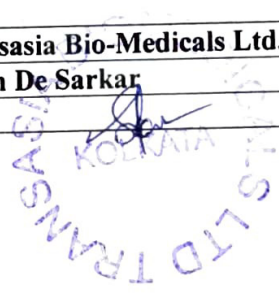
Study data has determined that the System described in this document either meets all criteria outlined in this Operational Protocol, or exceptional conditions have been identified and documentation included.

Exceptional conditions, if any, have been addressed.

The System is ready for specific usage.

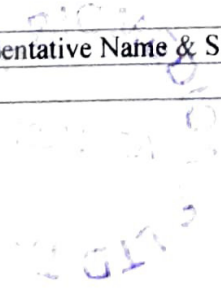
TBM, Technical Services Department

Protocol Performed By	M/s Transasia Bio-Medicals Ltd., Mumbai
Name	Subhasish De Sarkar
Designation	ASM



Customer Authorization	
Name	
Designation	

Company Representative Name & Sign <i>sdm</i>	Customer Name & Sign
Date	Date





XL-200 AUTOMATED BIOCHEMISTRY ANALYZER

INSTALLATION QUALIFICATION

For

**“GLOBAL ULTRA SCAN & DIAGNOSTIC CENTRE”
NARENDRAPUR, KOLKATA**

Marketed by:
Transasia Bio-Medicals Ltd.,
Transasia House,
Chandivali Studio road,
Andheri (E),
MUMBAI – 400 072

XL-200

FULLY AUTOMATED RANDOM ACCESS BIOCHEMISTRY ANALYZER

IQ OQ

For

**“GLOBAL ULTRASCAN & DIAGNOSTIC CENTRE”
KOLKATA**

Transasia Bio-Medicals Ltd.,
Transasia House,
Chandivali Studio road,
Andheri (E),
MUMBAI – 400 072

IQ

Installation Qualification:

The Site

The site have been inspected and found to be okay for installation.
The power points offered for the system is having controlled power.

External Requirements for Installation:

1. Input voltage of 220V-240V / 50Hz or 60Hz earthing $\leq 3V$.
2. Three 5A and one 15 A socket
3. Recommended Operating Temperature is 15-24 °C.
4. Relative Humidity 40-85% non- condensing
5. Atmospheric Pressure 70-106 kPa.
6. UPS 2KVA

Initial Inspection of the unit carried out and the details are as follows:

System Condition Report

Found the System to have been delivered in satisfactory condition and no external physical damaged observed on the same.

Found all the accessories as per the Packing List. **ANNEXURE I**

Installation

Instrument Setup

1. Instrument removed from packing.
2. Removed all buffers and tapes
3. Assembled the instrument with all Accessories
4. Installed the trays and covers.
5. Filled & connected the detergent in 10Lcan.
6. Connected & filled the DI water and Biohazard can and Waste Can.
7. Connected the waste tubing's.
8. Connected the interface USB cables.
9. Connected the power cable.
10. Setup the CPU, monitor and printer.
11. The system was powered ON.



Installation Details of XL200

Customer Name : GLOBAL ULTRASCAN & DIAGNOSTIC CENTRE
Address : 200 N.S.C BOSE ROAD , Narendrapur, Kolkata 700103
Instrument Name : Fully Automated Random Access Biochemistry Analyzer XL 200
Serial Number : 20P0092

Initial Inspection of the unit carried out and the details are as follows:

System Condition Report

Found the System to have been delivered in satisfactory condition and no external physical damaged observed on the same.
Found all the accessories as per the **Packing List**.

System Parameters Check for XL200

Done the Installation.

Checked Mechanical alignment of Sample arm w.r.t. RCT; RGT; cuvette ring set & ASP.

Stirrer and Laundry Assemblies and found OK

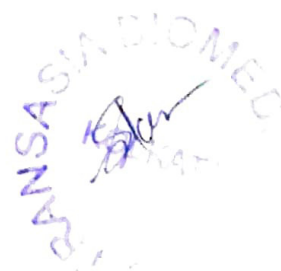
Checked 1Bar Pressure found OK

Checked the 37°C for RCT found OK

Checked the Auto span found OK

Checked the Cuvette blank and found OK

Handed over the Instrument for Operators Training & Qualifications.

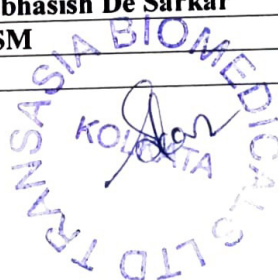


Installation Certificate of XL200

This is to certify that the **XL200** Instrument Serial No. is successfully installed and commissioned
By **M/s Transasia Bio-Medicals Ltd, Mumbai** and the Installation Protocol / checklist has been
Successfully completed for the above instrument at

TBM, Technical Services Department

Protocol Performed By	M/s Transasia Bio-Medicals Ltd., Mumbai
Name	Subhasish De Sarkar
Designation	ASM
Date	





**XL-200
AUTOMATED BIOCHEMISTRY ANALYZER**

**PERFORMANCE
QUALIFICATION**

For

**“GLOBAL ULTRA SCAN & DIAGNOSTIC CENTRE”
NARENDRAPUR, KOLKATA**

Marketed by:
Transasia Bio-Medicals Ltd.,
Transasia House,
Chandivali Studio road,
Andheri (E),
MUMBAI – 400 072

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

Instrument Name

XL-200


Instrument Serial Number

20P0092

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TRANSASIA BIOMEDICALS LTD
[Signature]

TRANSASIA BIOMEDICALS LIMITED			
PERFORMANCE QUALIFICATION			
Instrument Name	XL-200	Instrument Serial Number	

1.0 PRE APPROVAL

1.1 Prepared By

Name	Designation	Signature	Date
SUDIPTA JANA	APPLICATION MANAGER	<i>S. Jana</i> KO	25/5/24

1.2 Checked By

Name	Designation	Signature	Date
ANJAY DAS	Lab Technician	<i>Anjay Das</i>	25/5/24

1.3 Approved By

Name	Designation	Signature	Date
SK Mytuba AC	Lab Technician	<i>Mei</i>	25/05/24

TRANSASIA BIOMEDICALS LIMITED			TRANSASIA[®] Bio-Medicals Ltd.
PERFORMANCE QUALIFICATION			
Instrument Name	XL-200	Instrument Serial Number	

2.0 OBJECTIVE

The objective of this protocol is to establish documented evidence for the Performance Qualification of XL 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 XL 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
SK MUJTUBALI	PATHOLOGY	Lab Technician	<i>Ali</i>
ANJAY DAS	PATHOLOGY	Lab Technician	<i>AD</i>
UTTAM SARDAR	PATHOLOGY	LAB TECHNICIAN	<i>Uttam</i>
BISWASIT PATRA	PATHOLOGY	LAB TECHNICIAN	<i>B. Patra</i>

TRANSASIA BIOMEDICALS LIMITED			TRANSASIA[®] Bio-Medicals Ltd.
PERFORMANCE QUALIFICATION			
Instrument Name	XL-200	Instrument Serial Number	20P0092

7.0 EXECUTION OF TEST PLAN

- A. PRECISION CHECK FOR GLUCOSE & UREA → REPORT ATTACHED
- B. CARRYOVER TEST FOR GLUCOSE & UREA → REPORT ATTACHED
- C. LINEARITY TEST FOR GLUCOS & UREA → REPORT ATTACHED
- D. QC DATA FOR ALL PARAMETERS → REPORT ATTACHED

Reviewed by:

Name	Signature	Date
SK mykuba AL		25/05/24

TRANSASIA BIOMEDICALS LIMITED			
PERFORMANCE QUALIFICATION			
Instrument Name	XL-200	Instrument Serial Number	20P0092
			TRANSASIA[®] Bio-Medicals Ltd.

8.0 DEFICIENCIES / DEVIATIONS:

NA

Reviewed by:

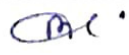
Name	Signature	Date
SK Mujibbe Aeo	<i>[Signature]</i>	25/05/24

TRANSASIA BIOMEDICALS LIMITED			
PERFORMANCE QUALIFICATION			
Instrument Name	XL-200	Instrument Serial Number	20P0092

9.0 SUMMARY AND EVALUATION:

NA

Reviewed by:

Name	Signature	Date
SK Mujib AC		25/05/24

TRANSASIA BIOMEDICALS LIMITED			TRANSASIA[®] Bio-Medicals Ltd.
PERFORMANCE QUALIFICATION			
Instrument Name	XL-200	Instrument Serial Number	

10.0 ABBREVIATIONS

SOP	Standard Operating Procedure
MOC	Material of Construction
PQ	Performance Qualification



TRANSASIA BIOMEDICALS LIMITED



PERFORMANCE QUALIFICATION			
Name	Designation	Signature	Date
Instrument Name	XL-200	Instrument Serial Number	20P0092
11.0	POST APPROVAL		
11.1	Checked by		
	SK Mujkuba-AC		

11.2 Approved by


SK Mujkuba-AC

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

Calibration - XL-200

Test : GLU

Revision : <A-200-GLU-2 18.06.2019>

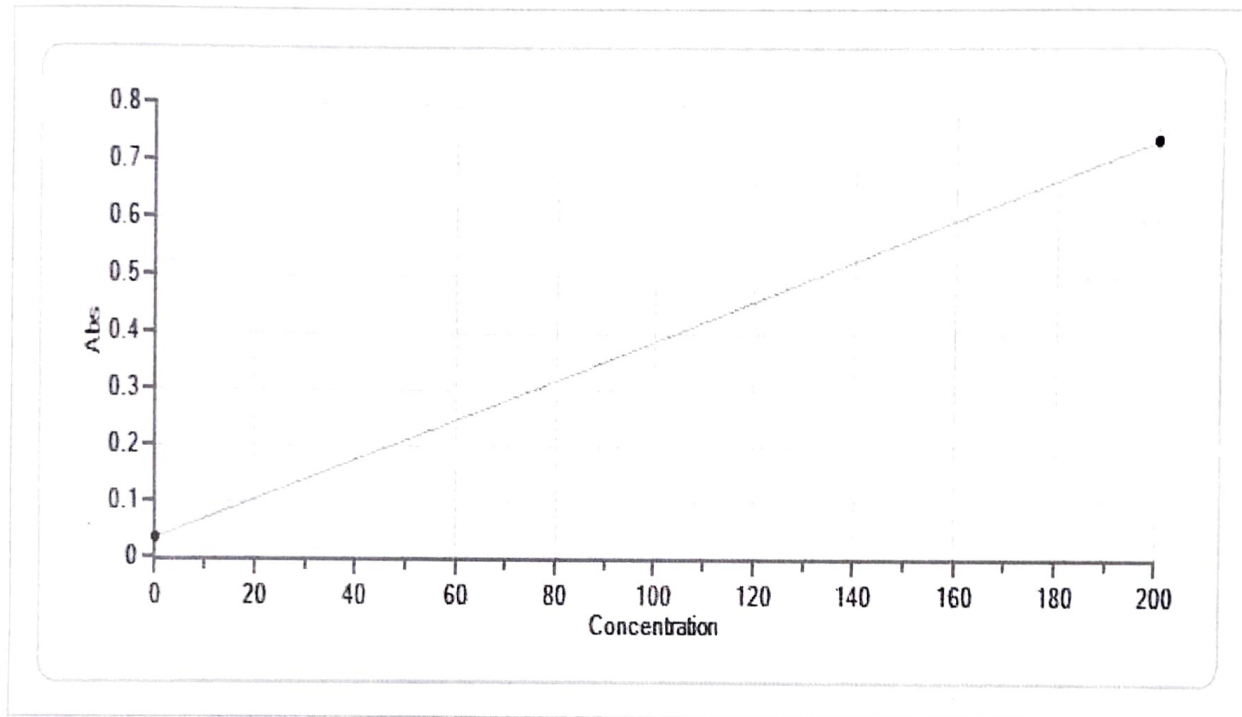
Curve Type : Linear

R1 Lot-Bottle No : B112338-346#1422

Calibration Date : 23-Apr-2024 13:58:38

R2 Lot-Bottle No : ---

Last Calibration Date : 23-Apr-2024 13:58:38



Pos	Consumable	LotNo.	Conc	Abs	Factor
-	BLANK	1234	0.000	0.0349	0.0000
-	MULTICAL	2310072	200.000	0.7387	284.1717

Calibration - XL-200

Test : UREA

Revision : <A-200-UREA-3 18.06.2019>

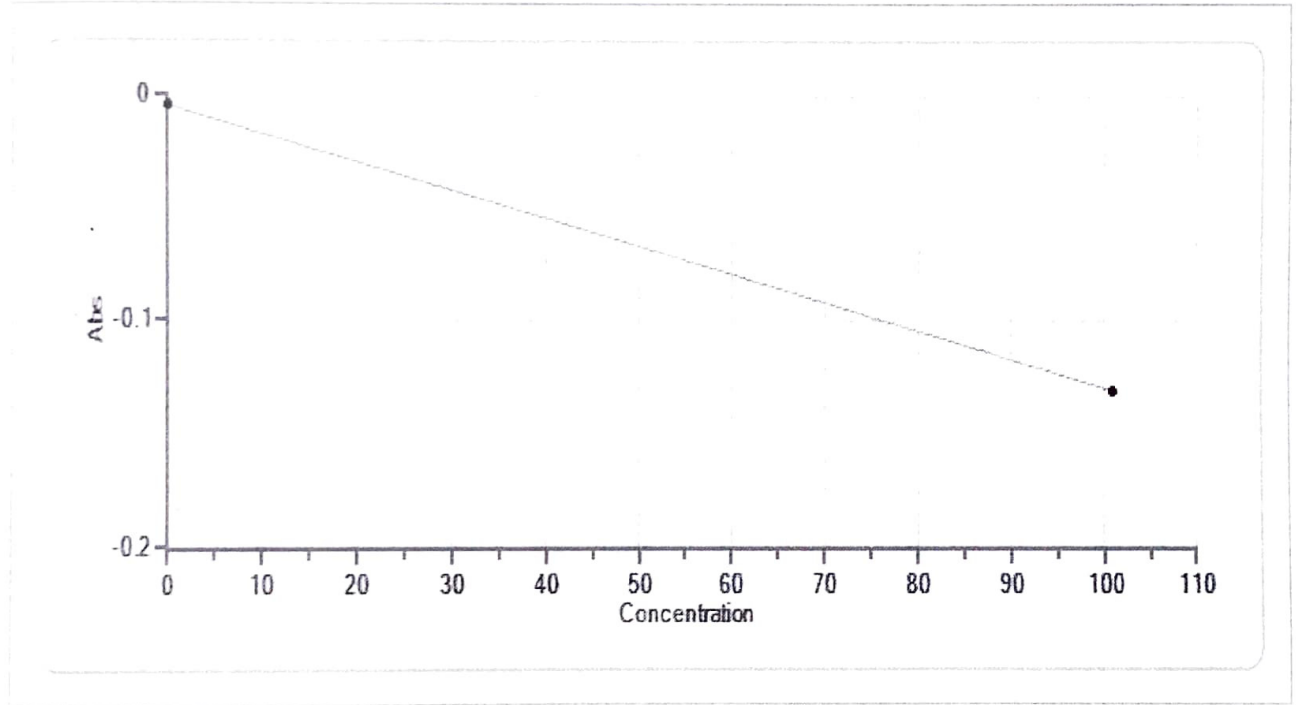
Curve Type : Linear

R1 Lot-Bottle No : S122387-348#3220

Calibration Date : 16-Jun-2024 11:41:33

R2 Lot-Bottle No : S122387-348#8294

Last Calibration Date : 16-Jun-2024 11:41:33



Pos	Consumable	LotNo.	Conc	Delta Abs/Min	Factor
-	BLANK	1234	0.000	-0.0044	0.0000
-	MULTICAL	2310072	101.000	-0.1310	-797.7883

Calibration - XL-200

Test : CRENZ

Revision : <A-200-CRENZ-4 26.11.2020>

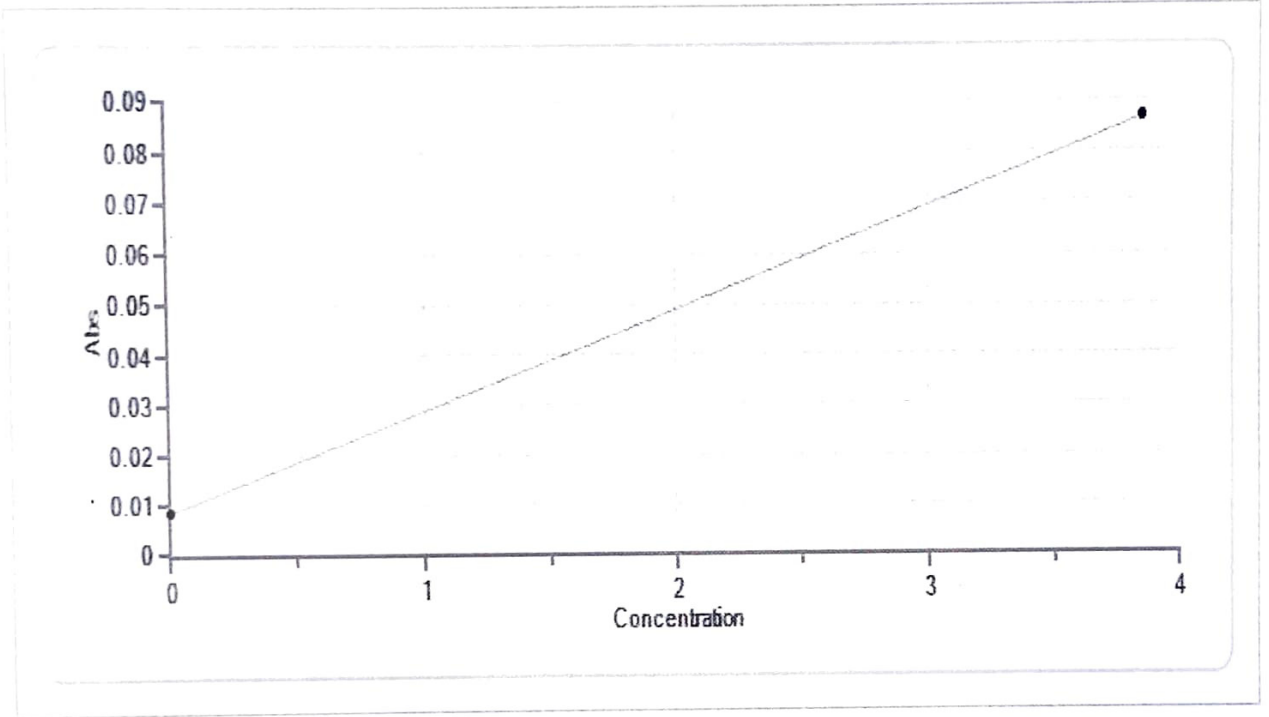
Curve Type : Linear

R1 Lot-Bottle No : S112383-349#8792

Calibration Date : 30-May-2024 15:57:20

R2 Lot-Bottle No : S112383-349#4653

Last Calibration Date : 30-May-2024 15:57:20



Pos	Consumable	LotNo.	Conc	Abs	Factor
-	BLANK	1234	0.000	0.0084	0.0000
-	MULTICAL	2310072	3.850	0.0867	49.1699

Calibration - XL-200

Test : BIT

Revision : <A-200-BIT-3 18.06.2019>

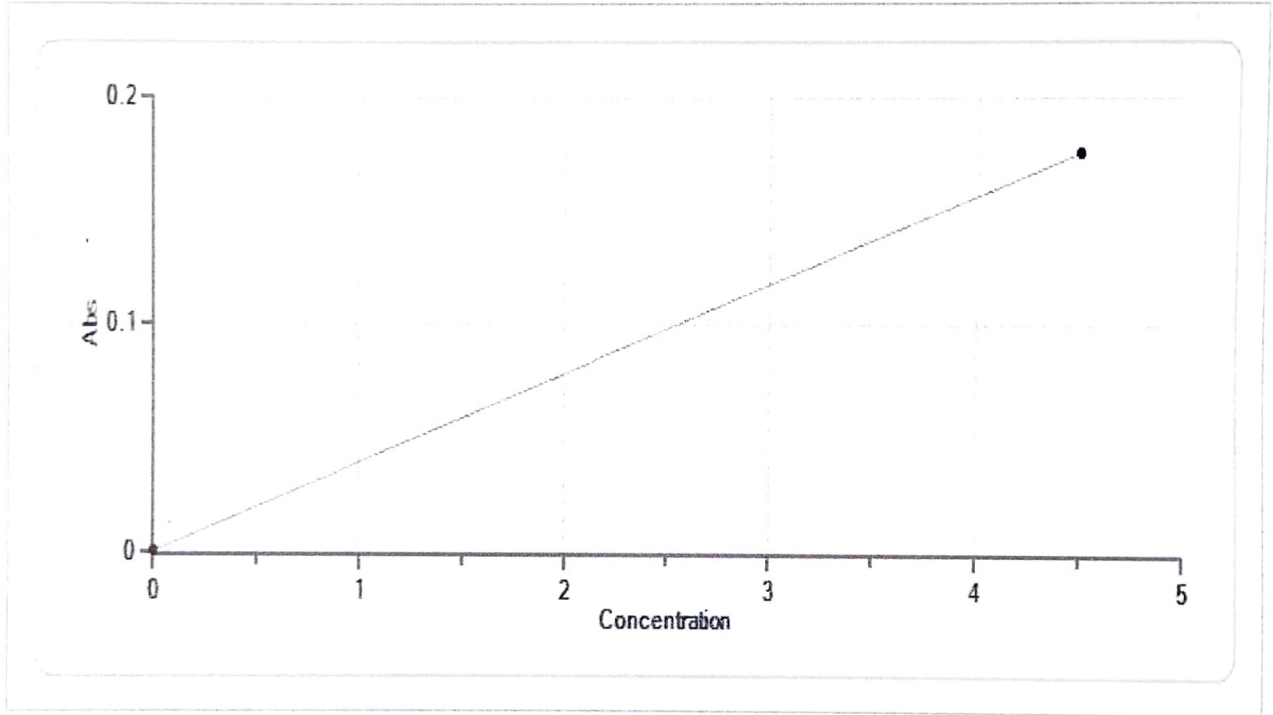
Curve Type : Linear

R1 Lot-Bottle No : S112355-346#5166

Calibration Date : 11-Jun-2024 13:43:06

R2 Lot-Bottle No : S112355-346#7148

Last Calibration Date : 11-Jun-2024 13:43:06



Pos	Consumable	LotNo.	Conc	Abs	Factor
-	BLANK	1234	0.000	0.0006	0.0000
-	MULTICAL	2310072	4.490	0.1758	25.6279

Calibration - XL-200

Test : TP1

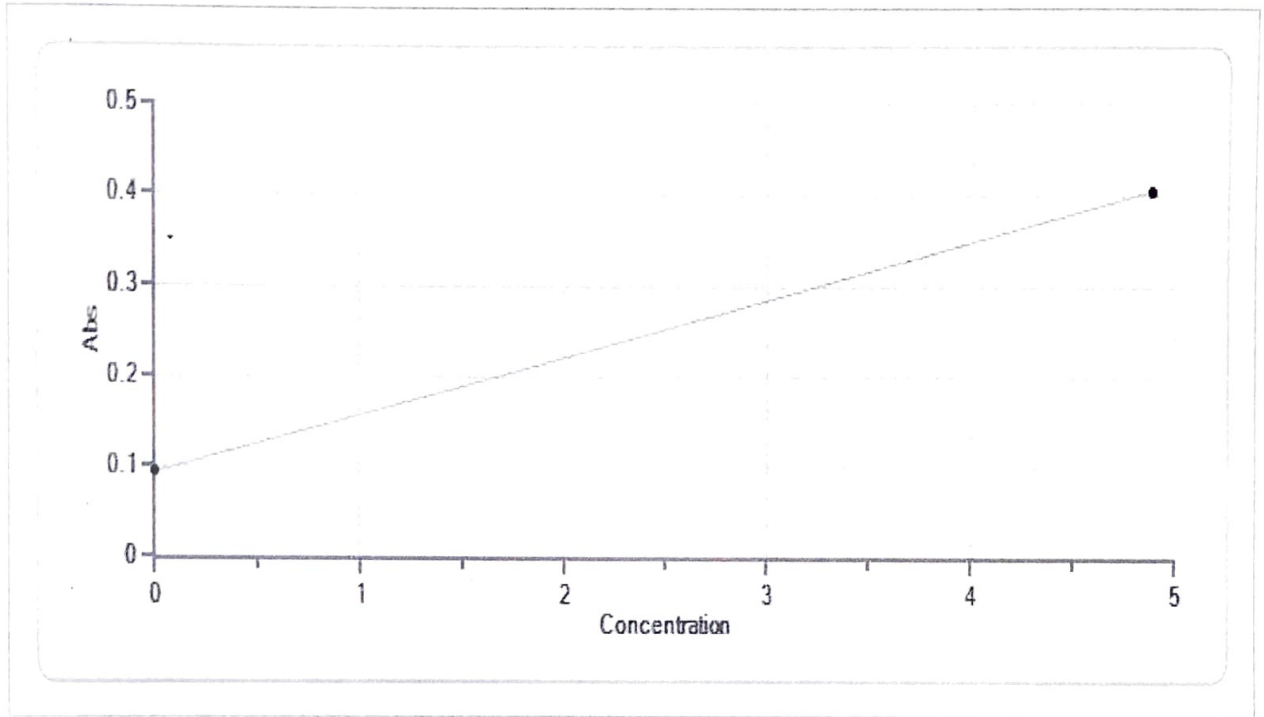
Curve Type : Linear

R1 Lot-Bottle No : ---

Calibration Date : 06-May-2024 13:57:45

R2 Lot-Bottle No : ---

Last Calibration Date : 06-May-2024 13:57:45



Pos	Consumable	LotNo.	Conc	Abs	Factor
-	BLANK	1234	0.000	0.0939	0.0000
-	MULTICAL	2310072	4.880	0.4059	15.6410

Calibration - XL-200

Test : ALBD

Curve Type : Linear

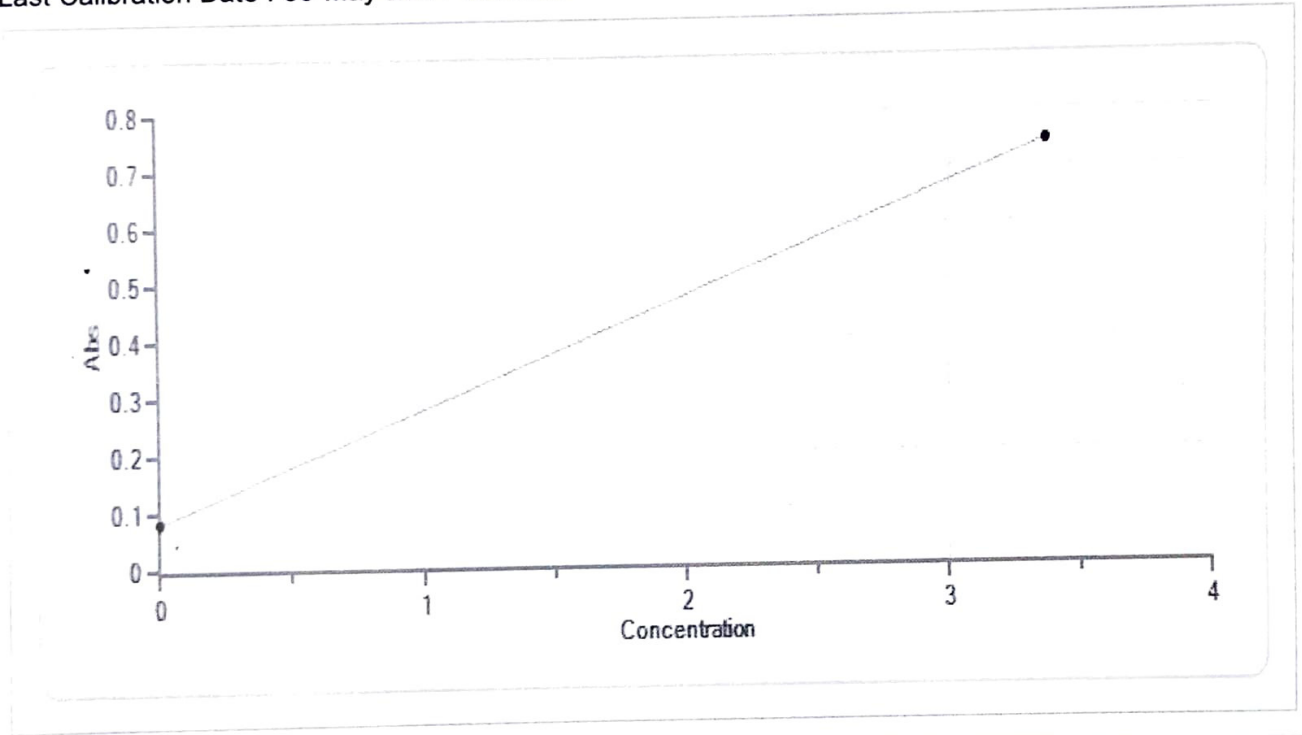
Calibration Date : 30-May-2024 16:00:03

Last Calibration Date : 30-May-2024 16:00:03

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

R1 Lot-Bottle No : B092260-238#1340

R2 Lot-Bottle No : ---



Pos	Consumable	LotNo.	Conc	Abs	Factor
-	BLANK	1234	0.000	0.0823	0.0000
-	MULTICAL	2310072	3.370	0.7455	5.0814

Calibration - XL-200

Test : UA

Revision : <A-200-UA-2 18.06.2019>

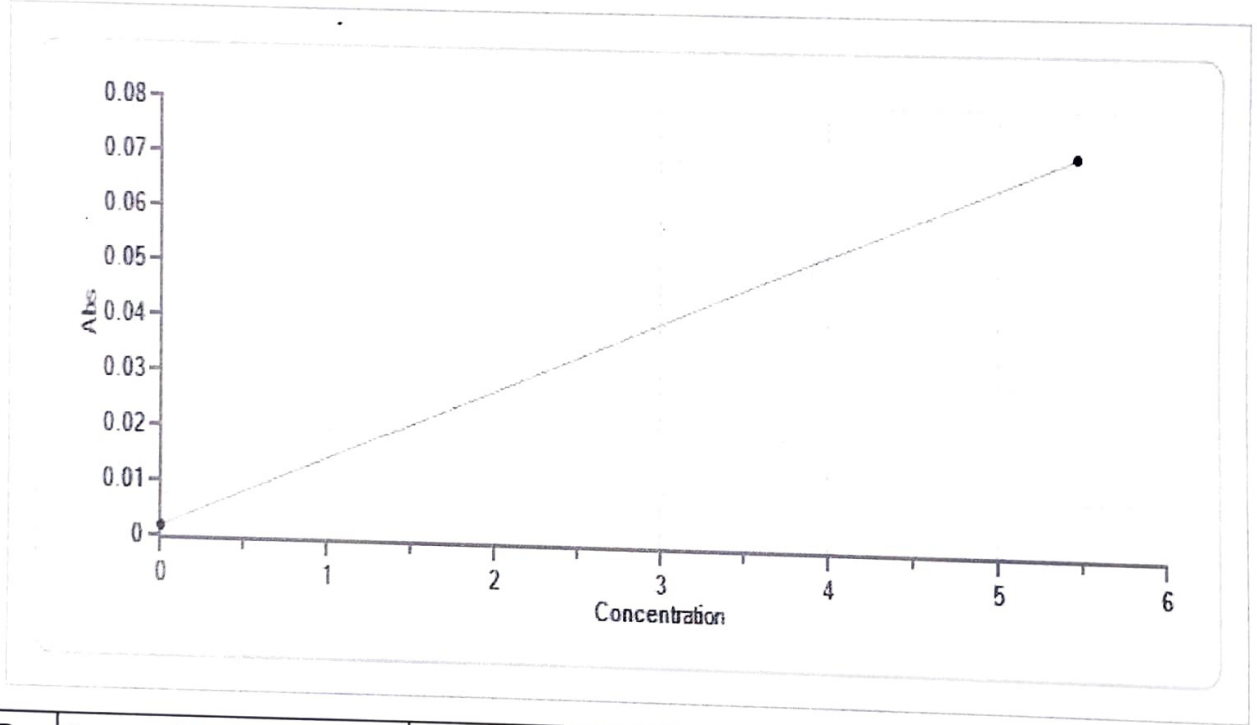
Curve Type : Linear

R1 Lot-Bottle No : S082395-336#7336

Calibration Date : 02-Jun-2024 12:42:59

R2 Lot-Bottle No : S082395-336#2694

Last Calibration Date : 02-Jun-2024 12:42:59



Pos	Consumable	LotNo.	Conc	Abs	Factor
-	BLANK	1234	0.000	0.0020	0.0000
-	MULTICAL	2310072	5.460	0.0715	78.5611

Calibration - XL-200

Test : CHOL

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

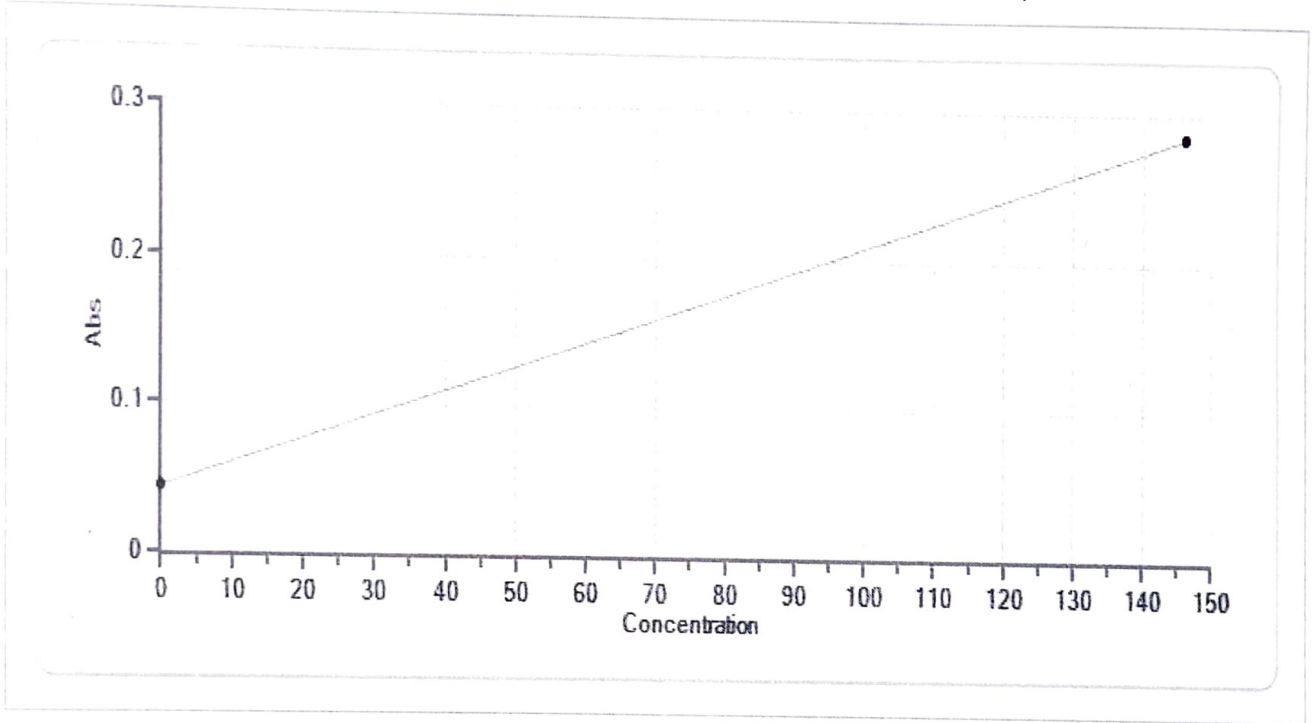
Curve Type : Linear

R1 Lot-Bottle No : S082362-333#8200

Calibration Date : 12-Mar-2024 14:25:16

R2 Lot-Bottle No : ---

Last Calibration Date : 12-Mar-2024 14:25:16



Pos	Consumable	LotNo.	Conc	Abs	Factor
-	BLANK	1234	0.000	0.0444	0.0000
-	MULTICAL	2310072	146.000	0.2847	607.5739

Calibration - XL-200

Test : TRIG

Curve Type : Linear

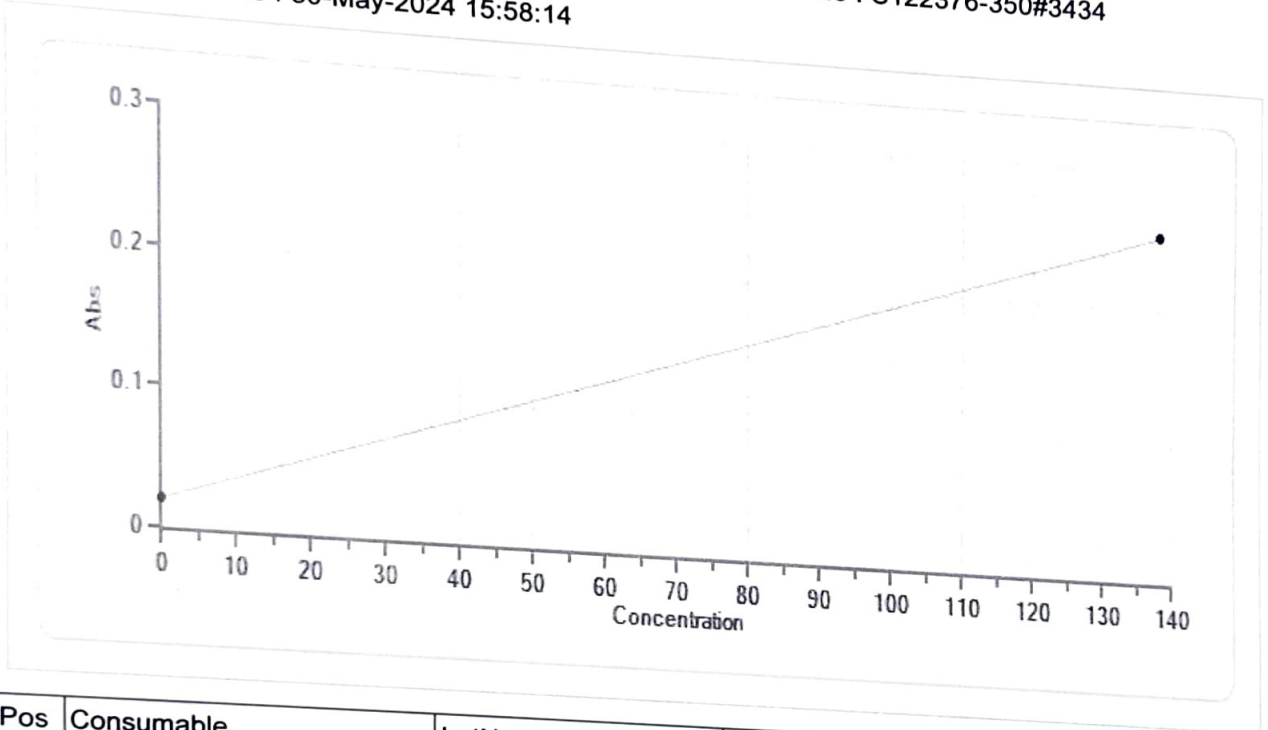
Calibration Date : 30-May-2024 15:58:14

Last Calibration Date : 30-May-2024 15:58:14

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

R1 Lot-Bottle No : S122376-350#8040

R2 Lot-Bottle No : S122376-350#3434



Pos	Consumable	LotNo.	Conc	Abs	Factor
-	BLANK	1234	0.000	0.0208	0.0000
-	MULTICAL	2310072	138.000	0.2530	594.3152