



Date: 11th May 2023

**Redcliffe Diagnostic Lab,
 Jalandhar.**

Dear Sir,

As desired by you please find enclosed herewith the Calibration report

1. Instrument & Serial No.: **XL 640, Serial No. 640489.**
2. Range of the instrument: Optical density Linear form 0-3.5 A
3. Precision & Accuracy study on XL-640 done on May 11, 2023.
4. Validity of this Calibration Certificate is till **May 10, 2024.**

Precision with Potassium Dichromate ($K_2Cr_2O_7$)

Reagent / Sample ratio -

Cup Position	Replicates	Absorbance (X)	SD	CV
Cup 1	20	1.5410 OD	0.0056	0.42%
Cup 2	20	1.5585 OD	0.0054	0.41 %
Cup 3	20	1.5436 OD	0.0049	0.40%

Accuracy study with Potassium Dichromate ($K_2Cr_2O_7$) in comparison with EM-360

Wavelengths scan on Referral Spectrophotometer for Potassium Dichromate ($K_2Cr_2O_7$)



Contd.....2



Wavelength	Spectrophotometer OD	
	Low	High
335	0.1891	1.7213
336	0.1923	1.7622
337	0.1988	1.8093
338	0.1999	1.8522
339	0.2040	1.8678
340	0.2063	1.8923
341	0.2109	1.9139
342	0.2163	1.9444
343	0.2211	1.9533
344	0.2289	1.9819
345	0.2314	2.0124



Contd.....3





Test of Potassium Dichromate ($K_2Cr_2O_7$) on EM-360

Pipetted / Measured by EM 360		Manually Pipettes EM		Manually pipetted & read in Autospan	
Low	High	Low	High	Low	High
0.2004	1.8736	0.1989	1.8879	0.2044	1.7583

This instrument is manufactured in accordance with the European law in force, in particular to "Electricity Safety" EN 610101 and "Electromagnetic Compatibility" EN 61326 Standards.

Item	Ideal	Actual
Pressure	0.9 bar	0.8 bar
Lamp Voltage	12 V	12.01 V
Temperature	37° C	37.0 ° C

Photometer Calibration Check	Ok
Cuvette Blank Check	Ok

Wavelength	Off Set	Gain
340	NA	95
376	NA	118
415	NA	129
450	NA	133
480	NA	138
505	NA	130
546	NA	122
570	NA	129
600	NA	131
660	NA	123
700	NA	126
750	NA	148

Contd.....4





UNMATCHED SERVICE
SINCE 1979...

Bio-Medicals Ltd., SCO No. 95, 1st Floor, Sector 44C, Chandigarh - 160047
0172-4643837 Email : nz3@transasia.co.in
33110MH1985PLC036198

-4-

The instrument does photometer check before each batch of tests is run. It will give an error message if the photometer test fails and it will not run any samples.

Thanking you and assuring of our prompt attention at all times.

Yours faithfully,

For **TRANSASIA BIO-MEDICALS LTD.**



Rashpal Singh Rana
Sr. Regional Service Manager
M: +91-9316004670
E mail: r.rana@transasia.co.in

Rana

Result Reprint

Report Type : Controls

28-Dec-2023

Consumable: BIORED L1

Sr #	Lot #	Consumable	Test	Result Unit	Flag	Curve #	Result Date	Mean	SD	Interval (3SD)
1	89731	BIORED L1	Na	136.50 mmol/L	-2SD	0	28-Dec-2023 10:13:05	149.000	5.000	134 - 164
2	89731	BIORED L1	K	3.48 mmol/L	-2SD	0	28-Dec-2023 10:13:05	3.740	0.120	3.38 - 4.1
3	89731	BIORED L1	Cl	96.80 mmol/L		0	28-Dec-2023 10:13:05	97.500	3.300	87.6 - 107.4
4	89731	BIORED L1	SGPTD	27.7 U/L		279826	28-Dec-2023 10:15:51	26.500	1.800	21.1 - 31.9
5	89731	BIORED L1	SGOTD	40.7 U/L		279828	28-Dec-2023 10:16:08	41.900	2.800	33.5 - 50.3
6	89731	BIORED L1	ALPU	125 U/L	-1SD	279830	28-Dec-2023 10:16:27	143.000	10.000	113 - 173
7	89731	BIORED L1	GGT	57.1 U/L		279832	28-Dec-2023 10:16:45	60.800	4.100	48.5 - 73.1
8	89731	BIORED L1	PHOS	4.48 mg/dL	+3SD	279834	28-Dec-2023 10:17:03	3.680	0.180	3.14 - 4.22
9	89731	BIORED L1	BIDD	0.55 mg/dL		279836	28-Dec-2023 10:17:21	0.520	0.040	0.4 - 0.64
10	89731	BIORED L1	BIT	1.17 mg/dL		279838	28-Dec-2023 10:17:39	1.280	0.110	0.95 - 1.61
11	89731	BIORED L1	UREA	35.3 mg/dL		279840	28-Dec-2023 10:17:57	34.600	1.700	29.5 - 39.7
12	89731	BIORED L1	CRENZ	1.65 mg/dL		279842	28-Dec-2023 10:18:15	1.630	0.110	1.3 - 1.96
13	89731	BIORED L1	GLU	87.4 mg/dL		279844	28-Dec-2023 10:18:33	85.200	4.400	72 - 98.4
14	89731	BIORED L1	TRIG	159.2 mg/dL		279846	28-Dec-2023 10:18:51	160.000	8.000	136 - 184
15	89731	BIORED L1	CHOL	237 mg/dL		279848	28-Dec-2023 10:19:09	237.000	12.000	201 - 273
16	89731	BIORED L1	HDLC	89.0 mg/dL	+1SD	279851	28-Dec-2023 10:19:36	79.200	5.300	63.3 - 95.1
17	89731	BIORED L1	UA	2.8 mg/dL	-3SD	279853	28-Dec-2023 10:19:54	5.210	0.260	4.43 - 5.99

Print Date

28-Dec-2023

1 / 2



Result Reprint

Report Type : Controls

28-Dec-2023

Consumable: BIORED L1

Sr #	Lot #	Consumable	Test	Result Unit	Flag	Curve #	Result Date	Mean	SD	Interval (3SD)
18	89731	BIORED L1	LDL	162.3 mg/dL	+1SD	279855	28-Dec-2023 10:20:12	145.000	10.000	115 - 175
19	89731	BIORED L1	CA	9.7 mg/dL		279857	28-Dec-2023 10:20:30	9.350	0.470	7.94 - 10.76
20	89731	BIORED L1	ALBD	4.47 g/dL		279859	28-Dec-2023 10:20:48	4.250	0.220	3.59 - 4.91
21	89731	BIORED L1	PRO	6.05 g/dL	-1SD	279861	28-Dec-2023 10:21:06	6.530	0.330	5.54 - 7.52
22	89731	BIORED L1	Na	134.70 mmol/L	-2SD	0	28-Dec-2023 10:43:53	149.000	5.000	134 - 164
23	89731	BIORED L1	K	3.40 mmol/L	-2SD	0	28-Dec-2023 10:43:53	3.740	0.120	3.38 - 4.1
24	89731	BIORED L1	Cl	96.30 mmol/L		0	28-Dec-2023 10:43:53	97.500	3.300	87.6 - 107.4
25	89731	BIORED L1	PHOS	3.50 mg/dL		279872	28-Dec-2023 10:50:58	3.680	0.180	3.14 - 4.22
26	89731	BIORED L1	UA	4.3 mg/dL	-3SD	279876	28-Dec-2023 10:51:34	5.210	0.260	4.43 - 5.99
27	89731	BIORED L1	FE	237.0 µg/dL	+2SD	279887	28-Dec-2023 10:58:11	205.000	14.000	163 - 247
28	89731	BIORED L1	UA	4.9 mg/dL	-1SD	279890	28-Dec-2023 11:44:40	5.210	0.260	4.43 - 5.99
29	89731	BIORED L1	FE	224.6 µg/dL	+1SD	279891	28-Dec-2023 12:37:42	205.000	14.000	163 - 247

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Result Reprint

Report Type : Controls

28-Dec-2023

Consumable: BIORED L2

Sr #	Lot #	Consumable	Test	Result Unit	Flag	Curve #	Result Date	Mean	SD	Interval (3SD)
1	89732	BIORED L2	Na	122.50 mmol/L	-1SD	0	28-Dec-2023 10:13:53	127.000	4.000	115 - 139
2	89732	BIORED L2	K	5.24 mmol/L	-1SD	0	28-Dec-2023 10:13:53	5.580	0.200	4.98 - 6.18
3	89732	BIORED L2	Cl	87.30 mmol/L		0	28-Dec-2023 10:13:53	84.700	2.800	76.3 - 93.1
4	89732	BIORED L2	SGPTD	105.9 U/L	+1SD	279827	28-Dec-2023 10:15:59	95.100	6.300	76.2 - 114
5	89732	BIORED L2	SGOTD	215.9 U/L		279829	28-Dec-2023 10:16:17	204.000	14.000	162 - 246
6	89732	BIORED L2	ALPU	555 U/L		279831	28-Dec-2023 10:16:36	571.000	38.000	457 - 685
7	89732	BIORED L2	GGT	164.1 U/L		279833	28-Dec-2023 10:16:54	165.000	11.000	132 - 198
8	89732	BIORED L2	PHOS	7.84 mg/dL	+2SD	279835	28-Dec-2023 10:17:12	6.900	0.350	5.85 - 7.95
9	89732	BIORED L2	BIDD	1.33 mg/dL		279837	28-Dec-2023 10:17:30	1.370	0.110	1.04 - 1.7
10	89732	BIORED L2	BIT	4.91 mg/dL		279839	28-Dec-2023 10:17:48	4.900	0.410	3.67 - 6.13
11	89732	BIORED L2	UREA	99.9 mg/dL		279841	28-Dec-2023 10:18:06	102.000	5.000	87 - 117
12	89732	BIORED L2	CRENZ	5.18 mg/dL		279843	28-Dec-2023 10:18:24	5.420	0.360	4.34 - 6.5
13	89732	BIORED L2	GLU	290.0 mg/dL		279845	28-Dec-2023 10:18:42	294.000	15.000	249 - 339
14	89732	BIORED L2	TRIG	83.4 mg/dL		279847	28-Dec-2023 10:19:00	87.300	4.480	73.86 - 100.74
15	89732	BIORED L2	CHOL	98 mg/dL	-1SD	279849	28-Dec-2023 10:19:18	104.000	5.000	89 - 119
16	89732	BIORED L2	HDLC	25.8 mg/dL		279852	28-Dec-2023 10:19:45	27.400	1.800	22 - 32.8
17	89732	BIORED L2	UA	9.4 mg/dL	-2SD	279854	28-Dec-2023 10:20:03	10.700	0.500	9.2 - 12.2

Print Date

28-Dec-2023

1 / 2



Result Reprint

Report Type : Controls

28-Dec-2023

Consumable: BIORED L2

Sr #	Lot #	Consumable	Test	Result Unit	Flag	Curve #	Result Date	Mean	SD	Interval (3SD)
18	89732	BIORED L2	LDL	74.5 mg/dL		279856	28-Dec-2023 10:20:21	70.700	4.700	56.6 - 84.8
19	89732	BIORED L2	CA	11.1 mg/dL	-1SD	279858	28-Dec-2023 10:20:39	12.200	0.600	10.4 - 14
20	89732	BIORED L2	ALBD	2.70 g/dL		279860	28-Dec-2023 10:20:57	2.720	0.140	2.3 - 3.14
21	89732	BIORED L2	PRO	3.66 g/dL	-2SD	279862	28-Dec-2023 10:21:15	4.230	0.210	3.6 - 4.86
22	89732	BIORED L2	PHOS	7.01 mg/dL		279873	28-Dec-2023 10:51:07	6.900	0.350	5.85 - 7.95
23	89732	BIORED L2	UA	10.2 mg/dL		279878	28-Dec-2023 10:51:52	10.700	0.500	9.2 - 12.2
24	89732	BIORED L2	PRO	4.23 g/dL		279881	28-Dec-2023 10:52:19	4.230	0.210	3.6 - 4.86
25	89732	BIORED L2	FE	72.0 µg/dL	+3SD	279888	28-Dec-2023 10:58:20	56.700	3.800	45.3 - 68.1
26	89732	BIORED L2	FE	64.3 µg/dL	+1SD	279892	28-Dec-2023 12:37:51	56.700	3.800	45.3 - 68.1



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IQC / EQAS Outlier Log

Department Biochemistry XL-640

Date/Time	Parameter	Rule violated	Corrective action	Tech Sign	Reviewed by
28/12/23	Phos level-1	+3SD	Random Error Re-run the fresh cc pass	Mavish] @
28/12/23	UA level-1	-3SD	Random Error Re-run with fresh cc pass	Mavish	
28/12/23	FE level-2	+3SD	Random Error After Re-run cc pass	Mavish	



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 certificate 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 - XL-640

Test : UREA

Revision : <A-640-UREA-3 18.06.2019>

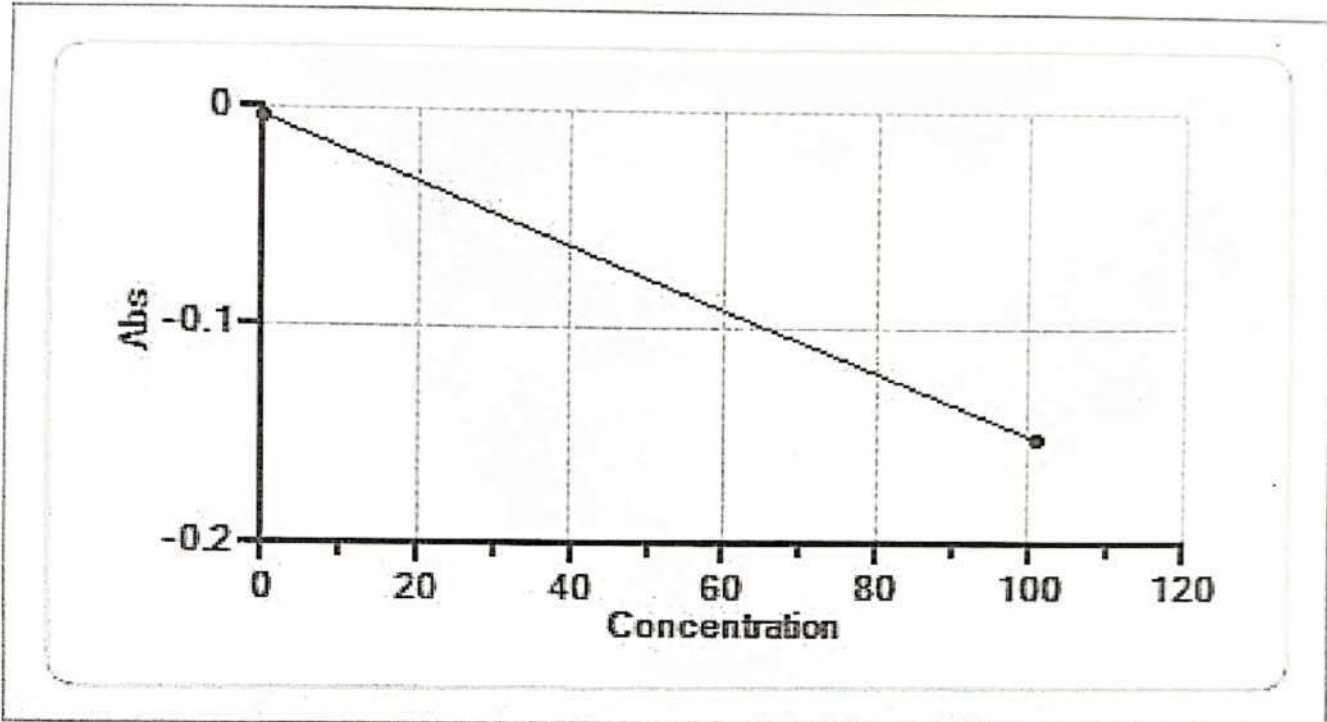
Curve Type : Linear

R1 Lot-Bottle No : S102353-343#0463

Calibration Date : 05-Jan-2024 10:14:02

R2 Lot-Bottle No : S102353-343#0066

Last Calibration Date : 05-Jan-2024 10:14:02



Pos	Consumable	LotNo.	Conc	Delta Abs/Min	Factor
-	MULTI BLK	123456	0.000	-0.0035	0.0000
-	XL MULTICAL	2310072	101.000	-0.1519	-680.5930

Calibration - XL-640

Test : CRENZ

Revision : <A-640-CRENZ-4 26.11.2020>

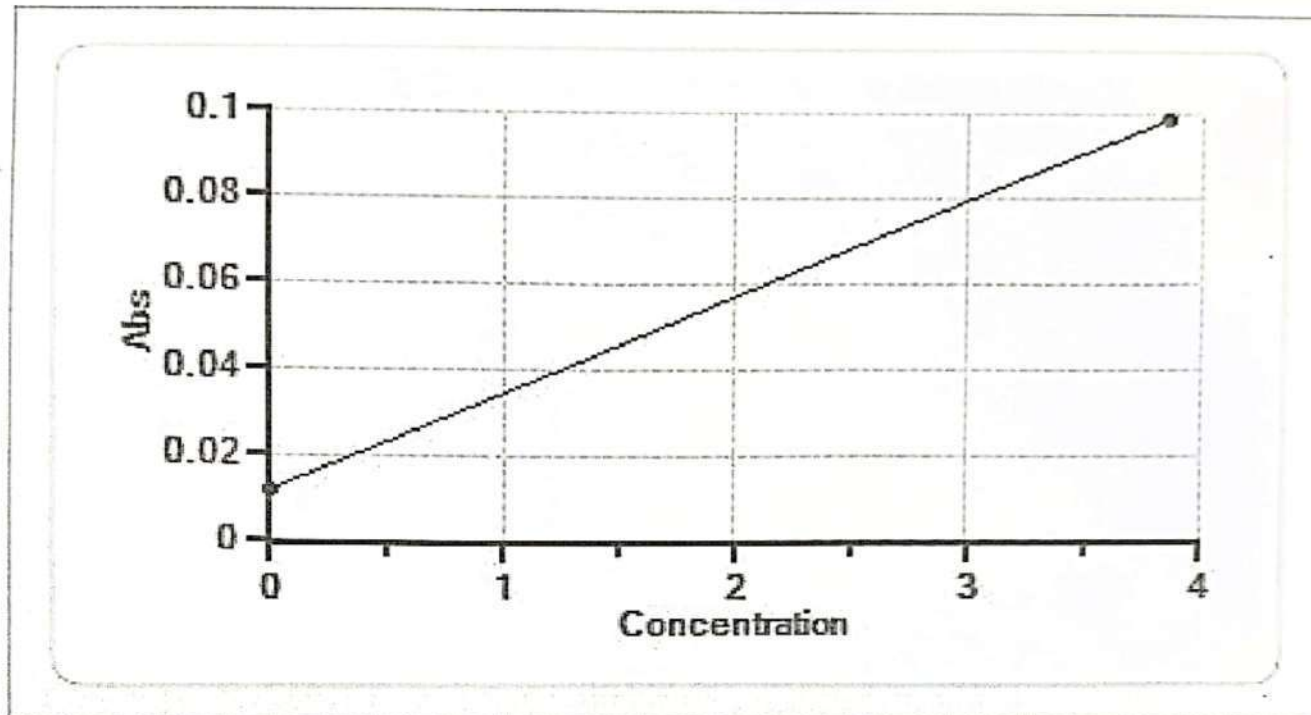
Curve Type : Linear

R1 Lot-Bottle No : T092319-341#3214

Calibration Date : 05-Jan-2024 10:14:38

R2 Lot-Bottle No : T092319-341#8724

Last Calibration Date : 05-Jan-2024 10:14:38



Pos	Consumable	LotNo.	Conc	Abs	Factor
-	MULTI BLK	123456	0.000	0.0121	0.0000
-	XL MULTICAL	2310072	3.850	0.0986	44.5087

Calibration - XL-640

Test : SGPTD

Revision : <A-640-SGPTD-3 21.06.2017>

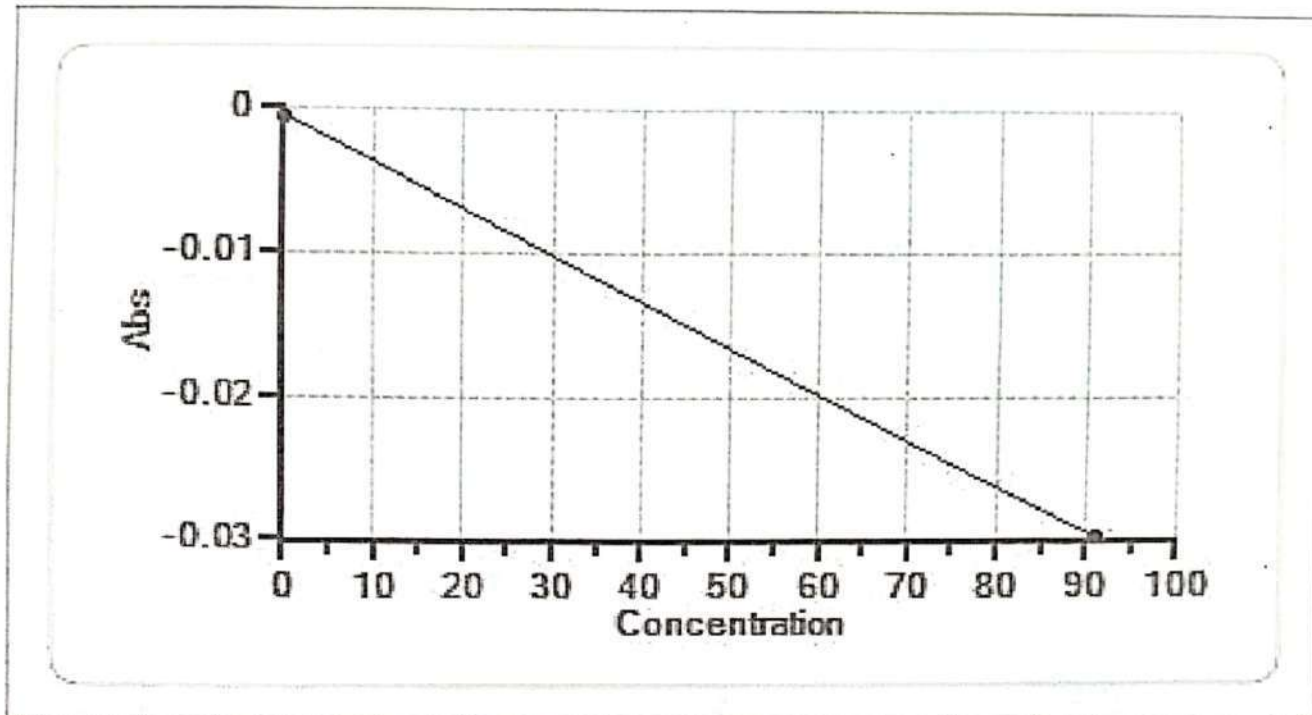
Curve Type : Linear

R1 Lot-Bottle No : T082308-335#5811

Calibration Date : 05-Jan-2024 10:09:40

R2 Lot-Bottle No : T082308-335#2393

Last Calibration Date : 05-Jan-2024 10:09:40



Pos	Consumable	LotNo.	Conc	Delta Abs/Min	Factor
-	MULTI BLK	123456	0.000	-0.0005	0.0000
-	XL MULTICAL	2310072	91.000	-0.0298	-3,105.8020

Calibration - XL-640

Test : SGOTD

Revision : <A-640-SGOTD-3 21.06.2017>

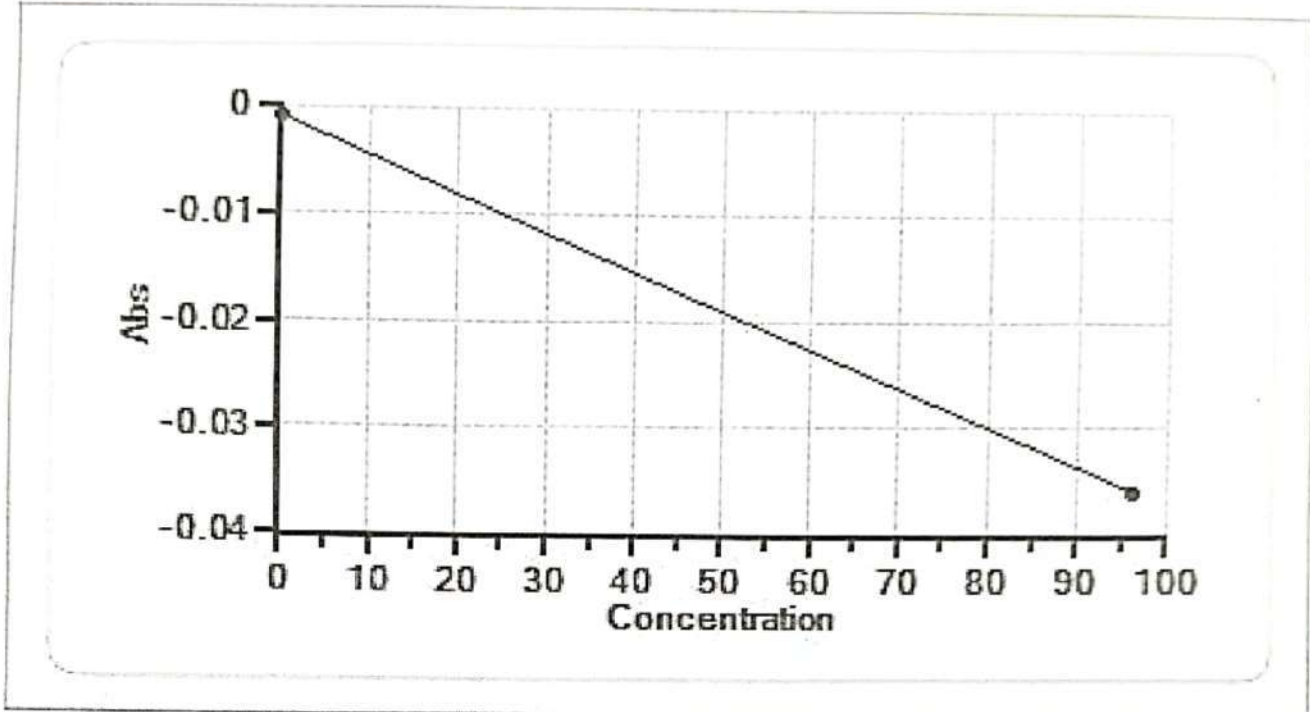
Curve Type : Linear

R1 Lot-Bottle No : S032309-310#7721

Calibration Date : 05-Jan-2024 10:10:16

R2 Lot-Bottle No : S032309-310#4178

Last Calibration Date : 05-Jan-2024 10:10:16



Pos	Consumable	LotNo.	Conc	Delta Abs/Min	Factor
-	MULTI BLK	123456	0.000	-0.0008	0.0000
-	XL MULTICAL	2310072	96.400	-0.0359	-2,746.4387

Calibration - XL-640

Test : PHOS

Revision : <A-640-PHOS-1 20.08.2013>

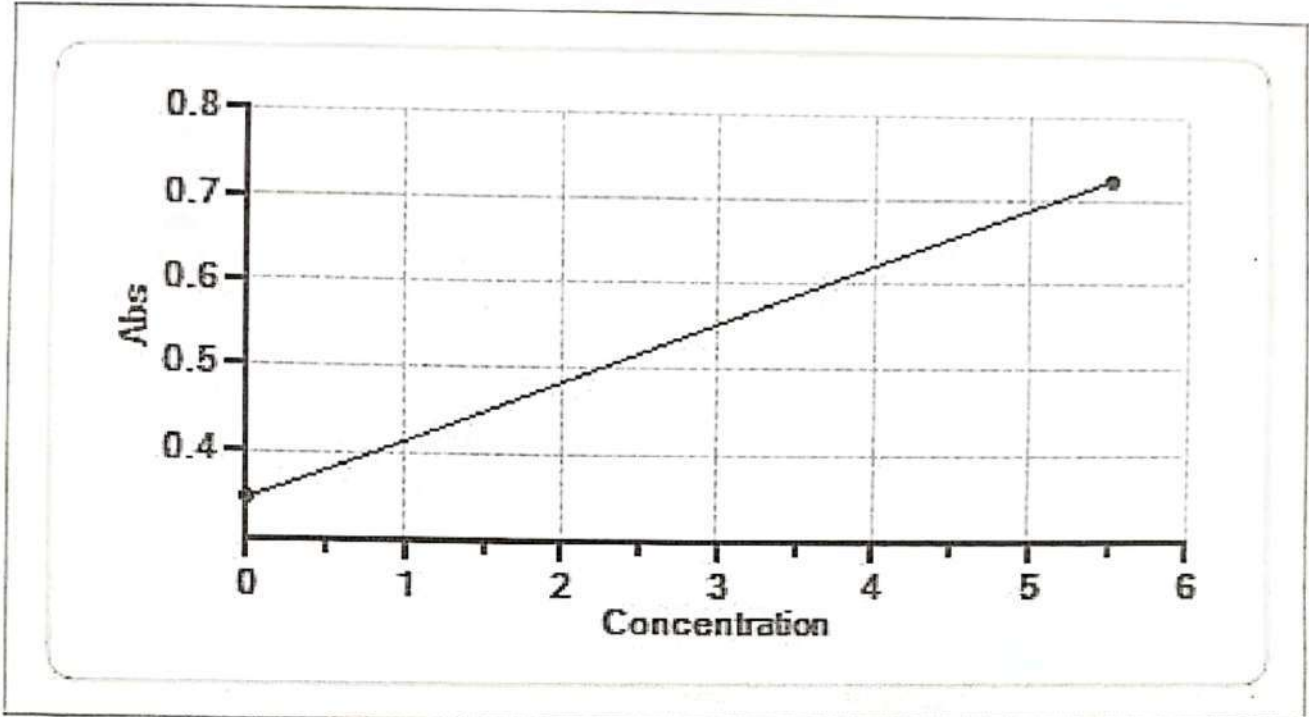
Curve Type : Linear

R1 Lot-Bottle No : S112277-246#2030

Calibration Date : 05-Jan-2024 10:12:13

R2 Lot-Bottle No : ---

Last Calibration Date : 05-Jan-2024 10:12:13



Pos	Consumable	LotNo.	Conc	Abs	Factor
-	MULTI BLK	123456	0.000	0.3452	0.0000
-	XL MULTICAL	2310072	5.520	0.7243	14.5608

Calibration - XL-640

Test : HA1cD

Revision :. <A-640-HA1cD-2 13.08.2020>

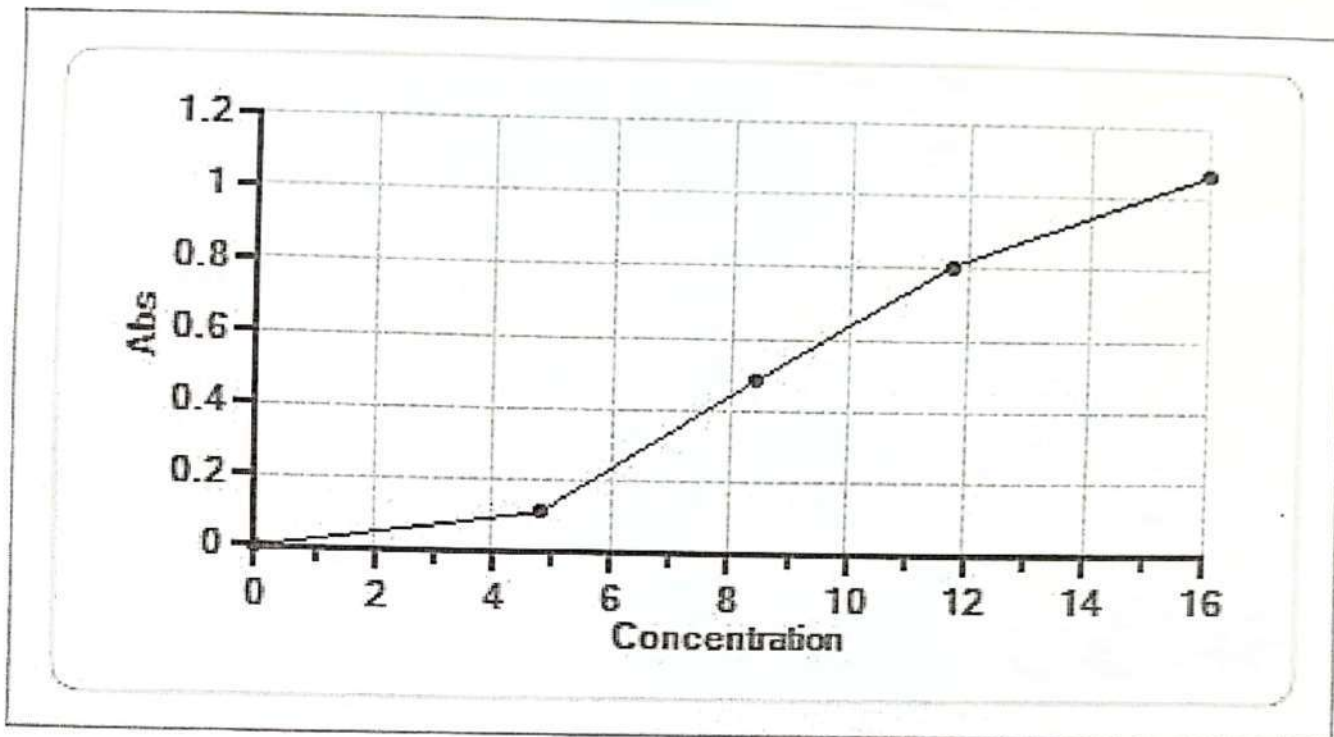
Curve Type : Point-To-Point

R1 Lot-Bottle No : S102319-343#2325

Calibration Date : 18-Dec-2023 11:36:30

R2 Lot-Bottle No : S102319-343#2654

Last Calibration Date : 18-Dec-2023 11:36:30



Pos	Consumable	LotNo.	Conc	Abs	Factor
C1	HBA1C BLK CAL 1	123	0.000	0.0009	0.0000
C2	HBA1C CAL 2	S102319	4.800	0.1079	44.8598
C3	HBA1C CAL 3	S102319	8.400	0.4822	17.4527
C4	HBA1C CAL 4	S102319	11.700	0.8054	14.5432
C5	HBA1C CAL 5	S102319	16.000	1.0637	15.0546

Calibration - XL-640

Test : BIT

Revision : <A-640-BIT-3 18.06.2019>

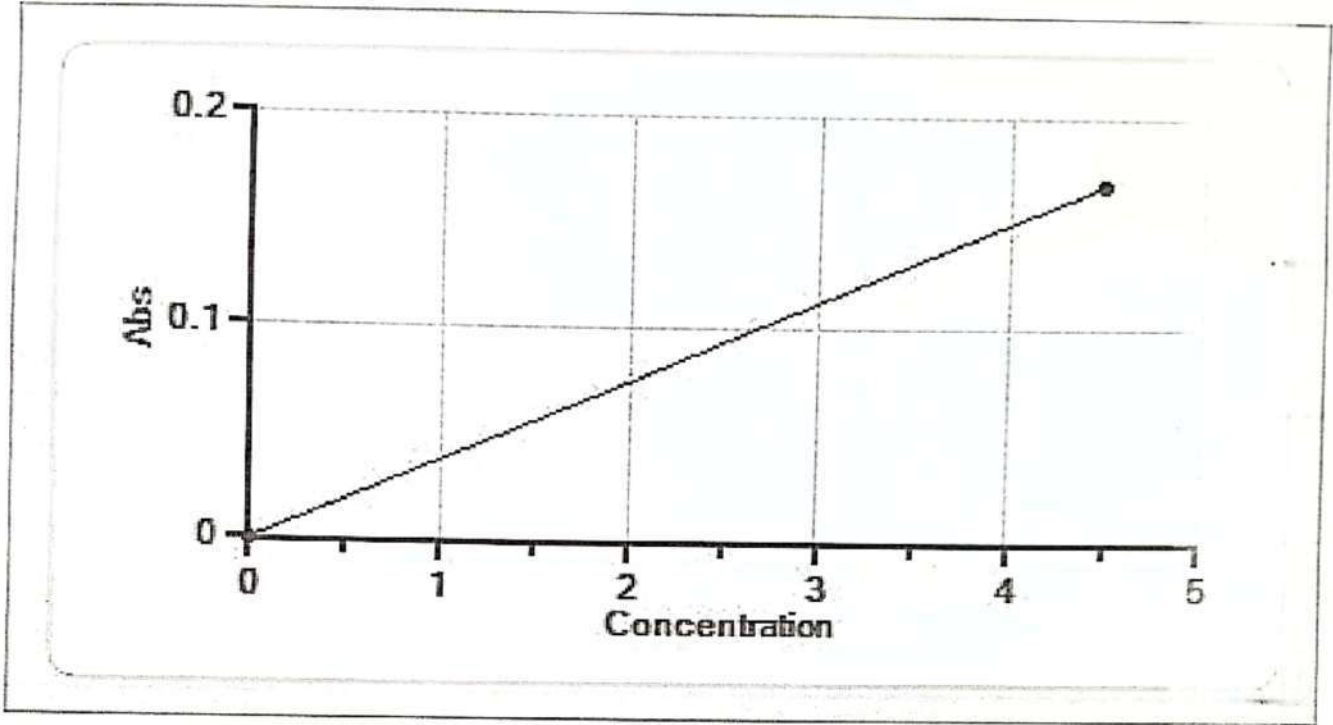
Curve Type : Linear

R1 Lot-Bottle No : S112219-245#3360

Calibration Date : 05-Jan-2024 10:13:25

R2 Lot-Bottle No : S112219-245#4152

Last Calibration Date : 05-Jan-2024 10:13:25



Pos	Consumable	LotNo.	Conc	Abs	Factor
-	MULTI BLK	123456	0.000	0.0003	0.0000
-	XL MULTICAL	2310072	4.490	0.1683	26.7262

Calibration - XL-640

Test : CA

Revision : <A-640-CA-2 18.06.2019>

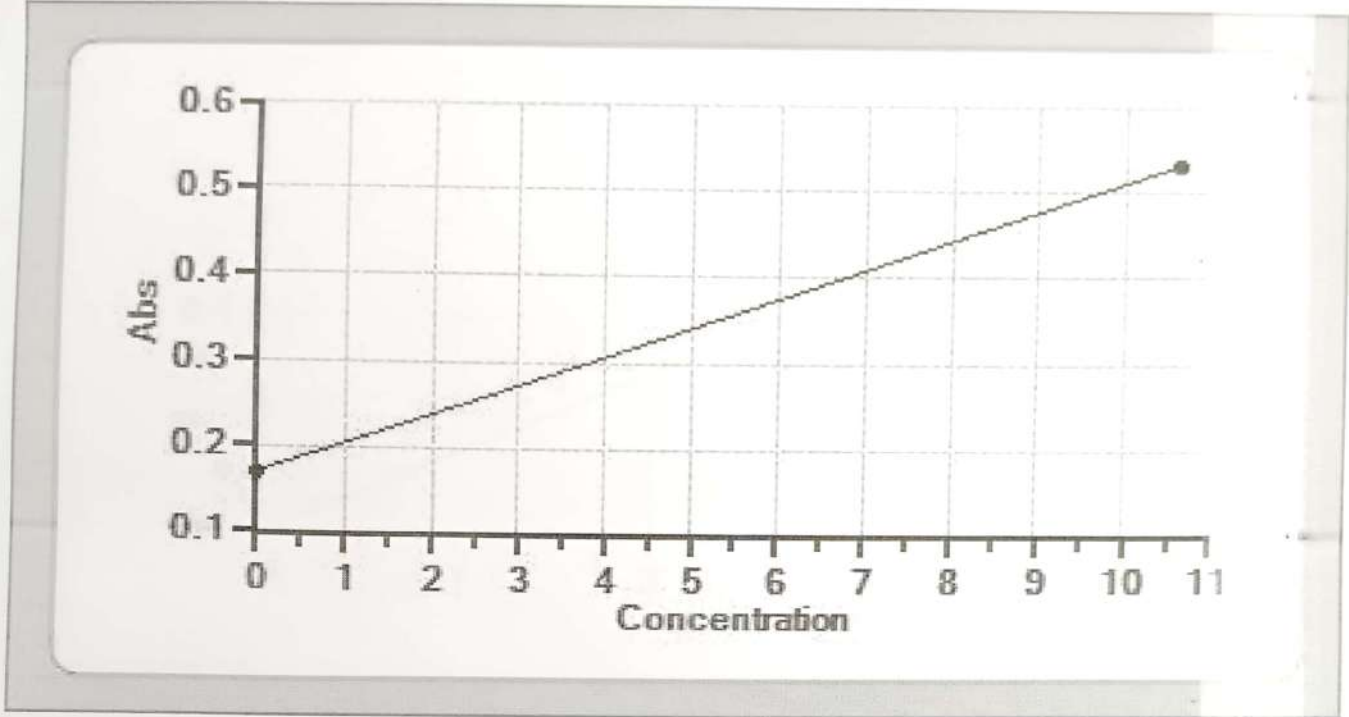
Curve Type : Linear

R1 Lot-Bottle No : S102351-343#5827

Calibration Date : 05-Jan-2024 10:18:23

R2 Lot-Bottle No : ---

Last Calibration Date : 05-Jan-2024 10:18:23



Pos	Consumable	LotNo.	Conc	Abs	Factor
-	MULTI BLK	123456	0.000	0.1708	0.0000
-	XL MULTICAL	2310072	10.600	0.5311	29.4199

Calibration - XL-640

Test : HDLC

Revision : <A-640-HDLC-1 20.08.2013>

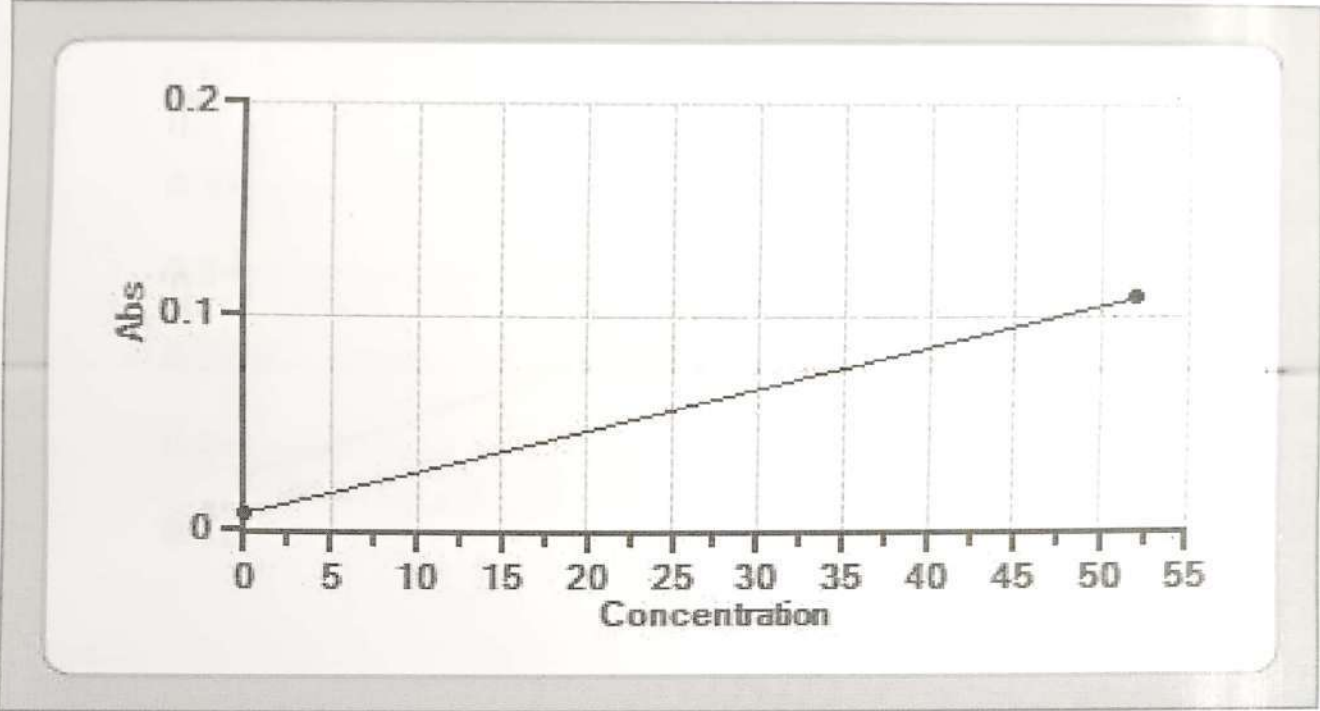
Curve Type : Linear

R1 Lot-Bottle No : T092315-338#1384

Calibration Date : 11-Dec-2023 10:43:46

R2 Lot-Bottle No : T092315-338#1397

Last Calibration Date : 11-Dec-2023 10:43:46



Pos	Consumable	LotNo.	Conc	Abs	Factor
-	HDL BLANK	S052364	0.000	0.0078	0.0000
-	NEW HDL	T092315	52.000	0.1089	514.3422

Calibration - XL-640

Test : TRIG

Revision : <A-640-TRIG-1 20.08.2013>

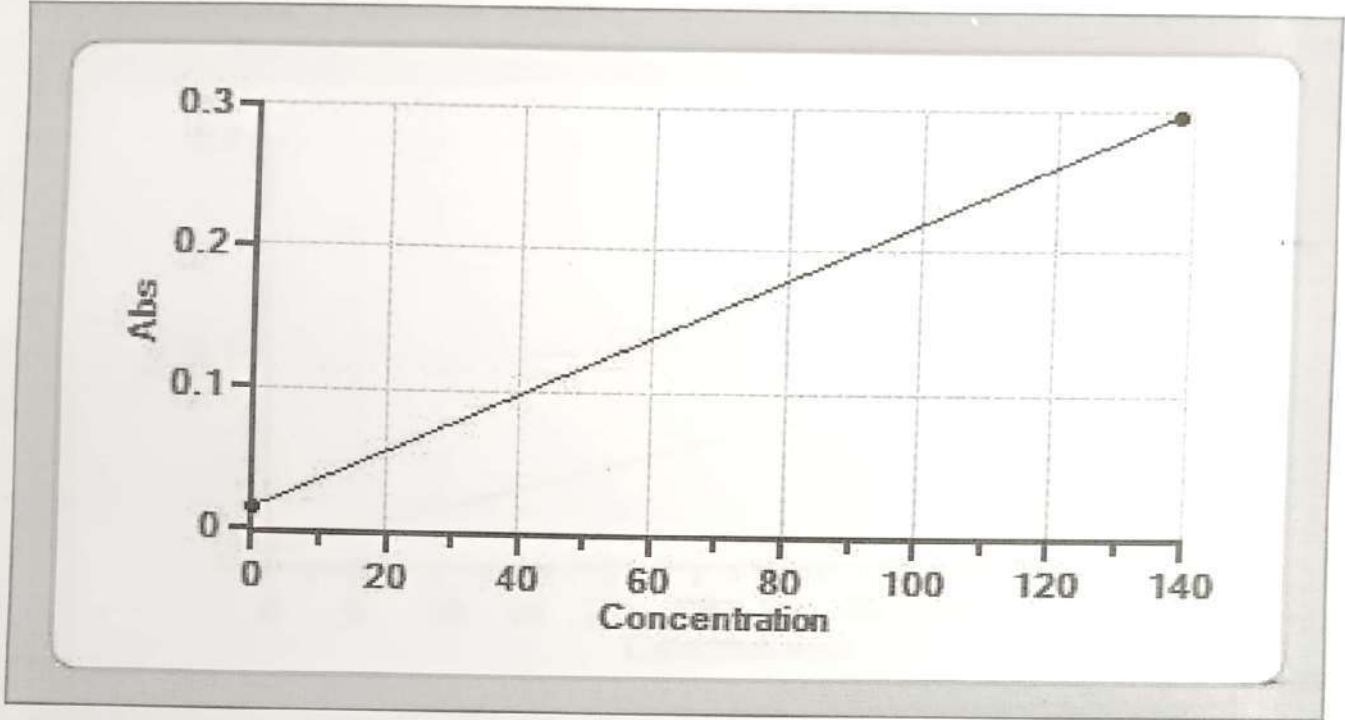
Curve Type : Linear

R1 Lot-Bottle No : S092353-337#2110

Calibration Date : 05-Jan-2024 10:15:50

R2 Lot-Bottle No : S092353-337#2653

Last Calibration Date : 05-Jan-2024 10:15:50



Pos	Consumable	LotNo.	Conc	Abs	Factor
-	MULTI BLK	123456	0.000	0.0162	0.0000
-	XL MULTICAL	2310072	138.000	0.2966	492.1541

Calibration - XL-640

Test : CHOL

Revision : <A-640-CHOL-1 20.08.2013>

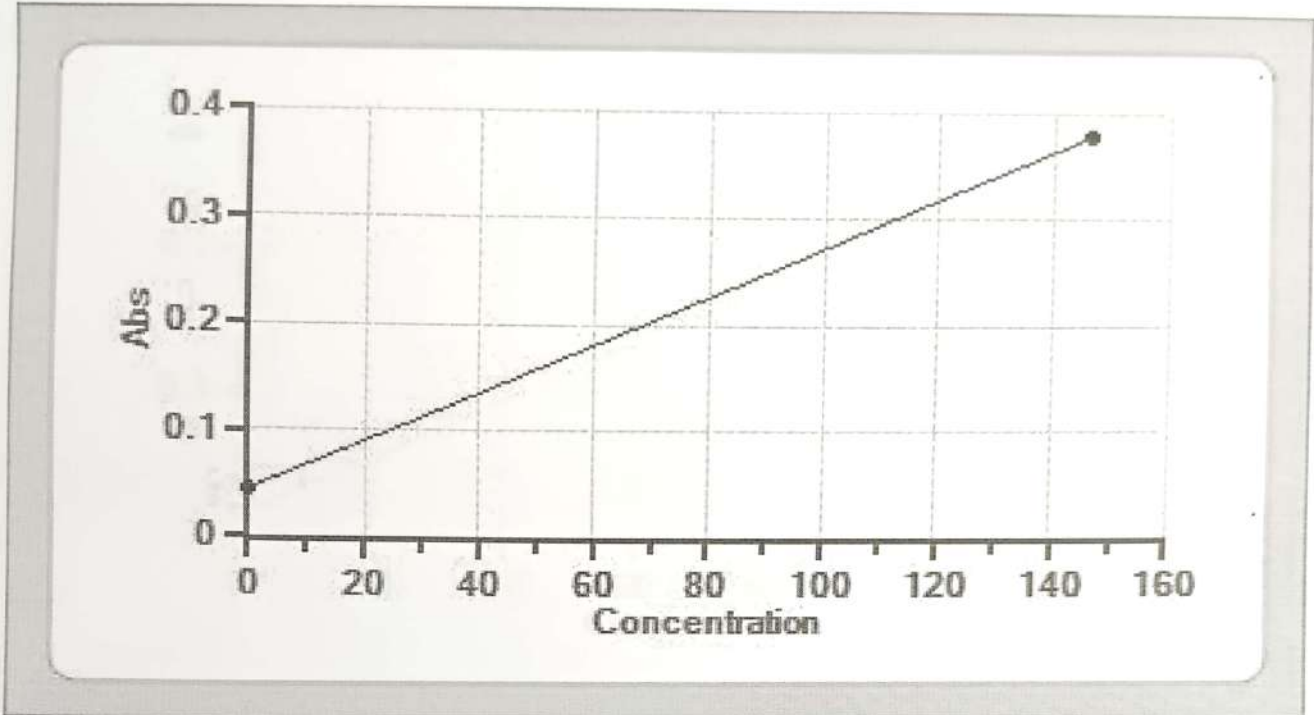
Curve Type : Linear

R1 Lot-Bottle No : S072326-328#0109

Calibration Date : 05-Jan-2024 11:23:35

R2 Lot-Bottle No : ---

Last Calibration Date : 05-Jan-2024 11:23:35



Pos	Consumable	LotNo.	Conc	Abs	Factor
S1	MULTI BLK	123456	0.000	0.0453	0.0000
S2	XL MULTICAL	2310072	146.000	0.3782	438.5702

Calibration - XL-640

Test : UA

Revision : <A-640-UA-2 18.06.2019>

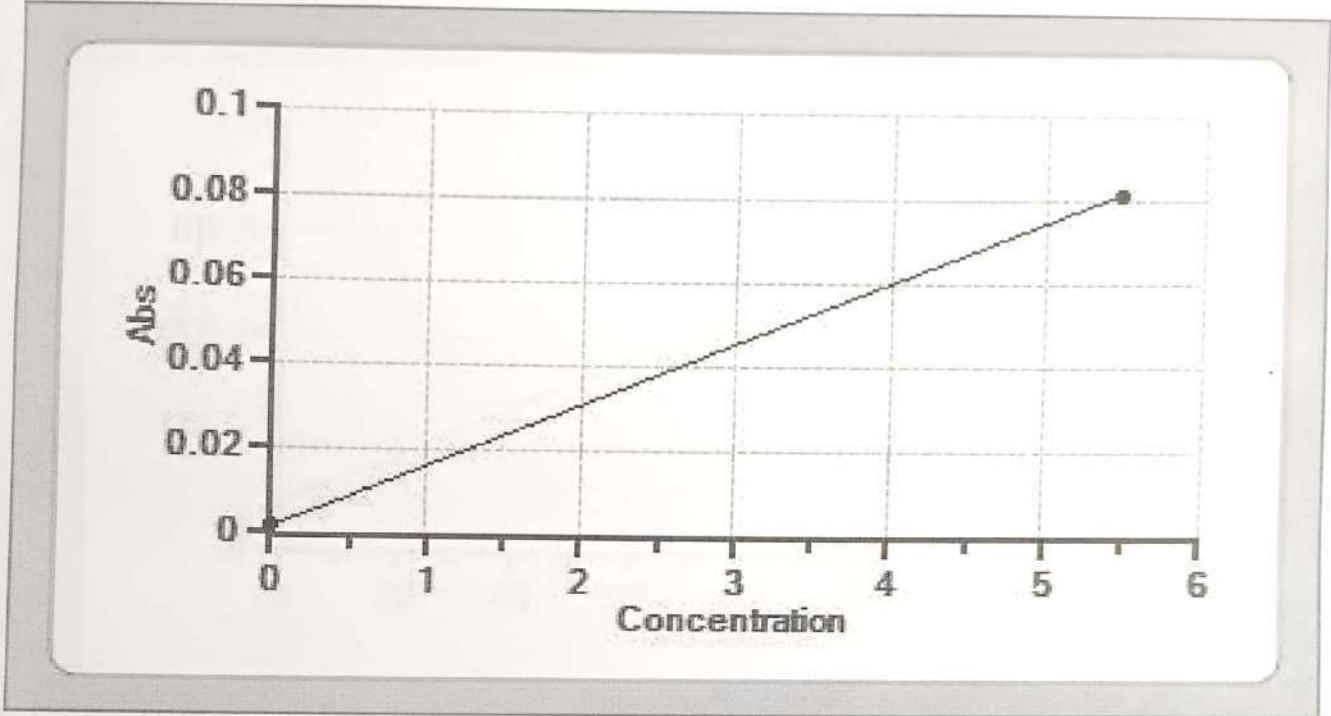
Curve Type : Linear

R1 Lot-Bottle No : T062309-327#3516

Calibration Date : 05-Jan-2024 11:24:11

R2 Lot-Bottle No : T062309-327#5172

Last Calibration Date : 05-Jan-2024 11:24:11



Pos	Consumable	LotNo.	Conc	Abs	Factor
S1	MULTI BLK	123456	0.000	0.0017	0.0000
S2	XL MULTICAL	2310072	5.460	0.0816	68.3354

Calibration - XL-640

Test : ALBD

Curve Type : Linear

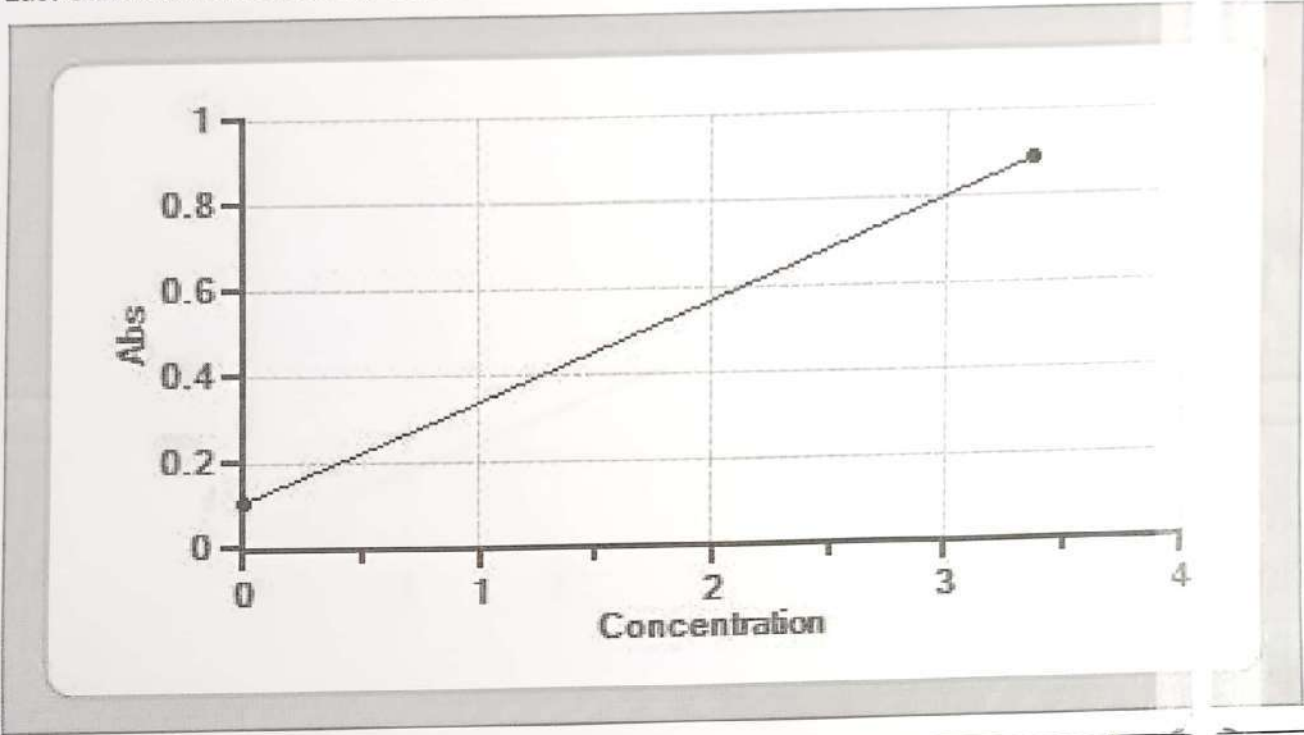
Calibration Date : 05-Jan-2024 10:18:59

Last Calibration Date : 05-Jan-2024 10:18:59

Revision : <A-640-ALB-1 07.11.2017>

R1 Lot-Bottle No : B102233-242#2693

R2 Lot-Bottle No : ---



Pos	Consumable	LotNo.	Conc	Abs	Factor
-	MULTI BLK	123456	0.000	0.1080	0.0000
-	XL MULTICAL	2310072	3.370	0.8867	4.3277

Print Date : 09-Jan-2024

Page 1 of 1

Calibration - XL-640

Test : ALPU

Revision : <A-640-ALPU-3 01.03.2016>

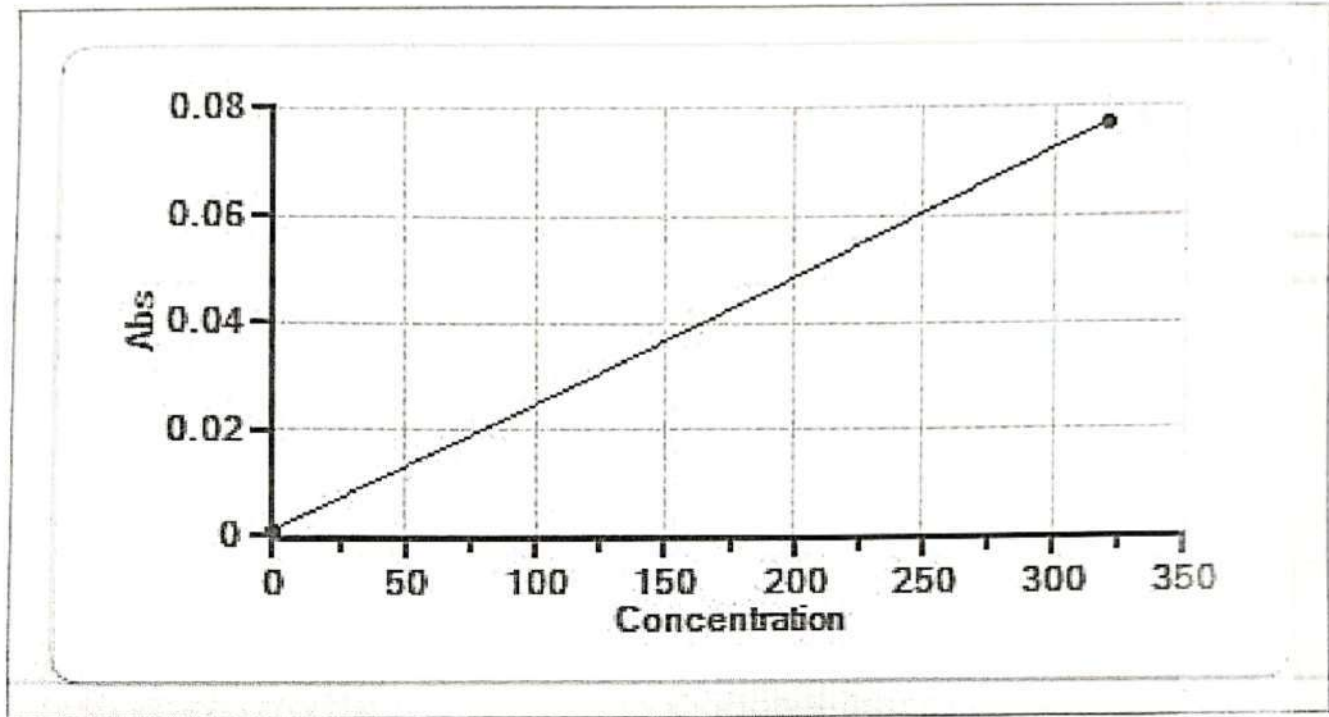
Curve Type : Linear

R1 Lot-Bottle No : B092232-237#1150

Calibration Date : 05-Jan-2024 10:11:01

R2 Lot-Bottle No : B092232-237#2083

Last Calibration Date : 05-Jan-2024 10:11:01



Pos	Consumable	LotNo.	Conc	Delta Abs/Min	Factor
-	MULTI BLK	123456	0.000	0.0013	0.0000
-	XL MULTICAL	2310072	320.000	0.0770	4,227.2129

Calibration - XL-640

Test : GLU

Revision : <A-640-GLU-2 18.06.2019>

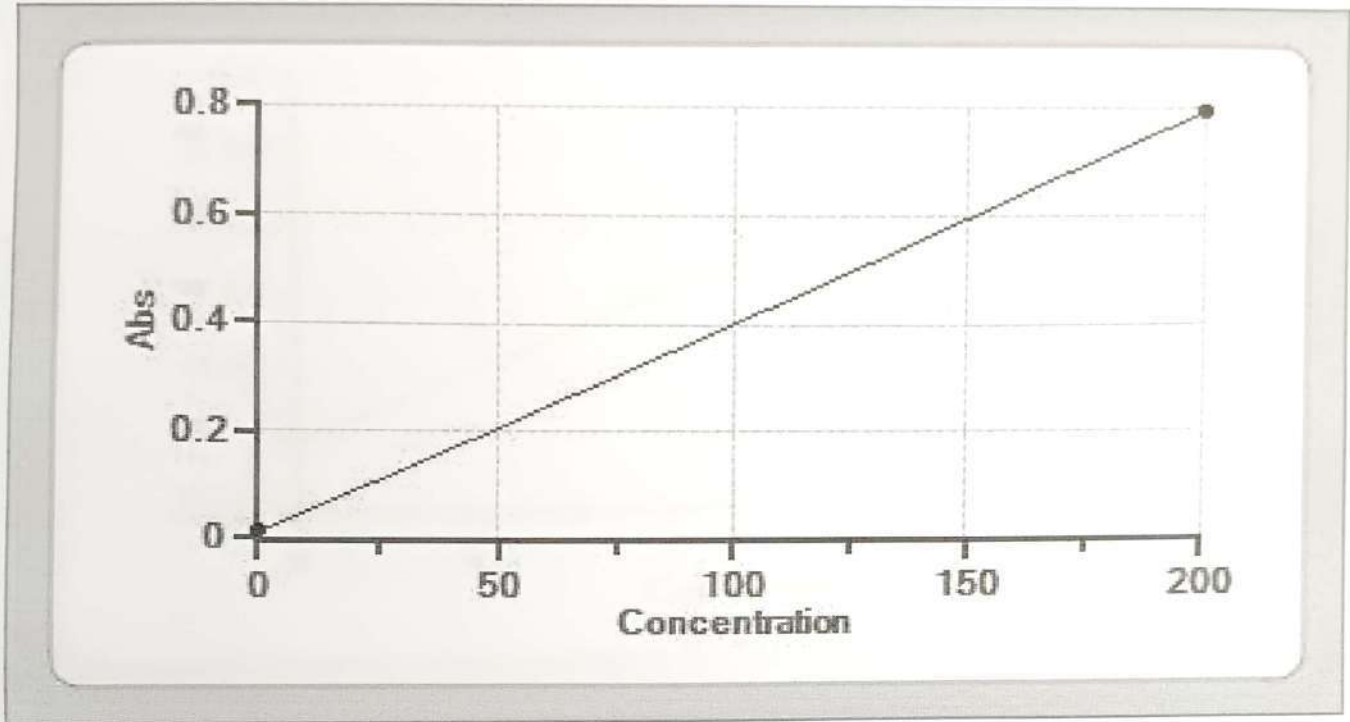
Curve Type : Linear

R1 Lot-Bottle No : B092365-339#3898

Calibration Date : 05-Jan-2024 10:15:14

R2 Lot-Bottle No : ---

Last Calibration Date : 05-Jan-2024 10:15:14



Pos	Consumable	LotNo.	Conc	Abs	Factor
-	MULTI BLK	123456	0.000	0.0137	0.0000
-	XL MULTICAL	2310072	200.000	0.7939	256.3445

Print Date : 09-Jan-2024

Calibration - XL-640

Test : PRO

Revision : <A-640-PRO-2 26.09.2013>

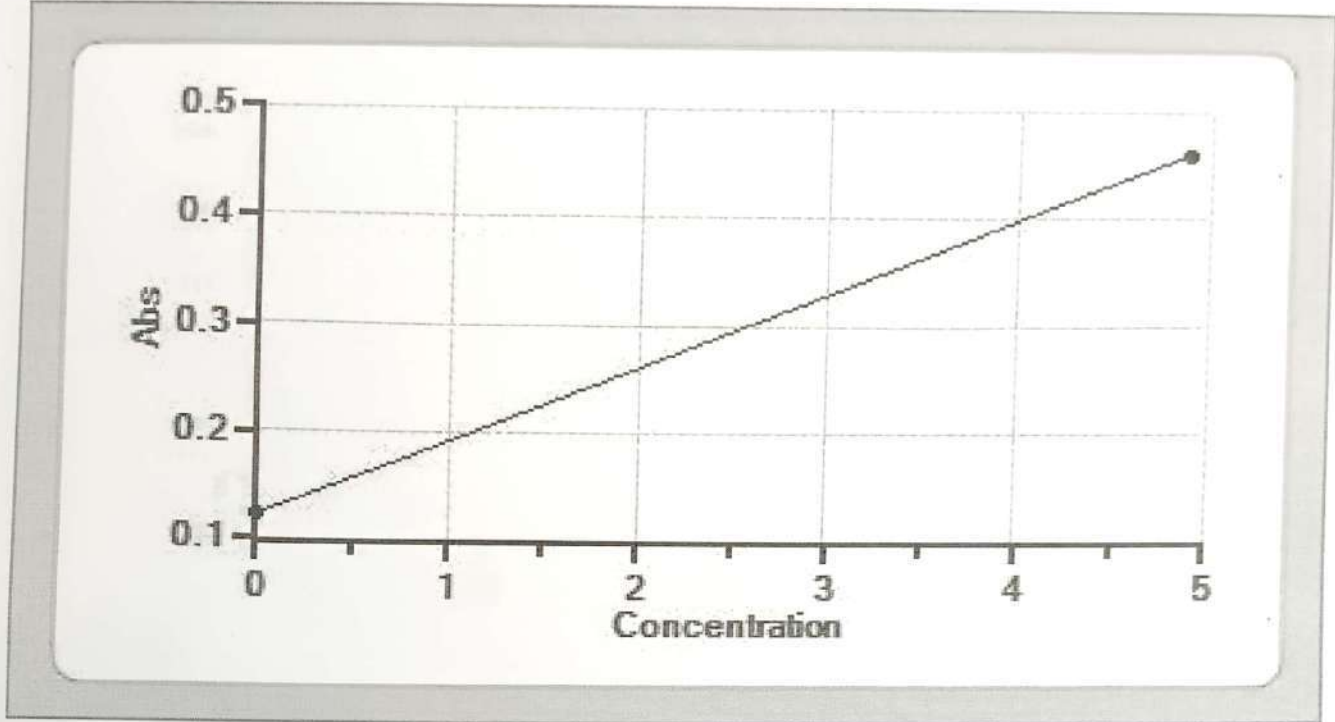
Curve Type : Linear

R1 Lot-Bottle No : B102243-243#8998

Calibration Date : 05-Jan-2024 10:19:36

R2 Lot-Bottle No : ---

Last Calibration Date : 05-Jan-2024 10:19:36



Pos	Consumable	LotNo.	Conc	Abs	Factor
-	MULTI BLK	123456	0.000	0.1240	0.0000
-	XL MULTICAL	2310072	4.880	0.4606	14.4979

ISE

ISE MAINTENANCE COMMANDS

- PURGE A
- PURGE B
- CALIBRATION
- CLEAN
- PUMP CALIBRATION
- BUBBLE CALIBRATION
- MAINTENANCE
- PRIME A
- PRIME B
- SHOW BUBBLE CALIBRATION
- SHOW LAST SLOPE CALCULATED**
- SHOW ISE PUMP CALIBRATION
- READ ISE VERSION

Na	57.53
K	54.38
Cl	47.54

ISE OFF

START

Lot No. : 23091053

Expiry Date : 31 Aug 2025