



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:- 20/04/2023

Manish Airan

Head Of Quality Department & Regulatory

Result Reprint

Report Type

: Controls

12-Jul-2023 To 12-Aug-2023

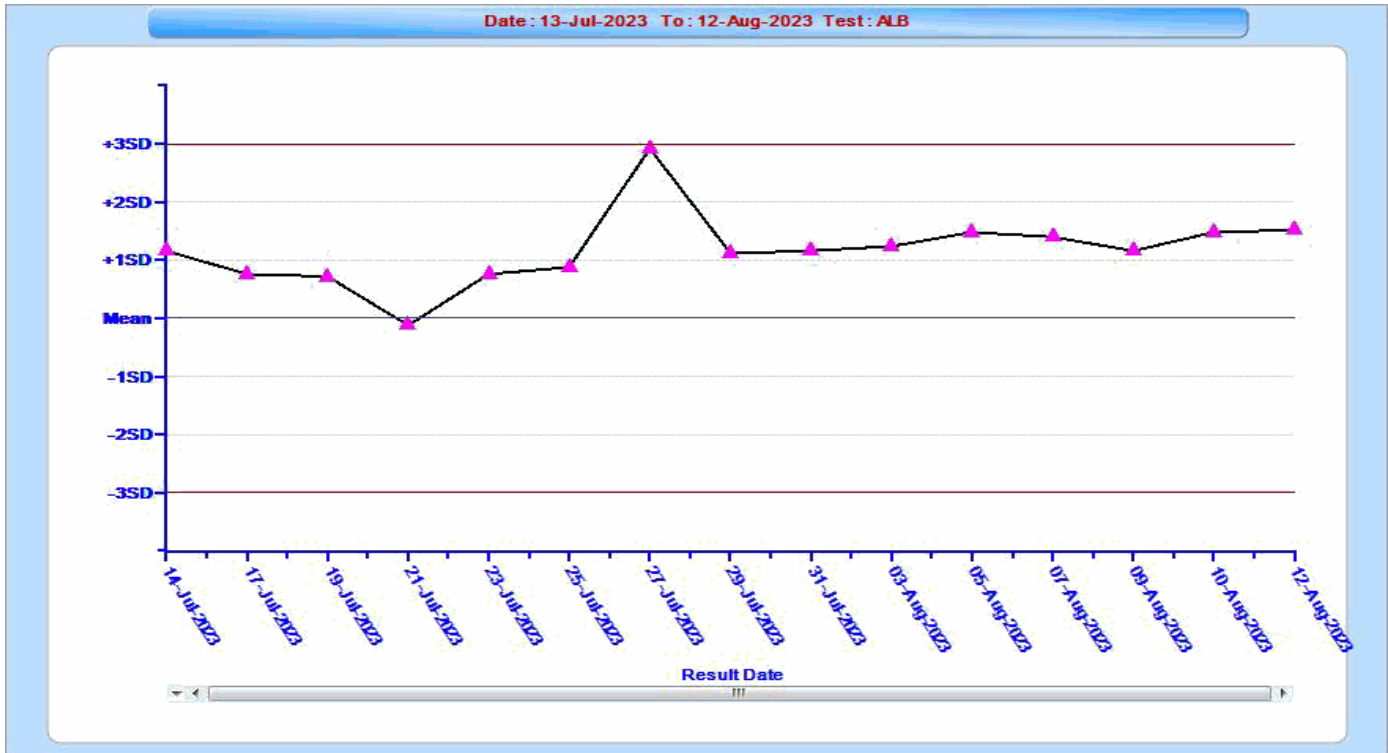
Test: ALB

Sr #	Lot #	Consumable	Test	Result Unit	Flag	Curve #	Result Date	Mean	SD	Interval (3SD)
1	S022359	ERBA PATH	ALB	5.18 g/dl		70194	12-Jul-2023 10:29:17	5.020	0.250	4.27 - 5.77
2	S022359	ERBA PATH	ALB	5.31 g/dl	+1SD	70323	14-Jul-2023 10:08:13	5.020	0.250	4.27 - 5.77
3	S022359	ERBA PATH	ALB	5.21 g/dl		70483	17-Jul-2023 10:11:07	5.020	0.250	4.27 - 5.77
4	S022359	ERBA PATH	ALB	5.20 g/dl		70605	19-Jul-2023 12:03:48	5.020	0.250	4.27 - 5.77
5	S022359	ERBA PATH	ALB	4.99 g/dl		70733	21-Jul-2023 10:55:24	5.020	0.250	4.27 - 5.77
6	S022359	ERBA PATH	ALB	5.21 g/dl		70906	23-Jul-2023 09:45:40	5.020	0.250	4.27 - 5.77
7	S022359	ERBA PATH	ALB	5.24 g/dl		71022	25-Jul-2023 10:30:09	5.020	0.250	4.27 - 5.77
8	S022359	ERBA PATH	ALB	5.75 g/dl	+2SD	71123	27-Jul-2023 11:05:27	5.020	0.250	4.27 - 5.77
9	S022359	ERBA PATH	ALB	5.30 g/dl	+1SD	71195	29-Jul-2023 09:32:18	5.020	0.250	4.27 - 5.77
10	S022359	ERBA PATH	ALB	5.31 g/dl	+1SD	71254	31-Jul-2023 11:20:59	5.020	0.250	4.27 - 5.77
11	S022359	ERBA PATH	ALB	5.33 g/dl	+1SD	71364	3-Aug-2023 09:12:14	5.020	0.250	4.27 - 5.77
12	S022359	ERBA PATH	ALB	5.39 g/dl	+1SD	71489	5-Aug-2023 11:26:53	5.020	0.250	4.27 - 5.77
13	S022359	ERBA PATH	ALB	5.37 g/dl	+1SD	71599	7-Aug-2023 11:19:15	5.020	0.250	4.27 - 5.77
14	S022359	ERBA PATH	ALB	5.31 g/dl	+1SD	71724	9-Aug-2023 11:34:58	5.020	0.250	4.27 - 5.77
15	S022359	ERBA PATH	ALB	5.39 g/dl	+1SD	71821	10-Aug-2023 10:42:46	5.020	0.250	4.27 - 5.77
16	S022359	ERBA PATH	ALB	5.40 g/dl	+1SD	71954	12-Aug-2023 12:04:16	5.020	0.250	4.27 - 5.77

QC Data - EM 200

Test : ALB
 Control : ERBA PATH
 Level : High
 Lot No. : S022359
 Batch No. : ---
 Mean : 5.02
 SD : 0.25

Date From : 13-Jul-2023
 Date To : 12-Aug-2023
 ExpDate :31-Dec-2025



X Calculation : R= Range of average of Results per day :

Level	N	Avg	SD	% CV	R
High	15	5.31	0.1599	3.0113	0.76

R Calculation : R= Range of Result Variations per day :

Level	N	Avg	SD	% CV	R
High	15	0	0	0	0

QC Data - EM 200

Sr #	Date	Result	Mean	SD	Interval (3SD)	Deviation	Dev %	Error%	Batch	QC Remarks
1	14 Jul 2023	5.31	5.020	0.25	4.27 - 5.77	+1SD	0.29	5.78	1	
2	17 Jul 2023	5.21	5.020	0.25	4.27 - 5.77		0.19	3.78	1	
3	19 Jul 2023	5.20	5.020	0.25	4.27 - 5.77		0.18	3.59	1	
4	21 Jul 2023	4.99	5.020	0.25	4.27 - 5.77		-0.03	-0.60	1	
5	23 Jul 2023	5.21	5.020	0.25	4.27 - 5.77		0.19	3.78	1	
6	25 Jul 2023	5.24	5.020	0.25	4.27 - 5.77		0.22	4.38	1	
7	27 Jul 2023	5.75	5.020	0.25	4.27 - 5.77	+2SD	0.73	14.54	1	
8	29 Jul 2023	5.30	5.020	0.25	4.27 - 5.77	+1SD	0.28	5.58	1	
9	31 Jul 2023	5.31	5.020	0.25	4.27 - 5.77	+1SD	0.29	5.78	1	
10	03 Aug 2023	5.33	5.020	0.25	4.27 - 5.77	+1SD	0.31	6.18	1	
11	05 Aug 2023	5.39	5.020	0.25	4.27 - 5.77	+1SD	0.37	7.37	1	
12	07 Aug 2023	5.37	5.020	0.25	4.27 - 5.77	+1SD	0.35	6.97	1	
13	09 Aug 2023	5.31	5.020	0.25	4.27 - 5.77	+1SD	0.29	5.78	1	
14	10 Aug 2023	5.39	5.020	0.25	4.27 - 5.77	+1SD	0.37	7.37	2	
15	12 Aug 2023	5.40	5.020	0.25	4.27 - 5.77	+1SD	0.38	7.57	1	

Result Reprint

Report Type

: Controls

12-Jul-2023 To 12-Aug-2023

Test: BIT

Sr #	Lot #	Consumable	Test	Result	Unit	Flag	Curve #	Result Date	Mean	SD	Interval (3SD)
1	S022359	ERBA PATH	BIT	5.58	mg/dl		70176	12-Jul-2023 10:23:52	5.270	0.440	3.95 - 6.59
2	S022359	ERBA PATH	BIT	5.64	mg/dl		70305	14-Jul-2023 10:02:48	5.270	0.440	3.95 - 6.59
3	S022359	ERBA PATH	BIT	5.50	mg/dl		70465	17-Jul-2023 10:05:43	5.270	0.440	3.95 - 6.59
4	S022359	ERBA PATH	BIT	5.45	mg/dl		70587	19-Jul-2023 11:58:23	5.270	0.440	3.95 - 6.59
5	S022359	ERBA PATH	BIT	5.15	mg/dl		70717	21-Jul-2023 10:50:35	5.270	0.440	3.95 - 6.59
6	S022359	ERBA PATH	BIT	5.12	mg/dl		70888	23-Jul-2023 09:40:16	5.270	0.440	3.95 - 6.59
7	S022359	ERBA PATH	BIT	5.40	mg/dl		71004	25-Jul-2023 10:24:44	5.270	0.440	3.95 - 6.59
8	S022359	ERBA PATH	BIT	6.06	mg/dl	+1SD	71105	27-Jul-2023 11:00:03	5.270	0.440	3.95 - 6.59
9	S022359	ERBA PATH	BIT	5.36	mg/dl		71177	29-Jul-2023 09:26:53	5.270	0.440	3.95 - 6.59
10	S022359	ERBA PATH	BIT	5.17	mg/dl		71236	31-Jul-2023 11:15:34	5.270	0.440	3.95 - 6.59
11	S022359 ~	ERBA PATH	BIT	4.23	mg/dl	-2SD	71346	3-Aug-2023 09:06:13	5.270	0.440	3.95 - 6.59
12	S022359 ~	ERBA PATH	BIT	4.10	mg/dl	-2SD	71471	5-Aug-2023 11:20:52	5.270	0.440	3.95 - 6.59

Result Reprint

Report Type

: Controls

12-Jul-2023 To 12-Aug-2023

Test: CHOL

Sr #	Lot #	Consumable	Test	Result Unit	Flag	Curve #	Result Date	Mean	SD	Interval (3SD)
1	S022359	ERBA PATH	CHOL	239 mg/dl		70185	12-Jul-2023 10:26:35	240.930	12.050	204.78 - 277.08
2	S022359	ERBA PATH	CHOL	237 mg/dl		70314	14-Jul-2023 10:05:30	240.930	12.050	204.78 - 277.08
3	S022359	ERBA PATH	CHOL	234 mg/dl		70474	17-Jul-2023 10:08:25	240.930	12.050	204.78 - 277.08
4	S022359	ERBA PATH	CHOL	237 mg/dl		70596	19-Jul-2023 12:01:06	240.930	12.050	204.78 - 277.08
5	S022359	ERBA PATH	CHOL	228 mg/dl	-1SD	70726	21-Jul-2023 10:53:17	240.930	12.050	204.78 - 277.08
6	S022359	ERBA PATH	CHOL	235 mg/dl		70897	23-Jul-2023 09:42:58	240.930	12.050	204.78 - 277.08
7	S022359	ERBA PATH	CHOL	236 mg/dl		71013	25-Jul-2023 10:27:26	240.930	12.050	204.78 - 277.08
8	S022359	ERBA PATH	CHOL	259 mg/dl	+1SD	71114	27-Jul-2023 11:02:45	240.930	12.050	204.78 - 277.08
9	S022359	ERBA PATH	CHOL	238 mg/dl		71186	29-Jul-2023 09:29:36	240.930	12.050	204.78 - 277.08
10	S022359	ERBA PATH	CHOL	237 mg/dl		71245	31-Jul-2023 11:18:16	240.930	12.050	204.78 - 277.08
11	S022359	ERBA PATH	CHOL	239 mg/dl		71355	3-Aug-2023 09:09:13	240.930	12.050	204.78 - 277.08
12	S022359	ERBA PATH	CHOL	241 mg/dl		71480	5-Aug-2023 11:23:52	240.930	12.050	204.78 - 277.08
13	S022359	ERBA PATH	CHOL	245 mg/dl		71590	7-Aug-2023 11:16:32	240.930	12.050	204.78 - 277.08
14	S022359	ERBA PATH	CHOL	244 mg/dl		71715	9-Aug-2023 11:32:16	240.930	12.050	204.78 - 277.08
15	S022359	ERBA PATH	CHOL	241 mg/dl		71815	10-Aug-2023 10:40:58	240.930	12.050	204.78 - 277.08
16	S022359	ERBA PATH	CHOL	241 mg/dl		71946	12-Aug-2023 12:01:51	240.930	12.050	204.78 - 277.08

QC Data - EM 200

Test : CHOL

Date From : 13-Jul-2023

Control : ERBA PATH

Date To : 12-Aug-2023

Level : High

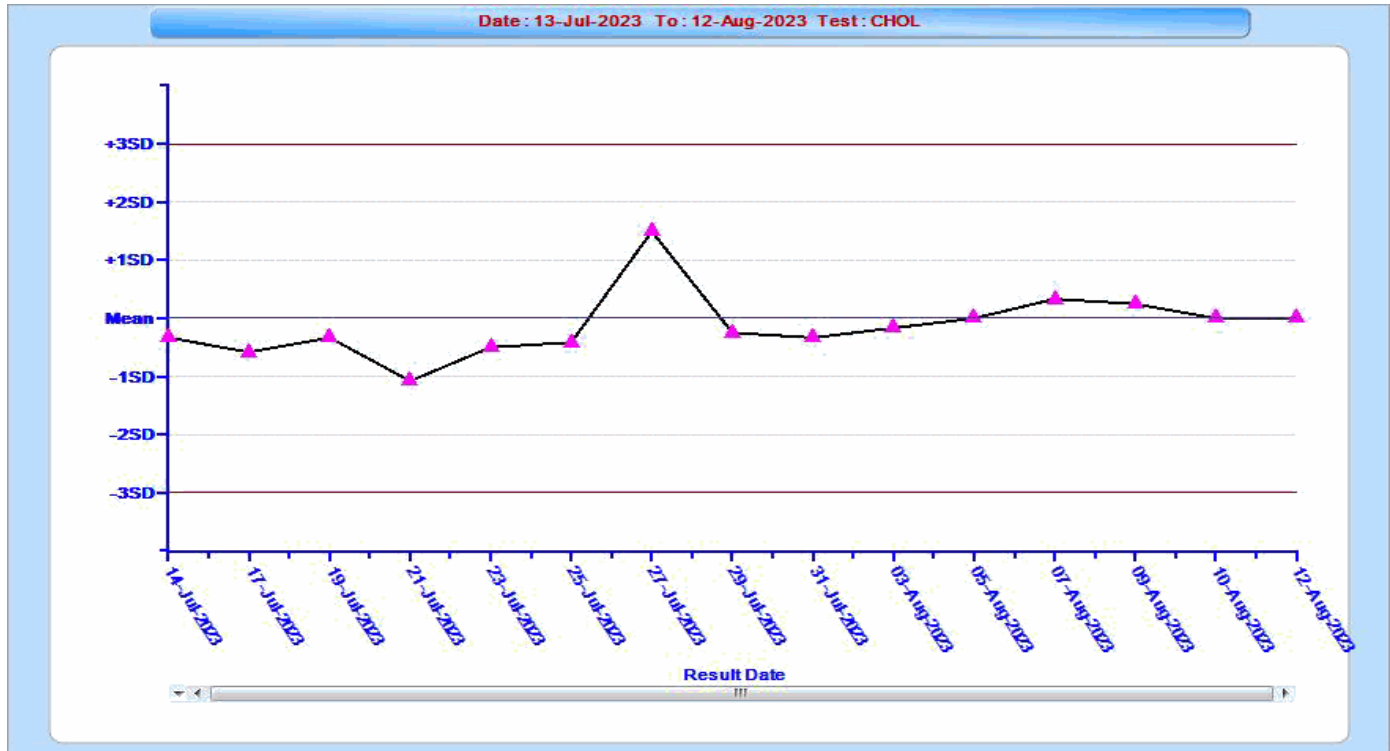
ExpDate :31-Dec-2025

Lot No. : S022359

Batch No. : ---

Mean : 240.93

SD : 12.05



X Calculation : R= Range of average of Results per day :

Level	N	Avg	SD	% CV	R
High	15	239	6.8504	2.8663	31

R Calculation : R= Range of Result Variations per day :

Level	N	Avg	SD	% CV	R
High	15	0	0	0	0

QC Data - EM 200

Sr #	Date	Result	Mean	SD	Interval (3SD)	Deviation	Dev %	Error %	Batch	QC Remarks
1	14 Jul 2023	237	240.930	12.05	204.78 - 277.08		-4	-1.66	1	
2	17 Jul 2023	234	240.930	12.05	204.78 - 277.08		-7	-2.91	1	
3	19 Jul 2023	237	240.930	12.05	204.78 - 277.08		-4	-1.66	1	
4	21 Jul 2023	228	240.930	12.05	204.78 - 277.08	-1SD	-13	-5.40	1	
5	23 Jul 2023	235	240.930	12.05	204.78 - 277.08		-6	-2.49	1	
6	25 Jul 2023	236	240.930	12.05	204.78 - 277.08		-5	-2.08	1	
7	27 Jul 2023	259	240.930	12.05	204.78 - 277.08	+1SD	18	7.47	1	
8	29 Jul 2023	238	240.930	12.05	204.78 - 277.08		-3	-1.25	1	
9	31 Jul 2023	237	240.930	12.05	204.78 - 277.08		-4	-1.66	1	
10	03 Aug 2023	239	240.930	12.05	204.78 - 277.08		-2	-0.83	1	
11	05 Aug 2023	241	240.930	12.05	204.78 - 277.08		0	0.00	1	
12	07 Aug 2023	245	240.930	12.05	204.78 - 277.08		4	1.66	1	
13	09 Aug 2023	244	240.930	12.05	204.78 - 277.08		3	1.25	1	
14	10 Aug 2023	241	240.930	12.05	204.78 - 277.08		0	0.00	2	
15	12 Aug 2023	241	240.930	12.05	204.78 - 277.08		0	0.00	1	

Result Reprint

Report Type

: Controls

12-Jul-2023 To 12-Aug-2023

Test: CRE1

Sr #	Lot #	Consumable	Test	Result Unit	Flag	Curve #	Result Date	Mean	SD	Interval (3SD)
1	S022359	ERBA PATH	CRE1	3.65 mg/dl	+3SD	70206	12-Jul-2023 10:32:54	2.970	0.210	2.34 - 3.6
2	S022359	ERBA PATH	CRE1	3.68 mg/dl	+1SD	70335	14-Jul-2023 10:11:49	3.290	0.230	2.6 - 3.98
3	S022359	ERBA PATH	CRE1	3.47 mg/dl		70495	17-Jul-2023 10:14:44	3.290	0.230	2.6 - 3.98
4	S022359	ERBA PATH	CRE1	3.63 mg/dl	+1SD	70617	19-Jul-2023 12:07:25	3.290	0.230	2.6 - 3.98
5	S022359	ERBA PATH	CRE1	3.56 mg/dl	+1SD	70745	21-Jul-2023 10:59:00	3.290	0.230	2.6 - 3.98
6	S022359	ERBA PATH	CRE1	3.57 mg/dl	+1SD	70918	23-Jul-2023 09:49:17	3.290	0.230	2.6 - 3.98
7	S022359	ERBA PATH	CRE1	3.46 mg/dl		71034	25-Jul-2023 10:33:45	3.290	0.230	2.6 - 3.98
8	S022359	ERBA PATH	CRE1	3.67 mg/dl	+1SD	71135	27-Jul-2023 11:09:04	3.290	0.230	2.6 - 3.98
9	S022359	ERBA PATH	CRE1	3.65 mg/dl	+1SD	71207	29-Jul-2023 09:35:55	3.290	0.230	2.6 - 3.98
10	S022359	ERBA PATH	CRE1	3.53 mg/dl	+1SD	71266	31-Jul-2023 11:24:35	3.290	0.230	2.6 - 3.98
11	S022359	ERBA PATH	CRE1	3.65 mg/dl	+1SD	71376	3-Aug-2023 09:15:50	3.290	0.230	2.6 - 3.98
12	S022359	ERBA PATH	CRE1	3.70 mg/dl	+1SD	71501	5-Aug-2023 11:31:06	3.290	0.230	2.6 - 3.98
13	S022359	ERBA PATH	CRE1	3.80 mg/dl	+2SD	71611	7-Aug-2023 11:22:51	3.290	0.230	2.6 - 3.98
14	S022359	ERBA PATH	CRE1	3.48 mg/dl		71736	9-Aug-2023 11:38:35	3.290	0.230	2.6 - 3.98
15	S022359	ERBA PATH	CRE1	3.77 mg/dl	+2SD	71827	10-Aug-2023 10:44:35	3.290	0.230	2.6 - 3.98
16	S022359	ERBA PATH	CRE1	3.75 mg/dl	+1SD	71963	12-Aug-2023 12:06:58	3.290	0.230	2.6 - 3.98

Print Date

12-Aug-2023

1 / 1

QC Data - EM 200

Test : CRE1

Date From : 13-Jul-2023

Control : ERBA PATH

Date To : 12-Aug-2023

Level : High

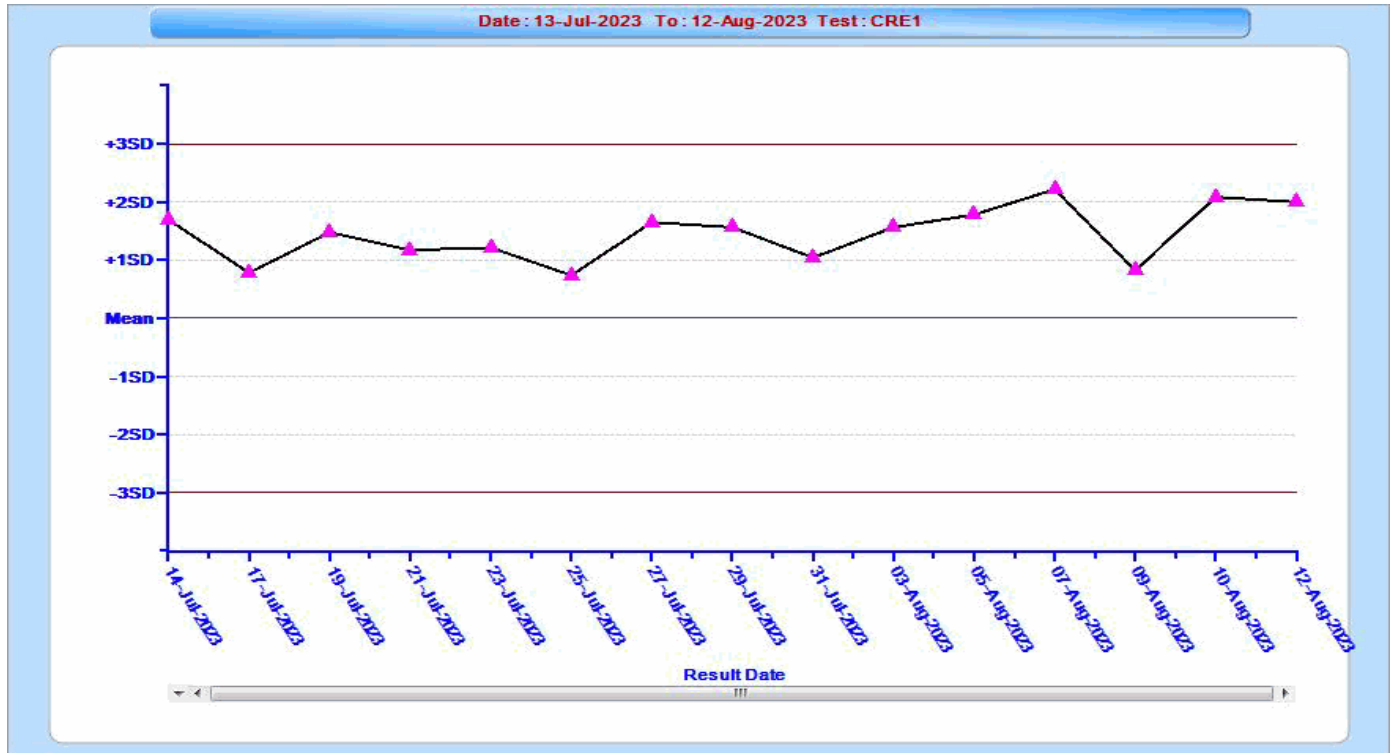
ExpDate :31-Dec-2025

Lot No. : S022359

Batch No. : ---

Mean : 3.29

SD : 0.23



X Calculation : R= Range of average of Results per day :

Level	N	Avg	SD	% CV	R
High	15	3.62	0.1096	3.0276	0.34

R Calculation : R= Range of Result Variations per day :

Level	N	Avg	SD	% CV	R
High	15	0	0	0	0

QC Data - EM 200

Sr #	Date	Result	Mean	SD	Interval (3SD)	Deviation	Dev %	Error %	Batch	QC Remarks
1	14 Jul 2023	3.68	3.290	0.23	2.60 - 3.98	+1SD	0.39	11.85	1	
2	17 Jul 2023	3.47	3.290	0.23	2.60 - 3.98		0.18	5.47	1	
3	19 Jul 2023	3.63	3.290	0.23	2.60 - 3.98	+1SD	0.34	10.33	1	
4	21 Jul 2023	3.56	3.290	0.23	2.60 - 3.98	+1SD	0.27	8.21	1	
5	23 Jul 2023	3.57	3.290	0.23	2.60 - 3.98	+1SD	0.28	8.51	1	
6	25 Jul 2023	3.46	3.290	0.23	2.60 - 3.98		0.17	5.17	1	
7	27 Jul 2023	3.67	3.290	0.23	2.60 - 3.98	+1SD	0.38	11.55	1	
8	29 Jul 2023	3.65	3.290	0.23	2.60 - 3.98	+1SD	0.36	10.94	1	
9	31 Jul 2023	3.53	3.290	0.23	2.60 - 3.98	+1SD	0.24	7.29	1	
10	03 Aug 2023	3.65	3.290	0.23	2.60 - 3.98	+1SD	0.36	10.94	1	
11	05 Aug 2023	3.70	3.290	0.23	2.60 - 3.98	+1SD	0.41	12.46	1	
12	07 Aug 2023	3.80	3.290	0.23	2.60 - 3.98	+2SD	0.51	15.50	1	
13	09 Aug 2023	3.48	3.290	0.23	2.60 - 3.98		0.19	5.78	1	
14	10 Aug 2023	3.77	3.290	0.23	2.60 - 3.98	+2SD	0.48	14.59	2	
15	12 Aug 2023	3.75	3.290	0.23	2.60 - 3.98	+1SD	0.46	13.98	1	

QC Data - EM 200

Test : GLU

Date From : 13-Jul-2023

Control : ERBA PATH

Date To : 12-Aug-2023

Level : High

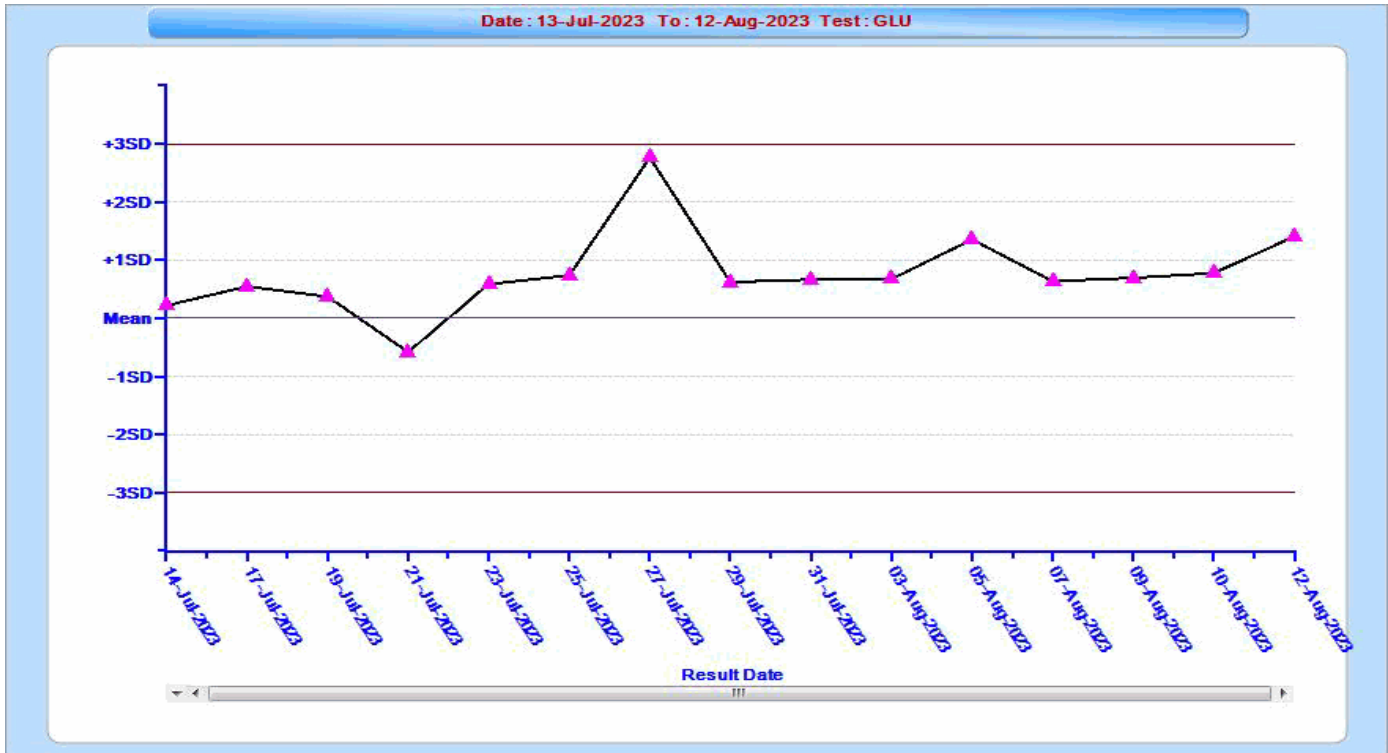
ExpDate :31-Dec-2025

Lot No. : S022359

Batch No. : ---

Mean : 272.82

SD : 13.64



X Calculation : R= Range of average of Results per day :

Level	N	Avg	SD	% CV	R
High	15	283.3	9.7498	3.4415	45.6

R Calculation : R= Range of Result Variations per day :

Level	N	Avg	SD	% CV	R
High	15	0	0	0	0

QC Data - EM 200

Sr #	Date	Result	Mean	SD	Interval (3SD)	Deviation	Dev %	Error%	Batch	QC Remarks
1	14 Jul 2023	275.8	272.820	13.64	231.90 - 313.74		3.0	1.10	1	
2	17 Jul 2023	280.3	272.820	13.64	231.90 - 313.74		7.5	2.75	1	
3	19 Jul 2023	277.9	272.820	13.64	231.90 - 313.74		5.1	1.87	1	
4	21 Jul 2023	264.9	272.820	13.64	231.90 - 313.74		-7.9	-2.90	1	
5	23 Jul 2023	280.8	272.820	13.64	231.90 - 313.74		8.0	2.93	1	
6	25 Jul 2023	282.9	272.820	13.64	231.90 - 313.74		10.1	3.70	1	
7	27 Jul 2023	310.5	272.820	13.64	231.90 - 313.74	+2SD	37.7	13.82	1	
8	29 Jul 2023	281.3	272.820	13.64	231.90 - 313.74		8.5	3.12	1	
9	31 Jul 2023	281.9	272.820	13.64	231.90 - 313.74		9.1	3.34	1	
10	03 Aug 2023	282.0	272.820	13.64	231.90 - 313.74		9.2	3.37	1	
11	05 Aug 2023	291.3	272.820	13.64	231.90 - 313.74	+1SD	18.5	6.78	1	
12	07 Aug 2023	281.5	272.820	13.64	231.90 - 313.74		8.7	3.19	1	
13	09 Aug 2023	282.3	272.820	13.64	231.90 - 313.74		9.5	3.48	1	
14	10 Aug 2023	283.4	272.820	13.64	231.90 - 313.74		10.6	3.89	2	
15	12 Aug 2023	292.0	272.820	13.64	231.90 - 313.74	+1SD	19.2	7.04	1	

Result Reprint

Report Type

: Controls

12-Jul-2023 To 12-Aug-2023

Test: GLU

Sr #	Lot #	Consumable	Test	Result Unit	Flag	Curve #	Result Date	Mean	SD	Interval (3SD)
1	S022359	ERBA PATH	GLU	281.7 mg/dl		70182	12-Jul-2023 10:25:41	272.820	13.640	231.9 - 313.74
2	S022359	ERBA PATH	GLU	275.8 mg/dl		70311	14-Jul-2023 10:04:36	272.820	13.640	231.9 - 313.74
3	S022359	ERBA PATH	GLU	280.3 mg/dl		70471	17-Jul-2023 10:07:31	272.820	13.640	231.9 - 313.74
4	S022359	ERBA PATH	GLU	277.9 mg/dl		70593	19-Jul-2023 12:00:11	272.820	13.640	231.9 - 313.74
5	S022359	ERBA PATH	GLU	264.9 mg/dl		70723	21-Jul-2023 10:52:23	272.820	13.640	231.9 - 313.74
6	S022359	ERBA PATH	GLU	280.8 mg/dl		70894	23-Jul-2023 09:42:04	272.820	13.640	231.9 - 313.74
7	S022359	ERBA PATH	GLU	282.9 mg/dl		71010	25-Jul-2023 10:26:32	272.820	13.640	231.9 - 313.74
8	S022359	ERBA PATH	GLU	310.5 mg/dl	+2SD	71111	27-Jul-2023 11:01:51	272.820	13.640	231.9 - 313.74
9	S022359	ERBA PATH	GLU	281.3 mg/dl		71183	29-Jul-2023 09:28:41	272.820	13.640	231.9 - 313.74
10	S022359	ERBA PATH	GLU	281.9 mg/dl		71242	31-Jul-2023 11:17:22	272.820	13.640	231.9 - 313.74
11	S022359	ERBA PATH	GLU	282.0 mg/dl		71352	3-Aug-2023 09:08:19	272.820	13.640	231.9 - 313.74
12	S022359	ERBA PATH	GLU	291.3 mg/dl	+1SD	71477	5-Aug-2023 11:22:58	272.820	13.640	231.9 - 313.74
13	S022359	ERBA PATH	GLU	281.5 mg/dl		71587	7-Aug-2023 11:15:38	272.820	13.640	231.9 - 313.74
14	S022359	ERBA PATH	GLU	282.3 mg/dl		71714	9-Aug-2023 11:31:58	272.820	13.640	231.9 - 313.74
15	S022359	ERBA PATH	GLU	283.4 mg/dl		71812	10-Aug-2023 10:40:04	272.820	13.640	231.9 - 313.74
16	S022359	ERBA PATH	GLU	292.0 mg/dl	+1SD	71943	12-Aug-2023 12:00:57	272.820	13.640	231.9 - 313.74

Result Reprint

Report Type

: Controls

12-Jul-2023 To 12-Aug-2023

Test: PRO

Sr #	Lot #	Consumable	Test	Result Unit	Flag	Curve #	Result Date	Mean	SD	Interval (3SD)
1	S022359	ERBA PATH	PRO	8.64 g/dl		70197	12-Jul-2023 10:30:12	8.430	0.560	6.75 - 10.11
2	S022359	ERBA PATH	PRO	8.68 g/dl		70326	14-Jul-2023 10:09:07	8.430	0.560	6.75 - 10.11
3	S022359	ERBA PATH	PRO	8.70 g/dl		70486	17-Jul-2023 10:12:02	8.430	0.560	6.75 - 10.11
4	S022359	ERBA PATH	PRO	8.70 g/dl		70608	19-Jul-2023 12:04:42	8.430	0.560	6.75 - 10.11
5	S022359	ERBA PATH	PRO	8.45 g/dl		70736	21-Jul-2023 10:56:18	8.430	0.560	6.75 - 10.11
6	S022359	ERBA PATH	PRO	8.69 g/dl		70909	23-Jul-2023 09:46:35	8.430	0.560	6.75 - 10.11
7	S022359	ERBA PATH	PRO	8.69 g/dl		71025	25-Jul-2023 10:31:03	8.430	0.560	6.75 - 10.11
8	S022359	ERBA PATH	PRO	9.60 g/dl	+2SD	71126	27-Jul-2023 11:06:22	8.430	0.560	6.75 - 10.11
9	S022359	ERBA PATH	PRO	8.83 g/dl		71198	29-Jul-2023 09:33:12	8.430	0.560	6.75 - 10.11
10	S022359	ERBA PATH	PRO	8.73 g/dl		71257	31-Jul-2023 11:21:53	8.430	0.560	6.75 - 10.11
11	S022359	ERBA PATH	PRO	8.60 g/dl		71367	3-Aug-2023 09:13:08	8.430	0.560	6.75 - 10.11
12	S022359	ERBA PATH	PRO	8.67 g/dl		71492	5-Aug-2023 11:27:47	8.430	0.560	6.75 - 10.11
13	S022359	ERBA PATH	PRO	9.01 g/dl	+1SD	71602	7-Aug-2023 11:20:09	8.430	0.560	6.75 - 10.11
14	S022359	ERBA PATH	PRO	8.53 g/dl		71727	9-Aug-2023 11:35:53	8.430	0.560	6.75 - 10.11
15	S022359	ERBA PATH	PRO	8.47 g/dl		71824	10-Aug-2023 10:43:40	8.430	0.560	6.75 - 10.11
16	S022359	ERBA PATH	PRO	8.40 g/dl		71957	12-Aug-2023 12:05:10	8.430	0.560	6.75 - 10.11

QC Data - EM 200

Test : PRO

Date From : 13-Jul-2023

Control : ERBA PATH

Date To : 12-Aug-2023

Level : High

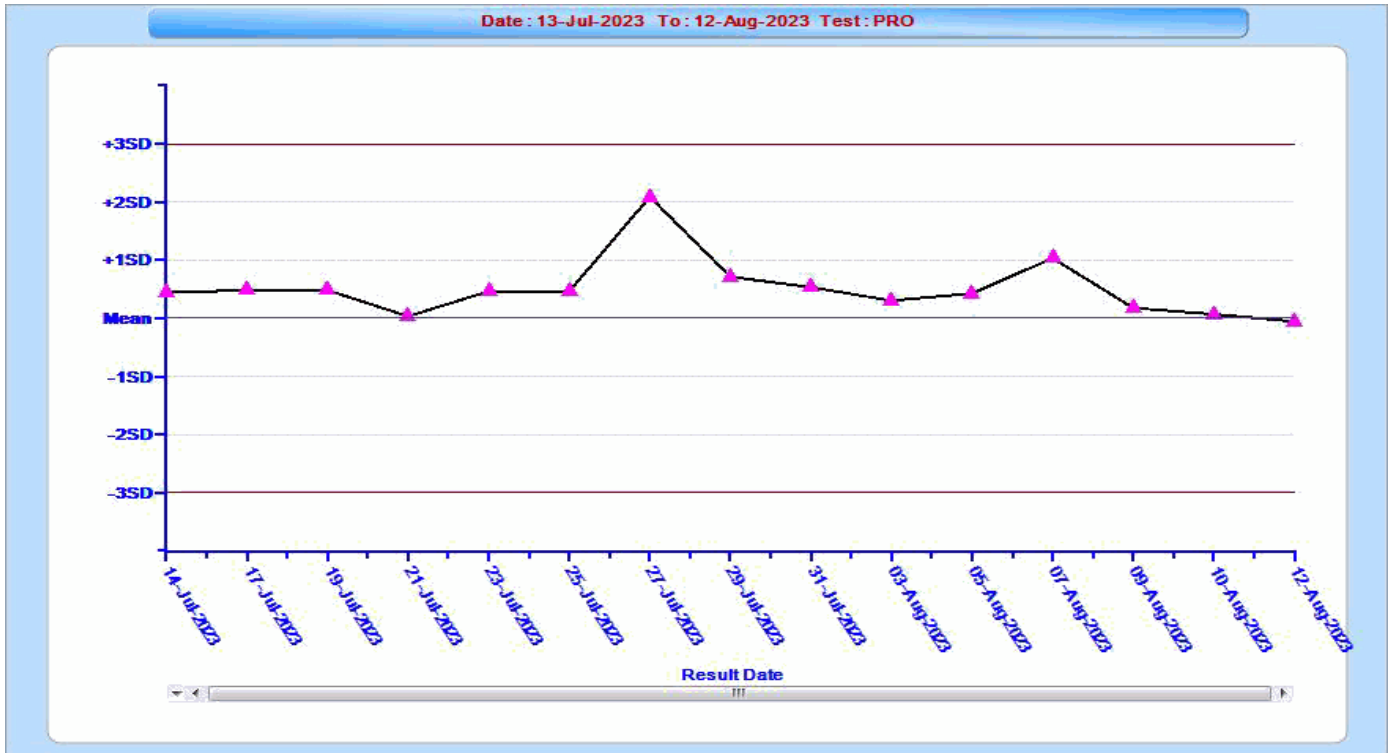
ExpDate :31-Dec-2025

Lot No. : S022359

Batch No. : ---

Mean : 8.43

SD : 0.56



X Calculation : R= Range of average of Results per day :

Level	N	Avg	SD	% CV	R
High	15	8.72	0.2886	3.3096	1.2

R Calculation : R= Range of Result Variations per day :

Level	N	Avg	SD	% CV	R
High	15	0	0	0	0

QC Data - EM 200

Sr #	Date	Result	Mean	SD	Interval (3SD)	Deviation	Dev %	Error%	Batch	QC Remarks
1	14 Jul 2023	8.68	8.430	0.56	6.75 - 10.11		0.25	2.97	1	
2	17 Jul 2023	8.70	8.430	0.56	6.75 - 10.11		0.27	3.20	1	
3	19 Jul 2023	8.70	8.430	0.56	6.75 - 10.11		0.27	3.20	1	
4	21 Jul 2023	8.45	8.430	0.56	6.75 - 10.11		0.02	0.24	1	
5	23 Jul 2023	8.69	8.430	0.56	6.75 - 10.11		0.26	3.08	1	
6	25 Jul 2023	8.69	8.430	0.56	6.75 - 10.11		0.26	3.08	1	
7	27 Jul 2023	9.60	8.430	0.56	6.75 - 10.11	+2SD	1.17	13.88	1	
8	29 Jul 2023	8.83	8.430	0.56	6.75 - 10.11		0.40	4.74	1	
9	31 Jul 2023	8.73	8.430	0.56	6.75 - 10.11		0.30	3.56	1	
10	03 Aug 2023	8.60	8.430	0.56	6.75 - 10.11		0.17	2.02	1	
11	05 Aug 2023	8.67	8.430	0.56	6.75 - 10.11		0.24	2.85	1	
12	07 Aug 2023	9.01	8.430	0.56	6.75 - 10.11	+1SD	0.58	6.88	1	
13	09 Aug 2023	8.53	8.430	0.56	6.75 - 10.11		0.10	1.19	1	
14	10 Aug 2023	8.47	8.430	0.56	6.75 - 10.11		0.04	0.47	2	
15	12 Aug 2023	8.40	8.430	0.56	6.75 - 10.11		-0.03	-0.36	1	

QC Data - EM 200

Test : BIT

Date From : 13-Jul-2023

Control : ERBA PATH

Date To : 12-Aug-2023

Level : High

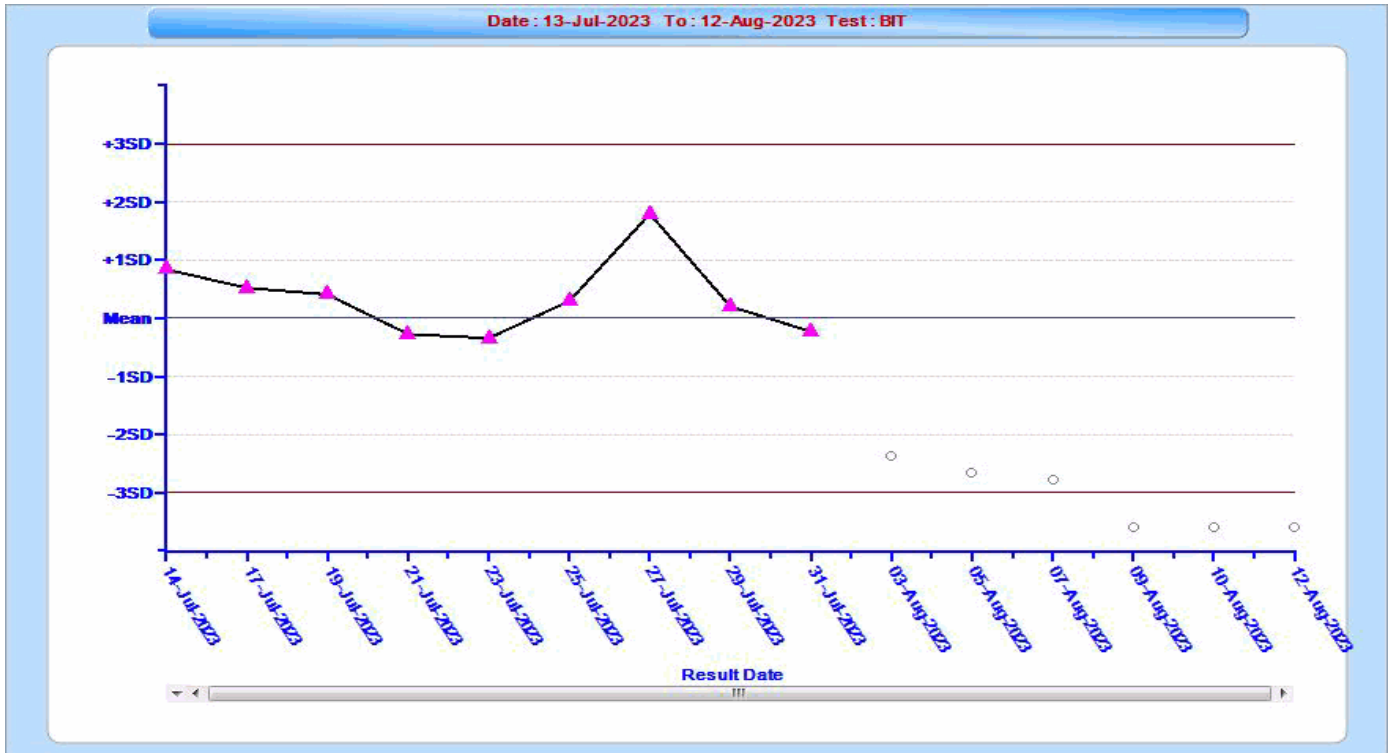
ExpDate :31-Dec-2025

Lot No. : S022359

Batch No. : ---

Mean : 5.27

SD : 0.44



X Calculation : R= Range of average of Results per day :

Level	N	Avg	SD	% CV	R
High	9	5.43	0.2946	5.4254	0.94

R Calculation : R= Range of Result Variations per day :

Level	N	Avg	SD	% CV	R
High	9	0	0	0	0

QC Data - EM 200

Sr #	Date	Result	Mean	SD	Interval (3SD)	Deviation	Dev %	Error%	Batch	QC Remarks
1	14 Jul 2023	5.64	5.270	0.44	3.95 - 6.59		0.37	7.02	1	
2	17 Jul 2023	5.50	5.270	0.44	3.95 - 6.59		0.23	4.36	1	
3	19 Jul 2023	5.45	5.270	0.44	3.95 - 6.59		0.18	3.42	1	
4	21 Jul 2023	5.15	5.270	0.44	3.95 - 6.59		-0.12	-2.28	1	
5	23 Jul 2023	5.12	5.270	0.44	3.95 - 6.59		-0.15	-2.85	1	
6	25 Jul 2023	5.40	5.270	0.44	3.95 - 6.59		0.13	2.47	1	
7	27 Jul 2023	6.06	5.270	0.44	3.95 - 6.59	+1SD	0.79	14.99	1	
8	29 Jul 2023	5.36	5.270	0.44	3.95 - 6.59		0.09	1.71	1	
9	31 Jul 2023	5.17	5.270	0.44	3.95 - 6.59		-0.10	-1.90	1	

Result Reprint

Report Type

: Controls

12-Jul-2023 To 12-Aug-2023

Test: TGL1

Sr #	Lot #	Consumable	Test	Result Unit	Flag	Curve #	Result Date	Mean	SD	Interval (3SD)
1	S022359	ERBA PATH	TGL1	208.1 mg/dl		70332	14-Jul-2023 10:10:55	210.790	10.540	179.17 - 242.41
2	S022359	ERBA PATH	TGL1	203.5 mg/dl		70492	17-Jul-2023 10:13:50	210.790	10.540	179.17 - 242.41
3	S022359	ERBA PATH	TGL1	204.5 mg/dl		70614	19-Jul-2023 12:06:31	210.790	10.540	179.17 - 242.41
4	S022359	ERBA PATH	TGL1	191.5 mg/dl	-1SD	70742	21-Jul-2023 10:58:06	210.790	10.540	179.17 - 242.41
5	S022359	ERBA PATH	TGL1	201.7 mg/dl		70915	23-Jul-2023 09:48:23	210.790	10.540	179.17 - 242.41
6	S022359	ERBA PATH	TGL1	204.2 mg/dl		71031	25-Jul-2023 10:32:51	210.790	10.540	179.17 - 242.41
7	S022359	ERBA PATH	TGL1	218.1 mg/dl		71132	27-Jul-2023 11:08:10	210.790	10.540	179.17 - 242.41
8	S022359	ERBA PATH	TGL1	209.0 mg/dl		71204	29-Jul-2023 09:35:01	210.790	10.540	179.17 - 242.41
9	S022359	ERBA PATH	TGL1	204.4 mg/dl		71263	31-Jul-2023 11:23:41	210.790	10.540	179.17 - 242.41
10	S022359	ERBA PATH	TGL1	214.3 mg/dl		71373	3-Aug-2023 09:14:56	210.790	10.540	179.17 - 242.41
11	S022359	ERBA PATH	TGL1	224.9 mg/dl	+1SD	71498	5-Aug-2023 11:29:53	210.790	10.540	179.17 - 242.41
12	S022359	ERBA PATH	TGL1	219.7 mg/dl		71608	7-Aug-2023 11:21:57	210.790	10.540	179.17 - 242.41
13	S022359	ERBA PATH	TGL1	225.0 mg/dl	+1SD	71733	9-Aug-2023 11:37:41	210.790	10.540	179.17 - 242.41
14	S022359	ERBA PATH	TGL1	218.9 mg/dl		71960	12-Aug-2023 12:06:04	210.790	10.540	179.17 - 242.41

QC Data - EM 200

Test : TGL1

Date From : 13-Jul-2023

Control : ERBA PATH

Date To : 12-Aug-2023

Level : High

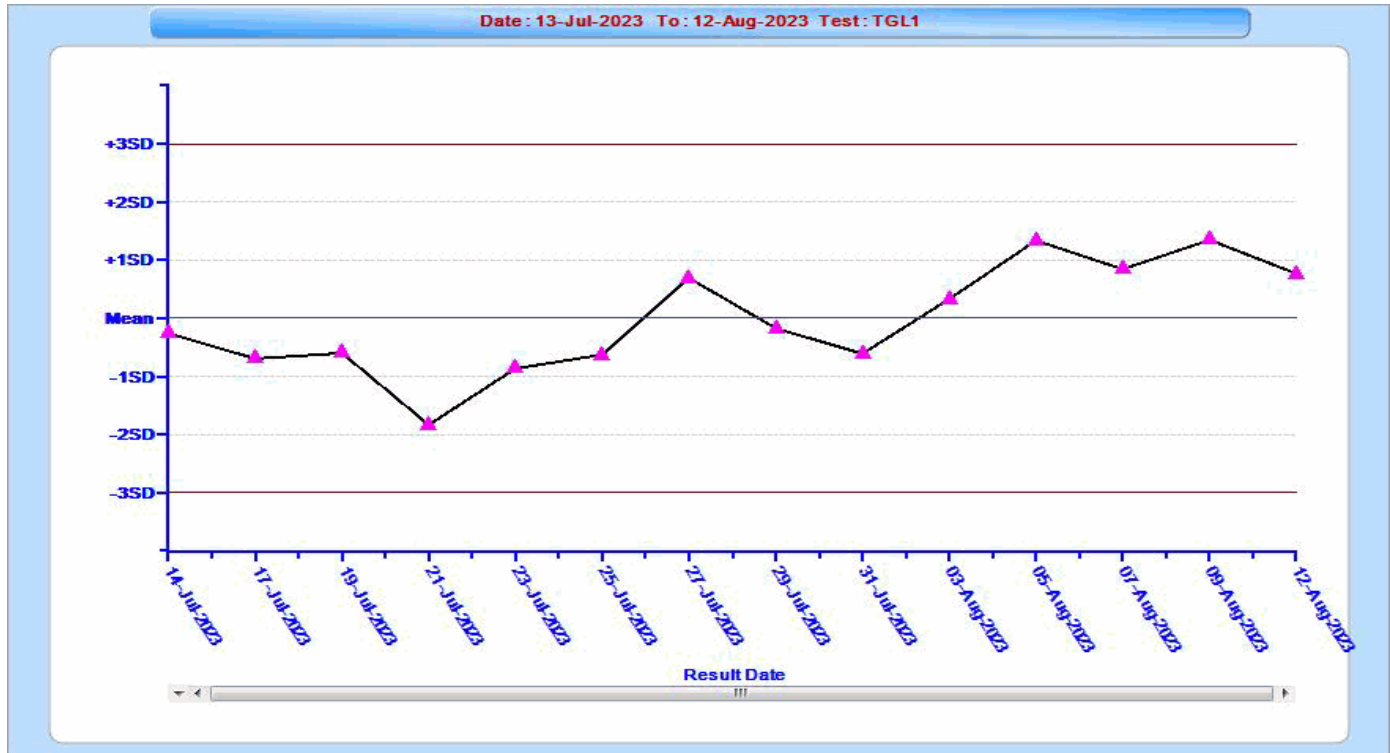
ExpDate :31-Dec-2025

Lot No. : S022359

Batch No. : ---

Mean : 210.79

SD : 10.54



X Calculation : R= Range of average of Results per day :

Level	N	Avg	SD	% CV	R
High	14	210.6	9.8189	4.6623	33.5

R Calculation : R= Range of Result Variations per day :

Level	N	Avg	SD	% CV	R
High	14	0	0	0	0

QC Data - EM 200

Sr #	Date	Result	Mean	SD	Interval (3SD)	Deviation	Dev %	Error %	Batch	QC Remarks
1	14 Jul 2023	208.1	210.790	10.54	179.17 - 242.41		-2.7	-1.28	1	
2	17 Jul 2023	203.5	210.790	10.54	179.17 - 242.41		-7.3	-3.46	1	
3	19 Jul 2023	204.5	210.790	10.54	179.17 - 242.41		-6.3	-2.99	1	
4	21 Jul 2023	191.5	210.790	10.54	179.17 - 242.41	-1SD	-19.3	-9.16	1	
5	23 Jul 2023	201.7	210.790	10.54	179.17 - 242.41		-9.1	-4.32	1	
6	25 Jul 2023	204.2	210.790	10.54	179.17 - 242.41		-6.6	-3.13	1	
7	27 Jul 2023	218.1	210.790	10.54	179.17 - 242.41		7.3	3.46	1	
8	29 Jul 2023	209.0	210.790	10.54	179.17 - 242.41		-1.8	-0.85	1	
9	31 Jul 2023	204.4	210.790	10.54	179.17 - 242.41		-6.4	-3.04	1	
10	03 Aug 2023	214.3	210.790	10.54	179.17 - 242.41		3.5	1.66	1	
11	05 Aug 2023	224.9	210.790	10.54	179.17 - 242.41	+1SD	14.1	6.69	1	
12	07 Aug 2023	219.7	210.790	10.54	179.17 - 242.41		8.9	4.22	1	
13	09 Aug 2023	225.0	210.790	10.54	179.17 - 242.41	+1SD	14.2	6.74	1	
14	12 Aug 2023	218.9	210.790	10.54	179.17 - 242.41		8.1	3.84	1	

Result Reprint

Report Type

: Controls

12-Jul-2023 To 12-Aug-2023

Test: UA

Sr #	Lot #	Consumable	Test	Result Unit	Flag	Curve #	Result Date	Mean	SD	Interval (3SD)
1	S022359	ERBA PATH	UA	11.4 mg/dl		70188	12-Jul-2023 10:27:29	11.990	0.600	10.19 - 13.79
2	S022359	ERBA PATH	UA	11.5 mg/dl		70317	14-Jul-2023 10:06:24	11.990	0.600	10.19 - 13.79
3	S022359	ERBA PATH	UA	11.4 mg/dl		70477	17-Jul-2023 10:09:19	11.990	0.600	10.19 - 13.79
4	S022359	ERBA PATH	UA	11.2 mg/dl	-1SD	70599	19-Jul-2023 12:02:00	11.990	0.600	10.19 - 13.79
5	S022359	ERBA PATH	UA	11.3 mg/dl	-1SD	70727	21-Jul-2023 10:53:35	11.990	0.600	10.19 - 13.79
6	S022359	ERBA PATH	UA	11.5 mg/dl		70900	23-Jul-2023 09:43:52	11.990	0.600	10.19 - 13.79
7	S022359	ERBA PATH	UA	11.3 mg/dl	-1SD	71016	25-Jul-2023 10:28:20	11.990	0.600	10.19 - 13.79
8	S022359	ERBA PATH	UA	12.4 mg/dl		71117	27-Jul-2023 11:03:39	11.990	0.600	10.19 - 13.79
9	S022359	ERBA PATH	UA	11.6 mg/dl		71189	29-Jul-2023 09:30:30	11.990	0.600	10.19 - 13.79
10	S022359	ERBA PATH	UA	11.5 mg/dl		71248	31-Jul-2023 11:19:10	11.990	0.600	10.19 - 13.79
11	S022359	ERBA PATH	UA	12.3 mg/dl		71358	3-Aug-2023 09:10:25	11.990	0.600	10.19 - 13.79
12	S022359	ERBA PATH	UA	12.3 mg/dl		71483	5-Aug-2023 11:25:04	11.990	0.600	10.19 - 13.79
13	S022359	ERBA PATH	UA	12.3 mg/dl		71593	7-Aug-2023 11:17:26	11.990	0.600	10.19 - 13.79
14	S022359	ERBA PATH	UA	11.7 mg/dl		71718	9-Aug-2023 11:33:10	11.990	0.600	10.19 - 13.79
15	S022359	ERBA PATH	UA	11.7 mg/dl		71949	12-Aug-2023 12:02:46	11.990	0.600	10.19 - 13.79

QC Data - EM 200

Test : UA

Date From : 13-Jul-2023

Control : ERBA PATH

Date To : 12-Aug-2023

Level : High

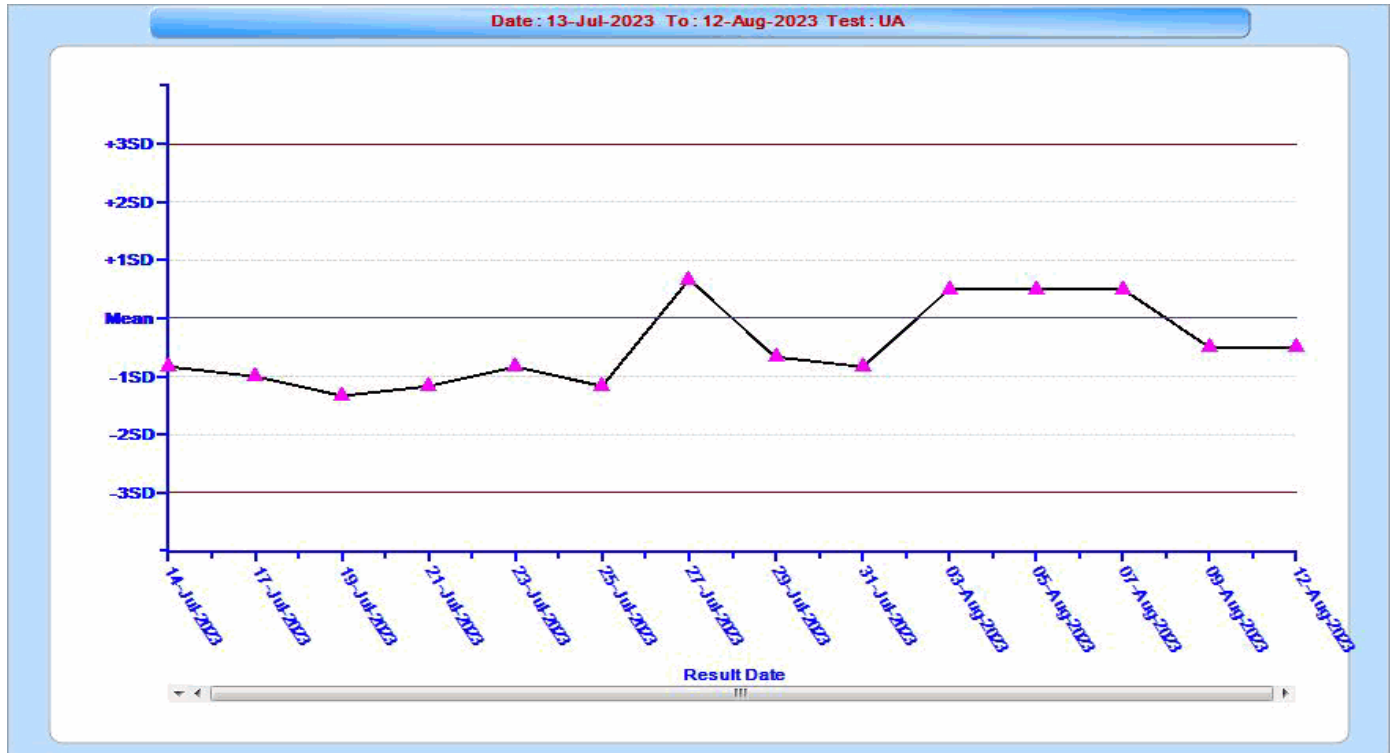
ExpDate :31-Dec-2025

Lot No. : S022359

Batch No. : ---

Mean : 11.99

SD : 0.6



X Calculation : R= Range of average of Results per day :

Level	N	Avg	SD	% CV	R
High	14	11.7	0.4261	3.6419	1.2

R Calculation : R= Range of Result Variations per day :

Level	N	Avg	SD	% CV	R
High	14	0	0	0	0

QC Data - EM 200

Sr #	Date	Result	Mean	SD	Interval (3SD)	Deviation	Dev %	Error %	Batch	QC Remarks
1	14 Jul 2023	11.5	11.990	0.60	10.19 - 13.79		-0.5	-4.17	1	
2	17 Jul 2023	11.4	11.990	0.60	10.19 - 13.79		-0.6	-5.00	1	
3	19 Jul 2023	11.2	11.990	0.60	10.19 - 13.79	-1SD	-0.8	-6.67	1	
4	21 Jul 2023	11.3	11.990	0.60	10.19 - 13.79	-1SD	-0.7	-5.84	1	
5	23 Jul 2023	11.5	11.990	0.60	10.19 - 13.79		-0.5	-4.17	1	
6	25 Jul 2023	11.3	11.990	0.60	10.19 - 13.79	-1SD	-0.7	-5.84	1	
7	27 Jul 2023	12.4	11.990	0.60	10.19 - 13.79		0.4	3.34	1	
8	29 Jul 2023	11.6	11.990	0.60	10.19 - 13.79		-0.4	-3.34	1	
9	31 Jul 2023	11.5	11.990	0.60	10.19 - 13.79		-0.5	-4.17	1	
10	03 Aug 2023	12.3	11.990	0.60	10.19 - 13.79		0.3	2.50	1	
11	05 Aug 2023	12.3	11.990	0.60	10.19 - 13.79		0.3	2.50	1	
12	07 Aug 2023	12.3	11.990	0.60	10.19 - 13.79		0.3	2.50	1	
13	09 Aug 2023	11.7	11.990	0.60	10.19 - 13.79		-0.3	-2.50	1	
14	12 Aug 2023	11.7	11.990	0.60	10.19 - 13.79		-0.3	-2.50	1	

Result Reprint

Report Type

: Controls

12-Jul-2023 To 12-Aug-2023

Test: UREA

Sr #	Lot #	Consumable	Test	Result	Unit	Flag	Curve #	Result Date	Mean	SD	Interval (3SD)
1	S022359	ERBA PATH	UREA	98.1	mg/dl		70179	12-Jul-2023 10:24:47	95.850	4.790	81.48 - 110.22
2	S022359	ERBA PATH	UREA	97.9	mg/dl		70308	14-Jul-2023 10:03:42	95.850	4.790	81.48 - 110.22
3	S022359	ERBA PATH	UREA	100.2	mg/dl		70468	17-Jul-2023 10:06:37	95.850	4.790	81.48 - 110.22
4	S022359	ERBA PATH	UREA	100.8	mg/dl	+1SD	70590	19-Jul-2023 11:59:17	95.850	4.790	81.48 - 110.22
5	S022359	ERBA PATH	UREA	93.3	mg/dl		70720	21-Jul-2023 10:51:29	95.850	4.790	81.48 - 110.22
6	S022359	ERBA PATH	UREA	101.2	mg/dl	+1SD	70891	23-Jul-2023 09:41:10	95.850	4.790	81.48 - 110.22
7	S022359	ERBA PATH	UREA	101.7	mg/dl	+1SD	71007	25-Jul-2023 10:25:38	95.850	4.790	81.48 - 110.22
8	S022359	ERBA PATH	UREA	108.8	mg/dl	+2SD	71108	27-Jul-2023 11:00:57	95.850	4.790	81.48 - 110.22
9	S022359	ERBA PATH	UREA	101.4	mg/dl	+1SD	71180	29-Jul-2023 09:27:47	95.850	4.790	81.48 - 110.22
10	S022359	ERBA PATH	UREA	100.9	mg/dl	+1SD	71239	31-Jul-2023 11:16:28	95.850	4.790	81.48 - 110.22
11	S022359	ERBA PATH	UREA	101.9	mg/dl	+1SD	71349	3-Aug-2023 09:07:07	95.850	4.790	81.48 - 110.22
12	S022359	ERBA PATH	UREA	103.1	mg/dl	+1SD	71474	5-Aug-2023 11:21:46	95.850	4.790	81.48 - 110.22
13	S022359	ERBA PATH	UREA	102.5	mg/dl	+1SD	71584	7-Aug-2023 11:14:44	95.850	4.790	81.48 - 110.22
14	S022359	ERBA PATH	UREA	97.9	mg/dl		71711	9-Aug-2023 11:31:04	95.850	4.790	81.48 - 110.22
15	S022359	ERBA PATH	UREA	101.9	mg/dl	+1SD	71809	10-Aug-2023 10:39:10	95.850	4.790	81.48 - 110.22
16	S022359	ERBA PATH	UREA	102.5	mg/dl	+1SD	71940	12-Aug-2023 12:00:03	95.850	4.790	81.48 - 110.22

QC Data - EM 200

Test : UREA

Date From : 13-Jul-2023

Control : ERBA PATH

Date To : 12-Aug-2023

Level : High

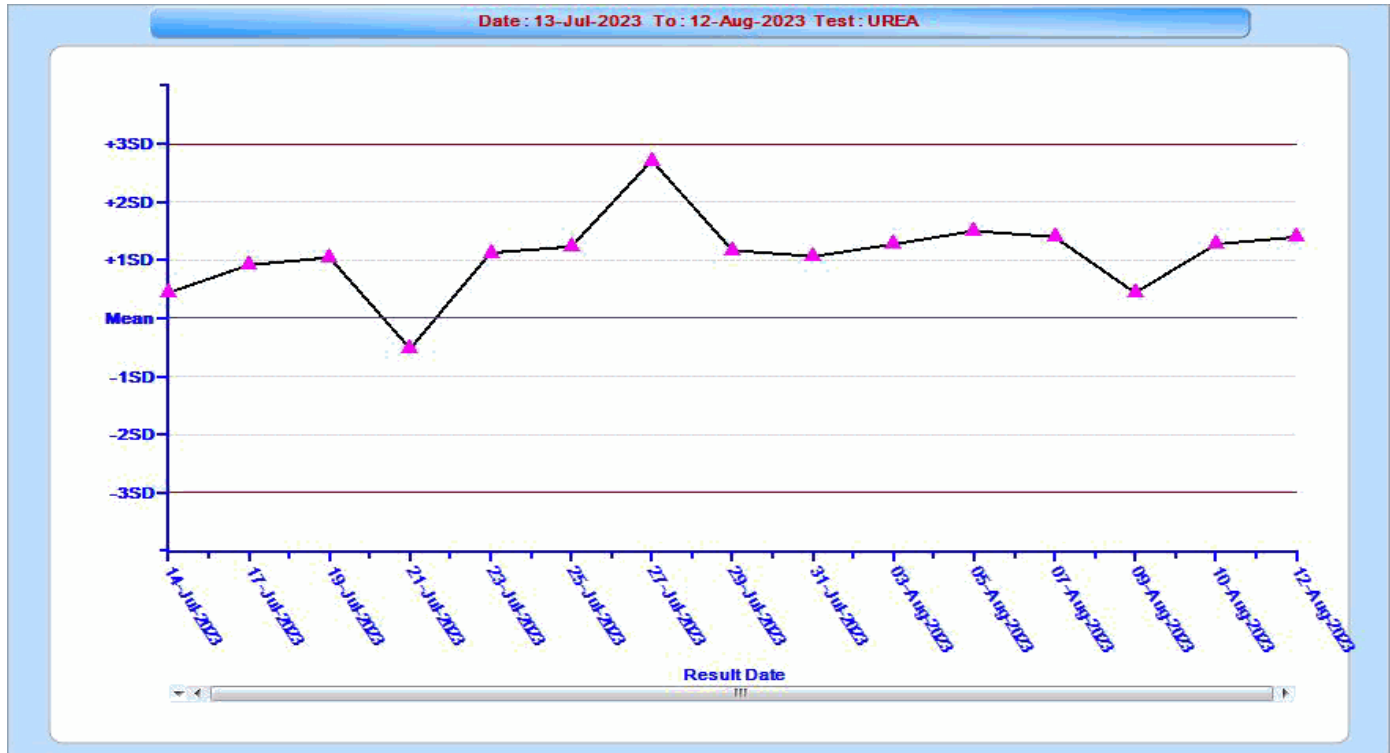
ExpDate :31-Dec-2025

Lot No. : S022359

Batch No. : —

Mean : 95.85

SD : 4.79



X Calculation : R= Range of average of Results per day :

Level	N	Avg	SD	% CV	R
High	15	101.1	3.2864	3.2506	15.5

R Calculation : R= Range of Result Variations per day :

Level	N	Avg	SD	% CV	R
High	15	0	0	0	0

QC Data - EM 200

Sr #	Date	Result	Mean	SD	Interval (3SD)	Deviation	Dev %	Error%	Batch	QC Remarks
1	14 Jul 2023	97.9	95.850	4.79	81.48 - 110.22		2.1	2.19	1	
2	17 Jul 2023	100.2	95.850	4.79	81.48 - 110.22		4.4	4.59	1	
3	19 Jul 2023	100.8	95.850	4.79	81.48 - 110.22	+1SD	5.0	5.22	1	
4	21 Jul 2023	93.3	95.850	4.79	81.48 - 110.22		-2.5	-2.61	1	
5	23 Jul 2023	101.2	95.850	4.79	81.48 - 110.22	+1SD	5.4	5.63	1	
6	25 Jul 2023	101.7	95.850	4.79	81.48 - 110.22	+1SD	5.9	6.16	1	
7	27 Jul 2023	108.8	95.850	4.79	81.48 - 110.22	+2SD	13.0	13.56	1	
8	29 Jul 2023	101.4	95.850	4.79	81.48 - 110.22	+1SD	5.6	5.84	1	
9	31 Jul 2023	100.9	95.850	4.79	81.48 - 110.22	+1SD	5.1	5.32	1	
10	03 Aug 2023	101.9	95.850	4.79	81.48 - 110.22	+1SD	6.1	6.36	1	
11	05 Aug 2023	103.1	95.850	4.79	81.48 - 110.22	+1SD	7.2	7.51	1	
12	07 Aug 2023	102.5	95.850	4.79	81.48 - 110.22	+1SD	6.7	6.99	1	
13	09 Aug 2023	97.9	95.850	4.79	81.48 - 110.22		2.1	2.19	1	
14	10 Aug 2023	101.9	95.850	4.79	81.48 - 110.22	+1SD	6.1	6.36	2	
15	12 Aug 2023	102.5	95.850	4.79	81.48 - 110.22	+1SD	6.7	6.99	1	