

June 01, 2022

*Calibration Certificate for Fully Automated Random Access Biochemistry Analyser,
Erba Em200 (SL.No. 2002795)*

*This is to certify that the Fully Automated Random Access Biochemistry Analyser, Model:
Em200 installed at Central Ayurveda Research Institute, CCRAS, Ministry Of
Ayush, Government Of India, 4-cn Block, Sector-V, Bidhannagar, Kolkata-700091, The
calibration value of filter gains, photometers and all other values have been checked and
found well within the limit.*

This calibration is valid till May 31, 2023.

For Transasia Bio-Medicals Ltd.



*Debraj Mondal
Dy. Regional Service Manager*

Report Type : Controls

20-Jul-2022 To 21-Jul-2022

Result Reprint

Sr #	Lot #	Consumable	Test	Result Unit	Flag	Curve #	Result Date	Mean	SD	Interval (3SD)
18	B072150	ERBA PATH	TRIG	185.2 mg/dL	✓	22405	20-Jul-2022 12:15:10	188.080	6.350	169.03 - 207.13
19	S062125BN	ERBA NORM	CHOL	126 mg/dL	-1SD	22406	20-Jul-2022 12:15:28	137.570	6.880	116.93 - 158.21
20	B072150	ERBA PATH	CHOL	247 mg/dL	-1SD	22407	20-Jul-2022 12:15:46	265.520	13.280	225.68 - 305.36
21	S062125BN	ERBA NORM	HDLC	37.5 mg/dL	-1SD	22408	20-Jul-2022 12:16:22	42.860	2.860	34.28 - 51.44
22	B072150	ERBA PATH	HDLC	80.4 mg/dL		22409	20-Jul-2022 12:16:40	84.200	5.620	67.34 - 101.06
23	S062125BN	ERBA NORM	UA	5.7 mg/dL	-1SD	22410	20-Jul-2022 12:16:58	6.080	0.300	5.18 - 6.98
24	B072150	ERBA PATH	UA	11.1 mg/dL	✓	22411	20-Jul-2022 12:17:16	11.400	0.480	9.96 - 12.84
25	S062125BN	ERBA NORM	CA	7.6 mg/dL	-1SD	22412	20-Jul-2022 12:17:34	8.090	0.400	6.89 - 9.29
26	B072150	ERBA PATH	CA	10.3 mg/dL	+1SD	22413	20-Jul-2022 12:17:52	9.760	0.490	8.29 - 11.23
27	S062125BN	ERBA NORM	ALBD	3.44 g/dL		22414	20-Jul-2022 12:18:10	3.570	0.180	3.03 - 4.11
28	B072150	ERBA PATH	ALBD	4.87 g/dL		22415	20-Jul-2022 12:18:28	4.780	0.240	4.06 - 5.5
29	S062125BN	ERBA NORM	PRO	5.77 g/dL	-1SD	22416	20-Jul-2022 12:18:46	6.240	0.310	5.31 - 7.17
30	B072150	ERBA PATH	PRO	8.91 g/dL		22417	20-Jul-2022 12:19:04	9.310	0.470	7.9 - 10.72
31	S062125BN	ERBA NORM	SGPTD	36.5 U/L	✓	22460	20-Jul-2022 13:31:14	38.390	2.560	30.71 - 46.07
32	B072150	ERBA PATH	SGPTD	152.2 U/L	+3SD	22461	20-Jul-2022 13:31:32	128.200	6.350	109.15 - 147.25
33	S062125BN	ERBA NORM	ALPU	145 U/L	+2SD	22468	20-Jul-2022 13:33:38	127.750	8.520	102.19 - 153.31
34	B072150	ERBA PATH	ALPU	553 U/L	+1SD	22469	20-Jul-2022 13:33:56	502.870	33.520	402.31 - 603.43

Print Date 21-Jul-2022

Result Reprint

Report Type : Controls

20-Jul-2022 To 21-Jul-2022

Sr #	Lot #	Consumable	Test	Result Unit	Flag	Curve #	Result Date	Mean	SD	Interval (3SD)
35	B072150	ERBA PATH	UREA	95.8 mg/dL		22470	20-Jul-2022 13:34:14	95.700	3.580	84.96 - 106.44
36	S062125BN	ERBA NORM	GLU	100.3 mg/dL		22477	20-Jul-2022 13:38:45	95.720	4.780	81.38 - 110.06
37	B072150	ERBA PATH	GLU	269.5 mg/dL	+1SD	22478	20-Jul-2022 13:39:03	262.030	12.600	214.23 - 289.83
38	S062125BN	ERBA NORM	TRIG	133.9 mg/dL	+3SD	22485	20-Jul-2022 13:41:10	113.350	5.670	96.34 - 130.36
39	S062125BN	ERBA NORM	CHOL	159 mg/dL	+3SD	22492	20-Jul-2022 13:43:16	137.570	6.880	116.93 - 158.21
40	B072150	ERBA PATH	CHOL	287 mg/dL	+1SD	22493	20-Jul-2022 13:43:34	265.520	13.280	225.68 - 305.36
41	S062125BN	ERBA NORM	UA	7.7 mg/dL	+3SD	22500	20-Jul-2022 13:45:40	6.080	0.300	5.18 - 6.98
42	S062125BN	ERBA NORM	CA	9.3 mg/dL	+3SD	22507	20-Jul-2022 13:47:47	8.090	0.400	6.89 - 9.29
43	B072150	ERBA PATH	CA	12.9 mg/dL	+3SD	22508	20-Jul-2022 13:48:05	9.760	0.490	8.29 - 11.23
44	S062125BN	ERBA NORM	PRO	6.70 g/dL	+1SD	22515	20-Jul-2022 13:50:29	6.240	0.310	5.31 - 7.17
45	S062125BN	ERBA NORM	TRIG	112.6 mg/dL		22523	20-Jul-2022 17:01:10	113.350	5.670	96.34 - 130.36
46	S062125BN	ERBA NORM	UA	6.1 mg/dL		22531	20-Jul-2022 17:03:34	6.080	0.300	5.18 - 6.98

Date: 20/02/22

DAILY CONTROL EVALUATION RECORD

Internal quality control

Parameters	Value Observed		Any Random or systematic error and rule violation multiple QC rule	Cause of Random and Systematic Error	Detailed of the corrective action taken	New Value		Values accepted / rejected	Relevant comments
	L1	L2				L1	L2		
CREATININE	1.17	3.66	NO					Accepted	
GLUCOSE	85.9	244.6	L1 → -2SD		calibration			Accepted	
UREIC ACID	5.7	11.1	L1 → -1SD		calibration			Accepted	
UREA	82.3	92.1	NO					Accepted	
ALB	3.44	4.87	NO					DD -	
TOTAL PROTEIN	57.2	8.91	L1 → -1SD					DD -	
SSGPT	29.2	127.2	L1 → -3SD		Calibration			DD -	
SSGOT	42.7	1480	NO					DD -	
ALP	100	465	L1 → -2SD L2 → -1SD		calibration			DD -	
GGT	NA							DD	
BLT	138	530	NO						

RANDOM ERROR

1. Proper Sampling
2. Quality of Water
3. Air bubble in water supply
4. Air bubble in reagent / sample reagent system
5. Wrong position of control sample
6. Control sample abnormal, reagent/analyte impurities storage

SYSTEMATIC ERROR

1. Inappropriate temperature / humidity level in testing area
2. Dirty / shift in reagent chamber temperature
3. Lot change - Reagent, calibrator, control
4. Decomposition of reagent / calibrator control in use / storage
5. Fading light source
6. Malfunction of equipment including calibration
7. Change in test operators

[Signature]
20/02/22

Date-

DAILY CONTROL EVALUATION RECORD

Parameters	Value Observed		Any Random or systematic error and rule violation multiple QC rule	Cause of Random and Systematic Error	Detailed of the corrective action taken	New value		Value accepted / rejected	Revised comments	
	L1	L2				L1	L2			
BIL-D	0.52	1.59	NO	NA	-	HA	NA	Accepted		
CHOL	126	247	L1 → -1SD L2 → -1SD	HA	HA	HA	HA	Accepted		
TRIG	104	185	FD	HA	HA	NA	NA	Accepted		
HDL	82.5	80.4	L1 → -1SD	HA	HA	NA	NA	Accepted		
LDL				NA						
CALCIUM	7.6	10.3	L1 → -1SD L2 → +1SD	HA	HA	HA	HA	Accepted		
PHOS										
SODIUM										
POTASSIUM										
CALORIDE										
AMYLASE										
URICASE										
RANDOM ERROR										
1. Power Supply	2. Air bubble in water supply		3. Wrong position of control sample		7. Operator mistake					
2. Quality of Water	4. Air bubble in reagent / sample specific system		6. Control sample incorrect reconstitution, inappropriate storage		1. Inappropriate temperature / handling used in testing area					
SYSTEMATIC ERROR										
		2. Date / shift is recorded incorrectly		3. Lot change - Reagent, calibration control used in testing area		4. Observation of reagent / calibration control is not / change		5. Fading light source		6. Change in test procedure
				1. Measurement of reagent / calibration control is not / change						

Dr. S. S. S. S.

Result Reprint

Report Type : Controls 21-Jul-2022

Sr #	Lot #	Consumable	Test	Result Unit	Flag	Curve #	Result Date	Mean	SD	Interval (3SD)
1	S062125BN	ERBA NORM	SGOTD	45.8 U/L		22547	21-Jul-2022 11:37:07	48.460	3.230	38.77 - 58.15
2	B072150	ERBA PATH	SGOTD	139.8 U/L		22548	21-Jul-2022 11:37:25	144.600	7.800	121.2 - 168
3	S062125BN	ERBA NORM	ALPU	114 U/L	-1SD	22555	21-Jul-2022 11:39:31	127.750	8.520	102.19 - 153.31
4	B072150	ERBA PATH	ALPU	445 U/L	-1SD	22556	21-Jul-2022 11:39:49	502.870	33.520	402.31 - 603.43
5	S062125BN	ERBA NORM	BIDD	0.53 mg/dL		22563	21-Jul-2022 11:41:55	0.580	0.050	0.43 - 0.73
6	B072150	ERBA PATH	BIDD	1.51 mg/dL		22564	21-Jul-2022 11:42:14	1.640	0.140	1.22 - 2.06
7	S062125BN	ERBA NORM	BIT	1.39 mg/dL		22571	21-Jul-2022 11:44:20	1.510	0.130	1.12 - 1.9
8	B072150	ERBA PATH	BIT	4.90 mg/dL		22572	21-Jul-2022 11:44:38	5.240	0.440	3.92 - 6.56
9	S062125BN	ERBA NORM	UREA	33.3 mg/dL		22579	21-Jul-2022 11:46:44	33.970	1.700	28.87 - 39.07
10	S062125BN	ERBA NORM	CRENZ	1.18 mg/dL	HVI	22587	21-Jul-2022 11:49:09	1.140	0.070	0.93 - 1.35
11	B072150	ERBA PATH	CRENZ	3.61 mg/dL	HVI	22588	21-Jul-2022 11:49:27	3.710	0.210	3.08 - 4.34
12	S062125BN	ERBA NORM	HDLc	42.1 mg/dL		22613	21-Jul-2022 11:57:52	42.860	2.860	34.28 - 51.44
13	B072150	ERBA PATH	HDLc	82.5 mg/dL		22614	21-Jul-2022 11:58:10	84.200	5.620	67.34 - 101.06
14	S062125BN	ERBA NORM	UA	5.8 mg/dL		22621	21-Jul-2022 12:00:17	6.080	0.300	5.18 - 6.98
15	B072150	ERBA PATH	UA	11.4 mg/dL		22622	21-Jul-2022 12:00:35	11.400	0.480	9.96 - 12.84
16	S062125BN	ERBA NORM	ALBD	3.49 g/dL		22637	21-Jul-2022 12:05:05	3.570	0.180	3.03 - 4.11
17	B072150	ERBA PATH	ALBD	4.75 g/dL		22638	21-Jul-2022 12:05:24	4.780	0.240	4.06 - 5.5

Report Type : Controls

21-Jul-2022

Result Reprint

Sr #	Lot #	Consumable	Test	Result Unit	Flag	Curve #	Result Date	Mean	SD	Interval (3SD)
18	S062125BN	ERBA NORM	PRO	6.00 g/dL		22645	21-Jul-2022 12:07:30	6.240	0.310	5.31 - 7.17
19	B072150	ERBA PATH	UREA	96.4 mg/dL		22661	21-Jul-2022 12:40:19	95.700	3.580	84.96 - 106.44
20	S062125BN	ERBA NORM	GLU	91.6 mg/dL		22676	21-Jul-2022 12:45:44	95.720	4.780	81.38 - 110.06
21	B072150	ERBA PATH	GLU	245.7 mg/dL		22677	21-Jul-2022 12:46:02	252.030	12.600	214.23 - 289.83
22	B072150	ERBA PATH	PRO	8.88 g/dL		22705	21-Jul-2022 12:54:46	9.310	0.470	7.9 - 10.72
23	S062125BN	ERBA NORM	SGPTD	34.9 U/L	-1SD	22712	21-Jul-2022 13:18:37	38.390	2.560	30.71 - 46.07
24	B072150	ERBA PATH	SGPTD	138.8 U/L	+1SD	22713	21-Jul-2022 13:18:55	128.200	6.350	109.15 - 147.25
25	S062125BN	ERBA NORM	TRIG	118.7 mg/dL		22720	21-Jul-2022 13:21:01	113.350	5.670	96.34 - 130.36
26	B072150	ERBA PATH	TRIG	196.8 mg/dL	+1SD	22721	21-Jul-2022 13:21:19	188.080	6.350	169.03 - 207.13
27	S062125BN	ERBA NORM	CHOL	141 mg/dL		22728	21-Jul-2022 13:23:25	137.570	6.880	116.93 - 158.21
28	B072150	ERBA PATH	CHOL	254 mg/dL		22729	21-Jul-2022 13:23:43	265.520	13.280	225.68 - 305.36
29	S062125BN	ERBA NORM	CA	7.7 mg/dL		22736	21-Jul-2022 13:25:50	8.090	0.400	6.89 - 9.29
30	B072150	ERBA PATH	CA	9.9 mg/dL		22737	21-Jul-2022 13:26:08	9.760	0.490	8.29 - 11.23