

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*

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)
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

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)
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	252.030	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	12.0 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- 20/9/22

DAILY CONTROL EVALUATION RECORD / Internal Quality control

Parameters	Value Obtained		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	Reviewed comments
	L1	L2				L1	L2		
CREATININE	1.17	3.66	N/D					Accepted	
GLUCOSE	85.3	244.6	L1 → -2SD		Calibration	100	289	Accepted	
URIC ACID	5.7	11.1	L1 → -1SD		Calibration	6.1	11.2	Accepted	
UREA	32.3	92.1	N/D					Accepted	
ALB	3.44	4.87	N/D					-DD-	
TOTAL PROTEIN	5.77	8.91	L1 → -1SD					-DD-	
SGPT	29.2	127.2	L1 → -3SD		Calibration	36.5	128	-DD-	
SGOT	42.7	1480	N/D					-DD-	
ALP	100	465	L1 → -2SD L2 → -1SD		Calibration	145	553	-DD-	
GGT	N/A								
BLT	1.38	5.30	N/D					-DD-	
RANDOM ERROR									
1. Power Supply	3. Air bubble in water supply	5. Wrong position of control sample	7. Operator technique						
2. Quality of Water	4. Air bubble in reagent / sample pipette system	6. Control sample incorrect, reconstitution inappropriate storage							
SYSTEMATIC ERROR									
			1. Inappropriate temperature / humidity level in testing area			3. Lot change - Reagent, calibrator, control			
			2. Drift / shift in incubator chamber temperature			4. Deterioration of reagent / calibrator control in use / storage			
						5. Failing light source			
						6. Maintenance of equipment including calibration			
						7. Change in test operator			

[Handwritten Signature]

Date-

DAILY CONTROL EVALUATION RECORD

Parameters	Value Obtained		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	Reviewed comments
	L1	L2				L1	L2		
BIL-D	0.52	1.59	ND	HA	—	HA	NA	Accepted	
CHOL	126	247	L1 → -1SD L2 → -1SD	HA	HA	HA	HA	Accepted	
TRIG	104	185	ND	HA	HA			Accepted	
HDL	33.5	80.4	L1 → -1SD	HA	HA	HA	HA	Accepted	
LDL									
CALCIUM	7.6	10.3	L1 → -1SD L2 → +1SD	HA	HA	HA	HA	Accepted	
PHOS									
SODIUM									
POTASSIUM									
CHLORIDE									
AMYLASE									
LIPASE									
RANDOM ERROR									
1. Power Supply	3. Air bubble in water supply	5. Wrong position of control sample	7. Operator technique						
2. Quality of Water	4. Air bubble in reagent / sample pipette system	6. Control sample incorrect reconstitution, inappropriate storage							
SYSTEMATIC ERROR									
1. Inappropriate temperature / humidity level in testing area			2. DMH / shift in incubator chamber temperature			3. Lot change - Reagent, calibrator, control		5. Fading light source	
4. Deterioration of reagent / calibrator / control in use / storage			6. Malfunction of equipment including calibration		7. Change in test operator				