



UNMATCHED SERVICE
SINCE 1979...

13/4/21

CALIBRATION CERTIFICATE

THIS IS TO CERTIFY THAT THE FULLY AUTOMATED BIO CHEMISTRY
ANALYSER EM 200 HAVING SR.NO.2002360 INSTALLED AT CPC LAB; CALICUT IS CALIBERATED ON
13/4/21 AND THE NEXT CALIBRATION DATE WILL BE ON 13/4/22.

CALIBRATOR: MULTICALIBRATOR

EXPIRY: 15/6/21

TRANSASIA BIO MEDICALS LTD

SR. A S M

CALICUT.

Result Reprint

Report Type : Controls

07-Jan-2022

Sr #	Lot #	Consumable	Test	Result Unit	Flag	Curve #	Result Date	Mean	SD	Interval (3SD)
1	B082182	ERBA NORM	SGPTD	40.5 U/L		21962	7-Jan-2022 10:12:03	38.390	3.840	26.87 - 49.91
2	B082182	ERBA NORM	SGOTD	54.9 U/L	+1SD	21963	7-Jan-2022 10:12:21	48.460	4.840	33.94 - 62.98
3	B082182	ERBA NORM	ALPU	149 U/L	+1SD	21964	7-Jan-2022 10:12:39	127.750	12.780	89.41 - 166.09
4	B082182	ERBA NORM	PHOS	4.80 mg/dl		21965	7-Jan-2022 10:12:57	4.730	0.360	3.65 - 5.81
5	B082182	ERBA NORM	BID	0.66 mg/dl	+1SD	21966	7-Jan-2022 10:13:15	0.580	0.070	0.37 - 0.79
6	B082182	ERBA NORM	BIT	1.48 mg/dl		21967	7-Jan-2022 10:13:33	1.510	0.190	0.94 - 2.08
7	B082182	ERBA NORM	UREA	31.0 mg/dl	-1SD	21968	7-Jan-2022 10:13:51	33.970	2.550	26.32 - 41.62
8	B082182	ERBA NORM	CRENZ	1.09 mg/dl		21969	7-Jan-2022 10:14:09	1.140	0.100	0.84 - 1.44
9	B082182	ERBA NORM	GLU	96.9 mg/dl		21970	7-Jan-2022 10:14:27	95.720	7.170	74.21 - 117.23
10	B082182	ERBA NORM	TRIG	117.9 mg/dl		21971	7-Jan-2022 10:14:45	113.350	8.500	87.85 - 138.85
11	B082182	ERBA NORM	CHOL	144 mg/dl		21972	7-Jan-2022 10:15:04	137.570	10.300	106.67 - 168.47
12	B082182	ERBA NORM	HDLC	42.1 mg/dl		21973	7-Jan-2022 10:15:21	42.860	4.290	29.99 - 55.73
13	B082182	ERBA NORM	LDL	68.7 mg/dl		21974	7-Jan-2022 10:15:40	73.900	7.390	51.73 - 96.07
14	B082182	ERBA NORM	UA	6.3 mg/dl		21975	7-Jan-2022 10:15:57	6.080	0.450	4.73 - 7.43
15	B082182	ERBA NORM	CA	8.6 mg/dl		21976	7-Jan-2022 10:16:16	8.090	0.600	6.29 - 9.89
16	B082182	ERBA NORM	ALBD	3.66 g/dl		21977	7-Jan-2022 10:16:34	3.570	0.270	2.76 - 4.38
17	B082182	ERBA NORM	PROT	6.54 g/dl		21978	7-Jan-2022 10:16:52	6.240	0.460	4.86 - 7.62

Result Reprint

Report Type : Controls

06-Jan-2022

Sr #	Lot #	Consumable	Test	Result Unit	Flag	Curve #	Result Date	Mean	SD	Interval (3SD)
1	B082182	ERBA NORM	SGPTD	40.5 U/L		21799	6-Jan-2022 09:14:41	38.390	3.840	26.87 - 49.91
2	B082182	ERBA NORM	SGOTD	48.1 U/L		21800	6-Jan-2022 09:14:59	48.460	4.840	33.94 - 62.98
3	B082182	ERBA NORM	ALPU	122 U/L		21801	6-Jan-2022 09:15:17	127.750	12.780	89.41 - 166.09
4	B082182	ERBA NORM	PHOS	4.73 mg/dl		21802	6-Jan-2022 09:15:35	4.730	0.360	3.65 - 5.81
5	B082182	ERBA NORM	BID	0.65 mg/dl		21803	6-Jan-2022 09:15:53	0.580	0.070	0.37 - 0.79
6	B082182	ERBA NORM	BIT	1.48 mg/dl		21804	6-Jan-2022 09:16:11	1.510	0.190	0.94 - 2.08
7	B082182	ERBA NORM	UREA	31.9 mg/dl		21805	6-Jan-2022 09:16:29	33.970	2.550	26.32 - 41.62
8	B082182	ERBA NORM	CRENZ	1.07 mg/dl		21806	6-Jan-2022 09:16:47	1.140	0.100	0.84 - 1.44
9	B082182	ERBA NORM	GLU	95.6 mg/dl		21807	6-Jan-2022 09:17:05	95.720	7.170	74.21 - 117.23
10	B082182	ERBA NORM	TRIG	116.1 mg/dl		21808	6-Jan-2022 09:17:23	113.350	8.500	87.85 - 138.85
11	B082182	ERBA NORM	CHOL	141 mg/dl		21809	6-Jan-2022 09:17:41	137.570	10.300	106.67 - 168.47
12	B082182	ERBA NORM	HDLC	41.6 mg/dl		21810	6-Jan-2022 09:17:59	42.860	4.290	29.99 - 55.73
13	B082182	ERBA NORM	LDL	68.3 mg/dl		21811	6-Jan-2022 09:18:17	73.900	7.390	51.73 - 96.07
14	B082182	ERBA NORM	UA	6.1 mg/dl		21812	6-Jan-2022 09:18:35	6.080	0.450	4.73 - 7.43
15	B082182	ERBA NORM	CA	9.2 mg/dl	+1SD	21813	6-Jan-2022 09:18:53	8.090	0.600	6.29 - 9.89
16	B082182	ERBA NORM	ALBD	3.62 g/dl		21814	6-Jan-2022 09:19:11	3.570	0.270	2.76 - 4.38
17	B082182	ERBA NORM	PROT	6.29 g/dl		21815	6-Jan-2022 09:19:29	6.240	0.460	4.86 - 7.62

Result Reprint

Report Type : Controls

06-Jan-2022

Sr #	Lot #	Consumable	Test	Result Unit	Flag	Curve #	Result Date	Mean	SD	Interval (3SD)
18	B082182	ERBA NORM	CA	8.3 mg/dl		21924	6-Jan-2022 12:42:12	8.090	0.600	6.29 - 9.89

Result Reprint

Report Type : Controls

05-Jan-2022

Sr #	Lot #	Consumable	Test	Result Unit	Flag	Curve #	Result Date	Mean	SD	Interval (3SD)
1	B082182	ERBA NORM	SGPTD	40.7 U/L		21695	5-Jan-2022 10:17:27	38.390	3.840	26.87 - 49.91
2	B082182	ERBA NORM	SGOTD	50.5 U/L		21700	5-Jan-2022 10:18:57	48.460	4.840	33.94 - 62.98
3	B082182	ERBA NORM	ALPU	138 U/L		21705	5-Jan-2022 10:20:28	127.750	12.780	89.41 - 166.09
4	B082182	ERBA NORM	PHOS	4.88 mg/dl		21706	5-Jan-2022 10:20:45	4.730	0.360	3.65 - 5.81
5	B082182	ERBA NORM	BID	0.67 mg/dl	+1SD	21711	5-Jan-2022 10:22:16	0.580	0.070	0.37 - 0.79
6	B082182	ERBA NORM	BIT	1.52 mg/dl		21712	5-Jan-2022 10:22:34	1.510	0.190	0.94 - 2.08
7	B082182	ERBA NORM	UREA	33.6 mg/dl		21713	5-Jan-2022 10:22:52	33.970	2.550	26.32 - 41.62
8	B082182	ERBA NORM	CRENZ	1.13 mg/dl		21718	5-Jan-2022 10:24:22	1.140	0.100	0.84 - 1.44
9	B082182	ERBA NORM	GLU	96.2 mg/dl		21719	5-Jan-2022 10:24:40	95.720	7.170	74.21 - 117.23
10	B082182	ERBA NORM	TRIG	117.6 mg/dl		21724	5-Jan-2022 10:26:10	113.350	8.500	87.85 - 138.85
11	B082182	ERBA NORM	CHOL	142 mg/dl		21725	5-Jan-2022 10:26:28	137.570	10.300	106.67 - 168.47
12	B082182	ERBA NORM	HDLC	41.9 mg/dl		21726	5-Jan-2022 10:26:46	42.860	4.290	29.99 - 55.73
13	B082182	ERBA NORM	LDL	69.8 mg/dl		21727	5-Jan-2022 10:27:05	73.900	7.390	51.73 - 96.07
14	B082182	ERBA NORM	UA	6.3 mg/dl		21728	5-Jan-2022 10:27:23	6.080	0.450	4.73 - 7.43
15	B082182	ERBA NORM	CA	8.0 mg/dl		21729	5-Jan-2022 10:27:41	8.090	0.600	6.29 - 9.89
16	B082182	ERBA NORM	ALBD	3.63 g/dl		21734	5-Jan-2022 10:29:11	3.570	0.270	2.76 - 4.38
17	B082182	ERBA NORM	PROT	6.39 g/dl		21739	5-Jan-2022 10:30:41	6.240	0.460	4.86 - 7.62

CPC MEDICAL LABORATORY

Sreedevi building, Behind Nandilath G mart, Mavoor road, Calicut

Calibration Monitor

No.	Test	Curve Type	Type	Consumable	Lot #	Conc.	Abs	Factor	Calib Exp. (Days)	Acceptable Limit
1	GLU	Linear	BLANK	BLANK	12345	0.000	0.0193	0.0000	0	15
		Linear	STD1	MULTI CAL	2005093E	202.000	0.6907	300.8863	0	15
2	CHOL	Linear	BLANK	BLANK	12345	0.000	0.0534	0.0000	0	15
		Linear	STD1	MULTI CAL	2005093E	157.000	0.3155	599.0080	0	15
3	TRIG	Linear	BLANK	BLANK	12345	0.000	0.0106	0.0000	0	15
		Linear	STD1	MULTI CAL	2005093E	136.000	0.2446	581.4450	0	15
4	HDLC	Linear	BLANK	BLANK	12345	0.000	0.0036	0.0000	0	15
		Linear	STD1	HDL LDL CAL	S022163	67.000	0.1132	611.3138	0	15
5	LDL	Linear	BLANK	BLANK	12345	0.000	0.0014	0.0000	0	15
		Linear	STD1	HDL LDL CAL	S022163	129.700	0.2128	613.5288	0	15
6	BIT	Linear	BLANK	BLANK	12345	0.000	0.0037	0.0000	0	15
		Linear	STD1	MULTI CAL	2005093E	5.180	0.2036	25.9130	0	15
7	BID	Linear	BLANK	BLANK	12345	0.000	-0.0033	0.0000	0	15
		Linear	STD1	MULTI CAL	2005093E	2.280	0.1029	21.4689	0	15
8	SGOTD	Linear	BLANK	BLANK	12345	0.000	-0.0002	0.0000	0	15
		Linear	STD1	MULTI CAL	2005093E	102.000	-0.0351	-2926.8296	0	15
9	SGPTD	Linear	BLANK	BLANK	12345	0.000	-0.0001	0.0000	0	15
		Linear	STD1	MULTI CAL	2005093E	92.700	-0.0340	-2734.5132	0	15

CPC MEDICAL LABORATORY

Sreedevi building, Behind Nandilath G mart, Mavoor road, Calicut

Calibration Monitor

No.	Test	Curve Type	Type	Consumable	Lot #	Conc.	Abs	Factor	Calib Exp. (Days)	Acceptable Limit
10	ALPU	Linear	BLANK	BLANK	12345	0.000	0.0005	0.0000	0	15
		Linear	STD1	MULTI CAL	2005093E	256.000	0.0569	4547.0693	0	15
11	PROT	Linear	BLANK	BLANK	12345	0.000	0.0809	0.0000	0	15
		Linear	STD1	MULTI CAL	2005093E	5.100	0.3945	16.2628	0	15
12	ALBD	Linear	BLANK	BLANK	12345	0.000	0.0970	0.0000	0	15
		Linear	STD1	MULTI CAL	2005093E	3.230	0.7095	5.2743	0	15
13	UREA	Linear	BLANK	BLANK	12345	0.000	-0.0022	0.0000	0	15
		Linear	STD1	MULTI CAL	2005093E	99.100	-0.1287	-783.7089	0	15
14	CRENZ	Linear	BLANK	BLANK	12345	0.000	0.0104	0.0000	0	15
		Linear	STD1	MULTI CAL	2005093E	3.820	0.0864	50.2962	0	15
15	UA	Linear	BLANK	BLANK	12345	0.000	0.0027	0.0000	0	15
		Linear	STD1	MULTI CAL	2005093E	5.830	0.0828	72.7386	0	15
16	CRPD	Linear	BLANK	BLANK	12345	0.000	0.0004	0.0000	0	15
		Linear	STD1	CRP CAL	B062171	62.000	0.7340	84.5147	0	15
17	CA	Linear	BLANK	BLANK	12345	0.000	0.1982	0.0000	0	15
		Linear	STD1	MULTI CAL	2005093E	11.300	0.5875	29.0227	0	15
18	PHOS	Linear	BLANK	BLANK	12345	0.000	0.2755	0.0000	0	15
		Linear	STD1	MULTI CAL	2005093E	5.460	0.5902	17.3499	0	15

CPC MEDICAL LABORATORY

Sreedevi building, Behind Nandilath G mart, Mavoor road, Calicut

Calibration Monitor

Jo.	Test	Curve Type	Type	Consumable	Lot #	Conc.	Abs	Factor	Calib Exp. (Days)	Acceptable Limit
19	HA1cD	Point-To-Point	BLANK	HBA1c CAL1	45681	0.000	-0.0018	0.0000	0	0
		Point-To-Point	STD1	HBA1c CAL2	S112033	4.900	0.1020	47.2062	0	0
		Point-To-Point	STD2	HBA1c CAL3	S112033	8.400	0.4083	20.4803	0	0
		Point-To-Point	STD3	HBA1c CAL4	S112033	11.800	0.6769	17.3862	0	0
		Point-To-Point	STD4	HBA1c CAL5	S112033	15.400	0.8866	17.3345	0	0

TRANSASIA BIO-MEDICAL LTD.

EM-200

SR. NO :2002360

IQ,OQ AND PQ

For

**CPC MEDICAL LABORATORY
CALICUT,KERALA**

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

Installation Qualification for EM200, Sr. No.:- 2002360

Customer Name : CPC LABORATORY
Address : Sreedevi Buildings, Mavoor Road, Calicut-4
Instrument Name : EM-200
Serial Number : 2002360

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. Package was kept in Good Condition as per the directional indicators like not tilt, indicating the System has not been subjected to mechanical shocks or stored in any manner, so as to cause any damage to the same.

Found all the required accessories as required.

Installation Procedure & Checklist Attached for records.

External Requirements for Installation:

1. Input voltage of 220V-240V / 50Hz or 60Hz.
2. Recommended Operating Temperature is 15-30 °C, with Relative Humidity 30-85% and Atmospheric Pressure 70-106 kPa.

Installation Certificate for EM-200, Sr. No.:- 2002360

This is to certify that the instrument **EM-200 Sr. No.:- 2002360** is successfully Installed and Commissioned at **CPC LABORATORY, CALICUT ,KERALA**, and the Installation Protocol / checklist has been successfully completed for the Above instrument.

Date of Installation : 15-04-2021

Protocol Performed By:

Transasia Bio-Medical Ltd., Technical Services Department

Name : Mr. Biju Mathew

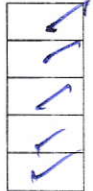
Designation : Service Engineer

Signature : 

Installation Qualifications for EM-200, Sr. No.:- 2002360

Performed/Verified

Installation Procedures as per Checklists.
Necessary checks and alignments.
Priming and Cleaning Operations
Check the results by running the controls.
Hand over the Instrument for Operators Training & Qualifications



Protocol Performed By:

For TBM, Technical Services Department

Name : Mr. Biju Mathew

Designation : Service Engineer

Signature : 

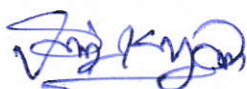
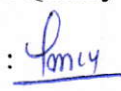
Installation Qualification for EM-200, Sr. No.:- 2002360

Customer Name : CPC LABORATORY,
Address : Sreedevi Buildings, Mavoor Road, Calicut-4
Contact Person : Jincy R Chandran, Quality manager
Instrument Model : EM-200
Serial Number : 2002360
Date of Installation : 15-04-2021

The instrument was installed and was found to be working satisfactorily. Preliminary Customer Training was provided and standardization of the parameters were done. The results were found to be within the expected range and System found to be working satisfactorily.

Protocol Performed By:

TBM, Technical Services Department **CUSTOMER : PRADO PVT. LTD.**

Name : Mr. Biju Matew	Contact Person : Jincy R Chandran
Designation : Service Engineer	Designation : Quality manager
Signature : 	Signature : 

Instrument Setup

1. Assembled the instrument accessories.
2. Removed the Shipping Clamps
3. Connected the Sampler
4. Set the Reagent Tubings
5. Connected the Reagents
6. Connected the waste Tank
7. Connected the Waste Tubings
8. Connected the Power Cord and Connection Cord.
9. Connected the External Printer
10. Perform the setting sequence

Result/Checks

✓
✓
✓
✓
✓
✓
✓
✓
✓
✓
✓

Operational Inspection

1. Mechanical Movements.
2. Hydraulics.
3. Electricals.
4. Controls and samples ,Results.

Result/Checks

✓
✓
✓
✓

Protocol Performed By:

TBM, Technical Services Department

Name : Mr. Biju Matew

Designation : Service Engineer

Signature : 

Operational Qualification:

System Certification:

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.

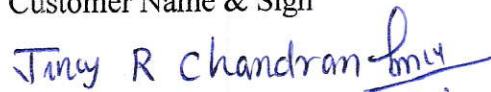
Protocol Performed By: Transasia Bio-Medical Ltd.
Name: Mr. Shabeer.T
Designation: Sr.Application Specialist
Customer Authorization: CPC LABORATORY
Name: Jincy R Chandran
Designation: Quality manager

Company Representative Name & Sign



Date: 22/12/2021

Customer Name & Sign



Date: 22/12/2021

Operations Qualifications for EM-200, Sr. No.:- 2002360

1. Mechanical Movements : Verified
2. Hydraulics. : Verified
3. Electrical Systems : Verified
4. Controls : Verified

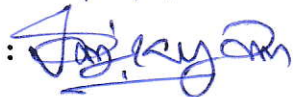
Protocol Performed By:

TBM, Technical Services Department

Name : Mr.Biju Matew

Designation : Service Engineer

Date : 22/12/21.

Signature : 

Performance Qualifications for EM-200, Sr. No.:- 2002360

1. **CONTROLS:** - Run QC Erba Normal and High of all the parameters, found within acceptable limit.
2. **PRECISION CHECK:** - Run the precision of all the parameters, calculate mean, and SD, found within range.

System Certification:

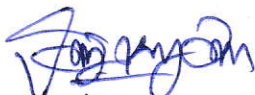
Study data has determined that the System described in this document either meets the necessary criteria outlined in this Performance Qualification Protocol, or exceptional conditions have been identified and documentation included.

The System is ready for specific usage.

Protocol Performed By:

Name : Mr. Biju Matew

Designation : Service Engineer


Signature : 

Date : 22/12/21.

PERFORMANCE QUALIFICATION DONE BY

Name : Mr. Shabeer. T

Designation: Sr. Application Specialist

Signature : 

Date : 22/12/2021.