



CERTIFICATE OF CALIBRATION/ VERIFICATION

Customer Name: GANGA DIAGNOSTIC CENTRE
Model: Fully Automated Bio-Chemistry Analyzer-EM 200
Serial No: B130303
Calibration Date: 23-06-2021
Next Calibration due on before : 23-06-2022
Calibrator Used: Multical Lot Number:2005093D
Quality Control Used: Randox- Lot Number:1393UN

This is to certify that the above mentioned instrument has been verified of calibration according to the procedures provided by the manufacturer -

General Parameters:

Parameter	Measured Value	Acceptable Range	
Line Voltage	230V	230 V +/- 5%	Pass
Logic Voltage	5.0 V	4.9 V to 5.1 V	Pass
Lamp Voltage	12.0 V	11.8 V to 12.2 V	Pass
Flow cell Temperature	37.0 deg	37 +/- 0.5	Pass
45Cuvette blank value for for all filter	Enclose valuesheet for all cuvette	Abs 0.02-0.2	Pass



Photometer Filter Gain Levels:

s.no	Filter Value in nm	Filter Gain in mv	Acceptable Range of gain
	340	578	50 mv to 200 mv
	405	517	50 mv to 200 mv
	505	528	50 mv to 200 mv
	546	516	50 mv to 200 mv
	578	495	50 mv to 200 mv
	600	498	50 mv to 200 mv
	660	478	50 mv to 200 mv
	700	460	50 mv to 200 mv

Transasia Biomedicals Ltd

Technical Service Department


Mr. Sandeep Andhale



TRANSASIA

EM- 200

SR. NO B130303

FULLY AUTOMATIC BIOCHEMISTRY ANALYZER

IQ,OQ AND PQ

For

Ganga Diagnostics Centre
Kolekar Hospital, 3rd floor, Ambedkar Garden, Chembur,
Mumbai-71.

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

H.O. address: Transasia House, 8 Chandivali Studio Road, Andheri (E), Mumbai - 440072 India
Tel. : +91 22 4030 9000

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.

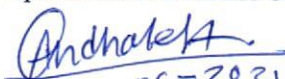
Exceptional conditions, if any, have been addressed.

The System is ready for specific usage.


Protocol Performed By: TBM, Mumbai
Name: Mr. Sandeep Andhale
Designation: Service Engineer

Customer Authorization: Ganga Diagnostics
Name: Mrs. Anagha Gadhave
Designation: Lab Manager

Company Representative Name & Sign


23-06-2021

Date:


Customer Name & Sign

Date:

23/06/2021

H.O. address: Transasia House, 8 Chandivali Studio Road, Andheri (E), Mumbai – 440072 India
Tel. : +91 22 4030 9000

Installation Qualification for EM200, Sr. No.:- B130303

Customer Name : Ganga Diagnostic

Address : Kolekar Hospital, 3rd floor, Ambedkar Garden, Chembur, Mumbai-71.

Instrument Name : EM-200

Serial Number : B130303

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.

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Installation Certificate for EM-200, Sr. No.:- B130303

This is to certify that the instrument **EM-200 Sr. No.:- B130303** is successfully Installed and Commissioned at Kolekar Hospital, 3rd floor, Ambedkar Garden, Chembur, Mumbai-71 and the Installation Protocol / checklist has been successfully completed for the above instrument.

Date of Installation: 30/03/2013

TBM, Technical Services Department

Andhale

Name : Sandeep Andhale
Designation : Service Engineer

H.O. address: Transasia House, 8 Chandivali Studio Road, Andheri (E), Mumbai – 440072 India
Tel. : +91 22 4030 9000

Installation Qualifications for EM-200, Sr. No.:- B130303

Carried out all the Installation Procedures as per the Installation Procedure & Checklists.

Carried out all the necessary checks and alignments.

Carried out all the necessary system checks and tests.

Carried out Priming and Cleaning Operations

Checked the results by running the controls and found OK.

Handed over the Instrument for Operators Training & Qualifications

For TBM, Technical Services Department

Name : Sandeep Andhale

Designation : Service Engineer

H.O. address: Transasia House, 8 Chandivali Studio Road, Andheri (E), Mumbai – 440072 India
Tel. : +91 22 4030 9000

Installation Qualification for EM-200, Sr. No.:- B130303

Customer Name : Ganga Diagnostic

Address : Kolekar Hospital, 3rd floor, Ambedkar Garden, Chembur,
Mumbai-71.

Contact Person : Mrs. Anagha Gadhave

Instrument Model : EM-200

Serial Number : B130303

Date of Installation : 30/03/2013

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.

TBM, Technical Services Department CUSTOMER : **Ganga Diagnostis**

Name : Mr. Sandeep Andhale

Designation: Service Engineer

Signature : 

Contact Person : Mrs Anagha Gadhave

Designation : Lab Manager

Signature : 

H.O. address: Transasia House, 8 Chandivali Studio Road, Andheri (E), Mumbai – 440072 India
Tel. : +91 22 4030 9000

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

Operational Inspection

1. Checked and found Mechanical Movements OK
2. Checked and found Hydraulics OK.
3. Checked and found Electricals OK.
4. Checked with controls and samples ,results are found OK.

TBM, Technical Services Department

Name : Mr. Sandeep Andhale

Designation : Service Engineer

H.O. address: Transasia House, 8 Chandivali Studio Road, Andheri (E), Mumbai – 440072 India
Tel. : +91 22 4030 9000

Operations Qualifications for EM-200, Sr. No.:- B130303

1. Verified all the Mechanical Movements : Done
2. Verified Hydraulics. : Done
3. Verified Electrical Systems : Done
4. Verified with Controls : Done

TBM, Technical Services Department

Name : Mr. Sandeep Andhale

Designation : Service Engineer

Date : 23-06-2021

H.O. address: Transasia House, 8 Chandivali Studio Road, Andheri (E), Mumbai – 440072 India
Tel. : +91 22 4030 9000

Performance Qualifications for EM-200, Sr. No.:- B130303

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

Designation : Application Specialist

PERFORMANCE QUALIFICATION DONE BY

Name : Mr. Krishnakant

Designation : Application Specialist

H.O. address: Transasia House, 8 Chandivali Studio Road, Andheri (E), Mumbai- 400 072 India
Tel. : +91 22 4030 9000





Result Reprint

Report Type : Calibration 13-Aug-2021 To 14-Aug-2021

Sr #	Lot #	Consumable	Test	Result Unit	Flag	Curve #	Result Date
1	ERBA	BLK NS	PHOE	0.2405 -		182145	14-Aug-2021 00:21:22
2	ERBA	BLK NS	PHOE	0.2310 -		182146	14-Aug-2021 00:21:40
3	ERBA	BLK NS	PHOE	0.2312 -		182147	14-Aug-2021 00:21:58
4	1806014A	Multical 1701084A	PHOE	0.8204 -		182148	14-Aug-2021 00:22:16
5	1806014A	Multical 1701084A	PHOE	0.7949 -		182149	14-Aug-2021 00:22:35
6	1806014A	Multical 1701084A	PHOE	0.8226 -		182150	14-Aug-2021 00:22:52
7	ERBA	BLK NS	TRIG	0.0141 -		182159	14-Aug-2021 00:35:49
8	ERBA	BLK NS	TRIG	0.0176 -		182160	14-Aug-2021 00:36:07
9	ERBA	BLK NS	TRIG	0.0133 -		182161	14-Aug-2021 00:36:25
10	1806014A	Multical 1701084A	TRIG	0.1962 -		182162	14-Aug-2021 00:36:43
11	1806014A	Multical 1701084A	TRIG	0.1975 -		182163	14-Aug-2021 00:37:01
12	1806014A	Multical 1701084A	TRIG	0.1906 -		182164	14-Aug-2021 00:37:19
13	ERBA	BLK NS	GLUEF	0.0096 -		182167	14-Aug-2021 00:38:13
14	ERBA	BLK NS	GLUEF	0.0094 -		182168	14-Aug-2021 00:38:31
15	ERBA	BLK NS	GLUEF	0.0087 -		182169	14-Aug-2021 00:38:49
16	1806014A	Multical 1701084A	GLUEF	0.6231 -		182170	14-Aug-2021 00:39:07
17	1806014A	Multical 1701084A	GLUEF	0.6273 -		182171	14-Aug-2021 00:39:25

Print Date 14-Aug-2021



Result Reprint

Report Type : Calibration 13-Aug-2021 To 14-Aug-2021

Sr #	Lot #	Consumable	Test	Result Unit	Flag	Curve #	Result Date
18	1806014A	Multical 1701084A	GLUEF	0.6301 -		182172	14-Aug-2021 00:39:43
19	ERBA	BLK NS	CHOE	0.0046 -		182174	14-Aug-2021 00:40:19
20	ERBA	BLK NS	CHOE	0.0047 -		182175	14-Aug-2021 00:40:37
21	ERBA	BLK NS	CHOE	0.0048 -		182176	14-Aug-2021 00:40:56
22	1806014A	Multical 1701084A	CHOE	0.0539 -		182177	14-Aug-2021 00:41:14
23	1806014A	Multical 1701084A	CHOE	0.0549 -		182178	14-Aug-2021 00:41:32
24	1806014A	Multical 1701084A	CHOE	0.0559 -		182179	14-Aug-2021 00:41:50
25	ERBA	BLK NS	SGOTE	-0.0006 -		182181	14-Aug-2021 00:42:26
26	ERBA	BLK NS	SGOTE	-0.0006 -		182182	14-Aug-2021 00:42:44
27	ERBA	BLK NS	SGOTE	-0.0002 -		182183	14-Aug-2021 00:43:02
28	1806014A	Multical 1701084A	SGOTE	-0.0549 -		182184	14-Aug-2021 00:43:20
29	1806014A	Multical 1701084A	SGOTE	-0.0541 -		182185	14-Aug-2021 00:43:38
30	1806014A	Multical 1701084A	SGOTE	-0.0540 -		182186	14-Aug-2021 00:43:56
31	ERBA	BLK NS	SGPTE	-0.0006 -		182188	14-Aug-2021 00:44:32
32	ERBA	BLK NS	SGPTE	-0.0004 -		182189	14-Aug-2021 00:44:50
33	ERBA	BLK NS	SGPTE	-0.0008 -		182190	14-Aug-2021 00:45:08
34	1806014A	Multical 1701084A	SGPTE	-0.0462 -		182191	14-Aug-2021 00:45:26



Result Reprint

Report Type : Calibration 13-Aug-2021 To 14-Aug-2021

Sr #	Lot #	Consumable	Test	Result Unit	Flag	Curve #	Result Date
35	1806014A	Multical 1701084A	SGPTE	-0.0471 -		182192	14-Aug-2021 00:45:44
36	1806014A	Multical 1701084A	SGPTE	-0.0466 -		182193	14-Aug-2021 00:46:02
37	ERBA	BLK NS	ALPE	0.0022 -		182195	14-Aug-2021 00:46:38
38	ERBA	BLK NS	ALPE	0.0020 -		182196	14-Aug-2021 00:46:57
39	ERBA	BLK NS	ALPE	0.0021 -		182197	14-Aug-2021 00:47:15
40	1806014A	Multical 1701084A	ALPE	0.0707 -		182198	14-Aug-2021 00:47:33
41	1806014A	Multical 1701084A	ALPE	0.0714 -		182199	14-Aug-2021 00:47:52
42	1806014A	Multical 1701084A	ALPE	0.0701 -		182200	14-Aug-2021 00:48:09
43	ERBA	BLK NS	BITE	0.0011 -		182202	14-Aug-2021 00:48:45
44	ERBA	BLK NS	BITE	0.0015 -		182203	14-Aug-2021 00:49:03
45	ERBA	BLK NS	BITE	0.0014 -		182204	14-Aug-2021 00:49:21
46	1806014A	Multical 1701084A	BITE	0.1973 -		182205	14-Aug-2021 00:49:39
47	1806014A	Multical 1701084A	BITE	0.1922 -		182206	14-Aug-2021 00:49:57
48	1806014A	Multical 1701084A	BITE	0.1938 -		182207	14-Aug-2021 00:50:15
49	ERBA	BLK NS	BIDE	0.0016 -		182209	14-Aug-2021 00:50:51
50	ERBA	BLK NS	BIDE	0.0013 -		182210	14-Aug-2021 00:51:09
51	ERBA	BLK NS	BIDE	0.0011 -		182211	14-Aug-2021 00:51:27



Result Reprint

Report Type : Calibration 13-Aug-2021 To 14-Aug-2021

Sr #	Lot #	Consumable	Test	Result Unit	Flag	Curve #	Result Date
52	1806014A	Multical 1701084A	BIDE	0.1222 -		182212	14-Aug-2021 00:51:45
53	1806014A	Multical 1701084A	BIDE	0.1224 -		182213	14-Aug-2021 00:52:03
54	1806014A	Multical 1701084A	BIDE	0.1203 -		182214	14-Aug-2021 00:52:21
55	ERBA	BLK NS	PROE	0.0892 -		182216	14-Aug-2021 00:52:58
56	ERBA	BLK NS	PROE	0.0935 -		182217	14-Aug-2021 00:53:16
57	ERBA	BLK NS	PROE	0.1030 -		182218	14-Aug-2021 00:53:34
58	1806014A	Multical 1701084A	PROE	0.3786 -		182219	14-Aug-2021 00:53:52
59	1806014A	Multical 1701084A	PROE	0.3764 -		182220	14-Aug-2021 00:54:10
60	1806014A	Multical 1701084A	PROE	0.3715 -		182221	14-Aug-2021 00:54:28
61	ERBA	BLK NS	UREE	-0.0073 -		182223	14-Aug-2021 00:55:04
62	ERBA	BLK NS	UREE	-0.0068 -		182224	14-Aug-2021 00:55:22
63	ERBA	BLK NS	UREE	-0.0052 -		182225	14-Aug-2021 00:55:40
64	1806014A	Multical 1701084A	UREE	-0.2048 -		182226	14-Aug-2021 00:55:58
65	1806014A	Multical 1701084A	UREE	-0.2051 -		182227	14-Aug-2021 00:56:16
66	1806014A	Multical 1701084A	UREE	-0.2141 -		182228	14-Aug-2021 00:56:34
67	ERBA	BLK NS	CREE	0.0126 -		182230	14-Aug-2021 00:57:10
68	ERBA	BLK NS	CREE	0.0116 -		182231	14-Aug-2021 00:57:28

Print Date 14-Aug-2021



Result Reprint

Report Type : Calibration 13-Aug-2021 To 14-Aug-2021

Sr #	Lot #	Consumable	Test	Result Unit	Flag	Curve #	Result Date
69	ERBA	BLK NS	CREE	0.0116 -		182232	14-Aug-2021 00:57:46
70	1806014A	Multical 1701084A	CREE	0.1135 -		182233	14-Aug-2021 00:58:04
71	1806014A	Multical 1701084A	CREE	0.1168 -		182234	14-Aug-2021 00:58:22
72	1806014A	Multical 1701084A	CREE	NA -	S**	182235	14-Aug-2021 00:58:40
73	ERBA	BLK NS	CALE	1.3465 -		182237	14-Aug-2021 00:59:17
74	ERBA	BLK NS	CALE	1.3737 -		182238	14-Aug-2021 00:59:35
75	ERBA	BLK NS	CALE	1.3938 -		182239	14-Aug-2021 00:59:53
76	ERBA	BLK NS	UAE	0.0076 -		182244	14-Aug-2021 01:01:23
77	ERBA	BLK NS	UAE	0.0074 -		182245	14-Aug-2021 01:01:41
78	ERBA	BLK NS	UAE	0.0075 -		182246	14-Aug-2021 01:01:59
79	ERBA	BLK NS	ALBAC	0.0349 -		182248	14-Aug-2021 01:02:35
80	ERBA	BLK NS	ALBAC	0.0335 -		182249	14-Aug-2021 01:02:53
81	ERBA	BLK NS	ALBAC	0.0041 -		182250	14-Aug-2021 01:03:11
82	ERBA	BLK NS	CREE	0.0132 -		182256	14-Aug-2021 01:31:28
83	ERBA	BLK NS	CREE	0.0105 -		182257	14-Aug-2021 01:31:46
84	ERBA	BLK NS	CREE	0.0117 -		182258	14-Aug-2021 01:32:04
85	1806014A	Multical 1701084A	CREE	0.1204 -		182259	14-Aug-2021 01:32:22



Result Reprint

Report Type : Calibration 13-Aug-2021 To 14-Aug-2021

Sr #	Lot #	Consumable	Test	Result Unit	Flag	Curve #	Result Date
86	1806014A	Multical 1701084A	CREE	0.1173 -		182260	14-Aug-2021 01:32:40
87	1806014A	Multical 1701084A	CREE	0.1149 -		182261	14-Aug-2021 01:32:58
88	ERBA	BLK NS	CALE	1.3395 -		182263	14-Aug-2021 01:33:34
89	ERBA	BLK NS	CALE	1.3570 -		182264	14-Aug-2021 01:33:52
90	ERBA	BLK NS	CALE	1.3708 -		182265	14-Aug-2021 01:34:10
91	1806014A	Multical 1701084A	CALE	1.3967 -		182266	14-Aug-2021 01:34:28
92	1806014A	Multical 1701084A	CALE	1.3948 -		182267	14-Aug-2021 01:34:46
93	1806014A	Multical 1701084A	CALE	1.3947 -		182268	14-Aug-2021 01:35:04
94	ERBA	BLK NS	UAE	0.0085 -		182269	14-Aug-2021 01:35:23
95	ERBA	BLK NS	UAE	0.0069 -		182270	14-Aug-2021 01:35:41
96	ERBA	BLK NS	UAE	0.0070 -		182271	14-Aug-2021 01:35:59
97	1806014A	Multical 1701084A	UAE	0.1682 -		182272	14-Aug-2021 01:36:17
98	1806014A	Multical 1701084A	UAE	0.1693 -		182273	14-Aug-2021 01:36:35
99	1806014A	Multical 1701084A	UAE	0.1717 -		182274	14-Aug-2021 01:36:53
100	ERBA	BLK NS	ALBAC	0.0337 -		182276	14-Aug-2021 01:37:29
101	ERBA	BLK NS	ALBAC	0.0375 -		182277	14-Aug-2021 01:37:47
102	ERBA	BLK NS	ALBAC	0.0365 -		182278	14-Aug-2021 01:38:05

Print Date 14-Aug-2021



Result Reprint

Report Type : Calibration 13-Aug-2021 To 14-Aug-2021

Sr #	Lot #	Consumable	Test	Result Unit	Flag	Curve #	Result Date
103	1806014A	Multical 1701084A	ALBAC	0.4524 -		182279	14-Aug-2021 01:38:23
104	1806014A	Multical 1701084A	ALBAC	0.4551 -		182280	14-Aug-2021 01:38:41
105	1806014A	Multical 1701084A	ALBAC	0.4617 -		182281	14-Aug-2021 01:38:59



Result Reprint

Report Type : Controls

Sr #	Lot #	Consumable	Test	Result Unit	Flag	Curve #	Result Date	Mean	SD
1	1416UN	RANDOX	PHOE	4.25 mg/dl	-1SD	182019	13-Aug-2021 09:46:59	4.620	0.330
2	1416UN	RANDOX	TRIG	110 mg/dl	+2SD	182020	13-Aug-2021 09:48:47	93.800	7.500
3	1416UN	RANDOX	HDLC	51.9 mg/dl	-1SD	182021	13-Aug-2021 09:49:05	59.700	4.000
4	1416UN	RANDOX	GLUEF	110.9 mg/dl		182022	13-Aug-2021 09:49:23	106.000	8.000
5	1416UN	RANDOX	CHOE	160.1 mg/dl		182023	13-Aug-2021 09:49:41	168.000	10.000
6	1416UN	RANDOX	SGOTE	42.5 IU/L	+1SD	182024	13-Aug-2021 09:49:59	38.200	4.000
7	1416UN	RANDOX	SGPTE	37.4 IU/L		182025	13-Aug-2021 09:50:18	37.600	4.000
8	1416UN	RANDOX	ALPE	171.6 IU/L		182026	13-Aug-2021 09:50:36	170.000	12.500
9	1416UN	RANDOX	BITE	1.90 mg/dl		182027	13-Aug-2021 09:50:54	1.830	0.180
10	1416UN	RANDOX	BIDE	1.31 mg/dl		182028	13-Aug-2021 09:51:12	1.280	0.120
11	1416UN	RANDOX	PROE	5.93 g/dl		182029	13-Aug-2021 09:51:30	6.040	0.600
12	1416UN	RANDOX	UREE	37.3 mg/dl	-1SD	182030	13-Aug-2021 09:51:48	43.200	4.000
13	1416UN	RANDOX	CREE	1.12 mg/dl	-1SD	182031	13-Aug-2021 09:52:06	1.300	0.160
14	1416UN	RANDOX	CALE	8.1 mg/dl	-3SD	182032	13-Aug-2021 09:52:24	11.500	1.000
15	1416UN	RANDOX	UAE	6.11 mg/dl		182033	13-Aug-2021 09:52:42	5.680	0.980
16	1416UN	RANDOX	ALBAC	3.81 g/dl		182034	13-Aug-2021 09:53:00	4.020	0.300