



## Calibration Certificate

Date: 10.03.2020

**Vignesh Multispeciality Diagnostic Center**  
Pudur  
Chennai

Dear Sir/ Madam,

As desired by you please find herewith the Calibration report of fully Automatic Bio chemistry Analyser

1. Model- **EM 200**
2. Serial No. – **B2001270**
3. Range of the Instrument: Optical density Linear form 0-3
4. Date of calibration: **10.03.2020**
5. Next calibration due on or before: **09.03.2021**

This instrument is manufactured in accordance with the European law in force, in particular to "Electricity Safety" EN 610101 and "Electromagnetic Compatibility" EN 61326 Standards.

	Ideal	Actual
Pressure	1.05 bar	1.04 bar
Lamp Voltage	12 V	11.88V
Temperature	37 <sup>0</sup> C	37.0 <sup>0</sup> C

Photometer Calibration Check	Ok
Cuvette Blank Check(0.01 -0.2 OD)	Ok



## Photometer Gain details:

Wavelength	Gain	Status
340	545	Ok
405	550	Ok
505	518	Ok
546	565	Ok
578	510	Ok
600	545	Ok
660	525	Ok
700	510	Ok

The instrument does photometer check before each batch of tests is run. It will give an error message if the photometer test fails and it will not run any samples.

Thanking you and assuring of our prompt attention at all times.

Yours faithfully,

For **TRANSASIA BIO-MEDICALS LTD.**

  
**Karthick K S**  
**Sr.Service Engineer.**



## SUNSHINE BIOMEDICAL SOLUTIONS

No:68, First floor , Poomagal Main Road,  
Ekkattuthangal, Chennai - 600 032, 044 - 2225 2087.



95512 66584/73387 32288



calibration@sunshinebiomedical.com



### CALIBRATION CERTIFICATE

**CUSTOMER NAME** : VIGNESH DIAGNOSTIC CENTRE

**CUSTOMER ADDRESS** : 79, REDHILLS HIGH ROAD, PUDUR,  
AMBATTUR, CHENNAI-600053

**EQUIPMENT NAME** : FULLY AUTOMATED BIOCHEMISTRY  
ANALYZER

**MAKE & MODEL** : ERBA & EM -200

**SERIAL NUMBER** : B2001270

**CALIBRATION DATE** : 03.10.2020

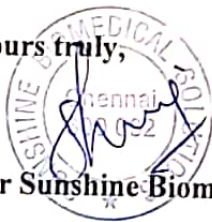
**DUE DATE** : 02.10.2021

# SUNSHINE

This is to certify that the above mentioned products has been verified  
of calibration and condition has been good

Thanking You,

Yours truly,



For Sunshine Biomedical Solutions

# QC TESTING PROTOCOL

PRODUCT : EM-200

SERIAL NO. : B2001270

PROV. NO. : 02/B61

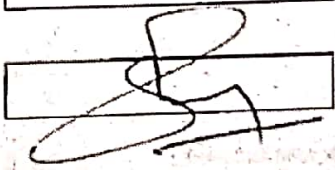
ASW VERSION : 2018.02A

ESW VERSION : 2018.R00.04

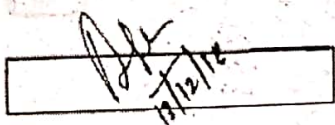
VOLTAGE SUPPLY : 220 V

DATE : 13-12-18

CONCLUSION: : PASS

REVIEWED BY: : 

(Prod. Head):

VERIFIED & APPROVED BY :   
13/12/18

(QA Head)

# QC TESTING PROTOCOL

Prov No 02/B61

## 1A) PHYSICAL CHECKING

Verified by: Name Bhupinder Singh Sign [Signature]

- |                                    |             |                             |               |                             |   |
|------------------------------------|-------------|-----------------------------|---------------|-----------------------------|---|
| 1) 50 POSITION REAGENT TRAY (RGT)  | Fitting :   | <input type="checkbox"/> OK | Movement :    | <input type="checkbox"/> OK |   |
| 2) SAMPLE TRAY ASSEMBLY (ASP)      | Fitting :   | <input type="checkbox"/> OK | Movement :    | <input type="checkbox"/> OK |   |
| 3) 45 POSITION REACTION TRAY (RCT) | Centering : | <input type="checkbox"/> OK | Movement :    | <input type="checkbox"/> OK |   |
| 4) REAGENT/SAMPLE PIPETTOR         | Centering : | <input type="checkbox"/> OK | Movement :    | <input type="checkbox"/> OK | Liquid Flow : <input type="checkbox"/> OK |
| 5) STIRRER                         | Centering : | <input type="checkbox"/> OK | Movement :    | <input type="checkbox"/> OK |   |
| 6) CUVETTE RINSING UNIT (CRU)      | Centering : | <input type="checkbox"/> OK | Liquid Flow : | <input type="checkbox"/> OK | Drier Chip : <input type="checkbox"/> OK  |
| 7) SYRINGE ( REAGENT/SAMPLE)       | Fitting :   | <input type="checkbox"/> OK | Movement :    | <input type="checkbox"/> OK |   |
| 8) REACTION TRAY COVER             | Fitting :   | <input type="checkbox"/> OK |               |                             |   |
| 9) REAGENT TRAY COVER              | Fitting :   | <input type="checkbox"/> OK |               |                             |   |
| 10) DOME COVER                     | Fitting :   | <input type="checkbox"/> OK |               |                             |   |
| 11) GAS SPRINGS                    | Closing :   | <input type="checkbox"/> OK | Movement :    | <input type="checkbox"/> OK |   |
| 12) INDICATOR LAMPS                |             |                             |               |                             |   |
| a) ANALYZER SWITCH                 |             | <input type="checkbox"/> OK |               |                             |   |
| b) LED ON STIRRER, ARM AND PANEL : |             | <input type="checkbox"/> OK |               |                             |   |



# QC TESTING PROTOCOL

Prov No 02/B51

[B] PRE-BIOCHEMISTRY CHECK Verified by: Name Bhupinder Singh Sign *Bhupinder*

**1) TEMPERATURE**

		Observed	Acceptance
SERVICE MENU	RCT	<span style="border: 1px solid black; padding: 2px;">37</span> °C	36.8 to 37.2 °C
	RGT	<span style="border: 1px solid black; padding: 2px;">8</span> °C	04 to 12 °C
RUN TEST	RCT	<span style="border: 1px solid black; padding: 2px;">37</span> °C	36.8 to 37.2 °C
	RGT	<span style="border: 1px solid black; padding: 2px;">7</span> °C	04 to 12 °C

**2) AUTO SPAN SET**

Acceptance criteria for Gain at all wavelength 380 to 600

WAVELENGTH	GAIN		
	1	2	3
340	401	402	402
405	461	462	462
505	402	403	403
546	449	449	450
578	429	429	429
600	426	426	427
660	462	462	463
700	442	442	443

**3) PRESSURE ERROR DISPLAY:**

- a) LESS THAN 0.6 BAR OK
- b) GREATER THAN 1.2 BAR OK
- c) BETWEEN 0.6 TO 1.2 BAR OK

**4) SENSORS:**

- |   |  |
|---|--|
| 1. RGT COVER SWITCH <span style="margin-left: 100px;"><span style="border: 1px solid black; padding: 2px;">OK</span></span> | 4. BIO-HAZARDOUS WASTE <span style="margin-left: 100px;"><span style="border: 1px solid black; padding: 2px;">OK</span></span> |
| 2. DEIONISED WATER <span style="margin-left: 100px;"><span style="border: 1px solid black; padding: 2px;">OK</span></span>  | 5. WASTE <span style="margin-left: 100px;"><span style="border: 1px solid black; padding: 2px;">OK</span></span>               |
| 3. DETERGENT <span style="margin-left: 100px;"><span style="border: 1px solid black; padding: 2px;">OK</span></span>        |  |

# QC TESTING PROTOCOL

.....Prov No 02/B61

**[C] OTHER FUNCTIONAL CHECKS**

Verified by : Name

Bhupinder Singh

Sign

*Bhupinder Singh*

1) PRIME MODE	<span style="border: 1px solid black; padding: 2px;">OK</span>	10) QC MODE	<span style="border: 1px solid black; padding: 2px;">OK</span>
2) CUVETTE RINSE	<span style="border: 1px solid black; padding: 2px;">OK</span>	11) MULTIPPOINT CALIBRATION	<span style="border: 1px solid black; padding: 2px;">OK</span>
3) AUTOWASH	<span style="border: 1px solid black; padding: 2px;">OK</span>	12) EMERGENCY MODE	<span style="border: 1px solid black; padding: 2px;">OK</span>
4) PROBE WASH	<span style="border: 1px solid black; padding: 2px;">OK</span>	13) DILUTION MODE	<span style="border: 1px solid black; padding: 2px;">OK</span>
5) WATER SAVE	<span style="border: 1px solid black; padding: 2px;">OK</span>	14) 2 REAGENT CHEMISTRY	<span style="border: 1px solid black; padding: 2px;">OK</span>
6) DEAD VOLUME CALIBRATION	<span style="border: 1px solid black; padding: 2px;">OK</span>	15) REACTION CURVE	<span style="border: 1px solid black; padding: 2px;">OK</span>
7) REAGENT LEVEL SCAN	<span style="border: 1px solid black; padding: 2px;">OK</span>	16) RECALCULATION	<span style="border: 1px solid black; padding: 2px;">OK</span>
8) HIBERNATE MODE	<span style="border: 1px solid black; padding: 2px;">OK</span>	17) RESULT REPRINT	<span style="border: 1px solid black; padding: 2px;">OK</span>
9) AUTOSTARTUP-SHUTDOWN MAINTAINANCE	<span style="border: 1px solid black; padding: 2px;">OK</span>	18) PATIENT REPORT PRINT	<span style="border: 1px solid black; padding: 2px;">OK</span>

**[D] DEAD VOLUME CHECK**

Verified by : Name

Bhupinder Singh

Sign

*Bhupinder Singh*

SAMPLE :	Observed	Acceptance
SAMPLE CUP (2ML) ..... in µl	<span style="border: 1px solid black; padding: 2px;">105</span>	50 µl - 150 µl
SAMPLE MICROCUP (500 ul) ... in µl	<span style="border: 1px solid black; padding: 2px;">95</span>	50 µl - 150 µl
SAMPLE TUBE( 5 - 7 ML) ..... in µl	<span style="border: 1px solid black; padding: 2px;">340</span>	250µl - 450 µl
REAGENT :	Observed	Acceptance
REAGENT : 50ML BOTTLE ... in ml	<span style="border: 1px solid black; padding: 2px;">2.1</span>	1.5 ml - 2.5 ml
REAGENT : 20ML BOTTLE .... in ml	<span style="border: 1px solid black; padding: 2px;">1.6</span>	1.0 ml - 2.0 ml
REAGENT : 5 ML ADAPTOR ..... in µl	<span style="border: 1px solid black; padding: 2px;">450</span>	350 µl - 650 µl

# QC TESTING PROTOCOL

Prov No 02/111

## E) OPTIONAL CONFIGURATION STATUS

Verified by Name

Dhupinder Singh

Sign

1) IS MACHINE WITH ISE MODULE? (YES / NO)

NO

Centering

NA

Electrodes

NA

2) IS MACHINE WITH BARCODE? (YES / NO)

YES

2.1) SAMPLE BARCODE SCAN

NA

2.2) REAGENT BARCODE SCAN

OK

## [F] ASTHETICS

Verified by Name

Dhupinder Singh

Sign

1) NO DENT MARKS & SCRATCHES ON FRONT PANEL, SIDE PANEL & REAR PANEL

OK

2) DOME OPEN & CLOSE MOVEMENT SMOOTHLY, WITHOUT ANY JERKS

OK

3) NO SHADE VARIATIONS IN PANELS

OK

4) NO DUST/FOREIGN PARTICLES ON THE INSTRUMENT

OK

5) PROPER PLACEMENT OF BUFFERS FOR PROTECTION TO PROBES, STIRRER

OK

6) PROPER FITMENT OF ARM COVER & STIRRER COVER

OK

7) CRU PROBES SPRING ACTIONS SHOULD BE SMOOTH

OK

8) SCREW OF CONTAINERS SHOULD NOT PROTRUDE OUT FROM CONTAINER SURFACE

OK

9) CONTAINER RING SHOULD BE FIRMLY FITTED ON TO THE TOP PANELS

OK

10) NO TEFLON COATING PEEL OFF FOR STIRRER PADDLE

OK



QJ WITHIN RUN PRECISION CHECK

PROV. NO. 02/B61

Verified by : Name

Bhupinder Singh

Sign



MULTICAL: 1806014A

ERBA NORM: B071836A

ERBA PATH: B051765C

ITEM	ALB		CHO		GGT		GLU		GPT		PRO		UREA	
	NORM	PATH	NORM	PATH	NORM	PATH	NORM	PATH	NORM	PATH	NORM	PATH	NORM	PATH
RGT lot no.	B091813		B061839		B101842		B101872		B111829		B101839		B101870	
Expiry Date	08/2021		11/2019		09/2020		09/2020		04/2020		09/2021		05/2020	
UNIT	g/dl		mg/dl		IU/L		mg/dl		IU/L		g/dl		mg/dl	
SPECIMEN	NORM	PATH	NORM	PATH	NORM	PATH	NORM	PATH	NORM	PATH	NORM	PATH	NORM	PATH
1	3.4	4.68	142	257	42.3	132.10	90.20	250.8	38.2	109.2	5.58	8.26	35.5	97.1
2	3.41	4.71	143	253	41.9	130.80	90.10	250.8	39.0	109.5	5.59	8.30	35.5	98.0
3	3.42	4.66	142	255	40.8	129.40	90.10	250.1	39.8	108.9	5.55	8.25	36.0	97.7
4	3.43	4.66	142	255	41.9	130.10	89.60	251.1	39.2	109.7	5.56	8.29	35.6	98.2
5	3.44	4.68	144	254	42.3	132.50	89.80	247.6	39	110	5.54	8.26	36	97.2
6	3.42	4.67	143	255	43.3	130.10	89.60	249.9	39.5	108.7	5.57	8.32	35.9	97.7
7	3.4	4.70	143	255	43	129.60	88.70	250	38.7	108.4	5.58	8.29	35.3	97.3
8	3.42	4.71	142	260	41.4	131.30	88.60	248.9	39.5	108.1	5.54	8.29	35.6	98
9	3.42	4.65	144	253	42.3	129.80	89.20	249.4	39.0	108.1	5.52	8.34	35.7	98.5
10	3.43	4.7	142	255	43.3	129.80	89.50	248.6	39.8	106.8	5.56	8.25	35.6	96.7
11	3.43	4.67	143	252	42.6	129.20	89.00	249.3	39.5	106.8	5.48	8.31	35.9	97.7
12	3.40	4.65	143	255	39.9	129.60	89.60	249.2	39.2	107.6	5.45	8.33	35.3	96.5
13	3.4	4.68	143	255	42.6	129.20	91.80	248.6	39.5	108.4	5.46	8.27	35.5	98.4
14	3.41	4.69	143	255	41.4	129.60	89.00	246.7	38.7	108.7	5.44	8.27	35.5	98.0
15	3.41	4.67	143	254	43.5	131.80	88.80	248.2	38.4	108.4	5.45	8.23	35.4	97.7
16	3.38	4.68	143	256	43.5	129.90	89.10	248.8	39.2	108.4	5.46	8.29	35.2	97
17	3.38	4.68	143	256	41.4	130.40	89.00	248.0	40.3	109.7	5.36	8.27	35.7	98.1
18	3.41	4.69	141	255	43.1	129.60	89.60	246.7	37.9	107.3	5.4	8.24	35.3	97.2
19	3.38	4.7	142	255	43.1	130.60	89.20	248.3	39.0	107.1	5.50	8.27	35	94.7
20	3.39	4.72	142	266	41.9	129.90	89.20	249.2	39.2	108.7	5.47	8.25	35.2	97
Mean	3.41	4.68	142.65	255.05	42.28	130.27	89.49	249.11	39.13	108.43	5.50	8.28	35.54	97.54
SD	0.018	0.020	0.745	1.638	0.966	0.966	0.716	1.120	0.570	0.950	0.066	0.030	0.278	0.855
CV(%)	0.52	0.43	0.52	0.64	2.29	0.74	0.80	0.45	1.46	0.88	1.19	0.37	0.78	0.88
Acceptance:	Erbnormm	< 3.00 %	Erbnormm	< 3.00 %	Erbnormm	< 4.99 %	Erbnormm	< 3.00 %	Erbnormm	< 4.99 %	Erbnormm	< 3.00 %	Erbnormm	< 3.00 %
	Erbapath	< 3.00 %	Erbapath	< 3.00 %	Erbapath	< 3.00 %	Erbapath	< 3.00 %	Erbapath	< 3.00 %	Erbapath	< 3.00 %	Erbapath	< 3.00 %

QCX2 - 401 / Issue No. 01

Revised : 08.02.16

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(Pg 7 is optional)