REPORT ON
ELECTRICAL SAFETY TESTING/ PERFORMANCE ANALYSIS/ CALIBRATION

Report No : TR/APHC/022/23-24
Page 1 0f 2

*Calibration Date : **08/03/2023***
*Calibration Due : **07/03/2024***

1.1 CUSTOMER DETAILS

Name and address of the organisation	***Primary Health Centre*** *New Gh Road, Opposite State Bank Of India,Ayalur, Gobichettipalayam, Erode District, Tamil Nadu. 638453*
Reference and Date	*Letter dated 08-03-2023*
Date of receipt of item	*08/'03/2023*

1.2 DESCRIPTION OF DEVICE UNDER TEST (DUT)

NOMENCLATURE	*BIO CHEMISTRY AMALYZER*
Manufactured by	*ROBONIK*
Model	*PRIETEST TOUCH*
Serial No.	*AT1110211RBK*
Biomedical Product ID	***APHC/LAB/BCA/01***
Supply	*220V-240V AC*
Device Type	*Type CF*
Device Classification	*Class II equipment*
Location	*LABORATORY*

1.3 CONDITION OF THE ITEM WHEN RECEIVED

No visible damage and in working order

1.4 ENVIRONMENTAL CONDITION OF MEASUREMENTS

A.Temperature	*28.6°C*
B.Relative Humidity	*45-75%*
C.Ambient Barometric Pressure	*756mmHg*

1.5 Applicable Specification — *IEC Specification IEC 60601-1, IEC 60601 -2-27*

1.6 Test Done — *Electrical Safety and Perfomance Testing*

Tested by :

Balamuralikrishnan K
(Biomedical Engineer)

FL BIOMEDICAL ERODE-638102

Approved by :

Priya M
(Quality Manager)

FL BIOMEDICAL
189, Vasantham Paradise,
Chithode, Erode-638102.
Cell: 7092848995

1.7 STATUS

Manuf Specification	Users Specification	Within Specification	Out of Specification	Calibration	Electrical Safety Test	Performance Analysis
✓	-	✓	-	✓	✓	✓

1.8 TRACEABILITY DETAILS OF INSTRUMENTS USED FOR TESTING

Sl No	Name of the Instrument	Make	Model	Serial No	Cal Due	Traceability Reference
2	ESA	RGM	288+	05H-0600	14-Aug-23	Annexure 3

2.0 PERFORMANCE ANALYSIS OF BIO CHEMISTRY ANALYZER

ELECTRICAL SAFETY TEST

Sl.No	Parameter	Observed value	Cal & M.capl	Acceptable limits as per the Std.	Remarks
1	Protective earth resistance	0.23 Ω	±3%	0.0 Ω - 0.3 Ω	ok
2	Chassis Leakage	27µA	±5%	1 µA - 100 µA NC	ok
		68 µA	±5%	1 µA - 500 µA SFC	ok
3	Patient leakage current	262 µA	±5%	1 µA - 100 µA B & BF(NC)	ok
		10 µA	±5%	1 µA - 10 µA CF (SFC)	ok
4	Earth Leakage	915 µA	±5%	1 µA - 1000 µA B.BF.CF (NC)	ok
		1868 µA	±5%	1 µA - 5000 µA B.BF.CF (SFC)	ok
5	Insulation Resistance 500 V DC	Success	±5%	≥2 MΩ	ok
6	Equipment current	0.1 A	-	As per manufacture spec	ok
7	Mains voltage	233V	-	As per manufacture spec	ok

3.0 REMARKS

3.1 This report is applicable to the sample tested only.

3.2 The instruments used for testing are under valid calibration and are traceable to National Standards.

3.3 Parameter of the DUT were verified and found to be within the specified limits.

3.4 refer NABL Doc No. 121 Clause 7.0 Accommodation and environmental Conditions sub Clause see 7.2.11 below in line with ISO/IEC 17025:2005 Clause 5.3

Tested by :

Balamuralikrishnan K
(Biomedical Engineer)

FL BIOMEDICAL ERODE-638102

Approved by :

Priya M
(Quality Manager)

FL BIOMEDICAL
189, Vasantham Paradise,
Chithode, Erode-638102.
Cell: 7092848995