

COTEX LAXMI HEALTHCARE PVT. LTD.

Sawangi Meghe, Wardha-442001

CALIBRATION CERTIFICATE

1. Customer

Name and Address of Customer:

SHALINITAI MEGHE HOSPITAL AND RESEARCH CENTER.

WANADONGARI, HINGNA, NAGPUR, 441110

Ambient Temp.: (25±2)°C

RH: 45 %RH to 75 %RH

Procedure No. CLH/CAL/21/ESA612/SOP/03

Date of Calibration: 21-04-2022

Due Date of Calibration: 22-04-2023

Location of Calibration: ON SITE

Equipment Status: OK

2. Description of item

Name: IMMUNOASSAY ANALYSER

Make: BECKMEN COULTER

Model: ACCESS 2

Sr.no. 512030

Department: BIOCHEMISTRY LAB

Location: BIOCHEMISTRY LAB

Asset No.: 3100

Calibration Certificate no.: CLH/CAL/SMHRC/CCL/BIOCHEM/IMA/01

3. Equipment used for Calibration (Master)

Name: Electrical Safety Analyzer

Make/ Model: Fluke Biomedical/ESA612

Sr.No. 5188505

Certificate no. M-220224-2-1

Validity 26-02-2023

The Masters are traceable to National/International Standards.

4. ELECTRICAL SAFETY

4.(1) Visual Test Inspection

SR.NO.	TEST	REMARK
1	Device clean and Decontaminated	OK
2	Physical Damange	OK
3	Power Cord, Cable checking	OK
4	Mains Socket Checking	OK
5	Alarm function	OK
6	Equipment type(B,BF,CF)	B
7	Equipment class(I,II,III)	I

B-Body Type, BF-Body Float Type, CF-Cardiac Float Type.

I-Properly Earthed, II-Double Insulated, III-With Extra Safety Low Voltage.

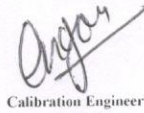
4.(2) Electrical Safety Test

SR.NO.	PARAMETERS	DESIRED VALUE	MEASURED VALUE	REMARK
1	Voltage between live to neutral (V In)	220-240 V	131.7 V	OK
2	Voltage between live to earth (V le)	220-240 V	228.9 V	OK
3	Voltage between neutral to earth (V ln)	0-5V	0.3 V	OK
4	Load Current (Ia)	0-10 A	1.2A	OK
5	Earth Leakage Current (IL)	0-500 µA	90.5 µA	OK
6	Enclosure Current	0-10 µA	0.5 µA	OK
7	Patient Leakage Current (PL)	BF 0-100 µA, CF 0-10µA	0.3 µA	OK
8	Ground Wire Resistance	0Ω -3Ω	1 Ω	OK

Note:

- 1) Prior to the calibration of this electrical safety parameters such as ground wire resistance, chassis Leakage, Patient Leakage Current, Patient Lead Leakage Current, Isolation Test (mains on applied part), Insulation (optional) 500 V etc. verified as per IEC-60601/62353 and found within limits.
- 2) The standards used for calibration were calibrated by using reference standard traceable to National/International standard & Calibration Points were selected as per customers Specification.
- 3) The reported uncertainty is expanded uncertainty in measurement obtained by multiplying the coverage factor $k=2$, which corresponds to coverage probability of approximately factor $k=2$, which corresponds to coverage probability of approximately 95% for normal distribution.
- 4) The certificate refers only to the particular item submitted for calibration. UUC stand for normal distribution.
- 5) The calibration results reported in the certificate are valid at the time for and under the stated condition of measurement.
- 6) Calibration point were selected as per customer specification and calibration report traceable to national or international standard
- 7) This certificate shall not be reproduced, except in full unless written permission for the publication of an approved abstract has been obtained from the Technical manager of COTEX LAXMI HEALTHCARE PVT. LTD. WARDHA.

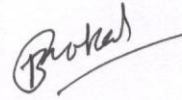
Calibrated By



Calibration Engineer



Approved By



Technical Manager

National Accreditation Board for Testing and Calibration Laboratories

Doc No.: 38	Specific Criteria for calibration of Medical Devices			
Issue No.:01	Issue Date:01/01/2021	Amend No.:01	Amend Date:01/01/2021	Page No.2