



AUTOCAL MEDI SYSTEMS

Calibration of Biomedical, QA of Radiology, Thermal, Mechanical, Electrotechnical, Mass, Volume, Weights, Mapping and Validation Testing Services of Laminar Air Flow, Biosafety Cabinet, OT Validation, AHU and Calibration Facility in Lab / Onsite.



CALIBRATION CERTIFICATE

1. Customer :- AARDHYA HEALTH CARE SUPER SPECIALITY HOSPITAL AARPEE CHAMBERS MAROL, METRO STATION ANDHERI EAST MUMBAI 400059	Page No. :- 1 of 2 Certificate No. :- ACMS/240801/313-3 Date of Calibration :- 3-Aug-24 Recommended Date :- 2-Aug-25 Date of Receipt :- 1-Aug-24 Date of Issue :- 5-Aug-24 SRF No. :- ACMS/240801/313 ULR No. :- CC360724000006993F Calibration Method :- CM-06 (Direct method)
Ambient Temp. :- (25 ±4)°c RH :- (50 ±20) %Rh Location of calibration :- ON SITE Condition of Item :- OK Discipline :- Medical Devices Parameter :- Mention in Electrical Safety Test Table	

2. Description Of Item	
Name :- ELECTRICAL SAFETY(Biochemistry Analyser)	Asset No. :- AH/PD/BA/4
Make :- CHEM-7	Sr. No. :- 5220171
Range :- AS PER REPORT	L.C. :- AS PER REPORT
Model :- Bio4	Department :- Pathology

3. Detail of Equipment Used For Calibration	
Name :- ELECTRICAL SAFETY ANALYZER	
Make/ID No. :- FLUKE/ACMS-EQP-05	
Certificate No. :- M-240327-22-1	
Certified By :- GODREJ	
Calibration Validity :- 27-03-2025	

4. IS Standard Used :- IEC 60601-1/62353 , NABL 126
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5. ELECTRICAL SAFETY:-

1) VISUAL TEST :-				
SR. NO.	TEST	Pass	Fail	N/A
1	Physical appearance of device	Pass	--	--
2	Device Clean and Decontaminated	Pass	--	--
3	Switches and controls operatable	Pass	--	--
4	Battery Power	Pass	--	--
5	Alarm Function	Pass	--	--

2) ELECTRICAL SAFETY TEST

SR. NO.	Parameters With Specified Limit	Pass	Fail	N/A
1	Protective Earth Resistance [Class I & II Type (<0.2 Ω)]	Pass	--	--
2	Earth Leakage Current NC [Class I & II B,BF,CF Type (<5000μA)]	Pass	--	--
3	Earth Leakage Current SFC [Class I & II B,BF,CF Type (<10000 μA)]	Pass	--	--
4	Enclosure Leakage Current NC [Class I & II B,BF,CF Type (<100 μA)]	Pass	--	--
5	Enclosure Leakage Current SFC [Class I & II B,BF,CF Type (<500μA)]	Pass	--	--
6	Patient Leakage Current NC [Class I & II B,BF (<100 μA) Class I & II CF (<10μA)]	--	--	N/A
7	Patient Leakage Current SFC [Class I & II B,BF (<500 μA) Class I & II CF (<50μA)]	--	--	N/A
8	Insulation Resistance [Class I, B Type (>=2 MΩ), Class I,BF & CF Type (>=70 MΩ), Class II, B Type (>=7 MΩ), Class II,BF,CF Type (>=70 MΩ)]	Pass	--	--

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Certificate No. :- ACMS/240801/313-3
ULR No. :- CC360724000006993F

Page No :- 02 of 02

Note:

- 1) The standards used for calibration were calibrated by using reference standard traceable to National/International standard & Calibration points were selected as per customer's specification.
- 2) The calibration results reported in this certificate are valid at the time of & under the stated conditions of measurement.
- 3) This certificate refers only to the particular item submitted for calibration. UUC stands for Unit Under Calibration.
- 4) This certificate shall not be reproduced except in full, unless written permission for the publication of an approved abstract has been obtained from **AUTOCAL MEDI SYSTEMS**, Pune.
- 5) The above mentioned instruments has been calibrated using Manufacturing standard recommended Protocols, using equipment having traceability to National/International Standards.
- 6) Decision rule: "Pass" indicates measured values are within tolerance limit of accuracy, and, "Fail" indicates measured values are not within tolerance limit of accuracy with considering measurement uncertainty. This clause is applicable only if tolerance limits are provided by the customer or mentioned in manufacturer specification.

Conclusion/Remarks:

- 1) For performance parameter Decision Rule:- Applicable Not Applicable
For Electrical Safety decision rule applicable as per ISO/IEC 60601-1/62353.
- 2) The Reported Expanded uncertainty of measurement is calculated at approximately 95% confidence level with coverage factor k=2
- 3) The Value Mentioned Above is the mean of 5 Readings.

End of Certificate

Calibrated By:

Dk

Calibration Engineer
(Mr. Deepak Kumar)



Approved By:

AK

Technical Manager
(Mr. Ankush Bagde)

Format No. - ACMS/RFT/29

Rev.No./Date : 00 / ---

Issue No./Date : 00 / 01.12.2022



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CALIBRATION CERTIFICATE

1. Customer	:-	Page No.	:- 1 of 2
AARDHYA HEALTH CARE SUPER SPECIALITY HOSPITAL		Certificate No.	:- ACMS/240801/313-2
AARPEE CHAMBERS MAROL, METRO STATION ANDHERI EAST		Date of Calibration	:- 3-Aug-24
MUMBAI 400059		Recommended Date	:- 2-Aug-25
Ambient Temp.	:- (25 ±4)°c	Date of Receipt	:- 1-Aug-24
RH	:- (50 ±20) %Rh	Date of Issue	:- 5-Aug-24
Location of calibration	:- ON SITE	SRF No.	:- ACMS/240801/313
Condition of Item	:- OK	ULR No.	:- CC360724000006992F
Discipline	:- Medical Devices	Calibration Method	:- CM-06 (Direct method)
Parameter	:- Mention in Electrical Safety Test Table		

2. Description Of Item			
Name	:- ELECTRICAL SAFETY(COAGULATION ANALYZER)	Asset No.	:- AH/PD/ECL/3
Make	:- Erba	Sr. No.	:- 4379-11-170821
Range	:- AS PER REPORT	L.C.	:- AS PER REPORT
Model	:- ECL105	Department	:- Pathology

3. Detail of Equipment Used For Calibration			
Name	:- ELECTRICAL SAFETY ANALYZER		
Make/ID No.	:- FLUKE/ACMS-EQP-05		
Certificate No.	:- M-240327-22-1		
Certified By	:- GODREJ		
Calibration Validity	:- 27-03-2025		

4. IS Standard Used :- IEC 60601-1/62353 , NABL 126

5. ELECTRICAL SAFETY:-

1) VISUAL TEST				
SR. NO.	TEST	Pass	Fail	N/A
1	Physical appearance of device	Pass	--	--
2	Device Clean and Decontaminated	Pass	--	--
3	Switches and controls operatable	Pass	--	--
4	Battery Power	Pass	--	--
5	Alarm Function	Pass	--	--

2) ELECTRICAL SAFETY TEST				
SR. NO.	Parameters With Specified Limit	Pass	Fail	N/A
1	Protective Earth Resistance [Class I & II Type (<0.2 Ω)]	Pass	--	--
2	Earth Leakage Current NC [Class I & II B,BF,CF Type (<5000μA)]	Pass	--	--
3	Earth Leakage Current SFC [Class I & II B,BF,CF Type (<10000 μA)]	Pass	--	--
4	Enclosure Leakage Current NC [Class I & II B,BF,CF Type (<100 μA)]	Pass	--	--
5	Enclosure Leakage Current SFC [Class I & II B,BF,CF Type (<500μA)]	Pass	--	--
6	Patient Leakage Current NC [Class I & II B,BF (<100 μA) Class I & II CF (<10μA)]	--	--	N/A
7	Patient Leakage Current SFC [Class I & II B,BF (<500 μA) Class I & II CF (<50μA)]	--	--	N/A
8	Insulation Resistance [Class I, B Type (>=2 MΩ), Class I,BF & CF Type (>=70 MΩ), Class II, B Type (>=7 MΩ), Class II,BF,CF Type (>=70 MΩ)]	Pass	--	--

1st Floor, 48/413, Beside Fire Brigade Station, Sant Tukaram Nagar, Pimpri, Pune - 411018.

☎ 09822136161 / 07722092715 ☎ autocalsystemsmed@gmail.com / autocalsystemsbio@gmail.com

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Certificate No. :- ACMS/240801/313-2
ULR No. :- CC360724000006992F

Page No :- 02 of 02

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AARPEE CHAMBERS MAROL, METRO STATION ANDHERI EAST		Date of Calibration	:- 3-Aug-24
MUMBAI 400059		Recommended Date	:- 2-Aug-25
Ambient Temp.	:- (25 ±4)°c	Date of Receipt	:- 1-Aug-24
RH	:- (50 ±20) %Rh	Date of Issue	:- 5-Aug-24
Location of calibration	:- ON SITE	SRF No.	:- ACMS/240801/313
Condition of Item	:- OK	ULR No.	:- CC360724000006995F
Discipline	:- Medical Devices	Calibration Method	:- CM-06 (Direct method)
Parameter	:- Mention in Electrical Safety Test Table		

2. Description Of Item			
Name	:- ELECTRICAL SAFETY(MINIVIDAS)	Asset No.	:- AH/PD/CM/9
Make	:- Biomerieux	Sr. No.	:- IVD5216237
Range	:- AS PER REPORT	L.C.	:- AS PER REPORT
Model	:- Mini Vides	Department	:- Pathology

3.Detail of Equipment Used For Calibration			
Name	:- ELECTRICAL SAFETY ANALYZER		
Make/ID No.	:- FLUKE/ACMS-EQP-05		
Certificate No.	:- M-240327-22-1		
Certified By	:- GODREJ		
Calibration Validity	:- 27-03-2025		

4. IS Standard Used	:- IEC 60601-1/62353 , NABL 126
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5. ELECTRICAL SAFETY:-

1) VISUAL TEST :-

SR. NO.	TEST	Pass	Fail	N/A
1	Physical appearance of device	Pass	--	--
2	Device Clean and Decontaminated	Pass	--	--
3	Switches and controls operatable	Pass	--	--
4	Battery Power	Pass	--	--
5	Alarm Function	Pass	--	--

2)ELECTRICAL SAFETY TEST

SR. NO.	Parameters With Specified Limit	Pass	Fail	N/A
1	Protective Earth Resistance [Class I & II Type (<0.2 Ω)]	Pass	--	--
2	Earth Leakage Current NC [Class I & II B,BF,CF Type (<5000μA)]	Pass	--	--
3	Earth Leakage Current SFC [Class I & II B,BF,CF Type (<10000 μA)]	Pass	--	--
4	Enclosuer Leakage Current NC [Class I & II B,BF,CF Type (<100 μA)]	Pass	--	--
5	Enclosure Leakage Current SFC [Class I & II B,BF,CF Type (<500μA)]	Pass	--	--
6	Patient Leakage Current NC [Class I & II B,BF (<100 μA) Class I & II CF (<10μA)]	--	--	N/A
7	Patient Leakage Current SFC [Class I & II B,BF (<500 μA) Class I & II CF (<50μA)]	--	--	N/A
8	Insulation Resistance [Class I, B Type (>=2 MΩ), Class I,BF & CF Type (>=70 MΩ), Class II, B Type (>=7 MΩ), Class II,BF,CF Type (>=70 MΩ)]	Pass	--	--

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