

## CALIBRATION CERTIFICATE



Customer Name & Address:	M/S. Sri.Vinayaga Micro Lab, No. 320, New Dharapuram Road, Palani – 624 601. Ph. 98656 39890	Certificate No:	AMS/LAB/2888999
		Issuing Date:	10/01/2021
		Page No:	1 of 2

### Details of Device under Calibration (DUC):

DUC:	Nephelometer	Id. No:	SVM/LAB/NPM/001
Make:	Agappe	Department:	Laboratory
Model:	MISPA i3	Calibrated On:	09/01/2021
Sl. No:	21192210634	Calibration Due Suggested:	08/01/2022
Type:	Cartridge Based	DUC Condition on Receipt:	OK
Range & Least Count:	---		

### Traceability Details:

Sl.No.	Test Equipment	Make	Certificate Number	Valid Up to
1	Electrical Safety Analyser	RigelSafeTest60	PSG/CIRD/BMCC/4424/2020	19/01/2021
2	Thermo Hygrometer	HTC	QC/AMS-DTI-004	22/02/2021

Room Temperature: 25°C±2 Room Humidity: 30-60% (At the time of Calibration)

### ESA Test Results:

SL.No	Parameter	ESA Reading	Unit	Normal Range	Condition
1	Current	0.169	Amps	1	Normal
2	Frequency	50.0	Hz	49 -50	Normal
3	Mains Voltage Line - Neutral	229.6	Volts	220 - 240	Normal
4	Mains Voltage Line - Earth	230.8	Volts	220 - 240	Normal
5	Mains Voltage Neutral - Earth	4.9	Volts	< 7	Normal

\*Electrical Safety: Please check the attached log sheet

1. Functional Tests – Passed
2. Temperature, Cartridge sensitivity Tests - Passed

Note:

1. Calibration Points were selected as per customer request.
2. Each reading were taken by Repeatability Test (i.e.) each reading in a row is a mean of 10 readings.
3. Results Reported are valid at the time of and under the stated conditions of measurements.

**Calibrated By:**

(Calibration Engineer)

B. Jeyaraj



**Approved by:**

(Technical Manager)

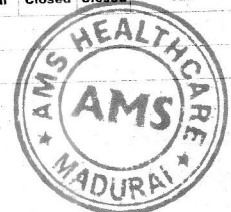
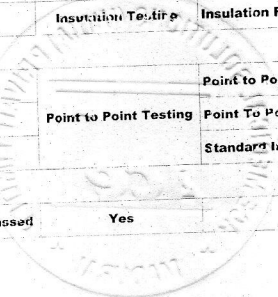
B. Jeyaraj



ESA Results:

Test Number	Test Standard	Test	Condition	Filter Selection	Reading Value	Reading Unit	Polarity	Neutral	Earth	Applied Parts
1	Earth Bonding	Earth Bond Voltage	Normal	AC+DC	0.1740	Ω	Normal	Closed	Closed	All
2	IEC60601	Leakage: Earth	Normal	AC+DC	141.24	μA	Normal	Closed	Closed	All
3		Leakage: Earth	Normal	AC+DC	132.42	μA	Reversed	Closed	Closed	All
4		Leakage: Enclosure	Normal	AC+DC	0.00	μA	Normal	Closed	Open	All
5		Leakage: Enclosure	Normal	AC+DC	0.00	μA	Reversed	Closed	Closed	All
6		Leakage: Earth	SFC	AC+DC	273.79	μA	Normal	Open	Closed	All
7		Leakage: Earth	SFC	AC+DC	261.91	μA	Reversed	Open	Closed	All
8		Leakage: Enclosure	SFC	AC+DC	142.96	μA	Normal	Closed	Open	All
9		Leakage: Enclosure	SFC	AC+DC	148.59	μA	Reversed	Closed	Open	All
10		Current	Normal	AC+DC	0.169	Amps	Normal	Closed	Closed	All
11		Frequency	Normal	AC+DC	50	Hz	Normal	Closed	Closed	All
12		Mains Voltage: Live to Neutral	Normal	AC+DC	229.6	V	Normal	Closed	Closed	All
13		Mains Voltage: Live to Earth	Normal	AC+DC	230.8	V	Normal	Closed	Closed	All
14		Mains Voltage: Neutral to Earth	Normal	AC+DC	4.9	V	Normal	Closed	Closed	All
15		IEC62353	Equipment Leakage	Direct Method	AC+DC	169.05	μA	Normal	Closed	Open
16	Equipment Leakage		Direct Method	AC+DC	168.68	μA	Reversed	Closed	Open	All
17	NFPA-99	Ground Leakage	Normal	AC+DC	143.69	μA	Normal	Closed	Closed	All
18		Ground Leakage	Normal	AC+DC	139.90	μA	Reversed	Closed	Closed	All
19		Ground Leakage	SFC	AC+DC	276.24	μA	Normal	Open	Closed	All
20		Ground Leakage	SFC	AC+DC	276.48	μA	Reversed	Open	Closed	All
21		Chassis Leakage	Normal	AC+DC	0.00	μA	Normal	Closed	Closed	All
22		Chassis Leakage	Normal	AC+DC	0.00	μA	Reversed	Closed	Closed	All
23		Chassis Leakage	SFC	AC+DC	146.14	μA	Normal	Closed	Open	All
24		Chassis Leakage	SFC	AC+DC	140.75	μA	Reversed	Closed	Open	All
25	IEC61010	Touch Leakage	Normal	AC+DC	0.00	μA	Normal	Closed	Closed	All
26		Touch Leakage	Normal	AC+DC	0.00	μA	Reversed	Closed	Closed	All
27		Touch Voltage	Normal	AC+DC	2.80	V	Normal	Closed	Closed	All
28		Touch Voltage	Normal	AC+DC	2.80	V	Reversed	Closed	Closed	All
29		Touch Leakage	SFC	AC+DC	136.05	μA	Normal	Closed	Open	All
30		Touch Leakage	SFC	AC+DC	135.12	μA	Reversed	Closed	Open	All
31		Touch Voltage	SFC	AC+DC	2.80	V	Normal	Closed	Open	All
32		Touch Voltage	SFC	AC+DC	2.80	V	Reversed	Closed	Open	All
33	Insulation Testing	Insulation Resistance	Normal	AC+DC	>20	MΩ	Normal	Closed	Closed	All
34	Point to Point Testing	Point to Point Earth Bond Test	Normal	AC+DC	>19.9	Ω	Normal	Closed	Closed	All
35		Point To Point Leakage Test	Normal	AC+DC	0	mA	Normal	Closed	Closed	All
36		Standard Insulation Test	Normal	AC+DC	>20	MΩ	Normal	Closed	Closed	All

Test Passed Yes Tested On 09.01.2021 Tested By *B. Srinivas*



**CALIBRATION CERTIFICATE**

ADL/CO/SER/820/20-21

Customer Name & Address	Sri Vinayaga Micro Lab, Palani
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INSTRUMENT	INSTALLED ON	CALIBRATED ON
Mispa I3	20/Jan/2020	20/Jan/2020

**EQUIPMENT DETAILS**

Instrument name	Mispa I3
Serial No	21192210634
Environmental condition:	Temperature: 22°C
Equipment calibration	Mispa I3.
Parameter calibration	Inhouse (Calibrated IC card provided along with each kit)

This is to certify that the above-mentioned instrument has been calibrated & tested for the performance of kits with Control.

**AGAPPE DIAGNOSTICS LTD.**

ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24239MH1998PLC115413

**CORPORATE OFFICE / REAGENT PLANT**  
Agappe Hills, Pattimattom (PO), Dist. Ernakulam, Kerala - 683 562, India.  
Tel: + 91 484 286 7000 | Email: agappe@agappe.in

**EQUIPMENT PLANT**  
X/588-CB, Block No. 32, KINFRA Small Industrial Park,  
Nellad, Cochin, Kerala, India - 686 721. Tel: +91 484 276 7477.

**KOLKATA OFFICE**  
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**MUMBAI [REGISTERED OFFICE]**  
401 & 402, 4<sup>th</sup> Floor, Jaisingh Business Centre, 119,  
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**BANGALORE OFFICE**  
5-6, 11<sup>th</sup> Floor, Red Cross Bhavan, No.26 Race Course Road,  
Bangalore - 560 001. Tel: +91 80 2228 8288  
Email: bangaloreoffice@agappe.in



## Equipment Test Report

Checked the IC Card Reader	: Found Ok
Checked the Probe	: Found Ok
Checked Mother Board	: Found Ok
Checked the Wash Assembly	: Found Ok
Channel-1 (with cartridge)	: Found O.K.
Channel-1 (without cartridge)	: Found O.K.
Channel-2 (with cartridge)	: Found O.K.
Channel-2 (without cartridge)	: Found O.K.

## Performance validation with Control

Protein Control

LOT NO: 30070037 EXP: 2023-04.

Parameter	Low	High	Result	Target
CRP	8.4	17.4	12.6	12.9
RF	47.2	65.6	56.7	56.4
ASO	142.5	183.9	161	163.2

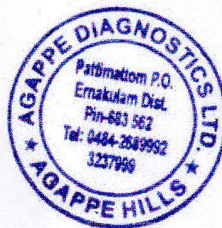
Next Calibration due on: 19/Jul/2020

For Agappe Diagnostics Ltd,

Authorized Signatory

Senthilkumar R

Engineer - Customer Service



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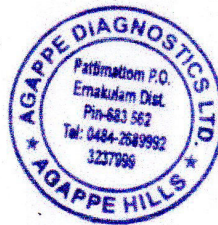
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