

Ace Medical Solutions (India) Pvt. Ltd.

An ISO 9001-2015 Certified Company

No : 3/751, 1st Cross Street, Surveyor Colony, K.Pudur, Madurai - 625 007.

Phone : 0452 - 2561691 Mobile : +91 94434 74610



GSTIN. 33AAHCA8053H1ZR • DL No. MDU/4205/20B,MDU/3971/21B • CIN : U33110TN2009PTC072140

CALIBRATION CERTIFICATE



Customer Name & Address:	M/S. New Green Lab& Biopsy Centre, #1/786, Bharathi Nagar 7 th Street, Ramanathapuram – 623 503	Certificate No:	AMS/LAB/2889808
		Issuing Date:	25/09/2021
		Page No:	1 of 1

Details of Device under Calibration (DUC):

DUC:	Bio Chemistry Analyser	Id. No:	NGC/LAB /BCA/001
Make:	MISPA VIVA	Department:	Laboratory
Model:	V1.190907	Calibrated On:	24/09/2021
Sl. No:	212030355476	Calibration Due Suggested:	23/09/2022
Type:	Semi Auto	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/5507/2021	18/01/2022
2	Thermo Hygrometer	Beetech/088	PC/01/21/ATL/0194-01	22/01/2022

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	0.228	mA	500	Normal
2	Frequency	50.1	Hz	49 -50	Normal
3	Mains Voltage Line - Neutral	225.6	Volts	220 - 240	Normal
4	Mains Voltage Line - Earth	114.9	Volts	220 - 240	Abnormal
5	Mains Voltage Neutral - Earth	111.2	Volts	< 7	No Earth

*Electrical Safety: Please check the attached log sheet

SL.No	Parameter	Measured	Standard	Correction	Unit
1	Lamp Voltage	11.83	12.00	-0.17	Volts
2	Detector Sensitivity	-0.00	0.0	0.0	% Absorbance
3	Sipper Volume	365	400	-35	µl
4	Peristaltic Pump pressure	-13.69	-15.00	+1.31	cmH2O

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. S. S.



Approved by:
(Technical Manager)

B. S. S.

INSTALLATION QUALIFICATION

Name of the instrument	MISPA VIVA
Instrument Model	Semi Automated Analyzer
Serial Number	212030355476
Date of installation	12/Sep/2020

Installation of Semi Automated Analyzer 'Mispa Viva' at **New Green Lab & Biopsy Centre, 1/786, Bharathi Nagar 7th Street, Ramanathapuram** involves the following checks done by the authorized Agappe Personnel as per the installation requirements given in Mispa Viva operation manual (OM), the respective sections and page numbers are given below

S No	Service	Section & Ref. page of OM	Status	Checked by
1	Installation requirements	Section 2.2 to 2.5 Page 11 to 13	OK	Senthilkumar R

For Agappe Diagnostics Ltd.

Customer: New Green Lab & Biopsy Centre,
Ramanathapuram

Name : Senthilkumar R

Name : N. MURUGAPRASATH

Date :

Date :

Signature :

Signature: *NP*

**New Green Lab
& Biopsy Centre**
1/786, 7th Street,
Bharathi Nagar,
Ramanathapuram.

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
406, Merlin Matrix, Plot No-10, Block-DN, Sector V,
Salt Lake City, Kolkata - 700 091.
Tel: +91 33 4003 0451 | Email: kolkataoffice@agappe.in

MUMBAI (REGISTERED OFFICE)
401 & 402, 4th Floor, Jaisingh Business Centre, 119,
Sahar Road, Parsiwada, Andheri (East), Mumbai - 400 099, India.
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BANGALORE OFFICE
5-6, IInd Floor, Red Cross Bhavan, No:26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in



ADL/DO/SER/IOP/0060/21-22

OPERATIONAL QUALIFICATION**SYSTEM CERTIFICATION**

Study data has determined that the system described in this document either meets all the criteria outlined in the Operational Qualification protocol.

S No	Service	Section & Ref. page of OM	Status	Checked by
1	Operational requirements	Section 3 to 4 Page 14 to 38	OK	Senthilkumar R

S No	Protocol	Status	Performed by
1	System Initialization	OK	Senthilkumar R
2	Temperature check	OK	Senthilkumar R
3	Filter check	OK	Senthilkumar R
4	Aspiration tube check	OK	Senthilkumar R
5	Reproducibility of Test	OK	Senthilkumar R
6	Printer Test	OK	Senthilkumar R
7	System menu check	OK	Senthilkumar R
8	QC validation	OK	Senthilkumar R

Data Sheets attached

THE SYSTEM IS READY TO USE

AGAPPE DIAGNOSTICS LTD.

Authorized Signatory



Name : Senthilkumar R
Designation : Manager - Customer Service
Date :

New Green Lab & Biopsy Centre,
Ramanathapuram

Authorized Signatory

Name : N. MURUGA PRASAD
Designation : LAB INCHARGE
Date :

**New Green Lab
& Biopsy Centre**
1/786, 7th Street,
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PERFORMANCE QUALIFICATION

SYSTEM CERTIFICATION

Study data has determined that the system described in this document either meets all the criteria outlined in the Performance Qualification protocol.

S No	Protocol	Status	Performed by
1	Touch screen response	OK	Senthilkumar R
2	Sample repeatability	OK	Senthilkumar R
3	QC response	OK	Senthilkumar R

Data Sheets attached

THE SYSTEM IS READY TO USE

AGAPPE DIAGNOSTICS LTD.

Authorized Signatory



Name : Senthilkumar R
 Designation : Manager - Customer Service
 Date :

**New Green Lab & Biopsy Centre,
 Ramanathapuram**

Authorized Signatory

Name : N. MURUGA PRASAD
 Designation : LAB INCHARGE
 Date :

**New Green Lab
 & Biopsy Centre**
 1/786, 7th Street,
 Bharathi Nagar,
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