

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. MURUGA PRASATH

Date :

Date :

Signature : Signature: 

**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,
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MUMBAI (REGISTERED OFFICE)
401 & 402, 4th Floor, Jaisingh Business Centre, 119,
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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

New Green Lab & Biopsy Centre,
Ramanathapuram

Authorized Signatory

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

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

New Green Lab & Biopsy Centre
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Email: bangaloreoffice@agappe.in



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

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. MIDRU GIA PRASAD
 Designation : LAB INCHARGE
 Date :

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

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INTERNAL QUALITY CONTROL

MISPA VIVA - SEMI AUTO ANALYZER

NORMAL CONTROL

DATE : 01.01.2022

LEVEL - 1

| S.NO | TEST NAME | MEAN VALUE | INTERVAL VALUE | TEST VALUE |
|------|-----------------|------------|-----------------|------------|
| 1 | SUGAR | 85.96 | 73.07 - 98.86 | 86.3 |
| 2 | UREA | 36.78 | 31.27 - 42.30 | 36.9 |
| 3 | CREATININE | 1.1 | 0.91 - 1.29 | 1.21 |
| 4 | URIC ACID | 6.12 | 5.20 - 7.04 | 6.15 |
| 5 | CHOLETSEROL | 140.73 | 119.62 - 161.84 | 142.6 |
| 6 | TRIGLYCERIDES | 109.19 | 92.81 - 125.57 | 111.3 |
| 7 | HDL DIRECT | 46.75 | 37.40 - 56.10 | 46.8 |
| 8 | LDL DIRECT | 75.61 | 60.49 - 90.74 | 75.7 |
| 9 | TOTAL BILIRUBIN | 1.46 | 1.10 - 1.83 | 1.49 |
| 10 | DIRECT BILIRUBN | 0.59 | 0.45 - 0.74 | 0.65 |
| 11 | SGOT | 44.75 | 35.80 - 83.70 | 44.9 |
| 12 | SGPT | 43.4 | 34.72 - 52.08 | 43.8 |
| 13 | ALK.PHOSPHATE | 135.59 | 108.47 - 162.71 | 135.7 |
| 14 | TOTAL PROTEIN | 5.9 | 5.02 - 6.79 | 6.08 |
| 15 | ALBUMIN | 3.52 | 2.99 - 4.05 | 3.59 |


Lab Incharge Sign

**New Green Lab
& Biopsy Centre**

1/786,7th Street,
Bharathi Nagar,
Ramanathapuram.

INTERNAL QUALITY CONTROL

MISPA VIVA - SEMI AUTO ANALYZER

NORMAL CONTROL

DATE : 02.01.2022

LEVEL - 1

| S.NO | TEST NAME | MEAN VALUE | INTERVAL VALUE | TEST VALUE |
|------|------------------|------------|-----------------|------------|
| 1 | SUGAR | 85.96 | 73.07 - 98.86 | 88.6 |
| 2 | UREA | 36.78 | 31.27 - 42.30 | 38.4 |
| 3 | CREATININE | 1.1 | 0.91 - 1.29 | 1.35 |
| 4 | URIC ACID | 6.12 | 5.20 - 7.04 | 6.32 |
| 5 | CHOLESTEROL | 140.73 | 119.62 - 161.84 | 141.9 |
| 6 | TRIGLYCERIDES | 109.19 | 92.81 - 125.57 | 112.7 |
| 7 | HDL DIRECT | 46.75 | 37.40 - 56.10 | 46.9 |
| 8 | LDL DIRECT | 75.61 | 60.49 - 90.74 | 76.3 |
| 9 | TOTAL BILIRUBIN | 1.46 | 1.10 - 1.83 | 1.24 |
| 10 | DIRECT BILIRUBIN | 0.59 | 0.45 - 0.74 | 0.69 |
| 11 | SGOT | 44.75 | 35.80 - 83.70 | 45.3 |
| 12 | SGPT | 43.4 | 34.72 - 52.08 | 44.7 |
| 13 | ALK.PHOSPHATE | 135.59 | 108.47 - 162.71 | 136.9 |
| 14 | TOTAL PROTEIN | 5.9 | 5.02 - 6.79 | 6.14 |
| 15 | ALBUMIN | 3.52 | 2.99 - 4.05 | 3.62 |


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

INTERNAL QUALITY CONTROL

MISPA VIVA - SEMI AUTO ANALYZER

NORMAL CONTROL

DATE : 03.01.2022

LEVEL - 1

| S.NO | TEST NAME | MEAN VALUE | INTERVAL VALUE | TEST VALUE |
|------|-----------------|------------|-----------------|------------|
| 1 | SUGAR | 85.96 | 73.07 - 98.86 | 86.4 |
| 2 | UREA | 36.78 | 31.27 - 42.30 | 39.5 |
| 3 | CREATININE | 1.1 | 0.91 - 1.29 | 1.09 |
| 4 | URIC ACID | 6.12 | 5.20 - 7.04 | 5.92 |
| 5 | CHOLETSEROL | 140.73 | 119.62 - 161.84 | 138.2 |
| 6 | TRIGLYCERIDES | 109.19 | 92.81 - 125.57 | 108.7 |
| 7 | HDL DIRECT | 46.75 | 37.40 - 56.10 | 47.5 |
| 8 | LDL DIRECT | 75.61 | 60.49 - 90.74 | 77.8 |
| 9 | TOTAL BILIRUBIN | 1.46 | 1.10 - 1.83 | 1.68 |
| 10 | DIRECT BILIRUBN | 0.59 | 0.45 - 0.74 | 0.72 |
| 11 | SGOT | 44.75 | 35.80 - 83.70 | 46.9 |
| 12 | SGPT | 43.4 | 34.72 - 52.08 | 44.7 |
| 13 | ALK.PHOSPHATE | 135.59 | 108.47 - 162.71 | 137.4 |
| 14 | TOTAL PROTEIN | 5.9 | 5.02 - 6.79 | 6.21 |
| 15 | ALBUMIN | 3.52 | 2.99 - 4.05 | 3.49 |

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

INTERNAL QUALITY CONTROL

MISPA VIVA - SEMI AUTO ANALYZER

NORMAL CONTROL

DATE : 01.02.2022

LEVEL - 1

| S.NO | TEST NAME | MEAN VALUE | INTERVAL VALUE | TEST VALUE |
|------|-----------------|------------|-----------------|------------|
| 1 | SUGAR | 85.96 | 73.07 - 98.86 | 88.1 |
| 2 | UREA | 36.78 | 31.27 - 42.30 | 35.5 |
| 3 | CREATININE | 1.1 | 0.91 - 1.29 | 1.15 |
| 4 | URIC ACID | 6.12 | 5.20 - 7.04 | 6.12 |
| 5 | CHOLETSEROL | 140.73 | 119.62 - 161.84 | 142.5 |
| 6 | TRIGLYCERIDES | 109.19 | 92.81 - 125.57 | 112.4 |
| 7 | HDL DIRECT | 46.75 | 37.40 - 56.10 | 47.8 |
| 8 | LDL DIRECT | 75.61 | 60.49 - 90.74 | 76.9 |
| 9 | TOTAL BILIRUBIN | 1.46 | 1.10 - 1.83 | 1.45 |
| 10 | DIRECT BILIRUBN | 0.59 | 0.45 - 0.74 | 0.61 |
| 11 | SGOT | 44.75 | 35.80 - 83.70 | 45.6 |
| 12 | SGPT | 43.4 | 34.72 - 52.08 | 44.4 |
| 13 | ALK.PHOSPHATE | 135.59 | 108.47 - 162.71 | 140.7 |
| 14 | TOTAL PROTEIN | 5.9 | 5.02 - 6.79 | 6.25 |
| 15 | ALBUMIN | 3.52 | 2.99 - 4.05 | 3.85 |


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INTERNAL QUALITY CONTROL

MISPA VIVA - SEMI AUTO ANALYZER

NORMAL CONTROL

DATE : 02.02.2022

LEVEL - 1

| S.NO | TEST NAME | MEAN VALUE | INTERVAL VALUE | TEST VALUE |
|------|------------------|------------|-----------------|------------|
| 1 | SUGAR | 85.96 | 73.07 - 98.86 | 89.5 |
| 2 | UREA | 36.78 | 31.27 - 42.30 | 36.2 |
| 3 | CREATININE | 1.1 | 0.91 - 1.29 | 1.25 |
| 4 | URIC ACID | 6.12 | 5.20 - 7.04 | 6.08 |
| 5 | CHOLESTEROL | 140.73 | 119.62 - 161.84 | 141.7 |
| 6 | TRIGLYCERIDES | 109.19 | 92.81 - 125.57 | 110.2 |
| 7 | HDL DIRECT | 46.75 | 37.40 - 56.10 | 47.5 |
| 8 | LDL DIRECT | 75.61 | 60.49 - 90.74 | 78.9 |
| 9 | TOTAL BILIRUBIN | 1.46 | 1.10 - 1.83 | 1.55 |
| 10 | DIRECT BILIRUBIN | 0.59 | 0.45 - 0.74 | 0.58 |
| 11 | SGOT | 44.75 | 35.80 - 83.70 | 45.6 |
| 12 | SGPT | 43.4 | 34.72 - 52.08 | 45.7 |
| 13 | ALK.PHOSPHATE | 135.59 | 108.47 - 162.71 | 138.7 |
| 14 | TOTAL PROTEIN | 5.9 | 5.02 - 6.79 | 6.01 |
| 15 | ALBUMIN | 3.52 | 2.99 - 4.05 | 3.65 |


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

INTERNAL QUALITY CONTROL

MISPA VIVA - SEMI AUTO ANALYZER


NORMAL CONTROL

DATE : 08.03.2022

LEVEL - 1

| S.NO | TEST NAME | MEAN VALUE | INTERVAL VALUE | TEST VALUE |
|------|-----------------|------------|-----------------|------------|
| 1 | SUGAR | 85.96 | 73.07 - 98.86 | 90.8 |
| 2 | UREA | 36.78 | 31.27 - 42.30 | 38.5 |
| 3 | CREATININE | 1.1 | 0.91 - 1.29 | 1.19 |
| 4 | URIC ACID | 6.12 | 5.20 - 7.04 | 6.25 |
| 5 | CHOLETSEROL | 140.73 | 119.62 - 161.84 | 145.5 |
| 6 | TRIGLYCERIDES | 109.19 | 92.81 - 125.57 | 120.2 |
| 7 | HDL DIRECT | 46.75 | 37.40 - 56.10 | 49.8 |
| 8 | LDL DIRECT | 75.61 | 60.49 - 90.74 | 71.5 |
| 9 | TOTAL BILIRUBIN | 1.46 | 1.10 - 1.83 | 1.39 |
| 10 | DIRECT BILIRUBN | 0.59 | 0.45 - 0.74 | 0.69 |
| 11 | SGOT | 44.75 | 35.80 - 83.70 | 46.5 |
| 12 | SGPT | 43.4 | 34.72 - 52.08 | 43.5 |
| 13 | ALK.PHOSPHATE | 135.59 | 108.47 - 162.71 | 138.5 |
| 14 | TOTAL PROTEIN | 5.9 | 5.02 - 6.79 | 5.98 |
| 15 | ALBUMIN | 3.52 | 2.99 - 4.05 | 3.42 |

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