

**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:

NPW



**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

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EQUIPMENT PLANT
K/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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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 PRASATH
Designation : LAB INCHARGE
Date :

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

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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**
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