

**INSTALLATION QUALIFICATION**

Name of the instrument	MISPA VIVA
Instrument Model	Semi Automated Analyzer
Serial Number	211930113606
Date of installation	28/MAR/2019

Installation of Semi Automated Analyzer 'Mispa Viva' at Ever Green Health Centre, 241/43, GT Road, Liluah, Howrah, West Bengal. 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	Sachin Kumar Singh

For Agappe Diagnostics Ltd.

Name : Sachin Kumar Singh  
 Designation : Assistant Manager Customer Service  
 Date : 18/12/2023  
 Signature : Sachin K. Singh



Customer: Ever Green Health Centre

Name : Saumitra Bhunia  
 Designation: Lab. Technologist  
 Date : 18/12/2023  
 Signature: Saumitra Bhunia

**AGAPPE DIAGNOSTICS LTD.** ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24239MH1998PLC115413

CORPORATE OFFICE / REAGENT PLANT  
 Agappe Hills, Pattimatton (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: kolkatoffice@agappe.in

MUMBAI (REGISTERED OFFICE)  
 401 & 402, 4<sup>th</sup> Floor, Jaisingh Business Centre, 119,  
 Sahar Road, Parsiwada, Andheri (East), Mumbai - 400 099, India.  
 Tel: +91 22 4300 8000 | Email: mumbaioffice@agappe.in

DELHI OFFICE  
 DSM 540, 5<sup>th</sup> Floor, DLF Tower, Shivaji Marg,  
 New Delhi - 110 015, India.  
 Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

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

**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	Sachin Kumar Singh

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

Data Sheets attached.

THE SYSTEM IS READY TO USE

**AGAPPE DIAGNOSTICS LTD**

**Ever Green Health Centre**

Authorized Signatory



Authorized Signatory

Name : Sachin Kumar Singh

Designation : Assistant Manager Customer Service

Date : 18/12/2023

Name : Saumitra Bhunia

Designation : Lab. Technologist

Date : 18/12/2023



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ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | EN 12423:2006 MH1998PLC115413

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

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 X/588-CB, Block No. 32, KINFRA Small Industrial Park,  
 Nelliad, 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, 4<sup>th</sup> Floor, Jaisingh Business Centre, 119,  
 Sahar Road, Parsiwada, Andheri (East), Mumbai - 400 099, India.  
 Tel: +91 22 4300 8000 | Email: mumbaioffice@agappe.in

**DELHI OFFICE**  
 DSM 540, 5<sup>th</sup> Floor, DLF Tower, Shivaji Marg,  
 New Delhi - 110 015, India.  
 Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

**BANGALORE OFFICE**  
 5-6, II<sup>nd</sup> Floor, Red Cross Bhavan, No-26 Race Course Road,  
 Bangalore - 560 001. Tel: +91 80 2228 8288  
 Email: bangaloreoffice@agappe.in



**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	Sachin Kumar Singh
2	Sample repeatability	OK	Sachin Kumar Singh
3	QC response	OK	Sachin Kumar Singh

Data Sheets attached.

**THE SYSTEM IS READY TO USE**

**AGAPPE DIAGNOSTICS LTD**

**Ever Green Health Centre**



**Authorized Signatory**

**Authorized Signatory**

**Name** : Sachin Kumar Singh  
**Designation** : Assistant Manager Customer Service

**Name** : Saumitra Bhunia  
**Designation** : Lab. Technologist

**Date** : 18/12/2023

**Date** : 18/12/2023



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ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24239MH1998PTC144783

**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,  
 Neilad, 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: kolkattooffice@agappe.in

**MUMBAI (REGISTERED OFFICE)**  
 401 & 402, 4<sup>th</sup> Floor, Jaisingh Business Centre, 119,  
 Sahar Road, Parsiwada, Andheri (East), Mumbai - 400 099, India.  
 Tel: +91 22 4360 8000 | Email: mumbaioffice@agappe.in

**DELHI OFFICE**  
 DSM 940, 5<sup>th</sup> Floor, DLF Tower, Shivaji Marg,  
 New Delhi - 110 015, India.  
 Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

**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

**CALIBRATION REPORT**

**Customer: Ever Green Health Centre, West Bengal**

**Serial No: 211930113606**

**Model: Mispa Viva**

**DOI: 28/MAR/2019**

**Date of Calibration: 22/SEP/2023**

**INSTRUMENT CONTROL**

**Visual Control: PASSED**

**Zero Drift after 1 Hour of zero setting (WL=340nm) 0.001**

**PHOTOMETRIC LINEARITY**

Solution	WL (nm)	100%	75%	50%	25%
Potassium dichromate	340nm	100.2	74.6	51.8	25.2
P-Nitrophenol	405nm	100.4	74.5	50.3	25.8
Cobaltous Ammonium Sulphate	505nm	100.8	76.9	50.1	24.7

**CHEMISTRY CONTROL**

	TEST	REAGENT	CONTROL SERUM	THEORETICAL VALUE	READ VALUE	RANGE
END POINT			Lot No: Expiry :			
KINETIC			Lot No: Expiry :			
FIXED TIME			Lot No: Expiry :			

**Validity: 6 months from the date of calibration.**

**For, Agappe Diagnostics Ltd,**



**Authorized Signatory**

**Name: Sachin Kumar Singh  
Assistant Manager Customer Service**

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