

INSTALLATION QUALIFICATION

Name of the instrument	MISPA VIVA
Instrument Model	Semi Automated Analyzer
Serial Number	21163010627
Date of installation	27/Jul/2016

Installation of Semi Automated Analyzer 'Mispa Viva' at **Modern Pathology Laboratory, Near Prem Dairy, New Colony Road, Behind SRS Value Bazaar, Palwal** 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	Durgesh Rajput

For Agappe Diagnostics Ltd.**Customer: Modern Pathology Laboratory, Palwal**

Name : Durgesh Rajput

Name :

Date :

Date :

Signature :

Signature:

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

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EQUIPMENT PLANT
 X/588-CB, Block No. 32, KINFRA Small Industrial Park,
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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	Durgesh Rajput

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

Data Sheets attached

THE SYSTEM IS READY TO USE

AGAPPE DIAGNOSTICS LTD.

Authorized Signatory



Name : Durgesh Rajput
Designation : Asst. Manager - Customer Service
Date :

Modern Pathology Laboratory, Palwal

Authorized Signatory

Name :
Designation :
Date :

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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	Durgesh Rajput
2	Sample repeatability	OK	Durgesh Rajput
3	QC response	OK	Durgesh Rajput

Data Sheets attached

THE SYSTEM IS READY TO USE

AGAPPE DIAGNOSTICS LTD.

Authorized Signatory



Name : Durgesh Rajput
Designation : Asst. Manager - Customer Service
Date :

Modern Pathology Laboratory, Palwal

Authorized Signatory

Name :
Designation :
Date :

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