



Calibration Certificate

ADL/DO/MS/C/0171/22-23

This is to certify that **Mispa-i2 Specific Protein Analyzer** with Serial No: **21211645747** at **Modern Pathology Laboratory, Near Prem Dairy, New Colony Road, Behind SRS Value Bazaar, Palwal** have been inspected and calibrated.

Calibration Details

Instrument Name	: Mispa-i2 Specific Protein Analyzer
Installation Date	: 05/06/2021
Calibration Date	: 04/07/2022
Calibration Certificate Due Date	: 03/01/2023
Checked the IC Card Reader	: Found OK
Checked Electronic Pipette Jack	: Found OK
Checked the Cuvette Motor	: Found OK
Checked Mother Board	: Found OK
Checked with Control	: Found OK

For Agappe Diagnostic Ltd.



Authorized Signatory

Durgesh Rajput

Asst. Manager - Customer Service

AGAPPE DIAGNOSTICS LTD.

ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24239MH1998PLC115413

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**CERTIFICATE OF CALIBRATION**

Customer Name : Modern Pathology Laboratory
 Address of the customer : Behind SRS Value Bazaar, Palwal
 Instrument Model : BC 3000 Plus - 3 Part Hematology Analyzer
 Serial No. : RJ-02129686
 Date of Installation : 20/08/2020
 Date of Calibration : 04/07/2022

This is to certify that the above-mentioned product has been calibrated for CBC parameters (WBC, RBC, HGB, MCV, PLT) according to the standard operating procedure given by the MINDRAY

The reference instruments used for value assignment are managed by the traceability system in Shenzhen Mindray Bio – Medical Electronics Co., Ltd, and these are traceable to the International Standards such as ICSH/WHO, NCCLS.

For Agappe Diagnostics Ltd.,



Authorized Signatory
 Name: Durgesh Rajput
 Designation: Asst. Manager - Customer Service

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CALIBRATION REPORT

ADL/DO/MS/C/0172/22-23

Customer: Modern Pathology Laboratory, Palwal

Serial No.: 21163010627

Model : Mispa Viva DOI : 27/Jul/2016

Date of Calibration :04/Jul/2022

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: Durgesh Rajput
Designation: Asst. Manager - Customer Service

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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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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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