



**CALIBRATION REPORT**

ADL/KO/SER/0077/23-24

Customer: **Suraha Speciality Laboratory**

Place: **Sonarpur, West Bengal**

Model : **Mispa Plus**

DOI: **21/11/2021**

Date of Calibration: **21/06/2023**

**INSTRUMENT CONTROL**

Visual Control: **PASSED**

From Machine Screen (System View )	
Software Version	1.6.5
S/No	2121103000298

**CHEMISTRY CONTROL**

	TEST	REAGENT	CONTROL SERUM	THEORETICAL VALUE	READ VALUE	RANGE
END POINT	GLUCOSE	ACCUREX LOT: 415D 2024-10	Lot No: 33030426 Expiry: 02/25	112	123	94-130
KINETIC	SUPT	DELTA LOT PT220 901	Lot No: 33030426 Expiry: 02/25	39	39	27-41
FIXED TIME	CRF	DELTA CRT 230101 12/29	Lot No: 33030426 Expiry: 02/25	1.25	1.41	0.95-1.55

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**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,  
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, 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



From Temperature Service Screen		
	Actual	Offset
37 °C	1560	0.5
30 °C	1830	0
25 °C	2045	0
From Pump Calibration Screen		
No of Steps	3378	

After Gain Calibration, From Filter Status		
Filter	ADC Value	Gain
340 nm	9263889	1.000
405 nm	14610497	1.577
505 nm	12754816	1.377
546 nm	10313788	1.113
578 nm	10917593	1.179
630 nm	10833726	1.169

Validity: 6 months from the date of calibration

Thanking you,

This is to certify that we have calibrated the instrument 2121103000298 and on inspection of the instrument it is observed that the instrument is working fine.

For, Agappe Diagnostics Ltd,

*(Signature)*  
21/06/2023



Authorized Signatory

Anindya Banerjee

Assistant Manager Customer Service

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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: 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, 1<sup>st</sup> Floor, Red Cross Bhavan, No:26 Race Course Road, Bangalore - 560 001. Tel: +91 80 2228 8288  
Email: bangaloreoffice@agappe.in



## INSTALLATION QUALIFICATION

Name of the instrument	MISPA PLUS
Instrument Model	Semi Automated Analyzer
Serial Number	2121103000298
Date of installation	21/11/2021

Installation of Semi-Automated Analyzer 'Mispa Plus' at **Suraha Speciality Laboratory, H.C Sarani, Sonarpur** involves the following checks done by the authorized Agappe Personnel as per the installation requirements given in Mispa Plus 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 2.1 to 2.7 Page 10 to 13	OK	SERVICE ENGINEER

For Agappe Diagnostics Ltd.



Suraha Speciality Laboratory

Name : ANINDYA BANERJEE  
 Date : 21/11/2021  
 Signature : *[Handwritten Signature]*

Name : Mukti Sada Pradhan  
 Date : 21.11.2021 (Lab. Ine)  
 Signature: *[Handwritten Signature]*  
 Suraha Speciality Laboratory  
 H.C. Sarani, Sonarpur  
 Kolkata - 700 150  
 Ph : 9836756428



## OPERATIONAL QUALIFICATION

### SYSTEM CERTIFICATION

Study data has determined that the system described in this document 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 3.1 to 3.5 Page 13 to 14	OK	ANINDYA BANNERJEE

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

Data Sheets attached

THE SYSTEM IS READY TO USE

AGAPPE DIAGNOSTICS LTD

Authorized Signatory



Name : ANINDYA BANNERJEE  
 Designation : ASSISTANT MANAGER  
 Date : 21/11/21

Suraha Speciality Laboratory

Authorized Signatory

Name : Mukti Pada Pradhan  
 Designation : 21.11.2021 (Lab. In-charge)  
 Date :  
 Suraha Speciality Laboratory  
 H.C. Sarani, Sonarpur  
 Kolkata - 700 150  
 Ph : 9836756428

AGAPPE DIAGNOSTICS LTD.

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**KOLKATA OFFICE / REAGENT PLANT**  
 Agappe Hills, Partimattom (PO), Dist. Ernakulam, Kerala - 681 562, India  
 Tel: +91 484 286 7000 | Email: agappe@agappe.in

**MUMBAI (REGISTERED OFFICE)**  
 Plot No. 402, 4<sup>th</sup> Floor, Jaisingh Business Centre, 119,  
 Kurla Road, Parsipada, Andheri (East), Mumbai - 400 099, India  
 Tel: +91 22 4900 8000 | Email: mumbai@agappe.in

**EQUIPMENT PLANT**  
 X/SAB-CB, Block No. 12, KINFRA Small Industrial Park,  
 Nellore (Coim), Kerala, India - 686 721. Tel: +91 484 276 7477

**DELHI OFFICE**  
 D5M 540, 5<sup>th</sup> Floor, DLI Tower, Sheraji Marg,  
 New Delhi - 110 015, India  
 Tel: +91 11 4558 8416 | Email: delhi@agappe.in

**KOLKATA OFFICE**  
 406, Merlin Mall, Plot No-10, Block-DN, Sector-V,  
 Salt Lake City, Kolkata - 700 091.  
 Tel: +91 33 4001 0451 | Email: kolkata@agappe.in

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



## PERFORMANCE QUALIFICATION

### SYSTEM CERTIFICATION

Study data has determined that the system described in this document meets all the criteria outlined in the Performance Qualification protocol.

S No	Protocol	Status	Performed by
1	Touch screen response	OK	SERVICE ENGINEER
2	Sample repeatability	OK	"
3	QC response	OK	"

Data Sheets attached

THE SYSTEM IS READY TO USE

AGAPPE DIAGNOSTICS LTD



Suraha Speciality Laboratory

Authorized Signatory

Name : ANINDYA BANERJEE  
 Designation : ASSISTANT MANAGER  
 Date : 21/11/2021

Authorized Signatory

Name : Mukti Pada Pradhan  
 Designation : Lab. In-charge  
 Date : 21.11.2021

Suraha Speciality Laboratory  
 H.C. Sarani, Sonarpur  
 Kolkata - 700 150  
 Ph : 9830750428

**AGAPPE DIAGNOSTICS LTD.** ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24239MH1998PLC15413

STATE OFFICE / REAGENT PLANT  
 Plot No. 11, Patilwadi (PD), GSI, Ernakulam, Kerala - 681 562, India  
 Tel: +91 484 296 7000 | Email: agappe@agappe.in

EQUIPMENT PLANT  
 A/388-CB, Block No. 12, KINFRA Small Industrial Park,  
 Nellikuzhi, Cochin, Kerala, India - 686 721. Tel: +91 484 276 7477

KOLKATA OFFICE  
 406, Merlin Matira, Plot No-10, Block DM, Sector V,  
 Salt Lake City, Kolkata - 700 091  
 Tel: +91 33 4003 0451 | Email: kolkataoffice@agappe.in

REGISTERED OFFICE  
 4th Floor, Jaisingh Business Centre, 119,  
 Road, Parsipada, Andheri (E-3), Mumbai - 400 099, India  
 Tel: +91 22 4300 8000 | Email: mumbai@agappe.in

DELHI OFFICE  
 D5M 540, 5th Floor, OJ Tower, Shriraj Marg,  
 New Delhi - 110 015, India  
 Tel: +91 11 4558 8416 | Email: delhi@agappe.in

BANGALORE OFFICE  
 5-6, 1st Floor, Red Cross Bhuvan, No.26 Race Course Road,  
 Bangalore - 560 001. Tel: +91 80 2225 8288  
 Email: bangaloreoffice@agappe.in



ADL/KO/SER/0073/23-24

## Certificate of Training

This is to certify that **Mr./Ms./Mrs. Pijush Halder (lab technician)** of **Suraha Speciality Laboratory, Sonarpur, West Bengal** has been trained by us in the operation and application of **Semi-Automated Clinical Chemistry Analyser - Mispa Plus** on **21/NOV/2022**

His/Her involvement and performance during the training session was highly appreciable.

For Agappe Diagnostics Ltd,



*[Signature]*  
21/11/2022

**Authorized Signatory**

Anindya Banerjee

Assistant Manager Customer Service.

### **AGAPPE DIAGNOSTICS LTD.**

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**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,  
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, 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



ADL/KO/SER/0076/23-24

# Certificate of Training

This is to certify that **Mr./Ms./Mrs. Mukti Pada Pradhan (lab in charge)** of **Suraha Speciality Laboratory, Sonarpur, West Bengal** has been trained by us in the operation and application of **Semi-Automated Clinical Chemistry Analyser - Mispa Plus** on **21/NOV/2022**

His/Her involvement and performance during the training session was highly appreciable.

For Agappe Diagnostics Ltd,



*Anindya Banerjee*  
21/11/2022

**Authorized Signatory**

Anindya Banerjee

Assistant Manager Customer Service.

**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: 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 - 110 013, 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 2278 8288  
Email: bangaloreoffice@agappe.in



ADL/KO/SER/0075/23-24

## Certificate of Training

This is to certify that **Mr./Ms./Mrs. Priyanka Sarkar (lab technician)** of **Suraha Speciality Laboratory, Sonarpur, West Bengal** has been trained by us in the operation and application of Semi-Automated Clinical Chemistry Analyser - Mispa Plus on 21/NOV/2022

His/Her involvement and performance during the training session was highly appreciable.

For Agappe Diagnostics Ltd,



*[Signature]*  
21/11/2022

**Authorized Signatory**

Anindya Banerjee

Assistant Manager Customer Service.

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

**EQUIPMENT PLANT**  
X/588-CB, Block No. 32, KINFRA Small Industrial Park, Neilad, Cochin, Kerala, India - 686 721. Tel: +91 484 276 7477.

**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

**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

**BANGALORE OFFICE**  
5-6, 11<sup>th</sup> Floor, Red Cross Bhavan, No.26 Race Course Road, Bangalore - 560 001. Tel: +91 80 2278 8288  
Email: bangaloreoffice@agappe.in





ADL/KO/SER/0074/23-24

## Certificate of Training

This is to certify that **Mr./Ms./Mrs. Amitabh Maity (lab technician)** of **Suraha Speciality Laboratory, Sonarpur, West Bengal** has been trained by us in the operation and application of **Semi-Automated Clinical Chemistry Analyser - Mispa Plus** on **21/NOV/2022**

His/Her involvement and performance during the training session was highly appreciable.

For Agappe Diagnostics Ltd,



*Anindya Banerjee*  
21/11/2022

Authorized Signatory

Anindya Banerjee

Assistant Manager Customer Service.

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**CORPORATE OFFICE / REAGENT PLANT**  
Agappe Hills, Pattimatam (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 72L. 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, Parslwada, Andheri (East), Mumbai - 400 099, India.  
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Bangalore - 560 001. Tel: +91 80 2228 8288  
Email: bangaloreoffice@agappe.in