



DATE:-30/12/2020

Purchase order

TO

UNIVERSAL BIOMARKETING,

PLOT NO:- 2/6,D5/1,

GROUND FLOOR ,LIG COLONY,

ANNA NAGAR,

MADURAI-625020.

Dear Sir,

We are placing the order of **MISPA CXL PRO**
(fully automated biochemistry analyser)

For 5,75,000 + 18% GST net rate of 6,78,500/-

Kindly supply the the instrument earliest

TERMS AND CONDITIONS

- 1) Free reagents of 1,20,000 on MRP
- 2) 5 years warrenty on wonder scheme
- 3) Lamp cost 12,500 + tax foc 6000 (FIVE YEARS)
- 4) Cuvette 21000+tax for 56 nos (five years)
- 5) 5 reagents position open and 5 will open in next two months



Handwritten signature and circular stamp of Quality Care Diagnostic Centre, Theni, 625 531.

Tax Invoice



UNIVERSAL BIO MARKETING
 P.NO 2/16 D 5/1 Ground Floor,
 LIG COLONY, Anna Nagar, Madurai-20
 DL.No: MDU/4401/20B
 DL.No: MDU/4166/21B
 Phone No. 0452 - 4378838
 Cell No. 98656 - 28838 / 9624603234
 E-Mail: Universal_biomarketing@yahoo.Com
 GSTIN/UIN: 33AACFU7151L1Z0
 State Name : Tamil Nadu, Code : 33

Buyer
Quality Care Diagnostics Centre(T)
 165, Kallar Society Bulding Near Ganapathy Silks,
 Opp to Saraswathy Hotel, Madurai Road, Theni
 State Name : Tamil Nadu, Code : 33

Contact person : Mr. Dhanapal
 Contact : 9842565998

Invoice No. 3572	Dated 11-Jan-2021
Delivery Note	Mode/Terms of Payment
Supplier's Ref. 3572	Other Reference(s)
Buyer's Order No.	Dated
Despatch Document No.	Delivery Note Date
Despatched through Lorry Parcel	Destination
Terms of Delivery	

Sl No.	Description of Goods	HSN/SAC	GST Rate	Quantity	Rate	per	Disc. %	Amount
1	Fully Automated Clinical Chemistry Analyser Batch : 21195000	90278090	18 %	1 NOS	5,75,000.00	NOS		5,75,000.00
2	Computer Batch : 42A	84713010	18 %	1 NOS	25,000.00	NOS	100 %	
3	Power Card Batch : 72000018	72000018	18 %	1 NOS	5,000.00	NOS	100 %	
								5,75,000.00
								51,750.00
								51,750.00
								9 %
								9 %
Total								₹ 6,78,500.00

Output CGST@9%
 Output SGST@9%

Amount Chargeable (in words)
INR Six Lakh Seventy Eight Thousand Five Hundred Only

HSN/SAC	Taxable Value	Central Tax		State Tax		Total Tax Amount
		Rate	Amount	Rate	Amount	
90278090	5,75,000.00	9%	51,750.00	9%	51,750.00	1,03,500.00
84713010		9%		9%		
72000018		9%		9%		
Total	5,75,000.00		51,750.00		51,750.00	1,03,500.00

Tax Amount (in words) : **INR One Lakh Three Thousand Five Hundred Only**

Declaration
 We declare that this invoice shows the actual price of the goods described and that all particulars are true and correct.

Company's Bank Details
 Bank Name : Karur Vysya Bank
 A/c No. : 1608135000000721
 Branch & IFS Code: Anna Nagar & KVBL00001608

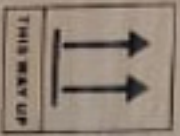
Customer's Seal and Signature

for UNIVERSAL BIO MARKETING



Prepared by _____ Verified by _____

Authorised Signatory



Auto-Chemistry Analyzer
 Shimadzu, Bldg. # 413300, 2700 N. 17th St.
 Mesa, AZ 85205
 Tel: 480-948-1000
 Fax: 480-948-1001
For Shipping Info
07/2014

AGAPPC **MISPA** 

**CERTIFICATE OF CALIBRATION**

ADL/CO/SER/895/20-21

Instrument: Mispa CXL PRO Fully Automated Biochemistry Analyser**Customer Name:** Quality Care Diagnostics Center,Theni**Date of Installation:** 19/Jan/2021**S/N:** 190T180CS0026K**Alignment Check**

Motion Check	Checked	Remark
Sample Probe	<input checked="" type="checkbox"/>	OK
Reagent Probe	<input checked="" type="checkbox"/>	OK
Mixing Bar	<input checked="" type="checkbox"/>	OK
Reaction Disk	<input checked="" type="checkbox"/>	OK
Reagent Disk	<input checked="" type="checkbox"/>	OK
Sample Disk	<input checked="" type="checkbox"/>	OK
Cuvette Check	<input checked="" type="checkbox"/>	OK
Lamp	<input checked="" type="checkbox"/>	OK

System	Checked	Remark
Main unit	<input checked="" type="checkbox"/>	OK
Temp. unit	<input checked="" type="checkbox"/>	OK
Mixing unit	<input checked="" type="checkbox"/>	OK
Reaction unit	<input checked="" type="checkbox"/>	OK
Reagent unit	<input checked="" type="checkbox"/>	OK
Sample unit	<input checked="" type="checkbox"/>	OK

AGAPPE DIAGNOSTICS LTD.

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

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: kolkattoffice@agappe.in

MUMBAI [REGISTERED OFFICE]
401 & 402, 4th 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, 5th Floor, DLF Tower, Shivaji Marg,
New Delhi - 110 015, India.
Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
5-6, IInd Floor, Red Cross Bhavan, No:26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in

OPTICAL SECTION

Filter	Light Intensity	
340	11001	✓
380	10940	✓
405	10842	✓
450	10776	✓
480	10700	✓
505	10584	✓
546	10542	✓
570	10578	✓
600	10154	✓
660	10296	✓
700	10528	✓
800	10624	✓

Power Supply : 12V 24V

The equipment is calibrated for the different parameters by using Multi Calibrator

Lot.No: 300 20180 Exp: 12-2021

This is to certify that the above mentioned product has been calibrated according to the standard operating procedure given by the Agappe Diagnostics.

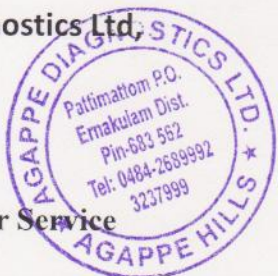
Date of Calibration : 19/Jan/2021

Next Due : 18/Jul/2021

For, Agappe Diagnostics Ltd.



Senthilkumar R
 Engineer-Customer Service

**AGAPPE DIAGNOSTICS LTD.**

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

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, 4th 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, 5th Floor, DLF Tower, Shivaji Marg,
 New Delhi - 110 015, India.
 Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
 5-6, 11th Floor, Red Cross Bhavan, No:26 Race Course Road,
 Bangalore - 560 001. Tel: +91 80 2228 8288
 Email: bangaloreoffice@agappe.in



INSTALLATION QUALIFICATION

For

FULLY AUTOMATED CLINICAL CHEMISTRY ANALYZER

MODEL : MISPA CXL PRO

AGAPPE DIAGNOSTICS LTD.

ADL/FO/MCD/082/2020/R00

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

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, 4th 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, 5th Floor, DLF Tower, Shivaji Marg,
New Delhi - 110 015, India.
Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
5-6, 11th Floor, Red Cross Bhavan, No:26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in

**TABLE OF CONTENTS**

S No.	Contents	Page No.
I	Approval of the IQ procedure	3
II	Instructions	4
III	Scope	5
V	Installation Qualification	6
V	Comments	11
VI	System Certification	12

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

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: kolkattoffice@agappe.in

MUMBAI [REGISTERED OFFICE]
401 & 402, 4th 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, 5th Floor, DLF Tower, Shivaji Marg,
New Delhi - 110 015, India.
Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
5-6, 11th Floor, Red Cross Bhavan, No.26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in



SURGING INNOVATION
SERVING MANKIND

I. APPROVAL OF THE INSTALLATION QUALIFICATION PROCEDURE

Both QUALITY CARE DIAGNOSTICS CENTER, THENI and AGAPPE DIAGNOSTICS LTD are jointly responsible for the installation of MISPA CXL PRO with serial number 190T180CS0026K at Quality Care Diagnostics Center, Near Canara Bank, Madhurai Road, Theni as per the attached Installation Qualification protocol.

Protocol Performed By: Representative of AGAPPE DIAGNOSTICS LTD.

Name	:	Senthilkumar R	Signature :	
Title	:	Engineer-Customer Service	Date	19/01/2021
Company	:	AGAPPE DIAGNOSTICS LTD.		



Validation Team from QUALITY CARE DIAGNOSTICS CENTER, THENI

Name	:	Mr. R. Dhanasalan	Signature :	
Designation	:	Chief of Lab Services	Date	19/01/2021
Department	:	Biochemistry		



Customer Authorizations:

Name : Mr. R. Dhanasalan
Title : INSTALLATION QUALIFICATION
Site : Theni

Signature :
Date : 19/01/2021



AGAPPE DIAGNOSTICS LTD.

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

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, 4th 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, 5th Floor, DLF Tower, Shivaji Marg,
New Delhi - 110 015, India.
Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
S-6, 11th Floor, Red Cross Bhavan, No:26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in



II. INSTRUCTIONS

1. An authorized **AGAPPE DIAGNOSTICS LTD.** representative will check and enter the specific data as outlined in the Installation Qualification. Each result will be noted and dated.
2. The concerned employees of **QUALITY CARE DIAGNOSTICS CENTER, THENI** will verify each result and sign in each page. The member of the validation team will carry this out.
3. ALL deviations from the acceptance criteria detailed in this document will be noted in the **COMMENTS** section at the end of the IQ protocol. All resolution to such problems will also be noted in the **COMMENTS** section, and must be resolved prior to issuance of a **SYSTEM CERTIFICATION**.

AGAPPE

AGAPPE DIAGNOSTICS LTD.

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

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, 4th 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, 5th Floor, DLF Tower, Shivaji Marg,
New Delhi - 110 015, India.
Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
5-6, IInd Floor, Red Cross Bhavan, No:26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in



This Installation Qualification protocol will be performed on the **MISPA CXL PRO** at **QUALITY CARE DIAGNOSTICS CENTER, THENI**. This Installation protocol will define the documentation that will be used to evaluate the instruments installation in accordance with the manufacturer's specifications and intended use. Successful completion of this protocol will verify that the instrument identified has been installed in accordance with the intended usage.

Trained, knowledgeable personnel will perform qualification studies. Any exceptional conditions encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated and the appropriate course of action determined. All documents will be initialed and dated.

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

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, 4th 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, Nellad, Cochin, Kerala, India - 686 721. Tel: +91 484 276 7477.

DELHI OFFICE

DSM 540, 5th 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

S-6, 11th Floor, Red Cross Bhavan, No:26 Race Course Road, Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in



IV. INSTALLATION QUALIFICATION

A. Instrument Identification

Verified Date : 19/01/2021

1. Model Name : MISPA CXL PRO
2. Serial Number : 190T180CS0026K

B. Following is a list of accessories /consumables verified:

S No.	Component	Present (Yes/No)	Verified By	Comments
01	Analyzer Main unit	Yes	Senthilkumar R	—
02	Computer	Yes	Senthilkumar R	—
03	Printer	No	Senthilkumar R	—
04	Connector cable	Yes	Senthilkumar R	—
05	Power cord	Yes	Senthilkumar R	—
06	Waste can	Yes	Senthilkumar R	—
07	Water can	Yes	Senthilkumar R	—
08	Water connector tube	Yes	Senthilkumar R	—
09	Waste connector tube	Yes	Senthilkumar R	—
10	Probe assembly	Yes	Senthilkumar R	—
11	Mixer assembly	Yes	Senthilkumar R	—
12	Reagent tray	Yes	Senthilkumar R	—
13	Cuvette blocks	Yes	Senthilkumar R	—
14	Reagent bottles	Yes	Senthilkumar R	—

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

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: kolkatatooffice@agappe.in

MUMBAI [REGISTERED OFFICE]
401 & 402, 4th 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, 5th Floor, DLF Tower, Shivaji Marg,
New Delhi - 110 015, India.
Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
S-6, 11th Floor, Red Cross Bhavan, No:26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in



C Installation Checks

Purpose: To make sure that the instrument is received with all the major components necessary for operation

S No.	Component	(Yes/No)	Verified By	Comments
1	Major components and accessories are present	Yes	Senthilkumar R	—
2	There is no physical damage to the components	Yes	Senthilkumar R	—
3	Ambient temperature is available	Yes	Senthilkumar R	—
4	Instrument is installed in the table leveled properly	Yes	Senthilkumar R	—
5	Power supply is correct	Yes	Senthilkumar R	—
6	Electric connections are tight, weatherproof & earthed	Yes	Senthilkumar R	—
7	Analyzer unit installed as per the manufacturers recommendations	Yes	Senthilkumar R	—

Summary:

The information is recorded against each data and the deviations if any is justified / explained properly.

Acceptance criteria:

PARAMETER

PASS ✓

FAIL

AGAPPE DIAGNOSTICS LTD.

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

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, 4th 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, 5th Floor, DLF Tower, Shivaji Marg,
New Delhi - 110 015, India.
Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
5-6, 11th Floor, Red Cross Bhavan, No.26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in

**D. Instrument Installation**

Date of Installation : 19/01/2021

Installed by : Senthilkumar R

S No.	Parameter	Done by	Comments
01	Installation of the main unit	Senthilkumar R	—
02	Installation of the computer system	Senthilkumar R	—
03	Installation of the printer	Senthilkumar R	— NA —
04	Connecting the waste tubing	Senthilkumar R	—
05	Connecting the system water tubing	Senthilkumar R	—
06	Installing the reagent tray	Senthilkumar R	—
07	Installation of the probe	Senthilkumar R	—
08	Installation of the mixer	Senthilkumar R	—
09	Installing the cuvettes	Senthilkumar R	—

Acceptance criteria: System should be "Ready" after daily maintenance without any error

PARAMETER PASS ✓ FAIL

Parameter values for verification: System found "Ready" after daily maintenance

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

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, 4th 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, 5th Floor, DLF Tower, Shivaji Marg,
New Delhi - 110 015, India.
Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
5-6, IInd Floor, Red Cross Bhavan, No:26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in



E. Cell Blank

Purpose: To check the cuvette blank OD at different wavelength

Procedure:

S No.	Activity	Done By	Date
01	Checking the Cell blank	Senthilkumar R	19/01/2021
02	340 nm	Senthilkumar R	19/01/2021
03	380 nm	Senthilkumar R	19/01/2021
04	405 nm	Senthilkumar R	19/01/2021
05	450 nm	Senthilkumar R	19/01/2021
06	480 nm	Senthilkumar R	19/01/2021
07	505 nm	Senthilkumar R	19/01/2021
08	546 nm	Senthilkumar R	19/01/2021
09	570 nm	Senthilkumar R	19/01/2021
10	600 nm	Senthilkumar R	19/01/2021
11	660 nm	Senthilkumar R	19/01/2021
12	700 nm	Senthilkumar R	19/01/2021
13	750 or 800 nm	Senthilkumar R	19/01/2021

Acceptance criteria:

- No error Messages displayed
- All Cuvettes should show acceptance

PARAMETER

PASS ✓

FAIL

Parameter values for verification: No Error Messages

AGAPPE DIAGNOSTICS LTD.

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

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: kolkattaoffice@agappe.in

MUMBAI [REGISTERED OFFICE]
401 & 402, 4th 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, 5th Floor, DLF Tower, Shivaji Marg,
New Delhi - 110 015, India.
Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
S-6, IInd Floor, Red Cross Bhavan, No:26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in



F. Priming

Purpose: To check the internal tubing's and flow of liquids

S No	Activity	Done By	Date
01	Do wash using the maintenance screen	Senthilkumar R	19/01/2021

Acceptance criteria:

- No error message or air bubbles in the internal tubing's
- All the dilutor working well without air bubbles / leakage

PARAMETER PASS ✓ FAIL

Parameter values for verification: No Error Messages

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

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: kolkattoffice@agappe.in

MUMBAI [REGISTERED OFFICE]
401 & 402, 4th Floor, Jaishigh 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, 5th Floor, DLF Tower, Shivaji Marg,
New Delhi - 110 015, India.
Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
5-6, 11th Floor, Red Cross Bhavan, No:26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in



This page is left blank intentionally

AGAPPE

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

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, 4th 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, 5th Floor, DLF Tower, Shivaji Marg,
New Delhi - 110 015, India.
Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
S-6, 11th Floor, Red Cross Bhavan, No:26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in

**VI. SYSTEM CERTIFICATION**

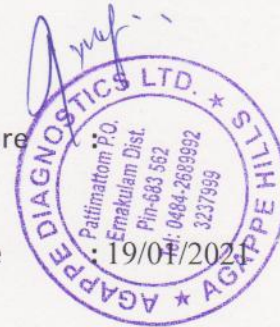
Study data has determined that the system described in this document either meets all criteria outline in this Installation Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been addressed. The system is ready for Operational Qualification.

Report Performed By: **AGAPPE DIAGNOSTICS LTD.** Representative

Name : Senthilkumar R
 Designation : Engineer-Customer Service
 Company : AGAPPE DIAGNOSTICS LTD.

Signature

Date



Customer Authorizations: **QUALITY CARE DIAGNOSTICS CENTER, THENI**

Name : Mr. R. Dhanabalan
 Designation : Chief of IQ Services
 Title : INSTALLATION QUALIFICATION

Signature

Date

**AGAPPE DIAGNOSTICS LTD.**

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

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, 4th Floor, Jaishigh 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, 5th Floor, DLF Tower, Shivaji Marg,
 New Delhi - 110 015, India.
 Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
 S-6, 1st Floor, Red Cross Bhavan, No:26 Race Course Road,
 Bangalore - 560 001. Tel: +91 80 2228 8288
 Email: bangaloreoffice@agappe.in



AGAPPE

OPERATIONAL QUALIFICATION

For

FULLY AUTOMATED CLINICAL CHEMISTRY ANALYZER

MODEL : MISPA CXL PRO

AGAPPE DIAGNOSTICS LTD.

ADL/FO/MCD/083/2020/R00

AGAPPE DIAGNOSTICS LTD.

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

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, 4th 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, 5th Floor, DLF Tower, Shivaji Marg,
New Delhi - 110 015, India.
Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
5-6, IInd Floor, Red Cross Bhavan, No:26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in



TABLE OF CONTENTS

S No.	Contents	Page No.
I	Approval of the OQ procedure	3
II	Instructions	4
III	Scope	5
IV	Operational Qualification	6
V	Comments	13
VI	System Certification	14

AGAPPE DIAGNOSTICS LTD.

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

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, 4th 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, 5th Floor, DLF Tower, Shivaji Marg,
New Delhi - 110 015, India.
Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
5-6, 11th Floor, Red Cross Bhavan, No:26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in



SURGING IN
SERVING EXCELLENCE

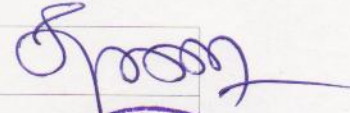

APPROVAL OF THE OPERATIONAL QUALIFICATION PROCEDURE

Both **QUALITY CARE DIAGNOSTICS CENTER, THENI** and **AGAPPE DIAGNOSTICS LTD.** are jointly responsible for the installation of **MISPA CXL PRO** with serial number **190T180CS0026K** at **Quality Care Diagnostics Center, Near Canara Bank, Madhurai Road, Theni** as per the attached **OPERATIONAL QUALIFICATION** protocol.

Protocol Performed By: Representative of **AGAPPE DIAGNOSTICS LTD.**


Name	: Senthilkumar R	Signature :	 
Designation	: Engineer-Customer Service	Date :	
Company	: AGAPPE DIAGNOSTICS LTD.		

Validation Team from QUALITY CARE DIAGNOSTICS CENTER, THENI

Name	: Mr. R. Dhanabalan	Signature :	 
Designation	: chief of lab services	Date :	
Department	: Biochemistry		

Customer Authorizations:

Name : Mr. R. Dhanabalan
 Title : OPERATIONAL QUALIFICATION
 Site : Theni

Signature : 
 Date : 19/01/2021



AGAPPE DIAGNOSTICS LTD.

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

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, 4th 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, 5th Floor, DLF Tower, Shivaji Marg,
 New Delhi - 110 015, India.
 Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
 S-6, 11th Floor, Red Cross Bhavan, No.26 Race Course Road,
 Bangalore - 560 001. Tel: +91 80 2228 8288
 Email: bangaloreoffice@agappe.in



II. INSTRUCTIONS

1. An authorized **AGAPPE DIAGNOSTICS LTD** representative will check and enter the specific data as outlined in the **OPERATIONAL QUALIFICATION**. Each result will be noted and dated.
2. ALL deviations from the acceptance criteria detailed in this document will be noted in the **COMMENTS** section at the end of the OQ protocol. All resolution to such problems will also be noted in the **COMMENTS** section, and must be resolved prior to issuance of a **SYSTEM CERTIFICATION**.

AGAPPE DIAGNOSTICS LTD.

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

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, 4th 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, 5th Floor, DLF Tower, Shivaji Marg,
New Delhi - 110 015, India.
Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
S-6, 1st Floor, Red Cross Bhavan, No:26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in



This Operational Qualification protocol will be performed on the **MISPA CXL PRO** at This Installation protocol will define the documentation that will be used to evaluate the instruments installation in accordance with the manufacturer's specifications and intended use. Successful completion of this protocol will verify that the instrument identified has been installed in accordance with the intended usage. Trained, knowledgeable personnel will perform qualification studies. Any exceptional conditions encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated and the appropriate course of action determined. All documents will be initialed and dated.

AGAPPE DIAGNOSTICS LTD.

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

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: kolkattoffice@agappe.in

MUMBAI [REGISTERED OFFICE]
401 & 402, 4th 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, 5th Floor, DLF Tower, Shivaji Marg,
New Delhi - 110 015, India.
Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
5-6, 11th Floor, Red Cross Bhavan, No:26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in



IV. OPERATIONAL QUALIFICATION

A. Instrument Identification

Verified Date : 19/01/2021

1. Model Name : MISPA CXL PRO
2. Serial Number : 190T180CS0026K

B. Following is a list of tests to be performed and verified:

Test No.	Test Name	Test purpose	Verified By and date
01	Start up	To make the equipment ready for operation	Senthilkumar R, 19/01/2021
02	Daily maintenance	To clean appropriate modules	Senthilkumar R, 19/01/2021
03	Calibration	To calibrate the system	Senthilkumar R, 19/01/2021
04	QC check	To confirm that the system is calibrated and working within specifications	Senthilkumar R, 19/01/2021
05	Reproducibility check	To check the precision [CV %] after calibration	Senthilkumar R, 19/01/2021
06	Sample programming and Analysis	To run the samples	Senthilkumar R, 19/01/2021
07	Shut down procedure	To shut down the system	Senthilkumar R, 19/01/2021

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

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, 4th 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, 5th Floor, DLF Tower, Shivaji Marg,
New Delhi - 110 015, India.
Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
5-6, 11th Floor, Red Cross Bhavan, No:26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in



Test 01: Starting the system

Purpose: To make the instrument READY for operation

Summary:

Instrument checks functioning of different parts of the instrument automatically. If there is an error code, initialize the system and follow corrective action instructions provided for the error message.

Procedure:

- Wait for the instrument to get ready after initialization
- Check the room temperature and switch on the Air Conditioner
- Check the UPS.
- Switch on the MISPA CXL PRO by pressing the main switch, then switch on the computer and then the system power
- Double click the analyzer icon to initialize the system software
- Input the password and do as prompted, the system menu pops up if start up is finished
- If not, initialize by again after solving the error displayed
- Follow instructions provided for the error message

Acceptance criteria: System to display READY status

PARAMETER PASS ✓ FAIL

Parameter values for verification: "READY" on Status Area

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

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, 4th 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, 5th Floor, DLF Tower, Shivaji Marg,
New Delhi - 110 015, India.
Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
5-6, 11th Floor, Red Cross Bhavan, No:26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in



S No.	Activity	Done by	Date
01	Empty waste container	Senthilkumar R	19/01/2021
02	Check Wash solutions	Senthilkumar R	19/01/2021
03	Check system water	Senthilkumar R	19/01/2021
04	Check Reagents	Senthilkumar R	19/01/2021
05	Clean Reagent Block	Senthilkumar R	19/01/2021
06	Clean out side area	Senthilkumar R	19/01/2021
07	Load supplies and remove outdated and empty reagents	Senthilkumar R	19/01/2021
08	Check main menu screen	Senthilkumar R	19/01/2021
09	Perform Quality Control	Senthilkumar R	19/01/2021

Acceptance criteria: System should be "Ready" after daily maintenance without any error

PARAMETER PASS ✓ FAIL

Parameter values for verification: System found "Ready" after daily maintenance

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

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, 4th 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, 5th Floor, DLF Tower, Shivaji Marg,
New Delhi - 110 015, India.
Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
S-6, 11th Floor, Red Cross Bhavan, No:26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in

**Test 03: Calibration of the system****Purpose:** To calibrate the system**Procedure:**

S No	Activity	Done By	Date
01	Preparation of the cal material	Senthilkumar R	19/01/2021
02	Performing Calibration with calibration programming screen	Senthilkumar R	19/01/2021

Acceptance criteria: Calibration data shows concordance OD values in triplicate measurement

PARAMETER	PASS ✓	FAIL
-----------	--------	------

Parameter values for verification : No error message in the printout

Test 04: QC check**Purpose:** To confirm that systems, reagents and consumables are acceptable & working within specifications for each assay used.**Procedure:**

S No.	Activity	Done By	Date
01	Preparing Biochemistry control material	Senthilkumar R	19/01/2021
02	Creating QC file	Senthilkumar R	19/01/2021
03	QC sample programming and analysis	Senthilkumar R	19/01/2021

Acceptance criteria: QC results within specified limits mentioned on the control product insert

PARAMETER	PASS ✓	FAIL
-----------	--------	------

Parameter values for verification: QC values within $\pm 2SD$ **AGAPPE DIAGNOSTICS LTD.** ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24239MH1998PLC115413

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, 4th 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, 5th Floor, DLF Tower, Shivaji Marg,
 New Delhi - 110 015, India.
 Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
 S-6, 11th Floor, Red Cross Bhavan, No.26 Race Course Road,
 Bangalore - 560 001. Tel: +91 80 2228 8288
 Email: bangaloreoffice@agappe.in

**Test 05: Reproducibility Check**

Purpose: To check the reproducibility of instrument

S No.	Activity	Done By	Date
01	Preparing control material/ sample	Senthilkumar R	19/01/2021
02	Running triplicates	Senthilkumar R	19/01/2021

Acceptance criteria: Results CV within specified limits

PARAMETER PASS ✓ FAIL

Parameter values for verification: CV% within the limits

Test 06: Sample programming and Analysis

Purpose: To run the samples

Procedure:

S No.	Activity	Done By	Date
01	Preparing and Processing of samples	Senthilkumar R	19/01/2021
02	Programming samples	Senthilkumar R	19/01/2021
03	Aspirating the samples	Senthilkumar R	19/01/2021
04	Viewing samples in process	Senthilkumar R	19/01/2021
05	Review results: Monitoring results	Senthilkumar R	19/01/2021

Acceptance criteria: Samples Analysis without any error

PARAMETER PASS ✓ FAIL

Parameter values for verification: Sample analysis without any error

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

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: kolkattaoffice@agappe.in

MUMBAI [REGISTERED OFFICE]
 401 & 402, 4th 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, 5th Floor, DLF Tower, Shivaji Marg,
 New Delhi - 110 015, India.
 Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
 S-6, IInd Floor, Red Cross Bhavan, No:26 Race Course Road,
 Bangalore - 560 001. Tel: +91 80 2228 8288
 Email: bangaloreoffice@agappe.in

**Test 07: Shut down**

Purpose: To shut down the system

Procedure:

S No.	Activity	Done By	Date
01	Preparing the system for shut down	Senthilkumar R	19/01/2021
02	Following the on screen instructions	Senthilkumar R	19/01/2021
03	Switch off the instrument when prompted	Senthilkumar R	19/01/2021

Acceptance criteria: Shut down without any error

PARAMETER PASS ✓ FAIL

Parameter values for verification: Shut down without any error

V. OPERATIONAL PROCEDURE

Certificate of Training

1. Technician Training

This certifies that the technicians have received basic user training in the following categories for the system described in this Operational Qualification.

S No.	Training program	Initials	Date
1	Instrument Setup	Senthilkumar R	19/01/2021
2	System Operation	Senthilkumar R	19/01/2021
3	Basic trouble shooting and Maintenance	Senthilkumar R	19/01/2021

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

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: kolkattoffice@agappe.in

MUMBAI [REGISTERED OFFICE]
401 & 402, 4th 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, 5th Floor, DLF Tower, Shivaji Marg,
New Delhi - 110 015, India.
Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
S-6, 11th Floor, Red Cross Bhavan, No:26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in



2. Operator Training

SURGING INNOVATION
SERVING MANKIND

The users responsible for the operation of this equipment have been trained in the proper usage of the system. Training focused on the basic operation and maintenance of the system.

S No.	Operators	Department	Initials	Date
1)	Mr. Dhanabalan	Biochemistry		19/01/2021
2)	Ms. K. Gayathri	Biochemistry		19/01/2021
3)	Mr. Muthukannan	Biochemistry		19/01/2021
4)	Mr. Ahamad Bidal	Biochemistry		19/01/2021
5)	Mr. A. Vignesh	Biochemistry		19/01/2021
6)	Mr. L. Mahendran	Biochemistry		19/01/2021
7)	Mr. V. Jayakumar	Biochemistry		19/01/2021
8)	Ms. S. Keerthiga	Biochemistry		19/01/2021

AGAPPE DIAGNOSTICS LTD.

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

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: kolkatatooffice@agappe.in

MUMBAI [REGISTERED OFFICE]
401 & 402, 4th 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, 5th Floor, DLF Tower, Shivaji Marg,
New Delhi - 110 015, India.
Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
S-6, 11th Floor, Red Cross Bhavan, No.26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in



VI. COMMENTS

This page is left blank intentionally

AGAPPE

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

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, 4th 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, 5th Floor, DLF Tower, Shivaji Marg,
New Delhi - 110 015, India.
Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
S-6, 11th Floor, Red Cross Bhavan, No:26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in



VII. SYSTEM CERTIFICATION

Study data has determined that the system described in this document either meets all criteria outline in this Operational Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been addressed. The system is ready for Performance Qualification.

Report Performed By: **AGAPPE DIAGNOSTICS LTD.** Representative

Name : Senthilkumar R

Designation : Engineer-Customer Service

Company : AGAPPE DIAGNOSTICS LTD.

Signature : 

Date : 19/01/2021




Customer Authorizations: **QUALITY CARE DIAGNOSTICS CENTER, THENI**

Name : Mr R. Dhanabalan

Designation : Chief of lab services

Title : OPERATIONAL QUALIFICATION

Signature : 

Date : 19/01/2021



AGAPPE DIAGNOSTICS LTD.

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

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, 4th 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, 5th Floor, DLF Tower, Shivaji Marg,
New Delhi - 110 015, India.
Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
5-6, 11th Floor, Red Cross Bhavan, No:26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in



AGAPPE

PERFORMANCE QUALIFICATION

For

FULLY AUTOMATED CLINICAL CHEMISTRY ANALYZER

MODEL : MISPA CXL PRO

AGAPPE DIAGNOSTICS LTD.

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

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 420842020 | Email: kolkataoffice@agappe.in

MUMBAI [REGISTERED OFFICE]
401 & 402, 4th 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, 5th Floor, DLF Tower, Shivaji Marg,
New Delhi - 110 015, India.
Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
S-6, 11th Floor, Red Cross Bhavan, No:26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in



SURGING INNOVATION
SERVING MANKIND

TABLE OF CONTENTS

S No.	Contents	Page No
I	Approval of the PQ procedure	3
II	Instructions	4
III	Scope	5
IV	Performance Qualification	6
V	Comments	15
VI	System Certification	16

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

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: kolkattooffice@agappe.in

MUMBAI [REGISTERED OFFICE]
401 & 402, 4th 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, 5th Floor, DLF Tower, Shivaji Marg,
New Delhi - 110 015, India.
Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
S-6, IInd Floor, Red Cross Bhavan, No:26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in



I. APPROVAL OF THE PERFORMANCE QUALIFICATION PROCEDURE

Both QUALITY CARE DIAGNOSTICS CENTER, THENI and AGAPPE DIAGNOSTICS LTD. are jointly responsible for the installation of MISPA CXL PRO with serial number 190T180CS0026K at Quality Care Diagnostics Center, Near Canara Bank, Madhurai Road, Theni as per the attached PERFORMANCE QUALIFICATION protocol.

Protocol Performed By: Representative of AGAPPE DIAGNOSTICS LTD.

Name	: Senthilkumar R	Signature :	<p>Pattimattom P.O. Ernakulam Dist. Pin: 683 562 Tel: 0484-2689992 3237999</p>	
Designation	: Engineer-Customer Service	Date		: 19/01/2021
Company	: AGAPPE DIAGNOSTICS LTD.			

Validation Team from QUALITY CARE DIAGNOSTICS CENTER, THENI

Name	: Mr. R. Dhanabalan	Signature :	<p>625 531</p>	
Designation	: Chief of Lab Services	Date		: 19/01/2021
Department	: Biochemistry			

Customer Authorizations:

Name : Mr. R. Dhanabalan
 Title : PERFORMANCE QUALIFICATION
 Site : Theni

Signature :

Date : 19/01/2021



AGAPPE DIAGNOSTICS LTD.

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

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, Merin 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, 4th 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, 5th Floor, DLF Tower, Shivaji Marg,
 New Delhi - 110 015, India.
 Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
 5-6, 11th Floor, Red Cross Bhavan, No:26 Race Course Road,
 Bangalore - 560 001. Tel: +91 80 2228 8288
 Email: bangaloreoffice@agappe.in



II. INSTRUCTIONS

1. An authorized **AGAPPE DIAGNOSTICS LTD.** representative will check and enter the specific data as outlined in the Performance Qualification. Each result will be noted and dated.
2. The concerned employees of **QUALITY CARE DIAGNOSTICS CENTER, THENI** will verify each result and sign in each page. The member of the validation team will carry this out.
3. All deviations from the acceptance criteria detailed in this document will be noted in the **COMMENTS** section at the end of the PQ protocol. All resolution to such problems will also be noted in the **COMMENTS** section, and must be resolved prior to issuance of a **SYSTEM CERTIFICATION**.

AGAPPE DIAGNOSTICS LTD.

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

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, 4th 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, 5th Floor, DLF Tower, Shivaji Marg,
New Delhi - 110 015, India.
Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
5-6, 11th Floor, Red Cross Bhavan, No:26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in



III. SCOPE

This Performance Qualification protocol will be performed on the **MISPA CXL PRO** at **QUALITY CARE DIAGNOSTICS CENTER, THENI**. This Performance protocol will define the documentation that will be used to evaluate the instruments installation in accordance with the manufacturer's specifications and intended use. Successful completion of this protocol will verify that the instrument identified has been installed in accordance with the intended usage. Trained, knowledgeable personnel will perform qualification studies. Any exceptional conditions encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated and the appropriate course of action determined. All documents will be initialed and dated.

AGAPPE DIAGNOSTICS LTD.

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

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, 4th 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,
Nellad, Cochin, Kerala, India - 686 721. Tel: +91 484 276 7477.

DELHI OFFICE

DSM 540, 5th 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

S-6, 11th Floor, Red Cross Bhavan, No:26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in



IV. PERFORMANCE QUALIFICATION

A. Instrument Identification

Verified Date : 19/01/2021

1. Model Name : MISPA CXL PRO.
2. Serial Number : 190T180CS0026K

B. Following is a list of tests to be performed and verified:

Test No.	Test Name	Test purpose	Verified By and date
01	Start up	To make the equipment ready for operation	Senthilkumar R, 19/01/2021
02	Daily maintenance	To clean appropriate modules	Senthilkumar R, 19/01/2021
03	Cell blank	To check the cuvettes	Senthilkumar R, 19/01/2021
04	Priming	To check the tubing's, and flow	Senthilkumar R, 19/01/2021
05	Auto gain	To check the cuvette and photometry system	Senthilkumar R, 19/01/2021
06	Calibration	To calibrate the system	Senthilkumar R, 19/01/2021
07	QC check	To confirm that the system and reagents are acceptable and working within specifications	Senthilkumar R, 19/01/2021
08	Reproducibility check	To check the precision [CV %]	Senthilkumar R, 19/01/2021
09	Sample programming and Analysis	To run the samples	Senthilkumar R, 19/01/2021
10	Shut down procedure	To shut down the system	Senthilkumar R, 19/01/2021

AGAPPE DIAGNOSTICS LTD.

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

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, 4th 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, 5th Floor, DLF Tower, Shivaji Marg,
New Delhi - 110 015, India.
Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
5-6, 11th Floor, Red Cross Bhavan, No:26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in



Test 01: Starting the system

Purpose: To make the instrument READY for operation

Summary:

Instrument checks functioning of different parts of the instrument automatically; if there is an error code, initialize the system and follow corrective action instructions provided for the error message.

Procedure:

- Wait for the instrument to get ready after initialization
- Check the room temperature and switch on the Air Conditioner
- Check the UPS.
- Switch on the MISPA CXL PRO by pressing the main switch, then switch on the computer and then the system power
- Double click the analyzer icon to initialize the system software
- Input the password and do as prompted, the system menu pops up if start up is finished
- If not, initialize by again after solving the error displayed
- Follow instructions provided for the error message

Acceptance criteria: System to display **READY** status

PARAMETER PASS ✓ FAIL

Parameter values for verification: "READY" on Status Area

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

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: kolkattoffice@agappe.in

MUMBAI [REGISTERED OFFICE]
401 & 402, 4th 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, 5th Floor, DLF Tower, Shivaji Marg,
New Delhi - 110 015, India.
Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
S-6, 11th Floor, Red Cross Bhavan, No:26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in



VI. SYSTEM CERTIFICATION

Study data has determined that the system described in this document either meets all criteria outline in this Performance Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been addressed. The system is ready for specified usage.

Report Performed By: **AGAPPE DIAGNOSTICS LTD.** Representative

Name : Senthilkumar R
Designation : Engineer-Customer Service
Company : AGAPPE DIAGNOSTICS LTD.

Signature :
Date :



Customer Authorizations: **QUALITY CARE DIAGNOSTICS CENTER, THENI**

Name : *Mr. R. Dhanaalan*
Designation : *Chief of Lab services*
Title : PERFORMANCE QUALIFICATION

Signature :
Date :



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

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: kolkattaoffice@agappe.in

MUMBAI [REGISTERED OFFICE]
401 & 402, 4th 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, 5th Floor, DLF Tower, Shivaji Marg,
New Delhi - 110 015, India.
Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
5-6, 11th Floor, Red Cross Bhavan, No-26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in



Test 02: Daily Maintenance

Purpose: To clean appropriate modules so as per the daily maintenance protocol

Method:

Refer detailed procedure for Daily Maintenance

S No.	Activity	Done by	Date
01	Empty waste container	Senthilkumar R	19/01/2021
02	Check Wash solutions	Senthilkumar R	19/01/2021
03	Check system water	Senthilkumar R	19/01/2021
04	Check Reagents	Senthilkumar R	19/01/2021
05	Clean Reagent Block	Senthilkumar R	19/01/2021
06	Clean out side area	Senthilkumar R	19/01/2021
07	Load supplies and remove outdated and empty reagents	Senthilkumar R	19/01/2021
08	Check main menu screen	Senthilkumar R	19/01/2021
09	Perform Quality Control	Senthilkumar R	19/01/2021

Acceptance criteria: System should be "Ready" after daily maintenance without any error

PARAMETER PASS ✓ FAIL

Parameter values for verification: System found "Ready" after daily maintenance

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

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, 4th 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, 5th Floor, DLF Tower, Shivaji Marg,
New Delhi - 110 015, India.
Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
S-6, 11th Floor, Red Cross Bhavan, No:26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in

Test 03: Cell Blank

Purpose: To check the cuvette blank OD at different wavelength

Procedure:

S No.	Activity	Done By	Date
01	Checking the Cell blank	Senthilkumar R	19/01/2021
	340 nm	Senthilkumar R	19/01/2021
	380 nm	Senthilkumar R	19/01/2021
	405 nm	Senthilkumar R	19/01/2021
	450 nm	Senthilkumar R	19/01/2021
	480 nm	Senthilkumar R	19/01/2021
	505 nm	Senthilkumar R	19/01/2021
	546 nm	Senthilkumar R	19/01/2021
	570 nm	Senthilkumar R	19/01/2021
	600 nm	Senthilkumar R	19/01/2021
	660 nm	Senthilkumar R	19/01/2021
	700 nm	Senthilkumar R	19/01/2021
	750 or 800 nm	Senthilkumar R	19/01/2021

AGAPPE DIAGNOSTICS LTD.

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

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, 4th 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, 5th Floor, DLF Tower, Shivaji Marg,
 New Delhi - 110 015, India.
 Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
 5-6, 11th Floor, Red Cross Bhavan, No:26 Race Course Road,
 Bangalore - 560 001. Tel: +91 80 2228 8288
 Email: bangaloreoffice@agappe.in



Acceptance criteria:

- No error Messages displayed
- All Cuvettes should show acceptance

PARAMETER PASS ✓ FAIL

Parameter values for verification: No Error Messages

Test 04: Priming

Purpose: To check the internal tubing's and flow of liquids

S No	Activity	Done By	Date
01	Do wash using the maintenance screen	Senthilkumar R	19/01/2021

Acceptance criteria:

- No error message or air bubbles in the internal tubing's
- All the dilutor working well without air bubbles / leakage

PARAMETER PASS ✓ FAIL

Parameter values for verification: No Error Messages

Test 05: Auto gain

Purpose: To Check the photometry system

Procedure:

S No.	Activity	Done By	Date
01	Performing the filter OD checking	Senthilkumar R	19/01/2021

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

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: kolkattoffice@agappe.in

MUMBAI [REGISTERED OFFICE]
401 & 402, 4th 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, 5th Floor, DLF Tower, Shivaji Marg,
New Delhi - 110 015, India.
Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
S-6, IInd Floor, Red Cross Bhavan, No.26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in



Acceptance criteria: Data shows OD values in the acceptable range

PARAMETER PASS ✓ FAIL

Parameter values for verification : No error message

Test 06: Calibration of the system

Purpose: To calibrate the system

Procedure:

S No.	Activity	Done By	Date
01	Preparation of the cal material *	Senthilkumar R	19/01/2021
02	Performing Calibration with calibration programming screen	Senthilkumar R	19/01/2021

*Traceability of the calibrator used is attached

Acceptance criteria: Calibration data shows concordance OD values in triplicate measurement

PARAMETER PASS ✓ FAIL

Parameter values for verification : No error message in the printout

Test 07: QC check

Purpose: To confirm that systems, reagents and consumables are acceptable & working within specifications for each assay used.

Procedure:

S No.	Activity	Done By	Date
01	Preparing Biochemistry control material	Senthilkumar R	19/01/2021
02	Creating QC file	Senthilkumar R	19/01/2021
03	QC sample programming and analysis	Senthilkumar R	19/01/2021

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

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, 4th 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, 5th Floor, DLF Tower, Shivaji Marg,
New Delhi - 110 015, India.
Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
5-6, 11th Floor, Red Cross Bhavan, No:26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in



Acceptance criteria: QC results within specified limits mentioned on the control product insert

PARAMETER

PASS ✓

FAIL

Parameter values for verification: QC values within $\pm 2SD$

Test 08: Reproducibility Check

Purpose: To check the reproducibility of instrument

S No.	Activity	Done By	Date
01	Preparing control material/ sample	Senthilkumar R	19/01/2021
02	Running triplicates	Senthilkumar R	19/01/2021

Acceptance criteria: Results CV within specified limits

PARAMETER

PASS ✓

FAIL

Parameter values for verification: CV% within the limits

Test 09: Sample programming and Analysis

Purpose: To run the samples

Procedure:

S No.	Activity	Done By	Date
01	Preparing and Processing of samples	Senthilkumar R	19/01/2021
02	Programming samples	Senthilkumar R	19/01/2021
03	Aspirating the samples	Senthilkumar R	19/01/2021
04	Viewing samples in process	Senthilkumar R	19/01/2021
05	Review results: Monitoring results	Senthilkumar R	19/01/2021

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

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, 4th 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, 5th Floor, DLF Tower, Shivaji Marg,
New Delhi - 110 015, India.
Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
5-6, 11th Floor, Red Cross Bhavan, No:26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in



Acceptance criteria: Samples Analysis without any error

PARAMETER PASS ✓ FAIL

Parameter values for verification: Sample analysis without any error

Test 10: Shut down

Purpose: To shut down the system

Procedure:

S No.	Activity	Done By	Date
01	Preparing the system for shut down	Senthilkumar R	19/01/2021
02	Following the on screen instructions	Senthilkumar R	19/01/2021
03	Switch off the instrument when prompted	Senthilkumar R	19/01/2021

Acceptance criteria: Shut down without any error

PARAMETER PASS ✓ FAIL

Parameter values for verification: Shut down without any error

OPERATIONAL PROCEDURE

Certificate of Training

1. Technician Training

This certifies that the technicians have received basic user training in the following categories for the system described in this Operational Qualification.

S No.	Training program	Initials	Date
1.	Instrument Setup		19/01/2021
2.	System Operation		19/01/2021
3.	Basic trouble shooting and Maintenance		19/01/2021

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

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, 4th 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, 5th Floor, DLF Tower, Shivaji Marg,
New Delhi - 110 015, India.
Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
5-6, 11th Floor, Red Cross Bhavan, No:26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in



V. COMMENTS

This page is left blank intentionally

AGAPPE

AGAPPE DIAGNOSTICS LTD.

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

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: kolkattoffice@agappe.in

MUMBAI [REGISTERED OFFICE]
401 & 402, 4th 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, 5th Floor, DLF Tower, Shivaji Marg,
New Delhi - 110 015, India.
Tel: +91 11 4558 8416 | Email: delhioffice@agappe.in

BANGALORE OFFICE
5-6, 11th Floor, Red Cross Bhavan, No:26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in