

**CERTIFICATE OF CALIBRATION**

Instrument : Mispa Ace Fully Automated Clinical Chemistry Analyser

Customer Name : Meditech Diagnostic Centre, West Mambalam, Chennai

Date of Installation : 09/July/2020

S/N:WK-95106413

Alignment Check

Motion Check	Checked	Remarks
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
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

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,
Nelkad, Cochin, Kerala, India - 686 72L. 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
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 SECTIONS**

Filter	Dark Current	Background
340	97	46099
405	100	45980
450	95	47234
510	92	49007
546	98	51085
578	94	51256
630	97	53013
670	91	55121
Reference		

Power Supply : 5V 12V 24V

The equipment is calibrated for the different parameters by using Multi

Calibrator Lot. No: 30020180 Exp: 07-2021

This is to certify that the above mentioned product has been calibrated according to the standard operating procedure given by the MINDRAY Medical Systems.

Date of Calibration : **07/July/2021**

Next Due on : **06/Jan/2022**

For Agappe Diagnostics Ltd,

M.Ty

Authorised signatory

Raja M

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,
Neilad, Cochin, Kerala, India - 686 721. Tel: +91 484 276 7477.

KOLKATA OFFICE
406, Merlin Matrix, Plot No-10, Block-DN, Sector V,
Salt Lake City, Kolkata - 700 091.
Tel: +91 33 4003 0451 | Email: 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



PERFORMANCE QUALIFICATION

For

FULLY AUTOMATED CLINICAL CHEMISTRY ANALYZER

MODEL : MISPA ACE

AGAPPE DIAGNOSTICS LTD.

ADL/BO/SER/IOP/0019/21-22

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



APPROVAL OF THE PERFORMANCE QUALIFICATION PROCEDURE

Both **MEDITECH DIAGNOSTIC CENTRE, WEST MAMBALAM** and **AGAPPE DIAGNOSTICS LTD.** are jointly responsible for the installation of **MISPA ACE** with serial number **WK-95106413** at "Meditech Diagnostic Centre, New No: 208, Old No : 99/1, Lake View Road, West Mambalam, Chennai District" as per the attached PERFORMANCE QUALIFICATION protocol.



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

Name	:	Raja M	Signature :
Designation	:	Manager Customer Service	Date : 09-07-2020
Company	:	AGAPPE DIAGNOSTICS LTD.	

Validation Team from MEDITECH DIAGNOSTIC CENTRE, WEST MAMBALAM

Name	:		Signature :
Designation	:		Date :
Department	:		

Customer Authorizations:

Name :

Title : PERFORMANCE QUALIFICATION

Signature :

Site :

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: 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



II. INSTRUCTIONS

AGAPPE

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 **MEDITECH DIAGNOSTIC CENTRE, WEST MAMBALAM** 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

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
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 Performance Qualification protocol will be performed on the **MISPA ACE** at **MEDITECH DIAGNOSTIC CENTRE, WEST MAMBALAM**. 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
5-6, IInd 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 : 09-07-2020

1. Model Name : MISPA ACE

B. Serial Number : WK-95106413

C. 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	Raja M 09-07-2020
02	Daily maintenance	To clean appropriate modules	Raja M 09-07-2020
03	Cell blank	To check the cuvettes	Raja M 09-07-2020
04	Priming	To check the tubing's, and flow	Raja M 09-07-2020
05	Auto gain	To check the cuvette and photometry system	Raja M 09-07-2020
06	Calibration	To calibrate the system	Raja M 09-07-2020
07	QC check	To confirm that the system and reagents are acceptable and working within specifications	Raja M 09-07-2020
08	Reproducibility check	To check the precision [CV %]	Raja M 09-07-2020
09	Sample programming and Analysis	To run the samples	Raja M 09-07-2020
10	Shut down procedure	To shut down the system	Raja M 09-07-2020

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 ACE 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

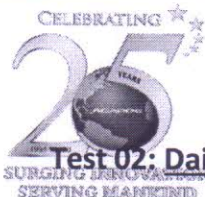
EQUIPMENT PLANT
X/588-CB, Block No. 32, KINFRA Small Industrial Park,
Nellad, Cochin, Kerala, India - 686 721. Tel: +91 484 276 7477.

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

**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	Raja M	09-07-2020
02	Check Wash solutions	Raja M	09-07-2020
03	Check system water	Raja M	09-07-2020
04	Check Reagents	Raja M	09-07-2020
05	Clean Reagent Block	Raja M	09-07-2020
06	Clean out side area	Raja M	09-07-2020
07	Load supplies and remove outdated and empty reagents	Raja M	09-07-2020
08	Check main menu screen	Raja M	09-07-2020
09	Perform Quality Control	Raja M	09-07-2020

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



Purpose: To check the cuvette blank OD at different wavelength

Procedure:

S No.	Activity	Done By	Date
01	Checking the Cell blank	Raja M	09-07-2020
	340 nm	Raja M	09-07-2020
	405 nm	Raja M	09-07-2020
	450 nm	Raja M	09-07-2020
	510 nm	Raja M	09-07-2020
	546 nm	Raja M	09-07-2020
	578 nm	Raja M	09-07-2020
	630 nm	Raja M	09-07-2020
	670 nm	Raja M	09-07-2020

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

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

EQUIPMENT PLANT
X/S88-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, D&F 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, 11th Floor, Red Cross Bhavan, No.26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in



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

S No	Activity	Done By	Date
01	Do wash using the maintenance screen	Raja M	09-07-2020

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	Raja M	09-07-2020

Acceptance criteria: Data shows OD values in the acceptable range

PARAMETER PASS FAIL

Parameter values for verification : No error message

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

**Test 08: Reproducibility Check**

Purpose: To check the reproducibility of instrument

S No.	Activity	Done By	Date
01	Preparing control material/ sample	Raja M	09-07-2020
02	Running triplicates	Raja M	09-07-2020

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	Raja M	09-07-2020
02	Programming samples	Raja M	09-07-2020
03	Aspirating the samples	Raja M	09-07-2020
04	Viewing samples in process	Raja M	09-07-2020
05	Review results: Monitoring results	Raja M	09-07-2020

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

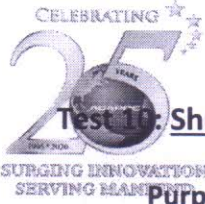
EQUIPMENT PLANT
X/588-CB, Block No. 32, KINFRA Small Industrial Park,
Nellad, Cochin, Kerala, India - 686 721. Tel: +91 484 276 7477.

KOLKATA OFFICE
406, Merlin Matrix, Plot No-10, Block-DN, Sector V,
Salt Lake City, Kolkata - 700 091.
Tel: +91 33 4003 0451 | Email: 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
5-6, 11th Floor, Red Cross Bhavan, No:26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in



Purpose: To shut down the system

Procedure:

S No.	Activity	Done By	Date
01	Preparing the system for shut down	Raja M	09-07-2020
02	Following the on screen instructions	Raja M	09-07-2020
03	Switch off the instrument when prompted	Raja M	09-07-2020

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	Raja M	09-07-2020
2.	System Operation	Raja M	09-07-2020
3.	Basic trouble shooting and Maintenance	Raja M	09-07-2020

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



2. Operator Training

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

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,
 Neilad, Cochin, Kerala, India - 686 721. Tel: +91 484 276 7477.

KOLKATA OFFICE
 406, Merlin Matrix, Plot No-10, Block-DN, Sector V,
 Salt Lake City, Kolkata - 700 091.
 Tel: +91 33 4003 0451 | Email: 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



V. 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 : Raja M

Designation : Manager Customer Service

Company : AGAPPE DIAGNOSTICS LTD.

Signature :

Date : 09-07-2020

Customer Authorizations: **MEDITECH DIAGNOSTIC CENTRE, WEST MAMBALAM**

Name :

Designation :

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, Pattinattom (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



INSTALLATION QUALIFICATION

For

FULLY AUTOMATED CLINICAL CHEMISTRY ANALYZER

MODEL : MISPA ACE

AGAPPE DIAGNOSTICS LTD.

ADL/BO/SER/IOP/0019/21-22

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: kolkattooffice@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

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



APPROVAL OF THE INSTALLATION QUALIFICATION PROCEDURE

Both **MEDITECH DIAGNOSTIC CENTRE, WEST MAMBALAM** and **AGAPPE DIAGNOSTICS LTD.** are jointly responsible for the installation of **MISPA ACE** with serial number **WK-95106413** at "Meditech Diagnostic Centre, New No : 208, Old No : 99/1, Lake View Road, West Mambalam, Chennai District" as per the attached Installation Qualification protocol.



Protocol Performed By : Representative of AGAPPE DIAGNOSTICS LTD.

Name	:	Raja M	Signature :
Designation	:	Manager Customer Service	Date : 09-07-2020
Company	:	AGAPPE DIAGNOSTICS LTD.	

Validation Team from MEDITECH DIAGNOSTIC CENTRE, WEST MAMBALAM

Name	:		Signature :
Designation	:		Date :
Department	:		

Customer Authorizations:

Name :

Title : INSTALLATION QUALIFICATION

Signature :

Site :

Date :

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

CORPORATE OFFICE / REAGENT PLANT
Agappe Hills, Pattimattom (PD), 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: kolkattaoffice@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 Installation Qualification. Each result will be noted and dated.
2. The concerned employees of **MEDITECH DIAGNOSTIC CENTRE, WEST MAMBALAM** 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 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
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 Installation Qualification protocol will be performed on the **MISPA ACE** at **MEDITECH DIAGNOSTIC CENTRE, WEST MAMBALAM**. 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
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****AGAPPE****A. Instrument Identification**

Verified Date : 09-07-2020

1. Model Name : MISPA ACE
2. Serial Number : WK-95106413

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

S No.	Component	Present (Yes/No)	Verified By	Comments
01	Analyzer Main unit	Yes	Raja M	
02	Computer	Yes	Raja M	
03	Printer	Yes	Raja M	
04	RS232 Connector cable	Yes	Raja M	
05	Power cord	Yes	Raja M	
06	Waste can	Yes	Raja M	
07	Water can	Yes	Raja M	
08	Water connector tube	Yes	Raja M	
09	Waste connector tube	Yes	Raja M	
10	Water pre filter	Yes	Raja M	
11	Probe assembly	Yes	Raja M	
12	Mixer assembly	Yes	Raja M	
13	Reagent tray	Yes	Raja M	
14	Cuvette blocks	Yes	Raja M	
15	Reagent bottles	Yes	Raja M	

AGAPPE DIAGNOSTICS LTD.

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

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

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 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	Raja M	
2	There is no physical damage to the components	Yes	Raja M	
3	Ambient temperature is available	Yes	Raja M	
4	Instrument is installed in the table leveled properly	Yes	Raja M	
5	Power supply is correct	Yes	Raja M	
6	Electric connections are tight, weatherproof & earthed	Yes	Raja M	
7	Analyzer unit installed as per the manufacturers recommendations	Yes	Raja M	

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

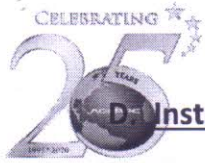
EQUIPMENT PLANT
X/588-CB, Block No. 32, KINFRA Small Industrial Park,
Nellad, Cochin, Kerala, India - 686 721. Tel: +91 484 276 7477.

KOLKATA OFFICE
406, Merlin Matrix, Plot No-10, Block-DN, Sector V,
Salt Lake City, Kolkata - 700 091.
Tel: +91 33 4003 0451 | Email: 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
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 : 09-07-2020

Installed by : Raja M

AGAPPE

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

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



Purpose: To check the cuvette blank OD at different wavelength

Procedure:

S No.	Activity	Done By	Date
01	Checking the Cell blank	Raja M	09-07-2020
02	340 nm	Raja M	09-07-2020
03	405 nm	Raja M	09-07-2020
04	450 nm	Raja M	09-07-2020
05	510 nm	Raja M	09-07-2020
06	546 nm	Raja M	09-07-2020
07	578 nm	Raja M	09-07-2020
08	630 nm	Raja M	09-07-2020
09	670 nm	Raja M	09-07-2020

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-0N, 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

**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	Raja M	09-07-2020

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: 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. 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 : Raja M

Designation : Manager Customer Service

Signature :

Company : AGAPPE DIAGNOSTICS LTD.

Date : 09-07-2020

Customer Authorizations: **MEDITECH DIAGNOSTIC CENTRE, WEST MAMBALAM**

Name :

Designation :

Signature :

Title : PERFORMANCE QUALIFICATION

Date :

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

CORPORATE OFFICE / REAGENT PLANT
Agappe Hills, Pattinattom (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



OPERATIONAL QUALIFICATION

For

FULLY AUTOMATED CLINICAL CHEMISTRY ANALYZER

MODEL : MISPA ACE

AGAPPE DIAGNOSTICS LTD.

ADL/BO/SER/IOP/0019/21-22

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



1. APPROVAL OF THE OPERATIONAL QUALIFICATION PROCEDURE

Both **MEDITECH DIAGNOSTIC CENTRE, WEST MAMBALAM** and **AGAPPE DIAGNOSTICS LTD.** are jointly responsible for the installation of **MISPA ACE** with serial number **WK-95106413** at "Meditech Diagnostic Centre, New No : 208, Old No : 99/1, Lake View Road, West Mambalam, Chennai District" as per the attached OPERATIONAL QUALIFICATION protocol.



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

Name	: Raja M	Signature :
Designation	: Manager Customer Service	Date : 09-07-2020
Company	: AGAPPE DIAGNOSTICS LTD.	

Validation Team from MEDITECH DIAGNOSTIC CENTRE, WEST MAMBALAM

Name	:	Signature :
Designation	:	Date :
Department	:	

Customer Authorizations:

Name :

Title : OPERATIONAL QUALIFICATION

Signature :

Site :

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, 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 **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

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,
Nelam, 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
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 Operational Qualification protocol will be performed on the **MISPA ACE** at **MEDITECH DIAGNOSTIC CENTRE, WEST MAMBALAM**. 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
5-6, 11th Floor, Red Cross Bhavan, No:26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in

**A. Instrument Identification**

Verified Date : 09-07-2020

1. Model Name : MISPA ACE
2. Serial Number : WK-95106413

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	Raja M 09-07-2020
02	Daily maintenance	To clean appropriate modules	Raja M 09-07-2020
03	Calibration	To calibrate the system	Raja M 09-07-2020
04	QC check	To confirm that the system is calibrated and working within specifications	Raja M 09-07-2020
05	Reproducibility check	To check the precision [CV %] after calibration	Raja M 09-07-2020
06	Sample programming and Analysis	To run the samples	Raja M 09-07-2020
07	Shut down procedure	To shut down the system	Raja M 09-07-2020

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: mumbai@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, DIF Tower, Shivaji Marg,
New Delhi - 110 015, India.
Tel: +91 11 4558 8416 | Email: delhi@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: kolkata@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: bangalore@agappe.in



Test 01: Starting the system

SURGING INNOVATION
SERVING MANAKI

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 ACE 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
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

AGAPPE

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	Raja M	09-07-2020
02	Check Wash solutions	Raja M	09-07-2020
03	Check system water	Raja M	09-07-2020
04	Check Reagents	Raja M	09-07-2020
05	Clean Reagent Block	Raja M	09-07-2020
06	Clean out side area	Raja M	09-07-2020
07	Load supplies and remove outdated and empty reagents	Raja M	09-07-2020
08	Check main menu screen	Raja M	09-07-2020
09	Perform Quality Control	Raja M	09-07-2020

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

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

S No	Activity	Done By	Date
01	Preparation of the cal material	Raja M	09-07-2020
02	Performing Calibration with calibration programming screen	Raja M	09-07-2020

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	Raja M	09-07-2020
02	Creating QC file	Raja M	09-07-2020
03	QC sample programming and analysis	Raja M	09-07-2020

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

CELEBRATING 20th Anniversary
Test 05: Reproducibility Check

AGAPPE

Purpose: To check the reproducibility of instrument

S.No.	Activity	Done By	Date
01	Preparing control material/ sample	Raja M	09-07-2020
02	Running triplicates	Raja M	09-07-2020

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	Raja M	09-07-2020
02	Programming samples	Raja M	09-07-2020
03	Aspirating the samples	Raja M	09-07-2020
04	Viewing samples in process	Raja M	09-07-2020
05	Review results: Monitoring results	Raja M	09-07-2020

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: 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 2226 8288
 Email: bangaloreoffice@agappe.in



Test 07: Shut down

SURGING INNOVATIONS
SERVING MAN

Purpose: To shut down the system

Procedure:

S No.	Activity	Done By	Date
01	Preparing the system for shut down	Raja M	09-07-2020
02	Following the on screen instructions	Raja M	09-07-2020
03	Switch off the instrument when prompted	Raja M	09-07-2020

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	Raja M	09-07-2020
2	System Operation	Raja M	09-07-2020
3	Basic trouble shooting and Maintenance	Raja M	09-07-2020

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
5-6, 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

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

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



VI. COMMENTS

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

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

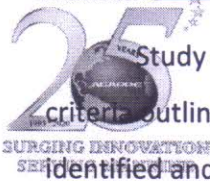
EQUIPMENT PLANT
X/588-CB, Block No. 32, KINFRA Small Industrial Park,
Nellad, Cochin, Kerala, India - 686 721. Tel: +91 484 276 7477.

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: kolkattoffice@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

VII. SYSTEM CERTIFICATION



AGAPPE

Study data has determined that the system described in this document either meets all criteria outlined 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 : Raja M

Designation : Engineer – Customer Service

Signature :

Company : AGAPPE DIAGNOSTICS LTD.

Date : 09-07-2020

Customer Authorizations: **MEDITECH DIAGNOSTIC CENTRE, WEST MAMBALAM**

Name :

Designation :

Signature :

Title : OPERATIONAL QUALIFICATION

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, 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

Current Calibration Results

Test	Rule	Status	Reagent Blank			SD
K	R0	A	B	C	D	
GLUCOSE	Two-point Linear	Passed		152.56110		0
		30.09967	-5.32486			
UREA	Two-point Linear	Passed		16065.13950		0
		37.96377	0.00000			
SGOT	Two-point Linear	Passed		12359.02484		0
		2.57107	0.00000			
SGPT	Two-point Linear	Passed		13039.43854		0
		2.30005	0.00000			
ALP IFCC	Two-point Linear	Passed		4885.78082		0
		3.13634	0.00000			
BIL TOTAL	Two-point Linear	Passed		567.78541		0
		222.61372	0.00000			
BIL DIRECT	Two-point Linear	Passed		-19.35200		0
		279.50433	0.00000			
CHOLESTROL	Two-point Linear	Passed		-403.90253		0
		18.04489	-78.04066			
HBA1C	Spline	Passed		3639.03963		0
	0.00000	289.46281	-55.46271	9.73030		
TGL	Two-point Linear	Passed		87.17426		0
		14.68744	-51.92976			
HDL DIRECT	Two-point Linear	Passed		-14.47136		0
		28.89950	0.00000			
CREA	Two-point Linear	Passed		-354.26681		0
		153.53830	0.00000			
URIC	Two-point Linear	Passed		174.95828		0
		260.76493	-75.57876			
GGT	Two-point Linear	Passed		5468.54281		0
		6.33374	0.00000			
TOTAL PRO	Two-point Linear	Passed		744.11465		0
		702.82864	-105.50458			
ALB	Two-point Linear	Passed		1200.23619		0
		3057.51833	-56.76482			
M PROTEIN	Two-point Linear	Passed		101.99174		0
		4.38427	-27.21241			

Current Calibration Date / Time : 1/4/2022 12:46:22 PM

QC Data Summary

Control: PATH

Start Date: 04-Jan-22

End Date: 04-Jan-22

Test	Results	Units	Time	Control Range	Remarks/Flag
BIL TOTAL	4.6	mg/dL	1/4/2022 4:08:41 PM	3.010-4.990	
UREA	85.1	mg/dL	1/4/2022 4:08:41 PM	68.000-96.000	
ALB	4.8	g/dL	1/4/2022 2:09:25 PM	4.110-5.890	
TOTAL PRO	10.1	g/dL	1/4/2022 2:09:25 PM	7.900-11.500	
URIC	11.6	mg/dL	1/4/2022 2:09:25 PM	10.350-13.850	
CREA	3.3	mg/dL	1/4/2022 2:09:25 PM	2.020-3.320	
TGL	468.5	mg/dL	1/4/2022 2:09:25 PM	373.000-533.000	
CHOLESTROL	227.4	mg/dL	1/4/2022 2:09:25 PM	186.000-254.000	
GLUCOSE	188.8	mg/dL	1/4/2022 2:09:25 PM	158.700-216.700	