



OPERATIONAL QUALIFICATION

For

FULLY AUTOMATED CLINICAL CHEMISTRY ANALYZER

MODEL : MISPA NANO

AGAPPE DIAGNOSTICS LTD.

ADL/BO/SER/0021/21-22

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

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 8268
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

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I. APPROVAL OF THE OPERATIONAL QUALIFICATION PROCEDURE

Both **POOJA DIAGNOSTICS, BANGALORE** and **AGAPPE DIAGNOSTICS LTD.** are jointly responsible for the installation of **MISPA NANO** with serial number **XJ 2100579** at **"POOJA DIAGNOSTICS, NO:8, ABOVE CANARA BANK, 80 FEET ROAD, CHANDRA LAYOUT, BANGALORE"** as per the attached OPERATIONAL QUALIFICATION protocol.



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

Name	:	DANI DAVIS V	Signature :
Designation	:	Engineer - Customer Service	Date : 19/03/2012
Company	:	AGAPPE DIAGNOSTICS LTD.	

Validation Team from POOJA DIAGNOSTICS, BANGALORE

Name	:		Signature :
Designation	:		Date :
Department	:		

Customer Authorizations:

Name :

Title : OPERATIONAL QUALIFICATION

Signature :

Site :

Date :

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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**.

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III. SCOPE

This Operational Qualification protocol will be performed on the **MISPA NANO** at **POOJA DIAGNOSTICS, BANGALORE**. 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.

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IV. OPERATIONAL QUALIFICATION

AGAPPE

Verified Date : 19/03/2012

A. Instrument Identification

1. Model Name : MISPA NANO
2. Serial Number : XJ 2100579

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

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DSM 340, 5th Floor, DLF Tower, Shivaji Marg,
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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 NANO 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
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Parameter values for verification: "READY" on Status Area

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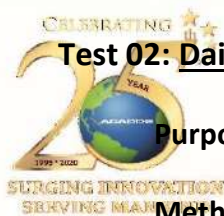
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Test 02: Daily Maintenance

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	DANI DAVIS V	19/03/2012
02	Check Wash solutions	DANI DAVIS V	19/03/2012
03	Check system water	DANI DAVIS V	19/03/2012
04	Check Reagents	DANI DAVIS V	19/03/2012
05	Clean Reagent Block	DANI DAVIS V	19/03/2012
06	Clean out side area	DANI DAVIS V	19/03/2012
07	Load supplies and remove outdated and empty reagents	DANI DAVIS V	19/03/2012
08	Check main menu screen	DANI DAVIS V	19/03/2012
09	Perform Quality Control	DANI DAVIS V	19/03/2012

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

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Test 05: Reproducibility Check

Purpose: To check the reproducibility of instrument

S No.	Activity	Done By	Date
01	Preparing control material/ sample	DANI DAVIS V	19/03/2012
02	Running triplicates	DANI DAVIS V	19/03/2012

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	DANI DAVIS V	19/03/2012
02	Programming samples	DANI DAVIS V	19/03/2012
03	Aspirating the samples	DANI DAVIS V	19/03/2012
04	Viewing samples in process	DANI DAVIS V	19/03/2012
05	Review results: Monitoring results	DANI DAVIS V	19/03/2012

Acceptance criteria: Samples Analysis without any error

PARAMETER **PASS** **FAIL**

Parameter values for verification: Sample analysis without any error

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Test 07: Shut down

Purpose: To shut down the system

Procedure:

S No.	Activity	Done By	Date
01	Preparing the system for shut down	DANI DAVIS V	19/03/2012
02	Following the on screen instructions	DANI DAVIS V	19/03/2012
03	Switch off the instrument when prompted	DANI DAVIS V	19/03/2012

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		
2	System Operation		
3	Basic trouble shooting and Maintenance		

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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

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VI. COMMENTS

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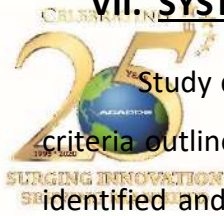
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VII. SYSTEM CERTIFICATION



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 : **DANI DAVIS V**

Designation : **Engineer - Customer Service**

Signature :

Company : **AGAPPE DIAGNOSTICS LTD.**

Date :

Customer Authorizations: **POOJA DIAGNOSTICS, BANGALORE**

Name :

Designation :

Signature :

Title : **OPERATIONAL QUALIFICATION**

Date :

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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, Shiveji 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,
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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

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I APPROVAL OF THE INSTALLATION QUALIFICATION PROCEDURE

Both **POOJA DIAGNOSTICS, BANGALORE** and **AGAPPE DIAGNOSTICS LTD.** are jointly responsible for the installation of **MISPA NANO** with serial number **XJ 2100579** at **“POOJA DIAGNOSTICS , NO:8, ABOVE CANARA BANK, 80 FEET ROAD, CHANDRA LAYOUT, BANGALORE”** as per the attached Installation Qualification protocol.



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

Name	:	DANI DAVIS V	Signature :
Title	:	Engineer - Customer Service	Date : 19/03/2012
Company	:	AGAPPE DIAGNOSTICS LTD.	

Validation Team from POOJA DIAGNOSTICS, BANGALORE

Name	:		Signature :
Designation	:		Date :
Department	:		

Customer Authorizations:

Name :

Title : INSTALLATION QUALIFICATION

Signature :

Site :

Date :

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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 **POOJA DIAGNOSTICS, BANGALORE** 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.

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DSM 540, 5th Floor, DLF Tower, Shivaji Marg, New Delhi - 110 015, India.
Tel: +91 11 4358 8416 | Email: delhioffice@agappe.in

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Tel: +91 33 4003 0451 | Email: kolkataoffice@agappe.in

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This Installation Qualification protocol will be performed on the **MISPA NANO** at **POOJA DIAGNOSTICS, BANGALORE**. 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.

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**INSTALLATION QUALIFICATION****A. Instrument Identification**

Verified Date :

1. Model Name : MISPA NANO
2. Serial Number : XJ 2100579

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

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

AGAPPE DIAGNOSTICS LTD.

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

Summary:

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

Acceptance criteria:

PARAMETER

PASS

FAIL

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Salt Lake City, Kolkata - 700 091.
Tel: +91 33 4003 0451 | Email: kolkataoffice@agappe.in

MUMBAI [REGISTERED OFFICE]

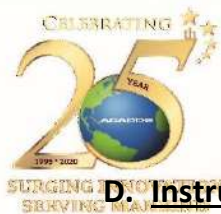
401 & 402, 4th Floor, Jaisingh Business Centre, 119,
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DSM 540, 5th Floor, DLF Tower, Shivaji Marg,
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**D. Instrument Installation**

Date of Installation : 19/03/2012

Installed by : DANI DAVIS V

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

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.**

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Tel: +91 484 286 7000 | Email: agappe@agappe.in**EQUIPMENT PLANT**X/588-C6, 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,
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Purpose: To check the cuvette blank OD at different wavelength

Procedure:

S No.	Activity	Done By	Date
01	Checking the Cell blank	DANI DAVIS V	19/03/2012
02	340 nm	DANI DAVIS V	19/03/2012
03	405 nm	DANI DAVIS V	19/03/2012
04	450 nm	DANI DAVIS V	19/03/2012
05	510 nm	DANI DAVIS V	19/03/2012
06	546 nm	DANI DAVIS V	19/03/2012
07	578 nm	DANI DAVIS V	19/03/2012
08	630 nm	DANI DAVIS V	19/03/2012
09	670 nm	DANI DAVIS V	19/03/2012

Acceptance criteria:

- No error Messages displayed
- All Cuvettes should show acceptance

PARAMETER **PASS** **FAIL**

Parameter values for verification: No Error Messages

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

S No	Activity	Done By	Date
01	Do wash using the maintenance screen	DANI DAVIS V	19/03/2012

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

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V. COMMENTS

AGAPPE

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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 : DANI DAVIS V

Designation : Engineer - Customer Service

Signature :

Company : AGAPPE DIAGNOSTICS LTD.

Date :

Customer Authorizations: **POOJA DIAGNOSTICS, BANGALORE**

Name :

Designation :

Signature :

Title : INSTALLATION QUALIFICATION

Date :

AGAPPE DIAGNOSTICS LTD.

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AGAPPE

PERFORMANCE QUALIFICATION

For

FULLY AUTOMATED CLINICAL CHEMISTRY ANALYZER

MODEL : MISPA NANO

AGAPPE DIAGNOSTICS LTD.

ADL/BO/SER/0031/21-22

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S No.	Contents	Page No
I	Approval of the PQ procedure	3
II	Instructions	4
III	Scope	5
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VI	System Certification	16

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I. APPROVAL OF THE PERFORMANCE QUALIFICATION PROCEDURE

Both **POOJA DIAGNOSTICS, BANGALORE** and **AGAPPE DIAGNOSTICS LTD.** are jointly responsible for the installation of **MISPA NANO** with serial number **XJ 2100579** at “**POOJA DIAGNOSTICS, NO:8, ABOVE CANARA BANK, 80 FEET ROAD, CHANDRA LAYOUT, BANGALORE**” as per the attached PERFORMANCE Qualification protocol.



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

Name	:	DANI DAVIS V	Signature :
Designation	:	Engineer - Customer Service	Date : 19/03/2012
Company	:	AGAPPE DIAGNOSTICS LTD.	

Validation Team from POOJA DIAGNOSTICS, BANGALORE

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

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 4358 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



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 **POOJA DIAGNOSTICS, BANGALORE** 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.

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III. SCOPE

This Performance Qualification protocol will be performed on the **MISPA NANO** at **POOJA DIAGNOSTICS, BANGALORE**. 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.

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IV. PERFORMANCE QUALIFICATION

A. Instrument Identification

Verified Date : 19/03/2012

1. Model Name : MISPA NANO
2. Serial Number : XJ 2100579

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

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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 NANO 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
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Parameter values for verification: "READY" on Status Area

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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	DANI DAVIS V	19/03/2012
02	Check Wash solutions	DANI DAVIS V	19/03/2012
03	Check system water	DANI DAVIS V	19/03/2012
04	Check Reagents	DANI DAVIS V	19/03/2012
05	Clean Reagent Block	DANI DAVIS V	19/03/2012
06	Clean out side area	DANI DAVIS V	19/03/2012
07	Load supplies and remove outdated and empty reagents	DANI DAVIS V	19/03/2012
08	Check main menu screen	DANI DAVIS V	19/03/2012
09	Perform Quality Control	DANI DAVIS V	19/03/2012

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

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**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	DANI DAVIS V	19/03/2012
	340 nm	DANI DAVIS V	19/03/2012
	405 nm	DANI DAVIS V	19/03/2012
	450 nm	DANI DAVIS V	19/03/2012
	510 nm	DANI DAVIS V	19/03/2012
	546 nm	DANI DAVIS V	19/03/2012
	578 nm	DANI DAVIS V	19/03/2012
	630 nm	DANI DAVIS V	19/03/2012
	670 nm	DANI DAVIS V	19/03/2012

Acceptance criteria:

- No error Messages displayed
- All Cuvettes should show acceptance

PARAMETER **PASS** **FAIL**

Parameter values for verification: No Error Messages

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Tel: +91 484 286 7000 | Email: agappe@agappe.in

EQUIPMENT PLANT
X/588-C6, Block No. 32, KINFRA Small Industrial Park,
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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	DANI DAVIS V	19/03/2012

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	DANI DAVIS V	19/03/2012

Acceptance criteria: Data shows OD values in the acceptable range

PARAMETER **PASS** **FAIL**

Parameter values for verification : No error message

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Test 08: Reproducibility Check

Purpose: To check the reproducibility of instrument

S No.	Activity	Done By	Date
01	Preparing control material/ sample	DANI DAVIS V	19/03/2012
02	Running triplicates	DANI DAVIS V	19/03/2012

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	DANI DAVIS V	19/03/2012
02	Programming samples	DANI DAVIS V	19/03/2012
03	Aspirating the samples	DANI DAVIS V	19/03/2012
04	Viewing samples in process	DANI DAVIS V	19/03/2012
05	Review results: Monitoring results	DANI DAVIS V	19/03/2012

Acceptance criteria: Samples Analysis without any error

PARAMETER **PASS** **FAIL**

Parameter values for verification: Sample analysis without any error

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**Test 10: Shut down****Purpose:** To shut down the system**Procedure:**

S No.	Activity	Done By	Date
01	Preparing the system for shut down	DANI DAVIS V	19/03/2012
02	Following the on screen instructions	DANI DAVIS V	19/03/2012
03	Switch off the instrument when prompted	DANI DAVIS V	19/03/2012

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		
2.	System Operation		
3.	Basic trouble shooting and Maintenance		

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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

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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 : DANI DAVIS V

Designation : Engineer - Customer Service

Signature :

Company : AGAPPE DIAGNOSTICS LTD.

Date :

Customer Authorizations: **POOJA DIAGNOSTICS, BANGALORE**

Name :

Designation :

Signature :

Title : PERFORMANCE QUALIFICATION

Date :

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QC TESTING PROTOCOL

PRODUCT : EM - 180

SERIAL NO. : B-180038

PROV. NO. : 09/B06

ASW VERSION : 2014.01.02

ESW VERSION : 2014.0.12

VOLTAGE SUPPLY : 220V

DATE : 31/07/2014

CONCLUSION : PASS

CHECKED BY : Divya [Signature]

REVIEWED BY : [Signature]
(Prod. Head)

VERIFIED & APPROVED BY : [Signature]
(QA Head)

[A] PHYSICAL CHECKING

1) 50 POSITION SAMPLE AND REAGENT TRAY (SRGT)

Fitting : OK Movement : OK

2) 2 EXTERNAL DILUENT POSITIONS

Fitting : OK

3) REACTION TRAY (RCT)

Centering : OK Movement : OK

4) REAGENT/SAMPLE PIPETTOR

Centering : OK Movement : OK Liquid Flow : OK

5) STIRRER

Centering : OK Movement : OK

6) REACTION TRAY COVER

Fitting : OK

7) SAMPLE & REAGENT TRAY COVER

Fitting : OK

8) DOME COVER

Fitting : OK

9) GAS SPRINGS

Closing : OK Movement : OK

10) INDICATOR LAMPS

a) ANALYZER SWITCH :

OK

b) LED ON ARM AND PANEL :

OK

QC TESTING PROTOCOL

.....Prov. No 09/B06

[B] PRE-BIOCHEMISTRY CHECK

1) TEMPERATURE

	Observed	Acceptance
SERVICE MENU	RCT: <input type="text" value="37"/> °C	36.5 to 37.5°C
	RGT: <input type="text" value="11"/> °C	04 to 12 °C
RUN TEST	RCT: <input type="text" value="37"/> °C	36.5 to 37.5°C
	RGT: <input type="text" value="11"/> °C	04 to 12 °C

2) AUTO SPAN SET

Acceptance criterial for Gain at all wavelength: 380 to 600

WAVELENGTH	GAIN		
	1	2	3
340	406	406	406
405	449	449	449
505	444	444	444
546	422	422	422
578	476	476	476
600	548	548	548
660	506	506	506
700	455	455	455

3) SENSORS :

1. DEIONISED WATER

2. WASTE

QC TESTING PROTOCOL

.....Prov. No. 09/B06

[C] OTHER FUNCTIONAL CHECKS

1) PRIME MODE	OK	9) MULTIPPOINT CALIBRATION	OK
2) ROTOR CHECK	OK	10) EMERGENCY MODE	OK
3) REAGENT LEVEL SCAN	OK	11) DILUTION MODE	OK
4) REACTION CURVE	OK	12) 2 REAGENT CHEMISTRY	OK
5) RECALCULATION	OK	13) QC MODE	OK
6) RESULT DATA REPRINT	OK	14) AUTOSTART-UP AND SHUT-DOWN MAINTAINANCE	OK
7) PATIENT REPORT PRINT	OK	15) HIBERNATE MODE	OK
8) MAINTENANCE - WASH	OK		

[D] DEAD VOLUME CHECK

	Observed	Acceptance
<u>SAMPLE :</u>		
SAMPLE CUP (2ML) in μ l	100	50 μ l TO 150 μ l
SAMPLE TUBE(5 - 7 ML)in μ l	350	250 μ l TO 450 μ l
<u>REAGENT :</u>		
REAGENT : 50ML BOTTLE ...in ml	2	1.5 ml TO 2.5 ml
REAGENT : 20ML BOTTLEin ml	1.5	1.0 ml TO 2.0 ml
REAGENT : 5 ML ADAPTORin μ l	455	350 μ l TO 650 μ l

QC TESTING PROTOCOL

.....Prov. No. 09/B06

E) OPTIONAL CONFIGURATION STATUS

1] IS MACHINE WITH ISE MODULE? (YES / NO)

NO

Centering:

NA

Electrodes:

NA

2] IS MACHINE WITH BARCODE? (YES / NO)

YES

BARCODE SCAN

OK

F1] WITHIN RUN PRECISION CHECK

PROV. NO. 09/B06

MULTICAL: 1091305C

ERBA NORM: 2071415

ERBA PATH: 2071416

ITEM	ALB		CHO		*GGT		GLU		SGPT		PRO		UREA	
RGT Lot No.	1031304		1041305U		1021403		1041301U		1061301U		1021305		1031402	
Expiry Date	03/2016		10/2014		02/2016		04/2015		02/2015		08/2015		11/2015	
UNIT	g/dl		mg/dl		IU/L		mg/dl		IU/L		g/dl		mg/dl	
SPECIMEN	NORM	PATH	NORM	PATH	NORM	PATH	NORM	PATH	NORM	PATH	NORM	PATH	NORM	PATH
1	4.64	5.46	175	213	47.3	93.8	104.7	272.8	56.4	133.8	6.73	8.23	44.50	176.30
2	4.63	5.42	174	214	46.1	95.4	104.0	275	50.9	127.6	6.63	8.33	44.60	174.10
3	4.65	5.51	176	212	47.0	97.2	103.6	271.7	47.2	128.6	6.68	8.23	44.00	175.10
4	4.60	5.49	176	217	43.9	93.4	104.2	275.4	49.2	126.4	6.63	8.30	44.40	174.10
5	4.66	5.45	174	216	42.6	89.8	103.7	277.9	48.4	125.9	6.68	8.25	44.40	177.00
6	4.69	5.45	178	218	44.6	96.8	104.0	274.7	50.4	123.7	6.71	8.32	44.70	178.80
7	4.64	5.45	175	216	44.3	92.7	104.2	273	49.2	126.9	6.68	8.22	44.40	176.70
8	4.61	5.47	178	211	44.6	91.2	104.7	276.1	49.7	127.9	6.63	8.35	44.10	174.10
9	4.70	5.50	177	211	43.2	97.8	103.9	271.4	48.9	126.4	6.66	8.33	43.50	175.70
10	4.65	5.48	178	215	44.4	91.6	104.0	276.6	49.9	124.4	6.67	8.32	43.60	175.80
11	4.69	5.47	175	211	46.3	90.9	103.9	275.3	48.2	128.1	6.66	8.22	44.40	174.90
12	4.63	5.54	175	214	44.8	94.7	104.4	277.2	49.2	126.4	6.61	8.30	43.40	173.70
13	4.62	5.43	172	210	46.4	92.3	103.6	278.8	48.9	127.9	6.68	8.30	43.80	170.90
14	4.63	5.43	172	215	48.1	91.4	103.4	279.4	49.9	130.1	6.60	8.30	43.80	176.60
15	4.64	5.44	174	213	40.8	95.6	103.6	278.5	48.7	125.9	6.69	8.27	43.60	173.70
16	4.61	5.48	173	213	46.8	91.6	102.0	280.7	50.7	125.6	6.65	8.29	44.70	173.00
17	4.67	5.53	176	212	45.7	94.5	102.3	275.3	45.2	128.1	6.68	8.27	44.20	175.00
18	4.60	5.39	173	215	41.6	91.4	102.7	279.3	49.9	128.1	6.68	8.28	43.00	172.00
19	4.65	5.44	173	211	44.4	91.4	102.0	276	48.9	127.4	6.70	8.24	43.60	176.00
20	4.62	5.35	175	213	45.5	91.1	102.4	274.5	52.6	130.4	6.64	8.26	42.60	173.60
Mean	4.64	5.46	174.95	213.50	44.92	93.23	103.57	275.98	49.62	127.48	6.66	8.28	43.97	174.86
SD	0.029	0.045	1.877	2.236	1.900	2.364	0.844	2.608	2.180	2.227	0.033	0.040	0.580	1.848
CV(%)	0.63	0.83	1.07	1.05	4.23	2.54	0.81	0.94	4.39	1.75	0.50	0.48	1.32	1.06

Acceptance: Erbanorm < 3.00 % Erbanorm < 3.00 % Erbanorm < 5.00 % Erbanorm < 3.00 % Erbanorm < 7.50 % Erbanorm < 3.00 % Erbanorm < 5.00 %
 Erbapath < 3.00 % Erbapath < 3.00 % Erbapath < 5.00 % Erbapath < 3.00 % Erbapath < 5.00 % Erbapath < 3.00 % Erbapath < 5.00 %
 Note: *GGT L1 Pooled Control 3 : 1 (Erba Norm & Erba Path)

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
1.	SHIBU	BIOCHEM	shbu	22-3-12
2.	SHIJI	BIOCHEM	Shji	26-3-12

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

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

MUMBAI (REGISTERED OFFICE)
401 & 402, 4th Floor, Jansingh Business Centre, 119,
Sahar Road, Parsiwada, Andhreev (East), Mumbai - 400 099, India.
Tel: +91 22 4300 8660 | Email: mumbai@office@agappe.in

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

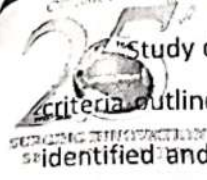
DELHI OFFICE
DSM 340, 5th Floor, DLF Tower, Shivaji Marg,
New Delhi - 110 015, India.
Tel: +91 11 4558 6416 | Email: delhi@office@agappe.in

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

BANGALORE OFFICE
5 & 8th Floor, Red Cross Bhawan, No.26 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8268
Email: bangalore@office@agappe.in

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VII. SYSTEM CERTIFICATION



AGAPPE

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 : **DANI DAVIS V**
Designation : **Engineer - Customer Service**
Company : **AGAPPE DIAGNOSTICS LTD.**

Signature : *Dani*
Date : **19-03-2012**

Customer Authorizations: **POOJA DIAGNOSTICS, BANGALORE**

Name : **DR. N. BHARAT**
Designation : **DIRECTOR**
Title : **OPERATIONAL QUALIFICATION**

Signature : *Bharat*
Date : **19-3-12**

POOJA DIAGNOSTICS & SUPER SPECIALITY CENTRE
No.8, 80 feet Road, Chandra Laya, Bangalore - 560 040

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

EQUIPMENT PLANT
X/588-CB, Block No. 32, KINFRA Small Industrial Park, Nellore, Cochin, Kerala, India - 606 721. 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

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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
1.	SHIBU	BIOCHEM	shu	22/3/2012
2.	JISI	BIOCHEM	jis	26/3/2012

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

MUMBAI (REGISTERED OFFICE)
401 & 402, 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.

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DSM 540, 5th Floor, DLF Tower, Shivaji Marg,
New Delhi - 110 015, India.
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406, We'llin 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
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Bangalore - 560 001. Tel: +91 80 2228 8288
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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 : DANI DAVIS V

Designation : Engineer - Customer Service Signature : *Dani*

Company : AGAPPE DIAGNOSTICS LTD. Date : 19-03-2012

Customer Authorizations: POOJA DIAGNOSTICS, BANGALORE

Name : DR. N. BHARAT

Designation : DIRECTOR Signature : *Bharat*

Title : INSTALLATION QUALIFICATION Date : 19-3-12

POOJA DIAGNOSTICS & SUPER SPECIALITY CENTRE
 No.8, 80 feet Road, Chandra L...
 Bangalore - 560 041

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

CORPORATE OFFICE / REAGENT PLANT
 Agappe Hills, Palmettatom (PO), Dist. Ernakulam, Kerala - 683 562, India.
 Tel: +91 484 266 7900 | Email: agappe@agappe.in

EQUIPMENT PLANT
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 Neelodi, Cochin, Kerala, India - 686 721. Tel: +91 484 276 7477.

KOLKATA OFFICE
 406, Verlin 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 (E-W), Mumbai - 400 099, India.
 Tel: +91 22 4300 8000 | Email: mumbaioffice@agappe.in

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 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 : **DANI DAVIS V**
Designation : **Engineer - Customer Service**
Company : **AGAPPE DIAGNOSTICS LTD.**

Signature : *Dani*
Date : **19-03-2012**

Customer Authorizations: **POOJA DIAGNOSTICS, BANGALORE**

Name : **DR. N. BHARAT**
Designation : **DIRECTOR**
Title : **PERFORMANCE QUALIFICATION**

Signature : *Bharat*
Date : **19-3-12**

POOJA DIAGNOSTICS & SUPER SPECIALITY CENTRE
No.8, 80 feet Road, Chandra Layout,
Bangalore - 560 040

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