



## OPTICAL SECTION

Filter	Dark Current	Background
340	90	31329
405	87	36968
450	84	37498
510	80	38539
546	86	38864
578	81	39752
630	78	40270
670	82	39992
Reference		

Power Supply : 5V  12V  24V

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

Lot.No: 1196 UE Exp: 2023-10

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 : 09/May/2022

Next Due : 08/Nov/2022

For, Agappe Diagnostic Ltd.



**Authorized Signatory**  
 Name : Vijender Pratap Singh  
 Designation : Engineer - Customer Service

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

**CORPORATE OFFICE / REAGENT PLANT**  
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**CERTIFICATE OF CALIBRATION**

Instrument : Mispa Ace Fully Automated Clinical Chemistry Analyser

Customer Name : Gola Path Labs, Rohini Sector: 28, New Delhi

Date of Installation : 17/Jan/2018

S/N : WK-71105084T

**Alignment Check**

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

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

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AGAPPE

# INSTALLATION QUALIFICATION

For

**FULLY AUTOMATED CLINICAL CHEMISTRY ANALYZER**

**MODEL : MISPA ACE**

**AGAPPE DIAGNOSTICS LTD.**

ADL/DO/SER/IOP/0051/21-22

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## I. APPROVAL OF THE INSTALLATION QUALIFICATION PROCEDURE

Both **GOLA PATH LABS, NEW DELHI** and **AGAPPE DIAGNOSTICS LTD.** are jointly responsible for the installation of **MISPA ACE** with serial number **WK-71105084T** at **“Gola Path Labs, A-4/252, Rohini Sector: 28, Opposite Bhagvan Apartments, New Delhi”** as per the attached Installation Qualification protocol.

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



Name	:	Vijender Pratap Singh	Signature :
Designation	:	Engineer - Customer Service	Date : 17/Jan/2018
Company	:	AGAPPE DIAGNOSTICS LTD.	

### Validation Team from GOLA PATH LABS, NEW DELHI

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

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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 **GOLA PATH LABS, NEW DELHI** 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

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### III. SCOPE

This Installation Qualification protocol will be performed on the **MISPA ACE** at **GOLA PATH LABS, NEW DELHI**. 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

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#### IV. INSTALLATION QUALIFICATION

##### A. Instrument Identification

Verified Date : 17/Jan/2018

1. Model Name : MISPA ACE
2. Serial Number : WK-71105084T

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

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

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

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

#### 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

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**D. Instrument Installation**

Date of Installation : 17/Jan/2018

Installed by : Vijender Pratap Singh

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

**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

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### E. Cell Blank

**Purpose:** To check the cuvette blank OD at different wavelength

**Procedure:**

S No.	Activity	Done By	Date
01	Checking the Cell blank	Vijender Pratap Singh	17/Jan/2018
02	340 nm	Vijender Pratap Singh	17/Jan/2018
03	405 nm	Vijender Pratap Singh	17/Jan/2018
04	450 nm	Vijender Pratap Singh	17/Jan/2018
05	510 nm	Vijender Pratap Singh	17/Jan/2018
06	546 nm	Vijender Pratap Singh	17/Jan/2018
07	578 nm	Vijender Pratap Singh	17/Jan/2018
08	630 nm	Vijender Pratap Singh	17/Jan/2018
09	670 nm	Vijender Pratap Singh	17/Jan/2018

**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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## 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	Vijender Pratap Singh	17/Jan/2018

### 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. 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 : Vijender Pratap Singh

Designation : Engineer - Customer Service

Company : AGAPPE DIAGNOSTICS LTD.

Signature :

Date : 17/Jan/2018

Customer Authorizations: **GOLA PATH LABS, NEW DELHI**

Name :

Designation :

Title : INSTALLATION QUALIFICATION

Signature :

Date :



# OPERATIONAL QUALIFICATION

For

**FULLY AUTOMATED CLINICAL CHEMISTRY ANALYZER**

**MODEL : MISPA ACE**

**AGAPPE DIAGNOSTICS LTD.**

ADL/DO/SER/IOP/0051/21-22

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

**KOLKATA OFFICE**  
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## I. APPROVAL OF THE OPERATIONAL QUALIFICATION PROCEDURE

Both **GOLA PATH LABS, NEW DELHI** and **AGAPPE DIAGNOSTICS LTD.** are jointly responsible for the installation of **MISPA ACE** with serial number **WK-71105084T** at “**Gola Path Labs, A-4/252, Rohini Sector: 28, Opposite Bhagvan Apartments, New Delhi**” as per the attached OPERATIONAL QUALIFICATION protocol.

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



Name	: Vijender Pratap Singh	Signature :
Designation	: Engineer - Customer Service	Date : 17/Jan/2018
Company	: AGAPPE DIAGNOSTICS LTD.	

**Validation Team from GOLA PATH LABS, NEW DELHI**

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

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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 ACE** at **GOLA PATH LABS, NEW DELHI**. 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.

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#### IV. OPERATIONAL QUALIFICATION

##### A. Instrument Identification

Verified Date : 17/Jan/2018

1. Model Name : MISPA ACE
2. Serial Number : WK-71105084T

##### 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	Vijender Pratap Singh 17/Jan/2018
02	Daily maintenance	To clean appropriate modules	Vijender Pratap Singh 17/Jan/2018
03	Calibration	To calibrate the system	Vijender Pratap Singh 17/Jan/2018
04	QC check	To confirm that the system is calibrated and working within specifications	Vijender Pratap Singh 17/Jan/2018
05	Reproducibility check	To check the precision [CV %] after calibration	Vijender Pratap Singh 17/Jan/2018
06	Sample programming and Analysis	To run the samples	Vijender Pratap Singh 17/Jan/2018
07	Shut down procedure	To shut down the system	Vijender Pratap Singh 17/Jan/2018

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

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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 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

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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	Vijender Pratap Singh	17/Jan/2018
02	Check Wash solutions	Vijender Pratap Singh	17/Jan/2018
03	Check system water	Vijender Pratap Singh	17/Jan/2018
04	Check Reagents	Vijender Pratap Singh	17/Jan/2018
05	Clean Reagent Block	Vijender Pratap Singh	17/Jan/2018
06	Clean out side area	Vijender Pratap Singh	17/Jan/2018
07	Load supplies and remove outdated and empty reagents	Vijender Pratap Singh	17/Jan/2018
08	Check main menu screen	Vijender Pratap Singh	17/Jan/2018
09	Perform Quality Control	Vijender Pratap Singh	17/Jan/2018

**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

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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	Vijender Pratap Singh	17/Jan/2018
02	Running triplicates	Vijender Pratap Singh	17/Jan/2018

**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	Vijender Pratap Singh	17/Jan/2018
02	Programming samples	Vijender Pratap Singh	17/Jan/2018
03	Aspirating the samples	Vijender Pratap Singh	17/Jan/2018
04	Viewing samples in process	Vijender Pratap Singh	17/Jan/2018
05	Review results: Monitoring results	Vijender Pratap Singh	17/Jan/2018

**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

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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	Vijender Pratap Singh	17/Jan/2018
02	Following the on screen instructions	Vijender Pratap Singh	17/Jan/2018
03	Switch off the instrument when prompted	Vijender Pratap Singh	17/Jan/2018

**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	Vijender Pratap Singh	17/Jan/2018
2	System Operation	Vijender Pratap Singh	17/Jan/2018
3	Basic trouble shooting and Maintenance	Vijender Pratap Singh	17/Jan/2018

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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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**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 : Vijender Pratap Singh

Designation : Engineer – Customer Service

Signature :

Company : AGAPPE DIAGNOSTICS LTD.

Date : 17/Jan/2018

Customer Authorizations: **GOLA PATH LABS, NEW DELHI**

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**  
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**KOLKATA OFFICE**  
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AGAPPE

# PERFORMANCE QUALIFICATION

For

**FULLY AUTOMATED CLINICAL CHEMISTRY ANALYZER**

**MODEL : MISPA ACE**

**AGAPPE DIAGNOSTICS LTD.**

ADL/DO/SER/IOP/0051/21-22

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## I. APPROVAL OF THE PERFORMANCE QUALIFICATION PROCEDURE

Both **GOLA PATH LABS, NEW DELHI** and **AGAPPE DIAGNOSTICS LTD.** are jointly responsible for the installation of **MISPA ACE** with serial number **WK-71105084T** at “**Gola Path Labs, A-4/252, Rohini Sector: 28, Opposite Bhagvan Apartments, New Delhi**” as per the attached PERFORMANCE QUALIFICATION protocol.

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



Name	:	Vijender Pratap Singh	Signature :
Designation	:	Engineer - Customer Service	Date : 17/Jan/2018
Company	:	AGAPPE DIAGNOSTICS LTD.	

**Validation Team from GOLA PATH LABS, NEW DELHI**

Name	:		Signature :
Designation	:		Date :
Department	:		

### Customer Authorizations:

Name :

Title : PERFORMANCE QUALIFICATION

Signature :

Site :

Date :

## **AGAPPE DIAGNOSTICS LTD.**

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## **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 **GOLA PATH LABS, NEW DELHI** 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 ACE** at **GOLA PATH LABS, NEW DELHI**. 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 : 17/Jan/2018

1. Model Name : MISPA ACE

B. Serial Number : WK-71105084T

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	Vijender Pratap Singh 17/Jan/2018
02	Daily maintenance	To clean appropriate modules	Vijender Pratap Singh 17/Jan/2018
03	Cell blank	To check the cuvettes	Vijender Pratap Singh 17/Jan/2018
04	Priming	To check the tubing's, and flow	Vijender Pratap Singh 17/Jan/2018
05	Auto gain	To check the cuvette and photometry system	Vijender Pratap Singh 17/Jan/2018
06	Calibration	To calibrate the system	Vijender Pratap Singh 17/Jan/2018
07	QC check	To confirm that the system and reagents are acceptable and working within specifications	Vijender Pratap Singh 17/Jan/2018
08	Reproducibility check	To check the precision [CV %]	Vijender Pratap Singh 17/Jan/2018
09	Sample programming and Analysis	To run the samples	Vijender Pratap Singh 17/Jan/2018
10	Shut down procedure	To shut down the system	Vijender Pratap Singh 17/Jan/2018

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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 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

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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	Vijender Pratap Singh	17/Jan/2018
02	Check Wash solutions	Vijender Pratap Singh	17/Jan/2018
03	Check system water	Vijender Pratap Singh	17/Jan/2018
04	Check Reagents	Vijender Pratap Singh	17/Jan/2018
05	Clean Reagent Block	Vijender Pratap Singh	17/Jan/2018
06	Clean out side area	Vijender Pratap Singh	17/Jan/2018
07	Load supplies and remove outdated and empty reagents	Vijender Pratap Singh	17/Jan/2018
08	Check main menu screen	Vijender Pratap Singh	17/Jan/2018
09	Perform Quality Control	Vijender Pratap Singh	17/Jan/2018

**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	Vijender Pratap Singh	17/Jan/2018
	340 nm	Vijender Pratap Singh	17/Jan/2018
	405 nm	Vijender Pratap Singh	17/Jan/2018
	450 nm	Vijender Pratap Singh	17/Jan/2018
	510 nm	Vijender Pratap Singh	17/Jan/2018
	546 nm	Vijender Pratap Singh	17/Jan/2018
	578 nm	Vijender Pratap Singh	17/Jan/2018
	630 nm	Vijender Pratap Singh	17/Jan/2018
	670 nm	Vijender Pratap Singh	17/Jan/2018

**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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**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	Vijender Pratap Singh	17/Jan/2018

**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	Vijender Pratap Singh	17/Jan/2018

**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	Vijender Pratap Singh	17/Jan/2018
02	Running triplicates	Vijender Pratap Singh	17/Jan/2018

**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	Vijender Pratap Singh	17/Jan/2018
02	Programming samples	Vijender Pratap Singh	17/Jan/2018
03	Aspirating the samples	Vijender Pratap Singh	17/Jan/2018
04	Viewing samples in process	Vijender Pratap Singh	17/Jan/2018
05	Review results: Monitoring results	Vijender Pratap Singh	17/Jan/2018

**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

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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	Vijender Pratap Singh	17/Jan/2018
02	Following the on screen instructions	Vijender Pratap Singh	17/Jan/2018
03	Switch off the instrument when prompted	Vijender Pratap Singh	17/Jan/2018

**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	Vijender Pratap Singh	17/Jan/2018
2.	System Operation	Vijender Pratap Singh	17/Jan/2018
3.	Basic trouble shooting and Maintenance	Vijender Pratap Singh	17/Jan/2018

## AGAPPE DIAGNOSTICS LTD.

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

**CORPORATE OFFICE / REAGENT PLANT**  
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Tel: + 91 484 286 7000 | Email: agappe@agappe.in

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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

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**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 : Vijender Pratap Singh

Designation : Engineer - Customer Service

Company : AGAPPE DIAGNOSTICS LTD.

Signature :

Date : 17/Jan/2018



Customer Authorizations: **GOLA PATH LABS, NEW DELHI**

Name :

Designation :

Title : PERFORMANCE QUALIFICATION

Signature :

Date :

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

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