

# Parashar Micro Measurement Pvt. Ltd.

Unit-II : J-22, Site-C, Surajpur Industrial Area, UPSIDC, Greater Noida (U.P.)

PH.: 0120-4252360-65, Email : pmmpl.india@gmail.com

Website : www.pmmpl.in, www.parashar.info



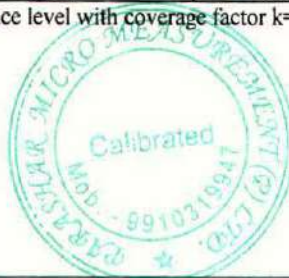
## Calibration Certificate

Certificate Number : PMM/BM/731437					Page 1	
Calibrated For		M/s. Som Datt Medical Centre S - 524, School Block , Shakarpur Delhi - 110092		Calibrated on		31.01.2022
				Valid Upto		30.01.2023
				Cert. Issue Date		01.02.2022
<b>Description of Equipments</b>						
Nomenclature		Bio Chemistry Analyzer		Accuracy/Class		As per specification
Test Type		Electrical Safety Test		Condition of UUC		Physically Ok
Make		Mispa ACE		Party ID Mark No.		9
Model No.		AGAPPE		Location		Path Lab
Mfr. S.No.		WK-671048277				
<b>Master Equipment / Standard Used</b>						
Sr.No.	Nomenclature	Make & Model	Serial No. / I/D Mark	Calibrated From	Certificate No.	Due Date of Calibration
1	Electrical Safety Analyzer	Fluke/ESA612	PMM/BM/ESA-01	FLUKE CORPORATION	PC-EVT-0D3B	31.03.2022
Standard used for calibration are traceable to National/International Standards through unbroken chain of calibration.						
Calibration Performed at		AT SITE		Environmental		Temperature = 25 ± 5° C
Calibration Procedure No.		PMM/II/BMCP/01		Condition(s)		Humidity = 50 ± 10 % RH
Reference Standard / Guideline		IEC-60601-1				
<b>CALIBRATION RESULTS</b>						
<b>1.0 Main Line Test</b>						
a. Main Line Voltage supply working properly					Yes	
b. Main Line ground connected properly					Yes	
<b>2.0 Earth Resistance Test</b>						
Sr.No.	Max Limit ( Ω )	Actual Observed Value ( Ω )			Remark	
1	2.0	0.229			Pass	
<b>3.0 Polarity Test Pass</b>					Yes	
<b>4.0 Safety test</b>						
Sr.No.	Parameter	Permitted Values	Measured Values	Deviation%	Remarks (Pass/Fail)	
1	Ground Wire Resistance	<0.3Ω	0.251	-0.00049	Pass	
2	Chassis Leakage	<100 μANC	96μA	-0.04	Pass	
		<500μASFC	N/A	N/A	N/A	
3	Pateint Leakage Current	<100μABandB F	N/A	N/A	N/A	
		<10μACF	1.3μA	-0.087	Pass	
4	Patient Lead Leakage Current, Isolation Test	<100μABF	N/A	N/A	N/A	
		<10μACF	1.2μA	-0.088	Pass	
5	Insulation (Optional) 500V	<2MΩ	OR MΩ	N/A	N/A	

Uncertainty of measurement (at approx. 95% confidence level with coverage factor k=2)

1.23%

Calibrated By : Gordhan Barwa  
Designation : Calibration Engineer



Approved By : Vikram Parashar  
Designation : Technical Manager

- Conditions : 1. This certificate refers only to the particular item submitted for calibration.  
2. The calibration result reported in this certificate are valid at the time of and under the stated conditions of measurement.  
3. This particular certificate can not be reproduced except in full, without prior permission of chief executive officer of the lab.

**CERTIFICATE OF CALIBRATION**Instrument : **Mispa Ace Fully Automated Clinical Chemistry Analyser**Customer Name : **Som Datt Medical Centre, New Delhi**Date of Installation : **18/May/2017**S/N : **WK-67104827T****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

*Jay9*  
*28/5/22*

**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, 4<sup>th</sup> Floor, Jaisingh Business Centre, 119,  
Sahar Road, Parsiwada, Andheri (East), Mumbai - 400 099, India.  
Tel: +91 22 4300 8000 | Email: mumbaioffice@agappe.in

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

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

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

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

**OPTICAL SECTION**

Filter	Dark Current	Background
340		
405		
450		
510		
546		
578		
630		
670		
Reference		

Power Supply : 5V  12V  24V

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

Lot.No: \_\_\_\_\_ Exp: \_\_\_\_\_

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 : 10/May/2021

Next Due : 09/Nov/2021

For, Agappe Diagnostic Ltd.



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28/5/22

Authorized Signatory

Name : Vijender Pratap Singh

Designation : Engineer - Customer Service

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# INSTALLATION QUALIFICATION

For

**FULLY AUTOMATED CLINICAL CHEMISTRY ANALYZER**

**MODEL : MISPA ACE**

**AGAPPE DIAGNOSTICS LTD.**

*Stamp*  
*28/5/22*

ADL/DO/SER/IOP/0011/22-23

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28/5/22

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AGAPPE

**I. APPROVAL OF THE INSTALLATION QUALIFICATION PROCEDURE**

Both **SOM DATT MEDICAL CENTRE, NEW DELHI** and **AGAPPE DIAGNOSTICS LTD.** are jointly responsible for the installation of **MISPA ACE** with serial number **WK-67104827T** at **"Som Datt Medical Centre, Poly Clinic Cum Diagnostic Centre, S-524, School Block, 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 : 18/May/2017
Company	:	AGAPPE DIAGNOSTICS LTD.	

**Validation Team from SOM DATT MEDICAL CENTRE, NEW DELHI**

*Jaya*

Name	:	JAYAUCCAS	Signature : <i>Jaya</i>
Designation	:	Lab Technician	Date : 28/5/22
Department	:	Path lab	

**Customer Authorizations:**

Name : *JAYAUCCAS*  
 Title : INSTALLATION QUALIFICATION  
 Site :

Signature : *Jaya*  
 Date : 28/5/22

*Jaya*  
 28/5/22

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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 **SOM DATT MEDICAL CENTRE, 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**.

Jays  
28/5/22

**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 **SOM DATT MEDICAL CENTRE, 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.

*Jays*  
28/5/22

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#### IV. INSTALLATION QUALIFICATION

##### A. Instrument Identification

Verified Date : 18/May/2017

1. Model Name : MISPA ACE
2. Serial Number : WK-67104827T

##### 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	

Jay  
28/5/22

### AGAPPE DIAGNOSTICS LTD.

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

#### CORPORATE OFFICE / REAGENT PLANT

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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

*Jay*  
28/5/22

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**D. Instrument Installation**

Date of Installation : 18/May/2017

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

*Top*  
28/5/22

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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	18/May/2017
02	340 nm	Vijender Pratap Singh	18/May/2017
03	405 nm	Vijender Pratap Singh	18/May/2017
04	450 nm	Vijender Pratap Singh	18/May/2017
05	510 nm	Vijender Pratap Singh	18/May/2017
06	546 nm	Vijender Pratap Singh	18/May/2017
07	578 nm	Vijender Pratap Singh	18/May/2017
08	630 nm	Vijender Pratap Singh	18/May/2017
09	670 nm	Vijender Pratap Singh	18/May/2017

**Acceptance criteria:**

- No error Messages displayed
- All Cuvettes should show acceptance

**PARAMETER**                      **PASS**                      **FAIL**

**Parameter values for verification:** No Error Messages

*Jay*  
28/5/22

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

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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	Vijender Pratap Singh	18/May/2017

**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

*Days*  
28/5/22

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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 : 18/May/2017



Customer Authorizations: **SOM DATT MEDICAL CENTRE, NEW DELHI**

Name : JAYAULLAS

Designation : Lab Technician

Title : INSTALLATION QUALIFICATION

Signature : Jays

Date : 28/5/22

Jays

Jays

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

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# OPERATIONAL QUALIFICATION

For

**FULLY AUTOMATED CLINICAL CHEMISTRY ANALYZER**

**MODEL : MISPA ACE**

**AGAPPE DIAGNOSTICS LTD.**

*Jays*  
28/3/22

ADL/DO/SER/IOP/0011/22-23

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*Jay*  
28/5/22

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## I. APPROVAL OF THE OPERATIONAL QUALIFICATION PROCEDURE

Both **SOM DATT MEDICAL CENTRE, NEW DELHI** and **AGAPPE DIAGNOSTICS LTD.** are jointly responsible for the installation of **MISPA ACE** with serial number **WK-67104827T** at "**Som Datt Medical Centre, Poly Clinic Cum Diagnostic Centre, S-524, School Block, 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 : 18/May/2017
Company	: AGAPPE DIAGNOSTICS LTD.	

Validation Team from **SOM DATT MEDICAL CENTRE, NEW DELHI**

*Jaya*

Name	: <i>Jayavillas</i>	Signature : <i>Jaya</i>
Designation	: <i>Lab Technician</i>	Date : <i>28/5/22</i>
Department	: <i>Path Lab</i>	

### Customer Authorizations:

Name : *Jayavillas*

Title : OPERATIONAL QUALIFICATION

Signature :

*Jaya*

Site :

Date

*28/5/22*

**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**.

*Jayg*  
*28/5/22*

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

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### III. SCOPE

This Operational Qualification protocol will be performed on the **MISPA ACE** at **SOM DATT MEDICAL CENTRE, 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.

*Jays*  
28/5/22

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

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#### IV. OPERATIONAL QUALIFICATION

##### A. Instrument Identification

Verified Date : 18/May/2017

1. Model Name : MISPA ACE
2. Serial Number : WK-67104827T

##### 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 18/May/2017
02	Daily maintenance	To clean appropriate modules	Vijender Pratap Singh 18/May/2017
03	Calibration	To calibrate the system	Vijender Pratap Singh 18/May/2017
04	QC check	To confirm that the system is calibrated and working within specifications	Vijender Pratap Singh 18/May/2017
05	Reproducibility check	To check the precision [CV %] after calibration	Vijender Pratap Singh 18/May/2017
06	Sample programming and Analysis	To run the samples	Vijender Pratap Singh 18/May/2017
07	Shut down procedure	To shut down the system	Vijender Pratap Singh 18/May/2017

Jays  
28/5/22

### 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

*Jaya*  
28/5/22

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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	18/May/2017
02	Check Wash solutions	Vijender Pratap Singh	18/May/2017
03	Check system water	Vijender Pratap Singh	18/May/2017
04	Check Reagents	Vijender Pratap Singh	18/May/2017
05	Clean Reagent Block	Vijender Pratap Singh	18/May/2017
06	Clean out side area	Vijender Pratap Singh	18/May/2017
07	Load supplies and remove outdated and empty reagents	Vijender Pratap Singh	18/May/2017
08	Check main menu screen	Vijender Pratap Singh	18/May/2017
09	Perform Quality Control	Vijender Pratap Singh	18/May/2017

**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

*Jayg*  
28/5/22

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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	18/May/2017
02	Running triplicates	Vijender Pratap Singh	18/May/2017

**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	18/May/2017
02	Programming samples	Vijender Pratap Singh	18/May/2017
03	Aspirating the samples	Vijender Pratap Singh	18/May/2017
04	Viewing samples in process	Vijender Pratap Singh	18/May/2017
05	Review results: Monitoring results	Vijender Pratap Singh	18/May/2017

**Acceptance criteria:** Samples Analysis without any error

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

**Parameter values for verification:** Sample analysis without any error

*Jays*  
28/5/22

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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	18/May/2017
02	Following the on screen instructions	Vijender Pratap Singh	18/May/2017
03	Switch off the instrument when prompted	Vijender Pratap Singh	18/May/2017

**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	18/May/2017
2	System Operation	Vijender Pratap Singh	18/May/2017
3	Basic trouble shooting and Maintenance	Vijender Pratap Singh	18/May/2017

*Jay*  
28/5/22

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

**CORPORATE OFFICE / REAGENT PLANT**  
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**EQUIPMENT PLANT**  
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**DELHI OFFICE**  
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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

*Jays*  
28/5/22

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**VI. COMMENTS**

*Jays*  
*28/5/22*

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**AGAPPE****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

Company : AGAPPE DIAGNOSTICS LTD.

Signature

Date

: 18/May/2017

Customer Authorizations: **SOM DATT MEDICAL CENTRE, NEW DELHI**

Name : Jays

Designation : Lab Technician

Title : OPERATIONAL QUALIFICATION

Signature

Date

: 28/5/22

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

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# PERFORMANCE QUALIFICATION

For

**FULLY AUTOMATED CLINICAL CHEMISTRY ANALYZER**

**MODEL : MISPA ACE**

**AGAPPE DIAGNOSTICS LTD.**

*Jays*  
*28/5/22*

ADL/DO/SER/IOP/0011/22-23

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

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*Jays*  
28/3/22

**AGAPPE DIAGNOSTICS LTD.** ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24239MH1998PLC115413
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**AGAPPE****I. APPROVAL OF THE PERFORMANCE QUALIFICATION PROCEDURE**

Both **SOM DATT MEDICAL CENTRE, NEW DELHI** and **AGAPPE DIAGNOSTICS LTD.** are jointly responsible for the installation of **MISPA ACE** with serial number **WK-67104827T** at "**Som Datt Medical Centre, Poly Clinic Cum Diagnostic Centre, S-524, School Block, 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 : 18/May/2017
Company	: AGAPPE DIAGNOSTICS LTD.	

**Validation Team from SOM DATT MEDICAL CENTRE, NEW DELHI**

Name	: JAYA ULLAS	Signature :
Designation	: Lab Technician	Date : 28/5/22
Department	: Path Lab	

**Customer Authorizations:**

Name : JAYA ULLAS

Title : PERFORMANCE QUALIFICATION

Site :

Signature :

Date :

28/5/22

28/5/22

**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 Performance Qualification. Each result will be noted and dated.
2. The concerned employees of **SOM DATT MEDICAL CENTRE, 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**.

*Jays*  
28/5/22

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

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AGAPPE

### III. SCOPE

This Performance Qualification protocol will be performed on the **MISPA ACE** at **SOM DATT MEDICAL CENTRE, 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.

Jays  
28/5/22

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

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## IV. PERFORMANCE QUALIFICATION

### A. Instrument Identification

Verified Date : 18/May/2017

1. Model Name : MISPA ACE

B. Serial Number : WK-67104827T

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 18/May/2017
02	Daily maintenance	To clean appropriate modules	Vijender Pratap Singh 18/May/2017
03	Cell blank	To check the cuvettes	Vijender Pratap Singh 18/May/2017
04	Priming	To check the tubing's, and flow	Vijender Pratap Singh 18/May/2017
05	Auto gain	To check the cuvette and photometry system	Vijender Pratap Singh 18/May/2017
06	Calibration	To calibrate the system	Vijender Pratap Singh 18/May/2017
07	QC check	To confirm that the system and reagents are acceptable and working within specifications	Vijender Pratap Singh 18/May/2017
08	Reproducibility check	To check the precision [CV %]	Vijender Pratap Singh 18/May/2017
09	Sample programming and Analysis	To run the samples	Vijender Pratap Singh 18/May/2017
10	Shut down procedure	To shut down the system	Vijender Pratap Singh 18/May/2017

*Jay*  
28/5/22

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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

*Joby*  
*28/5/22*

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

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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	18/May/2017
02	Check Wash solutions	Vijender Pratap Singh	18/May/2017
03	Check system water	Vijender Pratap Singh	18/May/2017
04	Check Reagents	Vijender Pratap Singh	18/May/2017
05	Clean Reagent Block	Vijender Pratap Singh	18/May/2017
06	Clean out side area	Vijender Pratap Singh	18/May/2017
07	Load supplies and remove outdated and empty reagents	Vijender Pratap Singh	18/May/2017
08	Check main menu screen	Vijender Pratap Singh	18/May/2017
09	Perform Quality Control	Vijender Pratap Singh	18/May/2017

**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

*Deep*  
28/5/22

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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	18/May/2017
	340 nm	Vijender Pratap Singh	18/May/2017
	405 nm	Vijender Pratap Singh	18/May/2017
	450 nm	Vijender Pratap Singh	18/May/2017
	510 nm	Vijender Pratap Singh	18/May/2017
	546 nm	Vijender Pratap Singh	18/May/2017
	578 nm	Vijender Pratap Singh	18/May/2017
	630 nm	Vijender Pratap Singh	18/May/2017
	670 nm	Vijender Pratap Singh	18/May/2017

**Acceptance criteria:**

- No error Messages displayed
- All Cuvettes should show acceptance

**PARAMETER**                      **PASS**                      **FAIL**

**Parameter values for verification:** No Error Messages

*Done*  
28/5/22

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

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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	18/May/2017

**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	18/May/2017

**Acceptance criteria:** Data shows OD values in the acceptable range

PARAMETER                      PASS                      FAIL

Parameter values for verification                      : No error message

*Jays*  
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**Test 06: Calibration of the system****Purpose:** To calibrate the system**Procedure:**

S No.	Activity	Done By	Date
01	Preparation of the cal material *	Vijender Pratap Singh	18/May/2017
02	Performing Calibration with calibration programming screen	Vijender Pratap Singh	18/May/2017

\*Traceability of the calibrator used is attached

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

PARAMETER	PASS	FAIL
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Parameter values for verification : No error message in the printout

**Test 07: QC check****Purpose:** To confirm that systems, reagents and consumables are acceptable & working within specifications for each assay used.**Procedure:**

S No.	Activity	Done By	Date
01	Preparing Biochemistry control material	Vijender Pratap Singh	18/May/2017
02	Creating QC file	Vijender Pratap Singh	18/May/2017
03	QC sample programming and analysis	Vijender Pratap Singh	18/May/2017

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

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

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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	18/May/2017
02	Running triplicates	Vijender Pratap Singh	18/May/2017

**Acceptance criteria:** Results CV within specified limits

<b>PARAMETER</b>	<b>PASS</b>	<b>FAIL</b>
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**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	18/May/2017
02	Programming samples	Vijender Pratap Singh	18/May/2017
03	Aspirating the samples	Vijender Pratap Singh	18/May/2017
04	Viewing samples in process	Vijender Pratap Singh	18/May/2017
05	Review results: Monitoring results	Vijender Pratap Singh	18/May/2017

**Acceptance criteria:** Samples Analysis without any error

<b>PARAMETER</b>	<b>PASS</b>	<b>FAIL</b>
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**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	Vijender Pratap Singh	18/May/2017
02	Following the on screen instructions	Vijender Pratap Singh	18/May/2017
03	Switch off the instrument when prompted	Vijender Pratap Singh	18/May/2017

**Acceptance criteria:** Shut down without any error

<b>PARAMETER</b>	<b>PASS</b>	<b>FAIL</b>
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**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	18/May/2017
2.	System Operation	Vijender Pratap Singh	18/May/2017
3.	Basic trouble shooting and Maintenance	Vijender Pratap Singh	18/May/2017

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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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*28/5/22*

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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 : 18/May/2017



Customer Authorizations: **SOM DATT MEDICAL CENTRE, NEW DELHI**

Name : *JAYA ULLAS*

Designation :

Title : PERFORMANCE QUALIFICATION

Signature :

Date :

*Jays*

*Jays*

*28/5/22*

*Jays*

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