

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



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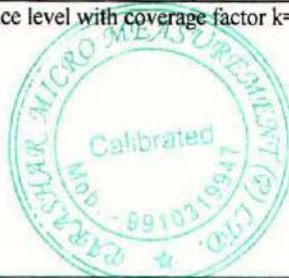
Calibration Certificate

| 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 | |
| Description of Equipments | | | | | | |
| 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 | | | | | |
| Master Equipment / Standard Used | | | | | | |
| 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 | | | | |
| CALIBRATION RESULTS | | | | | | |
| 1.0 Main Line Test | | | | | | |
| a. Main Line Voltage supply working properly | | | | | Yes | |
| b. Main Line ground connected properly | | | | | Yes | |
| 2.0 Earth Resistance Test | | | | | | |
| Sr.No. | Max Limit (Ω) | Actual Observed Value (Ω) | | Remark | | |
| 1 | 2.0 | 0.229 | | Pass | | |
| 3.0 Polarity Test Pass | | | | | Yes | |
| 4.0 Safety test | | | | | | |
| 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.

Real-time

Daily QC

Day to Day QC

QC Sum.

Control

Test Result

Test Statistics

Date

6/ 1/2022

Control

QC NROM

6/ 1/2022

| Test | Actual Result | Unit | Request Date | Ref. Range |
|-----------|---------------|-------|----------------------|-------------------|
| SGOT | 31.57 | U/L | 6/1/2022 12:06:40 PM | 31.0000-45.0000 |
| SGPT | 40.19 | U/L | 6/1/2022 11:48:04 AM | 39.6000-57.6000 |
| GGT | 37.51 | U/L | 6/1/2022 10:59:20 AM | 31.5000-45.5000 |
| ALB | 3.87 | g/dL | 6/1/2022 10:59:20 AM | 3.4500-4.6500 |
| TPR | 5.84 | g/dL | 6/1/2022 10:59:20 AM | 5.4500-7.3500 |
| ALP | 144.80 | U/L | 6/1/2022 10:59:20 AM | 126.0000-190.0000 |
| PHOS | 3.21 | mg/dL | 6/1/2022 10:59:20 AM | 2.4800-3.9200 |
| BILI-D | 0.11 | mg/dL | 6/1/2022 10:59:20 AM | 0.0300-0.2500 |
| BILI-T | 1.03 | mg/dL | 6/1/2022 10:59:20 AM | 0.6500-1.2500 |
| CAL | 8.25 | mg/dL | 6/1/2022 10:59:20 AM | 7.5800-9.4200 |
| CREAT | 0.96 | mg/dL | 6/1/2022 10:59:20 AM | 0.6500-1.1500 |
| URIC ACID | 5.28 | mg/dL | 6/1/2022 10:59:20 AM | 4.3000-6.1000 |
| UREA U.V | 26.36 | mg/dL | 6/1/2022 10:59:20 AM | 18.2000-33.8000 |
| HDL-D | 46.9 | mg/dL | 6/1/2022 10:59:20 AM | 41.700-60.300 |
| TGL | 100.3 | mg/dL | 6/1/2022 10:59:20 AM | 85.000-123.000 |
| CHO | 172.0 | mg/dL | 6/1/2022 10:59:20 AM | 147.000-193.000 |
| GLU | 74.4 | mg/dL | 6/1/2022 10:59:20 AM | 69.000-93.000 |

View searched QC test record

Refresh

Print

Delete

Reac. Curve

Test Result Date: Control:
 Test Statistics

| Test | Actual Result | Unit | Request Date | Ref. Range |
|-----------|---------------|-------|----------------------|-------------------|
| GGT | 143.87 | U/L | 6/1/2022 10:15:29 AM | 127.0000-177.0000 |
| ALB | 4.54 | g/dL | 6/1/2022 10:15:29 AM | 4.1100-5.8900 |
| TPR | 8.69 | g/dL | 6/1/2022 10:15:29 AM | 7.9000-11.5000 |
| ALP | 429.74 | U/L | 6/1/2022 10:15:29 AM | 372.0000-532.0000 |
| SGPT | 146.44 | U/L | 6/1/2022 10:15:29 AM | 131.0000-209.0000 |
| SGOT | 185.46 | U/L | 6/1/2022 10:15:29 AM | 177.0000-263.0000 |
| PHOS | 8.78 | mg/dL | 6/1/2022 10:15:29 AM | 7.9100-10.1100 |
| BILI-D | 0.29 | mg/dL | 6/1/2022 10:15:29 AM | 0.1000-0.6000 |
| BILI-T | 4.32 | mg/dL | 6/1/2022 10:15:29 AM | 3.0100-4.9900 |
| CAL | 11.73 | mg/dL | 6/1/2022 10:15:29 AM | 10.3000-13.7000 |
| CREAT | 2.90 | mg/dL | 6/1/2022 10:15:29 AM | 2.0000-3.6000 |
| URIC ACID | 11.59 | mg/dL | 6/1/2022 10:15:29 AM | 10.1500-13.6500 |
| UREA U.V | 80.15 | mg/dL | 6/1/2022 10:15:29 AM | 68.0000-96.0000 |
| HDL-D | 55.7 | mg/dL | 6/1/2022 10:15:29 AM | 42.720-78.720 |
| TGL | 411.4 | mg/dL | 6/1/2022 10:15:29 AM | 373.000-533.000 |
| CHO | 216.2 | mg/dL | 6/1/2022 10:15:29 AM | 186.000-254.000 |
| GLU | 168.1 | mg/dL | 6/1/2022 10:15:29 AM | 158.700-216.700 |

View searched QC test record



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

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.
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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

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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

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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

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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

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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

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OPERATIONAL QUALIFICATION

For

FULLY AUTOMATED CLINICAL CHEMISTRY ANALYZER

MODEL : MISPA ACE

AGAPPE DIAGNOSTICS LTD.

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28/3/22

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

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

Customer Authorizations:

Name : *Jayapullas*

Title : OPERATIONAL QUALIFICATION

Signature :

Jaya

Site :

Date

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 **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 **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.

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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 |

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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 | 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

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**Test 03: 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 |

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

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

| | |
|--|------------------------------------|
| Parameter values for verification | : No error message in the printout |
|--|------------------------------------|

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

| S No. | Activity | Done By | Date |
|-------|---|-----------------------|-------------|
| 01 | Preparing Biochemistry control material | 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 |
|------------------|-------------|-------------|

| |
|---|
| Parameter values for verification: QC values within \pm 2SD |
|---|

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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

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

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Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in

**Test 07: Shut down****Purpose:** To shut down the system**Procedure:**

| S No. | Activity | Done By | Date |
|-------|---|-----------------------|-------------|
| 01 | Preparing the system for shut down. | 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

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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

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

Jays
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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

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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

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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
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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 |

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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 | 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
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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

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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

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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 |
|-----------|------|------|

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 |
|-----------|------|------|

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

| | | |
|------------------|-------------|-------------|
| 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 | 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

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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

| | | |
|-----------|------|------|
| 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 | 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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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 :

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