CELEBRATING 25 YEARS
SURGING INNOVATION SERVING MANKIND

AGAPPE

INSTALLATION QUALIFICATION

For

FULLY AUTOMATED CLINICAL CHEMISTRY ANALYZER

MODEL : MISPA CXL PRO PLUS

AGAPPE DIAGNOSTICS LTD.

ADL/DO/SER/IOP/0086/22-23

Litewell Diagnostics Pvt. Ltd.
20/11/2022

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

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

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I. APPROVAL OF THE INSTALLATION QUALIFICATION PROCEDURE

Both **LIFE WELL DIAGNOSTICS LAJPAT NAGAR** and **AGAPPE DIAGNOSTICS LTD** are jointly responsible for the installation of **MISPA CXL PRO PLUS** with serial number **22T240PCS0144K** at **LIFE WELL DIAGNOSTICS LAJPAT NAGAR** as per the attached Installation Qualification protocol.

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

Name	:	Anil Kumar	Signature :	
Title	:	Manager Customer Service	Date :	20/11/2022
Company	:	AGAPPE DIAGNOSTICS LTD.		

Validation Team from **LIFE WELL DIAGNOSTICS LAJPAT NAGAR**

Name	:	ABHISHEK	Signature :	
Designation	:	Sr. Executive	Date :	20/11/2022
Department	:	LAB		

Customer Authorizations:

Name : Abhishek

Title : INSTALLATION QUALIFICATION Signature :

Site : Lajpat nagar Date : 20/11/2022

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 **LIFE WELL DIAGNOSTICS LAJPAT NAGAR** 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.

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.

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IV. INSTALLATION QUALIFICATION

A. Instrument Identification

Verified Date :

1. Model Name : MISPA CXL PRO PLUS
2. Serial Number : **22T240PCS0144K**

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

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

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

Summary:

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

Acceptance criteria:

PARAMETER **PASS** **FAIL**

D. Instrument Installation

Date of Installation : 20/11/2022

Installed by : Anil Kumar

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

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

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	Anil Kumar	20/11/2022
02	340 nm	Anil Kumar	20/11/2022
03	380 nm	Anil Kumar	20/11/2022
04	405 nm	Anil Kumar	20/11/2022
05	450 nm	Anil Kumar	20/11/2022
06	480 nm	Anil Kumar	20/11/2022
07	505 nm	Anil Kumar	20/11/2022
08	546 nm	Anil Kumar	20/11/2022
09	570 nm	Anil Kumar	20/11/2022
10	600 nm	Anil Kumar	20/11/2022
11	660 nm	Anil Kumar	20/11/2022
12	700 nm	Anil Kumar	20/11/2022
13	750 or 800 nm	Anil Kumar	20/11/2022

Acceptance criteria:

- No error Messages displayed
- All Cuvettes should show acceptance

PARAMETER **PASS** **FAIL**

Parameter values for verification: No Error Messages

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	Anil Kumar	20/11/2022

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

V. COMMENTS

VI. SYSTEM CERTIFICATION

Study data has determined that the system described in this document either meets all criteria outline in this Installation Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been addressed. The system is ready for Operational Qualification.

Report Performed By: **AGAPPE DIAGNOSTICS LTD.** Representative

Name : Anil Kumar

Designation : **Manager Customer Service**

Signature : Anil Kumar

Company : AGAPPE DIAGNOSTICS LTD.

Date : 20/11/2023

Customer Authorizations: **LIFE WELL DIAGNOSTICS LAJPAT NAGAR**

Name : ABHISHEK

Designation : Sr. Executive

Signature

Title : INSTALLATION QUALIFICATION

Date : 20/11/2023

CELEBRATING 25 YEARS 1995 - 2020
SURGING INNOVATION SERVING MANKIND

AGAPPE

OPERATIONAL QUALIFICATION

For

FULLY AUTOMATED CLINICAL CHEMISTRY ANALYZER

MODEL : MISPA CXL PRO PLUS

AGAPPE DIAGNOSTICS LTD.

ADL/DO/SER/IOP/0085/22-23

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

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I. APPROVAL OF THE OPERATIONAL QUALIFICATION PROCEDURE

Both **LIFE WELL DIAGNOSTICS LAJPAT NAGAR** and **AGAPPE DIAGNOSTICS LTD.** are jointly responsible for the installation of **MISPA CXL PRO PLUS** with serial number **22T240PCS0144K** at **LIFE WELL DIAGNOSTICS LAJPAT NAGAR** as per the attached OPERATIONAL QUALIFICATION protocol.

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

Name	:	Anil Kumar	Signature :	Anil Kum
Designation	:	Manager Customer Service	Date :	20/11/2022
Company	:	AGAPPE DIAGNOSTICS LTD.		

Validation Team from LIFE WELL DIAGNOSTICS LAJPAT NAGAR

Name	:	ABHISHEK.	Signature :	
Designation	:	Sr. Executive	Date :	20/11/2022
Department	:	Lab.		

Customer Authorizations:

Name : Abhishek

Title : OPERATIONAL QUALIFICATION

Site :

Signature

Date 2022

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.

III. SCOPE

This Operational Qualification protocol will be performed on the **MISPA CXL PRO PLUS** at **LIFE WELL DIAGNOSTICS LAJPAT NAGAR** 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.

IV. OPERATIONAL QUALIFICATION

A. **Instrument Identification** Verified Date : 20/11/2022

1. Model Name : MISPA CXL PRO PLUS
2. Serial Number : 22T240PCS0144K

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	20/11/22
02	Daily maintenance	To clean appropriate modules	20/11/22
03	Calibration	To calibrate the system	20/11/22
04	QC check	To confirm that the system is calibrated and working within specifications	20/11/22
05	Reproducibility check	To check the precision [CV %] after calibration	20/11/22
06	Sample programming and Analysis	To run the samples	20/11/22
07	Shut down procedure	To shut down the system	20/11/22

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 CXL PRO PLUS 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

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	Anil Kumar	20/11/22
02	Check Wash solutions	Anil Kumar	20/11/22
03	Check system water	Anil Kumar	20/11/22
04	Check Reagents	Anil Kumar	20/11/22
05	Clean Reagent Block	Anil Kumar	20/11/22
06	Clean out side area	Anil Kumar	20/11/22
07	Load supplies and remove outdated and empty reagents	Anil Kumar	20/11/22
08	Check main menu screen	Anil Kumar	20/11/22
09	Perform Quality Control	Anil Kumar	20/11/22

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

Test 03: Calibration of the system

Purpose: To calibrate the system

Procedure:

S No	Activity	Done By	Date
01	Preparation of the cal material	Anil Kumar	20/11/2022
02	Performing Calibration with calibration programming screen	Anil Kumar	20/11/2022

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	Anil Kumar	20/11/22
02	Creating QC file	Anil Kumar	20/11/22
03	QC sample programming and analysis	Anil Kumar	20/11/22

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

PARAMETER **PASS** **FAIL**

Parameter values for verification: QC values within ± 2SD

Test 05: Reproducibility Check

Purpose: To check the reproducibility of instrument

S No.	Activity	Done By	Date
01	Preparing control material/ sample	Anil Kumar	20/11/22
02	Running triplicates	Anil Kumar	20/11/22

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	Anil Kumar	20/11/22
02	Programming samples	Anil Kumar	20/11/22
03	Aspirating the samples	Anil Kumar	20/11/22
04	Viewing samples in process	Anil Kumar	20/11/22
05	Review results: Monitoring results	Anil Kumar	20/11/22

Acceptance criteria: Samples Analysis without any error

PARAMETER **PASS** **FAIL**

Parameter values for verification: Sample analysis without any error

Test 07: Shut down

Purpose: To shut down the system

Procedure:

S No.	Activity	Done By	Date
01	Preparing the system for shut down	Anil Kumar	20/11/22
02	Following the on screen instructions	Anil Kumar	20/11/22
03	Switch off the instrument when prompted	Anil Kumar	20/11/22

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	Anil Kumar	20/11/22
2	System Operation	Anil Kumar	20/11/22
3	Basic trouble shooting and Maintenance	Anil Kumar	20/11/22

2. Operator Training

The users responsible for the operation of this equipment have been trained in the proper usage of the system. Training focused on the basic operation and maintenance of the system.

S No.	Operators	Department	Initials	Date
1.	Abhishek	Lab		20/11/2022
2.	Puneet Gupta	Genetic Biochemistry		20/11/2022
3.	Anuj Kumar	Genetic Biochemistry		20/11/2022

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VI. COMMENTS

AGAPPE

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

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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 : Anil Kumar

Designation : Manager Customer Service Signature :

Company : AGAPPE DIAGNOSTICS LTD. Date : 20/11/2022

Customer Authorizations: **LIFE WELL DIAGNOSTICS LAJPAT NAGAR**

Name : ABHISHEK

Designation : Dr. Executive Signature

Title : OPERATIONAL QUALIFICATION Date 20/11/2022

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PERFORMANCE QUALIFICATION

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

Name	:	Anil Kumar	Signature :	Anil Kr
Designation	:	Manager Customer Service	Date :	20/11/2022
Company	:	AGAPPE DIAGNOSTICS LTD.		

Validation Team from LIFEWELL DIAGNOSTIC PRIVATE LIMITED, LAGPAT NAGAR

Name	:	Abhishek	Signature :	
Designation	:	Sr. Executive	Date :	20/11/22
Department	:	Lab		

Lifewell Diagnostics Pvt. Ltd.

Customer Authorizations:

Name : ABHISHEK

Title : PERFORMANCE QUALIFICATION Signature :

Site : Jagjeet Date : 20/11/2022

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 **LIFEWELL DIAGNOSTIC PRIVATE LIMITED, LAGPAT NAGAR** 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.

III. SCOPE

This Performance Qualification protocol will be performed on the **MISPA CXL PRO PLUS** at **LIFEWELL DIAGNOSTIC PRIVATE LIMITED, LAGPAT NAGAR.** 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.

IV. PERFORMANCE QUALIFICATION

A. Instrument Identification

Verified Date :

1. Model Name : MISPA CXL PRO PLUS
2. Serial Number : 22T240PCS0144K

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

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 CXL PRO PLUS 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

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	Anil Kumar	20/11/2022
02	Check Wash solutions	Anil Kumar	20/11/22
03	Check system water	Anil Kumar	20/11/22
04	Check Reagents	Anil Kumar	20/11/22
05	Clean Reagent Block	Anil Kumar	20/11/22
06	Clean out side area	Anil Kumar	20/11/22
07	Load supplies and remove outdated and empty reagents	Anil Kumar	20/11/22
08	Check main menu screen	Anil Kumar	20/11/22
09	Perform Quality Control	Anil Kumar	20/11/22

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

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	Anil Kumar	20/11/2022
	340 nm	Anil Kumar	20/11/22
	380 nm	Anil Kumar	20/11/22
	405 nm	Anil Kumar	20/11/22
	450 nm	Anil Kumar	20/11/22
	480 nm	Anil Kumar	20/11/22
	505 nm	Anil Kumar	20/11/22
	546 nm	Anil Kumar	20/11/22
	570 nm	Anil Kumar	20/11/22
	600 nm	Anil Kumar	20/11/22
	660 nm	Anil Kumar	20/11/22
	700 nm	Anil Kumar	20/11/22
	750 or 800 nm	Anil Kumar	20/11/22

Acceptance criteria:

- No error Messages displayed
- All Cuvettes should show acceptance

PARAMETER **PASS** **FAIL**

Parameter values for verification: No Error Messages

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	Anil Kumar	20/11/2022

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	Anil Kumar	20/11/2022

Acceptance criteria: Data shows OD values in the acceptable range

PARAMETER PASS FAIL

Parameter values for verification : No error message

Test 06: Calibration of the system

Purpose: To calibrate the system

Procedure:

S No.	Activity	Done By	Date
01	Preparation of the cal material *	Anil Kumar	20/11/22
02	Performing Calibration with calibration programming screen	Anil Kumar	20/11/22

*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	Anil Kumar	20/11/22
02	Creating QC file	Anil Kumar	20/11/22
03	QC sample programming and analysis	Anil Kumar	20/11/22

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

PARAMETER **PASS** **FAIL**

Parameter values for verification: QC values within ± 2SD

Test 08: Reproducibility Check

Purpose: To check the reproducibility of instrument

S No.	Activity	Done By	Date
01	Preparing control material/ sample	Anil Kumar	20/11/22
02	Running triplicates	Anil Kumar	20/11/22

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	Anil Kumar	20/11/22
02	Programming samples	Anil Kumar	20/11/22
03	Aspirating the samples	Anil Kumar	20/11/22
04	Viewing samples in process	Anil Kumar	20/11/22
05	Review results: Monitoring results	Anil Kumar	20/11/22

Acceptance criteria: Samples Analysis without any error

PARAMETER **PASS** **FAIL**

Parameter values for verification: Sample analysis without any error

Test 10: Shut down

Purpose: To shut down the system

Procedure:

S No.	Activity	Done By	Date
01	Preparing the system for shut down	Anil Kumar	20/11/22
02	Following the on screen instructions	Anil Kumar	20/11/22
03	Switch off the instrument when prompted	Anil Kumar	20/11/22

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	Abhishek	20/11/22
2.	System Operation	Abhishek	20/11/22
3.	Basic trouble shooting and Maintenance	Abhishek	20/11/22

2. Operator Training

The users responsible for the operation of this equipment have been trained in the proper usage of the system. Training focused on the basic operation and maintenance of the system.

S No.	Operators	Department	Initials	Date
1.	Abhishek	Lab		20/11/2022
2.	Puneet	Genetic Biochemistry		20/11/2022
3.	Anuj Kumar	Genetic Biochemistry		20/11/2022

VI. SYSTEM CERTIFICATION

Study data has determined that the system described in this document either meets all criteria outline in this Performance Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been addressed. The system is ready for specified usage.

Report Performed By: **AGAPPE DIAGNOSTICS LTD**. Representative

Name : Anil Kumar

Designation : Manager Customer Service Signature : Anil

Company : AGAPPE DIAGNOSTICS LTD. Date : 20/11/2022

Customer Authorizations: **LIFEWELL DIAGNOSTIC PRIVATE LIMITED, LAGPAT NAGAR**

Name : Abhishek

Designation : Sr. Executive Signature :

Title : PERFORMANCE QUALIFICATION Date : 20/11/2022

AGAPPE

V. COMMENTS

AGAPPE