

**CERTIFICATE OF CALIBRATION**

ADI/DO/MS/0061/24-25

Instrument: MISPA CXL PRO PLUS Fully Automated Biochemistry Analyser**Customer Name:** Arunosha Labs Pvt Ltd, DELHI.**Date of Installation:** 14/05/2024**S/N:** 23T240PCS0538K**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
Cuvette Check	<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

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24239MH1998PLC15413

CORPORATE OFFICE / REAGENT PLANT
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EQUIPMENT PLANT
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 5-6, 9th Floor, Red Cross Bhavan, No.26 Race Course Road,
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**OPTICAL SECTION**

Filter	Light Intensity	
340	10207	
380	10302	
405	10308	
450	10169	
480	10112	
505	10071	
546	10136	
570	10115	
600	10107	
660	10161	
700	10139	
800	10176	

Power Supply : 12V 24V

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

Lot.No: 32403646 Exp: 2025-06

This is to certify that the above mentioned product has been calibrated according to the standard operating procedure given by the Agappe Diagnostics Ltd.

Date of Calibration : 14/May/2024

Next Due : 13/Nov/2024

For Agappe Diagnostics Ltd.,



Authorized Signatory

Name: Deepak

Designation: Sr. Service engineer

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : 5024399612990PLC15413

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INSTALLATION QUALIFICATION

For

FULLY AUTOMATED CLINICAL CHEMISTRY ANALYZER

MODEL : MISPA CXL PRO PLUS

AGAPPE DIAGNOSTICS LTD.

ADL/DO/SER/0011/24-25

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

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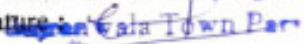
I. APPROVAL OF THE INSTALLATION QUALIFICATION PROCEDURE

Both ARUNOSHA LABS PVT LTD, DELHI and AGAPPE DIAGNOSTICS LTD are jointly responsible for the installation of MISPA CXL PRO PLUS with serial number 23T240PCS0538K at Arunosha Labs PVT LTD, Delhi as per the attached Installation Qualification protocol.

Protocol Performed By: Representative of AGAPPE DIAGNOSTICS LTD.

Name	: Deepak	Signature	 
Title	: Sr. Service engineer	Date	: 14/05/2024
Company	: AGAPPE DIAGNOSTICS LTD.		

Validation Team from ARUNOSHA LABS PVT LTD, DELHI

Name	: Dr. Usha Arun Kumar	Signature	 Dr. Usha Arun Kumar MI (Path & Micro) Arunosha Clinics & Labs B-4, Local Shopping Centre Gurgaon, Gurgaon, Haryana
Designation	: Pathologist & Director	Date	: 14/05/2024
Department	: Pathologist		

Customer Authorizations:

Name : Rohit
Title : INSTALLATION QUALIFICATION
Site :
Signature : 
Date : 14/05/2024

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24239MH2009PLC015413

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Email: bangalore@agappe.in



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 **ARUNOSHA LABS PVT LTD, DELHI** will verify each result and sign in each page. The member of the validation team will carry this out.
3. ALL deviations from the acceptance criteria detailed in this document will be noted in the COMMENTS section at the end of the IQ protocol. All resolution to such problems will also be noted in the COMMENTS section, and must be resolved prior to issuance of a SYSTEM CERTIFICATION.

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

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SURGING INNOVATION
SERVING HEALTHCARE

III. SCOPE

This Installation Qualification protocol will be performed on the **MISPA CXL PRO PLUS** at **ARUNOSHA LABS PVT LTD, DELHI**. This Installation protocol will define the documentation that will be used to evaluate the instruments installation in accordance with the manufacturer's specifications and intended use. Successful completion of this protocol will verify that the instrument identified has been installed in accordance with the intended usage.

Trained, knowledgeable personnel will perform qualification studies. Any exceptional conditions encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated, and the appropriate course of action determined. All documents will be initialed and dated.

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CN : U24239MH2998PLC125413

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 SURGING INNOVATIONS
SERVING

IV. INSTALLATION QUALIFICATION
A. Instrument Identification

Verified Date: 14/05/2024

1. Model Name : MISPA CXL PRO PLUS
2. Serial Number : 23T240PCS0538K

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

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

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

Summary:

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

Acceptance criteria:

PARAMETER

~~PASS~~

FAIL

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24200MH2006PLC125442

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Bangalore - 560 032, India | Tel: +91 90 2228 6780
Email: bangaloreoffice@agappe.in



D. Instrument Installation

Date of Installation : 14/05/2024

Installed by : Deepak

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

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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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	Deepak	14/05/2024
02	340 nm	Deepak	14/05/2024
03	380 nm	Deepak	14/05/2024
04	405 nm	Deepak	14/05/2024
05	450 nm	Deepak	14/05/2024
06	480 nm	Deepak	14/05/2024
07	505 nm	Deepak	14/05/2024
08	546 nm	Deepak	14/05/2024
09	570 nm	Deepak	14/05/2024
10	600 nm	Deepak	14/05/2024
11	660 nm	Deepak	14/05/2024
12	700 nm	Deepak	14/05/2024
13	750 or 800 nm	Deepak	14/05/2024

Acceptance criteria:

- No error Messages displayed
- All Cuvettes should show acceptance

PARAMETER **PASS** FAIL

Parameter values for verification: No Error Messages

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24239MH2019PLC125413

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F. Priming

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

S No	Activity	Done By	Date
01	Do wash using the maintenance screen	Deepak	14/05/2024

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

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24239MH1998PLC105413

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VI. SYSTEM CERTIFICATION

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

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

Name : Deepak

Designation : Asst. Manager Customer Service

Company : AGAPPE DIAGNOSTICS LTD.

Signature : 

Date : 14/05/2024

Customer Authorizations: **ARUNOSHA LABS PVT LTD, DELHI**

Name : Dr. Usha Arun Kumar

Designation : Director

Title : INSTALLATION QUALIFICATION

Signature : 

Date : 14/05/2024

Dr. USHA A KUMAR
MD (Path & Micro)
arunasha clinics & labs
202/4, Local Shopping Center
Shriyanagar Town Part
11A12

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CN : 0242700015P001C15413

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III. APPROVAL OF THE OPERATIONAL QUALIFICATION PROCEDURE

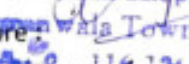
Both ARUNOSHA LABS PVT LTD, DELHI and AGAPPE DIAGNOSTICS LTD are jointly responsible for the installation of MISPA CXL PRO PLUS with serial number 23T240PCS0538K at Arunosha Labs PVT LTD, Delhi as per the attached Operational Qualification protocol.

Protocol Performed By: Representative of AGAPPE DIAGNOSTICS LTD.

Name	: Deepak	Signature :	
Designation	: Sr. Service engineer	Date	: 14/05/2024
Company	: AGAPPE DIAGNOSTICS LTD.		



Validation Team from ARUNOSHA LABS PVT LTD, DELHI

Name	: Dr. Arjun Usher Arun Kumar	Signature :	
Designation	: Pathologist & Director	Date	: 14/05/2024
Department	: Bio chemistry		

Dr. USHA A KUMAR
MD (Path & Micro)
Arunosha clinics & labs
103/4, Local Shopping Centre
Jangpura Wala Town Part

Customer Authorizations:

Name	: Rohit	Signature	: 
Title	: OPERATIONAL QUALIFICATION	Date	: 14/05/24
Site	:		

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CN : U24239MH0299BPLC115413

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EQUIPMENT PLANT
T/588-CB, Block No. 32, KINFRA Small Industrial Park,
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Email: bangalore@agappe.in



IV. 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**.

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24239MH2990PLC115413

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VII. SCOPE

This Operational Qualification protocol will be performed on the **MISPA CXL PRO PLUS** at **ARUNOSHA LABS PVT LTD, DELHI**. This Installation protocol will define the documentation that will be used to evaluate the instruments installation in accordance with the manufacturer's specifications and intended use. Successful completion of this protocol will verify that the instrument identified has been installed in accordance with the intended usage. Trained, knowledgeable personnel will perform qualification studies. Any exceptional conditions encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated and the appropriate course of action determined. All documents will be initialed and dated.

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2006 CERTIFIED COMPANY | CN : U24239MH1998PLC115411

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VIII. OPERATIONAL QUALIFICATION

• Instrument Identification

Verified Date : 14/05/2024

- Model Name : MISPA CXL PRO PLUS
- Serial Number : 23T240PCS0538K

- 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	Deepak , 14/05/2024
02	Daily maintenance	To clean appropriate modules	Deepak , 14/05/2024
03	Calibration	To calibrate the system	Deepak , 14/05/2024
04	QC check	To confirm that the system is calibrated and working within specifications	Deepak , 14/05/2024
05	Reproducibility check	To check the precision [CV %] after calibration	Deepak , 14/05/2024
06	Sample programming and Analysis	To run the samples	Deepak , 14/05/2024
07	Shut down procedure	To shut down the system	Deepak , 14/05/2024

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CN : 1024299M02990PLC135413

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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:

- G. Wait for the instrument to get ready after initialization
- H. Check the room temperature and switch on the Air Conditioner
- I. Check the UPS.
- J. Switch on the MISPA CXL PRO PLUS by pressing the main switch, then switch on the computer and then the system power
- K. Double click the analyzer icon to initialize the system software
- L. Input the password and do as prompted, the system menu pops up if start up is finished
- M. If not, initialize by again after solving the error displayed
- N. Follow instructions provided for the error message

Acceptance criteria: System to display READY status

PARAMETER	PASS	FAIL
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Parameter values for verification: "READY" on Status Area

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Email: bangalore@agappe.in

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	Deepak	14/05/2024
02	Check Wash solutions	Deepak	14/05/2024
03	Check system water	Deepak	14/05/2024
04	Check Reagents	Deepak	14/05/2024
05	Clean Reagent Block	Deepak	14/05/2024
06	Clean out side area	Deepak	14/05/2024
07	Load supplies and remove outdated and empty reagents	Deepak	14/05/2024
08	Check main menu screen	Deepak	14/05/2024
09	Perform Quality Control	Deepak	14/05/2024

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	Deepak	14/05/2024
02	Performing Calibration with calibration programming screen	Deepak	14/05/2024

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	Deepak	14/05/2024
02	Creating QC file	Deepak	14/05/2024
03	QC sample programming and analysis	Deepak	14/05/2024

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	Deepak	14/05/2024
02	Running triplicates	Deepak	14/05/2024

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	Deepak	14/05/2024
02	Programming samples	Deepak	14/05/2024
03	Aspirating the samples	Deepak	14/05/2024
04	Viewing samples in process	Deepak	14/05/2024
05	Review results: Monitoring results	Deepak	14/05/2024

Acceptance criteria: Samples Analysis without any error

PARAMETER **PASS** FAIL

Parameter values for verification: Sample analysis without any error

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Email: bangalore@agappe.in



5. 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.	Rohit	Bio chemistry		14/05/2024
2.	Rohit	Bio chemistry		14/05/2024

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 / EN ISO 13485:2016 CERTIFIED COMPANY | CN - 62429999999999999999

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XI. 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 : Deepak

Designation : Sr. Service engineer

Signature :



Company : AGAPPE DIAGNOSTICS LTD.

Date : 14/05/2024

Customer Authorizations: **ARUNOSHA LABS PVT LTD, DELHI**

Name : Dr. Usha Arun Kumar

Designation : Pathologist & Director

Title : OPERATIONAL QUALIFICATION

Signature : Usha A. Kumar
MD (Path & Micro)
Arunosha clinics & labs
10/4, Local Shopping Centre
Singh wala Town Part
11A/12
Date : 14/05/2024

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U64209MH2019PLC135413

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PERFORMANCE QUALIFICATION

For

FULLY AUTOMATED CLINICAL CHEMISTRY ANALYZER

MODEL : MISPA CXL PRO PLUS

AGAPPE DIAGNOSTICS LTD.

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

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Email: bangalore@agappe.in



V. APPROVAL OF THE PERFORMANCE QUALIFICATION PROCEDURE


Both ARUNOSHA LABS PVT LTD, DELHI and AGAPPE DIAGNOSTICS LTD are jointly responsible for the installation of MISPA CXL PRO PLUS with serial number 23T240PCS0538K at Arunosha Labs PVT LTD, Delhi as per the attached Performance Qualification protocol.

Protocol Performed By: Representative of AGAPPE DIAGNOSTICS LTD.

Name	: Deepak	Signature :	
Designation	: Sr. Service engineer	Date	: 14/05/2024
Company	: AGAPPE DIAGNOSTICS LTD.		



Validation Team from ARUNOSHA LABS PVT LTD, DELHI

Name	: Dr. Usha Arun Kumar	Signature :	
Designation	: Pathologist & Director	Date	: 14/05/2024
Department	: Biochemistry		

Usha A Kumar
MD (Path & Micro)
Arunosha Clinics & Labs
Local Shopping Centre
Gurgaon wala Town Park

Customer Authorizations:

Name	: Rohit	Signature	: 
Title	: PERFORMANCE QUALIFICATION	Date	: 14/05/24
Site	:		

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24239MH2009PTC0135433

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VIII. PERFORMANCE QUALIFICATION

O. Instrument Identification

Verified Date : 14/05/2024

1. Model Name : MISPA CXL PRO PLUS
2. Serial Number : 23T240PCS0538K

P. 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	Deepak , 14/05/2024
02	Daily maintenance	To clean appropriate modules	Deepak , 14/05/2024
03	Cell blank	To check the cuvettes	Deepak , 14/05/2024
04	Priming	To check the tubing's, and flow	Deepak , 14/05/2024
05	Auto gain	To check the cuvette and photometry system	Deepak , 14/05/2024
06	Calibration	To calibrate the system	Deepak , 14/05/2024
07	QC check	To confirm that the system and reagents are acceptable and working within specifications	Deepak , 14/05/2024
08	Reproducibility check	To check the precision [CV %]	Deepak , 14/05/2024
09	Sample programming and Analysis	To run the samples	Deepak , 14/05/2024
10	Shut down procedure	To shut down the system	Deepak , 14/05/2024

AGAPPE DIAGNOSTICS LTD.

ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24239MH2009PLC135413

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VIII. PERFORMANCE QUALIFICATION

O. Instrument Identification

Verified Date : 14/05/2024

1. Model Name : MISPA CXL PRO PLUS
2. Serial Number : 23T240PCS0538K

P. 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	Deepak , 14/05/2024
02	Daily maintenance	To clean appropriate modules	Deepak , 14/05/2024
03	Cell blank	To check the cuvettes	Deepak , 14/05/2024
04	Priming	To check the tubing's, and flow	Deepak , 14/05/2024
05	Auto gain	To check the cuvette and photometry system	Deepak , 14/05/2024
06	Calibration	To calibrate the system	Deepak , 14/05/2024
07	QC check	To confirm that the system and reagents are acceptable and working within specifications	Deepak , 14/05/2024
08	Reproducibility check	To check the precision [CV %]	Deepak , 14/05/2024
09	Sample programming and Analysis	To run the samples	Deepak , 14/05/2024
10	Shut down procedure	To shut down the system	Deepak , 14/05/2024

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CN : 624239902990PLC115413

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BANGALORE OFFICE

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Email: bangaloreoffice@agappe.in



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	Deepak	14/05/2024
02	Check Wash solutions	Deepak	14/05/2024
03	Check system water	Deepak	14/05/2024
04	Check Reagents	Deepak	14/05/2024
05	Clean Reagent Block	Deepak	14/05/2024
06	Clean out side area	Deepak	14/05/2024
07	Load supplies and remove outdated and empty reagents	Deepak	14/05/2024
08	Check main menu screen	Deepak	14/05/2024
09	Perform Quality Control	Deepak	14/05/2024

Acceptance criteria: System should be "Ready" after daily maintenance without any error

PARAMETER **PASS** **FAIL**

Parameter values for verification: System found "Ready" after daily maintenance

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Test 03: Cell Blank

Purpose: To check the cuvette blank OD at different wavelength

Procedure:

S No.	Activity	Done By	Date
01	Checking the Cell blank	Deepak	14/05/2024
	340 nm	Deepak	14/05/2024
	380 nm	Deepak	14/05/2024
	405 nm	Deepak	14/05/2024
	450 nm	Deepak	14/05/2024
	480 nm	Deepak	14/05/2024
	505 nm	Deepak	14/05/2024
	546 nm	Deepak	14/05/2024
	570 nm	Deepak	14/05/2024
	600 nm	Deepak	14/05/2024
	660 nm	Deepak	14/05/2024
	700 nm	Deepak	14/05/2024
	750 or 800 nm	Deepak	14/05/2024

Acceptance criteria:

- No error Messages displayed
- All Cuvettes should show acceptance

PARAMETER **PASS** **FAIL**

Parameter values for verification: No Error Messages

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

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Bangalore - 560 001, Tel : +91 80 2218 6788
Email: bangalore@agappe.in



7. 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	Rohit	Bio chemistry		14/05/24
2	Rohit	Bio chemistry		14/05/24

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

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5 & 6th Floor, Red Cross Bldg, No.76 Race Course Road,
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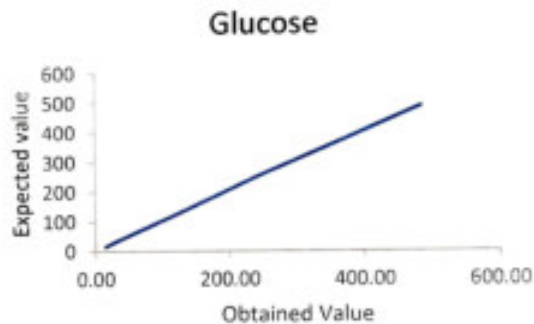


ADI/CO/APL/1214/24-25

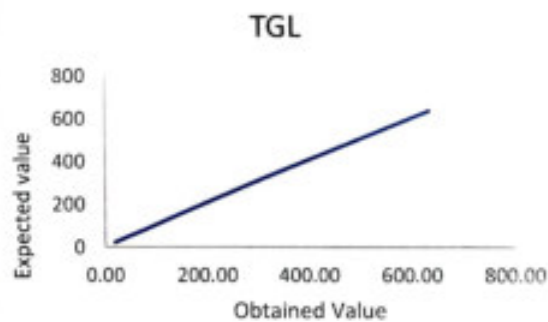
12/06/2024

Customer Name	Arunosha Labs pvt Ltd
Instrument	Mispa CXL Pro Plus
Protocol	Linearity Study
Date	12/06/2024

Parameters	Glucose	
	Expected value	Obtained Value
Dilution		
Direct	483.87	483.87
1:2	241.94	250.87
1:4	120.97	124.17
1:8	60.48	63
01:16	30.24	31.27
01:32	15.12	15.33



Parameters	TGL	
	Expected value	Obtained Value
Dilution		
Direct	635.37	635.37
1:2	317.69	325.2
1:4	158.84	163.93
1:8	79.42	81.83
01:16	39.71	40.71
01:32	19.86	20.59



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X/588-CB, Block No. 12, KINFRA Small Industrial Park,
Mellat, Cochin, Kerala, India - 586 721. Tel: +91 484 276 7477.

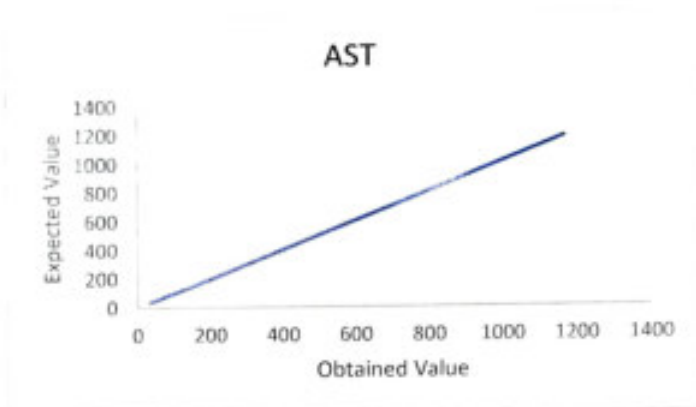
DELHI OFFICE
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New Delhi - 110 015, India.
Tel: +91 11 4558 8416 | Email: delhi@agappe.in

KOLKATA OFFICE
40A, Merin Matrix, Plot No-10, Block-DK, Sector V,
Salt Lake City, Kolkata - 700 091.
Tel: +91 33 4003 0451 | Email: kolkata@agappe.in

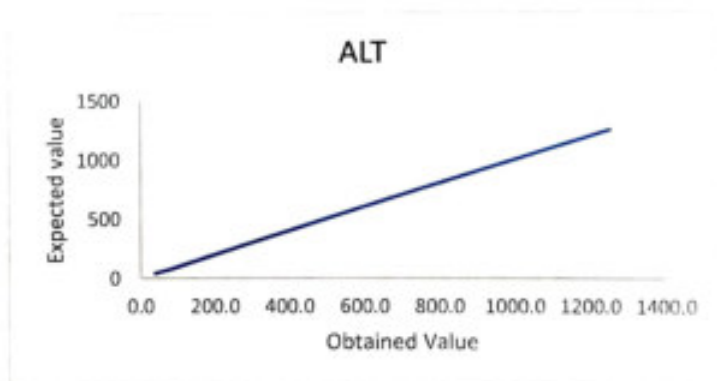
BANGALORE OFFICE
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Bangalore - 560 001. Tel: +91 80 2276 6288
Email: bangalore@agappe.in



Parameters	AST	
	Expected value	Obtained Value
Dilution		
Direct	1166.4	1166.4
1:2	583.2	584.3
1:4	291.6	289.9
1:8	145.8	141.7
01:16	72.9	71.01
01:32	36.45	35.02



Parameters	ALT	
	Expected value	Obtained Value
Dilution		
Direct	1256.3	1256.3
1:2	628.2	629.1
1:4	314.1	312.2
1:8	157.0	153.12
01:16	78.5	75.62
01:32	39.3	41.25



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ADL/CO/APL/1326/24-25

12/06/2024

Customer Name	Arunosha Labs pvt Ltd
Instrument	Mispa CXL Pro Plus
Protocol	Carryover Study
Date	12/06/2024

Low Level 1				High Level 2				Carry Over Ratio
Parameters	L1	L2	L3	Parameters	H1	H2	H3	
GLU	16.28	16.36	16.66	GLU	500.27	494.19	496.37	-0.079
TG	20.59	22.32	21.41	TG	695.07	694.17	707.87	-0.119
AST	35.67	33.74	35.67	AST	507.99	509.28	506.4	0.000
ALT	42.5	40.62	38.75	ALT	518.75	522.5	524.6	0.772

Customer Technical Support Department

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24239MH1998PLC15413

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ADI/CO/APL/1214/24-25

12/06/2024

Customer Name	Arunosha Labs pvt Ltd
Instrument	Mispa CXL Pro PLUS
Protocol	Precision Certificate
Date	12/06/2024

	Glu	Chol	Tgl	Urea	E-Crt	UA	AST
	93.45	139.33	155.03	24.1	0.76	5.75	26.76
	93.69	142.1	156.21	23.77	0.75	5.81	26.09
	94.24	140.23	157.25	23.89	0.77	5.62	24.08
	94.48	141.2	157.77	22.95	0.78	5.8	26.5
	94.44	138.88	156.66	25.53	0.73	5.75	27.43
	95.23	138.13	156.88	24.1	0.77	5.86	25.42
	92.74	137.61	151.85	23.44	0.77	5.75	25.0
	94.44	136.64	154.51	23.2	0.76	5.84	26
	93.97	141.87	154.44	24.0	0.77	5.8	25.42
	94.88	141.87	158.95	24.1	0.75	5.56	26.09
Mean	94.16	139.79	155.96	23.91	0.76	5.75	25.88
SD	0.72	1.96	2.04	0.70	0.01	0.10	0.95
CV%	0.77	1.40	1.31	2.93	1.90	1.66	3.67

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015, ISO 13485:2016 CERTIFIED COMPANY FOR GENERAL PURPOSES

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	ALT	Alb	TP	T-bil	Alp- IFCC	Cal
	39.53	4.18	6.73	0.44	83.92	9.89
	39	4.23	6.73	0.43	84.83	9.82
	40.19	4.22	6.7	0.45	86.21	9.81
	37.53	4.22	6.73	0.45	83.46	9.85
	38.86	4.23	6.69	0.47	85.75	9.83
	38.86	4.22	6.69	0.46	84.37	9.74
	38.86	4.23	6.63	0.45	85.75	9.73
	36.87	4.2	6.67	0.47	85.75	9.63
	38.86	4.17	6.69	0.46	84.37	9.78
	34.88	4.19	6.7	0.47	84.83	9.75
Mean	38.34	4.21	6.70	0.46	84.92	9.78
SD	1.53	0.02	0.03	0.01	0.91	0.07
CV%	4.00	0.53	0.46	2.98	1.07	0.76

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Email: bangalore@agappe.in

Item Name	S1 ABS	K	A	B	C	State	Calibration Name
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Calibration Curve

Test Item: Std.:

S1 Abs. K A B C

0.0516 7.319 0 0 0

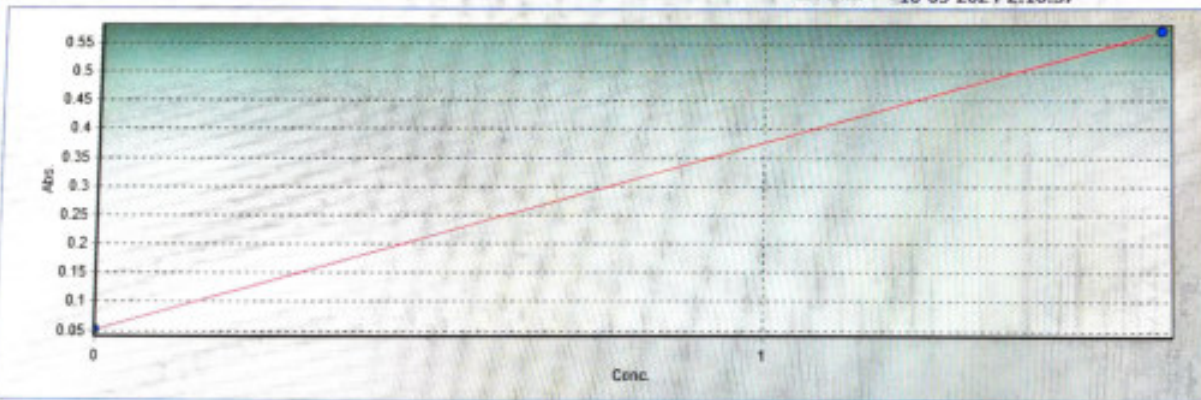
Abs. 0.0516

Cal. method this time: 2 Point Linear

Cal. method current:

Cal. time: 10-05-2024 2:10:37

Std.	Conc.	Abs.
S1	<input type="text" value="0"/>	<input type="text" value="0.0516"/>
S2	<input type="text" value="1.6"/>	<input type="text" value="0.5708"/>
S3	<input type="text" value="0"/>	<input type="text" value="0"/>
S4	<input type="text" value="0"/>	<input type="text" value="0"/>
S5	<input type="text" value="0"/>	<input type="text" value="0"/>
S6	<input type="text" value="0"/>	<input type="text" value="0"/>
S7	<input type="text" value="0"/>	<input type="text" value="0"/>
S8	<input type="text" value="0"/>	<input type="text" value="0"/>
S9	<input type="text" value="0"/>	<input type="text" value="0"/>
S10	<input type="text" value="0"/>	<input type="text" value="0"/>



Calibration Curve

Test Item: ALP - IFFC

Std. 1

S1 Abs. K A B C

0.0008 4585.5379 0 0 0

Abs. 0.0008

Cal. method this time: 2 Point Linear

Cal. method current: 2 Point Linear

Cal. time: 12-06-2024 12:09:08

Std.

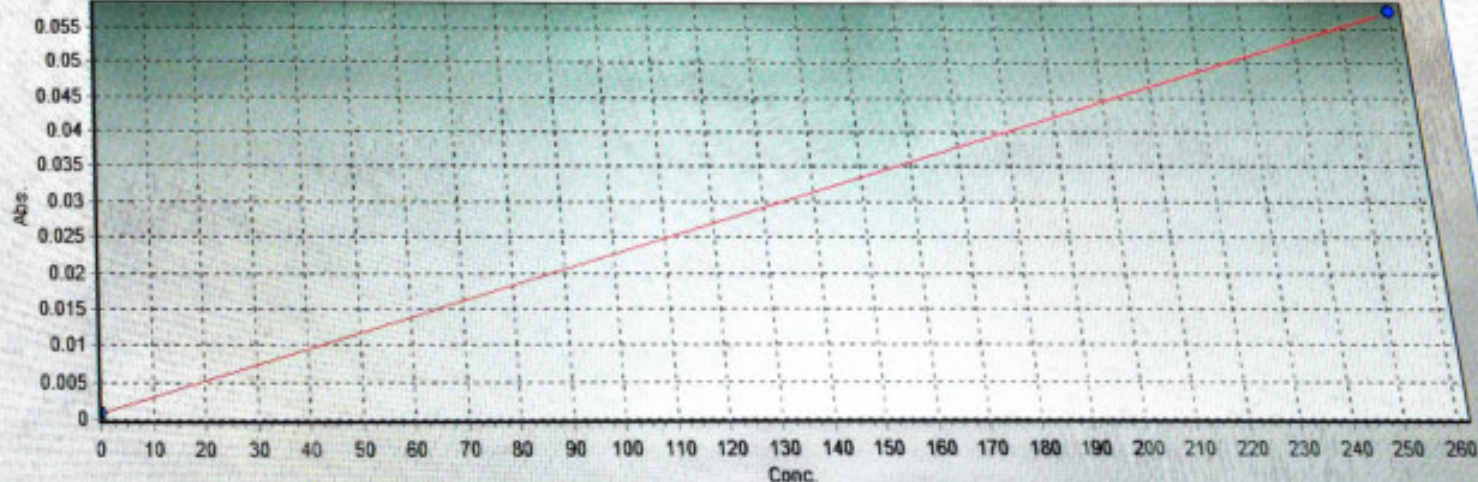
S1

S2

S3

S4

S5



Set Range

Print

Refresh

Close

Calibration Curve

Test Item: **ALT**

Std. **1**

S1 Abs

K

A

B

C

Abs.

0.0003

Cal. method this time:

2 Point Linear

Cal. method current:

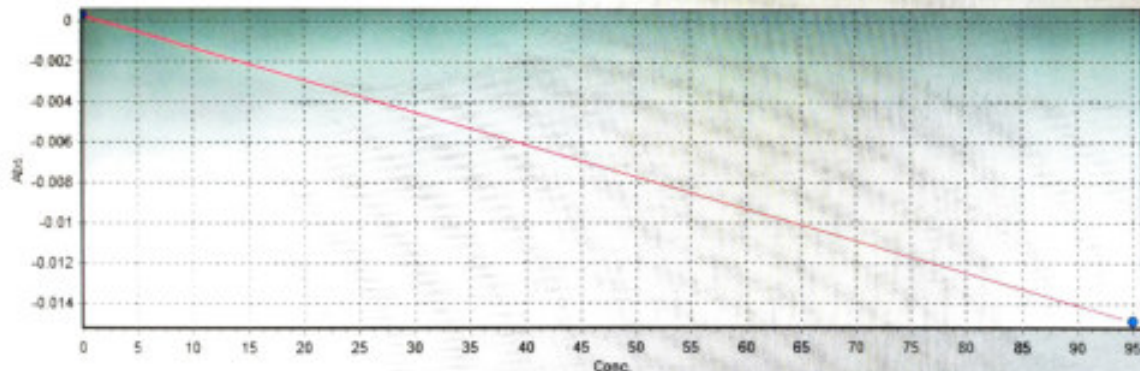
2 Point Linear

Cal. time:

01-06-2024 13:01:10

Std. Conc. Abs.

Std.	Conc.	Abs.
S1	0	0.0003
S2	95.0	-0.0149
S3	0	0
S4	0	0
S5	0	0
S6	0	0
S7	0	0
S8	0	0
S9	0	0
S10	0	0



Set Range

Print

Refresh

Close

Close



Calibration Curve

Test Item: AST Std. 1

S1 Abs: K A B C

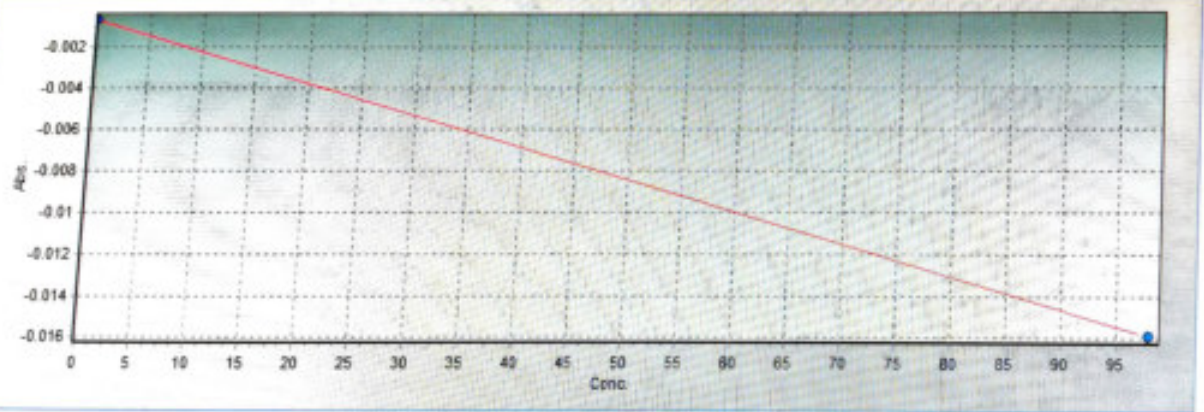
-0.00065 -6426.22 0 0 0

Abs. -0.00065

Cal. method this time: 2 Point Linear

Cal. method current: 2 Point Linear

Cal. time: 05-06-2024 13:46:48



Std.	Conc.	Abs.
S1	<input type="text" value="0"/>	<input type="text" value="-0.00065"/>
S2	<input type="text" value="98.0"/>	<input type="text" value="-0.015"/>
S3	<input type="text" value="0"/>	<input type="text" value="0"/>
S4	<input type="text" value="0"/>	<input type="text" value="0"/>
S5	<input type="text" value="0"/>	<input type="text" value="0"/>
S6	<input type="text" value="0"/>	<input type="text" value="0"/>
S7	<input type="text" value="0"/>	<input type="text" value="0"/>
S8	<input type="text" value="0"/>	<input type="text" value="0"/>
S9	<input type="text" value="0"/>	<input type="text" value="0"/>
S10	<input type="text" value="0"/>	<input type="text" value="0"/>

Test Item: CHOL

Std. 1

S1 Abs.

K

A

B

C

0.0119

744.2299

0

0

0

Abs. 0.0119

Cal. method this time:

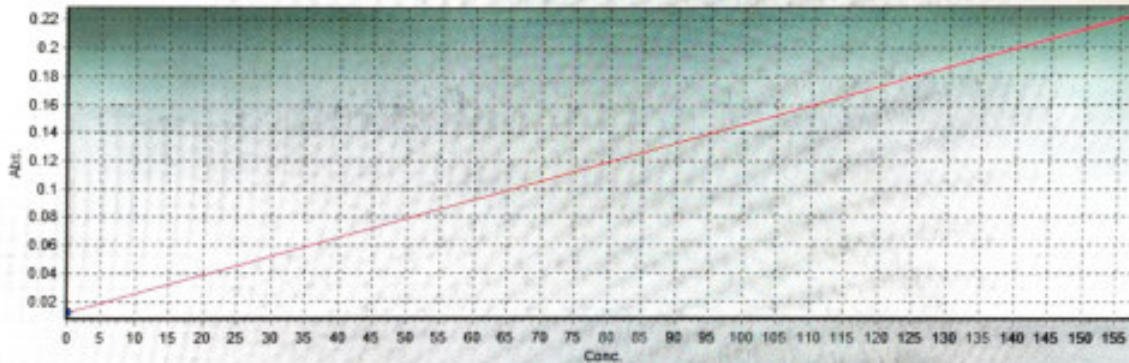
2 Point Linear

Cal. method current:

2 Point Linear

Cal. time:

01-06-2024 12:58:40



Set Range

Print

Refresh

Close

Std.

Conc.

S1

0

S2

158.0

S3

0

S4

0

S5

0

S6

0

S7

0

S8

0

S9

0

S10

0

Item Name	SI ABS	K	A	B	C	State	Calibration
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Calibration Curve

Test Item: Std.

SI Abs. K A B C

0.00015 26.0586 0 0 0

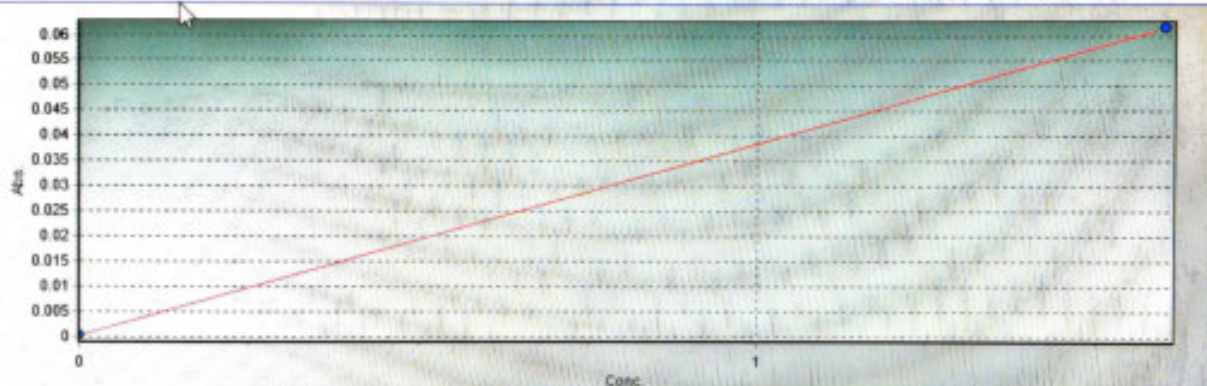
Abs. 0.00015

Cal. method this time: 2 Point Linear

Cal. method current: 2 Point Linear

Cal. time: 01-06-2024 13:06:10

Std.	Conc.	Abs.
S1	<input type="text" value="0"/>	<input type="text" value="0.00015"/>
S2	<input type="text" value="1.6"/>	<input type="text" value="0.06155"/>
S3	<input type="text" value="0"/>	<input type="text" value="0"/>
S4	<input type="text" value="0"/>	<input type="text" value="0"/>
S5	<input type="text" value="0"/>	<input type="text" value="0"/>
S6	<input type="text" value="0"/>	<input type="text" value="0"/>
S7	<input type="text" value="0"/>	<input type="text" value="0"/>
S8	<input type="text" value="0"/>	<input type="text" value="0"/>
S9	<input type="text" value="0"/>	<input type="text" value="0"/>
S10	<input type="text" value="0"/>	<input type="text" value="0"/>



Set Range

Print

Refresh

Close

Item Name	S1 Abs	K	A	B	C	State	Calibration
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Calibration Curve

Test Item:

E-CRE

Std.:

1

S1 Abs.

K

A

B

C

Abs.

0.0018

0.0018

77.0878

0

0

0

Cal. method this time:

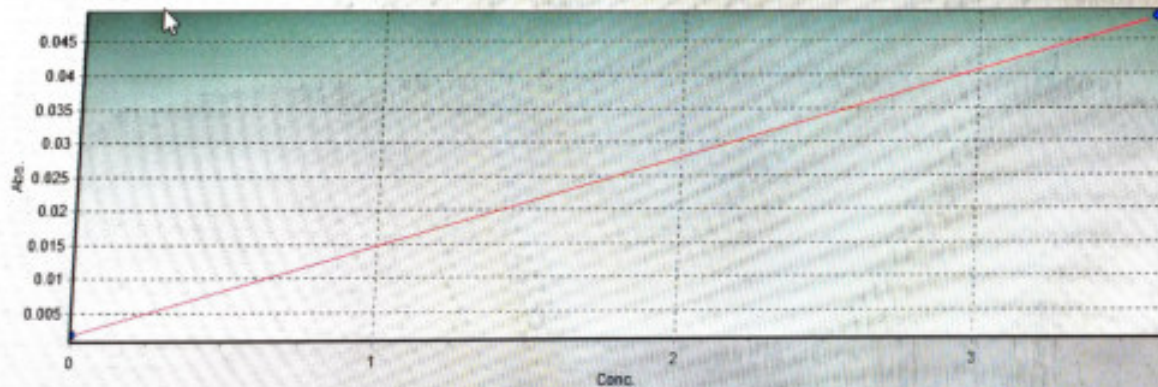
2 Point Linear

Cal. method current:

2 Point Linear

Cal. time:

01-06-2024 13:07:09



Std.	Conc.	Abs.
S1	0	0.0018
S2	3.6	0.0485
S3	0	0
S4	0	0
S5	0	0
S6	0	0
S7	0	0
S8	0	0
S9	0	0
S10	0	0

Set Range

Print

Refresh

Close

Calibration Curve

Test Item: **GLU**

Std. **1**

S1 Abs. **K** **A** **B** **C**
 0.0083 417.4654 0 0 0

Abs. **0.0083**

Cal. method this time:

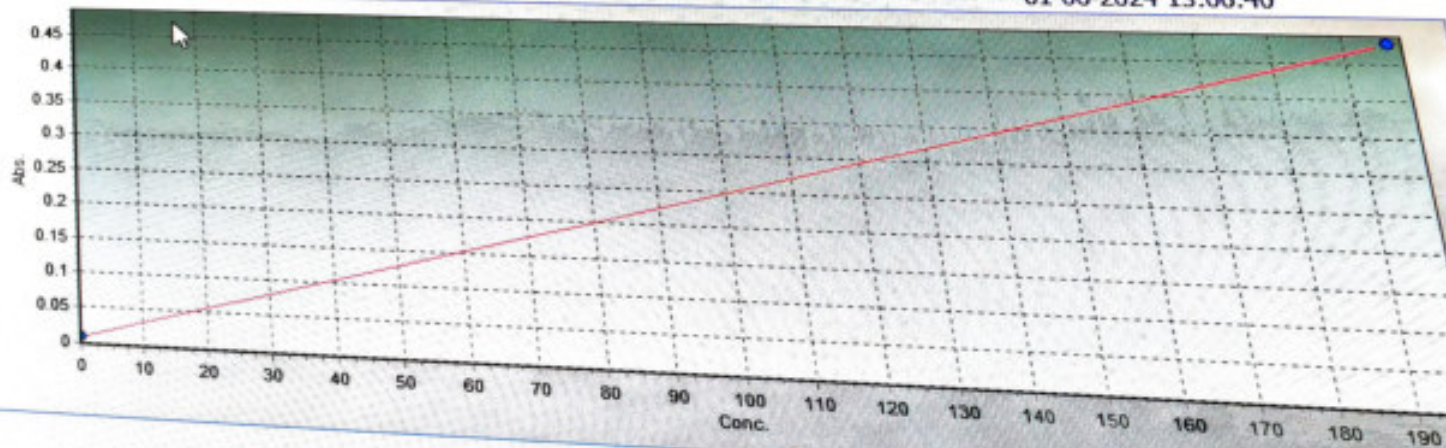
2 Point Linear

Cal. method current:

2 Point Linear

Cal. time:

01-06-2024 13:06:40



Set Range

Print

Refresh

Close

Calibration Curve

Test Item: HEL C-ACC Std. 1

S1 Abs K A B C
 0.0008 11.320755 0 0 0

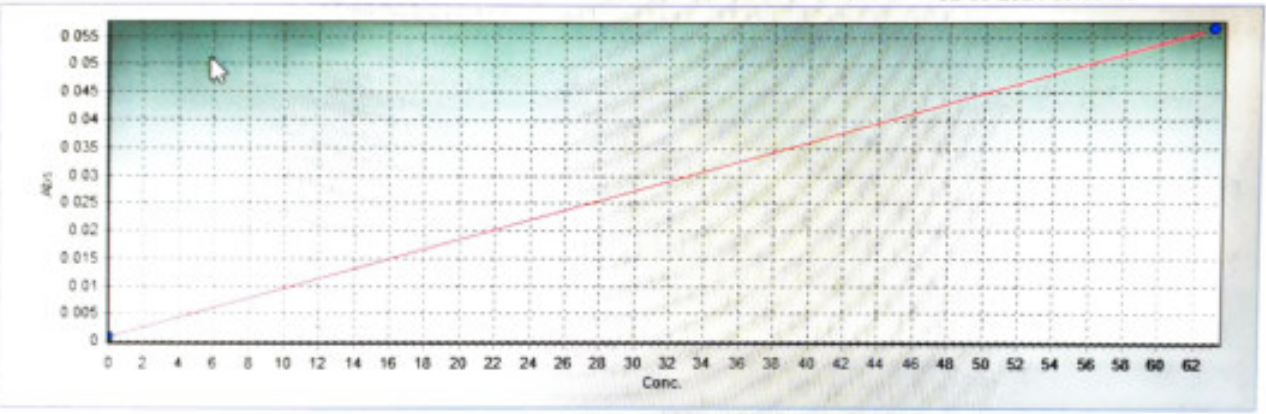
Abs. 0.0008

Cal. method this time: 2 Point Linear

Cal. method current: 2 Point Linear

Cal. time: 01-06-2024 13:09:10

Std.	Conc.	Abs.
S1	<input type="text" value="0"/>	<input type="text" value="0.0008"/>
S2	<input type="text" value="63.0"/>	<input type="text" value="0.0564"/>
S3	<input type="text" value="0"/>	<input type="text" value="0"/>
S4	<input type="text" value="0"/>	<input type="text" value="0"/>
S5	<input type="text" value="0"/>	<input type="text" value="0"/>
S6	<input type="text" value="0"/>	<input type="text" value="0"/>
S7	<input type="text" value="0"/>	<input type="text" value="0"/>
S8	<input type="text" value="0"/>	<input type="text" value="0"/>
S9	<input type="text" value="0"/>	<input type="text" value="0"/>
S10	<input type="text" value="0"/>	<input type="text" value="0"/>





Item Name

S1 Abs

K

A

B

C

State

Calibration Name

Calibration Curve

Test Item:

TMBL

Std.:

1

S1 Abs

K

A

B

C

0.00035

28.451

0

0

0

Abs.

0.00035

Cal. method this time:

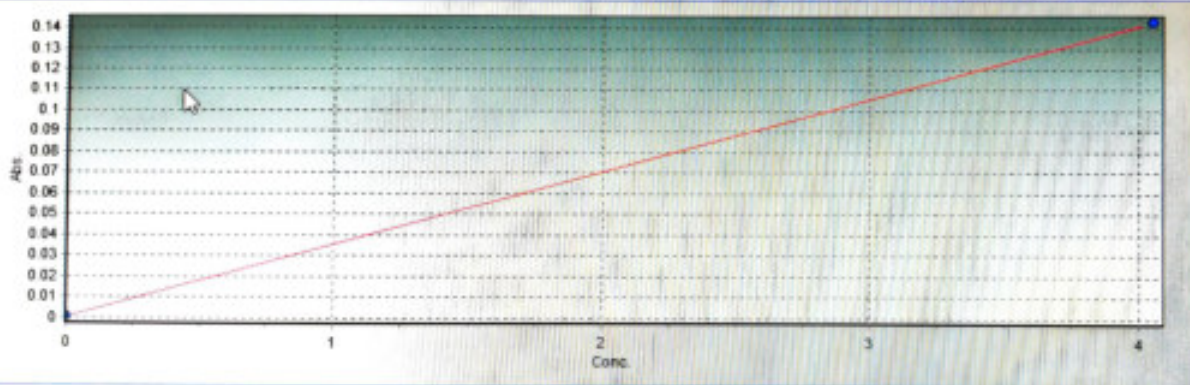
2 Point Linear

Cal. method current:

2 Point Linear

Cal. time:

01-06-2024 13:10:09



Std.

Conc.

Abs.

S1

0

0.00035

S2

4.05

0.14265

S3

0

0

S4

0

0

S5

0

0

S6

0

0

S7

0

0

S8

0

0

S9

0

0

S10

0

0

Set Range

Print

Refresh

Close

Close



Test Item: TGL

Std. 1

S1 Abs.

K

A

B

C

Abs. 0.00945

Cal. method this time: 2 Point Linear

Cal. method current: 2 Point Linear

Cal. time: 01-06-2024 13:04:40

Std.

Conc.

Abs.

S1

0

0.00

S2

126

0.1

S3

0

0

S4

0

0

S5

0

0

S6

0

0

S7

0

0

S8

0

0

S9

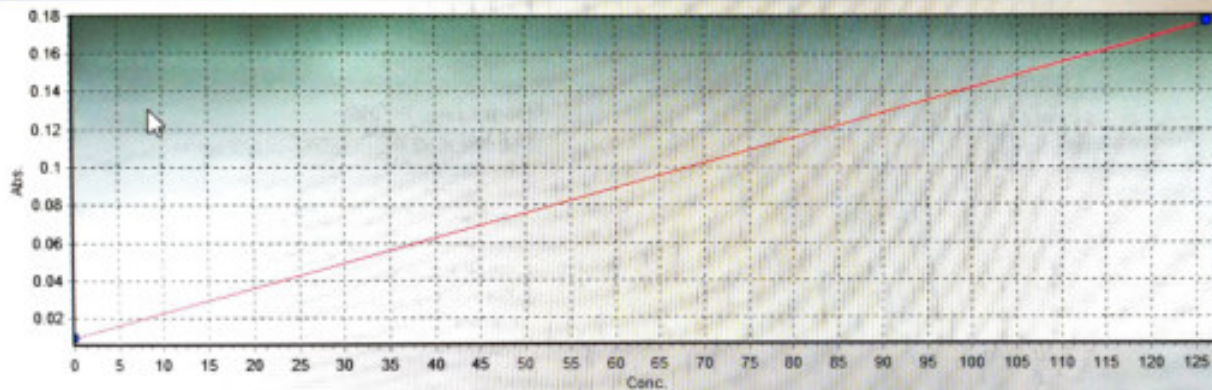
0

0

S10

0

0



Set Range

Print

Refresh

Close

Calibration Curve

Test Item: TP

Std. 1

S1 Abs. K A B C

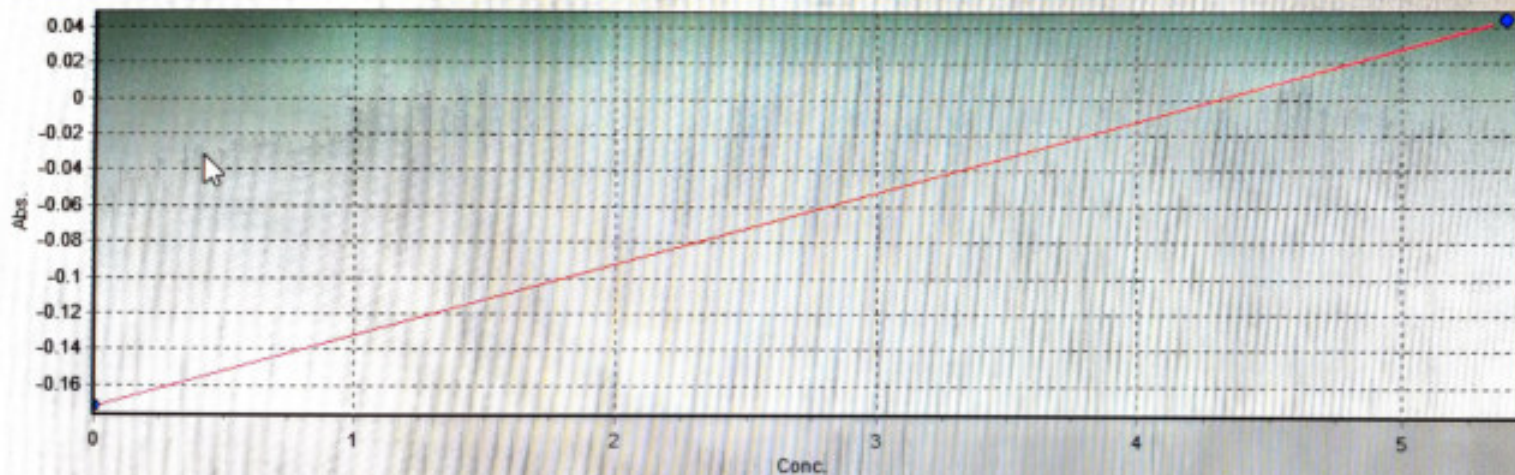
-0.1721 25 0 0 0

Abs. -0.1721

Cal. method this time: 2 Point Linear

Cal. method current: 2 Point Linear

Cal. time: 01-06-2024 13:10:40



Set Range

Print

Refresh

Close

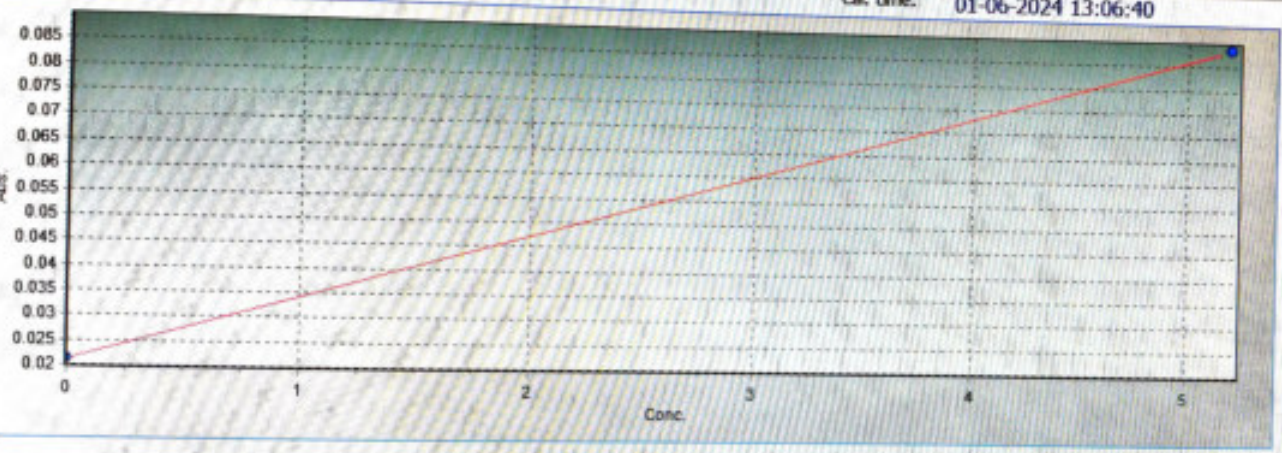
Cal. Result

Item Name	S1 ABS	K	A	B	C	State	Cal.
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Item: Std.
 S1 Abs.
 213 77.4386 0 0 0

Abs. 0.0213
 Cal. method this time: 2 Point Linear
 Cal. method current: 2 Point Linear
 Cal. time: 01-06-2024 13:06:40

Std.	Conc.	Abs.
S1	<input type="text" value="0"/>	<input type="text" value="0.0213"/>
S2	<input type="text" value="5.2"/>	<input type="text" value="0.0884"/>
S3	<input type="text" value="0"/>	<input type="text" value="0"/>
S4	<input type="text" value="0"/>	<input type="text" value="0"/>
S5	<input type="text" value="0"/>	<input type="text" value="0"/>
S6	<input type="text" value="0"/>	<input type="text" value="0"/>
S7	<input type="text" value="0"/>	<input type="text" value="0"/>
S8	<input type="text" value="0"/>	<input type="text" value="0"/>
S9	<input type="text" value="0"/>	<input type="text" value="0"/>
S10	<input type="text" value="0"/>	<input type="text" value="0"/>



Cal. Result

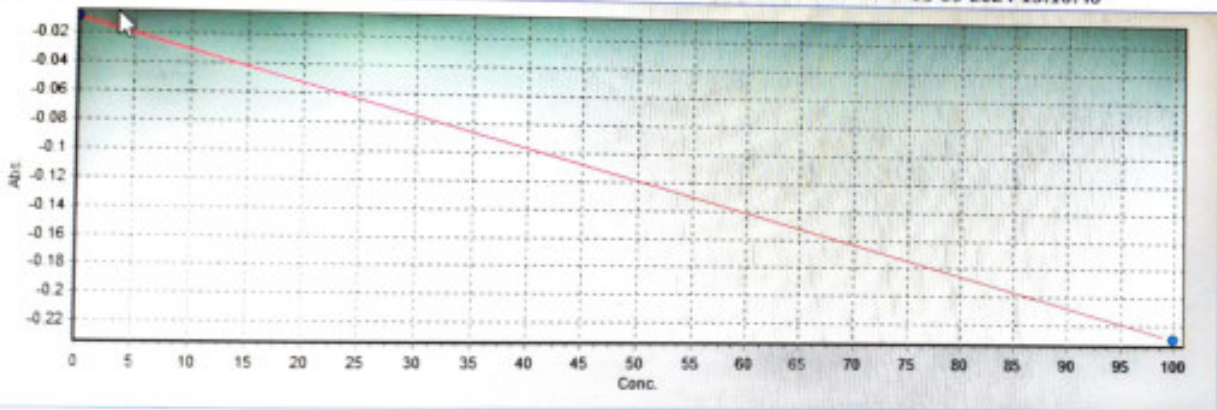
Item Name	S1 ABS	K	A	B	C	State	Calibration No.
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Calibration Curve

Test Item: UREA
Std. I
S1 Abs: K A B C
-0.00855 -451.9774 0 0 0

Abs. -0.00855
Cal. method this time: 2 Point Linear
Cal. method current: 2 Point Linear
Cal. time: 01-06-2024 13:10:40

Std.	Conc.	Abs.
S1	0	-0.00855
S2	100	-0.2298
S3	0	0
S4	0	0
S5	0	0
S6	0	0
S7	0	0
S8	0	0
S9	0	0
S10	0	0



Set Range Print Refresh Close

Close

