

**CERTIFICATE OF CALIBRATION**Instrument : **Mispa Ace Fully Automated Clinical Chemistry Analyser**Customer Name : **Lotus Diagnostics**Date of Installation : **06/03/2019**S/N : **WK-88106098****Alignment Check**

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

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

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

CORPORATE OFFICE / REAGENT PLANT
 Agappe Mills, Pattomattom (PO), Dist. Thrissur, Kerala - 683 562, India
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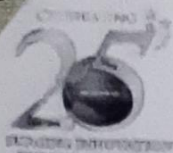
EQUIPMENT PLANT
 K/5/8B CB, Block No. 32, KINFRA Small Industrial Park,
 Nellikud, Cochin, Kerala, India - 686 721. Tel: +91 484 276 7477.

KOLKATA OFFICE
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 Tel: +91 33 4003 0451 | Email: kolkataproffice@agappe.in

MUMBAI (REGISTERED OFFICE)
 401 B-402, 4th Floor, Jansagah Business Centre, 119,

DELHI OFFICE
 DSM 340, 5th Floor, DLF Tower, Shivaji Marg,

BANGALORE OFFICE
 3-6, 8th Floor, And Cross, Bhaswan, Near 26 Race Course Road,

**OPTICAL SECTION**

Filter	Dark Current	Background
340	100	43215
405	100	42569
450	93	42933
510	92	45564
546	96	46189
578	89	45978
630	96	44965
670	86	47491
Reference		

Power Supply : 5V 12V 24V

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

Lot.No: 31050609 Exp: 30/04/23.

This is to certify that the above mentioned product has been calibrated according to the standard operating procedure given by the MINDRAY Medical Systems.

Date of Calibration : **03-03-2022**

Next Due : **02-09-2022**

For Agappe Diagnostics Ltd.



Authorized signatory

Name: Shivshankar Verma

Designation: Engineer Customer Service

ADL/MO/SER/0180/21-22

AGAPPE DIAGNOSTICS LTD.

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KOLKATA OFFICE
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BANGALORE OFFICE
5-6, 4th Floor, Red Cross Bhawan, No-26 Race Course Road,
Bastara - 560 001, Tel: +91 80 2228 8202

Calibration Curve

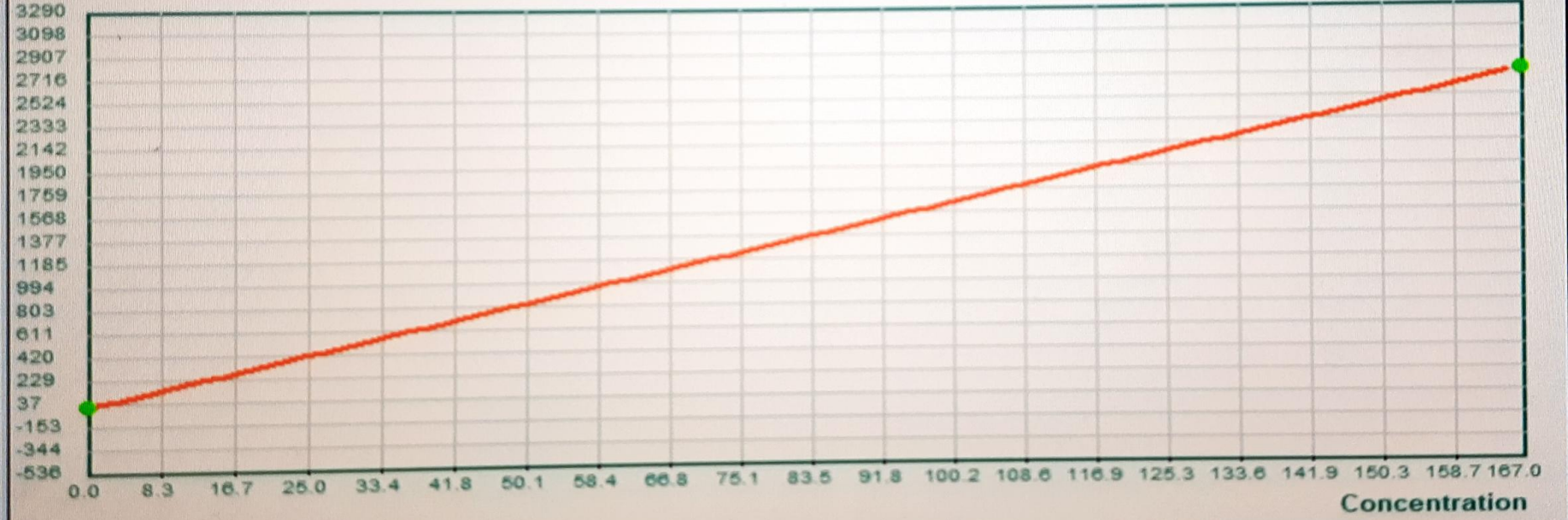
Test Date/Time Rule

Rgt. Blank

$$R = aC + b$$

K R0 A
B C D

Response



Test Date/Time Rule

Rgt. Blank

$$R = aC + b$$

K

R0

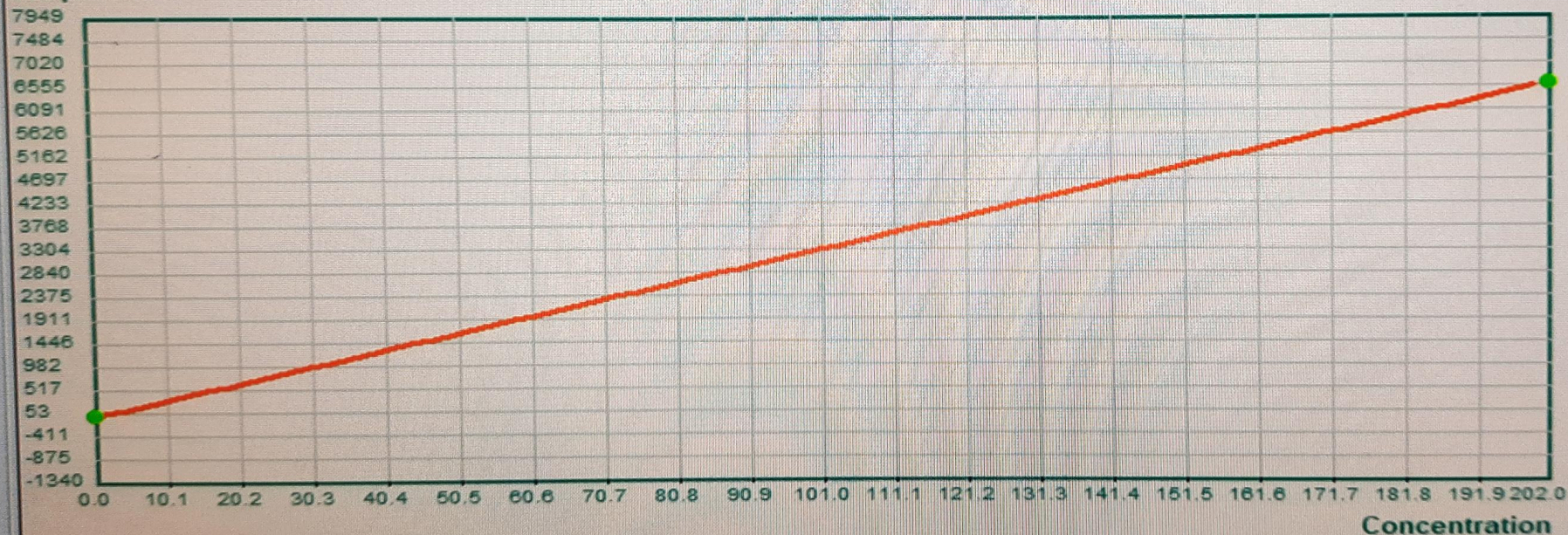
A

B

C

D

Response



Calibration Curve

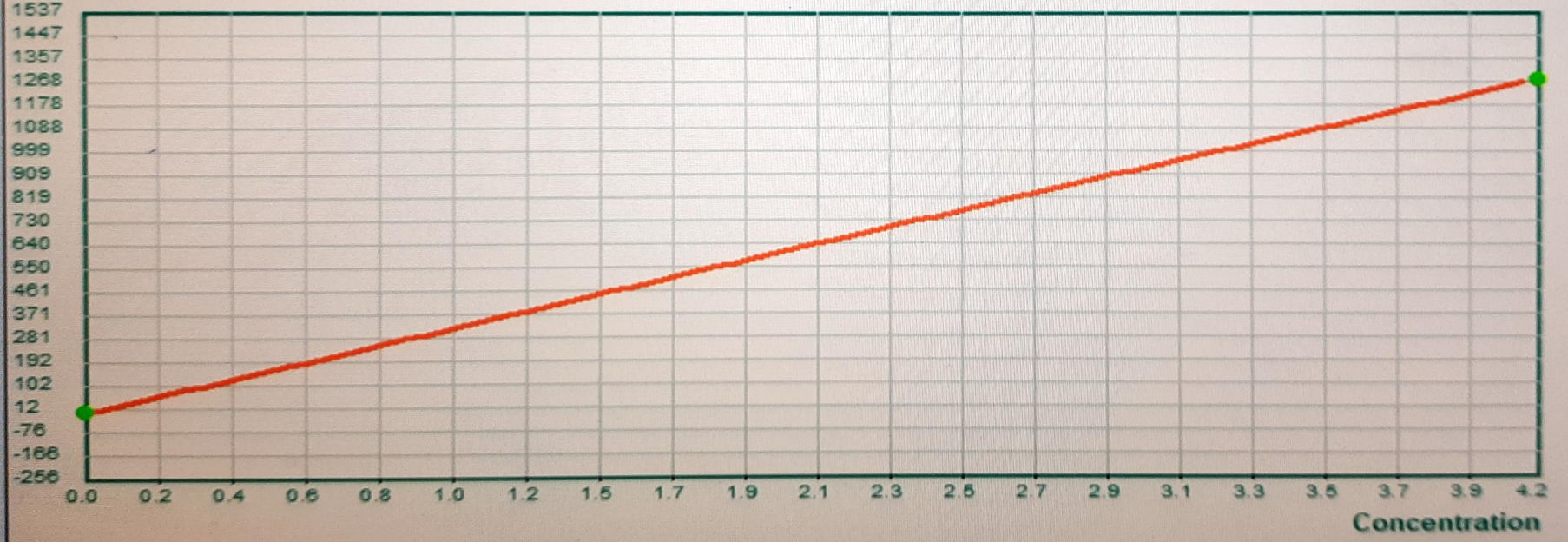
Test **BILI-T AG** Date/Time **3-03-2022 14:32:27** Rule **Two-point Linear**

Rgt. Blank **-26.611786353092**

$$R = aC + b$$

K R0 A **308.78015**
B **0.00000** C D

Response



Range

Refresh

Print

Previous

Next

Close

Calibration Curve

Test Date/Time Rule

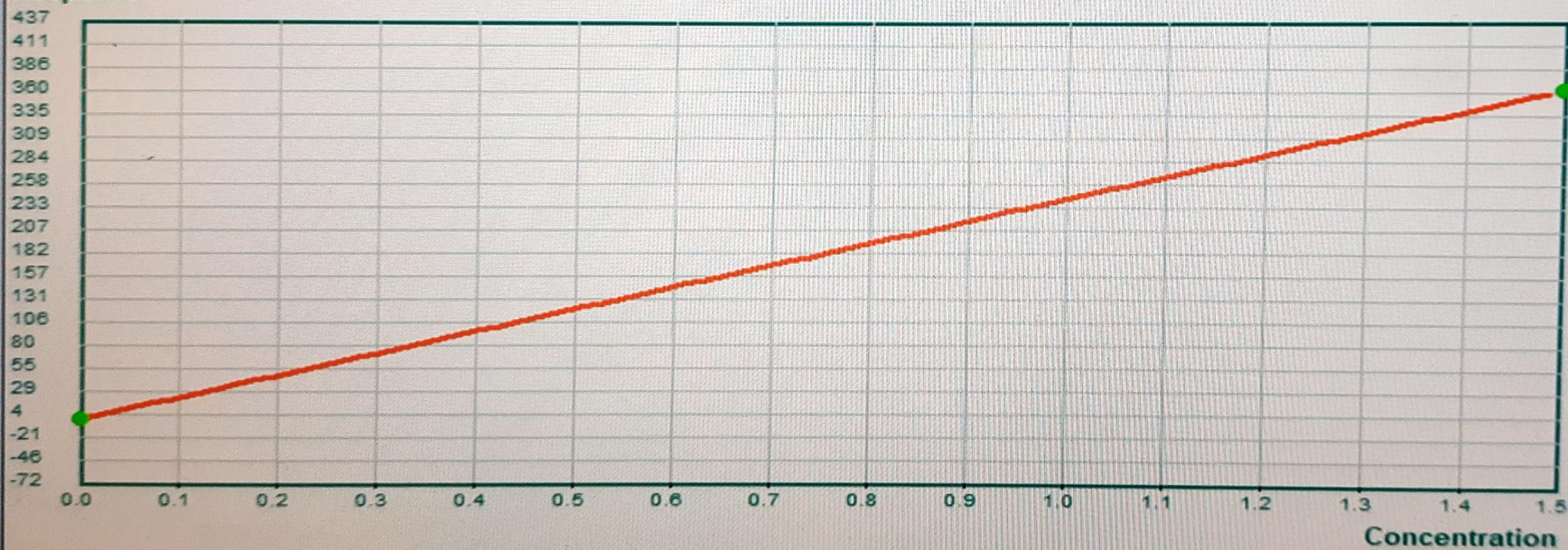
Rgt. Blank

$$R = aC + b$$

K R0 A

B C D

Response



Set range of calibration curve

Test Date/Time Rule

Rgt. Blank

$$R = aC + b$$

K

R0

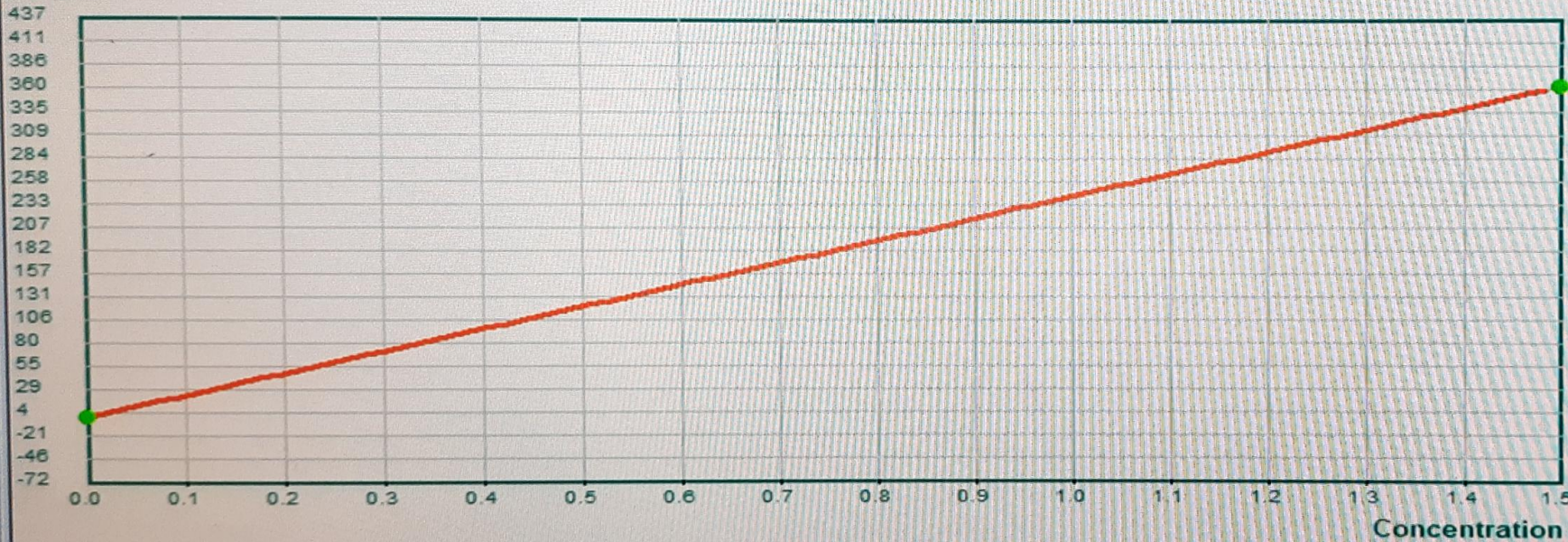
A

B

C

D

Response



Set range of calibration curve

Calibration Curve

Test

HDL AG

Date/Time

3-03-2022 14:32:27

Rule

Two-point Linear

Rgt. Blank

-21.948451405252

$$R = aC + b$$

K

R0

A

32.51981

Up

B

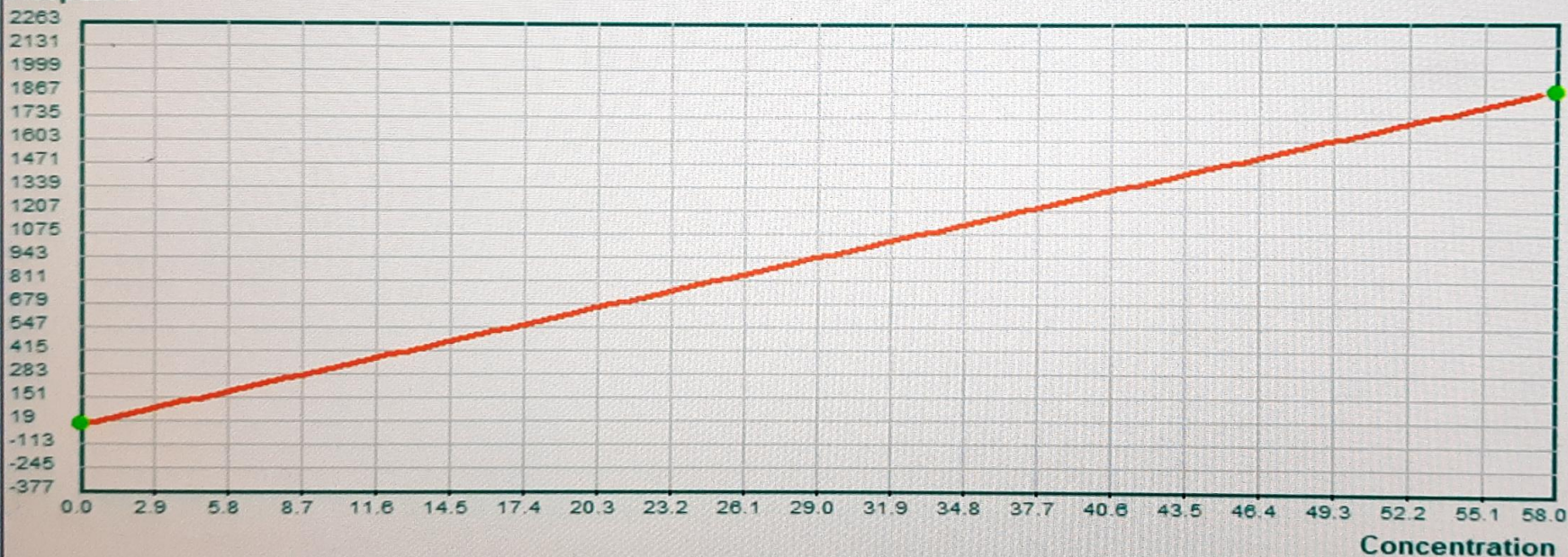
0.00000

C

D

Down

Response



Calibration Curve

Test

SGOT AG

Date/Time

3-03-2022 14:32:27

Rule

Two-point Linear

Rgt. Blank

13433.531185626

$$R = aC + b$$

K

R0

A

2.54498

Up

B

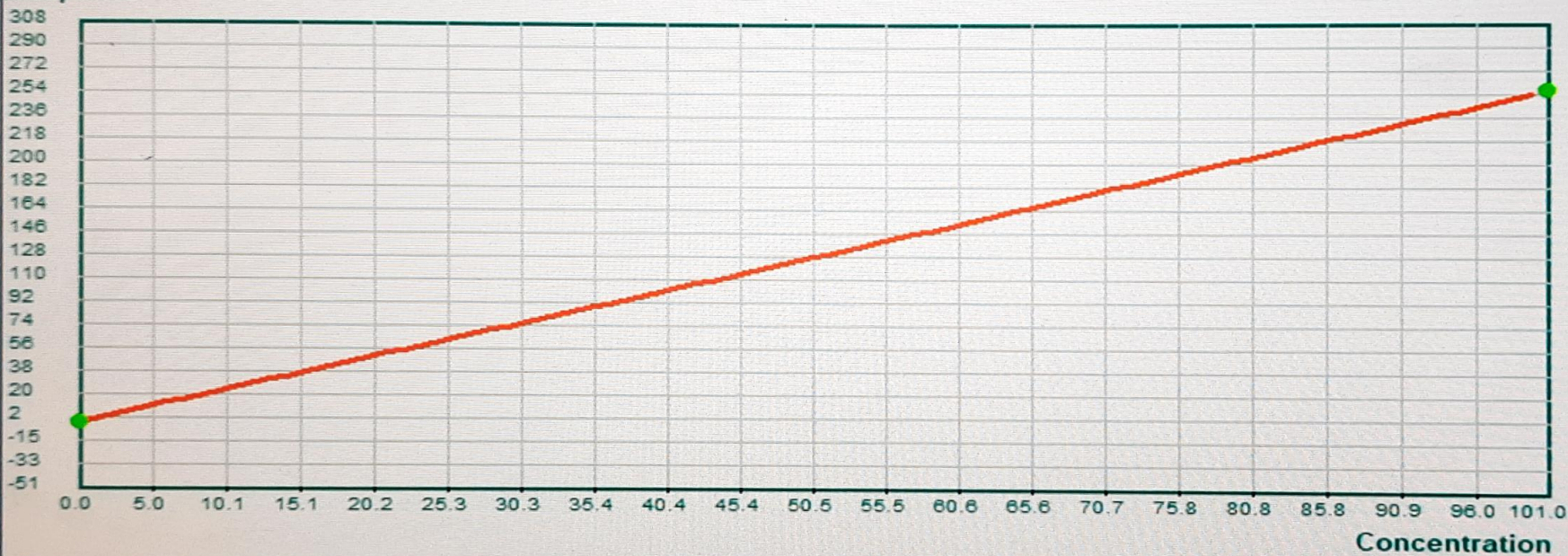
0.00000

C

D

Down

Response



Calibration Curve

Test Date/Time Rule

Rgt. Blank

$$R = aC + b$$

K

R0

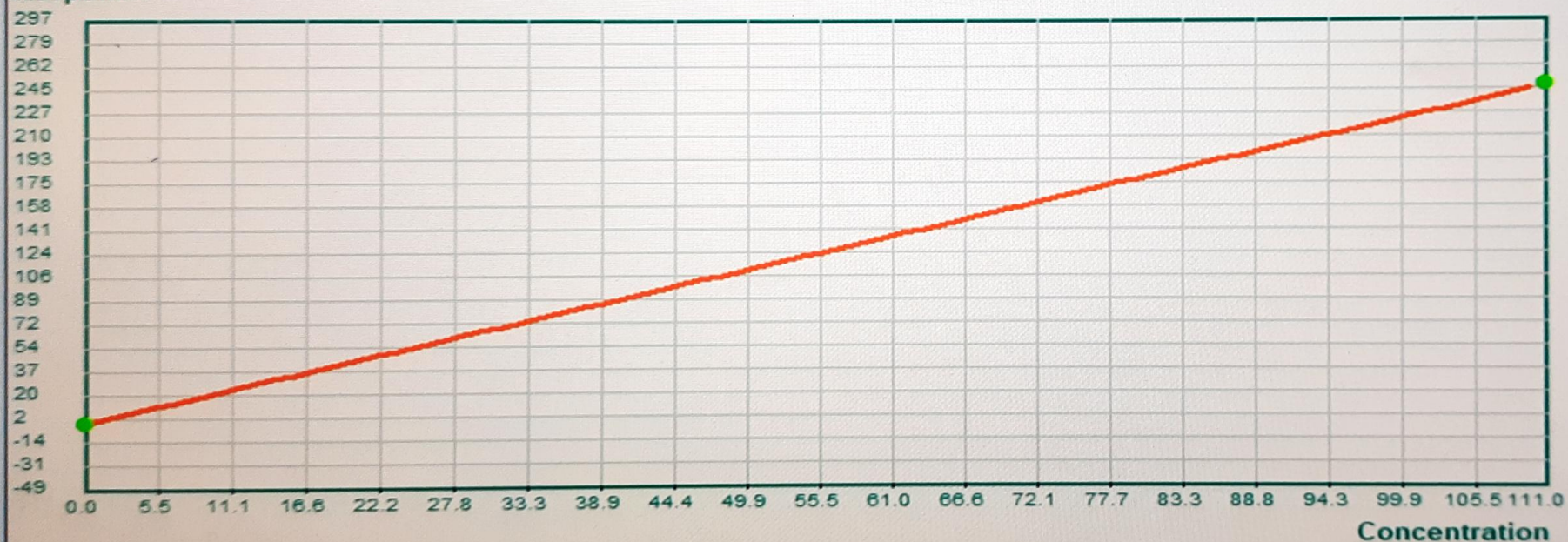
A

B

C

D

Response



Calibration Curve

Test Date/Time Rule

Rgt. Blank

$$R = aC + b$$

K

R0

A

B

C

D

Response



Concentration



Test **UREA AGAPPE** Date/Time **3-03-2022 14:32:27** Rule **Two-point Linear**

Rgt. Blank **16180.420876885!**

$$R = aC + b$$

K

R0

A **32.99537**

Up

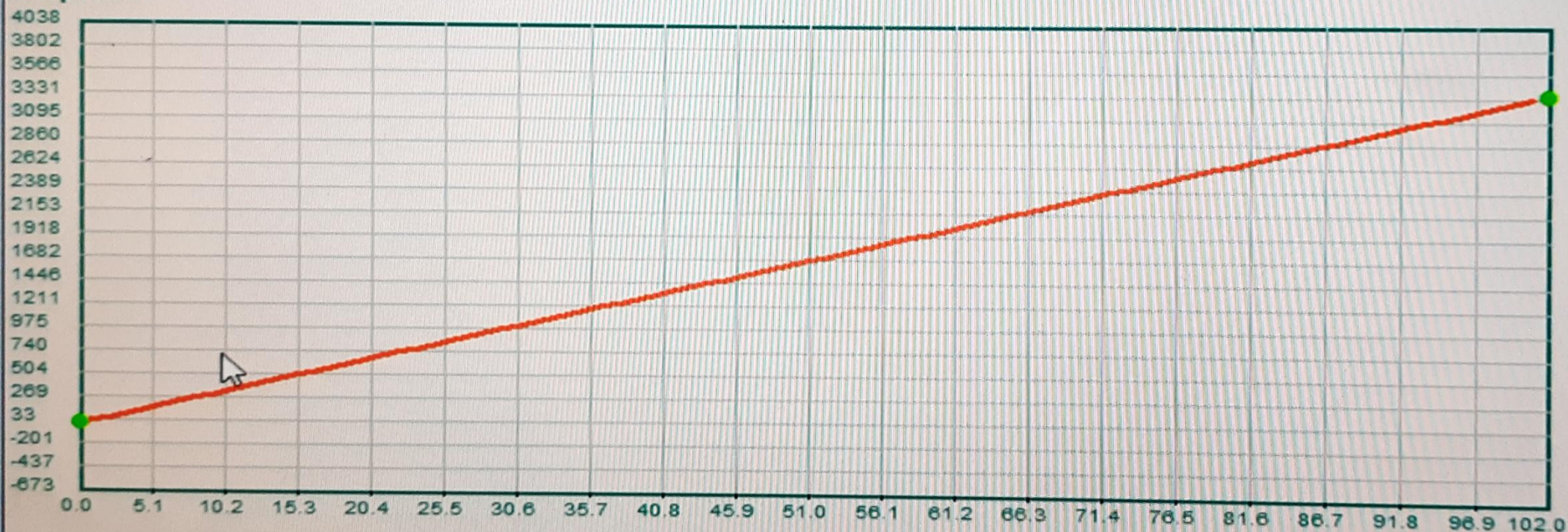
B **0.00000**

C

D

Down

Response



Concentration

Calibration Curve

Test Date/Time Rule

Rgt. Blank

$$R = aC + b$$

K

R0

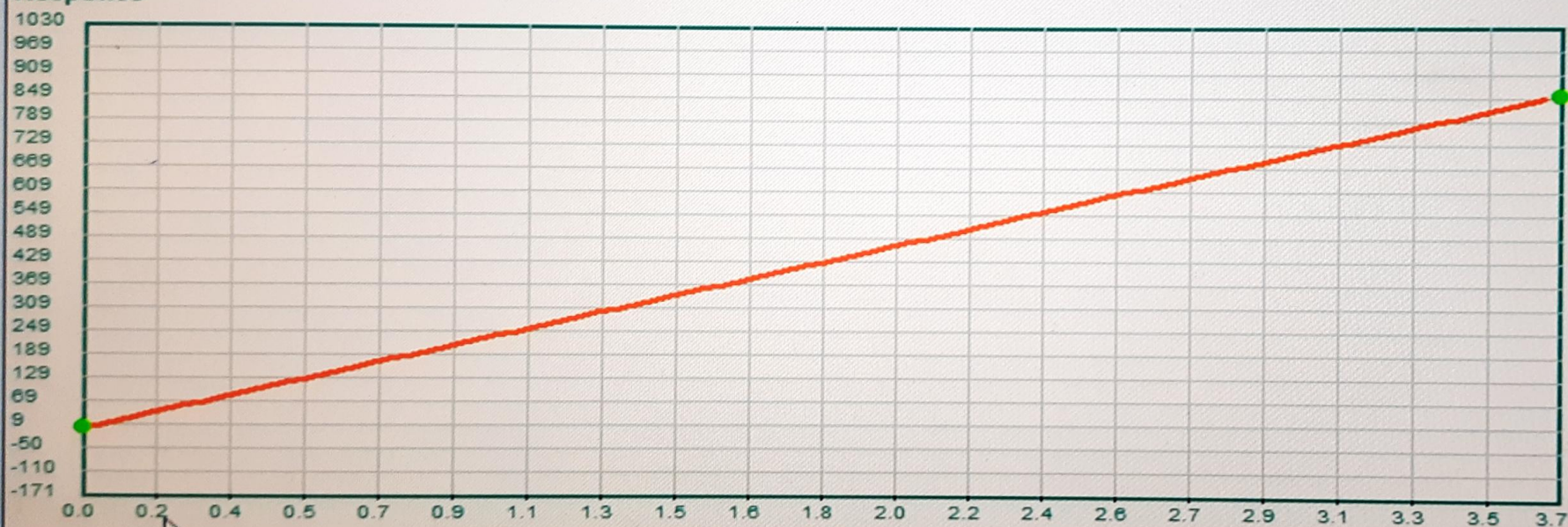
A

B

C

D

Response



Concentration

Test

GGT AG

Date/Time

3-03-2022 15:53:02

Rule

Two-point Linear

Rgt. Blank

4888.90465824937

$$R = aC + b$$

K

R0

A

5.90059

Up

B

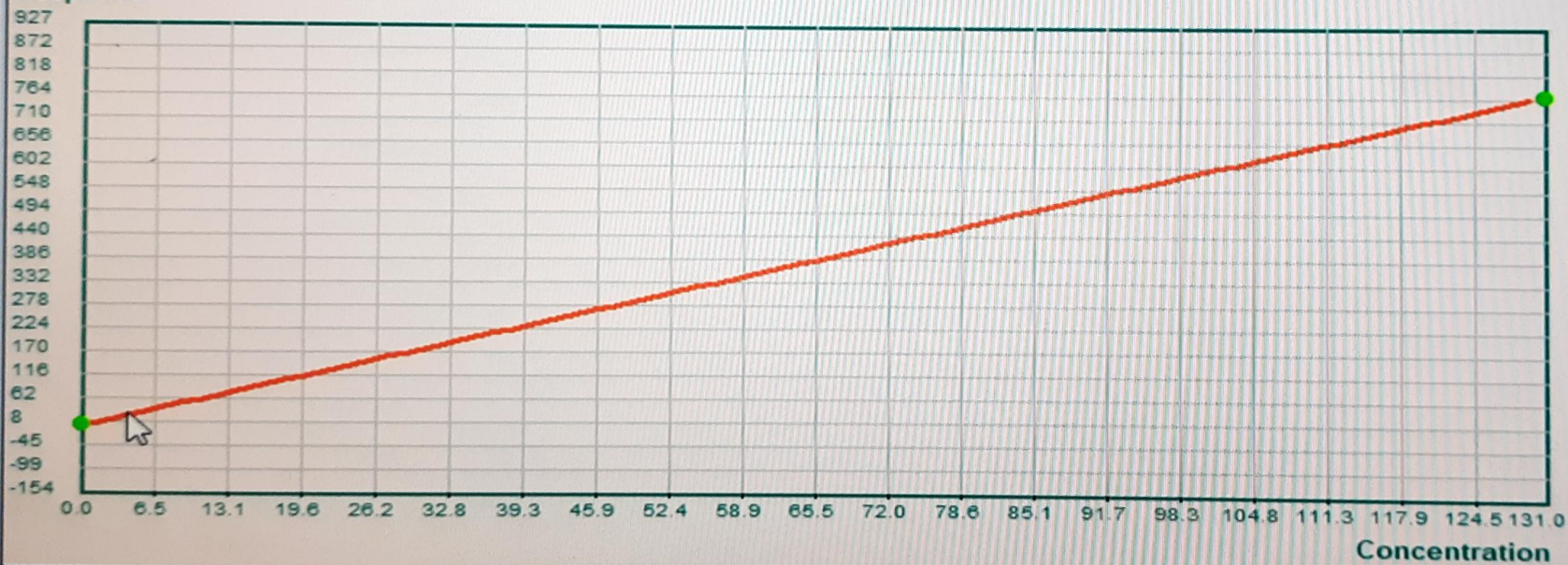
0.00000

C

D

Down

Response



Calibration Curve

Test

ALP AGP

Date/Time

3-03-2022 14:32:27

Rule

Two-point Linear

Rgt. Blank

5817.4018543885

$$R = aC + b$$

K

R0

A

1.74512

Up

B

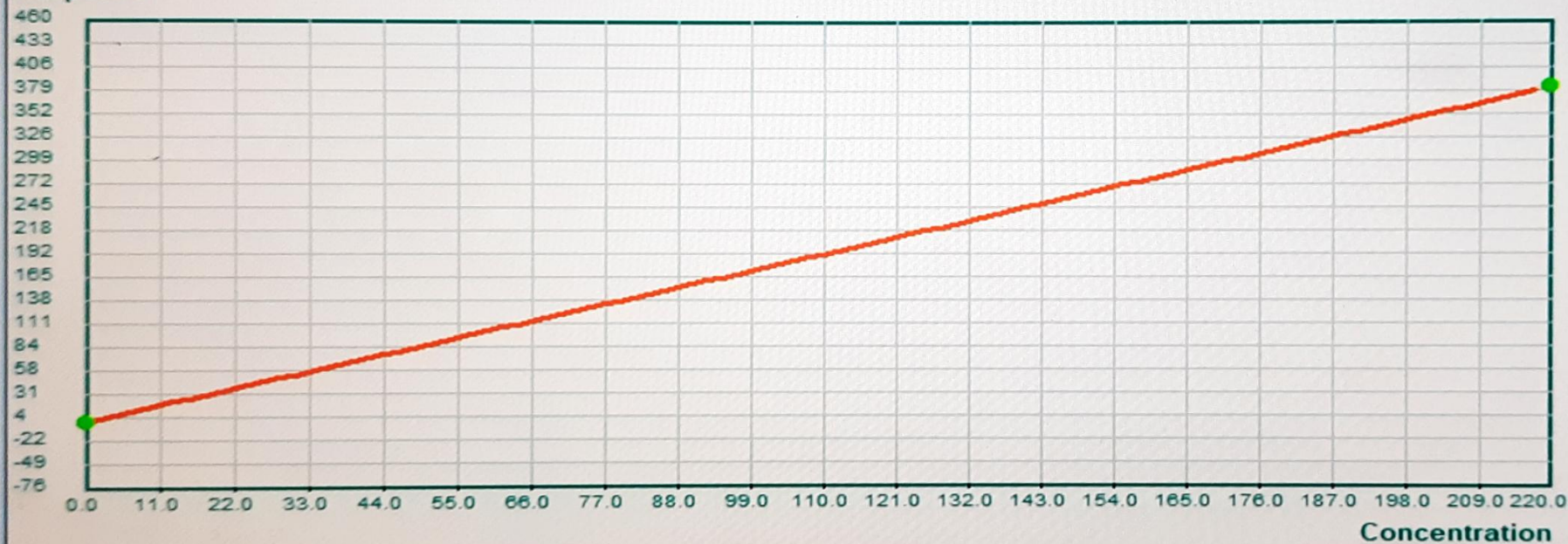
0.00000

C

D

Down

Response



Test

ALB ERBA

Date/Time

3-03-2022 14:32:27

Rule

Two-point Linear

Rgt. Blank

-376.91832085150

$$R = aC + b$$

K

R0

A

1572.32418

Up

B

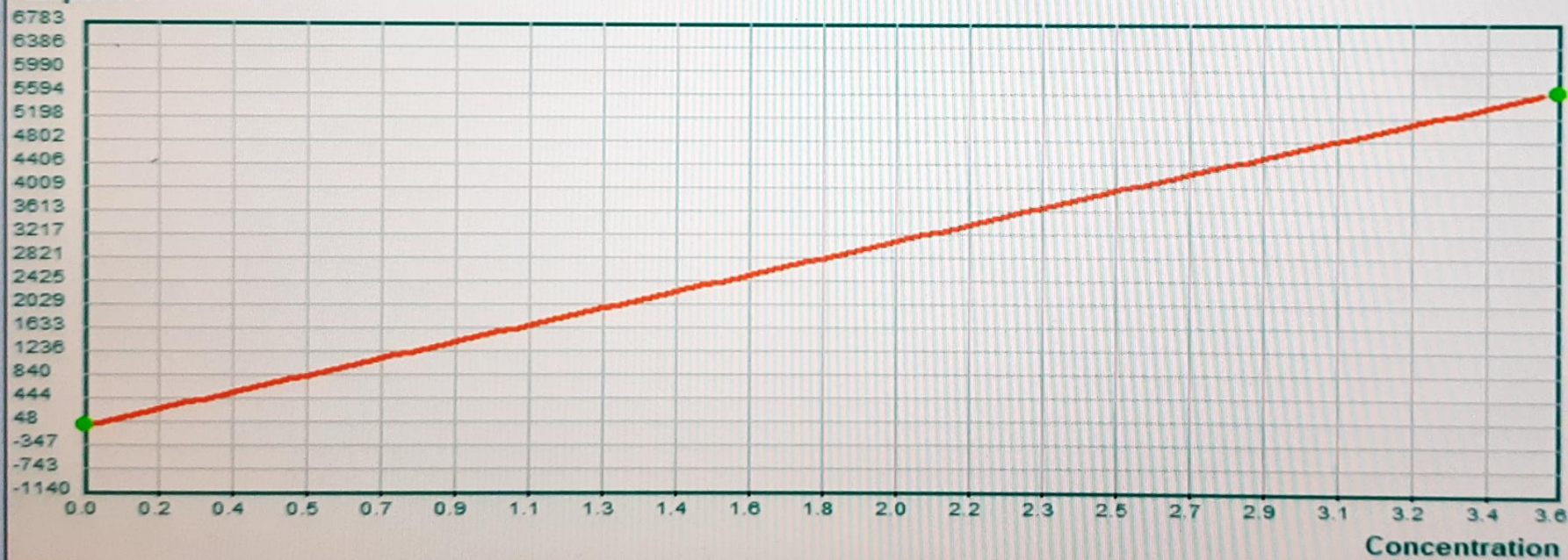
-8.74262

C

D

Down

Response



Set range of calibration curve

Calibration Curve

Test Date/Time Rule

Rgt. Blank

$$R = aC + b$$

K

R0

A

Up

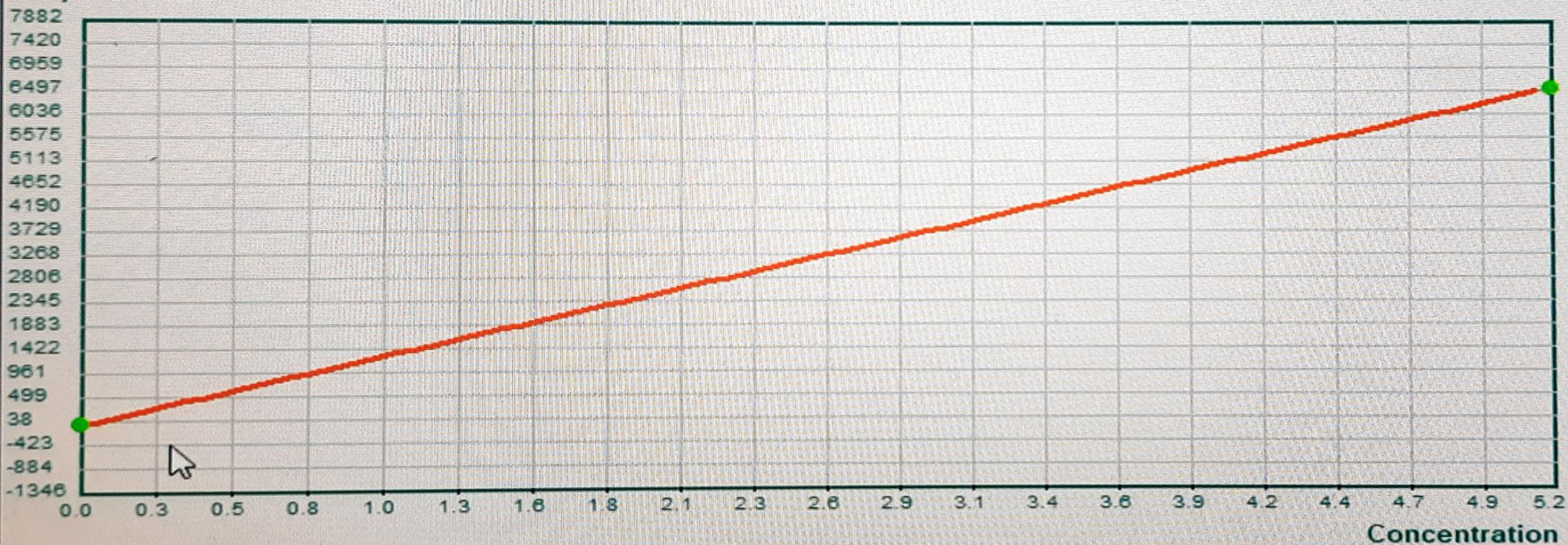
B

C

D

Down

Response



Calibration Curve

Test Date/Time Rule

Rgt. Blank

$$R = aC + b$$

K

R0

A

B

C

D

Response



Concentration

Calibration Curve

Test: CAL Date/Time: 3-03-2022 15:52:21 Rule: Two-point Linear

Rgt. Blank: 2431.76678973688

$$R = aC + b$$

K

R0

A

409.75626

Up

B

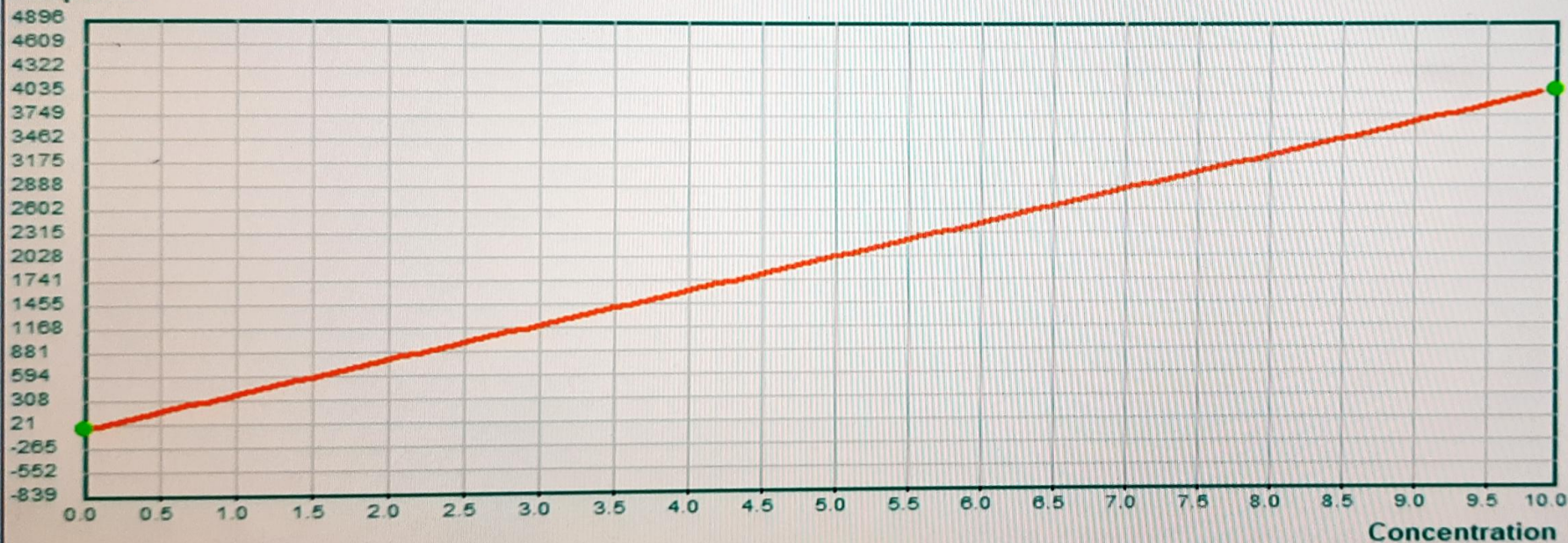
-20.21958

C

D

Down

Response



Calibration Curve

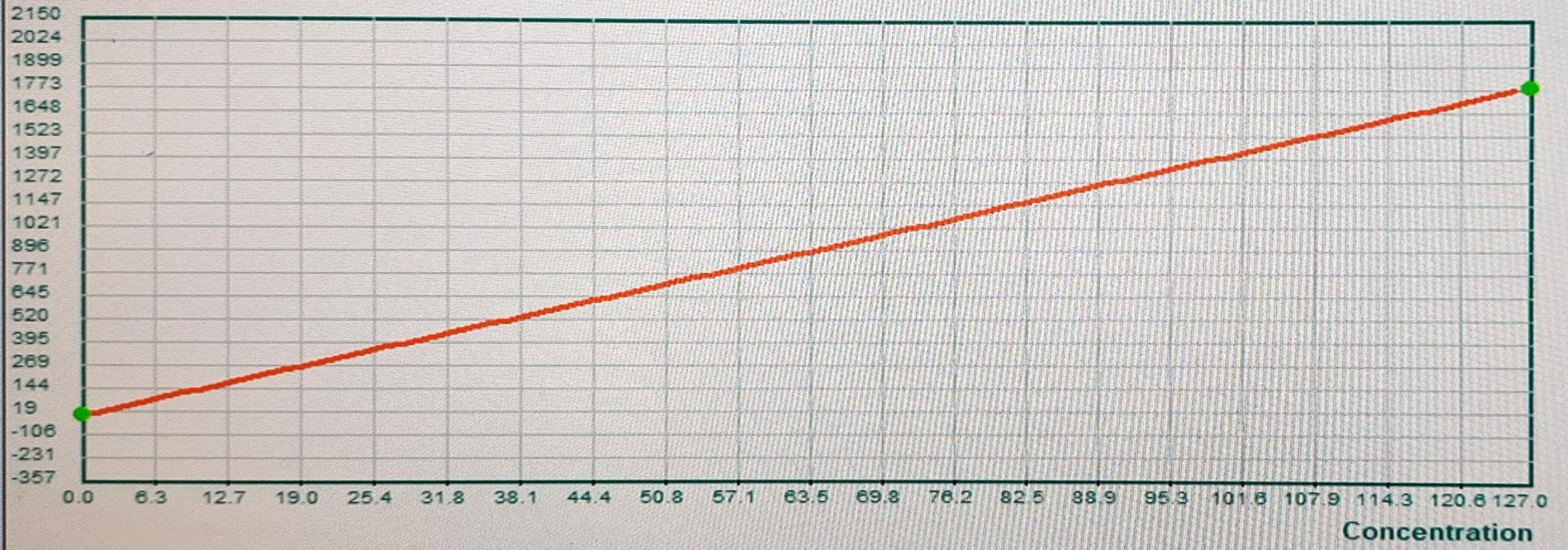
Test Date/Time Rule

Rgt. Blank

$$R = aC + b$$

K R0 A
 B C D

Response





AGAPPE

INSTALLATION QUALIFICATION

For

FULLY AUTOMATED CLINICAL CHEMISTRY ANALYZER

MODEL : MISPA ACE

AGAPPE DIAGNOSTICS LTD.

ADL/MO/SER/020/21-22

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24239MH0998PLC125413

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42c, Merinikh Street, Plot No-63, Block OR, Sector V,
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TABLE OF CONTENTS

S No.	Contents	Page No.
I	Approval of the IQ procedure	3
II	Instructions	4
III	Scope	5
V	Installation Qualification	6
V	Comments	11
VI	System Certification	12


AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24239MH1998PLC115413**CORPORATE OFFICE / REAGENT PLANT**
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Tel: +91 484 276 7000 | Email: agappediagn@agappe.in**EQUIPMENT PLANT**
X/584 CB, Block No. 37, KINFRA Small Industrial Park,
Nellad, Cochin, Kerala, India - 686 721. Tel: +91 484 276 7477.**KOLKATA OFFICE**
416, Merin Matrix, Plot No-10, Block DM, Sector V,
Salt Lake City, Kolkata - 700 091.
Tel: +91 33 4003 0451 | Email: kolkataoffice@agappe.in**MUMBAI (REGISTERED OFFICE)****DELHI OFFICE****BANGALORE OFFICE**



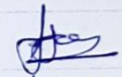
I. APPROVAL OF THE INSTALLATION QUALIFICATION PROCEDURE

Both **LOTUS DIAGNOSTICS, MUMBAI** and **AGAPPE DIAGNOSTICS LTD.** are jointly responsible for the installation of **MISPA ACE** with serial number **WK-88106098** at "**Lotus Diagnostics, Shop No: 5, Chandresh CHS, Devki Nagar, Next to Lotus Multispeciality Hospital, Mumbai - 400103**" as per the attached Installation Qualification protocol.

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

Name	: Vaibhav Varpe	Signature :	
Designation	: Assistant Manager Application Support	Date	: 06/03/2019
Company	: AGAPPE DIAGNOSTICS LTD.		


Validation Team from LOTUS DIAGNOSTICS, MUMBAI

Name	: Yogesh Ade,	Signature :	
Designation	: Senior Lab Technician	Date	: 6/3/19
Department	: Biochemistry		

Customer Authorizations:

Name : Dr. Tanvi Ahuja
 Title : INSTALLATION QUALIFICATION
 Site : Lotus diagnostics.

Signature : 
 Date : 6/3/19



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 **LOTUS DIAGNOSTICS, MUMBAI** 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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KOLKATA OFFICE

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



This Installation Qualification protocol will be performed on the **MISPA ACE** at **LOTUS DIAGNOSTICS, MUMBAI**. 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. INSTALLATION QUALIFICATION

AGAPPE

Instrument Identification

1. Model Name : MISPA ACE
2. Serial Number : WK-88106098

Verified Date : 06/03/2019

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

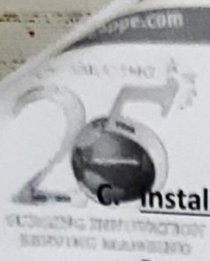
S No.	Component	Present (Yes/No)	Verified By	Comments
01	Analyzer Main unit	Yes	Vaibhav Varpe	OK
02	Computer	Yes	Vaibhav Varpe	OK
03	Printer	Yes	Vaibhav Varpe	OK
04	RS232 Connector cable	Yes	Vaibhav Varpe	OK
05	Power cord	Yes	Vaibhav Varpe	OK
06	Waste can	Yes	Vaibhav Varpe	OK
07	Water can	Yes	Vaibhav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

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

CORPORATE OFFICE / REAGENT PLANT
Agappe Hills, Pattanamthottam (PO), Dist. Ernakulam, Kerala - 683 562, India.

EQUIPMENT PLANT
X/586-CB, Block No. 32, KINFRA Small Industrial Park,

KOLKATA OFFICE
406, MerBin Matrix, Plot No-10, Block-ON, Sector V,



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

Summary:

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

Acceptance criteria:

PARAMETER

PASS ✓

FAIL

MISPACE

Standby

HOST 37.0 06/03/2019 10:16:02 ?

Reagent Calibration QC Status Statistics Parameters Setup Maintenance

Sample Request

QC Request

Start

Power Stop

Stop

Results

Replace

Relog

Exit

Daily Maint Log Import/Export Alignment

System Status

Reaction Temp. 36.99

Preheat Temp. 45.03

Waste Tank Normal

Deionized Water Normal

Printer Idle

Unit Status

Main Unit Idle

Reaction Unit Idle

Sample Unit Idle

Reagent Unit Idle

Temperature Unit Idle

Mixing Unit Idle

Dark Current/Background

	Dark Current	Background
340	99	34180
405	99	35401
450	92	35347
510	91	39302
546	95	39199
578	89	39312
630	95	39263
670	86	41556

Wash reagent probe, sample probe and mixing bar with deionized water

Startup Check Reagent Wash Enhanced Dark Current Reset

Admin

~~✓~~
Performed By.

APPROVED BY



ULTRASONIC BIOPROCESS MONITORING
SERVING MANUFACTURING

Date of Installation : 06/03/2019

Installed by : Vaibhav Varpe

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

Standby HOST 37.0 06/03/2015 10:21:07 ?

Reagent Calibration QC Status Statistics Parameters Setup Maintenance

Daily Maint Log Import/Export Alignment

Conditions

- View Latest
- Search History

Log List

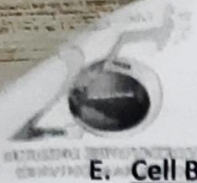
Request Date	Type	Code	Level	Details

Refresh Details

Admin < > X Clear


 Performed By.

APPROVED BY



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	Vaibhav Varpe	06/03/2019
02	340 nm	Vaibhav Varpe	06/03/2019
03	405 nm	Vaibhav Varpe	06/03/2019
04	450 nm	Vaibhav Varpe	06/03/2019
05	510 nm	Vaibhav Varpe	06/03/2019
06	546 nm	Vaibhav Varpe	06/03/2019
07	578 nm	Vaibhav Varpe	06/03/2019
08	630 nm	Vaibhav Varpe	06/03/2019
09	670 nm	Vaibhav Varpe	06/03/2019

Acceptance criteria: *RAW DATA*

- No error Messages displayed ~
- All Cuvettes should show acceptance

PARAMETER **PASS** **FAIL**

Parameter values for verification: No Error Messages

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	Vaibhav Varpe	06/03/2019

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

ADVANCED INFORMATION
SUPPORT SERVICES

V.COMMENTS


Successfully installed Mispa Ace, fully automated clinical chemistry analyzer & gives training to user.

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 : Vaibhav Varpe
Designation : Assistant Manager Application Support

Signature : 



Company : AGAPPE DIAGNOSTICS LTD.

Date : 06/03/2019

Customer Authorizations: **LOTUS DIAGNOSTICS, MUMBAI**

Name : *Dr. Janhvi Ahuja*

Designation : *< Pathologist*

Title : INSTALLATION QUALIFICATION

Signature : *< Janhvi*

Date : *< 6/3/19*



AGAPPE

OPERATIONAL QUALIFICATION

For

FULLY AUTOMATED CLINICAL CHEMISTRY ANALYZER

MODEL : MISPA ACE

AGAPPE DIAGNOSTICS LTD.

ADL/MO/SER/020/21-22

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

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806, Merin Mall, Plot No-10, Block-DK, Sector-V,
Salt Lake City, Kolkata - 700 091.
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MUMBAI (REGISTERED OFFICE)

DELHI OFFICE

BANGALORE OFFICE

**TABLE OF CONTENTS**

S No.	Contents	Page No.
I	Approval of the OQ procedure	3
II	Instructions	4
III	Scope	5
IV	Operational Qualification	6
V	Comments	13
VI	System Certification	14

AGAPPE DIAGNOSTICS LTD.

ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24239MH1998PLC115433

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

EQUIPMENT PLANT
X/584 CD, Block No. 32, KINFRA Small Industrial Park,
Nellad, Cochin, Kerala, India - 686 721. Tel: +91 484 276 7477.

KOLKATA OFFICE
4/6, Merlin Matrix, Plot No-10, Block-DH, Sector V,
Salt Lake City, Kolkata - 700 091.
Tel: +91 33 4029 0451 | Email: kolkataoffice@agappe.in

BANGALORE OFFICE

MUMBAI REGISTRY NO. 182/2015


DELHI OFFICE



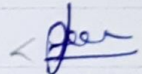
III. APPROVAL OF THE OPERATIONAL QUALIFICATION PROCEDURE

Both **LOTUS DIAGNOSTICS, MUMBAI** and **AGAPPE DIAGNOSTICS LTD.** are jointly responsible for the installation of **MISPA ACE** with serial number **WK-88106098** at "Lotus Diagnostics, Shop No: 5, Chandresh CHS, Devki Nagar, Next to Lotus Multispeciality Hospital, Mumbai - 400103 " as per the attached OPERATIONAL QUALIFICATION protocol.

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

Name	: Vaibhav Varpe	 Signature :
Designation	: Assistant Manager Application Support	
Company	: AGAPPE DIAGNOSTICS LTD.	Date : 06/03/2019

Validation Team from **LOTUS DIAGNOSTICS, MUMBAI**

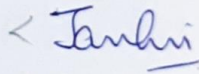
Name	: Yogesh Ade	Signature : 
Designation	: Senior Lab Technician	Date : 6/3/19
Department	: Biochemistry	

Customer Authorizations:

Name : Dr. Janki Ahuja

Title : OPERATIONAL QUALIFICATION

Site : Lotus diagnostics.

Signature : 

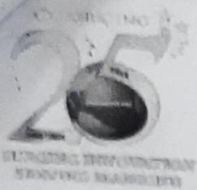
Date : 6/3/19

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

CORPORATE OFFICE / REAGENT PLANT
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 Tel: +91 484 216 7100 | Email: agappe@agappe.in

EQUIPMENT PLANT
 X/585 CB, Block No. 32, KINFRA Small Industrial Park,
 Neral, Cochin, Kerala, India - 686 721. Tel: +91 484 276 7473.

KOLKATA OFFICE
 406, Merkin Akhila, Plot No-10, Block-DK, Sector-V,
 Salt Lake City, Kolkata - 700 098.
 Tel: +91 31 4021 0451 | Email: kolkataoffice@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 : U24239MH1998PLC115413

CORPORATE OFFICE / REAGENT PLANT
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EQUIPMENT PLANT
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KOLKATA OFFICE
406, Verkhli Mitra, Plot No-10, Block DM, Sector V,
Salt Lake City, Kolkata - 700 091.
Tel: +91 33 4003 0451 | Email: kolkataoffice@agappe.in

MUMBAI REGISTERED OFFICE

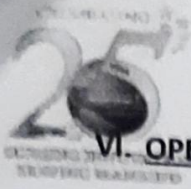
DELHI OFFICE

BANGALORE OFFICE



V. SCOPE

This Operational Qualification protocol will be performed on the **MISPA ACE** at **LOTUS DIAGNOSTICS, MUMBAI**. 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.



VI. OPERATIONAL QUALIFICATION

• Instrument Identification

Verified Date : 06/03/2019

- Model Name : MISPA ACE
- Serial Number : WK-88106098

• 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	Vaibhav Varpe 06/03/2019
02	Daily maintenance	To clean appropriate modules	Vaibhav Varpe 06/03/2019
03	Calibration	To calibrate the system	Vaibhav Varpe 06/03/2019
04	QC check	To confirm that the system is calibrated and working within specifications	Vaibhav Varpe 06/03/2019
05	Reproducibility check	To check the precision [CV %] after calibration	Vaibhav Varpe 06/03/2019
06	Sample programming and Analysis	To run the samples	Vaibhav Varpe 06/03/2019
07	Shut down procedure	To shut down the system	Vaibhav Varpe 06/03/2019

AGAPPE DIAGNOSTICS LTD.

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CORPORATE OFFICE / REAGENT PLANT
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EQUIPMENT PLANT
X/508-C6, Block No. 32, KINFRA Small Industrial Park,
Nellad, Cochin, Kerala, India - 686 72L Tel: +91 484 276 7477.

KOLKATA OFFICE
406, Merin Metro, Plot No-10, Block DR, Sector X,
Salt Lake City, Kolkata - 700 091.
Tel: +91 33 4003 0451 | Email: kolkatoffice@agappe.in

MUMBAI (REGISTERED OFFICE)

DELHI OFFICE

BANGALORE OFFICE



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.

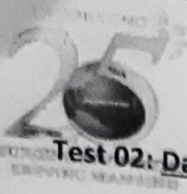
Procedure:

- 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 ACE 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
------------------	-------------	-------------

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	Vaibhav Varpe	06/03/2019
02	Check Wash solutions	Vaibhav Varpe	06/03/2019
03	Check system water	Vaibhav Varpe	06/03/2019
04	Check Reagents	Vaibhav Varpe	06/03/2019
05	Clean Reagent Block	Vaibhav Varpe	06/03/2019
06	Clean out side area	Vaibhav Varpe	06/03/2019
07	Load supplies and remove outdated and empty reagents	Vaibhav Varpe	06/03/2019
08	Check main menu screen	Vaibhav Varpe	06/03/2019
09	Perform Quality Control	Vaibhav Varpe	06/03/2019

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	Vaibhav Varpe	06/03/2019
02	Performing Calibration with calibration programming screen	Vaibhav Varpe	06/03/2019

Acceptance criteria: Calibration data shows satisfactory OD values in single 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	Vaibhav Varpe	06/03/2019
02	Creating QC file	Vaibhav Varpe	06/03/2019
03	QC sample programming and analysis	Vaibhav Varpe	06/03/2019

Acceptance criteria: QC results within specified limits

PARAMETER **PASS** **FAIL**

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

AGAPPE DIAGNOSTICS LTD.

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CORPORATE OFFICE / REAGENT PLANT
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KOLKATA OFFICE
40A, Vedaia Mohita, Plot No-10, Block-DK, Sector V,
Salt Lake City, Kolkata - 700 096.
Tel: +91 33 4003 0451 | Email: kolkatasoffice@agappe.in

MUMBAI (REGISTERED OFFICE)
401 & 402, 4th Floor, Airovath Business Centre, 119.

DELHI OFFICE
DSM 540, 5th Floor, DLF Tower, Shivaji Marg.

BANGALORE OFFICE
5-6, 8th Floor, Red Cross Bhavan, No.26 Race Course Road.

Test 05: Reproducibility Check

Purpose: To check the reproducibility of instrument

S No.	Activity	Done By	Date
01	Preparing control material/ sample	Vaibhav Varpe	06/03/2019
02	Running triplicates	Vaibhav Varpe	06/03/2019

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	Vaibhav Varpe	06/03/2019
02	Programming samples	Vaibhav Varpe	06/03/2019
03	Aspirating the samples	Vaibhav Varpe	06/03/2019
04	Viewing samples in process	Vaibhav Varpe	06/03/2019
05	Review results: Monitoring results	Vaibhav Varpe	06/03/2019

Acceptance criteria: Samples Analysis without any error

PARAMETER **PASS** FAIL

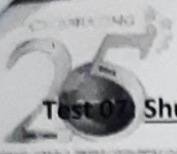
Parameter values for verification: Sample analysis without any error

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CORPORATE OFFICE / REAGENT PLANT
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KOLKATA OFFICE
606, Merin Matrix, Plot No-10, Block OR, Sector V,
Salt Lake City, Kolkata - 700 091.
Tel: +91 33 4003 0451 | Email: kolkataoffice@agappe.in



Test 02 Shut down

Purpose: To shut down the system

Procedure:

S No.	Activity	Done By	Date
01	Preparing the system for shut down	Vaibhav Varpe	06/03/2019
02	Following the on screen instructions	Vaibhav Varpe	06/03/2019
03	Switch off the instrument when prompted	Vaibhav Varpe	06/03/2019

Acceptance criteria: Shut down without any error

PARAMETER **PASS** **FAIL**

Parameter values for verification: Shut down without any error

VII. OPERATIONAL PROCEDURE

Certificate of Training

4. 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	Vaibhav Varpe	06/03/2019
2	System Operation	Vaibhav Varpe	06/03/2019
3	Basic trouble shooting and Maintenance	Vaibhav Varpe	06/03/2019



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.	Yogesh Ade	Sr. technician		06/03/2019
2.	Hetal Gandhi	Sr. technician		06/03/2019
3.	Aarti Gurav	Sr. technician		06/03/2019
4.	Pooja Jadhav	Sr. technician		06/03/2019

VIII. COMMENTS

2 Successfully performed Operation qualification with all mentioned requirements.

AGAPPE DIAGNOSTICS LTD.

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

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

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Nellaiad, Cochin, Kerala, India - 686 722. Tel: +91 484 276 7477.

KOLKATA OFFICE
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Salt Lake City, Kolkata - 700 091.
Tel: +91 33 4003 0451 | Email: kolkataoffice@agappe.in



IX. 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 : Vaibhav Varpe
Designation : Assistant Manager Application Support

Signature :



Company : AGAPPE DIAGNOSTICS LTD.

Date : 06/03/2019

Customer Authorizations: **LOTUS DIAGNOSTICS, MUMBAI**

Name : ✓ Dr. Jahvi Ahuja

Designation : ✓ Pathologist

Signature :

Title : OPERATIONAL QUALIFICATION

Date :

6/3/19



PERFORMANCE QUALIFICATION

For

FULLY AUTOMATED CLINICAL CHEMISTRY ANALYZER

MODEL : MISPA ACE

AGAPPE DIAGNOSTICS LTD.

ADL/MO/SER/020/21-22

AGAPPE DIAGNOSTICS LTD.

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

CORPORATE OFFICE / REAGENT PLANT
Agappe Hills, Pattimattom (PO), Dist. Ernakulam, Kerala - 681562, India.
Tel : +91 484 256 7000 | Email: agappe@agappe.in

EQUIPMENT PLANT
7/565-CB, Block No. 32, KINFRA Small Industrial Park,
Nellad, Cochin, Kerala, India - 686721. Tel: +91 404 276 7477.

KOLKATA OFFICE
406, Merlin Matrix, Plot No-10, Block-09, Sector V,
Salt Lake City, Kolkata - 700 091.
Tel: +91 33 4003 0451 | Email: kolkata@agappe.in



TABLE OF CONTENTS

S No.	Contents	Page No
I	Approval of the PQ procedure	3
II	Instructions	4
III	Scope	5
IV	Performance Qualification	6
V	Comments	15
VI	System Certification	16

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

CORPORATE OFFICE / REAGENT PLANT
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Bellari, Cochin, Kerala, India - 686 721. Tel: +91 484 276 7477.

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Salt Lake City, Kolkata - 700 091.
Tel: +91 33 4003 0451 | Email: kolkataoffice@agappe.in

MUMBAI (REGISTERED OFFICE)
406, Verdy Matrix, Plot No-10, Block-DK, Sector V,
Salt Lake City, Kolkata - 700 091.

DELHI OFFICE
406, Verdy Matrix, Plot No-10, Block-DK, Sector V,
Salt Lake City, Kolkata - 700 091.

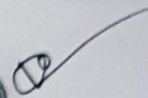
BANGALORE OFFICE
406, Verdy Matrix, Plot No-10, Block-DK, Sector V,
Salt Lake City, Kolkata - 700 091.



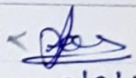
V. APPROVAL OF THE PERFORMANCE QUALIFICATION PROCEDURE

Both **LOTUS DIAGNOSTICS, MUMBAI** and **AGAPPE DIAGNOSTICS LTD.** are jointly responsible for the installation of **MISPA ACE** with serial number **WK-88106098** at "**Lotus Diagnostics, Shop No: 5, Chandresh CHS, Devki Nagar, Next to Lotus Multispeciality Hospital, Mumbai - 400103**" as per the attached PERFORMANCE QUALIFICATION protocol.

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

Name	: Vaibhav Varpe	Signature :	
Designation	: Assistant Manager Application Support	Date	: 06/03/2019
Company	: AGAPPE DIAGNOSTICS LTD.		

Validation Team from **LOTUS DIAGNOSTICS, MUMBAI**

Name	: < Yogesh Ade	Signature :	<  >
Designation	: Senior Lab Technician	Date	: < 6/3/19 >
Department	: Biochemistry		

Customer Authorizations:

Name : **Dr. Janhvi Ahuja**
 Title : PERFORMANCE QUALIFICATION
 Site : Lotus < diagnostics >

Signature : **Janhvi**
 Date : < 6/3/19 >

VI. INSTRUCTIONS

3. 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.
4. The concerned employees of **LOTUS DIAGNOSTICS, MUMBAI** will verify each result and sign in each page. The member of the validation team will carry this out.
5. 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**.

AGAPPE DIAGNOSTICS LTD.

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

CORPORATE OFFICE / REAGENT PLANT

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7/525 C5, Block No. 32, KINFRA Small Industrial Park,
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Salt Lake City, Kolkata - 700 091.
Tel: +91 33 4003 0451 | Email: kolkataoffice@agappe.in



VII. SCOPE

This Performance Qualification protocol will be performed on the **MISPA ACE** at **LOTUS DIAGNOSTICS, MUMBAI**. 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.

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

CORPORATE OFFICE / REAGENT PLANT
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KOLKATA OFFICE
 406, Westin Mall's, Plot No-103, Block-08, Sector V,
 Salt Lake City, Kolkata - 700 096.
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MUMBAI (REGISTERED OFFICE)

DELHI OFFICE

BANGALORE OFFICE

PERFORMANCE QUALIFICATION

O. Instrument Identification

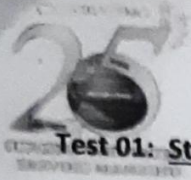
Verified Date : 06/03/2019

1. Model Name : MISPA ACE

P. Serial Number : **WK-88106098**

Q. 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	Vaibhav Varpe 06/03/2019
02	Daily maintenance	To clean appropriate modules	Vaibhav Varpe 06/03/2019
03	Cell blank	To check the cuvettes	Vaibhav Varpe 06/03/2019
04	Priming	To check the tubing's, and flow	Vaibhav Varpe 06/03/2019
05	Auto gain	To check the cuvette and photometry system	Vaibhav Varpe 06/03/2019
06	<u>Calibration</u>	To calibrate the system	Vaibhav Varpe 06/03/2019
07	<u>QC check</u>	To confirm that the system and reagents are acceptable and working within specifications	Vaibhav Varpe 06/03/2019
08	<u>Reproducibility check</u>	To check the precision [CV %]	Vaibhav Varpe 06/03/2019
09	<u>Sample programming and Analysis</u>	To run the samples	Vaibhav Varpe 06/03/2019
10	Shut down procedure	To shut down the system	Vaibhav Varpe 06/03/2019



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.

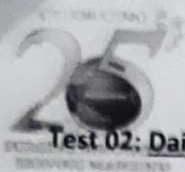
Procedure:

- X. Wait for the instrument to get ready after initialization
- XI. Check the room temperature and switch on the Air Conditioner
- XII. Check the UPS.
- XIII. Switch on the MISPA ACE by pressing the main switch, then switch on the computer and then the system power
- XIV. Double click the analyzer icon to initialize the system software
- XV. Input the password and do as prompted, the system menu pops up if start up is finished
- XVI. If not, initialize by again after solving the error displayed
- XVII. Follow instructions provided for the error message

Acceptance criteria: System to display **READY** status

PARAMETER	<u>PASS</u>	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	Vaibhav Varpe	06/03/2019
02	Check Wash solutions	Vaibhav Varpe	06/03/2019
03	Check system water	Vaibhav Varpe	06/03/2019
04	Check Reagents	Vaibhav Varpe	06/03/2019
05	Clean Reagent Block	Vaibhav Varpe	06/03/2019
06	Clean out side area	Vaibhav Varpe	06/03/2019
07	Load supplies and remove outdated and empty reagents	Vaibhav Varpe	06/03/2019
08	Check main menu screen	Vaibhav Varpe	06/03/2019
09	Perform Quality Control	Vaibhav Varpe	06/03/2019

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

PARAMETER PASS FAIL

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

AGAPPE DIAGNOSTICS LTD.

ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24239MH1998PLC101413

CORPORATE OFFICE / REAGENT PLANT

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KOLKATA OFFICE

406, Virendra Mohan, Plot No-03, Block-DH, Sector-V,

Salt Lake City, Kolkata - 700 199.

Tel: +91 33 4003 0454 | Email: kolkata@agappe.in

AGAPPE DIAGNOSTICS



Test 3: Cell Blank

AGAPPE DIAGNOSTICS LTD.
KOLKATA OFFICE

AGAPPE

Purpose: To check the cuvette blank OD at different wavelength

Procedure:

S No.	Activity	Done By	Date
01	Checking the Cell blank	Vaibhav Varpe	06/03/2019
	340 nm	Vaibhav Varpe	06/03/2019
	405 nm	Vaibhav Varpe	06/03/2019
	450 nm	Vaibhav Varpe	06/03/2019
	510 nm	Vaibhav Varpe	06/03/2019
	546 nm	Vaibhav Varpe	06/03/2019
	578 nm	Vaibhav Varpe	06/03/2019
	630 nm	Vaibhav Varpe	06/03/2019
	670 nm	Vaibhav Varpe	06/03/2019

Acceptance criteria:

- No error Messages displayed
- All Cuvettes should show acceptance

PARAMETER

PASS ✓

FAIL ✗

Parameter values for verification: No Error Messages

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Tel. : +91 484 256 7000 | Email: agappe@agappe.in

EQUIPMENT PLANT
K/506 CB, Block No. 32, KINFRA Small Industrial Park,
Newlas, Cochin, Kerala, India - 686 721. Tel: +91 484 276 7477.

KOLKATA OFFICE
40/c, Modelo Mitra, Plot No-00, Block-DH, Sector V,
Salt Lake City, Kolkata - 700 091.
Tel. : +91 33 4003 0451 | Email: kolkataoffice@agappe.in

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	Vaibhav Varpe	06/03/2019

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	Vaibhav Varpe	06/03/2019

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 *	Vaibhav Varpe	06/03/2019
02	Performing Calibration with calibration programming screen	Vaibhav Varpe	06/03/2019

*Traceability of the calibrator used is attached

Acceptance criteria: Calibration data shows satisfactory OD values in single 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	Vaibhav Varpe	06/03/2019
02	Creating QC file	Vaibhav Varpe	06/03/2019
03	QC sample programming and analysis	Vaibhav Varpe	06/03/2019

Acceptance criteria: QC results within specified limits

PARAMETER **PASS** FAIL

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

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

KOLKATA OFFICE
406, Manika Matra, Plot No-10, Block-DH, Sector V,
Salt Lake City, Kolkata - 700 091.
Tel: +91 33 4003 0451 | Email: kolkata@agappe.in

Test 08: Reproducibility Check**Purpose:** To check the reproducibility of instrument

Raw data

S No.	Activity	Done By	Date
01	Preparing control material/ sample ✓	Vaibhav Varpe	06/03/2019
02	Running triplicates	Vaibhav Varpe	06/03/2019

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	Vaibhav Varpe	06/03/2019
02	Programming samples	Vaibhav Varpe	06/03/2019
03	Aspirating the samples	Vaibhav Varpe	06/03/2019
04	Viewing samples in process	Vaibhav Varpe	06/03/2019
05	Review results: Monitoring results	Vaibhav Varpe	06/03/2019

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	Vaibhav Varpe	06/03/2019
02	Following the on screen instructions	Vaibhav Varpe	06/03/2019
03	Switch off the instrument when prompted	Vaibhav Varpe	06/03/2019

Acceptance criteria: Shut down without any error

PARAMETER PASS FAIL - ?

Parameter values for verification: Shut down without any error

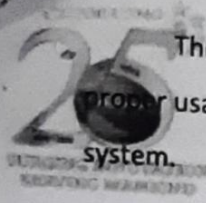
OPERATIONAL PROCEDURE

Certificate of Training

6. 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	Vaibhav Varpe	06/03/2019
2.	System Operation	Vaibhav Varpe	06/03/2019
3.	Basic trouble shooting and Maintenance	Vaibhav Varpe	06/03/2019



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.	Yogesh Ade	Sr. technician		06/03/2019
2.	Hetal Gandhi	Sr. technician		06/03/2019
3.	Aarti Gurnav	Sr. technician		06/03/2019
4.	Pooja Jadhav	Sr. technician		06/03/2019



Successfully performed Performance Qualification with all requirements fulfilled without any error.

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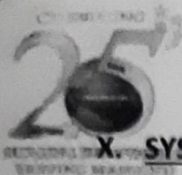
EQUIPMENT PLANT
X/586-CB, Block No. 32, KINFRA Small Industrial Park,
Nellikud, Cochin, Kerala, India - 686 721. Tel: +91 484 276 7477.

KOLKATA OFFICE
406, Virelin Matrix, Plot No-03, Block-09, Sector-16,
Salt Lake City, Kolkata - 700 096.
Tel: +91 33 4003 0484 | Email: kolkataoffice@agappe.in

MUMBAI (REGISTERED OFFICE)

DELHI OFFICE

BANGALORE OFFICE



SYSTEM CERTIFICATION

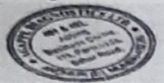
Study data has determined that the system described in this document either meets all criteria outline in this Performance Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been addressed.

The system is ready for specified usage.

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

Name : Vaibhav Varpe
Designation : Assistant Manager Application Support

Signature:



Company : AGAPPE DIAGNOSTICS LTD.

Date : 06/03/2019

Customer Authorizations: **LOTUS DIAGNOSTICS, MUMBAI**

Name : *Ds. Janhvi Ahuja*

Designation : *Pathologist*

Signature : *Janhvi*

Title : PERFORMANCE QUALIFICATION

Date : *6/3/19*

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Tel: +91 33 4009 0451 | Email: kolkataoffice@agappe.in

MUMBAI (REGISTERED OFFICE)

DELHI OFFICE

BANGALORE OFFICE

PO

1

system ready

MISAPAGE

Standby HOST 37.0 06/03/2019 16:16:02 ?

Reagent Calibration QC Status Statistics Parameters Setup Maintenance

Sample Request

QC Request

Start

Probe Stop

Stop

Results

Replace

Relog

Exit

Admin

Daily Maint Log Import/Export Alignment

System Status

Reaction Temp.	Preheat Temp.	Waste Tank	Deionized Water	Printer	Unit Status	Main Unit	Reaction Unit	Sample Unit	Reagent Unit	Temperature Unit	Mixing Unit
36.99	45.03	Normal	Normal	Idle	Idle	Idle	Idle	Idle	Idle	Idle	Idle

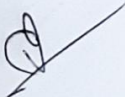
Dark Current/Background

	Dark Current	Background
340	09	34180
405	09	35401
450	02	35347
510	01	30302
546	05	30199
578	09	30312
630	05	33253
670	08	41556

Wash reagent probe, sample probe and mixing bar with deionized water

Startup Check Wash Enhanced Dark Current Reset

← cuvette & lamp check


performed by.

Jankin
APPROVED BY

QC Data Summary

Control: ERBA PATH


Start Date: 06/03/2019

End Date: 06/03/2019

Test	Results	Units	Time	Control Range	Remarks/Flag
SGPT AG	113.7	U/L	06-03-2019 15:36:59	111.730-193.090	
SGOT AG	154.2	U/L	06-03-2019 15:36:59	104.410-180.250	
BILI-D AG	0.71	mg/dL	06-03-2019 15:36:59	0.2100-4.2100	
UREA AGAPPE	100.9	mg/dL	06-03-2019 14:37:49	83.300-124.900	
URIC AC AGAPPE	7.3	mg/dL	06-03-2019 14:37:49	4.150-7.750	
HDL AG	76.0	mg/dL	06-03-2019 14:37:49	75.300-140.900	
BILI-T AG	5.1	mg/dL	06-03-2019 14:37:49	3.170-6.290	
GLUC AG	262.2	mg/dL	06-03-2019 14:37:49	190.220-285.340	
CHOL AG	265.7	mg/dL	06-03-2019 14:37:49	215.410-324.050	
TGL AG	249.6	mg/dL	06-03-2019 14:37:49	168.000-250.000	



Performed by.



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3

Patient: ARYA
Sample: Serum
Sender:
Characteristic:

Gender:
MRN.:
Sent from:

Age:

Blood Type:

Sample ID: 1

Zone:

Bed No.:

Priority: No

Diagnosis:

Test	Full Name	Concentration	Unit	Results	Remark	Reference
GLUC AG		208.9	mg/dL	Normal		
GLUC AG		207.8	mg/dL	Normal		

Test Date: 06-03-2019 16:45:13
Send Date: 06-03-2019 16:45:13
Print Date: 30-09-2021 15:26:34

Tester:

Reviewed By:

The results are for this sample only

Tanvir
APPROVED BY

Performed By.

Sample results without error

PHANDRAKANTA


Sender: Serum
Characteristic:
Diagnosis:

Gender: Age: Blood Type: Sample ID: 2
MRN.: Zone: Bed No.:
Sent from: Priority: No

Test	Full Name	Concentration	Unit	Results	Remark	Reference
GLUC AG		161.7	mg/dL	Normal		
GLUC AG		164.2	mg/dL	Normal		

Test Date: 06-03-2019 16:45:36
Send Date: 06-03-2019 16:45:36
Print Date: 30-09-2021 15:26:37

Tester:
Reviewed By:
The results are for this sample only


Performed By.


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Sample: Serum
Sender:
Characteristic:
Diagnosis:

Gender: Age: Blood Type: Sample ID: 3
MRN.: Zone: Bed No.:
Sent from: Priority: No

Test	Full Name	Concentration	Unit	Results	Remark	Reference
GLUC AG		101.5	mg/dL	Normal		
GLUC AG		101.1	mg/dL	Normal		

Test Date: 06-03-2019 16:46:10
Send Date: 06-03-2019 16:46:10
Print Date: 30-09-2021 15:26:42

Tester:
Reviewed By:
The results are for this sample only


Performed By.


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Sample ID: 304
Sample: Serum
Sender:
Characteristic:
Diagnosis:

Gender:
MRN.:
Sent from:

Age:

Blood Type:
Zone:
Priority: No

Sample ID: 4
Bed No.:

Test	Full Name	Concentration	Unit	Results	Remark	Reference
GLUC AG		311.6	mg/dL	Normal		
GLUC AG		307.2	mg/dL	Normal		

Test Date: 06-03-2019 16:47:50
Send Date: 06-03-2019 16:47:50
Print Date: 30-09-2021 15:25:53

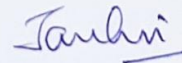
Tester:

Reviewed By:

The results are for this sample only



Performed By.



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Sent: TRIPPLICATE
 Sample: Serum
 Sender:
 Characteristic:
 Diagnosis:

Gender: Age: Blood Type: Sample ID: 7
 MRN.: Zone: Bed No.:
 Sent from: Priority: No


Test	Full Name	Concentration	Unit	Results	Remark	Reference
GLUC AG		147.8	mg/dL	Normal		
GLUC AG		148.8	mg/dL	Normal		
GLUC AG		148.4	mg/dL	Normal		

Test Date: 06-03-2019 17:02:58
 Send Date: 06-03-2019 17:02:58
 Print Date: 06-03-2019 17:34:24

Tester:
 Reviewed By:
 The results are for this sample only

Mean = 148.33
 SD = 0.411
 % CV = 0.28 (< 5%)


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TRIPPLICATE.
Patient:
Sample: Serum
Sender:
Characteristic:
Diagnosis:

Gender: Age: Blood Type: Sample ID: 8
MRN.: Zone: Bed No.:
Sent from: Priority: No

Test	Full Name	Concentration	Unit	Results	Remark	Reference
SGOT AG		96.4	U/L	Normal		
SGOT AG		96.0	U/L	Normal		
SGOT AG		94.8	U/L	Normal		
UREA AGAPPE		203.1	mg/dL	Normal		
UREA AGAPPE		205.2	mg/dL	Normal		
UREA AGAPPE		204.7	mg/dL	Normal		


Test Date: 06-03-2019 17:03:34
Send Date: 06-03-2019 17:03:34
Print Date: 06-03-2019 17:34:41

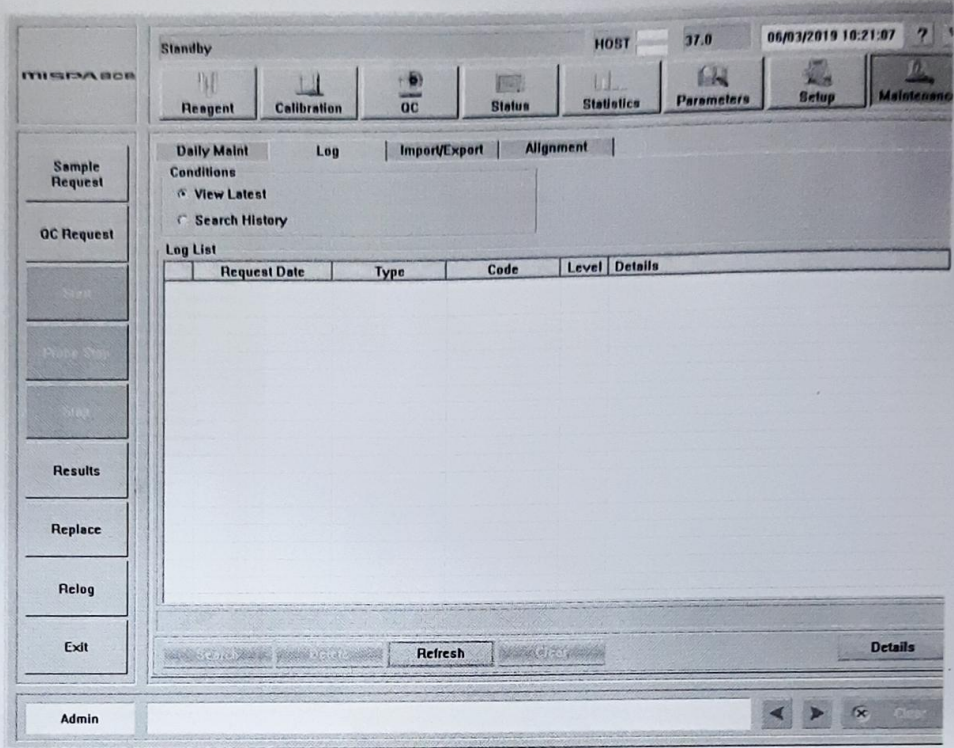
Tester:
Reviewed By:
The results are for this sample only

SGOT AG
mean = 95.733
SD = 0.83
%.CV = 0.87 (< 5%)


Urea Agappe
mean = 204.33
SD = 0.89
%.CV = 0.44 (< 5%)

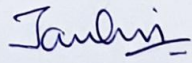
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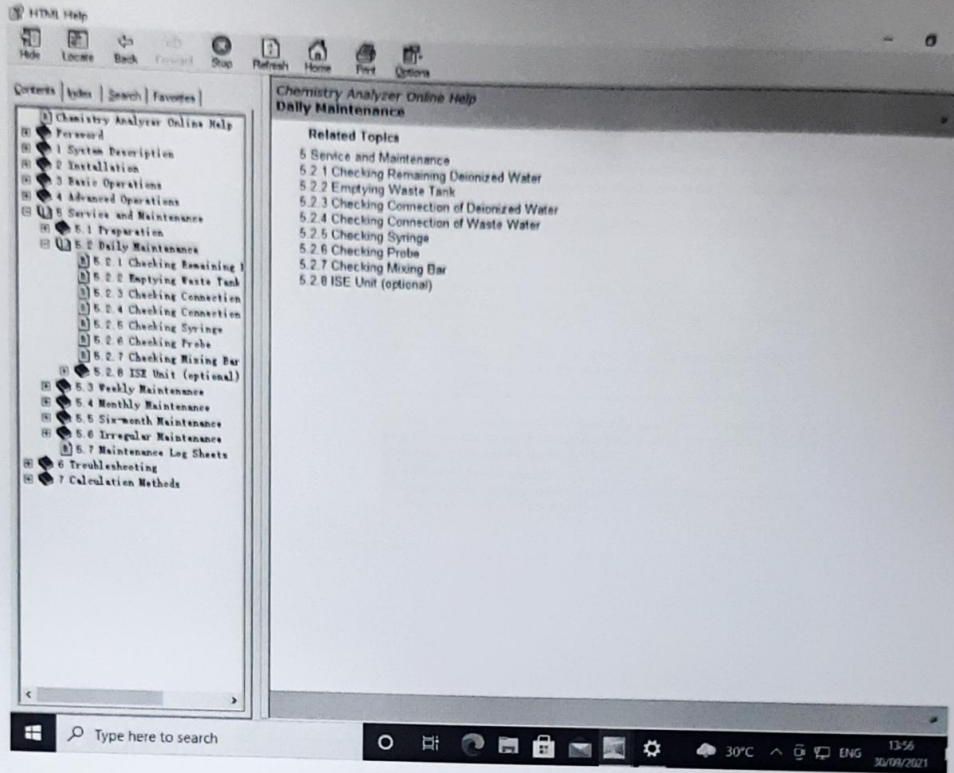

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Error Screen


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Daily maintenance

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HTML Help

Hide Locate Back Forward Stop Refresh Home Print Options

Contents | Index | Search | Favorites

- Chemistry Analyzer Online Help
 - 1 System Description
 - 2 Installation
 - 3 Basic Operations
 - 4 Advanced Operations
 - 5 Service and Maintenance
 - 5.1 Preparation
 - 5.2 Daily Maintenance
 - 5.2.1 Checking Remaining
 - 5.2.2 Emptying Waste Tank
 - 5.2.3 Checking Connection
 - 5.2.4 Checking Connection
 - 5.2.5 Checking Springs
 - 5.2.6 Checking Probs
 - 5.2.7 Checking Mixing Bar
 - 5.2.8 IET Out (optional)
 - 5.3 Weekly Maintenance
 - 5.4 Monthly Maintenance
 - 5.5 Six-month Maintenance
 - 5.6 Irregular Maintenance
 - 5.7 Maintenance Log Sheets
 - 6 Troubleshooting
 - 7 Calculation Methods

Chemistry Analyzer Online Help
Checking Remaining Deionized Water

CAUTION
The water must meet requirements of the CAP Type II water. When placing the deionized water tank, ensure the top of the tank is lower than the bearing platform on which the system is placed. Ensure the deionized water pickup tube is not blocked, bent, or relaxed.

- 1 Place the Power to OFF.
- 2 Check how much deionized water is left in the tank. If not much, proceed to the next step.

CAUTION:
After removing the cap of the deionized water tank (together with the pickup tube, sensor and the filter), place it on a clean table.

Unscrew (counter-clockwise) the tank cap assembly and remove the cap together with the pickup tube, sensor and the filter. Do not detach the cap assembly, otherwise leakage might happen.

- 4 Add deionized water to the tank.
- 5 Screw (clockwise) the cap assembly together with the pickup tube, sensor and the filter back onto the tank until secure.

Related Topics
5.2 Daily Maintenance

Admin

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Jauhin
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File Locate Back Forward Stop Refresh Home Print Options

Contents | Index | Search | Favorites

Chemistry Analyzer Online Help

Emptying Waste Tank

BIOHAZARD

Wear gloves and lab coat and, if necessary, goggles. Dispose of the wastewater in accordance with your local or national guidelines for biohazard waste disposal, and consult the manufacturer or distributor of the reagents for details.

CAUTION

When placing the waste tank, ensure the top of the tank is lower than the bearing platform on which the system is placed. Ensure the waste tube is over the tank and not blocked, bent, or twisted. A blocked, bent or twisted waste tube may lead to wastewater overflow that may damage the analyzer.

- 1 Place the Power to OFF.

BIOHAZARD

After removing the cap of the waste tank (together with the tube and sensor), place it on an appropriate place to avoid infection.

Unscrew (counter-clockwise) the tank cap and remove it together with the waste tube and the sensor from the tank.

- 3 Empty the waste tank.
- 4 Screw (clockwise) the cap (together with the waste tube and the sensor) back onto the tank until secure.

Related Topics

5.2 Daily Maintenance

1 System Description
2 Installation
3 Basic Operations
4 Advanced Operations
5 Service and Maintenance
5.1 Preparation
5.2 Daily Maintenance
5.2.1 Checking Remaining I
5.2.2 Emptying Waste Tank
5.2.3 Checking Connection
5.2.4 Checking Connection
5.2.5 Checking Settings
5.2.6 Checking Probe
5.2.7 Checking Mixing Bar
5.2.8 ISE Unit (optional)
5.3 Weekly Maintenance
5.4 Monthly Maintenance
5.5 Six-month Maintenance
5.6 Irregular Maintenance
5.7 Maintenance Log Sheets
6 Troubleshooting
7 Calculation Methods

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View Locate Back Forward Stop Refresh Home Print Options

Contents Index Search Favorites

- 0 Chemistry Analyzer Online Help
 - 1 Foreword
 - 2 System Description
 - 3 Installation
 - 4 Basic Operations
 - 5 Advanced Operations
 - 6 Service and Maintenance
 - 7 Preparation
 - 8 Daily Maintenance
 - 8.2.1 Checking Remaining I
 - 8.2.2 Emptying Waste Tank
 - 8.2.3 Checking Connection
 - 8.2.4 Checking Connection
 - 8.2.5 Checking Springs
 - 8.2.6 Checking Probe
 - 8.2.7 Checking Mixing Bar
 - 8.2.8 ISE Unit (optional)
 - 9 Weekly Maintenance
 - 10 Monthly Maintenance
 - 11 Six-month Maintenance
 - 12 Irregular Maintenance
 - 13 Maintenance Log Sheets
 - 6 Troubleshooting
 - 7 Calculation Methods

Chemistry Analyzer Online Help

Checking Connection of Deionized Water

CAUTION

When placing the deionized water tank, ensure the top of the tank is lower than the bearing platform of the analyzer. Ensure the deionized water pickup tube is not blocked, bent, or twisted.

- 1 Place the Power to OFF
- 2 Check the connections between the two connectors (green and red) marked DEIONIZED WATER on the analyzer and their counterparts. If no leakage occurs, skip to step 4. If you see leaks, wipe off the water with clean gauze and proceed to the next step.
- 3 Check whether the connectors are loose. If not, proceed to the next step. If yes, unscrew the connector counter-clockwise to remove it and then screw it back on.
- 4 Check the connections between the pickup tubes and their connectors. If no leakage occurs, proceed to the next step. If you see leaks, wipe off the water with clean gauze and tighten the connections and proceed to the next step.
- 5 Check the connection between the pickup tube and the tank cap. If you see leaks, wipe off the water with clean gauze and tighten the pickup tube.
- 6 Check the connection between the pickup tube and the filter. If you see leaks, wipe off the water with clean gauze and tighten the pickup tube.

NOTE

If leakage remains after the above operations are finished, please contact

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Tanvir

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Chemistry Analyzer Online Help
Checking Connection of Waste Water

BIOHAZARD
 Wear gloves and lab coat and, if necessary, goggles.
 Dispose of the used gauze in accordance with your local or national guidelines for biohazard waste disposal.

CAUTION
 When placing the waste tank, ensure the top of the tank is lower than the bearing platform on which the system is placed.
 Ensure the waste tube is over the tank and not blocked, bent, or twisted. A blocked, bent or twisted waste tube may lead to wastewater overflow that may damage the analyzer.

- 1 Place the Power to OFF.
- 2 Check the connections between connector marked WASTE on the analyzing unit and its counterpart.
 If no leakage occurs, proceed to the next step.
 If you see leaks, wipe off the water with clean gauze, and then reconnect the waste tube.
- 3 Check the connection between the waste tube and the connector.
 If no leakage occurs, proceed to the next step.
 If you see leaks, wipe them off with clean gauze and tighten the waste tube.
- 4 Check the connection between the waste tube and the waste tank cap.
 If you see leaks, wipe them off with clean gauze and tighten the waste tube.

NOTE
 If leakage remains after the above operations are finished, please contact our customer service department or your local distributor.

Related Topics
 5.2 Daily Maintenance

Contents Index Search Favorites

- Chemistry Analyzer Online Help
- 1 System Description
- 2 Installation
- 3 Basic Operations
- 4 Advanced Operations
- 5 Service and Maintenance
 - 5.1 Preparation
 - 5.2 Daily Maintenance
 - 5.2.1 Checking Remaining
 - 5.2.2 Emptying Waste Tank
 - 5.2.3 Checking Connection
 - 5.2.4 Checking Connection
 - 5.2.5 Checking Springs
 - 5.2.6 Checking Probe
 - 5.2.7 Checking Mixing Bar
 - 5.2.8 ISE Unit (optional)
 - 5.3 Weekly Maintenance
 - 5.4 Monthly Maintenance
 - 5.5 Six-month Maintenance
 - 5.6 Irregular Maintenance
 - 5.7 Maintenance Log Sheets
 - 5.8 Troubleshooting
 - 5.9 Calculation Methods

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Internet Explorer - Chemistry Analyzer Online Help

File Location Back Forward Stop Refresh Home Print Options

Converts | Index | Search | Favorites

Chemistry Analyzer Online Help

- 1 System Description
- 2 Installation
- 3 Basic Operations
- 4 Advanced Operations
- 5 Service and Maintenance
 - 5.1 Preparation
 - 5.2 Daily Maintenance
 - 5.2.1 Checking Remaining I
 - 5.2.2 Emptying Waste Tank
 - 5.2.3 Checking Connection
 - 5.2.4 Checking Connection
 - 5.2.5 Checking Syringe
 - 5.2.6 Checking Probe
 - 5.2.7 Checking Mixing Bar
 - 5.2.8 IDE Unit (optional)
 - 5.3 Weekly Maintenance
 - 5.4 Monthly Maintenance
 - 5.5 Six-month Maintenance
 - 5.6 Irregular Maintenance
 - 5.7 Maintenance Log Sheets
- 6 Troubleshooting
- 7 Calculation Methods

WARNING
The probe tip is sharp and can cause puncture wounds. To prevent injury, exercise caution when working around the probe.

BIOHAZARD
Wear gloves and lab coat and, if necessary, goggles.

Figure 5-1 Syringe

- 1 Place the Power to OFF.
- 2 Unscrew the screws on the syringe cover and remove the cover. The structure of the syringe is as shown in the figure below.

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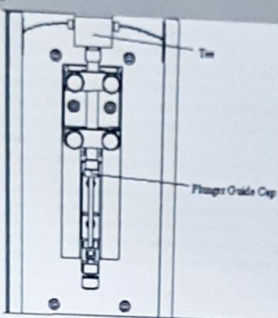
Contents Index Search Favorites

Chemistry Analyzer Online Help

- [-] Forward
- [-] 1 System Description
- [-] 2 Installation
- [-] 3 Basic Operations
- [-] 4 Advanced Operations
- [-] 5 Service and Maintenance
 - [-] 5.1 Preparation
 - [-] 5.2 Daily Maintenance
 - [-] 5.2.1 Checking Remaining I
 - [-] 5.2.2 Emptying Waste Tank
 - [-] 5.2.3 Checking Connection
 - [-] 5.2.4 Checking Connection
 - [-] 5.2.5 Checking Syringe
 - [-] 5.2.6 Checking Probe
 - [-] 5.2.7 Checking Mixing Bar
 - [-] 5.2.8 ISE Unit (optional)
 - [-] 5.3 Weekly Maintenance
 - [-] 5.4 Monthly Maintenance
 - [-] 5.5 Six-month Maintenance
 - [-] 5.6 Irregular Maintenance
 - [-] 5.7 Maintenance Log Sheets
- [-] 6 Troubleshooting
- [-] 7 Calculation Methods

Chemistry Analyzer Online Help

Checking Syringe



- 3 Check whether the T-piece leaks.
If no leakage occurs, proceed to the next step.
If you see leaks, please contact our customer service department or your local distributor.
- 4 Check whether the plunger guide cap leaks.
If no leakage occurs, proceed to the next step.
If you see leaks, replace the plunger assembly of syringe as instructed by 5.6.4 Replacing Plunger Assembly of Syringe.
- 5 Check whether air bubbles exist in the syringe.
If so, proceed to the next step.
If yes, remove the bubbles as instructed by 5.6.5 Removing Air Bubbles.
- 6 Place the cover of syringe back and tighten the screws.

Related Topics

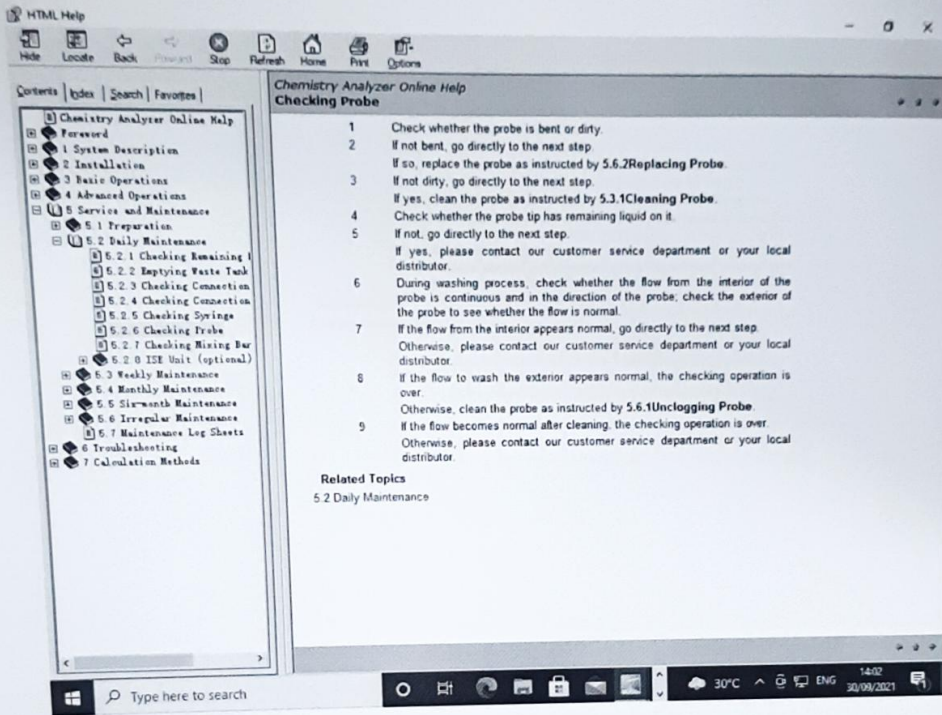
5.2 Daily Maintenance


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30°C ENG 14:07

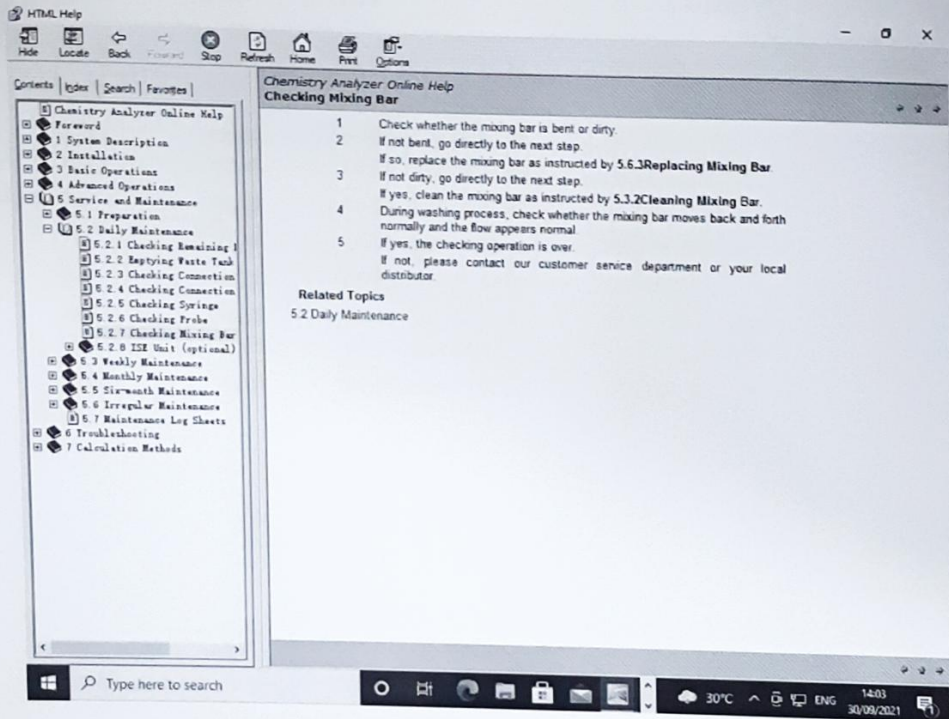
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QC Data Summary

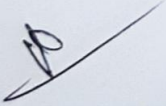
Control: ERBA PATH

Start Date: 06/03/2019

End Date: 06/03/2019

Test	Results	Units	Time	Control Range	Remarks/Flag
SGPT AG	113.7	U/L	06-03-2019 15:36:59	111.730-193.090	
SGOT AG	154.2	U/L	06-03-2019 15:36:59	104.410-180.250	
BILI-D AG	0.71	mg/dL	06-03-2019 15:36:59	0.2100-4.2100	
UREA AGAPPE	100.9	mg/dL	06-03-2019 14:37:49	83.300-124.900	
URIC AC AGAPPE	7.3	mg/dL	06-03-2019 14:37:49	4.150-7.750	
HDL AG	76.0	mg/dL	06-03-2019 14:37:49	75.300-140.900	
BILI-T AG	5.1	mg/dL	06-03-2019 14:37:49	3.170-6.290	
GLUC AG	262.2	mg/dL	06-03-2019 14:37:49	190.220-285.340	
CHOL AG	265.7	mg/dL	06-03-2019 14:37:49	215.410-324.050	
TGL AG	249.6	mg/dL	06-03-2019 14:37:49	168.000-250.000	

QC data


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Calibration Curve

Test: SGOT AG

Date/Time: 06-03-2019 14:04:53

Rule: Two-point Linear

Reagent Blank: 15480.7140167272

K:

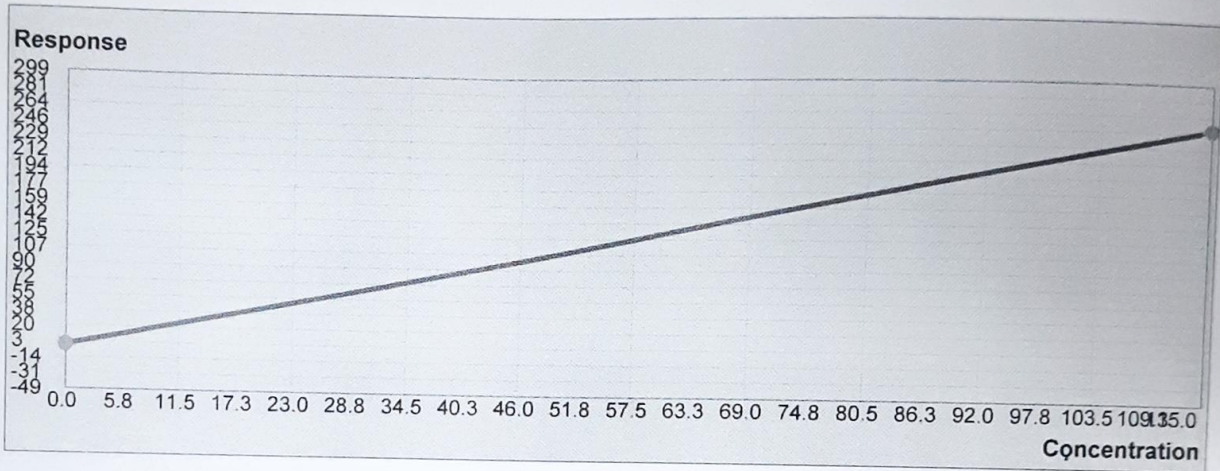
R0:

A: 2.17361

B: 0.00000

C:

D:



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Calibration Curve

Test: SGPT AG

Rule: Two-point Linear

K:

B: 0.00000

Date/Time: 06-03-2019 14:04:53

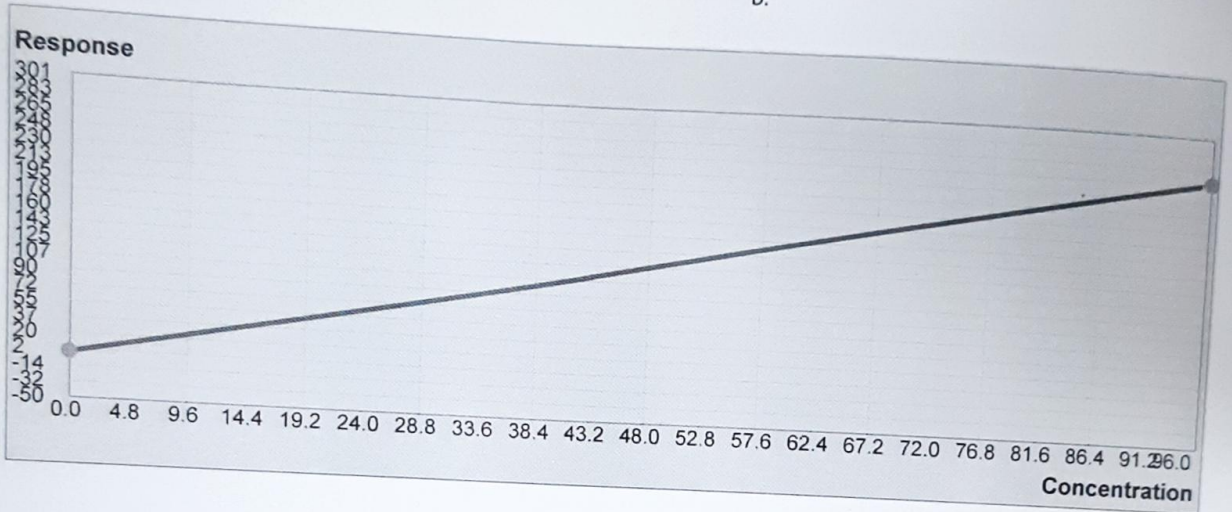
Reagent Blank: 16632.800764329

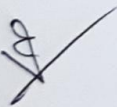
A: 2.61496

D:

R0:

C:




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Calibration Curve

Test: BILI-D AG

Date/Time: 06-03-2019 14:04:53

Rule: Two-point Linear

Reagent Blank: -32.0236078575423

K:

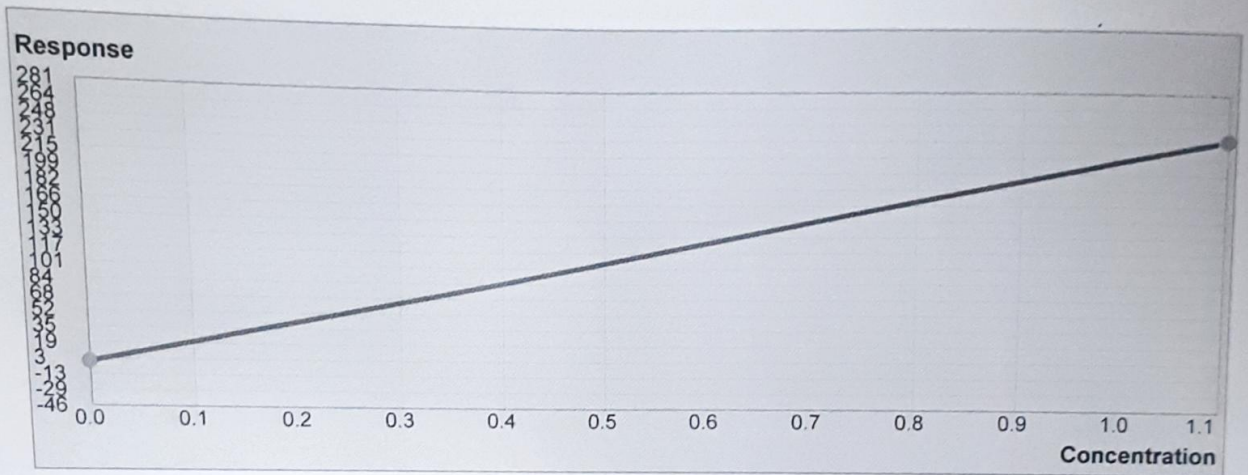
R0:

A: 213.37407

B: 0.00000

C:

D:



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Calibration Curve

Test: UREA AGAPPE

Rule: Two-point Linear

K:

B: 0.00000

Date/Time: 06-03-2019 14:04:53

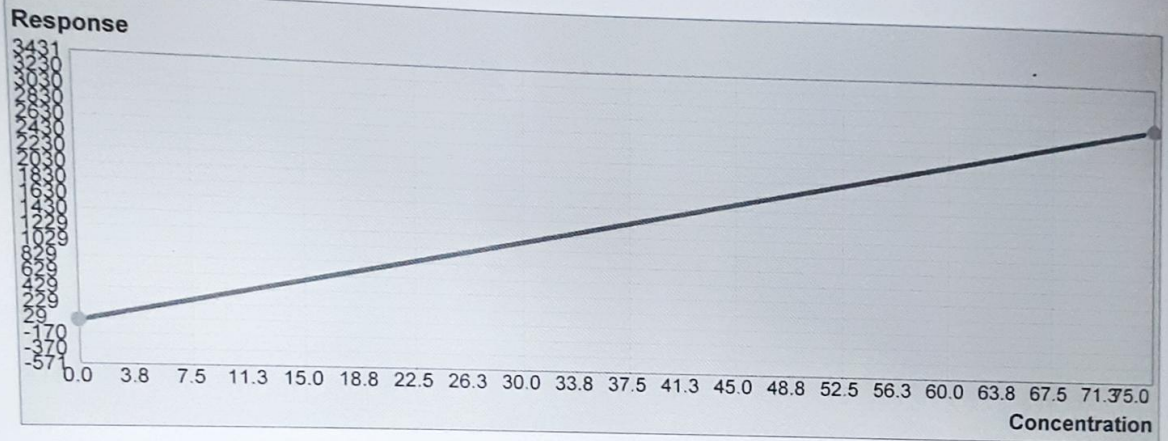
Reagent Blank: 16234.6012234647


A: 38.12526

R0:

C:

D:




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Calibration Curve

Test: URIC AC AGAPPE

Date/Time: 06-03-2019 14:04:53

Rule: Two-point Linear

Reagent Blank: 125.164969326246

K:

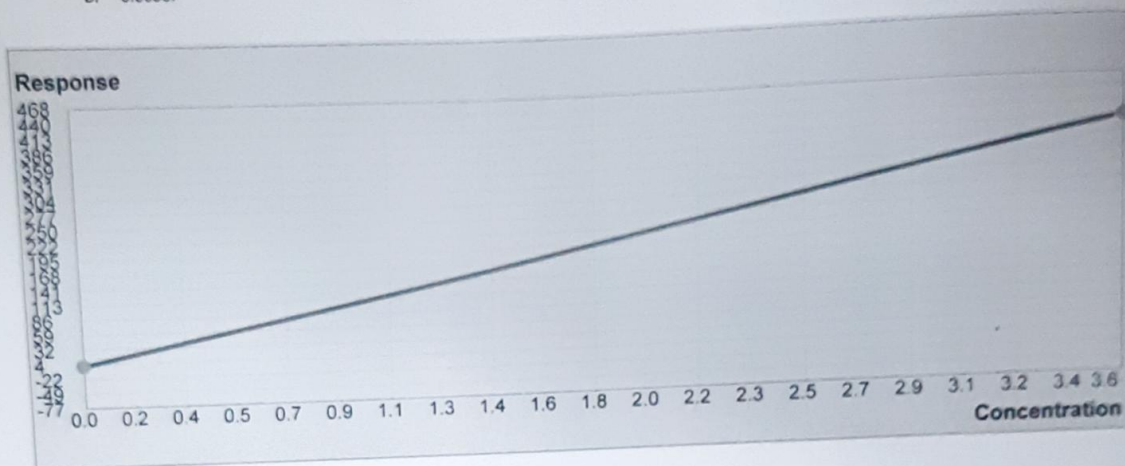
R0:

A: 108.28357

B: 0.80867

C:

D:



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Jankhi

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Calibration Curve

Test: HDL AG
Rule: Two-point Linear

Date/Time: 06-03-2019 14:04:53

K:
B: 0.00000

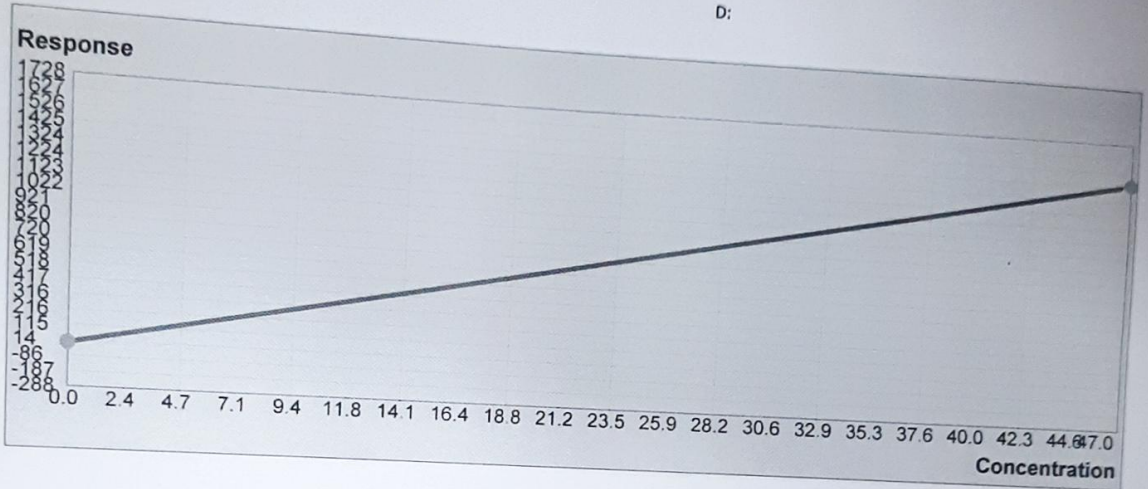
R0:


Reagent Blank: -17.5422440734328

A: 30.63990

C:

D:




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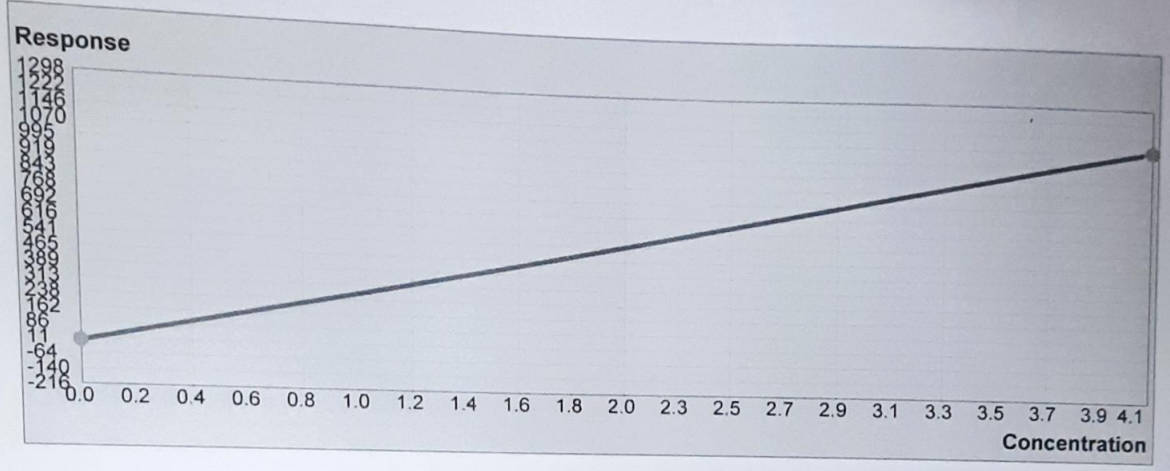

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Calibration Curve

Test: BILI-T AG
Rule: Two-point Linear
K:
B: 0.00000

Date/Time: 06-03-2019 14:04:53
Reagent Blank: -26.3219461102018
A: 263.99940
D:

R0:
C:




Performed BY.


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Calibration Curve

Test: GLUC AG
Rule: Two-point Linear
K:

B: 1.13280

R0:

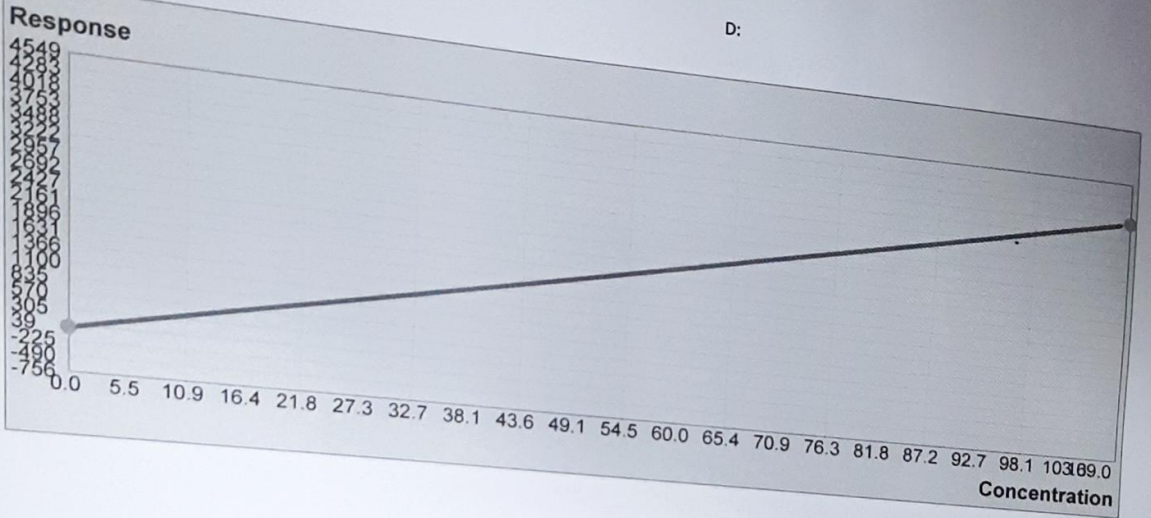
C:


Date/Time: 06-03-2019 14:04:53

Reagent Blank: 83.8583516711894

A: 34.77514

D:




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Calibration Curve

Test: CHOL AG

Date/Time: 06-03-2019 14:04:53

Rule: Two-point Linear

Reagent Blank: 118.729027777279

K:

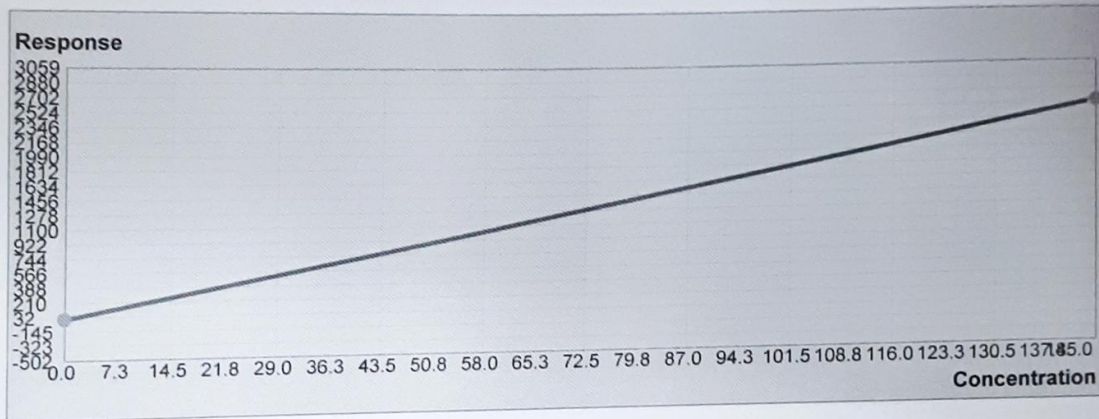
R0:

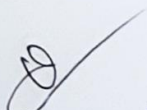
A: 17.54506

B: 6.52184

C:

D:



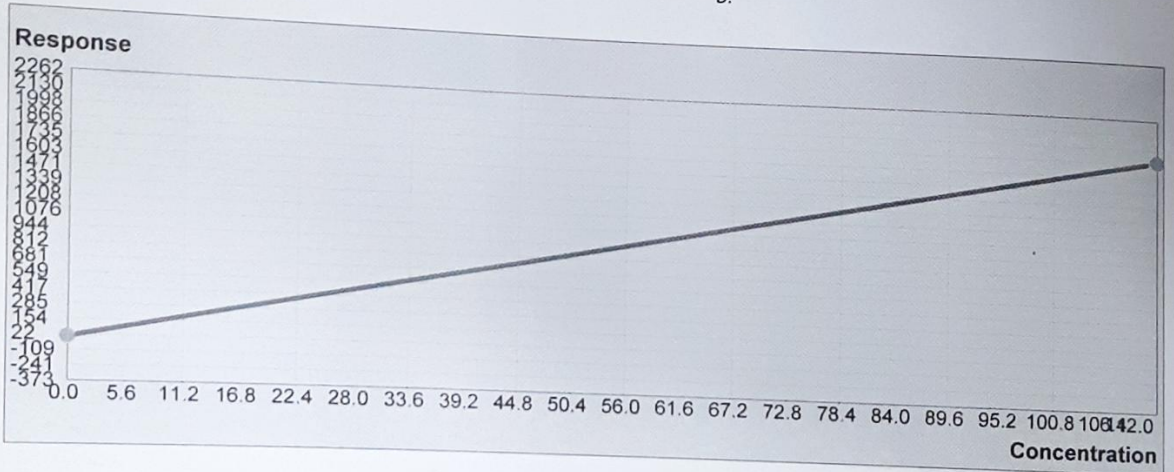

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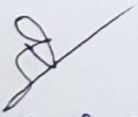

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Calibration Curve

Test: TGL AG
Rule: Two-point Linear
K:
B: 2.75914

Date/Time: 06-03-2019 14:04:53
Reagent Blank: -12.062941292207
A: 16.81299
R0:
C:
D:




performed By.


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