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**AGAPPE**

# INSTALLATION QUALIFICATION

For

**FULLY AUTOMATED CLINICAL CHEMISTRY**

**ANALYZER MODEL : MISPA NANO PLUS**

**AGAPPE DIAGNOSTICS LTD**

ADL/MO/SER/062/23-24

**AGAPPE DIAGNOSTICS LTD.** ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24239MM1998PLC115413

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## 1. APPROVAL OF THE INSTALLATION QUALIFICATION PROCEDURE

Both **MICROPATH LABORATORY, KOLHAPUR** and **AGAPPE DIAGNOSTICS LTD.** are jointly

responsible for the installation of **MISPA NANO PLUS** with serial number **BAI-34001973** at “**MICROPATH LABORATORY, OM PLAZA KONDA LANE, LAXMI PURI, KOLHAPUR, PIN NO - 416002**” as per the attached

Installation Qualification protocol.

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

Name	: PRASAD UNDE	Signature :	
Designation	: Product Specialist	Date	: 14-07-2023
Company	: AGAPPE DIAGNOSTICS LTD		

### Validation Team from MICROPATH LABORATORY, KOLHAPUR

Name	: Dr. Manishy Kulkarni	Signature :	
Designation	: M.D. Path	Date	: 14/7/23
Department	: Pathology		

### Customer Authorizations:

Name : Dr. Manishy Kulkarni  
Title : INSTALLATION QUALIFICATION  
Site : Kolhapur  
Signature :  
Date : 14/7/23

H5/R00

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

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## II. INSTRUCTIONS

1. An authorized **AGAPPE DIAGNOSTICS LTD.** representative will check and enter the specific data as outlined in the Installation Qualification. Each result will be noted and dated.
2. The concerned employees of **MICROPATH LABORATORY , KOLHAPUR** 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**.

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### **III. SCOPE**

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

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

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**IV. INSTALLATION QUALIFICATION**

**A. Instrument Identification**

Verified Date : 14-07-2023

1. Model Name : MISPA NANO PLUS
2. Serial Number : BAI-34001973

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

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

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

**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 : U24239MH1998PLC115413

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**Instrument Installation**

**AGAPPE**

Date of Installation : 14-07-2023  
 Installed by : PRASAD  
 UNDE

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

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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	PRASAD UNDE	14-07-2023
02	340 nm	PRASAD UNDE	14-07-2023
03	380 nm	PRASAD UNDE	14-07-2023
04	412 nm	PRASAD UNDE	14-07-2023
05	450 nm	PRASAD UNDE	14-07-2023
06	505 nm	PRASAD UNDE	14-07-2023
07	546 nm	PRASAD UNDE	14-07-2023
08	570 nm	PRASAD UNDE	14-07-2023
09	605 nm	PRASAD UNDE	14-07-2023
10	660 nm	PRASAD UNDE	14-07-2023
11	700 nm	PRASAD UNDE	14-07-2023
12	740 nm	PRASAD UNDE	14-07-2023
13	800 nm	PRASAD UNDE	14-07-2023

**Acceptance criteria:**

- No error Messages displayed
- All Cuvettes should show acceptance

**PARAMETER**                      **PASS** ✓

**EAII Parameter values for verification:** No

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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	PRASAD UNDE	14-07-2023

### 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 : U24239MH1998PLC15413

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**V. COMMENTS**

*Instrument working OK*

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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 : PRASAD UNDE

Designation : Product Specialist

Signature :



Company : AGAPPE DIAGNOSTICS LTD.

Date : 14/7/2023

Customer Authorizations: **MICROPATH LABORATORY**

Name : *Dr. Manish Kumar*

Designation : *m.d. path*

Signature :

Title : INSTALLATION QUALIFICATION

Date : 14/7/2023

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**AGAPPE**

# OPERATIONAL QUALIFICATION

For

**FULLY AUTOMATED CLINICAL**

**CHEMISTRY ANALYZER MODEL : MISPA**

**NANO PLUS**

**AGAPPE DIAGNOSTICS LTD.**

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

Both **MICROPATH LABORATORY , KOLHAPUR** and **AGAPPE DIAGNOSTICS LTD.** are

jointly responsible for the installation of **MISPA NANO PLUS** with serial number **BAI-34001973** at **"MICROPATH LABORATORY , OM PLAZA, KONDA LANE LAXMIPURI , KOLHAPUR , PIN NO - 416002"** as per the attached OPERATIONAL QUALIFICATION protocol.

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

Name	: PRASAD UNDE	 Signature :
Designation	: Product Specialist	
Company	: AGAPPE DIAGNOSTICS LTD.	Date : 14-07-2023

**Validation Team from MICROPATH LABORATORY , KOLHAPUR**

Name	: Dr Manisha Kulkarni	Signature :
Designation	: M.D. Path	Date : 14/7/23
Department	: Pathology	

**Customer Authorizations:**

Name : Dr Manisha Kulkarni  
 Title : OPERATIONAL QUALIFICATION      Signature :  
 Site : Kolhapur      Date : 14/7/23





**ii. INSTRUCTIONS**

- 4. 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.
  
- 5. ALL deviations from the acceptance criteria detailed in this document will be noted in the **COMMENTS** section at the end of the OQ protocol. All resolution to such problems will also be noted in the **COMMENTS** section, and must be resolved prior to issuance of a **SYSTEM CERTIFICATION**.

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### III. SCOPE

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

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#### IV. OPERATIONAL QUALIFICATION

- Instrument Identification**

Verified Date : 14-07-2023

- Model Name : MISPA NANO PLUS
- Serial Number : BAI-34001973

- 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	PRASAD UNDE14- 07-2023
02	Daily maintenance	To clean appropriate modules	PRASAD UNDE14- 07-2023
03	Calibration	To calibrate the system	PRASAD UNDE 14- 07-2023
04	QC check	To confirm that the system is calibrated and working within specifications	PRASAD UNDE14- 07-2023
05	Reproducibility check	To check the precision [CV %] after calibration	PRASAD UNDE14- 07-2023
06	Sample programming and Analysis	To run the samples	PRASAD UNDE 14- 07-2023
07	Shut down procedure	To shut down the system	PRASAD UNDE 14-07-2023

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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:

- iii. Wait for the instrument to get ready after initialization
- iv. Check the room temperature and switch on the Air Conditioner
- v. Check the UPS.
- vi. Switch on the MISPA NANO PLUS by pressing the main switch, then switch on the computer and then the system power
- vii. Double click the analyzer icon to initialize the system software
- viii. Input the password and do as prompted, the system menu pops up if start up is finished
- ix. If not, initialize by again after solving the error displayed
- x. 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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**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	PRASAD UNDE	14-07-2023
02	Check Wash solutions	PRASAD UNDE	14-07-2023
03	Check system water	PRASAD UNDE	14-07-2023
04	Check Reagents	PRASAD UNDE	14-07-2023
05	Clean Reagent Block	PRASAD UNDE	14-07-2023
06	Clean out side area	PRASAD UNDE	14-07-2023
07	Load supplies and remove outdated and empty reagents	PRASAD UNDE	14-07-2023
08	Check main menu screen	PRASAD UNDE	14-07-2023
09	Perform Quality Control	PRASAD UNDE	14-07-2023

**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	PRASAD UNDE	14-07-2023
02	Performing Calibration with calibration programming screen	PRASAD UNDE	14-07-2023

**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	PRASAD UNDE	14-07-2023
02	Creating QC file	PRASAD UNDE	14-07-2023
03	QC sample programming and analysis	PRASAD UNDE	14-07-2023

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

PARAMETER PASS FAIL

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



### Test 05: Reproducibility Check

**Purpose:** To check the reproducibility of instrument

S No.	Activity	Done By	Date
01	Preparing control material/ sample	PRASAD UNDE	14-07-2023
02	Running triplicates	PRASAD UNDE	14-07-2023

**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	PRASAD UNDE	14-07-2023
02	Programming samples	PRASAD UNDE	14-07-2023
03	Aspirating the samples	PRASAD UNDE	14-07-2023
04	Viewing samples in process	PRASAD UNDE	14-07-2023
05	Review results: Monitoring results	PRASAD UNDE	14-07-2023

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

PARAMETER      **PASS**      FAIL

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

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## Test 10: Shut down

# AGAPPE

**Purpose:** To shut down the system

**Procedure:**

S No.	Activity	Done By	Date
01	Preparing the system for shut down	PRASAD UNDE	14-07-2023
02	Following the on screen instructions	PRASAD UNDE	14-07-2023
03	Switch off the instrument when prompted	PRASAD UNDE	14-07-2023

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

**PARAMETER**    **PASS**    **FAIL**

**Parameter values for verification:** Shut down without any error

## IX. 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	TM	14/7/23
2	System Operation	TM	14/7/23
3	Basic trouble shooting and Maintenance	MP	14/7/23

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**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)	ms. sujatha Bhiraj	Lub Tech	SB	14/7/23
2)	ms. madhavi prasad V	Lub Tech	MP	14/7/23
3)	ms. Tonyyuba mulla	Lub Tech	TM	14/7/23
4)	ms. pratik neelamde	Lub Tech	PN	14/7/23
5)	ms. Adhul khatage	Lub Tech	AG	14/7/23
6)	ms. vaishya Kozari	Lub Tech	VK	14/7/23

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**AGAPPE**

**VI. 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.**

RepresentativeName : **PRASAD UNDE**

Designation : **Product Specialist**

Designation :  
Company : **AGAPPE DIAGNOSTICS LTD.**



Signature :  
Date : **14/7/23**

Customer Authorizations: **MICROPATH LABORATORY , KOLHAPUR**

Name : **Dr. Manisha Kulkarni**

Designation : **M.D. Path**

Title : **OPERATIONAL QUALIFICATION**

Signature :  
Date : **14/7/23**

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# PERFORMANCE QUALIFICATION

For

**FULLY AUTOMATED CLINICAL  
CHEMISTRY ANALYZER MODEL : MISPA  
NANO PLUS**

**AGAPPE DIAGNOSTICS LTD.**

ADL/MO/SER/052/23-24  
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**I. APPROVAL OF THE PERFORMANCE QUALIFICATION PROCEDURE**

Both **MICROPATH LABORATORY , KOLHAPUR** and **AGAPPE DIAGNOSTICS LTD.** are

jointly responsible for the installation of **MISPA NANO PLUS** with serial number **BAI-34001973** at **"MICROPATH LABORATORY , OM PLAZA ,KONDA LANE ,LAXMIPURI KOLHAPUR , PIN NO - 416002 "** as per the attached **PERFORMANCE QUALIFICATION** protocol.

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

Name	: PRASAD UNDE	 Signature :
Designation	: Product Specialist	
Company	: AGAPPE DIAGNOSTICS LTD.	Date : 14-07-2023

**Validation Team from MICROPATH LABORATORY , KOLHAPUR**

Name	: <i>Dr. Manisha Kulkarni</i>	Signature :
Designation	: <i>m. D. path</i>	Date : <i>14/7/23</i>
Department	: <i>pathology</i>	

**Customer Authorizations:**

Name : *Dr. Manisha Kulkarni*  
 Title : PERFORMANCE QUALIFICATION  
 Site : *Kolhapur*  
 Signature :  
 Date : *14/7/23*

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

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## II. INSTRUCTIONS

**AGAPPE**

1. An authorized **AGAPPE DIAGNOSTICS LTD.** representative will check and enter the specific data as outlined in the Performance Qualification. Each result will be noted and dated.
2. The concerned employees of **MICROPATH LABORATORY , KOLHAPUR** will verify each result and sign in each page. The member of the validation team will carry this out.
3. All deviations from the acceptance criteria detailed in this document will be noted in the **COMMENTS** section at the end of the PQ protocol. All resolution to such problems will also be noted in the **COMMENTS** section, and must be resolved prior to issuance of a **SYSTEM CERTIFICATION**.

### AGAPPE DIAGNOSTICS LTD.

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### III.SCOPE

This Performance Qualification protocol will be performed on the **MISPA NANO PLUS** at **MICROPATH LABORATORY , KOLHAPUR** . 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.**

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## PERFORMANCE QUALIFICATION

# AGAPPE

### G. Instrument Identification

Verified Date : 14-07-2023

1. Model Name : MISPA NANO PLUS
2. Serial Number : BAI-34001973

### H. 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	PRASAD UNDE14- 07-2023
02	Daily maintenance	To clean appropriate modules	PRASAD UNDE14- 07-2023
03	Cell blank	To check the cuvettes	PRASAD UNDE14- 07-2023
04	Priming	To check the tubing's, and flow	PRASAD UNDE14- 07-2023
05	Auto gain	To check the cuvette and photometry system	PRASAD UNDE14- 07-2023
06	Calibration	To calibrate the system	PRASAD UNDE14- 07-2023
07	QC check	To confirm that the system and reagents are acceptable and working within specifications	PRASAD UNDE14- 07-2023
08	Reproducibility check	To check the precision [CV %]	PRASAD UNDE14- 07-2023
09	Sample programming and Analysis	To run the samples	PRASAD UNDE14- 07-2023
10	Shut down procedure	To shut down the system	PRASAD UNDE14- 07-2023

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**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:**

- I.** Wait for the instrument to get ready after initialization
- II.** Check the room temperature and switch on the Air Conditioner
- III.** Check the UPS.
- IV.** Switch on the MISPA NANO PLUS by pressing the main switch, then switch on the computer and then the system power
- V.** Double click the analyzer icon to initialize the system software
- VI.** Input the password and do as prompted, the system menu pops up if start up is finished
- VII.** If not, initialize by again after solving the error displayed
- VIII.** 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

## AGAPPE DIAGNOSTICS LTD.

ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN - U24239MH1998PL115413

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### Test: Daily Maintenance

# AGAPPE

**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	PRASAD UNDE	14-07-2023
02	Check Wash solutions	PRASAD UNDE	14-07-2023
03	Check system water	PRASAD UNDE	14-07-2023
04	Check Reagents	PRASAD UNDE	14-07-2023
05	Clean Reagent Block	PRASAD UNDE	14-07-2023
06	Clean out side area	PRASAD UNDE	14-07-2023
07	Load supplies and remove outdated and empty reagents	PRASAD UNDE	14-07-2023
08	Check main menu screen	PRASAD UNDE	14-07-2023
09	Perform Quality Control	PRASAD UNDE	14-07-2023

**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.

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**Test 03: Cell Blank**
**AGAPPE****Purpose:** To check the cuvette blank OD at different wavelength**Procedure:**

S No.	Activity	Done By	Date
01	Checking the Cell blank	PRASAD UNDE	14-07-2023
	340 nm	PRASAD UNDE	14-07-2023
	380 nm	PRASAD UNDE	14-07-2023
	412 nm	PRASAD UNDE	14-07-2023
	450 nm	PRASAD UNDE	14-07-2023
	505 nm	PRASAD UNDE	14-07-2023
	546 nm	PRASAD UNDE	14-07-2023
	570 nm	PRASAD UNDE	14-07-2023
	605 nm	PRASAD UNDE	14-07-2023
	660 nm	PRASAD UNDE	14-07-2023
	700 nm	PRASAD UNDE	14-07-2023
	740 nm	PRASAD UNDE	14-07-2023
	800 nm	PRASAD UNDE	14-07-2023

**Acceptance criteria:**

- No error Messages displayed
- All Cuvettes should show acceptance

PARAMETER

PASS ✓

FAIL

Parameter values for verification: No Error Messages

**AGAPPE DIAGNOSTICS LTD.**

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**Test 04: Priming**

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

S No	Activity	Done By	Date
01	Do wash using the maintenance screen	PRASAD UNDE	14-07-2023

**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	PRASAD UNDE	14-07-2023

**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 *	PRASAD UNDE	14-07-2023
02	Performing Calibration with calibration programming screen	PRASAD UNDE	14-07-2023

\*Traceability of the calibrator used is attached

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

PARAMETER      **PASS**      **FAIL**

**Parameter values for verification** : No error message in the printout

**Test 07: QC check**

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

**Procedure:**

S No.	Activity	Done By	Date
01	Preparing Biochemistry control material	PRASAD UNDE	14-07-2023
02	Creating QC file	PRASAD UNDE	14-07-2023
03	QC sample programming and analysis	PRASAD UNDE	14-07-2023

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

PARAMETER

**PASS**      **FAIL**

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

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### Test 08: Reproducibility Check

**Purpose:** To check the reproducibility of instrument

S No.	Activity	Done By	Date
01	Preparing control material/ sample	PRASAD UNDE	14-07-2023
02	Running triplicates	PRASAD UNDE	14-07-2023

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	PRASAD UNDE	14-07-2023
02	Programing samples	PRASAD UNDE	14-07-2023
03	Aspirating the samples	PRASAD UNDE	14-07-2023
04	Viewing samples in process	PRASAD UNDE	14-07-2023
05	Review results: Monitoring results	PRASAD UNDE	14-07-2023

Acceptance criteria: Samples Analysis without any error

PARAMETER    PASS    FAIL

Parameter values for verification: Sample analysis without any error

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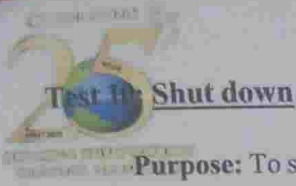
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**Purpose:** To shut down the system

**Procedure:**

S No.	Activity	Done By	Date
01	Preparing the system for shut down	PRASAD UNDE	14-07-2023
02	Following the on screen instructions	PRASAD UNDE	14-07-2023
03	Switch off the instrument when prompted	PRASAD UNDE	14-07-2023

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

PARAMETER  PASS  FAIL

**Parameter values for verification:** Shut down without any error

**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	mt	14/7/23
2.	System Operation	tm	14/7/23
3.	Basic trouble shooting and Maintenance	mt	14/7/23

**AGAPPE DIAGNOSTICS LTD.**

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**MUMBAI (REGISTERED OFFICE)**  
 401 B 402, 4<sup>th</sup> Floor, Jai Singh Business Centre, 119,  
 Sakar Road, Parkshada, Andheri (East), Mumbai - 400 099, India.  
 Tel: +91 22 4300 8000 | Email: mumbai@agappe.in

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

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

**KOLKATA OFFICE**  
 406, Merlin Matrix, Plot No-10, Block-08, Sector V,  
 Salt Lake City, Kolkata - 700 091.  
 Tel: +91 33 4003 0451 | Email: kolkata@agappe.in

**BANGALORE OFFICE**  
 5-0, II<sup>nd</sup> Floor, Red Cross Bhawan, No-26 Race Course Road,  
 Bangalore - 560 001. Tel: +91 80 2228 8288.  
 Email: bangalore@agappe.in

www.agappe.com



**V. COMMENTS**

**AGAPPE**

All staffs trained & found satisfactory  
to work on instrument

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

**CORPORATE OFFICE / REAGENT PLANT**  
Agappe Hills, Parturattian (PO), Dec, Ernakulam, Kerala - 687 562, India.  
Tel: +91 484 286 7000 | Email: agappe@agappe.in

**MUMBAI (REGISTERED OFFICE)**  
401 & 402, 4<sup>th</sup> Floor, Eastleigh Business Centre, 119,  
Silver Road, Parklands, Andheri (East), Mumbai - 400 099, India.  
Tel: +91 22 4300 8000 | Email: mumbai@agappe.in

**EQUIPMENT PLANT**  
K/588 CB, Block No. 32, KINFRA Small Industrial Park,  
Heliad, Cochin, Kerala, India - 685 721. Tel: +91 484 276 7477.

**DELHI OFFICE**  
DSM 540, 5<sup>th</sup> Floor, DLF Tower, Shivalik Marg,  
New Delhi - 110 015, India.  
Tel: +91 11 4350 8416 | Email: delhi@agappe.in

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

**BANGALORE OFFICE**  
5-6, 1<sup>st</sup> Floor, Red Cross Bhawan, No-25 Race Course Road,  
Bangalore - 560 001. Tel: +91 80 2378 8288  
Email: bangalore@agappe.in

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**AGAPPE**

**VI. SYSTEM CERTIFICATION**

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

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

RepresentativeName : PRASAD UNDE

Designation : Product Specialist

Company : AGAPPE DIAGNOSTICS LTD.

Signature :

Date :



14/7/23

Customer Authorizations: **MICROPATH LABORATORY , KOLHAPUR**

Name : Dr. Manisha Juykumari

Designation : M.D. Path

Title : PERFORMANCE QUALIFICATION

Signature :

Date :

14/7/23

**AGAPPE DIAGNOSTICS LTD.**

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

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

**MUMBAI (REGISTERED OFFICE)**  
471 & 452, 4<sup>th</sup> Floor, Jaisingh Business Centre, 119, Sahar Road, Park Road, Andheri (East), Mumbai - 400 099, India.  
Tel: +91 22 4300 8000 | Email: mumbai@agappe.in

**EQUIPMENT PLANT**  
3/238-1B, Block No. 32, KINFRA Small Industrial Park, Helipad, Cochin, Kerala, India - 686 722. Tel: +91 484 276 7477.

**DELHI OFFICE**  
D5M 540, 5<sup>th</sup> Floor, DLF Tower, Shivaji Marg, New Delhi - 110 015, India.  
Tel: +91 11 4356 8416 | Email: delhi@agappe.in

**KOLKATA OFFICE**  
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Tel: +91 33 4903 0451 | Email: kolkata@agappe.in

**BANGALORE OFFICE**  
5-6, 6<sup>th</sup> Floor, Red Cross Bhawan, Near Race Course Road, Bangalore - 560 001. Tel: +91 80 2228 8288  
Email: bangalore@agappe.in

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### Cuvette Blank Result

CLV	340	380	412	450	505	546	570	605	660	700	740	800
1	14491	13926	13029	12443	11854	11403	11224	11024	10693	10471	10269	10082
2	15233	14536	13669	13066	12429	11940	11740	11521	11148	10897	10672	10448
3	15116	14478	13609	13036	12442	11978	11793	11592	11247	11019	10814	10628
4	13382	12661	11838	11259	10639	10151	9955	9736	9368	9114	8894	8674
5	13226	12523	11697	11107	10480	9991	9795	9572	9197	8946	8721	8493
6	13828	13215	12347	11764	11153	10680	10489	10274	9911	9666	9443	9217
7	14503	13776	12910	12299	11635	11119	10902	10663	10263	9995	9754	9513
8	13481	12914	11972	11372	10752	10282	10087	9875	9515	9279	9058	8851
9	13708	13093	12152	11548	10926	10449	10254	10033	9670	9430	9207	8993
10	13731	13076	12151	11553	10919	10429	10233	10005	9633	9389	9161	8933
11	14326	13595	12719	12093	11433	10934	10723	10493	10101	9845	9609	9383
12	14459	13674	12861	12251	11590	11072	10857	10615	10204	9925	9671	9403
13	13773	13015	12216	11643	11013	10501	10298	10056	9654	9378	9137	8892
14	14123	13539	12651	12043	11416	10935	10745	10519	10152	9899	9669	9439
15	13809	13126	12289	11716	11100	10617	10421	10202	9824	9567	9339	9109
16	14091	13417	12520	11908	11252	10738	10528	10283	9880	9608	9366	9115
17	13992	13291	12393	11773	11109	10598	10388	10147	9753	9486	9244	9002
18	13990	13321	12448	11859	11241	10750	10555	10327	9949	9699	9466	9232
19	14434	13611	12744	12129	11482	10985	10784	10550	10167	9908	9672	9433
20	14262	13480	12592	11984	11342	10848	10646	10417	10037	9782	9555	9326
21	13690	13109	12306	11727	11133	10674	10491	10282	9938	9704	9491	9283
22	14447	13810	12949	12344	11714	11226	11030	10809	10438	10192	9964	9741
23	13790	13183	12397	11861	11299	10850	10675	10479	10139	9907	9699	9498
24	13647	12979	12126	11547	10940	10469	10280	10071	9720	9482	9269	9062
25	14384	13631	12780	12173	11515	11004	10793	10559	10165	9900	9665	9423
26	13633	12987	12084	11471	10828	10344	10144	9925	9554	9312	9091	8873
27	13159	12533	11695	11136	10547	10077	9892	9680	9327	9088	8870	8658
28	13186	12537	11690	11121	10510	10030	9839	9621	9255	9007	8781	8553
29	14285	13571	12729	12117	11453	10933	10722	10476	10071	9798	9550	9289
30	13268	12693	11719	11115	10488	10013	9822	9603	9247	9012	8795	8588
31	14141	13362	12562	11956	11297	10772	10563	10316	9908	9629	9379	9111

## Cuvette Blank Result

Cuv	340	380	412	450	505	546	570	605	660	700	740	800
32	14023	13393	12563	11947	11310	10828	10632	10409	10039	9791	9561	9332
33	13395	12680	11805	11185	10526	10018	9812	9574	9187	8925	8692	8462
34	13156	12414	11588	11005	10377	9878	9677	9450	9068	8808	8581	8348
35	13913	13169	12294	11663	10981	10456	10239	9991	9579	9305	9059	8803
36	13663	12993	12060	11430	10760	10255	10046	9809	9418	9159	8924	8689
37	13369	12686	11814	11207	10561	10064	9860	9630	9249	8992	8761	8532
38	14521	13719	12851	12218	11506	10943	10716	10445	10003	9705	9441	9159
39	14203	13502	12588	11946	11264	10749	10536	10292	9893	9635	9392	9152
40	14051	13310	12424	11834	11192	10683	10479	10246	9861	9613	9378	9148
41	14735	13975	13207	12619	11986	11479	11281	11046	10664	10402	10165	9922
42	14241	13548	12670	12044	11395	10898	10696	10470	10098	9848	9623	9405
43	12897	12274	11480	10935	10373	9928	9757	9562	9237	9011	8808	8617
44	12889	12173	11336	10787	10209	9746	9565	9367	9026	8789	8585	8393
45	13498	12812	11994	11402	10778	10294	10102	9881	9515	9260	9037	8811
46	12504	11889	11088	10557	9997	9556	9377	9187	8855	8630	8427	8229
47	12808	12176	11462	10950	10395	9934	9756	9550	9201	8954	8737	8508
48	12594	11870	11148	10662	10113	9647	9466	9266	8908	8662	8443	8217
49	13929	13361	12523	11966	11382	10923	10741	10535	10190	9962	9746	9537
50	12968	12346	11580	11090	10549	10092	9913	9713	9366	9126	8911	8694
51	12070	11431	10686	10162	9626	9202	9036	8857	8540	8320	8125	7938
52	14812	14154	13469	12933	12348	11873	11689	11470	11098	10834	10599	10354
53	12485	11784	11046	10531	9979	9525	9345	9151	8809	8569	8362	8154
54	11779	11182	10368	9826	9270	8831	8659	8470	8149	7930	7733	7548
55	12144	11654	10897	10389	9873	9459	9300	9125	8822	8611	8424	8245
56	11784	11172	10403	9900	9375	8948	8780	8602	8287	8071	7877	7694
57	13172	12469	11639	11083	10489	10015	9829	9621	9268	9033	8820	8620
58	12248	11551	10786	10280	9731	9275	9095	8901	8558	8325	8116	7908
59	12401	11855	11016	10483	9948	9535	9376	9201	8908	8713	8529	8370
60	12116	11560	10751	10250	9738	9322	9163	8987	8682	8478	8293	8123
61	12389	11801	10949	10409	9866	9442	9280	9102	8804	8606	8425	8272
62	13267	12687	11844	11274	10711	10286	10120	9936	9634	9427	9239	9073

### Cuvette Blank Result

Cuv	340	380	412	450	505	546	570	605	660	700	740	800
63	12741	12112	11301	10763	10202	9761	9591	9400	9080	8864	8671	8497
64	12691	12160	11332	10800	10257	9831	9668	9483	9173	8957	8765	8584
65	12317	11684	10889	10367	9820	9383	9215	9024	8698	8476	8275	8074
66	11975	11394	10555	10013	9455	9020	8847	8661	8339	8123	7927	7738
67	11846	11242	10410	9876	9321	8885	8712	8524	8203	7985	7787	7602
68	11567	11038	10213	9693	9159	8740	8574	8398	8091	7881	7691	7514
69	11546	10991	10189	9671	9146	8727	8564	8386	8082	7875	7685	7513
70	11956	11389	10525	9985	9425	8983	8808	8615	8290	8071	7871	7681
71	12350	11722	10954	10424	9874	9434	9268	9074	8752	8531	8331	8136
72	11749	11157	10399	9886	9365	8946	8787	8612	8309	8098	7912	7742
73	12012	11458	10549	9974	9400	8973	8802	8617	8314	8111	7923	7767
74	11621	11014	10230	9711	9174	8742	8574	8391	8078	7857	7663	7480
75	12627	12113	11265	10715	10166	9747	9585	9403	9096	8890	8696	8512
76	13270	12689	11763	11180	10582	10122	9937	9733	9391	9164	8958	8769
77	11567	10995	10179	9655	9112	8687	8519	8338	8030	7816	7626	7447
78	11526	11059	10193	9671	9150	8748	8592	8424	8134	7941	7761	7605
79	11961	11348	10563	10048	9511	9082	8911	8728	8411	8196	8002	7818
80	13739	13129	12270	11706	11116	10651	10466	10257	9914	9677	9467	9265

# Photometer Check

## Current Result

Test Time: 12-07-2023

## Last Result

Test Time: 29-10-2024

Wavelength(nm)	Absorbance	Wavelength(nm)	Absorbance
340	14280	340	12638
380	13612	380	12113
412	12764	412	11346
450	12178	450	10855
505	11564	505	10363
546	11088	546	9966
570	10897	570	9812
605	10681	605	9644
660	10326	660	9367
700	10086	700	9166
740	9869	740	8992
800	9661	800	8836

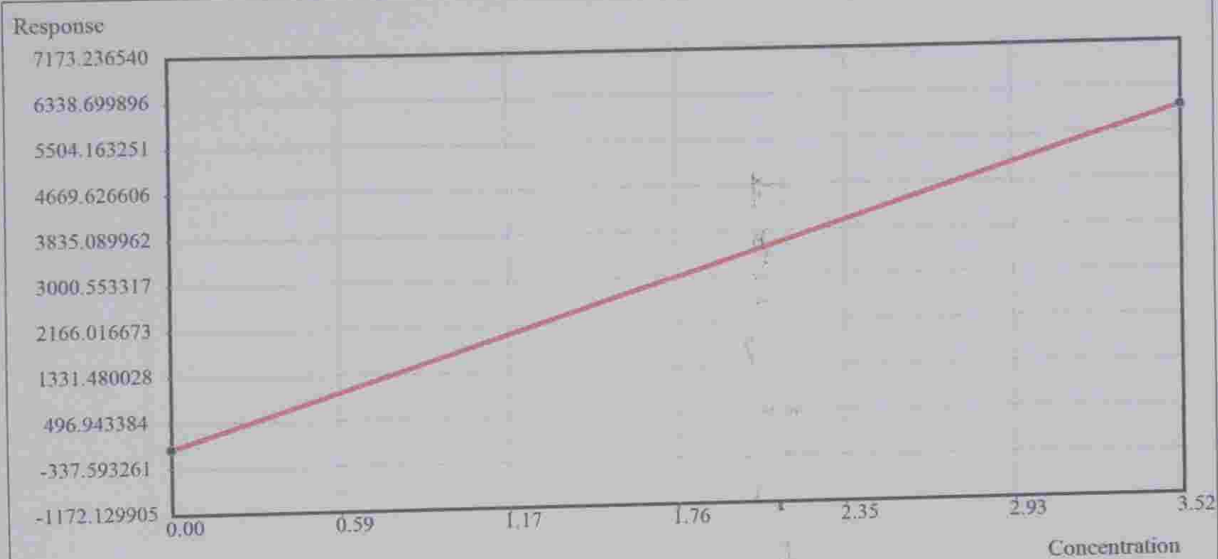
Print Date/Time: 12-07-2023 13:01:41

Page 1 of 1

# Calibration Report

Chemistry:	ALB	Math Model:	Two-Point Linear
Unit:	g/dL	Replicates:	1
		Cal Date/Time:	11-07-2023 13:03:22
Rgt Type	Lot No.	Serial No.	
		Rgt Type	Lot No.
			Serial No.

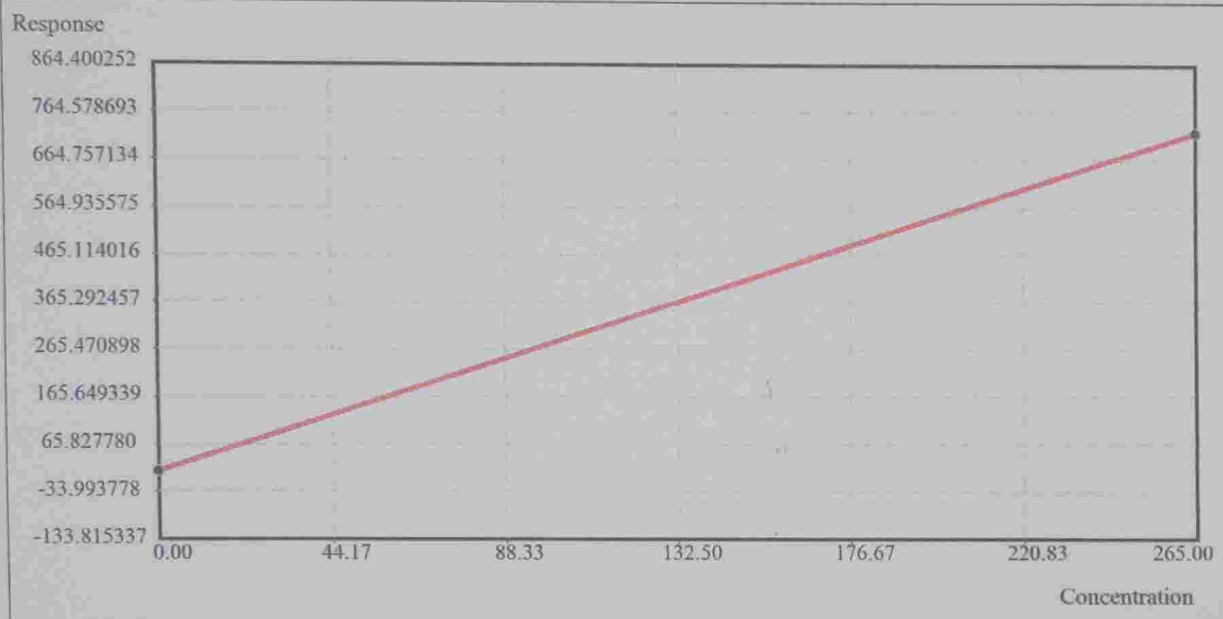
R1



Calibration Data			Calibration Parameter				
Calibrator	Conc	Resp	Lot No.	Parameter	Value	Parameter	Value
Water	0.00	20.1	123456	R0	20.0653		
Multi Cal	3.52	5981.0	33020264	K	0.0006		

# Calibration Report

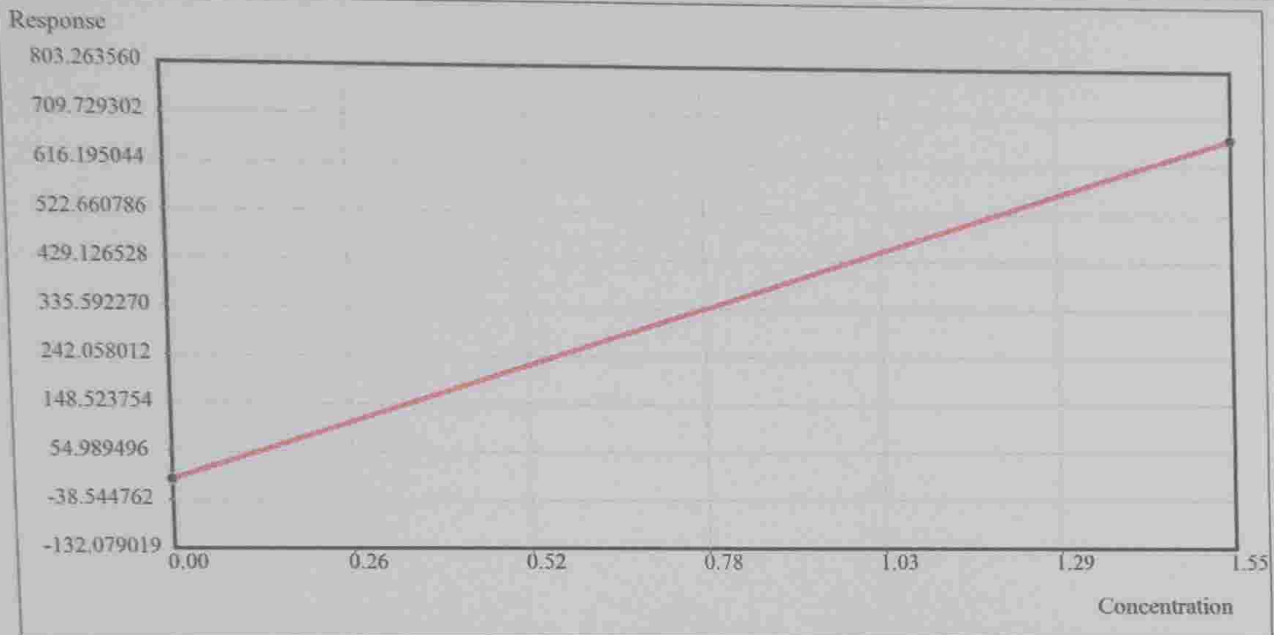
Chemistry:	ALP IFCC	Math Model:	Two-Point Linear
Unit:	IU/L	Replicates:	1
		Cal Date/Time:	11-07-2023 13:02:32
Rgt Type	Lot No.	Serial No.	
R1			
		Rgt Type	Lot No.
			Serial No.
		R2	



Calibration Data				Calibration Parameter			
Calibrator	Conc	Resp	Lot No.	Parameter	Value	Parameter	Value
Water	0.0	8.8	123456	R0	8.7869		
Multi Cal	265.0	721.8	33020264	K	0.3717		

# Calibration Report

Chemistry:	BIL D	Math Model:	Two-Point Linear
Unit:	mg/dL	Replicates:	1
		Cal Date/Time:	11-07-2023 13:04:52
Rgt Type	Lot No.	Serial No.	
		Rgt Type	Lot No.
			Serial No.
			R2

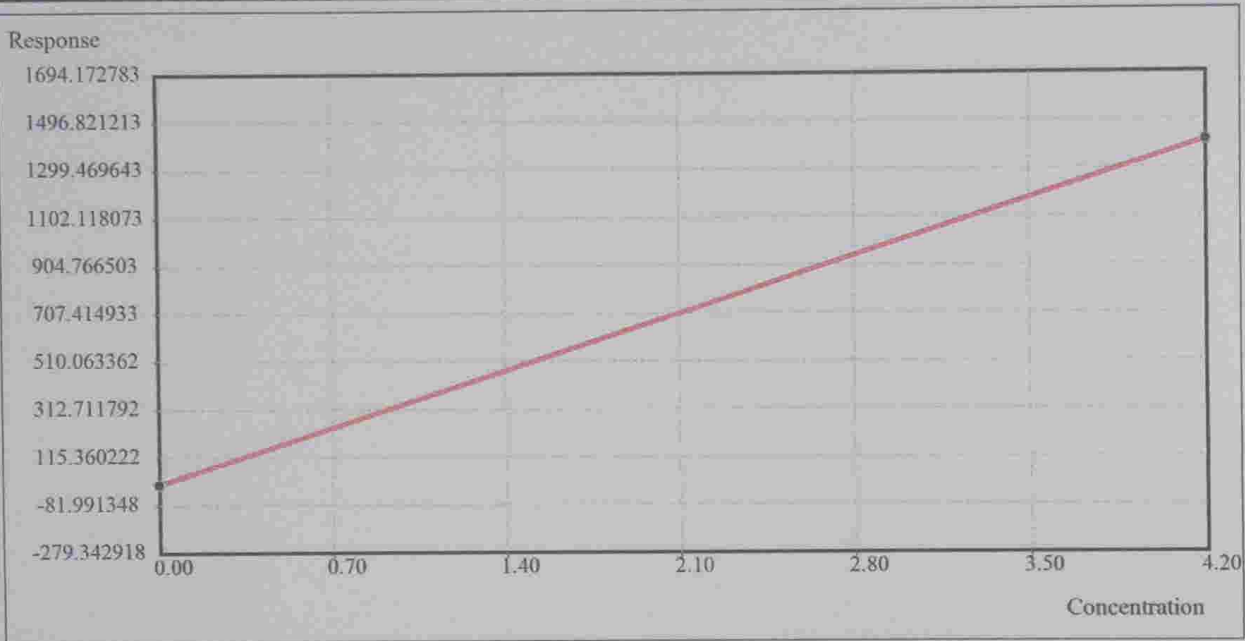


Calibration Data			Calibration Parameter				
Calibrator	Conc	Resp	Lot No.	Parameter	Value	Parameter	Value
Water	0.00	1.5	123456	R0	1.5413		
Multi Cal	1.55	669.6	33020264	K	0.0023		



# Calibration Report

Chemistry:	BIL T	Math Model:	Two-Point Linear
Unit:	mg/dL	Replicates:	1
		Cal Date/Time:	11-07-2023 13:05:31
Rgt Type	Lot No.	Serial No.	
R1			R2

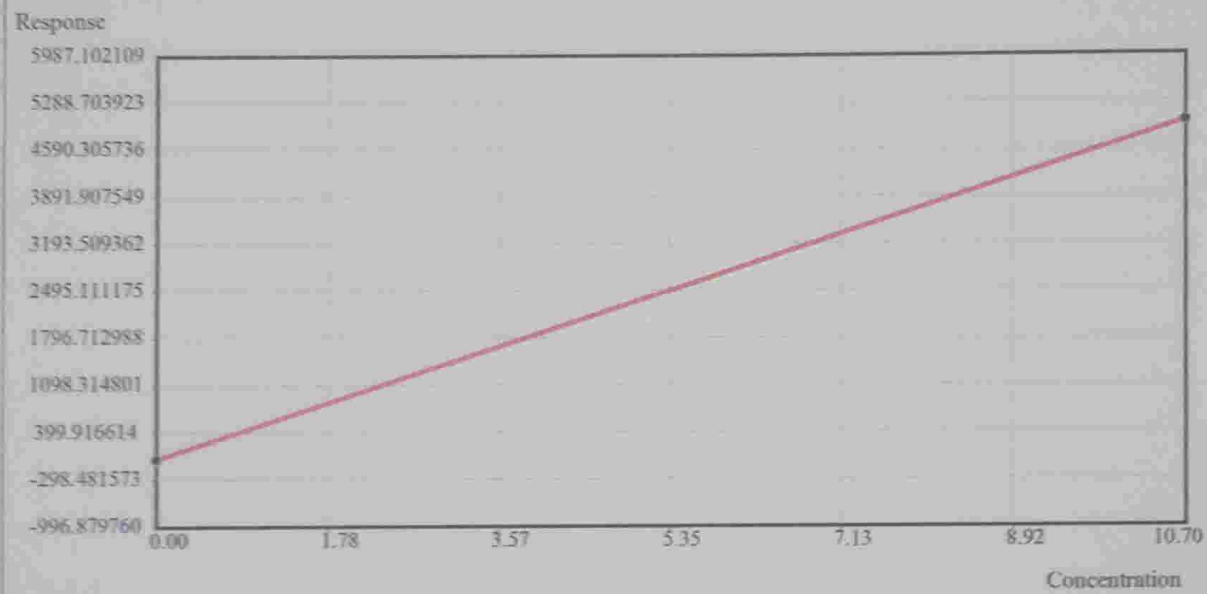


Calibration Data				Calibration Parameter			
Calibrator	Conc	Resp	Lot No.	Parameter	Value	Parameter	Value
Water	0.00	2.6	123456	R0	2.5879		
Multi Cal	4.20	1412.2	33020264	K	0.0030		

# Calibration Report

Chemistry:	CAL A	Math Model:	Two-Point Linear
Unit:	mg/dL	Replicates:	1
		Cal Date/Time:	11-07-2023 13:01:52
Rgt Type	Lot No.	Serial No.	Rgt Type
		Lot No.	Serial No.

R1

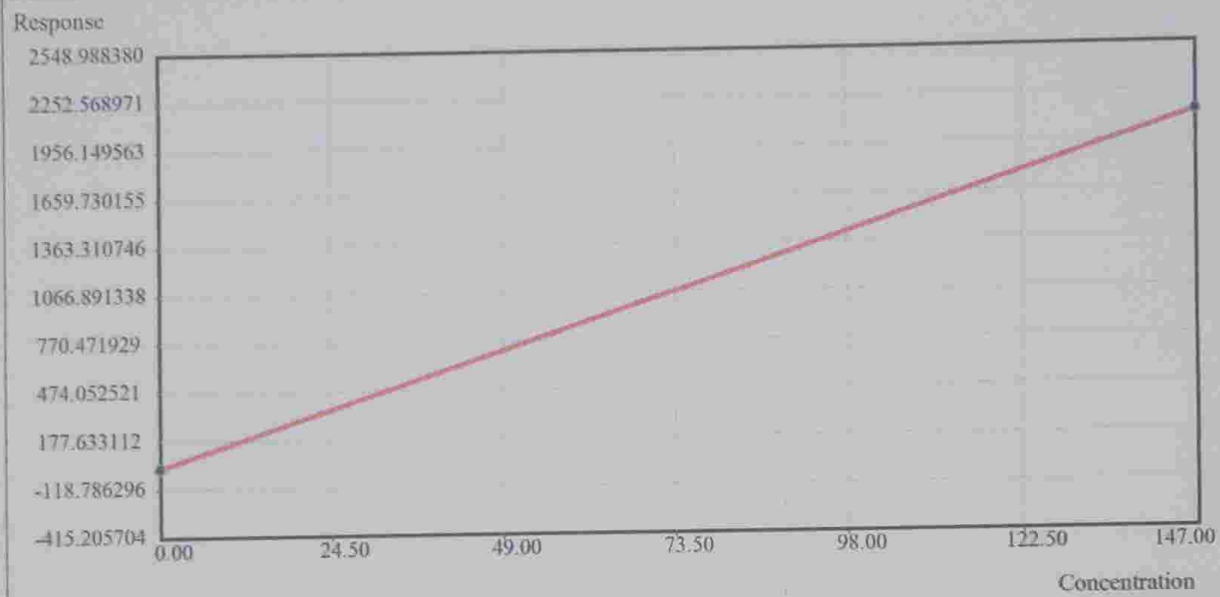


Calibration Data			Calibration Parameter				
Calibrator	Conc	Resp	Lot No.	Parameter	Value	Parameter	Value
Water	0.00	0.8	123456	R0	0.8319		
Multi Cal	10.70	4989.4	33020264	K	0.0021		

# Calibration Report

Chemistry:	CHOL	Math Model:	Two-Point Linear		
Unit:	mg/dL	Replicates:	1	Cal Date/Time:	11-07-2023 13:05:02
Rgt Type	Lot No.	Serial No.	Rgt Type	Lot No.	Serial No.

R1

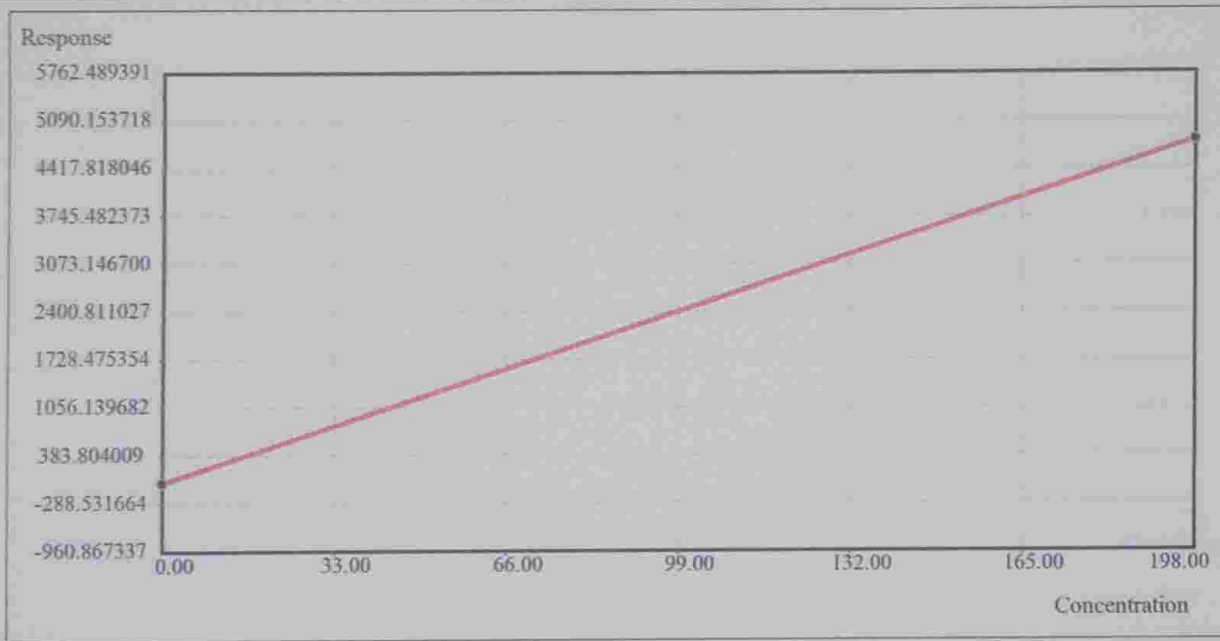


Calibration Data			Calibration Parameter				
Calibrator	Conc	Resp	Lot No.	Parameter	Value	Parameter	Value
Water	0.00	8.3	123456	R0	8.2506		
Multi Cal	147.00	2125.5	33020264	K	0.0694		

# Calibration Report

Chemistry: GLU POD      Math Model: Two-Point Linear  
Unit: mg/dL      Replicates: 1      Cal Date/Time: 11-07-2023 13:10:11  
Rgt Type      Lot No.      Serial No.      Rgt Type      Lot No.      Serial No.

R1



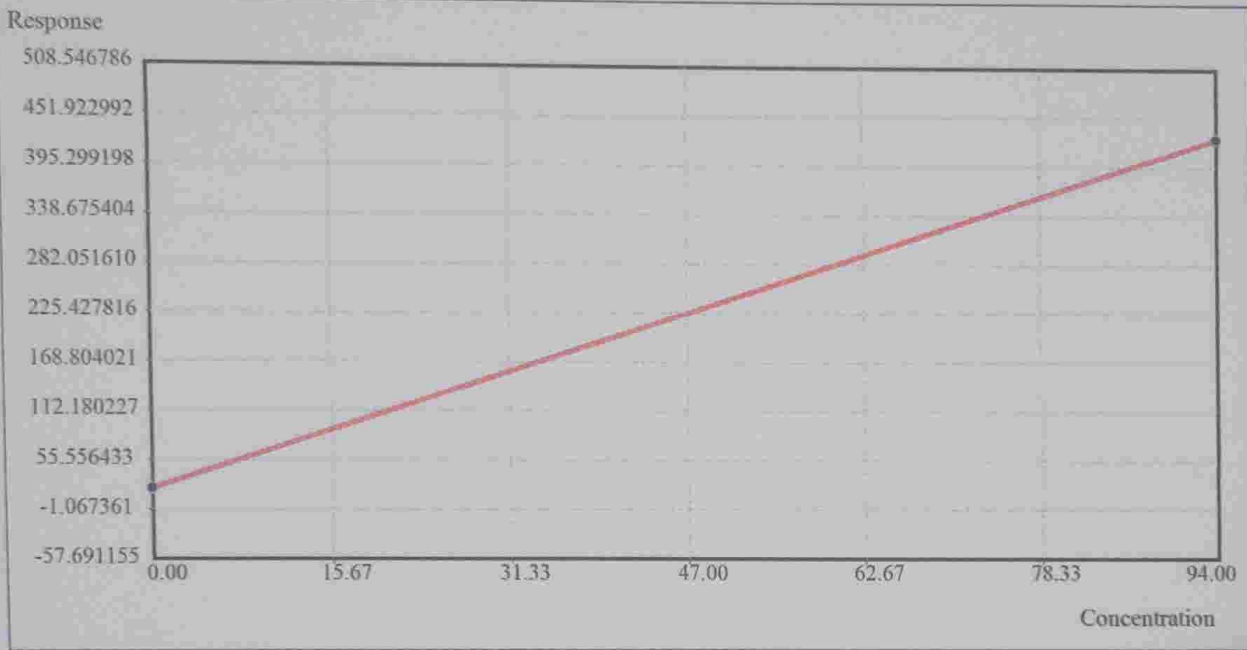
Calibration Data			Calibration Parameter				
Calibrator	Conc	Resp	Lot No.	Parameter	Value	Parameter	Value
Water	0.0	-0.4	123456	R0	-0.3878		
Multi Cal	198.0	4802.0	33020264	K	0.0412		

# Calibration Report

Chemistry: SGOT  
 Unit: IU/L  
 Rgt Type: Lot No. Serial No. Rgt Type Lot No. Serial No.

Math Model: Two-Point Linear  
 Cal Date/Time: 11-07-2023 13:04:42

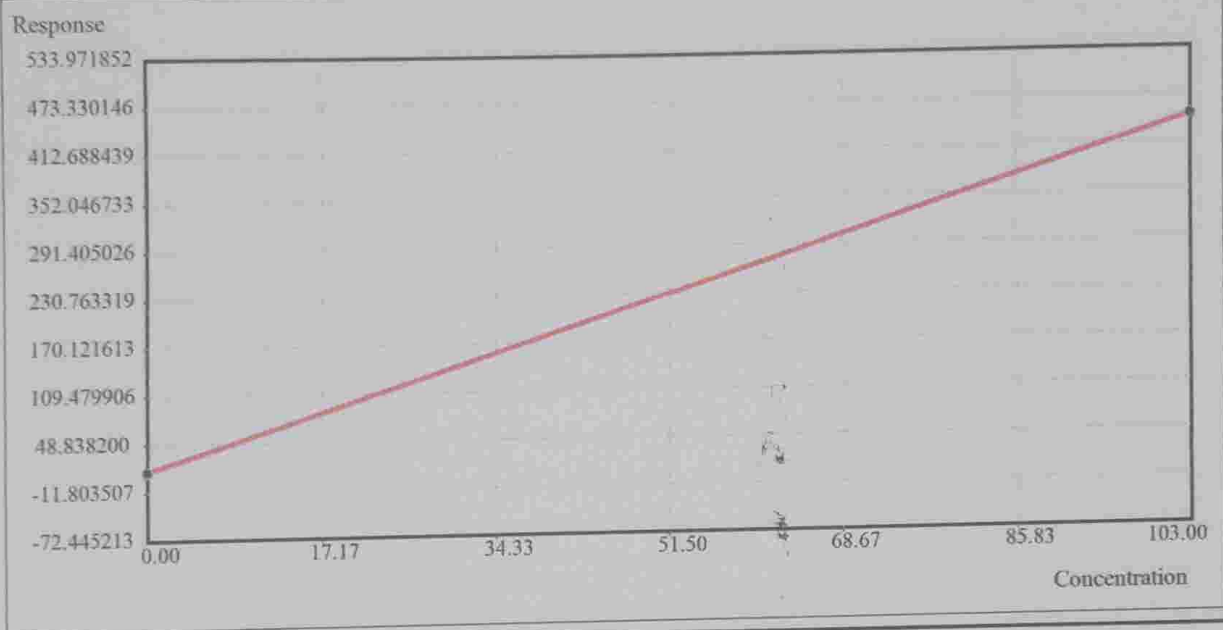
R1 R2



Calibration Data				Calibration Parameter			
Calibrator	Conc	Resp	Lot No.	Parameter	Value	Parameter	Value
Water	0.00	23.2	123456	R0	23.2000		
Multi Cal	94.00	427.7	33020264	K	0.2324		

# Calibration Report

Chemistry:	SGPT	Math Model:	Two-Point Linear		
Unit:	IU/L	Replicates:	1	Cal Date/Time:	11-07-2023 13:05:02
Rgt Type	Lot No.	Serial No.	Rgt Type	Lot No.	Serial No.
R1			R2		

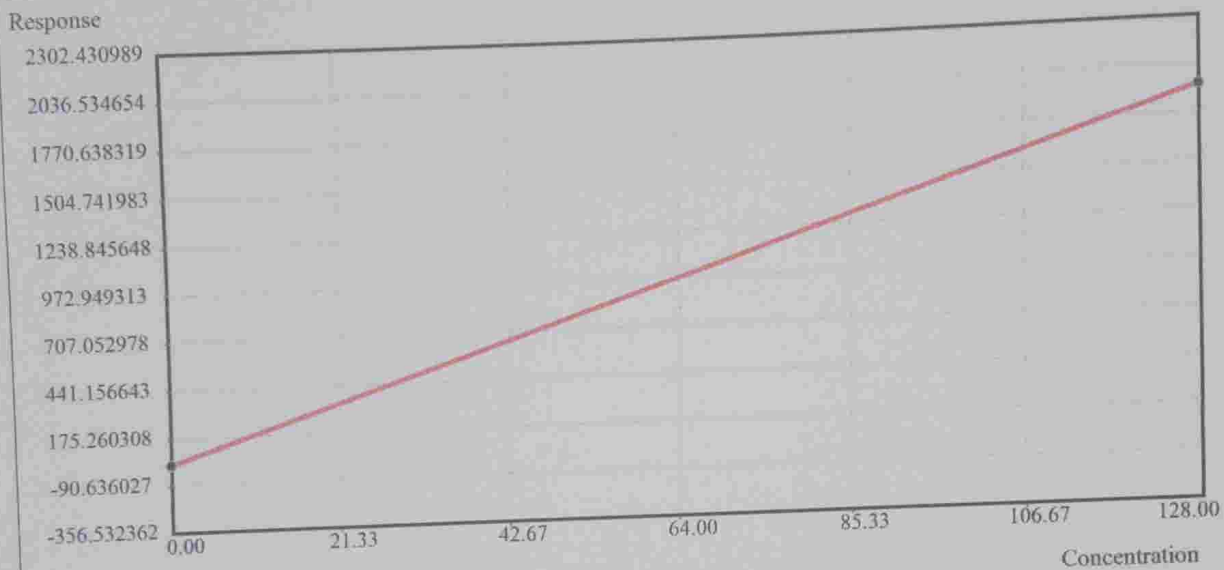


Calibration Data				Calibration Parameter			
Calibrator	Conc	Resp	Lot No.	Parameter	Value	Parameter	Value
Water	0.00	14.2	123456	R0	14.1858		
Multi Cal	103.00	447.3	33020264	K	0.2378		

# Calibration Report

Chemistry:	TGL	Math Model:	Two-Point Linear		
Unit:	mg/dL	Replicates:	1		
Rgt Type	Lot No.	Serial No.	Cal Date/Time:	11-07-2023 13:06:22	
			Rgt Type	Lot No.	Serial No.

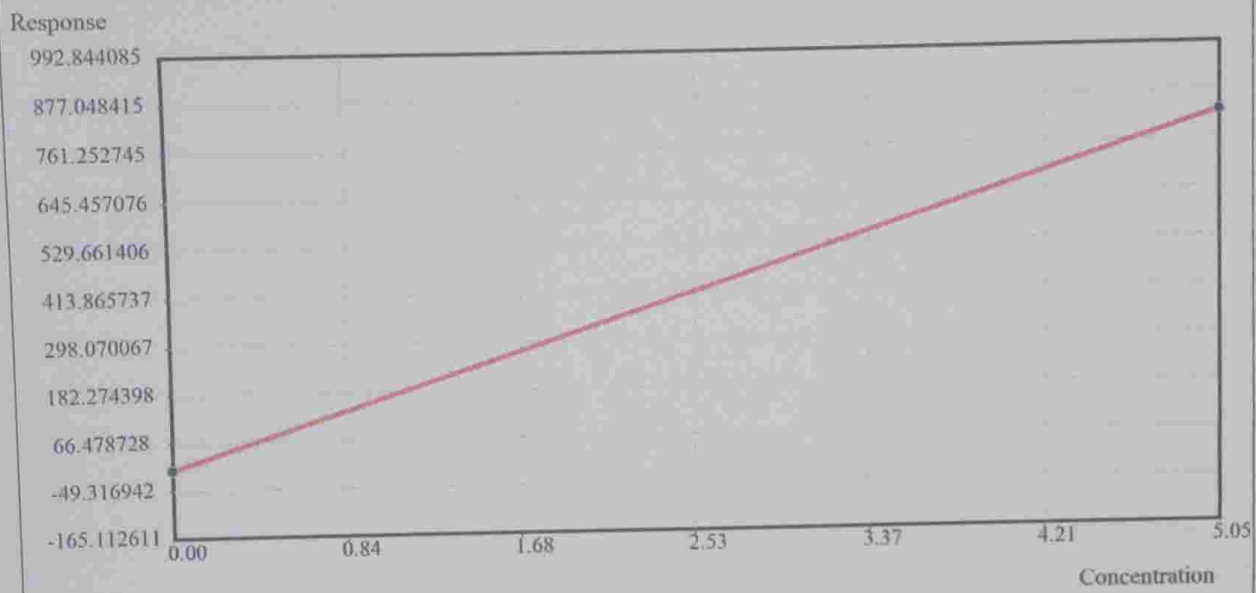
R1



Calibration Data				Calibration Parameter			
Calibrator	Conc	Resp	Lot No.	Parameter	Value	Parameter	Value
Water	0.00	23.3	123456	R0	23,3195		
Multi Cal	128.00	1922.6	33020264	K	0.0674		

# Calibration Report

Chemistry:	UAC	Math Model:	Two-Point Linear
Unit:	mg/dL	Replicates:	1
		Cal Date/Time:	11-07-2023 17:44:47
Rgt Type	Lot No.	Serial No.	
		Rgt Type	Lot No.
			Serial No.

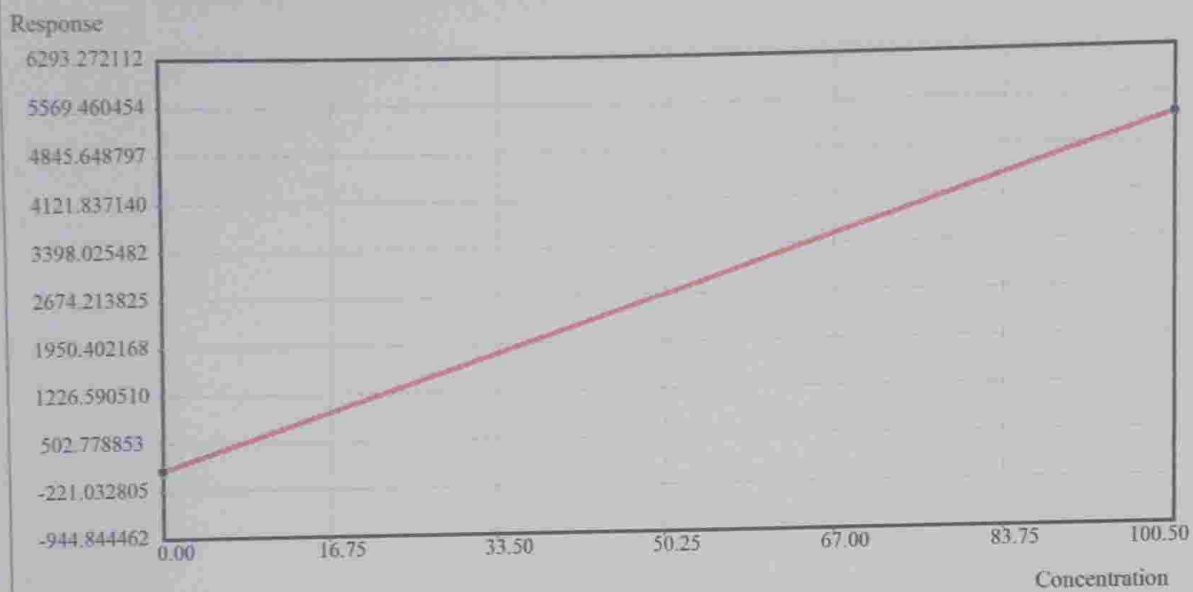


Calibration Data			Calibration Parameter				
Calibrator	Conc	Resp	Lot No.	Parameter	Value	Parameter	Value
Water	0.00	0.3	123456	R0	0.3098		
Multi Cal	5.05	827.4	33020264	K	0.0061		



# Calibration Report

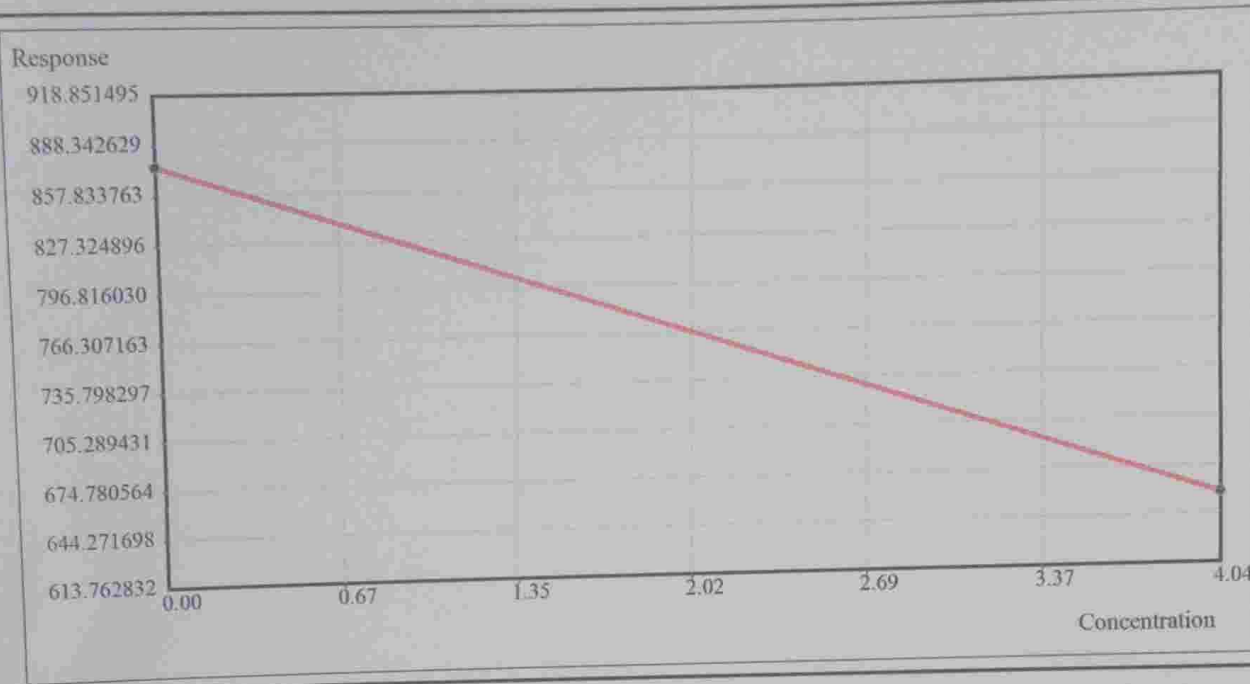
Chemistry:	UREA UV	Math Model:	Two-Point Linear
Unit:	mg/dL	Replicates:	1
		Cal Date/Time:	11-07-2023 13:04:32
Rgt Type	Lot No.	Serial No.	
R1			R2



Calibration Data				Calibration Parameter			
Calibrator	Conc	Resp	Lot No.	Parameter	Value	Parameter	Value
Water	0.00	89.2	123456	R0	89.1722		
Multi Cal	100.50	5259.3	33020264	K	0.0194		

# Calibration Report

Chemistry:	E CRT	Math Model:	Two-Point Linear		
Unit:	mg/dL	Replicates:	1		
		Cal Date/Time:	11-07-2023 17:49:16		
Rgt Type	Lot No.	Serial No.	Rgt Type	Lot No.	Serial No.
1			R2		



Calibration Data			Calibration Parameter				
Calibrator	Conc	Resp	Lot No.	Parameter	Value	Parameter	Value
WATER	0.00	875.3		R0	875.2674		
Multi Cal	4.04	657.3	33020264	K	-0.0185		

Standby

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Current

History

Statistics

Reaction Carousel

By Sample

By Chemistry



Type	Sample ID	Bar Code	Status	Completion Time	Print	Revi	Chemistry	Result	Flag
C	PATH	32402455	Complete	12-07-2023 09:58	Y		ALB	3.48	
C	QC NORM	32402455	Complete	12-07-2023 10:05	N		ALP IFCC	121.5	
R	1	74521F	Complete	12-07-2023 13:03	N	N	BIL D	0.40	
R	1	74613 F	Complete	13-07-2023 12:15	N	N	BIL T	0.74	
R	1	74687 R	Complete	14-07-2023 12:57	N	N	CAL A	8.62	
R	2	74522 F	Complete	12-07-2023 13:04	N	N	CHOL	152.50	
R	2	74618	Complete	13-07-2023 12:08	N	N	E CRT	1.02	
R	2	74688 R	Complete	14-07-2023 12:57	N	N	GLU POD	89.9	
R	3		Complete	11-07-2023 18:10	N	N	HDL D	39.59	
R	3	74524 F	Complete	12-07-2023 13:04	N	N	LDL D	105.12	
R	3	74623	Complete	13-07-2023 14:12	N	N	SGOT	30.75	
R	3	74696 F	Complete	14-07-2023 12:58	N	N	SGPT	31.01	
R	4	74420	Complete	11-07-2023 18:03	N	N	TGL	112.74	
R	4	74525 R	Complete	12-07-2023 13:04	N	N	UAC	4.77	

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Current

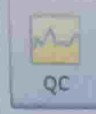
History

Statistics

Reaction Carousel

By Sample

By Chemistry



Type	Sample ID	Bar Code	Status	Completion Time	Print	Revi
C	PATH	32402455	Complete	12-07-2023 09:58	Y	
C	QC NORM	32402455	Complete	12-07-2023 10:05	N	
R	1	74521F	Complete	12-07-2023 13:03	N	N
R	1	74613 F	Complete	13-07-2023 12:15	N	N
R	1	74687 R	Complete	14-07-2023 12:57	N	N
R	2	74522 F	Complete	12-07-2023 13:04	N	N
R	2	74618	Complete	13-07-2023 12:08	N	N
R	2	74688 R	Complete	14-07-2023 12:57	N	N
R	3		Complete	11-07-2023 18:10	N	N
R	3	74524 F	Complete	12-07-2023 13:04	N	N
R	3	74623	Complete	13-07-2023 14:12	N	N
R	3	74696 F	Complete	14-07-2023 12:58	N	N
R	4	74420	Complete	11-07-2023 18:03	N	N
R	4	74525 R	Complete	12-07-2023 13:04	N	N

Chemistry	Result	Flag
ALP IFCC	121.5	
BIL D	0.40	
BIL T	0.74	
CAL A	8.62	
CHOL	152.50	
E CRT	1.02	
GLU POD	89.9	
HDL D	39.59	
LDL D	105.12	
SGOT	30.75	
SGPT	31.01	
TGL	112.74	
UAC	4.77	
UREA UV	27.94	

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Standby

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- Program
- Result
- Reagent
- QC
- Utility
- Alarm
- Exit

Type	Sample ID	Bar Code	Status	Completion Time	Print	Revi	Chemistry	Result	Flag
C	PATH	32402455	Complete	12-07-2023 09:58	Y		ALB	4.41	
C	QC NORM	32402455	Complete	12-07-2023 10:05	N		ALP IFCC	426.6	
R	1	74521F	Complete	12-07-2023 13:03	N	N	BIL D	2.18	
R	1	74613 F	Complete	13-07-2023 12:15	N	N	BIL T	4.63	
R	1	74687 R	Complete	14-07-2023 12:57	N	N	CAL A	14.09	
R	2	74522 F	Complete	12-07-2023 13:04	N	N	CHOL	317.51	
R	2	74618	Complete	13-07-2023 12:08	N	N	E CRT	5.46	
R	2	74688 R	Complete	14-07-2023 12:57	N	N	GLU POD	244.4	
R	3		Complete	11-07-2023 18:10	N	N	HDL D	61.40	
R	3	74524 F	Complete	12-07-2023 13:04	N	N	LDL D	243.36	
R	3	74623	Complete	13-07-2023 14:12	N	N	SGOT	142.67	
R	3	74696 F	Complete	14-07-2023 12:58	N	N	SGPT	136.51	
R	4	74420	Complete	11-07-2023 18:03	N	N	TGL	272.08	
R	4	74525 R	Complete	12-07-2023 13:04	N	N	UAC	11.64	

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Reaction Carousel

By Sample

By Chemistry

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Reagent

QC

Utility

Alarm

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Type	Sample ID	Bar Code	Status	Completion Time	Print	Revi	Chemistry	Result	Flag
C	PATH	32402455	Complete	12-07-2023 09:58	Y		ALP IFCC	426.6	
C	QC NORM	32402455	Complete	12-07-2023 10:05	N		BIL D	2.18	
R	1	74521F	Complete	12-07-2023 13:03	N	N	BIL T	4.63	
R	1	74613 F	Complete	13-07-2023 12:15	N	N	CAL A	14.09	
R	1	74687 R	Complete	14-07-2023 12:57	N	N	CHOL	317.51	
R	2	74522 F	Complete	12-07-2023 13:04	N	N	E CRT	5.46	
R	2	74618	Complete	13-07-2023 12:08	N	N	GLU POD	244.4	
R	2	74688 R	Complete	14-07-2023 12:57	N	N	HDL D	61.40	
R	3		Complete	11-07-2023 18:10	N	N	LDL D	243.36	
R	3	74524 F	Complete	12-07-2023 13:04	N	N	SGOT	142.67	
R	3	74623	Complete	13-07-2023 14:12	N	N	SGPT	136.51	
R	3	74696 F	Complete	14-07-2023 12:58	N	N	TGL	272.08	
R	4	74420	Complete	11-07-2023 18:03	N	N	UAC	11.64	
R	4	74525 R	Complete	12-07-2023 13:04	N	N	UREA UV	136.90	BOE

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Options F2

Demog F3

Reac Curve F4

Rerun F5

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HOST

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Program

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Reaction Carousel

By Sample  By Chemistry

Result

Reagent

QC

Utility

Alarm

Exit

Type	Sample ID	Bar Code	Status	Completion Time	Print	Revi	Chemistry	Result	Flag
R	5	74637	Complete	13-07-2023 15:53	N	N	CAL A	7.78	
R	5	74700	Complete	14-07-2023 12:54	N	N	CAL A	7.88	
R	6	74466	Complete	11-07-2023 18:08	N	N	CAL A	7.91	
R	6	74537R	Complete	12-07-2023 13:10	N	N	CAL A	7.83	
R	6	74644 R	Complete	13-07-2023 15:54	N	N	CAL A	8.03	
R	6	74707 R	Complete	14-07-2023 16:19	N	N	GLU POD	116.7	
R	7	74537	Complete	12-07-2023 13:03	N	N	GLU POD	117.6	
R	7	74644	Complete	13-07-2023 15:54	N	N	GLU POD	117.7	
R	7	74713 R	Complete	14-07-2023 16:19	N	N	GLU POD	118.1	
R	8	74541	Complete	12-07-2023 14:06	N	N	GLU POD	118.7	
R	8	74716 PP	Complete	14-07-2023 16:22	N	N	SGPT	18.21	LIN
R	9	PRECESION	Complete	12-07-2023 16:31	N	N	SGPT	17.67	LIN
R	9	74613 PP	Complete	13-07-2023 17:22	N	N	SGPT	17.61	LIN
R	9	74716	Complete	14-07-2023 16:20	N	N	SGPT	17.44	LIN

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Successfully saved

Current		History		Statistics		Reaction Carousel			
By Sample		By Chemistry							
Type	Sample ID	Bar Code	Status	Completion Time	Print	Revl	Chemistry	Result	Flag
R	5	74637	Complete	13-07-2023 15:53	N	N	GLU POD	118.7	
R	5	74700	Complete	14-07-2023 12:54	N	N	SGPT	18.21	LIN
R	6	74466	Complete	11-07-2023 18:08	N	N	SGPT	17.67	LIN
R	6	74537R	Complete	12-07-2023 13:10	N	N	SGPT	17.61	LIN
R	6	74644 R	Complete	13-07-2023 15:54	N	N	SGPT	17.44	LIN
R	6	74707 R	Complete	14-07-2023 16:19	N	N	SGPT	18.32	LIN
R	7	74537	Complete	12-07-2023 13:03	N	N	UREA UV	83.51	
R	7	74644	Complete	13-07-2023 15:54	N	N	UREA UV	83.76	
R	7	74713 R	Complete	14-07-2023 16:19	N	N	UREA UV	83.81	
R	8	74541	Complete	12-07-2023 14:06	N	N	UREA UV	86.38	
R	8	74716 PP	Complete	14-07-2023 16:22	N	N	UREA UV	83.56	
R	9	PRECISION	Complete	12-07-2023 16:31	N	N			
R	9	74613 PP	Complete	13-07-2023 17:22	N	N			
R	9	74716	Complete	14-07-2023 16:20	N	N			

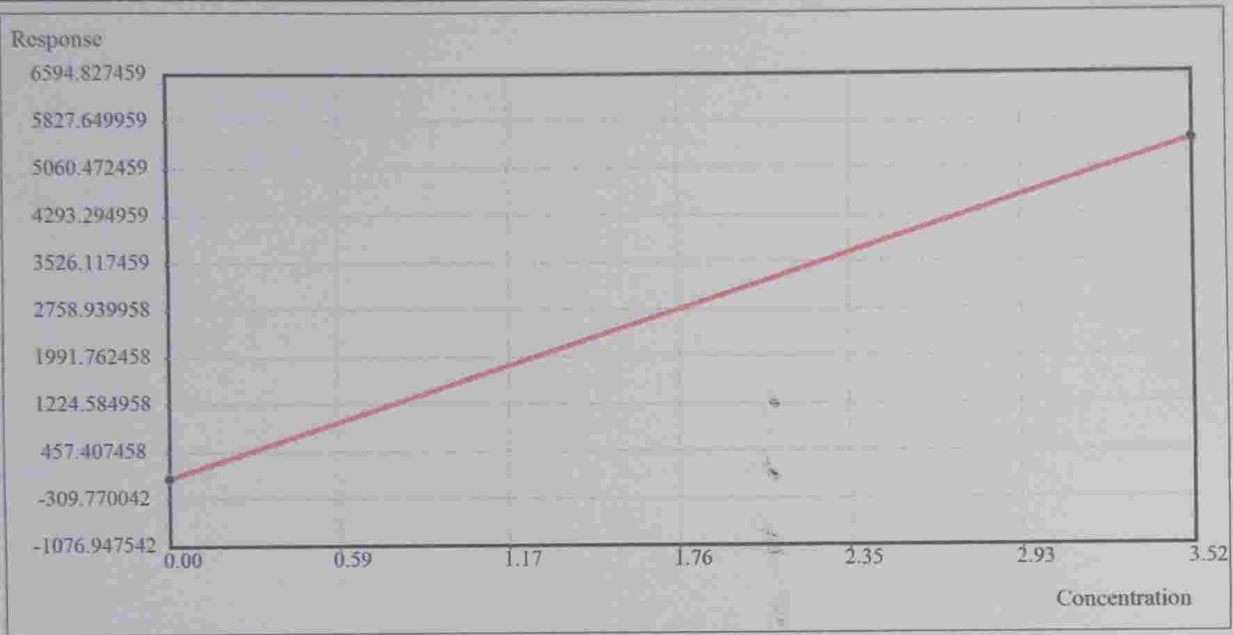
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# Calibration Report

Chemistry:	ALB	Math Model:	Two-Point Linear		
Unit:	g/dL	Replicates:	1	Cal Date/Time:	12-10-2024 10:58:13
Rgt Type	Lot No.	Serial No.	Rgt Type	Lot No.	Serial No.

R1



Calibration Data				Calibration Parameter			
Calibrator	Conc	Resp	Lot No.	Parameter	Value	Parameter	Value
WATER	0.00	19.0	12345	R0	19.0203		
MULTI CAL	3.52	5498.9	33020264	K	0.0006		

# Calibration Report

Chemistry:	ALP IFCC	Math Model:	Two-Point Linear		
Unit:	IU/L	Replicates:	1	Cal Date/Time:	31-10-2024 10:13:21
Rgt Type	Lot No.	Serial No.	Rgt Type	Lot No.	Serial No.
R1			R2		

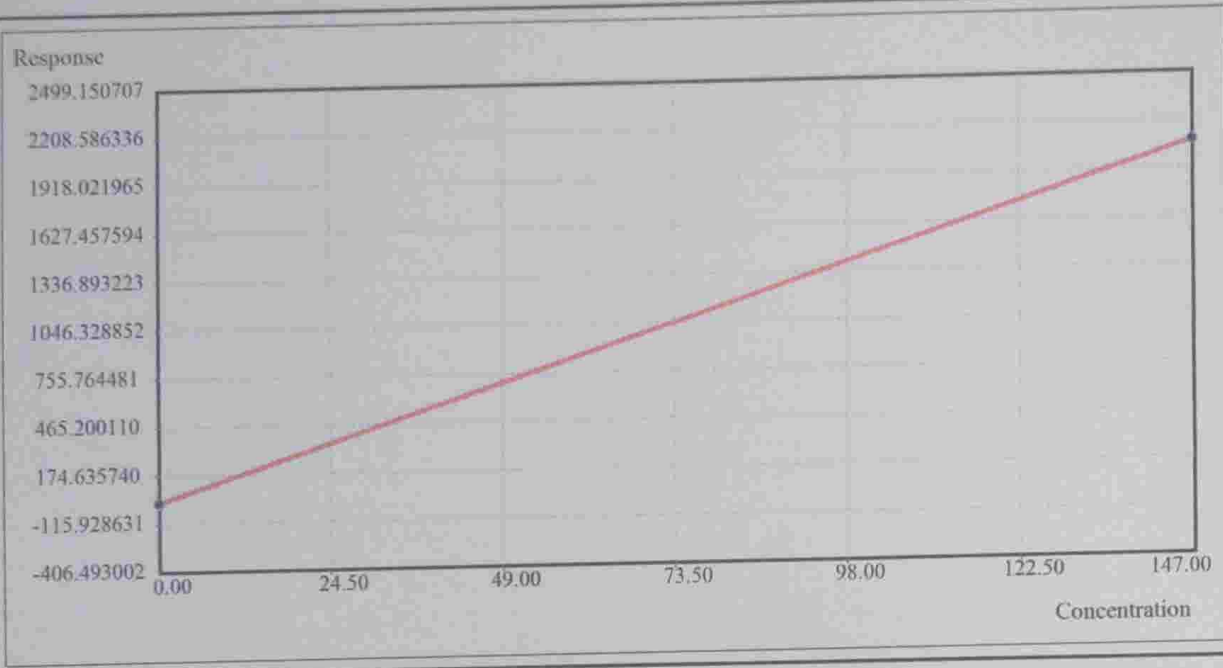


Calibration Data				Calibration Parameter			
Calibrator	Conc	Resp	Lot No.	Parameter	Value	Parameter	Value
WATER	0.0	6.0	12345	R0	6.0241		
MULTI CAL	265.0	561.8	33020264	K	0.4768		

# Calibration Report

Chemistry:	CHOL	Math Model:	Two-Point Linear		
Unit:	mg/dL	Replicates:	1	Cal Date/Time:	12-10-2024 10:58:33
Rgt Type	Lot No.	Serial No.	Rgt Type	Lot No.	Serial No.

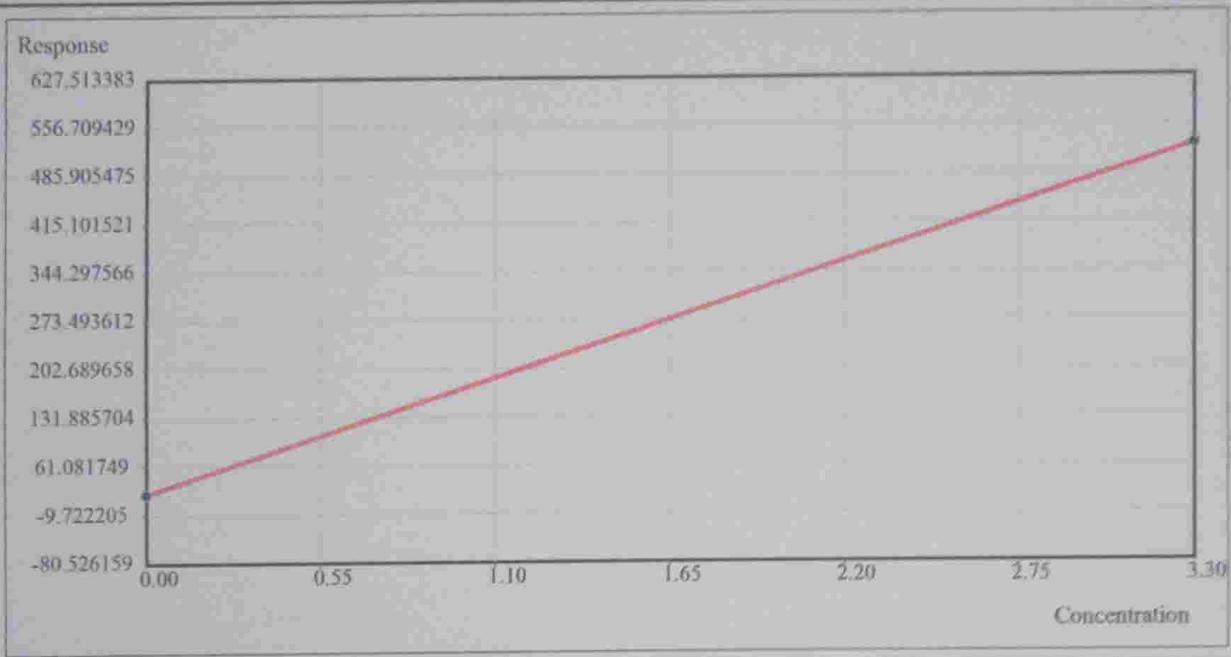
R1



Calibration Data				Calibration Parameter			
Calibrator	Conc	Resp	Lot No.	Parameter	Value	Parameter	Value
WATER	0.00	8.6	12345	R0	8.5990		
MULTI CAL	147.00	2084.1	33020264	K	0.0708		

# Calibration Report

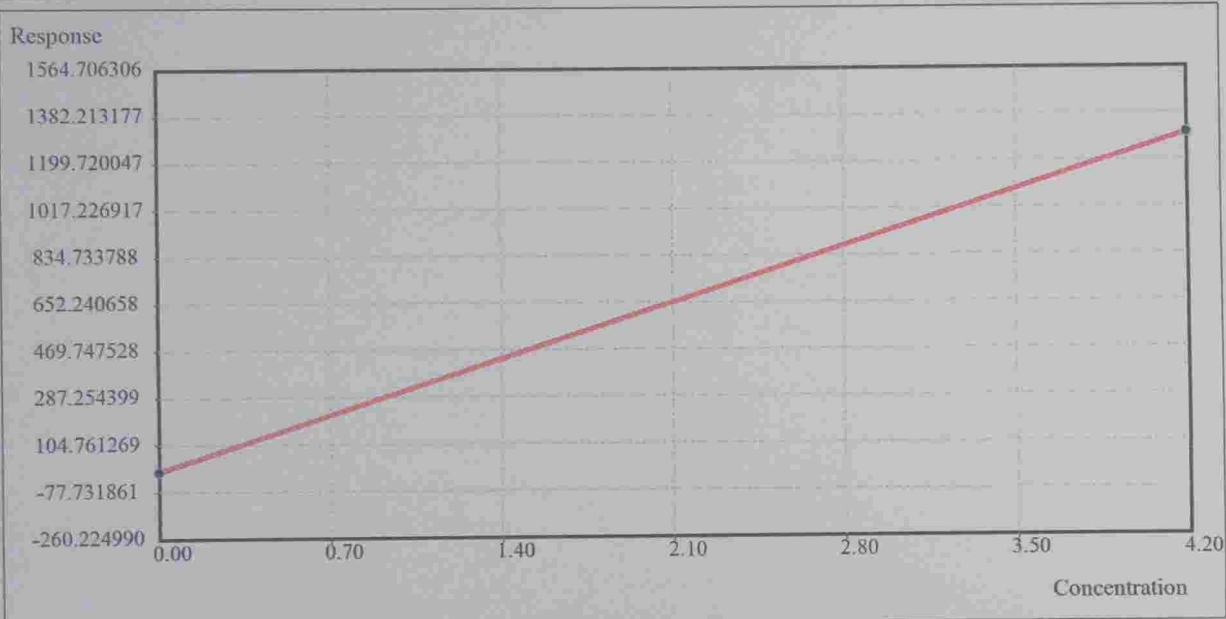
Chemistry:	E CRT		Math Model:	Two-Point Linear		
Unit:	mg/dL	Replicates:	1	Cal Date/Time:	19-10-2024 09:57:45	
Rgt Type	Lot No.	Serial No.		Rgt Type	Lot No.	Serial No.
R1				R2		



Calibration Data				Calibration Parameter			
Calibrator	Conc	Resp	Lot No.	Parameter	Value	Parameter	Value
WATER	0.00	20.6	12345	R0	20.6223		
MULTI CAL	3.30	526.4	33020264	K	0.0065		

# Calibration Report

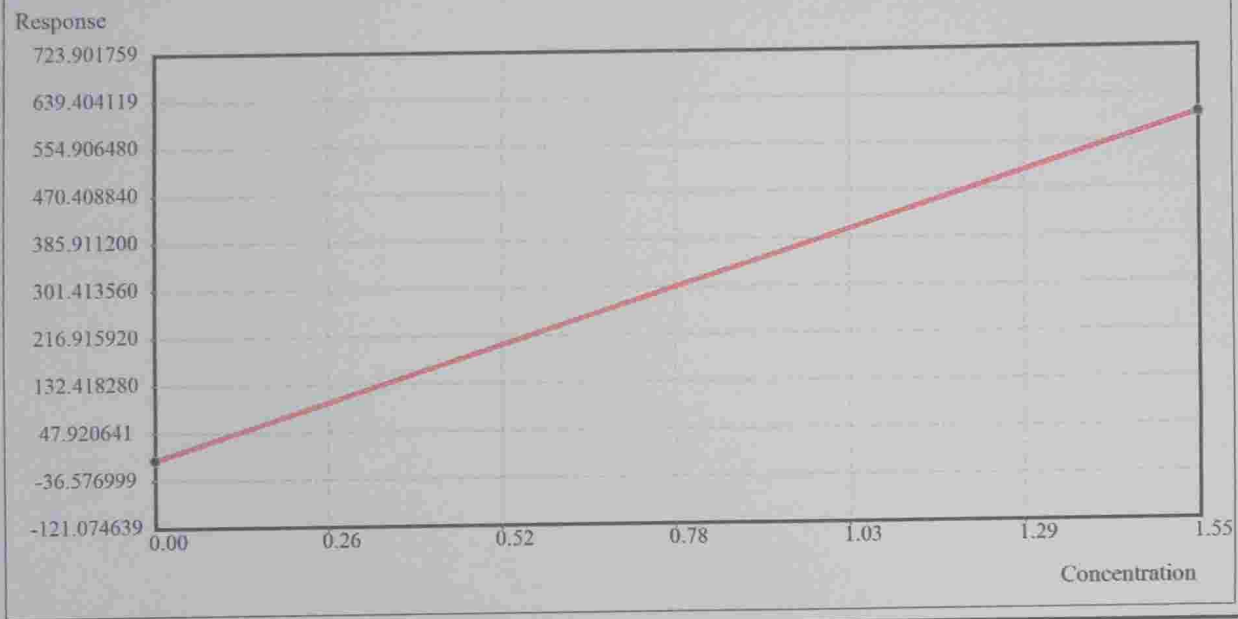
Chemistry:	BIL T	Math Model:	Two-Point Linear		
Unit:	mg/dL	Replicates:	1	Cal Date/Time:	24-10-2024 13:59:43
Rgt Type	Lot No.	Serial No.	Rgt Type	Lot No.	Serial No.
R1			R2		



Calibration Data				Calibration Parameter			
Calibrator	Conc	Resp	Lot No.	Parameter	Value	Parameter	Value
WATER	0.00	0.5	12345	R0	0.4795		
MULTI CAL	4.20	1304.0	33020264	K	0.0032		

# Calibration Report

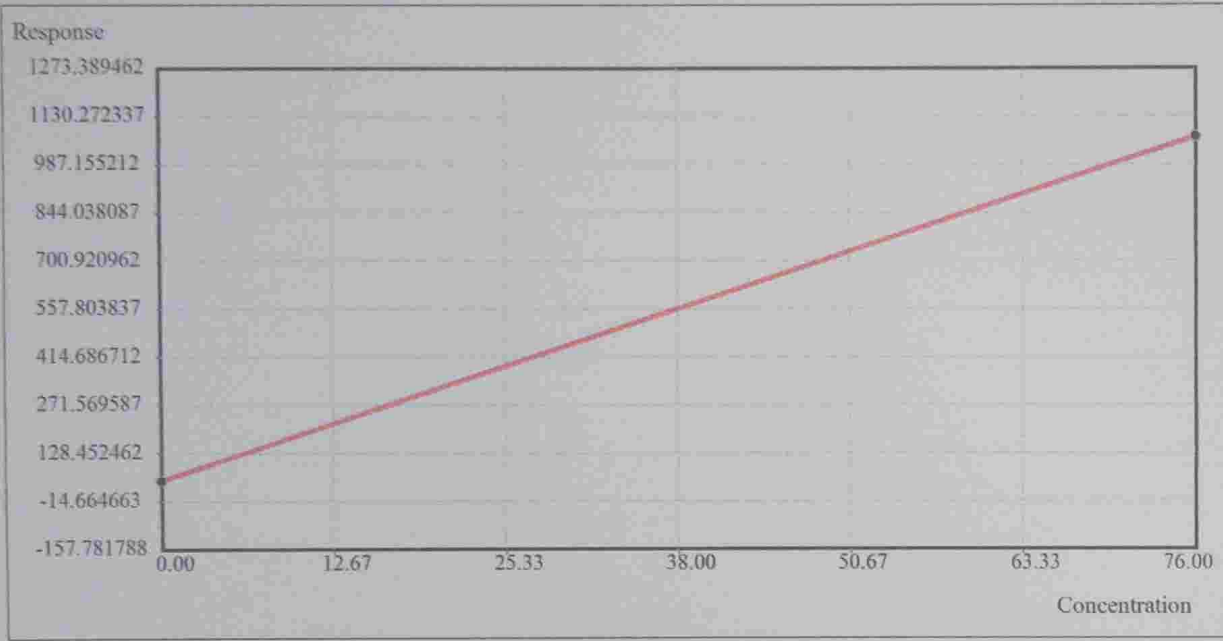
Chemistry:	BIL D	Math Model:	Two-Point Linear
Unit:	mg/dL	Replicates:	1
		Cal Date/Time:	16-10-2024 16:30:42
Rgt Type	Lot No.	Serial No.	
R1			R2



Calibration Data			Calibration Parameter				
Calibrator	Conc	Resp	Lot No.	Parameter	Value	Parameter	Value
WATER	0.00	-0.4	12345	R0	-0.3637		
MULTI CAL	1.55	603.2	33020264	K	0.0026		

# Calibration Report

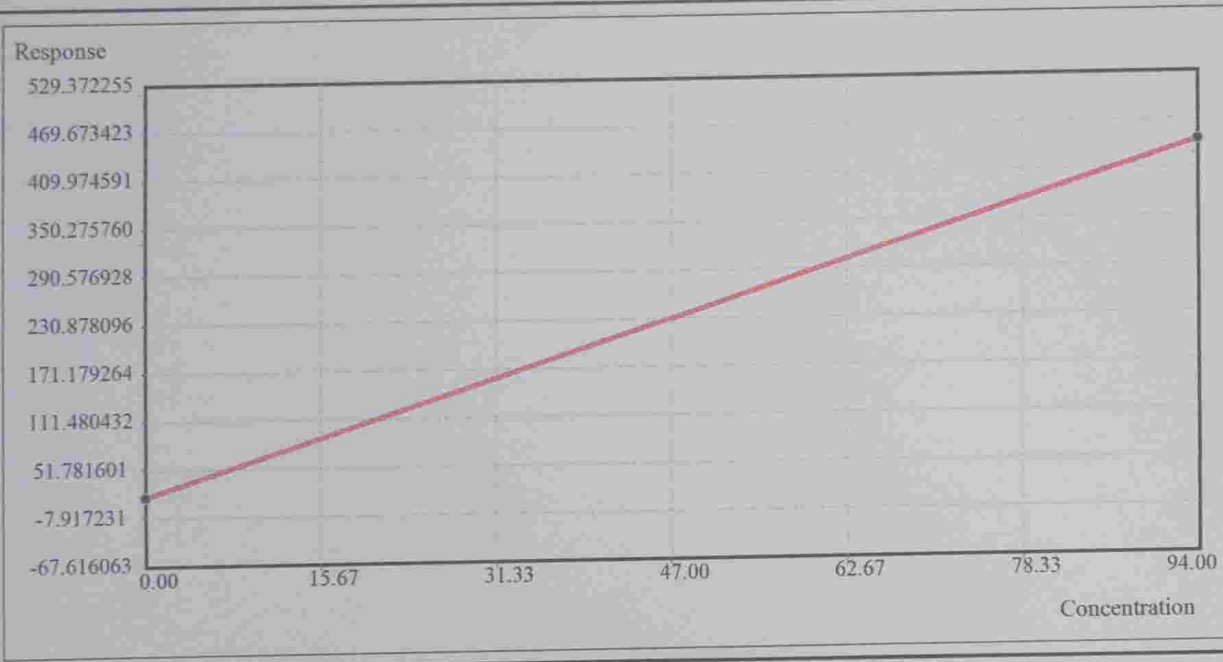
Chemistry:	LDL D	Math Model:	Two-Point Linear
Unit:	mg/dL	Replicates:	1
		Cal Date/Time:	12-10-2024 10:59:53
Rgt Type	Lot No.	Serial No.	
R1			R2



Calibration Data				Calibration Parameter			
Calibrator	Conc	Resp	Lot No.	Parameter	Value	Parameter	Value
WATER	0.00	46.7	12345	R0	46.6712		
MULTI CAL	76.00	1068.9	33020264	K	0.0743		

# Calibration Report

Chemistry:	SGOT	Math Model:	Two-Point Linear			
Unit:	IU/L	Replicates:	1	Cal Date/Time:	22-10-2024 10:16:12	
Rgt Type	Lot No.	Serial No.		Rgt Type	Lot No.	Serial No.
R1				R2		

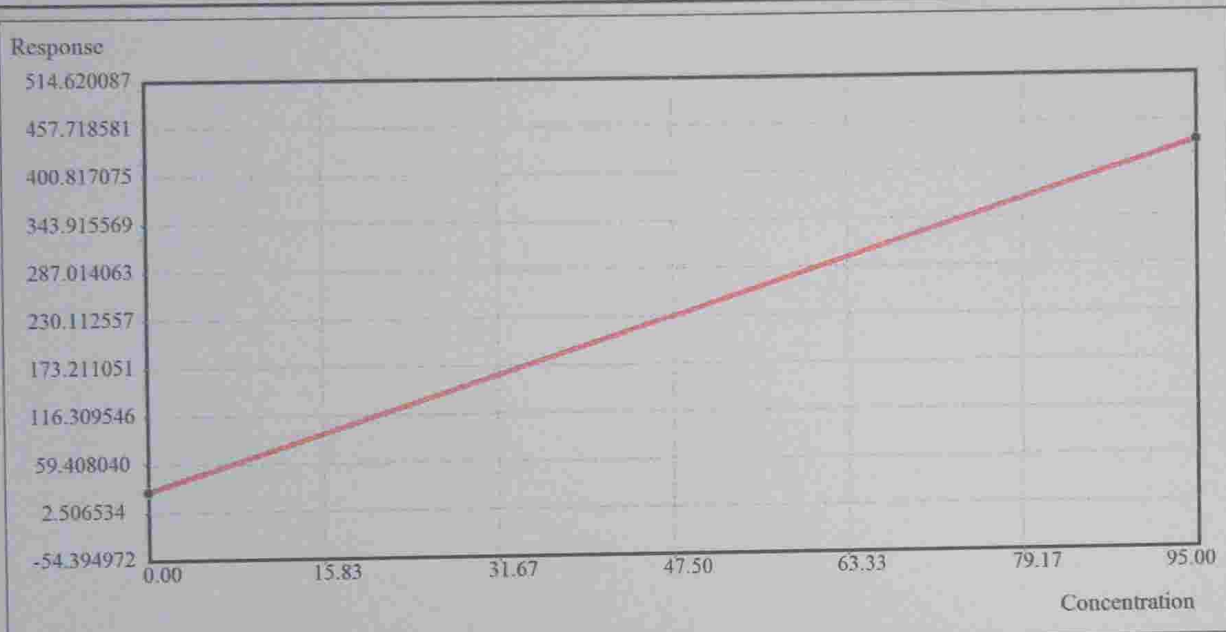


Calibration Data			Calibration Parameter				
Calibrator	Conc	Resp	Lot No.	Parameter	Value	Parameter	Value
WATER	0.00	17.7	12345	R0	17.6680		
MULTI CAL	94.00	444.1	33020264	K	0.2204		



# Calibration Report

Chemistry:	SGPT	Math Model:	Two-Point Linear		
Unit:	IU/L	Replicates:	1	Cal Date/Time:	22-10-2024 10:16:22
Rgt Type	Lot No.	Serial No.	Rgt Type	Lot No.	Serial No.
R1			R2		

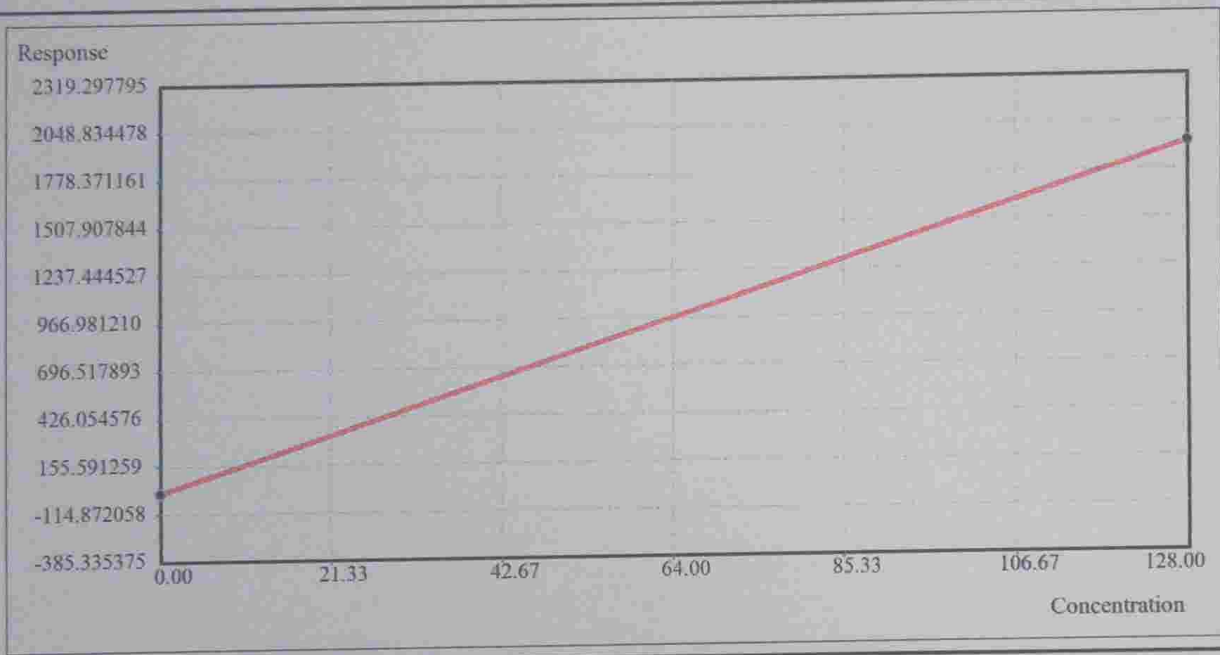


Calibration Data			Calibration Parameter				
Calibrator	Conc	Resp	Lot No.	Parameter	Value	Parameter	Value
WATER	0.00	26.9	12345	R0	26.8929		
MULTI CAL	95.00	433.3	33020264	K	0.2337		

# Calibration Report

Chemistry:	TGL		Math Model:	Two-Point Linear		
Unit:	mg/dL	Replicates:	1	Cal Date/Time:	12-10-2024 10:59:13	
Rgt Type	Lot No.	Serial No.	Rgt Type	Lot No.	Serial No.	

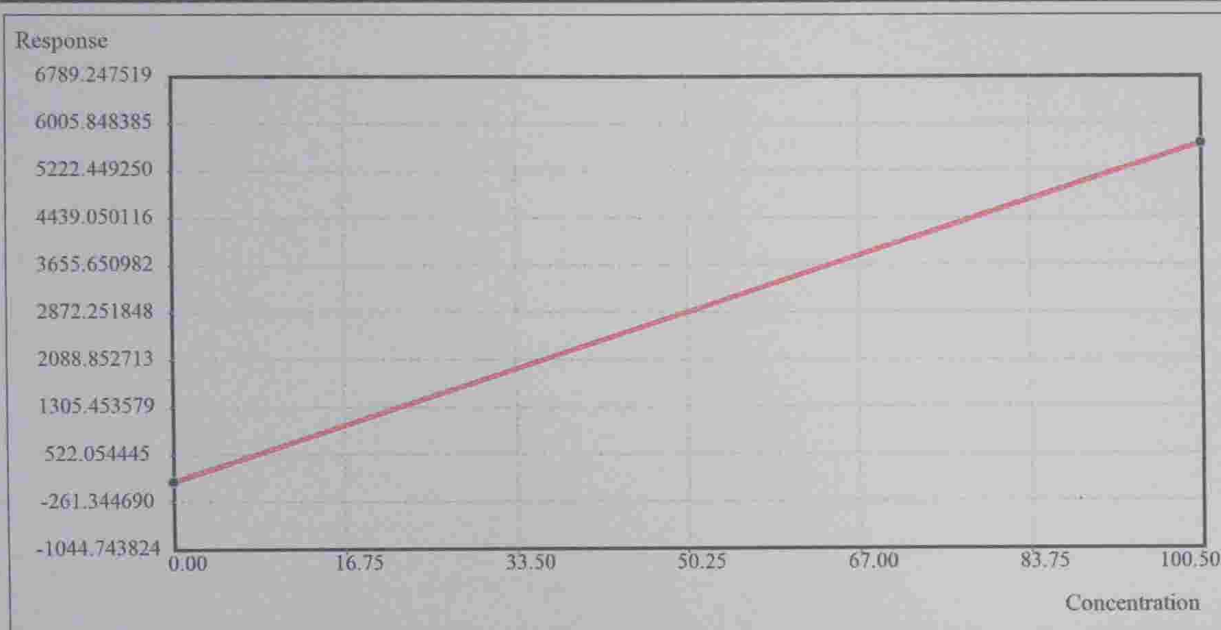
R1



Calibration Data			Calibration Parameter				
Calibrator	Conc	Resp	Lot No.	Parameter	Value	Parameter	Value
WATER	0.00	1.0	12345	R0	1.0408		
MULTI CAL	128.00	1932.9	33020264	K	0.0663		

# Calibration Report

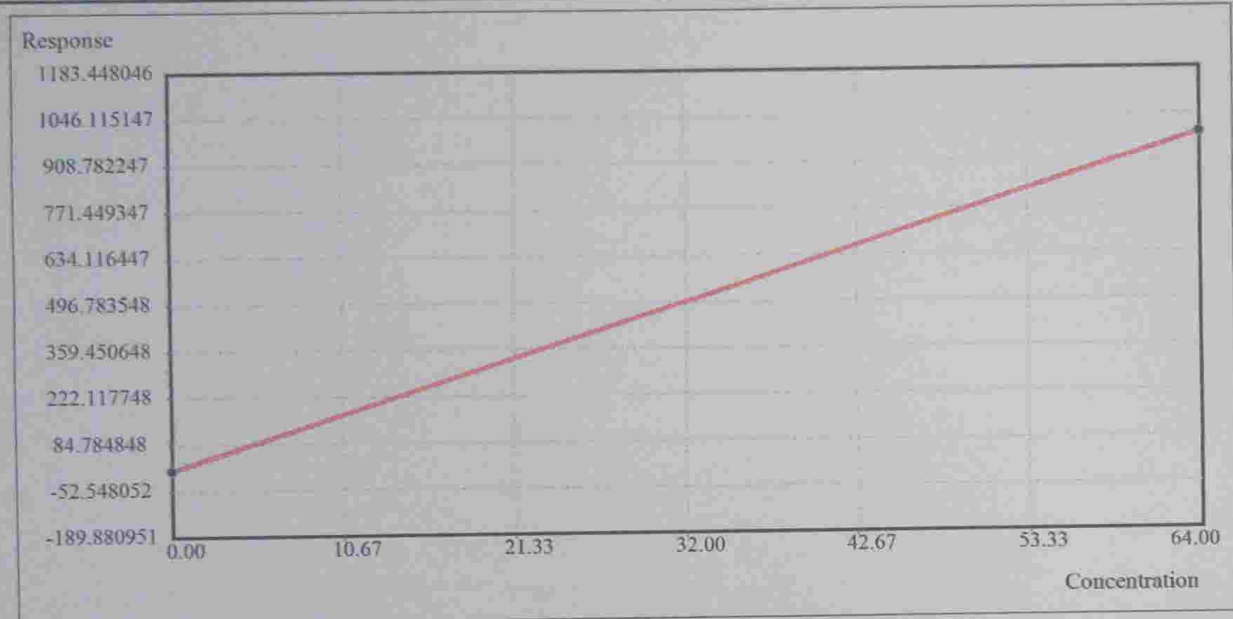
Chemistry:	UREA UV	Math Model:	Two-Point Linear		
Unit:	mg/dL	Replicates:	1	Cal Date/Time:	05-10-2024 10:02:28
Rgt Type	Lot No.	Serial No.	Rgt Type	Lot No.	Serial No.
R1			R2		



Calibration Data			Calibration Parameter				
Calibrator	Conc	Resp	Lot No.	Parameter	Value	Parameter	Value
WATER	0.00	74.4	12345	R0	74.3978		
MULTI CAL	100.50	5670.1	33020264	K	0.0180		

# Calibration Report

Chemistry:	HDL D	Math Model:	Two-Point Linear		
Unit:	mg/dL	Replicates:	1	Cal Date/Time:	18-10-2024 10:07:19
Rgt Type	Lot No.	Serial No.	Rgt Type	Lot No.	Serial No.
R1			R2		

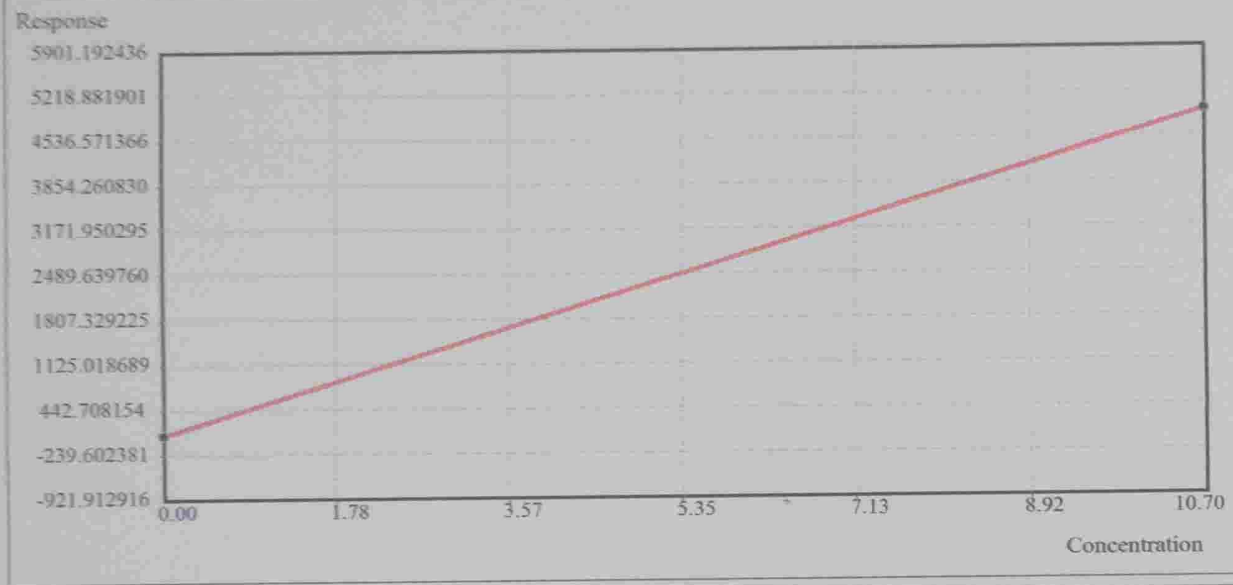


Calibration Data			Calibration Parameter				
Calibrator	Conc	Resp	Lot No.	Parameter	Value	Parameter	Value
WATER	0.00	6.3	12345	R0	6.3089		
MULTI CAL	64.00	987.3	33020264	K	0.0652		

# Calibration Report

Chemistry:	CAL A	Math Model:	Two-Point Linear
Unit:	mg/dL	Replicates:	1
		Cal Date/Time:	31-10-2024 10:11:52
Rgt Type	Lot No.	Serial No.	

R1

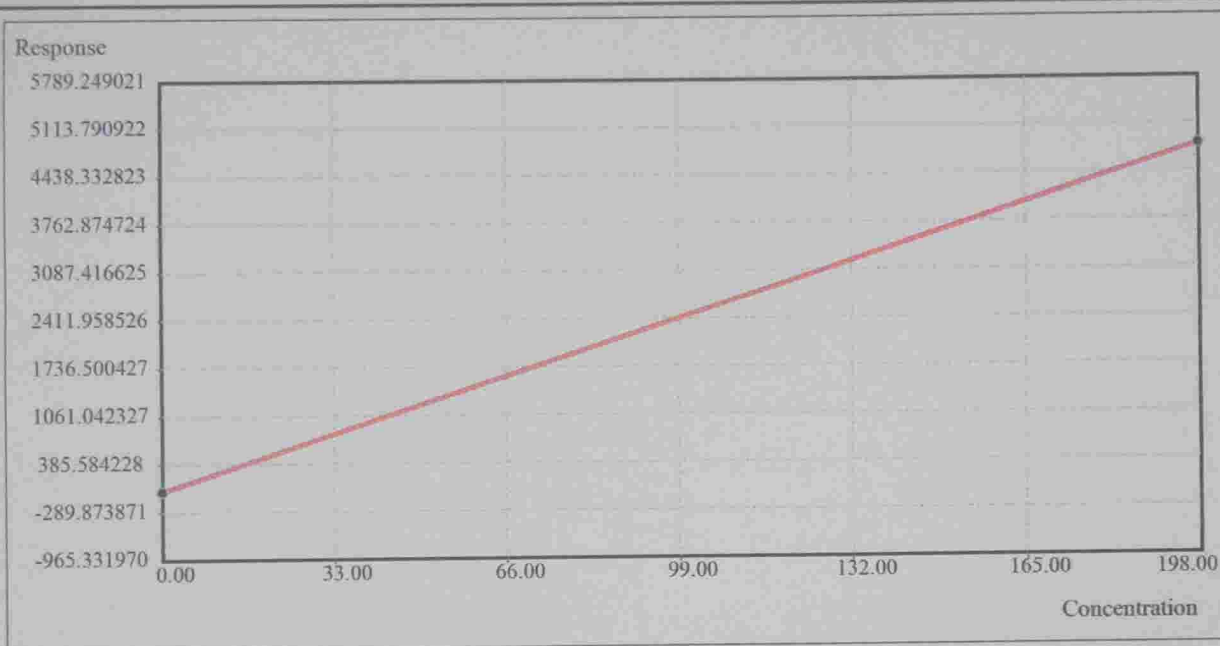


Calibration Data				Calibration Parameter			
Calibrator	Conc	Resp	Lot No.	Parameter	Value	Parameter	Value
WATER	0.00	52.8	12345	R0	52.8164		
MULTI CAL	10.70	4926.5	33020264	K	0.0022		

# Calibration Report

Chemistry:	GLU POD	Math Model:	Two-Point Linear		
Unit:	mg/dL	Replicates:	1	Cal Date/Time:	25-10-2024 11:32:27
Rgt Type	Lot No.	Serial No.	Rgt Type	Lot No.	Serial No.

R1



Calibration Data			Calibration Parameter				
Calibrator	Conc	Resp	Lot No.	Parameter	Value	Parameter	Value
WATER	0.0	-0.4	12345	R0	-0.3918		
MULTI CAL	198.0	4824.3	33020264	K	0.0410		