DIATEK

CALIBRATION CERTIFICATE

DIATEK HEALTHCARE PVT. LTD.
CIN. NO. U85100WB2010PTC142635
An ISO 9001:2015 Company

CUSTOMER NAME: **VELYS DIAGNOSTICS AND PATHOLOGY CENTER**

803, A SHRIDHAR ATHENS

ABOVE KALA MANDIR, SATTELITE

AHMEDABAD -

INSTRUMENT NAME	:	FULLY AUTOMATED BIOCHEMISTRY ANALYZER
MAKE	:	DIATEK
MODEL	:	Dia-CHEM-240
SERIAL NUMBER	:	CA24-201100440
DATE OF CALIBRATION	:	30/10/2023
NEXT DUE ON	:	29/04/2024

This is to certify that, we have calibrated FULLY AUTOMATED BIOCHEMISTRY ANALYZER,

Model: Dia-CHEM-240 made by DIATEK VELYS **DIAGNOSTICS AND PATHOLOGY CENTER**

on 30/10/2023.

Thanking you,

For, DIATEK HEALTHCARE PVT . LTD

CHIRAG SOLANKI,

SALES & SERVICE ENGINEER,

Contact No. +91 6351779284

INSTALLATION QUALIFICATION (IQ)

NO	Description	Conformance to Requirement
Installation Qualification Preparation	Check the completeness of analyzer package and accessory box.	Yes
	Check that if logistics label status is normal or not.	Yes
	Unpack the instrument to check if the instrument appearance is normal or not.	Yes
	Instrument should be kept up-right, prevent slope.	Yes
	Open the accessory box, check each Accessory according to packing list.	Yes
Installation Condition Verification	Instrument installation place should keep away from interference source of strong electromagnetic.	Yes
	Instrument for indoor use only.	Yes
	Installation counter tops or ground should smooth and steady.	Yes
	Installation environment altitude below 2000 meters.	Yes
	Installation environment no corrosive gas and combustible gas.	Yes
	Instrument usage environment temperature:10° C to 30° C, suggest to install air conditioner.	Yes
	Instrument assemble environment relative humidity: ≤70%.	Yes

	Instrument assemble space required :	
	The distance between back side of analyzer and wall	20cm
	The distance between left & right side of analyzer and wall	Sufficient
	The distance between front side of analyzer and other instrument	Sufficient
	Keep enough space around power outlet position for convenient connection of power cable.	Sufficient
	Instrument power requirement:	
	Input voltage: 200-240V AC; (Frequency: 50Hz)	225 VAC
	Voltage between Neutral and Ground	1.1 VAC 1.2
	Analyzer and instrument should have UPS regulated power supply.	Connectd to UPS Power supply
	Unwrap the instrument	Done
	Connect system electrical circuit.	Done
	Connect DI water tank	Done
	Connect the waste liquid tank and tubings.	Done

Performed by: _____ Date : 30/10/2023

OPERATIONALQUALIFICATION (OQ)

NO.	Description	Conformance to Requirements
Operation Qualification Preparation	Switch on PC system.	Done
	Switch on Analyzer.	Done
	Check the connection between the PC and the instrument.	Done
	Fill the refrigeration unit with water as mentioned in the manual.	Done
	Program Glucose test. Place a blank reagent bottle filled with water. Place a sample cup filled with water. Program glucose test for 100 times. Run the test. (this helps to clear all the bubbles in the tubing's)	Performed.
	Program other parameters, calibrators and controls.	Performed

Performed by

Date: 30/10/2023

PERFORMANCE QUALIFICATION (PQ)

NO	Description	Conformance To requirements
Performance Qualification Preparation	Initialize the machine Login the user software with correct user name and password ,and then machine initializes automatically. Wait 30 minutes after the initialization of the machine, to have the analyzer fully warm-up, Prepare the calibrator and control. Load the proper reagent bottles and at the reagent positions. Place the calibrator and control at the sample area. Program the parameters to be calibrated. Results are mentioned below :- **Calibrated :** **Glucose = K Factor= 44.9740** **Creatinine = K Factor = 150.2238** **Cholesterol = K Factor = 22.1446** **Run control :** **Glucose : 269.8 (Tgt - 265.2; SD – 6.4)** **76.6 (Tgt – 78.9; SD – 3.37)** **Creatinine : 5.02 (Tgt – 5.04; SD – 0.243)** **1.99 (Tgt – 1.94; SD – 0.1)** **Cholesterol : 98.12 (Tgt – 97.57; SD – 2.89)** **252.21 (Tgt – 246.05; SD – 5.72)**	Performed

Performed by: Dhruva

Date: 30/10/2023

Calibration Result(albumin)

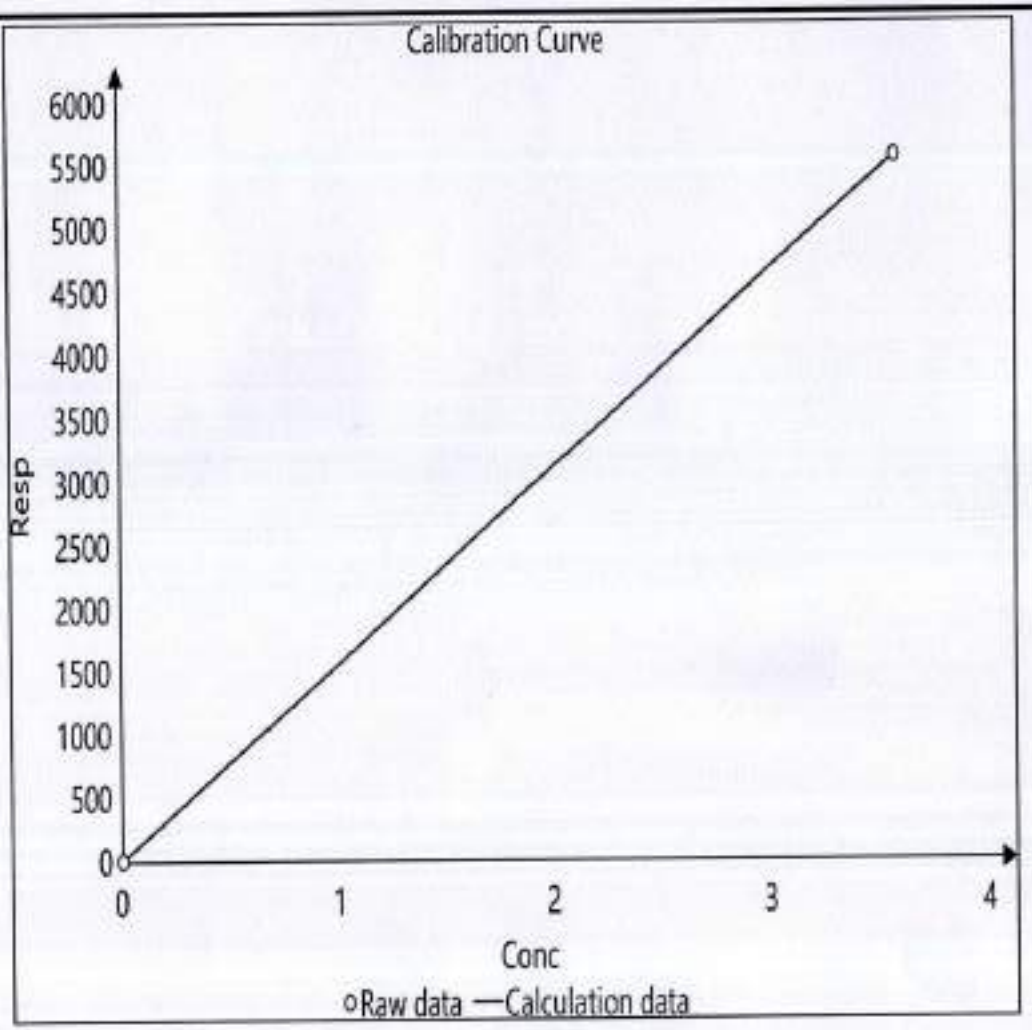
Calibrator Name	Concentration	Unit	Average Response	Lot No.
WATER	0.00	g/dl	6.65	QFT10058
ELICAL-2	3.57	g/dl	5571.85	220782

Cal Method
Linear

Calibration Parameter
K = 1558.8775;b = 6.6532

Reagent Blank
0.0000

Calibration time
10/30/2023 6:27:02 PM



Calibration Result(ALKP)

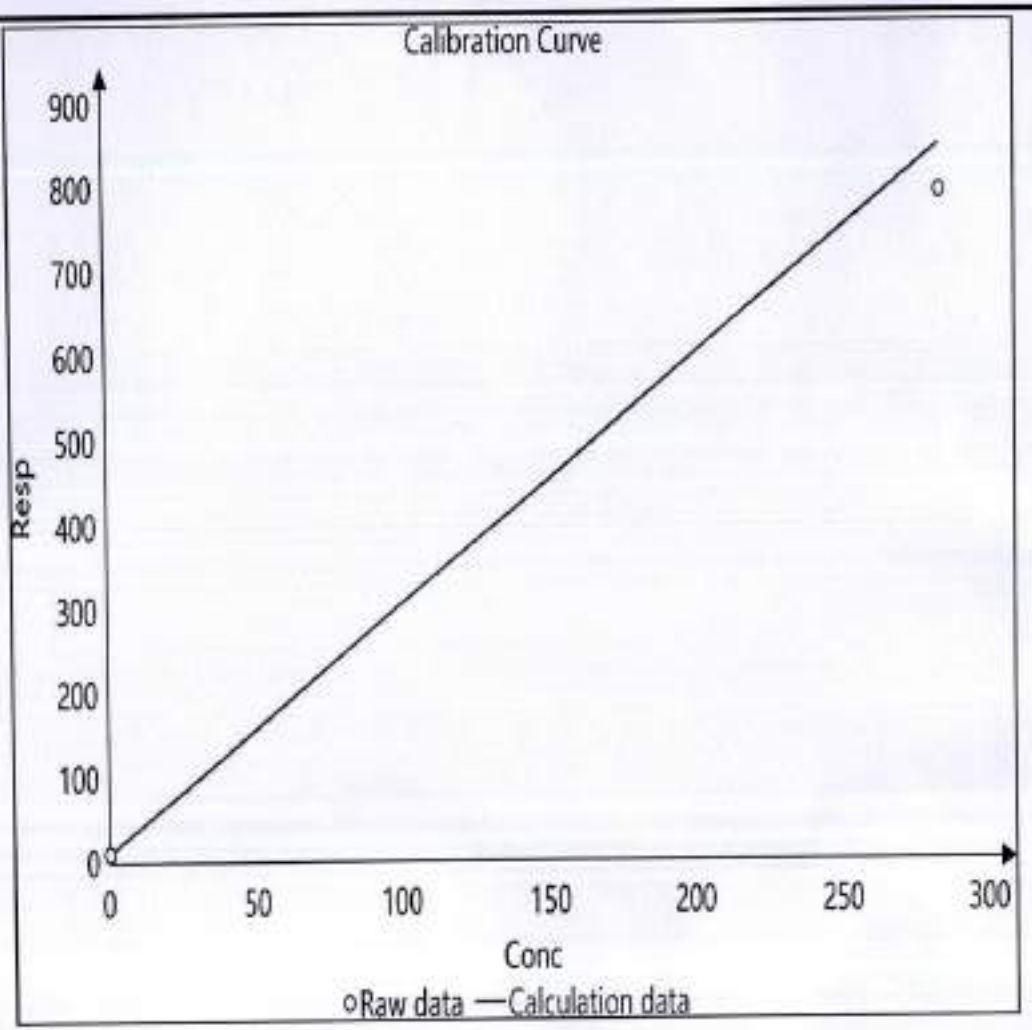
Calibrator Name	Concentration	Unit	Average Response	Lot No.
WATER	0.00	U/L	10.62	QFT10058
ELICAL-2	284.00	U/L	792.79	220782

Cal Method
Linear

Calibration Parameter
K = 2.9500;b = 10.6154

Reagent Blank
0.0000

Calibration time
10/30/2023 6:33:03 PM



Calibration Result(Bil-Direct)

Calibrator Name	Concentration	Unit	Average Response	Lot No.
WATER	0.00	mg/dl	-114.63	QFT10058
ELICAL-2	2.27	mg/dl	1352.35	220782

Cal Method
Linear

Calibration Parameter
K = 646.2457;b = -114.6254

Reagent Blank
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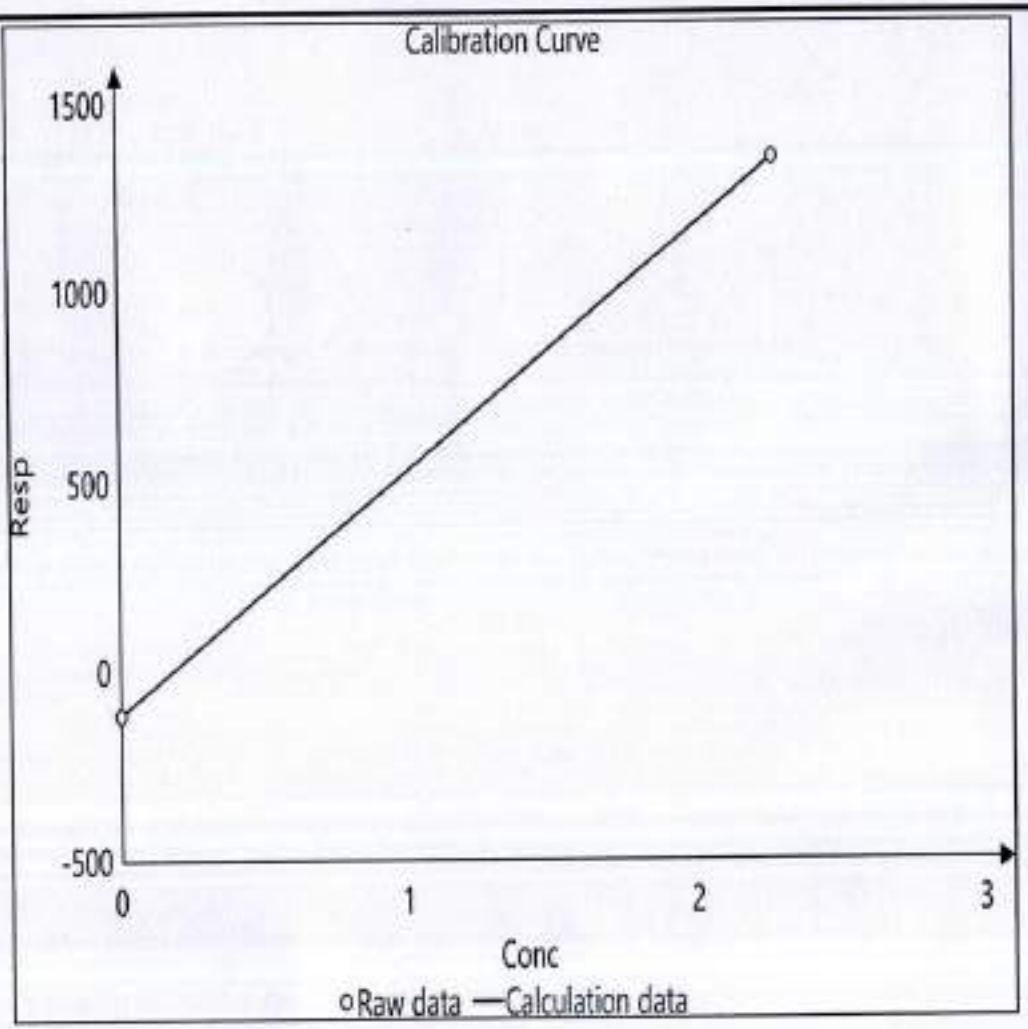
Calibration time
10/30/2023 6:30:47 PM



Calibration Result(CALCIUM)

Calibrator Name	Concentration	Unit	Average Response	Lot No.
WATER	0.00	mg/dl	-5.36	QFT10058
ELICAL-2	10.70	mg/dl	4078.98	220782

Cal Method
Linear

Calibration Parameter
K = 384.7100;b = -5.3589

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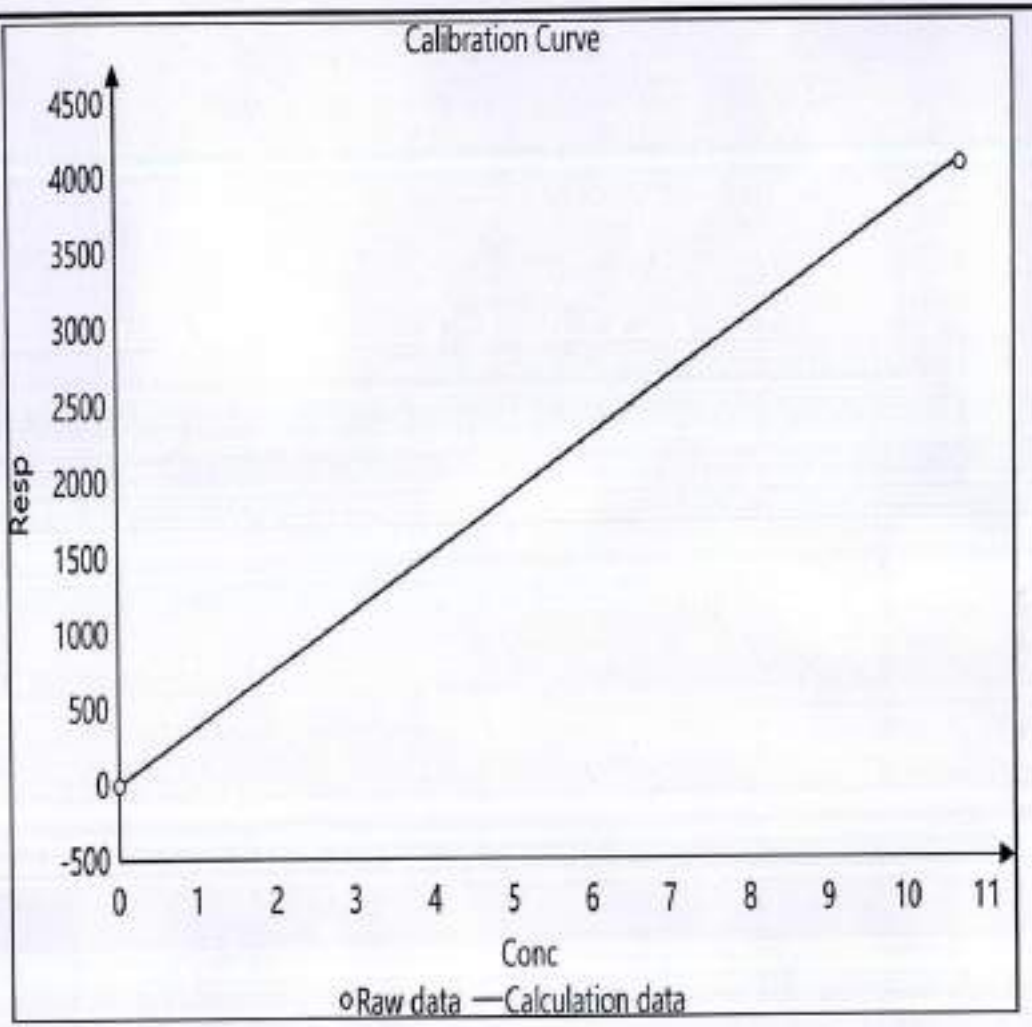
Calibration time
10/30/2023 6:29:40 PM



Calibration Result(Bil-Total)

Calibrator Name	Concentration	Unit	Average Response	Lot No.
WATER	0.00	mg/dl	-62.19	QFT10058
ELICAL-2	4.15	mg/dl	634.99	220782

Cal Method
Linear

Calibration Parameter
K = 167.9938;b = -62.1853

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Calibration time
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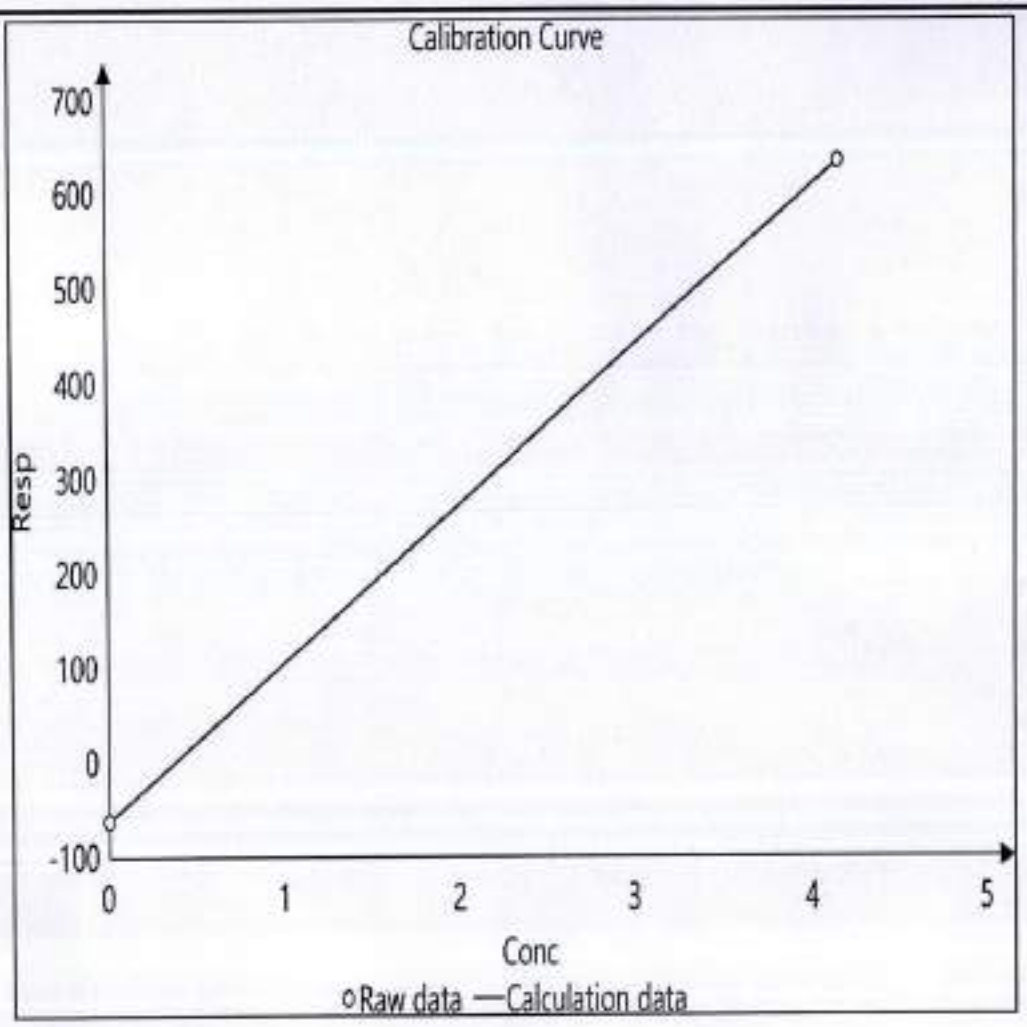

Calibration Result(FBS)

Calibrator Name	Concentration	Unit	Average Response	Lot No.
WATER	0.00	mg/dl	-12.95	QFT10058
ELICAL-2	188.70	mg/dl	8473.64	220782

Cal Method
Linear

Calibration Parameter
K = 44.9740;b = -12.9498

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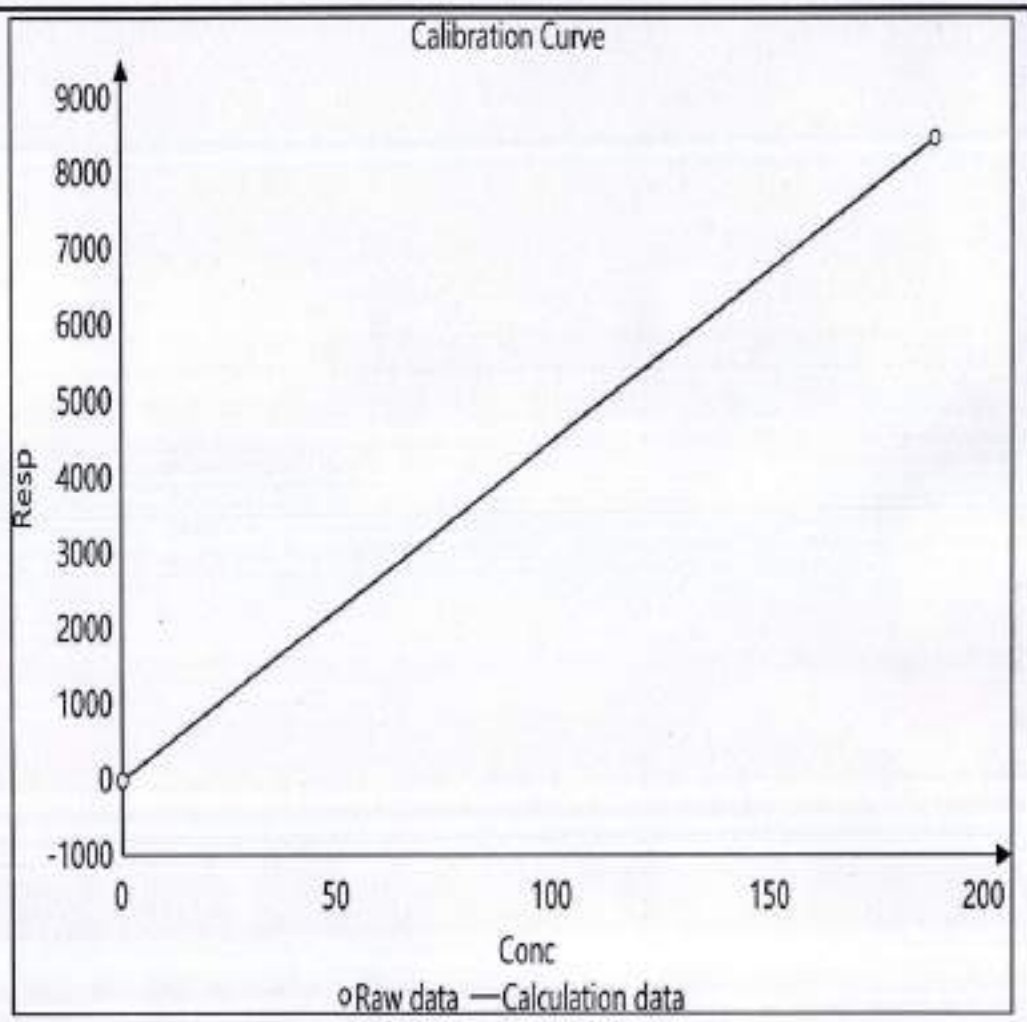
0.0000

Calibration time
10/30/2023 6:25:09 PM



Calibration Result(GGT)

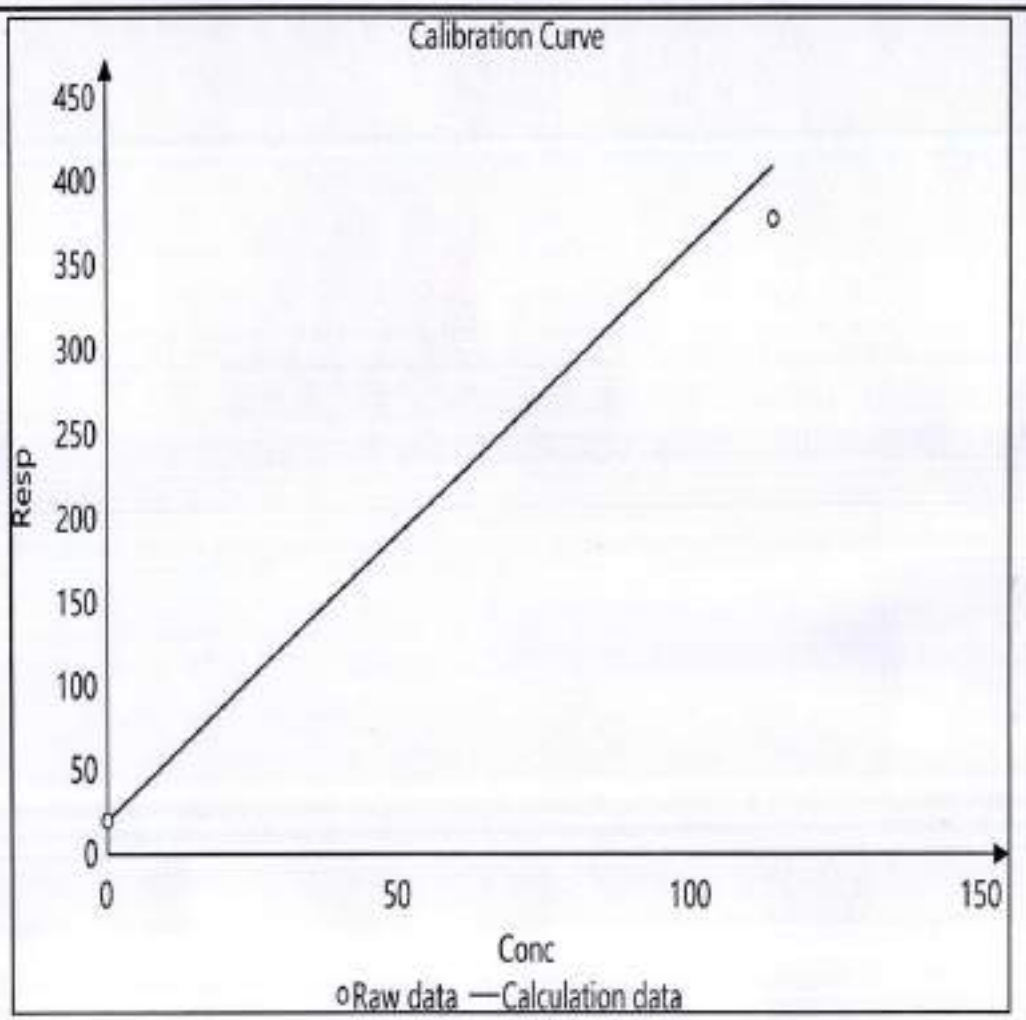
Calibrator Name	Concentration	Unit	Average Response	Lot No.
WATER	0.00	U/L	19.78	QFT10058
ELICAL-2	114.00	U/L	377.78	220782

Cal Method
Linear

Calibration Parameter
K = 3.4200;b = 19.7824

Reagent Blank
0.0000

Calibration time
10/30/2023 6:34:33 PM



Calibration Result(SGOT)

Calibrator Name	Concentration	Unit	Average Response	Lot No.
WATER	0.00	U/L	-8.37	QFT10058
ELICAL-2	110.40	U/L	-511.82	220782

Cal Method
Linear

Calibration Parameter
K = -4.5602;b = -8.3661

Reagent Blank
0.0000

Calibration time
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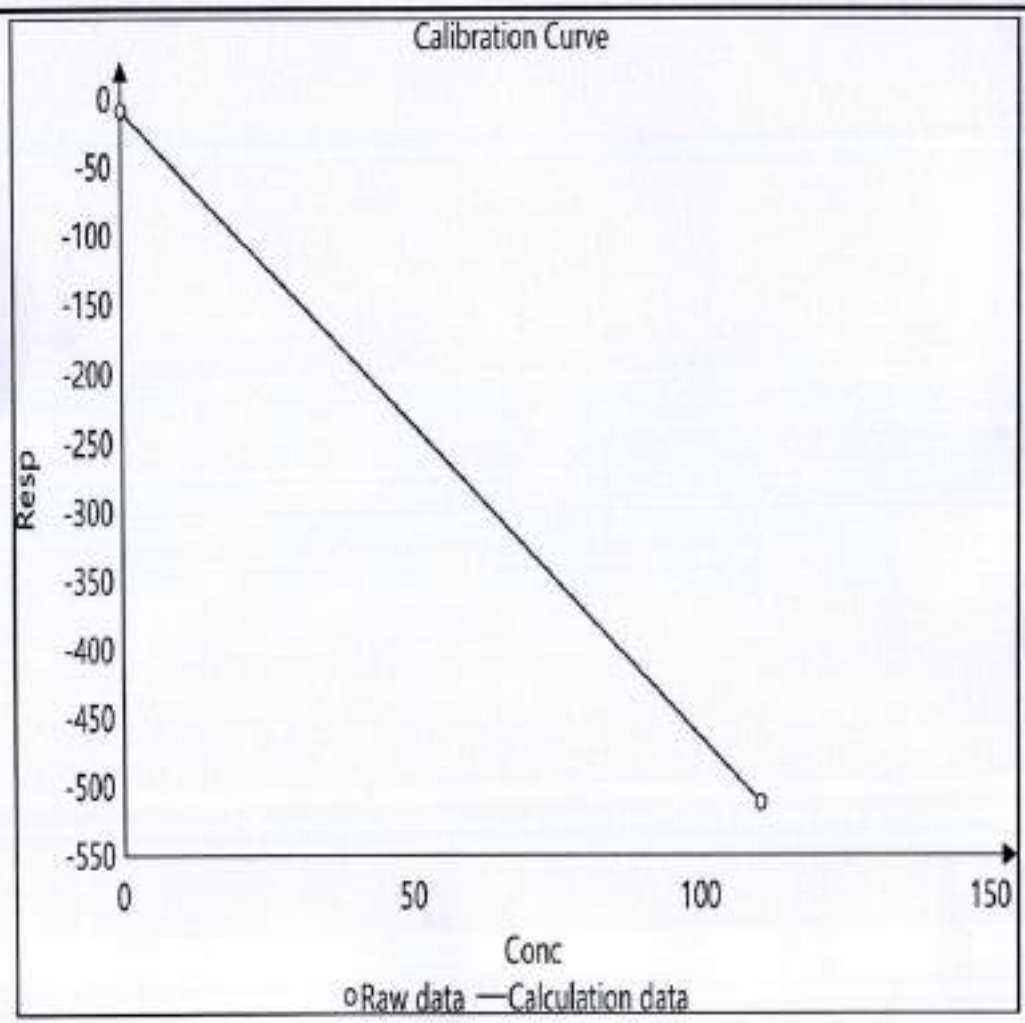


Calibration Result(SGPT)

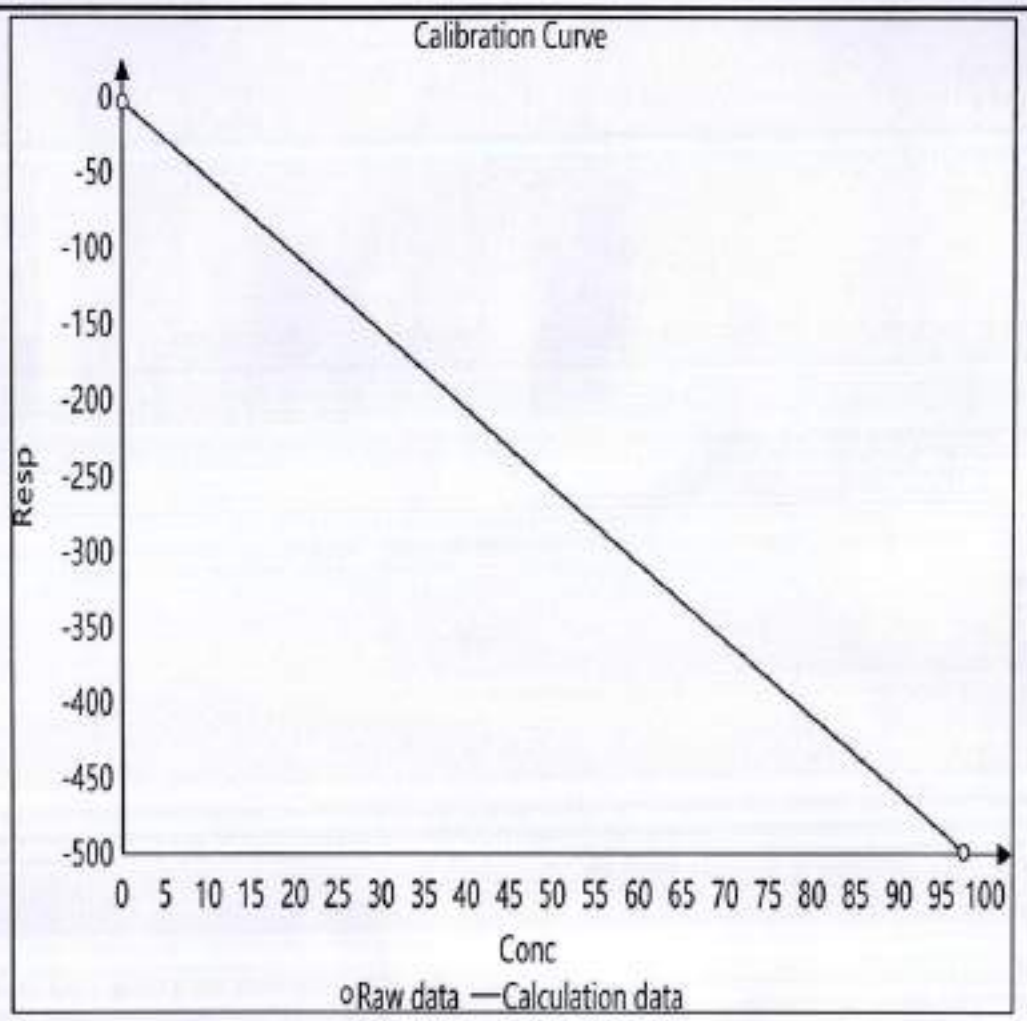
Calibrator Name	Concentration	Unit	Average Response	Lot No.
WATER	0.00	U/L	-2.59	QFT10058
ELICAL-2	97.40	U/L	-498.59	220782

Cal Method
Linear

Calibration Parameter
K = -5.0924;b = -2.5941

Reagent Blank
0.0000

Calibration time
10/30/2023 6:27:47 PM



Calibration Result(TRIGLYCERIDE-DIATEK)

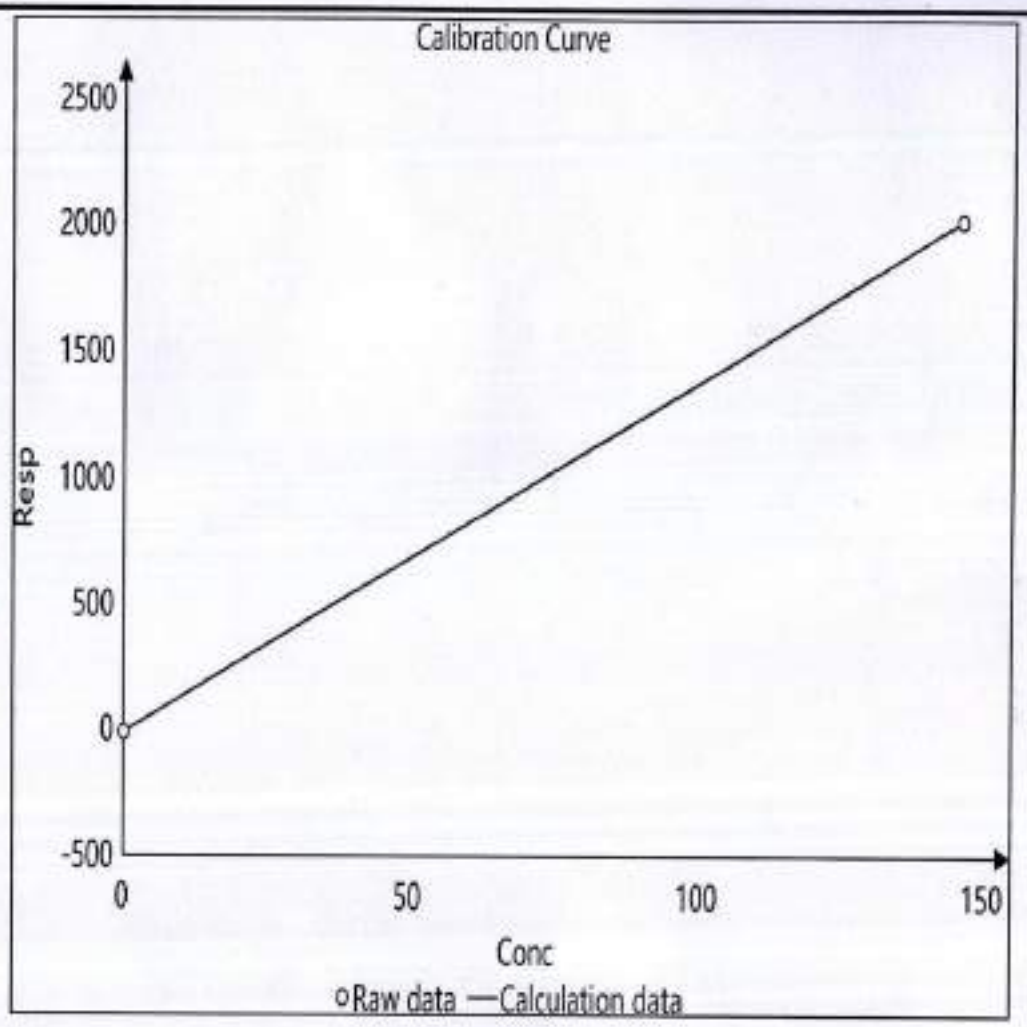
Calibrator Name	Concentration	Unit	Average Response	Lot No.
WATER	0.00	mg/dl	-10.75	QFT10058
ELICAL-2	146.00	mg/dl	2019.10	220782

Cal Method
Linear

Calibration Parameter
K = 13.9000;b = -10.7502

Reagent Blank
0.0000

Calibration time
10/30/2023 6:24:16 PM



Calibration Result(CHOLESTEROL-DIATEK)

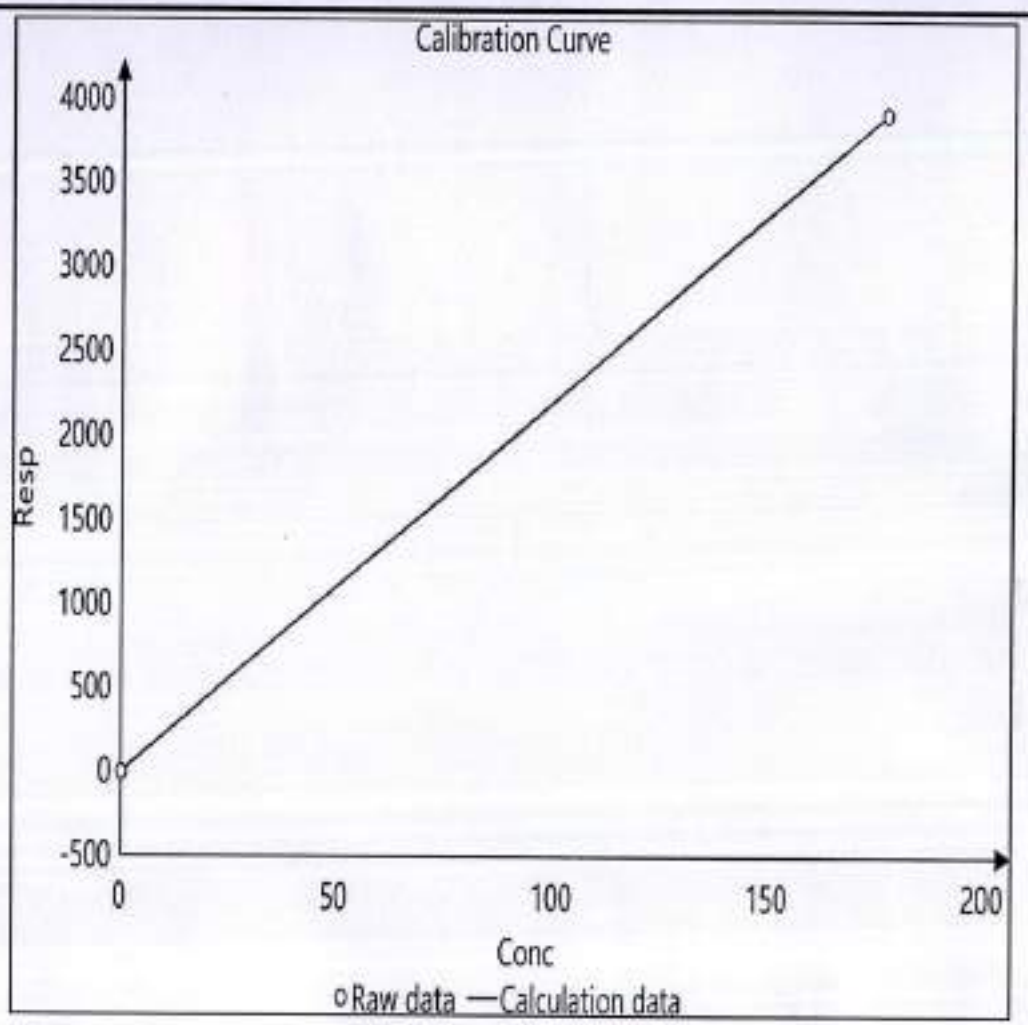
Calibrator Name	Concentration	Unit	Average Response	Lot No.
WATER	0.00	mg/dl	-0.71	QFT10058
ELICAL-2	177.00	mg/dl	3918.87	220782

Cal Method
Linear

Calibration Parameter
K = 22.1446;b = -0.7139

Reagent Blank
0.0000

Calibration time
10/30/2023 6:23:26 PM



Calibration Result(UREA)

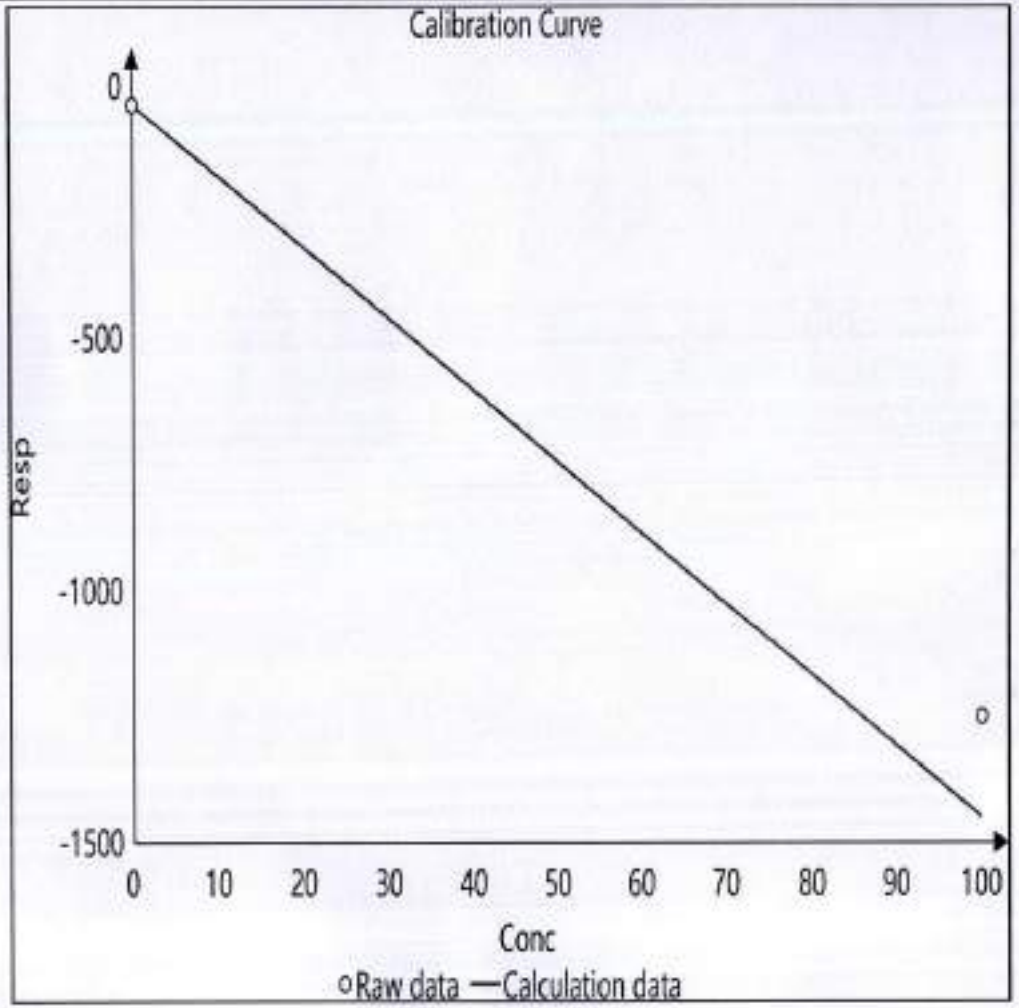
Calibrator Name	Concentration	Unit	Average Response	Lot No.
WATER	0.00	mg/dl	-36.82	QFT10058
ELICAL-2	100.00	mg/dl	-1249.77	220782

Cal Method
Linear

Calibration Parameter
K = -14.1300;b = -36.8200

Reagent Blank
0.0000

Calibration time
10/30/2023 6:23:26 PM



Calibration Result(URIC ACID)

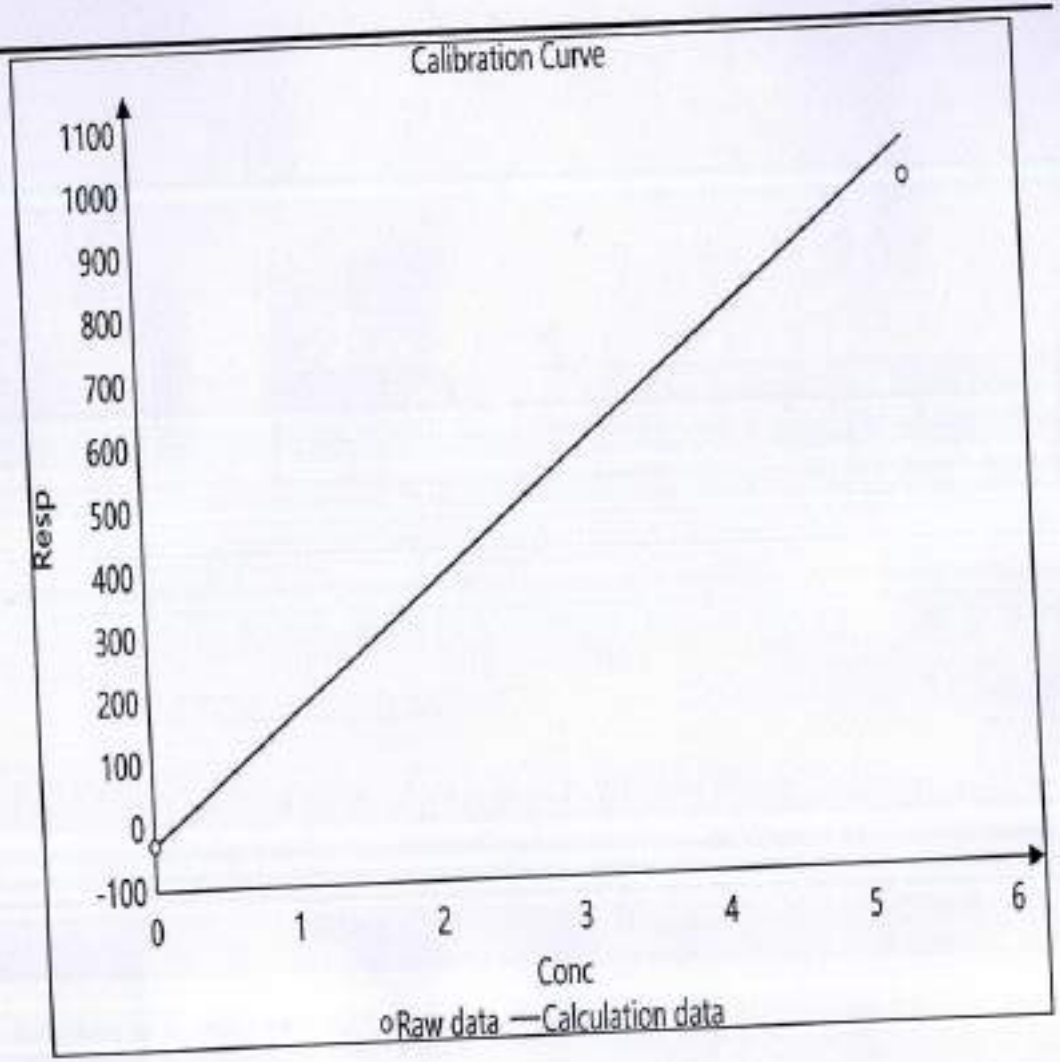
Calibrator Name	Concentration	Unit	Average Response	Lot No.
WATER	0.00	mg/dl	-28.68	QFT10058
ELICAL-2	5.39	mg/dl	987.01	220782

Cal Method
Linear

Calibration Parameter
K = 200.4400;b = -28.6807

Reagent Blank
0.0000

Calibration time
10/30/2023 6:28:10 PM



Calibration Result(TOTAL Protein)

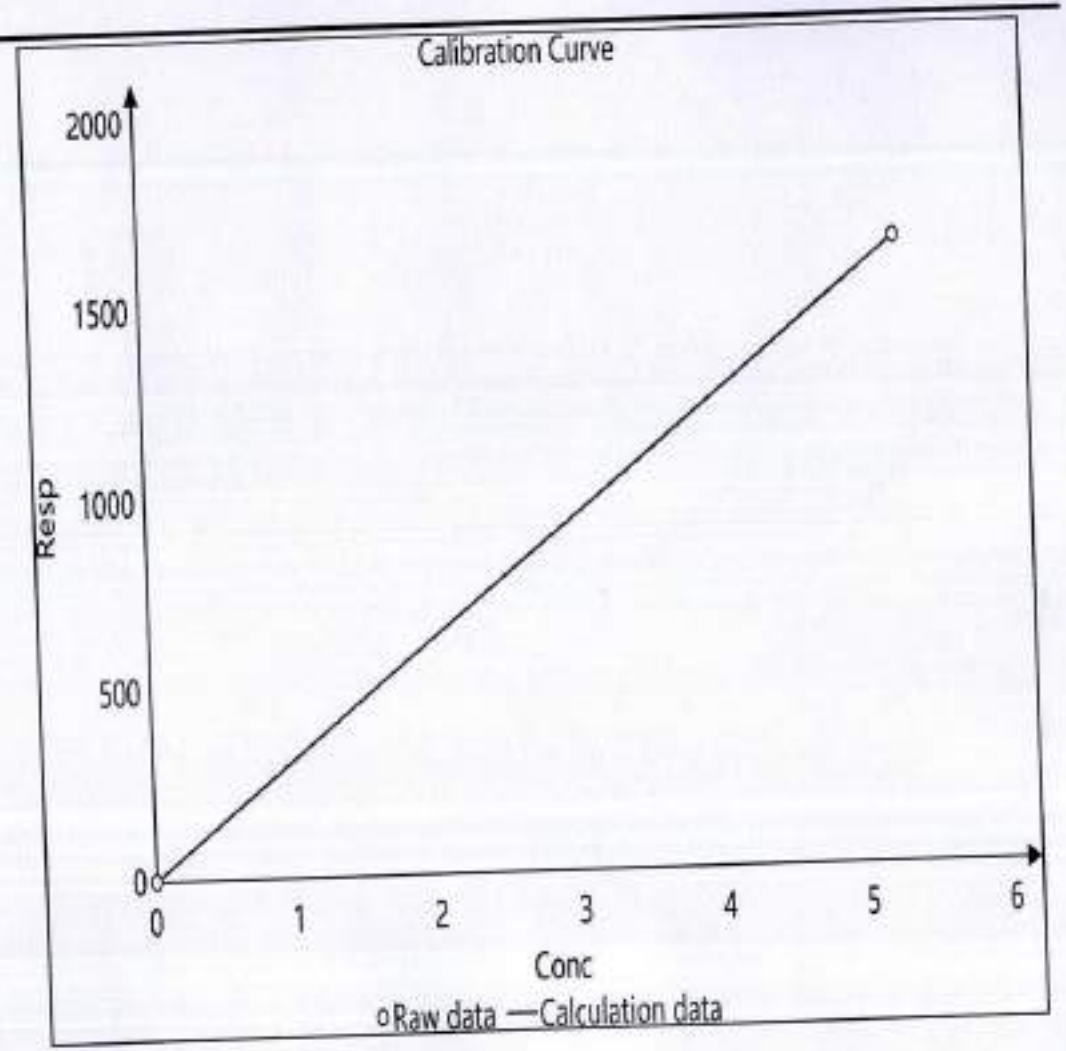
Calibrator Name	Concentration	Unit	Average Response	Lot No.
WATER	0.00	g/dl	0.89	QFT10058
ELICAL-2	5.26	g/dl	1648.72	220782

Cal Method
Linear

Calibration Parameter
K = 313.2762;b = 0.8856

Reagent Blank
0.0000

Calibration time
10/30/2023 6:27:47 PM



Calibration Result(CRE-D)

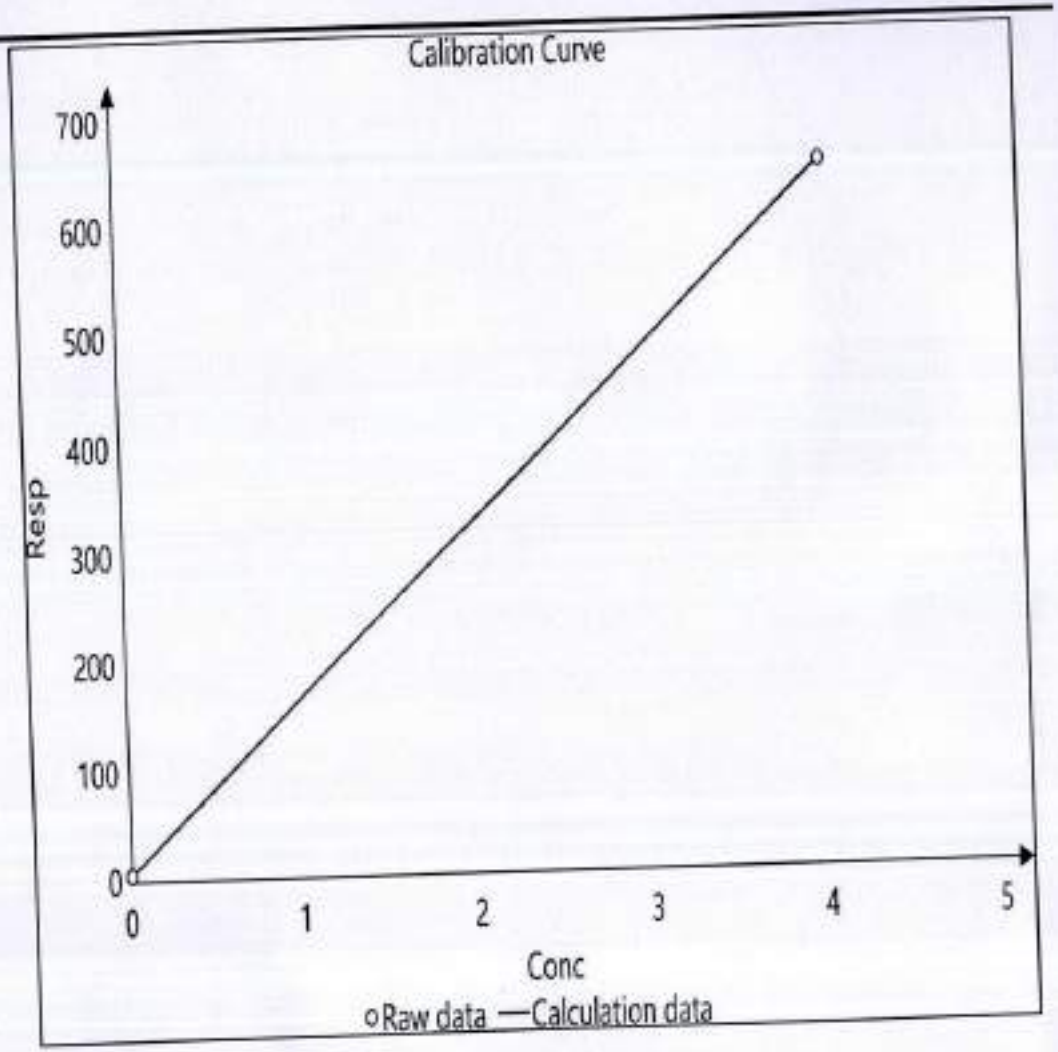
Calibrator Name	Concentration	Unit	Average Response	Lot No.
WATER	0.00	mg/dl	5.98	QFT10058
ELICAL-2	4.03	mg/dl	651.16	220782

Cal Method
Linear

Calibration Parameter
K = 160.0928;b = 5.9839

Reagent Blank
0.0000

Calibration time
10/30/2023 06:27:05 PM



Calibration Result(HDL)

Calibrator Name	Concentration	Unit	Average Response	Lot No.
WATER	0.00	mg/dl	-85.85	QFT10058
HDL CAL	66.28	mg/dl	2434.04	22-0829

Cal Method
Linear

Calibration Parameter
K = 38.0200;b = -85.8460

Reagent Blank
0.0000

Calibration time
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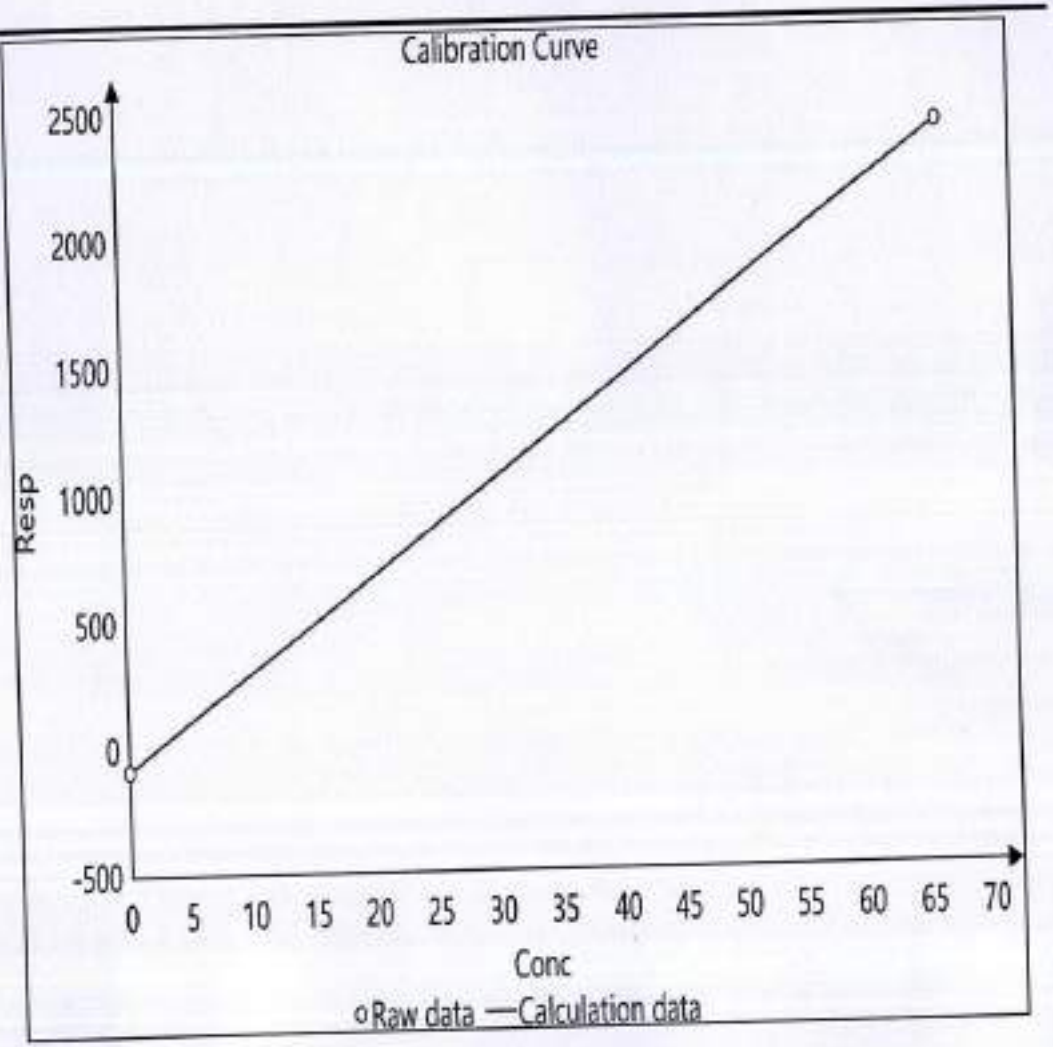

Calibration Result(HBA1C)

Calibrator Name	Concentration	Unit	Average Response	Lot No.
WATER	0.00	%	360.47	QFT10058
HBA1C 1	5.30	%	2017.00	
HBA1C 2	8.00	%	4989.00	
HBA1C 3	12.00	%	12318.51	
HBA1C 4	15.20	%	17133.47	

Cal Method
Spline

Calibration Parameter
R0(1) = 360.4745;R0(2) = 2017.0000;R0(3) = 4989.0000;R0(4) = 12318.5139;a(1) = 312.5520;a(2) = 688.4438;a(3) = 1542.3506;a(4) = 1714.7711;b(1) = -70.9230;b(2) = 141.8460;b(3) = 174.4158;b(4) = -131.3107;c(1) = 13.3817;c(2) = 4.0210;c(3) = -25.4772;c(4) = 20.5173

Reagent Blank
0.0000

Calibration time
10/30/2023 6:29:27 PM