



**Beckman Coulter India Pvt. Ltd.**

Local Office:

The DLF Galleria Bearing Unit No. 1201

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Email ID: [NHAQUE@beckman.com](mailto:NHAQUE@beckman.com)

To

Dated : 30/01/2021

**To Whomsoever it may concern**

This is to certify that the Fully Automated Biochemistry Analyzer , Model AU480 with ISE { Sr.No. 2020093813} has been calibrated to day { 30/01/2021} as per the standard Beckman Coulter Protocol at KINS Care and Research Foundation Pvt Ltd, Siliguri, West Bengal. The next calibration is due on 30/01/2022.

Thanking you and with Regards.

For Souvik Maiti  
{ Field Service Engineer, East}

**Beckman Coulter India Pvt. Ltd**

Registered Office: Unit-Nos. TF-B-07 (A) to 15, 3<sup>rd</sup> Floor, B Wing, Art Guild House, Phoenix Market City,

LBS Road Kurla (West), Mumbai 400070 Tel: +91 22 3080 5000 Fax: +91 22 3080 5060,

CIN: U33119MH2005PTC157177 ● [www.beckmancoulter.com](http://www.beckmancoulter.com)

**AU-680 Performance Qualification Document Page 2 of 3**

## KINS DIAGNOSTICS

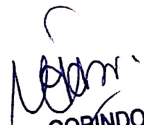
A UNIT OF KINS CARE & RESEARCH FOUNDATION PVT LTD

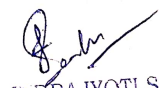
DEPARTMENT OF KINS LABORATORY SERVICES

1ST FLOOR, GOLDEN HEIGHT BUILDING, JHANKAR MORE, SILIGURI -05, PHONE NO- 0353 0-2500091 MOBILE - 9775530737

### SCOPE FOR AU-480 BECKMAN COULTER AUTO ANALYSER

S. No.	Product / Material of Test	Specific Test Performed	Test Method	Range of Testing / Limit of detection	CV%
1	Plasma	GLUCOSE	GOD - POD	10 - 800 mg/dl	1.7
2	Serum	UREA	Urease UV/GLDH	2 - 140 mg/dl	2.8
3	Serum	CREATININE	Enzymatic	10 - 2000 U/L	2.2
4	Serum	TOTAL - BILIRUBIN	Diazonium salt/ Colorimetric	0 - 30 mg/dl	6.3
5	Serum	TOTAL PROTIEN	Biuret - Colorimetric	3 - 12 g/dl	4
6	Serum	ALBUMIN	BCG - Colorimetric	1.5 - 6.0 g/dl	1.4
7	Serum	CALCIUM	Arsenazo-III	4 - 18 mg/dl	1
8	Serum	URIC ACID	Uricase	1.5 - 30 mg/dl	1.1
9	Serum	CHOLESTEROL	CHOD-PAP	25 - 700 mg/dl	1.2
10	Serum	TRIGLYCERIDE	GPO-PAP	10- 1000 mg/dl	2.9
11	Serum	HDL -CHOLESTROL	Direct Method	2.5 200 mg/dl	1.5
12	Serum	SODIUM	ISE Direct	50 - 200 mmol/L	1.5
13	Serum	POTASSIUM	ISE Direct	1 -10 mmol/L	1.5
14	Serum	CHLORIDE	ISE Direct	50 - 200 mmol/L	1.6
15	Serum	PHOSPHORUS	MolybdateUV	1 - 20 mg/dl	1
16	Serum	SGOT /AST	UV Kinetic without PLP	3 -1000 U/L	1.6
17	Serum	SGPT /ALT	UV Kinetic without PLP	3 - 500 U/L	3.5
18	Serum	ALKALINE PHOSPHATASE/ ALP	PNP AMP Kinetic	3 -500 U/L	5.5
19	Serum	AMYLASE	CNPG3	10 - 2000 U/L	1.6
20	WHOLE BLOOD	HBA1C	IMMUNO TURBIDIMETRY	3.2 - 14.5 %	2.4

  
GOBINDO GHOSH  
MANAGER - QM  
KINS CARE & RESEARCH FOUNDATION PVT. LTD.

  
DR. INDRAJYOTI SARKAR  
MD (BIOCHEMISTRY)

**Annexure 2.**  
**AU-480 Chemistry System Performance Evaluation.**

Following Procedure was Carried out as part of the Performance Qualification:-

**1. Calibration of Assay.**

Assays calibrated and checked –: GLU, UREA, CREAT.AST,ALP,ALB,  
TP,LDH,HDL,AMY, CALA etc.

Checked and found all calibrations are within the acceptable CV limits and in  
range.

See Print out Attached.

**2. Internal Quality Control Performance.**

Randox Chemistry Control -L2

Checked and found all level Controls are within the acceptable SD.

See print out Attached.

**3. Precision Study**

A Within Run Precision for all assays for 10 replicates was carried out, CV % obtained  
are within the acceptable limit for the assay.

See print out attached.

Calibration

Calibration Monitor

Status

RB History

RB Detail

Calibration History

Calibration Detail

Test Name

3.GLUC

Type

Serum

Date/Time

01/25/2021 17:32

Passed

Reagent

Lot No.

Bottle No.

R1(R1-1)

2584

C462

R2(R2-1)

2584

C731

Cal Expiration Date

02/24/2021 17:32

Reagent Blank

01/25/2021 17:26

Cal Type

AB

Measure Type

Rack

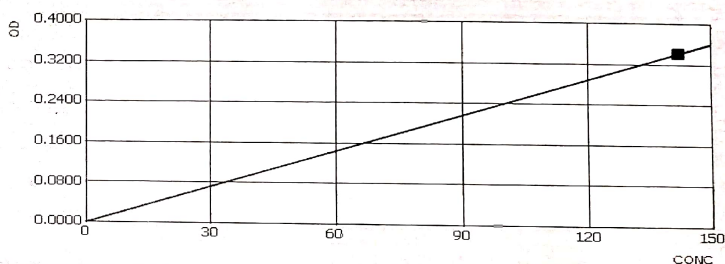
Formula

Y=AX+B

Factor

A = 4.1605E002

B = 0.0000E000



	Cal No.	CONC	OD
1	1	142	0.3413

Comment

Lot to Lot Calibration

RB/CAL Selection

Data Select

Comment

Graph Scale

Print



**Calibration**

**Calibration Monitor**

Status

RB History

RB Detail

Calibration History

Calibration Detail

Test Name



Type

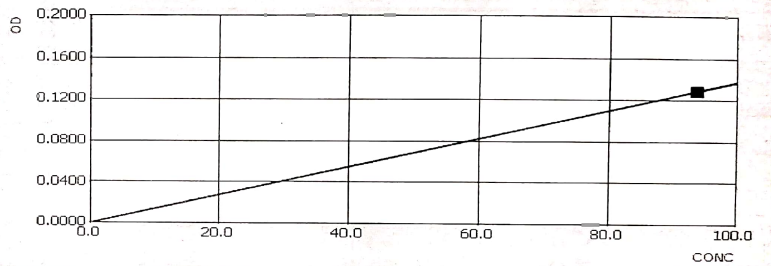
Date/Time

Passed

Reagent Lot No. Bottle No.

R1(R1-1) 2591 1808

R2(R2-1) 2591 1881



Cal Expiration Date

Reagent Blank

Cal Type

Measure Type

Formula

Factor

A = 7.2712E002

B = 0.0000E000

Cal No.	CONC	OD
1	93.6	0.1287

Comment

Lot to Lot Calibration

RB/CAL Selection

Data Select

Comment

Graph Scale

Print

**Calibration**

**Calibration Monitor**

Test Name: 17.CREZ Type: Serum

Date/Time: 01/25/2021 17:36 Passed

Reagent Lot No. Bottle No.  
 R1(R1-1) 2490 B464  
 R2(R2-1) 2490 B404

Cal Expiration Date: 02/08/2021 17:36

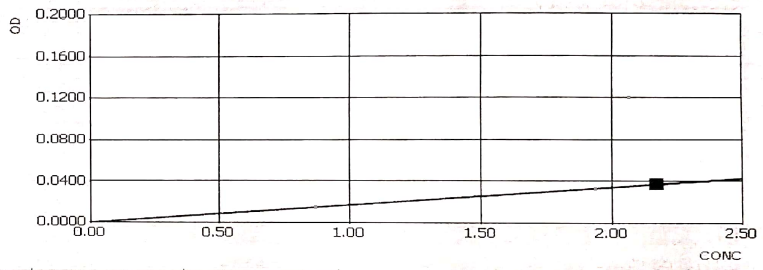
Reagent Blank: 01/25/2021 17:30

Cal Type: AB

Measure Type: Rack

Formula: Y=AX+B

Factor  
 A = 5.8517E001  
 B = 0.0000E000



	Cal No.	CONC	OD
1	1	2.17	0.0371

Comment

MEASURE 2

01/29/2021  
10:52

Calibration

Calibration Monitor

Status

RB History

RB Detail

Calibration History

Calibration Detail

Test Name

1.ALB

Type

Serum

Date/Time

01/25/2021 17:31

Passed

Reagent

Lot No.

Bottle No.

R1(R1-1)

2557

2339

R2(R2-1)

Cal Expiration Date

Reagent Blank

01/25/2021 17:25

Cal Type

AB

Measure Type

Rack

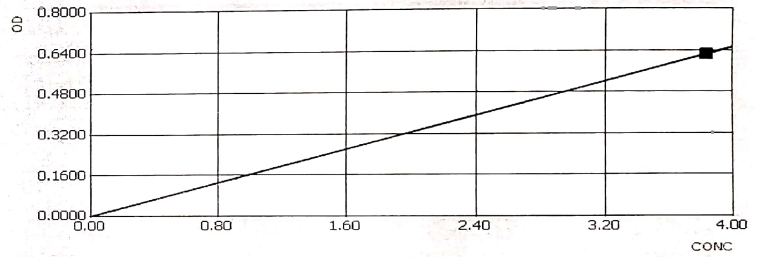
Formula

Y=AX+B

Factor

A = 6.1308E000

B = 0.0000E000



	Cal No.	CONC	OD
1	1	3.83	0.6247

Comment

Lot to Lot  
Calibration

RB/CAL  
Selection

Data Select

Comment

Graph Scale

Print



**Calibration**

**Calibration Monitor**

Status      RB History      RB Detail      Calibration History      Calibration Detail

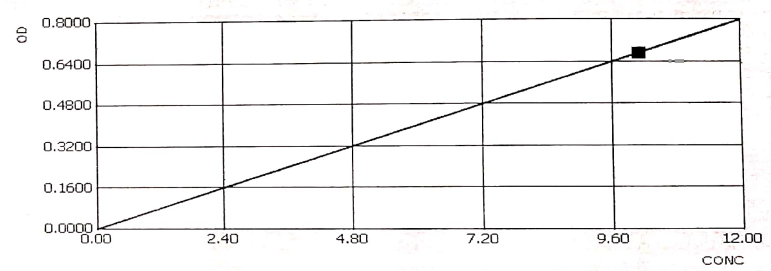
Test Name: 10.CALA      Type: Serum

Date/Time: 01/25/2021 17:34      Passed

Reagent: Lot No. 2538      Bottle No. 8801

R1(R1-1)

R2(R2-1)



Cal Expiration Date:

Reagent Blank: 01/25/2021 17:27

Cal Type: AB

Measure Type: Rack

Formula:  $Y=AX+B$

Factor:  
 $A = 1.5026E001$   
 $B = 0.0000E000$

	Cal No.	CONC	OD
1	1	10.10	0.6722

Comment

Lot to Lot Calibration      RB/CAL Selection      Data Select      Comment      Graph Scale      Print



MEASUR 2

01/29/2021  
10:55

Calibration

Calibration Monitor

Status

RB History

RB Detail

Calibration History

Calibration Detail

Test Name 11.PHOS

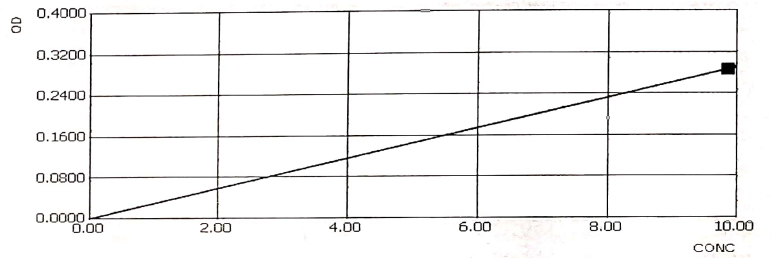


Type Serum

Date/Time 01/25/2021 17:34

Passed

Reagent	Lot No.	Bottle No.
R1(R1-1)	2567	2390
R2(R2-1)	2567	3256



Cal Expiration Date 02/24/2021 17:34

Reagent Blank 01/25/2021 17:28

Cal Type AB

Measure Type Rack

Formula Y=AX+B

Factor

A = 3.4397E001

B = 0.0000E000

Cal No.	CONC	OD
1	9.86	0.2867

Comment

Lot to Lot Calibration

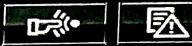
RB/CAL Selection

Data Select

Comment

Graph Scale

Print



Calibration

Calibration Monitor

Status

RB History

RB Detail

Calibration History

Calibration Detail

Test Name 18.UA

Type Serum

Date/Time 01/25/2021 17:36 Passed

Reagent Lot No. Bottle No.  
 R1(R1-1) 2564 3200  
 R2(R2-1) 2564 3117

Cal Expiration Date 02/24/2021 17:36

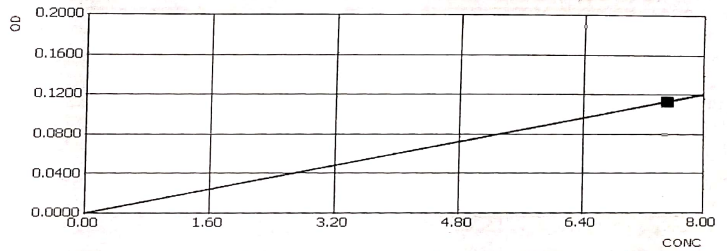
Reagent Blank 01/25/2021 17:30

Cal Type AB

Measure Type Rack

Formula  $Y=AX+B$

Factor  
 A = 6.6314E001  
 B = 0.0000E000



	Cal No.	CONC	OD
1	1	7.51	0.1132

Comment

Lot to Lot Calibration

RB/CAL Selection

Data Select

Comment

Graph Scale

Print

MEASURE 2

01/29/20  
10:53

Calibration

Calibration Monitor

Status

RB History

RB Detail

Calibration History

Calibration Detail

Test Name 2.CHOL

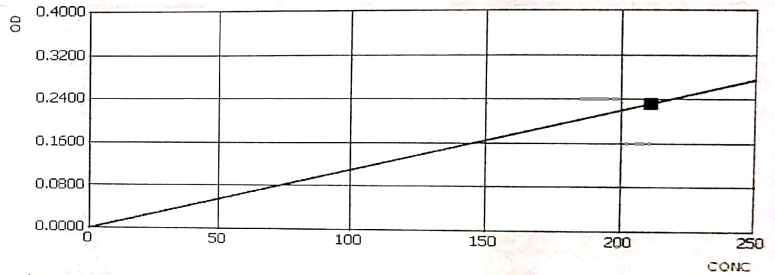
Type Serum

Date/Time 01/25/2021 17:32 Passed

Reagent Lot No. Bottle No.

R1(R1-1) 2567 2230

R2(R2-1)



Cal Expiration Date

Reagent Blank 01/25/2021 17:25

Cal Type AB

Measure Type Rack

Formula Y=AX+B

Factor

A = 9.0855E002

B = 0.0000E000

	Cal No.	CONC	OD
1	1	211	0.2322

Comment

Lot to Lot Calibration

RB/CAL Selection

Data Select

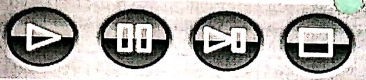
Comment

Graph Scale

Print



MEASU 2



01/29/2021  
10:54

### Calibration

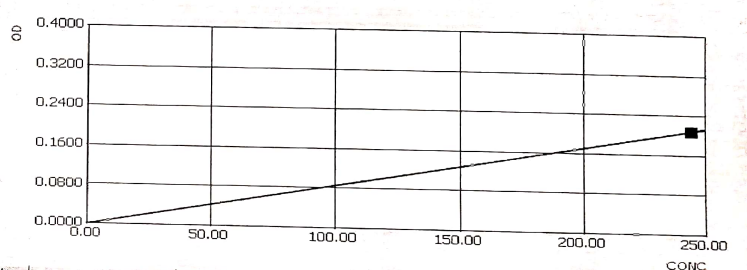
### Calibration Monitor

- Status
- RB History
- RB Detail
- Calibration History
- Calibration Detail

Test Name: 5.TRIG Print Copy Type: Serum

Date/Time: 01/25/2021 17:32 Print Passed

Reagent Lot No. Bottle No.  
 R1(R1-1) 2564 4189  
 R2(R2-1) 2564 4134



Cal Expiration Date: 02/24/2021 17:32  
 Reagent Blank: 01/25/2021 17:26  
 Cal Type: AB  
 Measure Type: Rack  
 Formula: Y=AX+B  
 Factor:  
 A = 1.1732E003  
 B = 0.0000E000

	Cal No.	CONC	OD
1	1	244.00	0.2080

Comment

- Lot to Lot Calibration
- RB/CAL Selection
- Data Select
- Comment
- Graph Scale
- Print



**Calibration**

**Calibration Monitor**

- Status
- RB History
- RB Detail
- Calibration History
- Calibration Detail

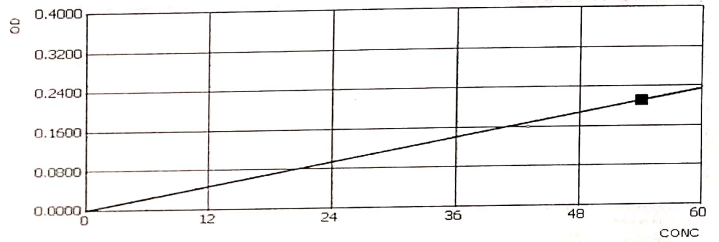
Test Name: 4.HDL-C

Type: Serum

Date/Time: 01/28/2021 11:09

Passed

Reagent	Lot No.	Bottle No.
R1(R1-1)	2442	2793
R2(R2-1)	2442	2799



Cal Expiration Date: 02/27/2021 11:09

Reagent Blank: 01/28/2021 11:03

Cal Type: AB

Measure Type: Rack

Formula: Y=AX+B

Factor  
 A = 2.5560E002  
 B = 0.0000E000

	Cal No.	CONC	OD
1	2	54	0.2113

Comment

- Lot to Lot Calibration
- RB/CAL Selection
- Data Select
- Comment
- Graph Scale
- Print

**Maintenance**

**User Maintenance**

Analyzer Maintenance | **ISE Maintenance** | PROService | Load Reagent Parameters

Maintenance | Calibration | Slope Chart | Selectivity Check | CRS Calibration

ISE Status: READY | Electrode Status: Na | K | Cl | Reagent Status: REF | MID | Buffer

Type: Serum

Date/Time	Slope			MID Solution Factor		
	Na	K	Cl	Na	K	Cl
03/17/2021 16:10	54.2	52.8	-47.8	0.968	1.023	0.968
03/17/2021 08:01	52.6	51.9	-46.9	0.976	1.033	0.977
03/16/2021 07:56	53.0	51.8	-47.3	0.977	1.033	0.979
03/15/2021 08:21	53.3	52.0	-47.8	0.975	1.030	0.976
03/14/2021 10:46	53.3	52.0	-47.3	0.974	1.030	0.977
03/13/2021 08:22	52.7	51.6	-46.9	0.974	1.028	0.975
03/12/2021 08:12	54.1	52.2	-48.1	0.974	1.030	0.975
03/11/2021 08:16	53.3	52.1	-48.0	0.974	1.030	0.975
03/10/2021 10:30	54.7	53.0	-48.7	0.978	1.034	0.980
03/10/2021 08:13	53.7	52.6	-48.5	0.976	1.033	0.979
03/09/2021 08:23	53.6	52.3	-48.6	0.974	1.030	0.976
03/08/2021 08:10	53.3	52.1	-48.8	0.974	1.030	0.977
03/07/2021 11:00	55.2	52.6	-49.7	0.977	1.031	0.979
03/06/2021 08:11	52.9	52.2	-48.8	0.974	1.029	0.978
03/05/2021 08:13	53.6	52.4	-49.5	0.971	1.028	0.975

Calibration Slope Normal Range

	High	Low
Na	68.0	38.0
K	68.0	38.0
Cl	-38.0	-68.0

MID Std. Factor Range

	High	Low
Na	1.200	0.800
K	1.200	0.800
Cl	1.200	0.800

Serum Start | Urine Start | Serum/Urine Start

ISE Stop



MEASURE 1



03/05/2021

09:30

### Calibration

### Calibration Monitor

Status

RB History

RB Detail

Calibration History

Calibration Detail

Test Name

11.PHOS



Type

Serum

Date/Time

03/04/2021 09:17

Passed

Reagent

Lot No.

Bottle No.

R1(R1-1)

2567

2390

R2(R2-1)

2567

3256

Cal Expiration Date

04/03/2021 09:17

Reagent Blank

03/04/2021 09:14

Cal Type

AB

Measure Type

Rack

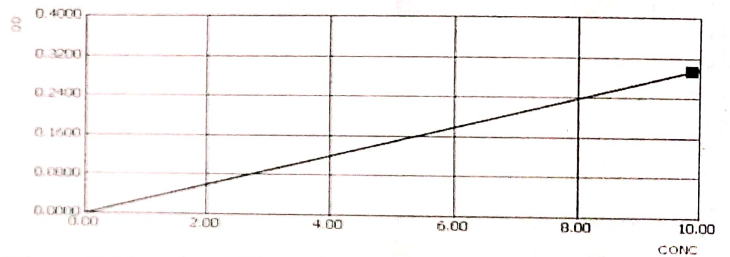
Formula

Y=AX+B

Factor

A = 3.3585E001

B = 0.0000E000



Cal No.	CONC	OD
1	9.86	0.2936

Comment

Lot to Lot  
Calibration

RB/CAL  
Selection

Data Select

Comment

Graph Scale

Print



**Calibration**

**Calibration Monitor**

Status

RB History

RB Detail

Calibration History

Calibration Detail

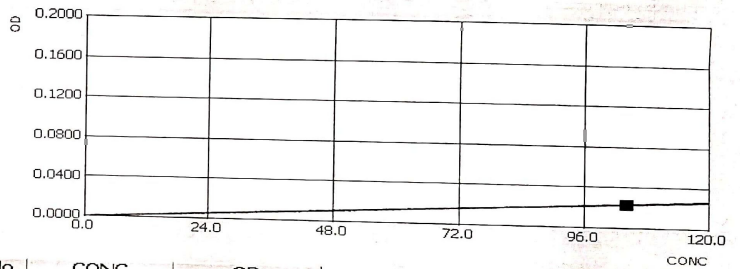
Test Name: 12.AST

Date/Time: 01/25/2021 17:35

Reagent: R1(R1-1) Lot No. 2545 Bottle No. I074  
 R2(R2-1) Lot No. 2545 Bottle No. H724

Type: Serum

Passed



Cal Expiration Date:   
 Reagent Blank: 01/25/2021 17:28  
 Cal Type: AB  
 Measure Type: Rack  
 Formula: Y=AX+B  
 Factor:  
 A = 4.5055E003  
 B = 0.0000E000

Cal No.	CONC	OD
1	104.0	0.0231

Comment





MEASURE 2



01/29/2021  
10:53

Calibration

Calibration Monitor

Status

RB History

RB Detail

Calibration History

Calibration Detail

Test Name 13.ALT

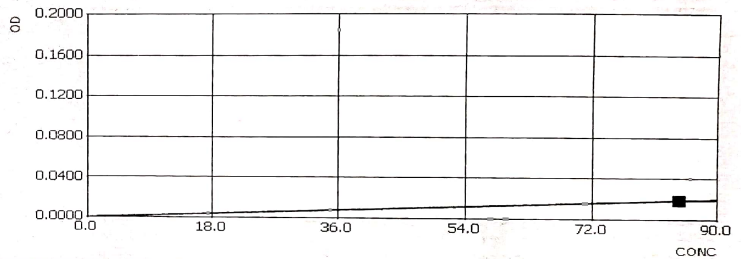


Type Serum

Date/Time 01/25/2021 17:35

Passed

Reagent	Lot No.	Bottle No.
R1(R1-1)	2570	H521
R2(R2-1)	2570	H953



Cal Expiration Date

Reagent Blank 01/25/2021 17:28

Cal Type AB

Measure Type Rack

Formula  $Y = AX + B$

Factor  
 $A = 4.5163E003$   
 $B = 0.0000E000$

	Cal No.	CONC	OD
1	1	84.5	0.0187

Comment

Lot to Lot Calibration

RB/CAL Selection

Data Select

Comment

Graph Scale

Print





MEASU 2



01/29/2021  
10:52

Calibration

Calibration Monitor

Status

RB History

RB Detail

Calibration History

Calibration Detail

Test Name 6.ALPO4

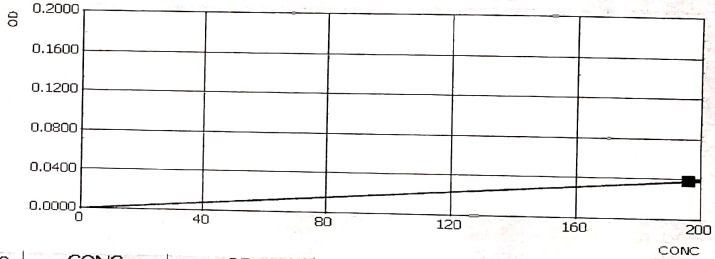


Type Serum

Date/Time 01/25/2021 17:33

Passed

Reagent	Lot No.	Bottle No.
R1(R1-1)	2563	A642
R2(R2-1)	2563	A521



Cal Expiration Date

Reagent Blank 01/25/2021 17:26

Cal Type AB

Measure Type Rack

Formula  $Y=AX+B$

Factor  
 $A = 5.1766E003$   
 $B = 0.0000E000$

	Cal No.	CONC	OD
1	1	196	0.0379

Comment

Lot to Lot Calibration

RB/CAL Selection

Data Select

Comment

Graph Scale

Print



MEASURE 2

03/05/2021  
09:55

Calibration

Calibration Monitor

Status

RB History

RB Detail

Calibration History

Calibration Detail

Test Name

19.AMY

Type

Serum

Date/Time

03/05/2021 09:45

Passed

Reagent

Lot No.

Bottle No.

R1(R1-1)

2553

6803

R2(R2-1)

Cal Expiration Date

Reagent Blank

03/05/2021 09:41

Cal Type

AB

Measure Type

Rack

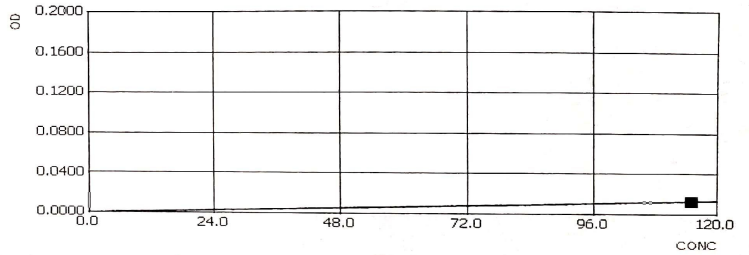
Formula

Y=AX+B

Factor

A = 8.9544E003

B = 0.0000E000



	Cal No.	CONC	OD
1	1	115.0	0.0128

Comment

Lot to Lot  
Calibration

RB/CAL  
Selection

Data Select

Comment

Graph Scale

Print





MEASURE 2



01/29/2021  
10:58

### Calibration

### Calibration Monitor

- Status
- RB History
- RB Detail
- Calibration History
- Calibration Detail

Test Name: 23.HbA1c

Date/Time: 01/28/2021 12:29

Reagent	Lot No.	Bottle No.
R1(R1-1)	1051	3272
R2(R2-1)	1051	2240

Cal Expiration Date:

Reagent Blank: 01/28/2021 12:22

Cal Type: 5AB

Measure Type: Rack

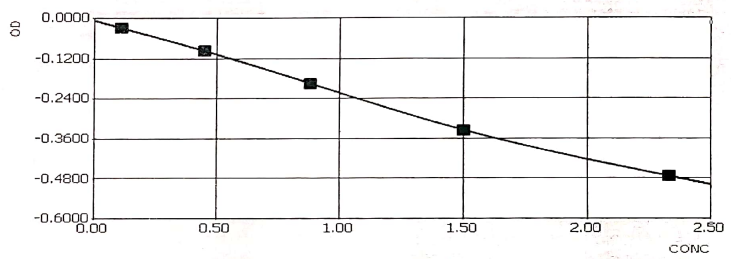
Formula: Spline

Factor

A0 = 0.0000E000  
 B0 = 0.0000E000  
 C0 = -1.9722E-001

Type: Serum

Passed



Cal No.	CONC	OD
1	0.11	-0.0283
2	0.45	-0.0971
3	0.88	-0.1946
4	1.50	-0.3347
5	2.33	-0.4729

Comment

Lot to Lot Calibration

RB/CAL Selection

Data Select

Comment

Graph Scale

Print

