

AAMX BIOMEDICALS



Shop No. 01 Shiv Mandir Tara Nagar District Sonapat-131001, State - Haryana, India
Email: aamxbiomedicals@rediffmail.com, Mob: +91 9813151502

INSTALLATION QUALIFICATION

The Installation for Trace 120 Marketed By AAMX Biomedicals Sr.No. AE2K0KH09127 carried at Sanjivani Diagnostics, 2085, Near Delite Cinema, Behind Asaf Ali Road, Petrol Pump, Delhi- 110002

Checked all the Mechanisms through the Software like Reagent Arm/Sample Arm/Mixer, Reagent Disk/ Sample Disk/ Reaction Disk Movement for different position.

Checked the system performance for different Parameters .

Calibration & Control for all the Assays was satisfactory.

Carried out the Precision Check for above parameters which was also good.

For AAMX Biomedicals,

*Nitin Choudhary
Zonal Manager
Delhi*

Date : 05/04/2022

INSTALLATION CERTIFICATE

This is to certify that the Trace 120 Marketed By AAMX Biomedicals Bio Chemistry Analyzer Sr.No.: AES2K0KH09127 has been successfully Installed and Commissioned at Sanjivani Diagnostics, 2085, Near Delite Cinema, Behind Asaf Ali Road, Petrol Pump, Delhi-110002 as per the Installation Procedure & Checklist.

For AAMX Biomedicals

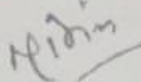

For Sanjivani Diagnostics

Name : Nitin Choudhary

Name : SHIV KUMAR.

Designation: Zonal Manager

Designation: Director.

Signature:  

Signature: 

Date: 05/04/2022

Date: 05/04/2022

AAMX BIOMEDICALS



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PERFORMANCE QUALIFICATION

*Carried out the following Checks for the Performance of the System Trace 120
Marketed By AAMX Biomedicals Sr. No. AE2K0KH09127*

Run the TruCal U Calibrator, TruLab N control (DiaSys).

*Quality Checks for which the performance is OK & the Results are Satisfactory,
within the Specified range.*

*Precision Checks: Carried out the Precision checks for different Parameters for which
Precision was found to be satisfactory.*

For AAMX Biomedicals,

Nitin Choudhary
Zonal Manager
Delhi

Date : 05/04/2022

Calibration Certificate

Following voltages have been checked & adjusted on Trace 120 Marketed By AAMX Biomedicals (Sr. No. -AE2K0KH09127) at Sanjivani Diagnostics, 2085, Near Delite Cinema, Behind Asaf Ali Road, Petrol Pump, Delhi-110002.

System Voltages DC:

S.No.	Module	Observed Value	Acceptable Range
1	Main Power Voltage	225 VAC	220 +/- 10.0 VAC
2	24 Voltage Supply	24.4 VDC	24.0 +/- 1.0 VDC
3	12 Voltage Supply	12.3 VDC	12.0 +/- 0.5 VDC
4	Liquid Level Sensor Board Supply	4.52 VDC	4.50 +/- 0.1 VDC

System Temperature:

S.No.	Module	Observed Value	Acceptable Range
1	Reaction Disk Temp.	37 °C	37 +/- 0.4 °C
2	Reagent Compartment Temp.	10 °C	8 to 12 °C

Photometer Adjustment:

S.No.	Module	Observed Value	Acceptable Range
1	Background Count for all Wavelength	40,000 to 49,000	20,000 to 60,000

Syringes Module:

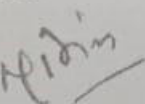
S.No.	Module	Observed Value	Acceptable Range
1	Reagent Syringe	500 uL	500 +/- 1uL
2	Sample Syringe	100 uL	100 +/- 0.1uL

Washing Dispense:

S.No.	Module	Observed Value	Acceptable Range
1	Interior Washing	3.01 mL	3.00 +/- 500uL
2	Exterior Washing	3.01 mL	3.00 +/- 500uL

- All other mechanisms have been checked through software and found OK.
- Performed calibration for End Point, Kinetic & Fixed Time-Kinetic. Run control & sample, Results were satisfactory.
- Next Calibration will be performed on 04/04/2023

For AAMX Biomedicals

Nitin Choudhary
Zonal Manager
Delhi

Date : 05/04/2022

- Test
- Reagent
- Calibration**
- QC
- Maintenance
- System Setting
- Replace Cuvettes

Calibration Register Calibration Results

No.	Test Name	Hint
1	GLU	
2	ALB	
3	AST(OT)	
4	ALT(PT)	
5	ALP	
6	T BILL	
7	DBILL	
8	CAL	
9	CHOL	
10	CREAT	
11	HDL-C	
12	TP	
13	TG	
14	UA	
15	UREA	
16	AMY	
17	HBA1C	
18	CRP	
19	LDH	
20	RA-F	
21	FERITIN	
22	p04	
23	HDL C	
24	IRON	
25	D-DIMER	
26	IGE	
27	ASO	

Calibration Type: Blank Type:

S1 Abs.: K Value: A: B: C:

Test Date:



Standard	<0>	<1>	<2>	<3>	<4>	<5>	<6>	<7>
Concentration	<input type="text" value="0.0"/>	<input type="text" value="106.0"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Abs.	<input type="text" value="-0.0827"/>	<input type="text" value="-0.4134"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Position	<input type="text" value="39"/>	<input type="text" value="40"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

-
-
-
-
-
-
-

Operator:admin

Max Delay :0.492 ms

Machine IP:192.168.2.30



Test



Reagent



Calibration



QC



Maintenance



System Setting



Replace Cuvettes

Calibration Register

Calibration Results

No.	Test Name	Hint
1	GLU	
2	ALB	
3	AST(OT)	
4	ALT(PT)	
5	ALP	
6	T BILL	
7	D BILL	
8	CAL	
9	CHOL	
10	CREAT	
11	HDL-C	
12	TP	
13	TG	
14	UA	
15	UREA	
16	AMY	
17	HBA1C	
18	CRP	
19	LDH	
20	RA-F	
21	FERITIN	
22	p04	
23	HDL C	
24	IRON	
25	D-DIMER	
26	IGE	
27	ASO	

Calibration Type

2 point linear

Blank Type

Reagent blank

S1 Abs.

K Value

A

B

C

0.0103

244.6170

0.0000

0.0000

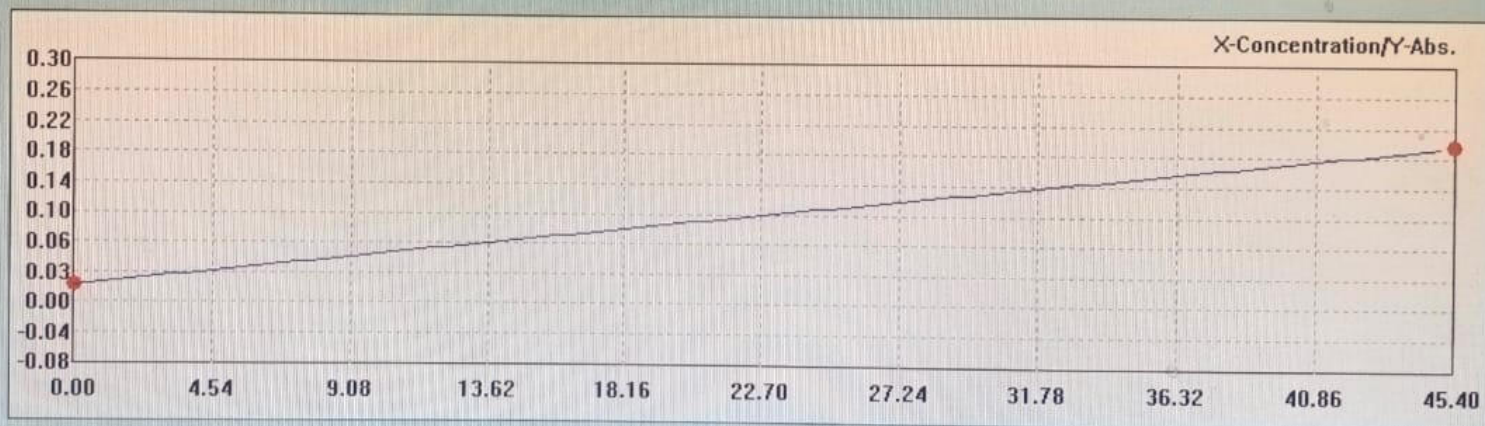
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Test Date

2022-07-07 20:11:54

Reaction Curve

Calibration Trace



Standard

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<1>

<2>

<3>

<4>

<5>

<6>

<7>

Concentration

0.0

45.4

Abs.

0.0103

0.1959

Position

39

38

Operator:admin

Max Delay :0.492 ms

Machine IP:192.168.2.30

Type here to search



Test Reagent **Calibration** QC Maintenance System Setting Replace Cuvettes

Calibration Register Calibration Results

No.	Test Name	Hint
1	GLU	
2	ALB	
3	AST(OT)	
4	ALT(PT)	
5	ALP	
6	T BILL	
7	D BILL	
8	CAL	
9	CHOL	
10	CREAT	
11	HDL-C	
12	TP	
13	TG	
14	UA	
15	UREA	
16	AMY	
17	HBA1C	
18	CRP	
19	LDH	
20	RA-F	
21	FERITIN	
22	p04	
23	HDL C	
24	IRON	
25	D-DIMER	
26	IGE	
27	ASO	

Calibration Type: Blank Type:

S1 Abs.: K Value:

A: B: C:

Test Date:



Standard	<0>	<1>	<2>	<3>	<4>	<5>	<6>	<7>
Concentration	<input type="text" value="0.00"/>	<input type="text" value="5.25"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Abs.	<input type="text" value="0.0009"/>	<input type="text" value="0.1907"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Position	<input type="text" value="39"/>	<input type="text" value="40"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Start Cond. Sample Stop Stop Status Alarm Shut Down Log Off

- Test
- Reagent
- Calibration**
- QC
- Maintenance
- System Setting
- Replace Cuvettes

Calibration Register Calibration Results

No.	Test Name	Hint
1	GLU	
2	ALB	
3	AST(OT)	
4	ALT(PT)	
5	ALP	
6	T BILL	
7	D BILL	
8	CAL	
9	CHOL	
10	CREAT	
11	HDL-C	
12	TP	
13	TG	
14	UA	
15	UREA	
16	AMY	
17	HBA1C	
18	CRP	
19	LDH	
20	RA-F	
21	FERITIN	
22	p04	
23	HDL C	
24	IRON	
25	D-DIMER	
26	IGE	
27	ASO	

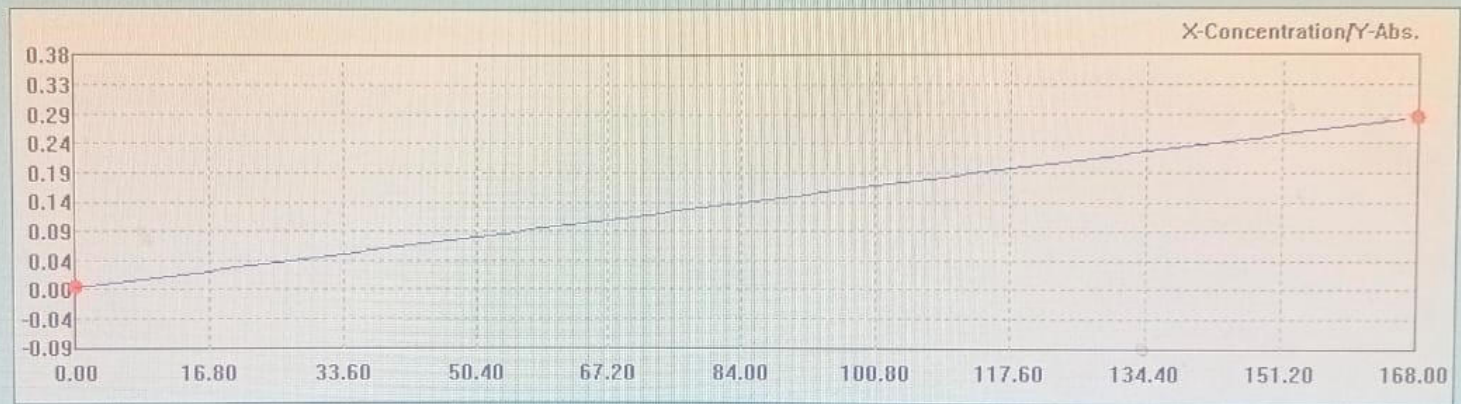
Calibration Type: **2 point linear** Blank Type: **Reagent blank**

S1 Abs. K Value A B C

-0.0001 595.4821 0.0000 0.0000 0.0000

Test Date: **2022-06-07 13:38:18**

Reaction Curve Calibration Trace



Standard	<0>	<1>	<2>	<3>	<4>	<5>	<6>	<7>
Concentration	0.0	168.0						
Abs.	-0.0001	0.2820						
Position	39	40						

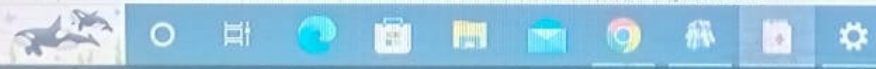
- Start Cond.
- Sample Stop
- Stop
- Status
- Alarm
- Shut Down
- Log Off

Operator:admin

Max Delay:0.492 ms

Machine IP:192.168.2.30

Type here to search



38°C ENG 12:45 PM 14-07-2022





Test



Reagent



Calibration



QC



Maintenance



System Setting



Replace Cuvettes

Calibration Register Calibration Results

No.	Test Name	Hint
1	GLU	
2	ALB	
3	AST(OT)	
4	ALT(PT)	
5	ALP	
6	T BILL	
7	D BILL	
8	CAL	
9	CHOL	
10	CREAT	
11	HDL-C	
12	TP	
13	TG	
14	UA	
15	UREA	
16	AMY	
17	HBA1C	
18	CRP	
19	LDH	
20	RA-F	
21	FERITIN	
22	p04	
23	HDL C	
24	IRON	
25	D-DIMER	
26	IGE	
27	ASO	

Calibration Type

2 point linear

Blank Type

Reagent blank

S1 Abs.

K Value

A

B

C

-0.0093

41.2848

0.0000

0.0000

0.0000

Test Date

2022-07-11 14:36:07

Reaction Curve

Calibration Trace



Standard

<0>

<1>

<2>

<3>

<4>

<5>

<6>

<7>

Concentration

0.00

11.10

Abs.

-0.0093

0.2595

Position

39

40



Start Cond.



Sample Stop



Stop



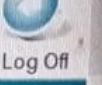
Status



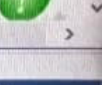
Alarm



Shut Down



Log Off



Operator: admin

Max Delay :0.492 ms

Machine IP:192.168.2.30

Type here to search



38°C 12:45 PM 14-07-2022

Test Reagent **Calibration** QC Maintenance System Setting Replace Cuvettes

Calibration Required Calibration Results

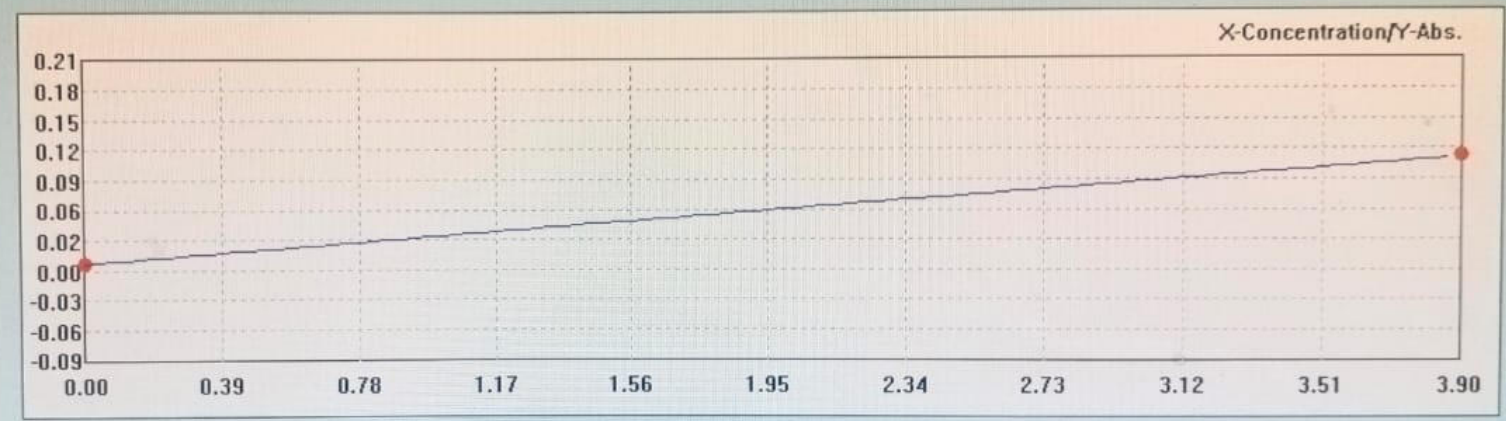
No.	Test Name	Hint
1	GLU	
2	ALB	
3	AST(OT)	
4	ALT(PT)	
5	ALP	
6	T BILL	
7	D BILL	
8	CAL	
9	CHOL	
10	CREAT	
11	HDL-C	
12	TP	
13	TG	
14	UA	
15	UREA	
16	AMY	
17	HBATC	
18	CRP	
19	LDH	
20	RA-F	
21	FERITIN	
22	p04	
23	HDL C	
24	IRON	
25	D-DIMER	
26	IGE	
27	ASO	

Calibration Type: 2 point linear
 Blank Type: Reagent blank

S1 Abs. K Value A B C
 0.0010 36.0268 0.0000 0.0000 0.0000

Test Date: 2022-05-31 15:47:13

Reaction Curve Calibration Trace



Standard	<0>	<1>	<2>	<3>	<4>	<5>	<6>	<7>
Concentration	0.00	3.90						
Abs.	0.0010	0.1093						
Position	39	40						

Start Cond. Sample Stop Stop Status Alarm Shut Down Log Off

Operator: admin

Max Delay :0.492 ms

Machine IP:192.168.2.30

Test Reagent **Calibration** QC Maintenance System Setting Replace Cuvettes

Calibration Register Calibration Results

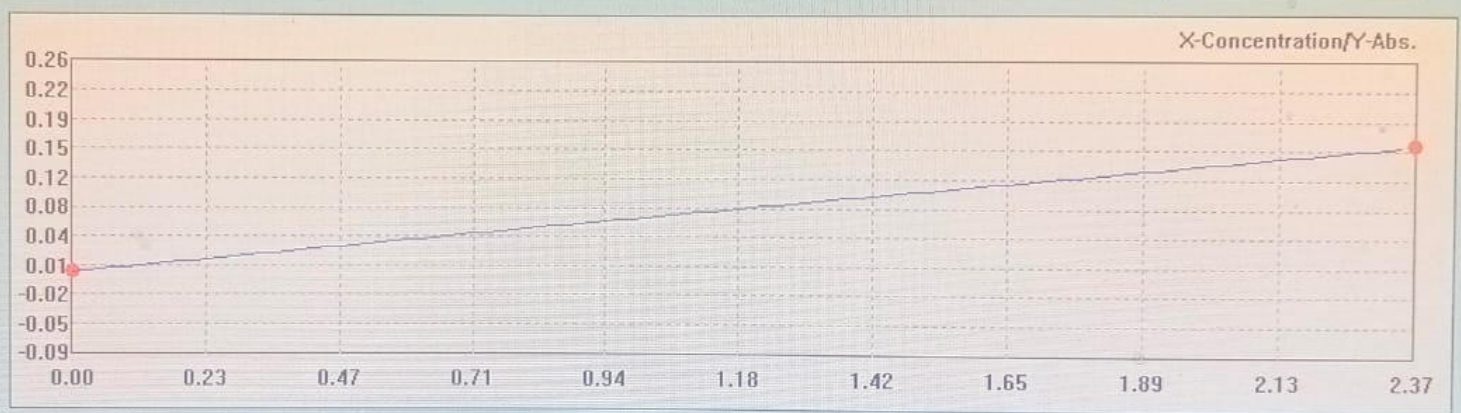
No.	Test Name	Hint
1	GLU	
2	ALB	
3	AST(OT)	
4	ALT(PT)	
5	ALP	
6	T BILL	
7	DBILL	
8	CAL	
9	CHOL	
10	CREAT	
11	HDL-C	
12	TP	
13	TG	
14	UA	
15	UREA	
16	AMY	
17	HBA1C	
18	CRP	
19	LDH	
20	RA - F	
21	FERITIN	
22	p04	
23	HDL C	
24	IRON	
25	D-DIMER	
26	IGE	
27	ASO	

Calibration Type: 2 point linear
 Blank Type: Reagent blank

S1 Abs. K Value A B C
 0.0008 15.0726 0.0000 0.0000 0.0000

Test Date: 2022-07-11 13:32:53

Reaction Curve Calibration Trace



Standard	<0>	<1>	<2>	<3>	<4>	<5>	<6>	<7>
Concentration	0.00	2.37						
Abs.	0.0008	0.1581						
Position	39	40						

Start Cond
 Sample Stop
 Stop
 Status
 Alarm
 Shut Down
 Log Off

Operator:admin

Max Delay :0.492 ms

Machine IP:192.168.2.30

Test Reagent Calibration QC Maintenance System Setting Replace Cuvette

Calibration Register Calibration Results

No.	Test Name	Hint
1	GLU	
2	ALB	
3	AST(OT)	
4	ALT(PT)	
5	ALP	
6	T BILL	
7	DBILL	
8	CAL	
9	CHOL	
10	CREAT	
11	HDL-C	
12	TP	
13	TG	
14	UA	
15	UREA	
16	AMY	
17	HBA1C	
18	CRP	
19	LDH	
20	RA-F	
21	FERITIN	
22	p04	
23	HDL C	
24	IRON	
25	D-DIMER	
26	IGE	
27	ASO	

Calibration Type: 2 point linear

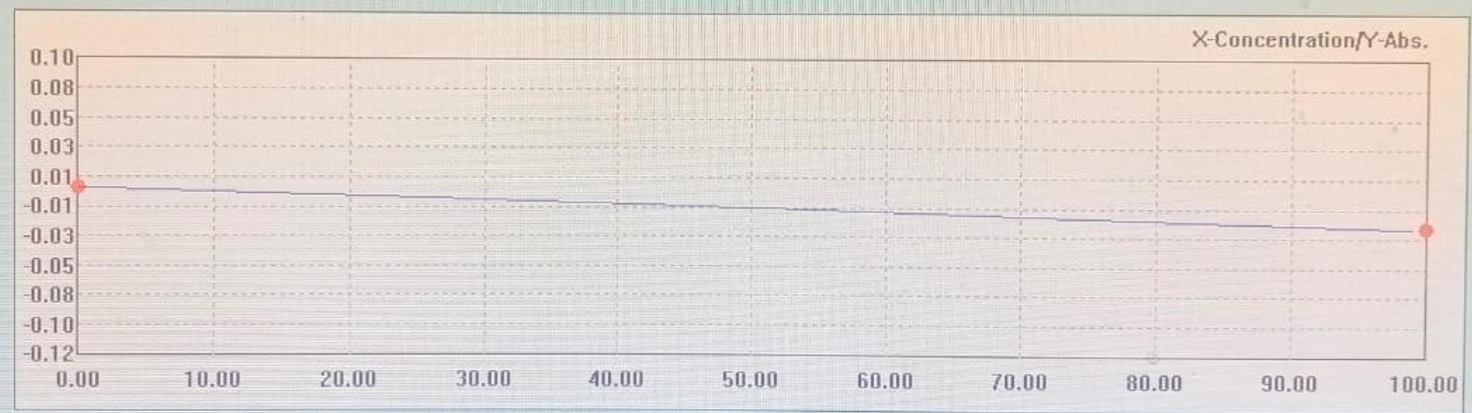
Blank Type: Reagent blank

S1 Abs. K Value A B C

-0.0018 -3280.9662 0.0000 0.0000 0.0000

Test Date: 2022-05-23 14:08:52

Reaction Curve Calibration Trace



Standard	<0>	<1>	<2>	<3>	<4>	<5>	<6>	<7>
Concentration	0.0	100.0						
Abs.	-0.0018	-0.0323						
Position	39	40						

Start Cond.

Sample Stop

Stop

Status

Alarm

Shut Down

Log Off

- Test
- Reagent
- Calibration
- QC
- Maintenance
- System Setting
- Replace Cuvettes

Calibration Request Calibration Results

No.	Test Name	Hint
1	GLU	
2	ALB	
3	AST(OT)	
4	ALT(PT)	
5	ALP	
6	T BILL	
7	DBILL	
8	CAL	
9	CHOL	
10	CREAT	
11	HDL-C	
12	TP	
13	TG	
14	UA	
15	UREA	
16	AMY	
17	HBA1C	
18	CRP	
19	LDH	
20	RA - F	
21	FERITIN	
22	p04	
23	HDL C	
24	IRON	
25	D-DIMER	
26	IGE	
27	ASO	

Calibration Type: 2 point linear

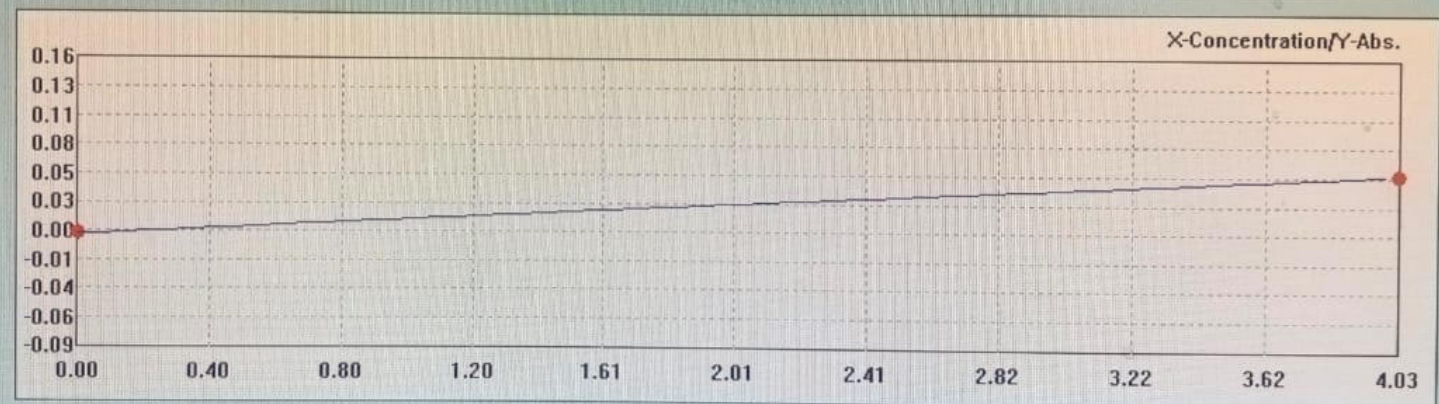
Blank Type: Reagent blank

S1 Abs.: 0.0009 K Value: 71.5856

A: 0.0000 B: 0.0000 C: 0.0000

Test Date: 2022-07-11 13:03:34

Reaction Curve Calibration Trace



Standard	<0>	<1>	<2>	<3>	<4>	<5>	<6>	<7>
Concentration	0.00	4.03						
Abs.	0.0009	0.0572						
Position	39	40						

- Start Cond.
- Sample Stop
- Stop
- Status
- Alarm
- Shut Down
- Log Off

Operator:admin

Max Delay :0.492 ms

Machine IP:192.168.2.30



Test



Reagent



Calibration



QC



Maintenance



System Setting



Replace Cuvettes

Calibration Register

Calibration Results

No.	Test Name	Hint
1	GLU	
2	ALB	
3	AST(OT)	
4	ALT(PT)	
5	ALP	
6	T BILL	
7	DBILL	
8	CAL	
9	CHOL	
10	CREAT	
11	HDL-C	
12	TP	
13	TG	
14	UA	
15	UREA	
16	AMY	
17	HBA1C	
18	CRP	
19	LDH	
20	RA-F	
21	FERITIN	
22	p04	
23	HDL C	
24	IRON	
25	D-DIMER	
26	IGE	
27	ASO	

Calibration Type

2 point linear

Blank Type

Reagent blank

S1 Abs.

-0.0015

K Value

242.5933

A

0.0000

B

0.0000

C

0.0000

Test Date

2022-06-13 15:00:52

Reaction Curve

Calibration Trace



Standard

<0>

<1>

<2>

<3>

<4>

<5>

<6>

<7>

Concentration

0.00

192.00

Abs

-0.0015

0.7900

Position

39

40

Operator: admin

Max Delay : 0.492 ms

Machine IP: 192.168.2.30

Type here to search



Test

Reagent

Calibration

QC

Maintenance

System Setting

Replace Cuvettes

Calibration Register Calibration Results

No.	Test Name	Hint
1	GLU	
2	ALB	
3	AST(OT)	
4	ALT(PT)	
5	ALP	
6	T BILL	
7	D BILL	
8	CAL	
9	CHOL	
10	CREAT	
11	HDL-C	
12	TP	
13	TG	
14	UA	
15	UREA	
16	AMY	
17	HBA1C	
18	CRP	
19	LDH	
20	RA-F	
21	FERITIN	
22	p04	
23	HDL C	
24	IRON	
25	D-DIMER	
26	IGE	
27	ASO	

Calibration Type: 2 point linear

Blank Type: Reagent blank

S1 Abs: 0.0013 K Value: 9.5093

A: 0.0000 B: 0.0000 C: 0.0000

Test Date: 2022-05-23 14:08:16

Reaction Curve Calibration Trace



Standard	<0>	<1>	<2>	<3>	<4>	<5>	<6>	<7>
Concentration	0.00	3.57						
Abs.	0.0013	0.3767						
Position	39	40						

Operator: admin

- Test
- Reagent
- Calibration**
- QC
- Maintenance
- System Setting
- Replace Cuvettes

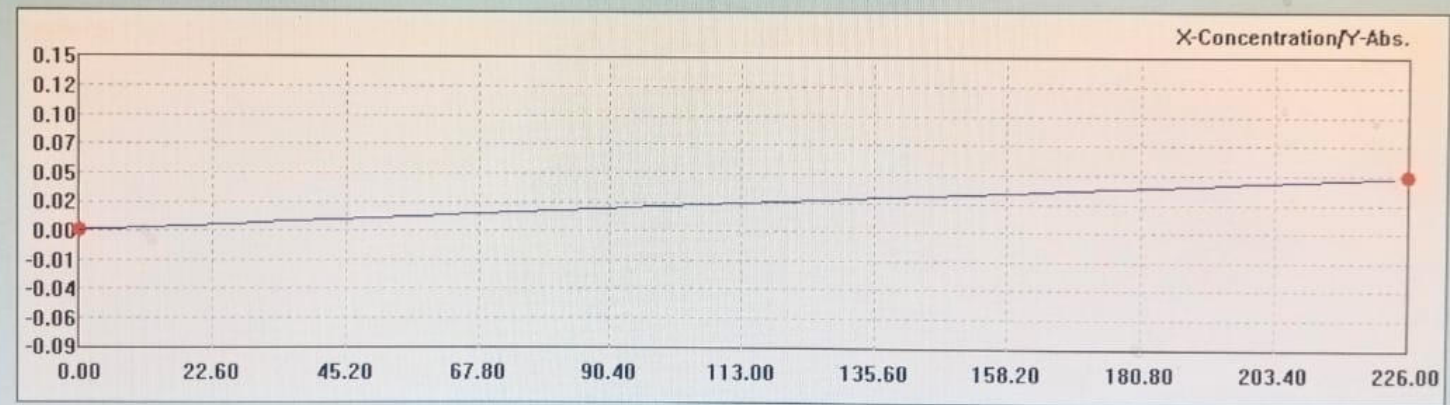
Calibration Register Calibration Results

No.	Test Name	Hint
1	GLU	
2	ALB	
3	AST(OT)	
4	ALT(PT)	
5	ALP	
6	T BILL	
7	D BILL	
8	CAL	
9	CHOL	
10	CREAT	
11	HDL-C	
12	TP	
13	TG	
14	UA	
15	UREA	
16	AMY	
17	HBA1C	
18	CRP	
19	LDH	
20	RA - F	
21	FERITIN	
22	p04	
23	HDL C	
24	IRON	
25	D-DIMER	
26	IGE	
27	ASO	

Calibration Type: Blank Type:

S1 Abs. K Value A B C

Test Date:



Standard	<0>	<1>	<2>	<3>	<4>	<5>	<6>	<7>
Concentration	<input type="text" value="0.0"/>	<input type="text" value="226.0"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Abs.	<input type="text" value="0.0010"/>	<input type="text" value="0.0482"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Position	<input type="text" value="39"/>	<input type="text" value="40"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

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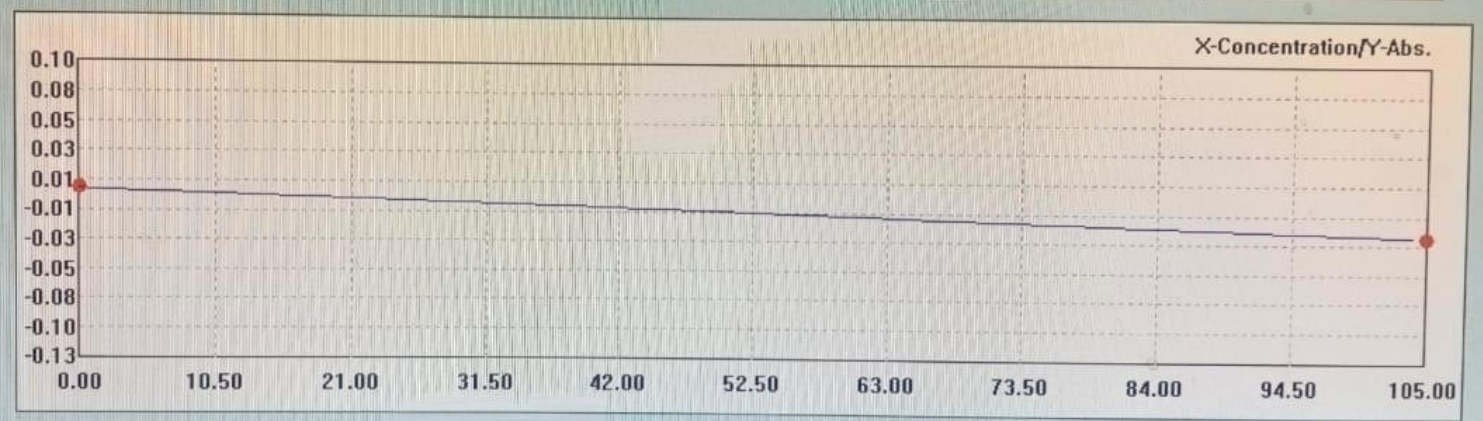
Test Reagent **Calibration** QC Maintenance System Setting Replace Cuvettes

Calibration Register Calibration Results

No.	Test Name	Hint
1	GLU	
2	ALB	
3	AST(OT)	
4	ALT(PT)	
5	ALP	
6	T BILL	
7	D BILL	
8	CAL	
9	CHOL	
10	CREAT	
11	HDL-C	
12	TP	
13	TG	
14	UA	
15	UREA	
16	AMY	
17	HBA1C	
18	CRP	
19	LDH	
20	RA - F	
21	FERITIN	
22	p04	
23	HDL C	
24	IRON	
25	D-DIMER	
26	IGE	
27	ASO	

Calibration Type: 2 point linear
 Blank Type: Reagent blank
 S1 Abs.: -0.0011 K Value: -3089.6746
 A: 0.0000 B: 0.0000 C: 0.0000
 Test Date: 2022-06-18 15:32:43

Reaction Curve Calibration Trace



Standard	<0>	<1>	<2>	<3>	<4>	<5>	<6>	<7>
Concentration	0.0	105.0						
Abs.	-0.0011	-0.0351						
Position	39	40						

Start Cond. Sample Sto. Stop Status Alarm Shut Down Log Off