



STAR 20 –Clinical Chemistry Analyzer

INSTALLATION QUALIFICATION
OPERATIONAL QUALIFICATION
PERFORMANCE QUALIFICATION
(IQ/OQ/PQ)

(Healthledger Diagnostics Pvt. Ltd.)

**Shop No.6, Ground Floor, Maitri Icon, Plot No.35/36, Sector-19,
Kharghar, Panvel, Raigad-410210**

By: Rapid Diagnostic Pvt. Ltd.






CERTIFICATE OF INSTALLATION


Customer Name : Healthledger Diagnostics Pvt. Ltd.
Address : Shop No.6, Ground Floor, Maitri Icon, Plot No. 35/36
Sector-19, Kharghar, Panvel, Raigad-410210
Instrument Name : Star-20 Analyzer
Serial Number : ES1001911P9022

The undersigned performers certify that the Installation Qualification Protocol has been successfully completed for the instrument stated above.

Engineer/Application Person

Signature : 
Name : Mr. Arvind Singh
Designation : Service Engineer
Company : Rapid Diagnostics Pvt. Ltd.

Quality Manager

Signature : 
Name : Dr. Akshay Dhotre
Designation : Quality Manager
Company : Healthledger Diagnostics Pvt. Ltd.



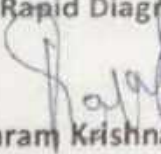


INSTALLATION REPORT

Customer Name : Healthledger Diagnostics Pvt. Ltd.
Place : Kharghar, Panvel, Raigad-410210
Department : Clinical Biochemistry
Contact Person : Dr. Akshay Dhotre
Instrument Name : Star-20 Analyzer
Serial Number : ES1001911P9022
Date of Installation : 04.06.2020

The Analyzer was installed along with the necessary standard accessories. All basic requirements and adjustments were checked and are found to be satisfactory. The preliminary standardization of the analyzer and the training were provided to the complete satisfaction of the customer. The analyzer is found to be working satisfactorily.

For Rapid Diagnostics Pvt. Ltd.


Rajaram Krishnamurthy
National Service Manager





INSTALLATION QUALIFICATION

IQ PROTOCOL

1. System Unpacking
2. System Checking For any Damages
3. All accessories as per check List verification
4. Space Requirement
5. Power Requirement
6. Reagents, Control, Calibrators verification.

1. SYSTEM UNPACKING & 2. SYSTEM CHECKING

Un packed Star 20 instrument carefully and checked for any physical Damages.

3. ACCESSORIES CHECK-

Check all accessories as per check List.

4. SPACE REQUIREMENT -

- Checked site for proper space allocation. At least 100 CM on each side and enough room for the below mentioned dimensions

Dimensions	
Parameter	Analyzer OV
Width(mm) (W)	300
Depth (mm)(L)	400
Height (mm)(H)	160
Weight (Kg)	7.5



5. POWER REQUIREMENT -

Requirement	Acceptable Range	Observed Ranged
Input Voltage	220 + / - 10 V	225 V
Line Frequency	50 HZ	50 HZ
Ambient Temperature	15 C - 30 C	23

6. REAGENTS, CALIBRATORS, CONTROL CHECK

QC NAME: Quality Control Level 2-Normal Control

Qc Name	Lot No	Expiry	Test	Target	Range	Result Obtained
Randox Control	1543UN	2025-3-28	Glucose	109	92.4-126	112
			Urea	43.3	36.8-49.8	40
			SGPT	42	33-51	38
			Bilirubin	1.52	1.2-1.84	1.38

QC NAME : Quality Control Level 3-Abnormal Control

Qc Name	Lot No.	Expiry	Test	Target	Range	Result Obtained
Randox Control	1195UE	2025/4/28	Glucose	283	240-326	275.23
			Urea	122	103-141	105
			SGPT	142	113-171	139
			Bilirubin	5.65	4.47-6.83	5.15





PRE-INSTALLTION VERIFICATION REPORT:-

PRE-INSTALLATION VERIFICATION REPORT		
S/No.	Parameter	Remark
1	Unpacking Instrument	OK
2	System Checking for damages	OK
3	Accessories check	OK
4	Space Check	OK
5	Power Check	OK
6	Reagents Check	OK

OPERATIONAL QUALIFICATION

The Operational Qualification procedure specifies the methodology for installation of specified system after successful installation qualification. Successful completion of procedure identifies that system is ready for operation and subsequent performance analysis.

OQ PROTOCOL

1. System Connections
2. Reagent & Waste Connections
3. Customizing the Analyzer Software
4. System Booting , Initialization & Check
5. Maintenance procedures.
6. Customer Training – Operation & Maintenance.





1. SYSTEM CONNECTION –

SYSTEM CONNECTIONS			
S/No.	Name	Check	Remark
1	Pump Tube Installation	Operating Manual	Ok
2	Waste Tube Connection	Operating Manual	Ok
4	Printer Paper Insertion	Operating Manual	Ok

2. REAGENT & WASTE CONNECTIONS -

Please refer to the User Manual and the Kit Literature supplied with the Reagent Kit:

3. CUSTOMIZING ANALYZER SOFTWARE –

CUSTOMIZING ANALYZER SOFTWARE			
S/No.	Parameters	Check	Remark
1	Date & Time	Operating Manual	Ok
2	Reagents	Operating Manual	Ok
3	Reference Ranges	Operating Manual	Ok
4	Reference Units	Operating Manual	Ok
5	Printing format	Operating Manual	Ok
6	Creating New User	Operating Manual	Ok



4. SYSTEM BOOTING, INITIALIZATION & CHECK -

Power ON System and check for successful initialization of the instrument.

5. MAINTENANCE PROCEDURES:-

MAINTENANCE			
S/No.	Parameters	Check	Remark
1	Using Maintenance Menu	Operator Manual	Ok

PERFORMANCE QUALIFICATION-

Parameter	Range	Results	Remarks
A/D Value for all filters	35000-59000	Around 45650	Ok
Lamp Voltage	6V	5.9V	Ok
Pump Calibration	2748	2748	Ok
Flowcell Temp	37(+ & -)0.2 C	37.01	Ok

PRECISION-FOR NORMAL CONTROL(for run of 5 times)				
S/No.	Parameter	Actual	Range	Remark
1	SGPT	4.91%	0-7%	Ok
2	Glucose	2.55%	0-5%	Ok
3	Total Bilirubin	3.03%	0-5%	Ok
4	Urea	4.28%	0-5%	Ok



PRECISION FOR ABNORMAL CONTROL (for run of 5 times)

S/No.	Parameter	Actual	Range CV%	Remark
1	SGPT	3.87%	0-7%	Ok
2	Glucose	4.25%	0-5%	Ok
3	Total Bilirubin	2.00%	0-5%	Ok
4	Urea	3.02%	0-5%	Ok

For Rapid Diagnostics Pvt. Ltd.


Rajaram Krishnamurthy
National Service Manager



22 - level 2 - P. Dada

LEVEL 2(NORMAL) MONTH: Oct 2022 EXP 2025-03-28 LOT NO 1543UN					
DATE/PARA	ALT	GLU	UREA	TBH1	
METER NAME					
MEAN	42	109	43.3	1.52	
HIGHER	51	125	49.8	1.84	
LOWER	33	92.4	36.8	1.2	
1	38	112	40	1.30	

performed by :- Shubhangi
 checked by :- (Signature)

Sample ID: 0017

Name:
 Sex:
 Age:
 Doctor:
 Department:

Test Name: ERSQPT
 Abs.: -0.0214
 Result: 38
 Unit: u/l
 Ref. Low: 0
 Ref. High: 40

Test Name: ERSGPDR
 Abs.: 0.0000
 Result: 112.00 T
 Unit: mg/dl
 Ref. Low: 74.00
 Ref. High: 100.00

Sample ID: 0011
 Name:
 Sex:
 Age:
 Doctor:
 Department:

Test Name: ER7B1L1
 Abs.: 0.0000
 Result: 1.38
 Unit: mg/dl
 Ref. Low: 0.00
 Ref. High: 2.00

Sample ID: 0001

Name:
 Sex:
 Age:
 Doctor:
 Department:

Test Name: ERUREA
 Abs.: -0.0880
 Result: 40
 Unit: mg/dl
 Ref. Low: 13
 Ref. High: 45

IQ - Level 3 - AC Data

LEVEL: 3 (ABNORMAL) MONTH: Oct -2022 EXP 2025-04-28 LOT NO.1195UE				
DATE/PARAMETER NAME	ALT	GLU	UREA	TBILI
MEAN	142	283	122	5.65
HIGHER	171	326	141	6.83
LOWER	113	240	103	4.47
1	139	275.23	105	5.15

Performed by :- Shubhangi

Checked by :- Shobhu

Sample ID: 0006
Name:
Sex:
Age:
Doctor:
Department:

Test Name: ERSPT
Abs.: -0.0784
Result: 139 ↑
Unit: μ/L
Ref. Low: 0
Ref. High: 40
Test Date: 2022-10-07 13:32:08

Test Name: ERBGPDR
Abs.: 1.1296
Result: 275.23 ↑
Unit: mg/dl
Ref. Low: 74.00
Ref. High: 100.00
Test Date: 2022-10-07 13:00:45

Test Name: ERUREA
Abs.: -0.1897
Result: 105 ↑
Unit: mg/dl
Ref. Low: 13
Ref. High: 45
Test Date: 2022-10-07 13:35:03

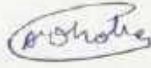
Sample ID: 0019
Name:
Sex:
Age:
Doctor:
Department:

Test Name: ERTBILI
Abs.: 0.0000
Result: 5.15 ↑
Unit: mg/dl
Ref. Low: 0.00
Ref. High: 2.00
Test Date: 2022-10-07 13:47:29

Precision for Abnormal

LEVEL: 3(ABNORMAL) MONTH: Oct -2022 EXP 2025-04-28 LOT NO.1195UE				
DATE/PARAMETER NAME	ALT	GLU	UREA	TBILI
MEAN	142	283	122	5.65
HIGHER	171	326	141	6.83
LOWER	113	240	103	4.47
1	139	275.23	105	5.15
2	143	288.38	113	5.2
3	151	287.02	113	5.04
4	149	262.35	110	4.94
5	139	260.06	109	5.12
MEAN	144.2	270.608	110	5.09
SD	5.585696018	11.50581896	3.31662479	0.10198039
CV	3.873575602	4.251839917	3.015113446	2.003544013

Performed by:- Shubhangi

Checked by:- 

Sample ID: 0002
Test Name: ERSQPT
p.s.: -0.0784
Result: 130 ↑
Unit: µ/l
Ref. Low: 0
Ref. High: 40
Test Date: 2022-10-07 13:11:43

Sample ID: 0003
Test Name: ERSQPT
p.s.: -0.0806
Result: 143 ↑
Unit: µ/l
Ref. Low: 0
Ref. High: 40
Test Date: 2022-10-07 13:17:29

Sample ID: 0004
Test Name: ERSQPT
p.s.: -0.0854
Result: 151 ↑
Unit: µ/l
Ref. Low: 0
Ref. High: 40
Test Date: 2022-10-07 13:22:31

Sample ID: 0005
Test Name: ERSQPT
p.s.: -0.0840
Result: 149 ↑
Unit: µ/l
Ref. Low: 0
Ref. High: 40
Test Date: 2022-10-07 13:27:14

Sample ID: 0000
Test Name: ERSQPT
p.s.: -0.0784
Result: 130 ↑
Unit: µ/l
Ref. Low: 0
Ref. High: 40
Test Date: 2022-10-07 13:32:08

Sample Name: ERBGPDR
Osmolality Blank Abs.: 0.0338
Sample ID: 0001
Test Name: ERBGPDR
p.s.: 1.1200
Result: 275.23 ↑
Unit: mg/dl
Ref. Low: 74.00
Ref. High: 100.00
Test Date: 2022-10-07 13:00:45

Sample ID: 0002
Test Name: ERBGPDR
p.s.: 1.1820
Result: 288.38 ↑
Unit: mg/dl
Ref. Low: 74.00
Ref. High: 100.00
Test Date: 2022-10-07 13:01:16

Sample ID: 0003
Test Name: ERBGPDR
p.s.: 1.0069
Result: 267.02 ↑
Unit: mg/dl
Ref. Low: 74.00
Ref. High: 100.00
Test Date: 2022-10-07 13:01:46

Sample ID: 0004
Test Name: ERBGPDR
p.s.: 1.0783
Result: 262.35 ↑
Unit: mg/dl
Ref. Low: 74.00
Ref. High: 100.00
Test Date: 2022-10-07 13:02:15

Sample ID: 0005
Test Name: ERBGPDR
p.s.: 1.0602
Result: 260.06 ↑
Unit: mg/dl
Ref. Low: 74.00
Ref. High: 100.00
Test Date: 2022-10-07 13:02:43

Sample ID: 0001
Test Name: ERUREA
p.s.: -0.1807
Result: 105 ↑
Unit: mg/dl
Ref. Low: 13
Ref. High: 45
Test Date: 2022-10-07 13:35:03

Sample ID: 0002
Test Name: ERUREA
p.s.: -0.2050
Result: 113 ↑
Unit: mg/dl
Ref. Low: 13
Ref. High: 45
Test Date: 2022-10-07 13:37:25

Sample ID: 0003
Test Name: ERUREA
p.s.: -0.2056
Result: 113 ↑
Unit: mg/dl
Ref. Low: 13
Ref. High: 45
Test Date: 2022-10-07 13:39:26

Sample ID: 0004
Test Name: ERUREA
p.s.: -0.1990
Result: 110 ↑
Unit: mg/dl
Ref. Low: 13
Ref. High: 45
Test Date: 2022-10-07 13:40:57

Sample ID: 0005
Test Name: ERUREA
p.s.: -0.1970
Result: 109 ↑
Unit: mg/dl
Ref. Low: 13
Ref. High: 45
Test Date: 2022-10-07 13:42:28

LEVEL 3
PR -
Prediction for
Abnormal

Performed by -
Shubhangi

Checked by -
(Signature)

Precision for Normal

LEVEL: ZINCIMAL MONTH: OCT 2022 EXP 2025-03-28 LOT NO. 1343UM					
DATE/PARA METER NAME	ALT	GLU	UREA	TBLU	
MEAN	42	109	41.3		1.52
HIGHER	51	126	49.8		1.84
LOWER	33	92.4	36.8		1.2
1	36	112	40		1.50
2	42	115	43		1.40
3	36	112	44		1.50
4	40	110.12	41		1.40
5	37	114.25	44		1.45
MEAN	39.2	114.678	42.4		1.42
SD	1.9	2.9	1.8		0.0
CV	4.9	2.6	4.3		3.0

Performed By: - Shubhangi

Checked By: - Atkinson

Sample ID: 0017
Name:
Sex:
Age:
Doctor:
Department:

Test Name: ERSIPT
Abs.: 0.0000
Result: 38
Unit: μ /l
Ref. Low: 0
Ref. High: 40
Test Date: 2022-10-07 14:22:04

Sample ID: 0024
Name:
Sex:
Age:
Doctor:
Department:

Test Name: ERSIPT
Abs.: 0.0000
Result: 37
Unit: μ /l
Ref. Low: 0
Ref. High: 40
Test Date: 2022-10-07 14:23:15

Test Name: ERBGPDR
Abs.: 0.0000
Result: 112.00 T
Unit: mg/dl
Ref. Low: 74.00
Ref. High: 100.00
Test Date: 2022-10-07 14:14:54

Sample ID: 0010
Name:
Sex:
Age:
Doctor:
Department:

Test Name: ERBGPDR
Abs.: 0.0000
Result: 114.25 T
Unit: mg/dl
Ref. Low: 74.00
Ref. High: 100.00
Test Date: 2022-10-07 14:17:10

Sample ID: 0022
Name:
Sex:
Age:
Doctor:
Department:

Test Name: ERSIPT
Abs.: 0.0000
Result: 42 T
Unit: μ /l
Ref. Low: 0
Ref. High: 40
Test Date: 2022-10-07 14:22:26

Sample ID: 0007
Name:
Sex:
Age:
Doctor:
Department:

Test Name: ERBGPDR
Abs.: 0.0000
Result: 115.00 T
Unit: mg/dl
Ref. Low: 74.00
Ref. High: 100.00
Test Date: 2022-10-07 14:15:21

*PQ - Level-2
precision data
for closed*

Sample ID: 0022
Name:
Sex:
Age:
Doctor:
Department:

Test Name: ERSIPT
Abs.: 0.0000
Result: 39
Unit: μ /l
Ref. Low: 0
Ref. High: 40
Test Date: 2022-10-07 14:38:46

*Performed By: -
Shubhangi*

*checked By: -
Alpha*

Sample ID: 0008
Name:
Sex:
Age:
Doctor:
Department:

Test Name: ERBGPDR
Abs.: 0.0000
Result: 112.00 T
Unit: mg/dl
Ref. Low: 74.00
Ref. High: 100.00
Test Date: 2022-10-07 14:15:54

Sample ID: 0021
Name:
Sex:
Age:
Doctor:
Department:

Test Name: ERSIPT
Abs.: 0.0000
Result: 40
Unit: μ /l
Ref. Low: 0
Ref. High: 40
Test Date: 2022-10-07 14:23:37

Sample ID: 0009
Name:
Sex:
Age:
Doctor:
Department:

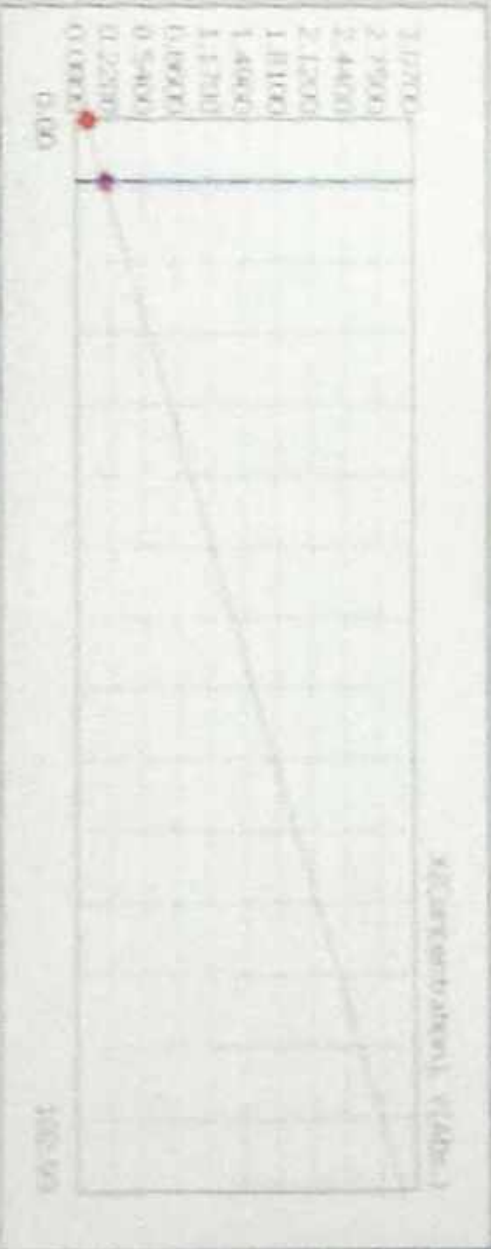
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Abs.: 0.0000
Result: 119.12 T
Unit: mg/dl
Ref. Low: 74.00
Ref. High: 100.00
Test Date: 2022-10-07 14:16:46

Calibration Data

- URICA
- ERCREA
- ERURICA**
- ERBCAL
- ERCHOL
- ERTRIG
- ERGLUC
- ERPROT
- ERALBU
- ERSGOT
- ERSGPT
- ERALKPH
- ERUREA

Type: B: K: a: b: c:

Point: Conc. / Abs.:



Return

Calibration Data

Parameter

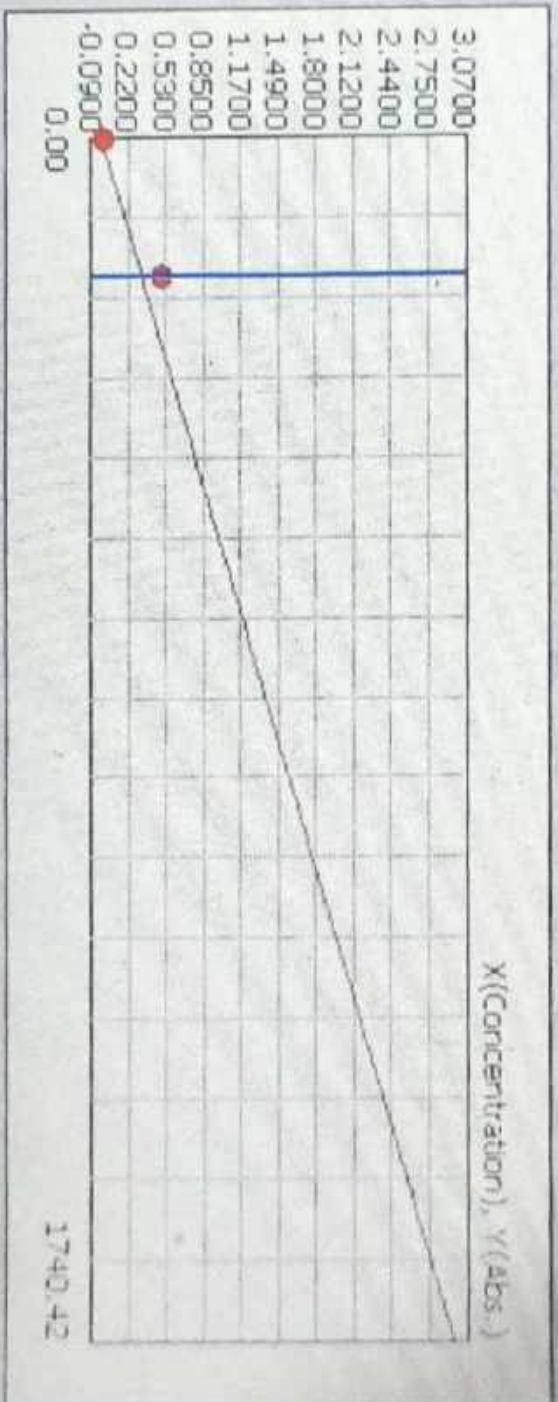
Type

2 Point Linear

Point & Curve

Point Conc. / Abs.

- URICA
- ERCREAT
- ERURICA
- ERBCAL
- ERCHOL**
- ERTRIG
- ERGLUC
- ERPROT
- ERALBUM
- ERSGOT
- ERSGPT
- ERALKPH
- ERUREA



Calibration Data

Parameter

Type

B

K

a

b

c

GGT

2 Point Linear

0.0384

410.0000

ERBACRI

Point & Curve

Point

2

Conc. / Abs.

25.00 / 0.0441

CKAGD

G6ppd

AMMONI

ddimer

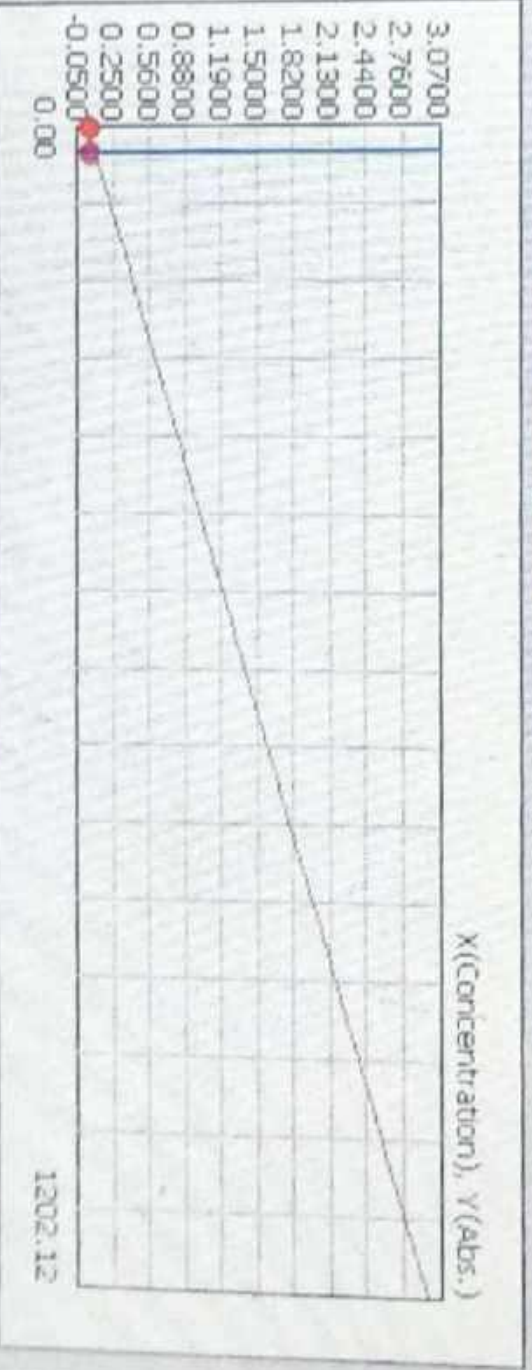
EMGLU

AMY

LIPAGD

HDL

lipase



Return

Calibration Data

- ERCREAT
- ERURICA
- ERBCAL
- ERCHOL
- ERTRIG
- ERGLUC
- ERPROT
- ERALBUR
- ERSGOT
- ERSGPT
- ERALKPH
- ERUREA**
- ERTBILI

Parameter

Type

B

K

a

b

c

2 Point Linear

0.0000

-445.2360

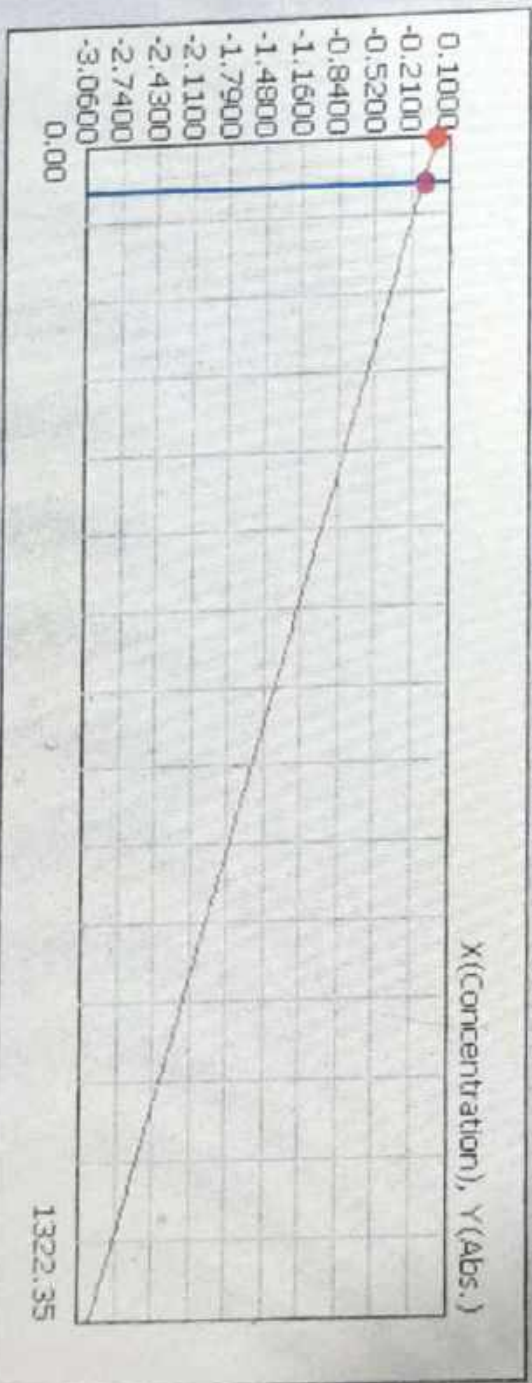
Point & Curve

Point

2

Conc. / Abs.

50 / -0.1123



Return

Calibration Data

- URICA
- ERCREAT
- ERURICA
- ERBCAL**
- ERCHOL
- ERTRIG
- ERGLUC
- ERPROT
- ERALBUM
- ERSGOT
- ERSGPT
- ERALKPH
- ERUREA

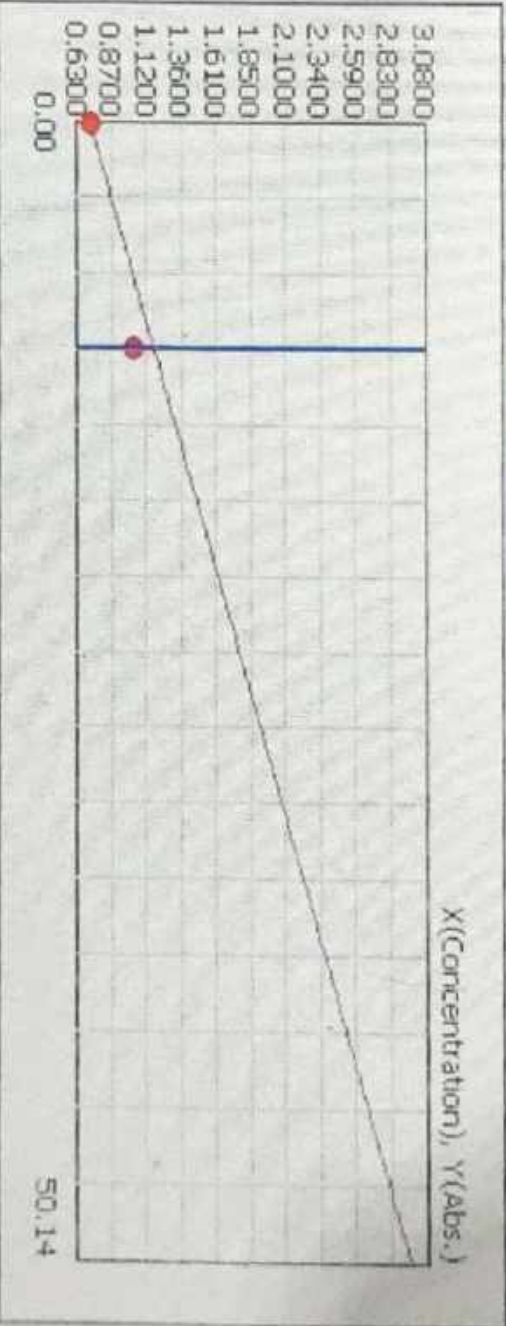
Parameter

Type: B: K: a: b: c:

Point & Curve

Point:

Conc. / Abs.:



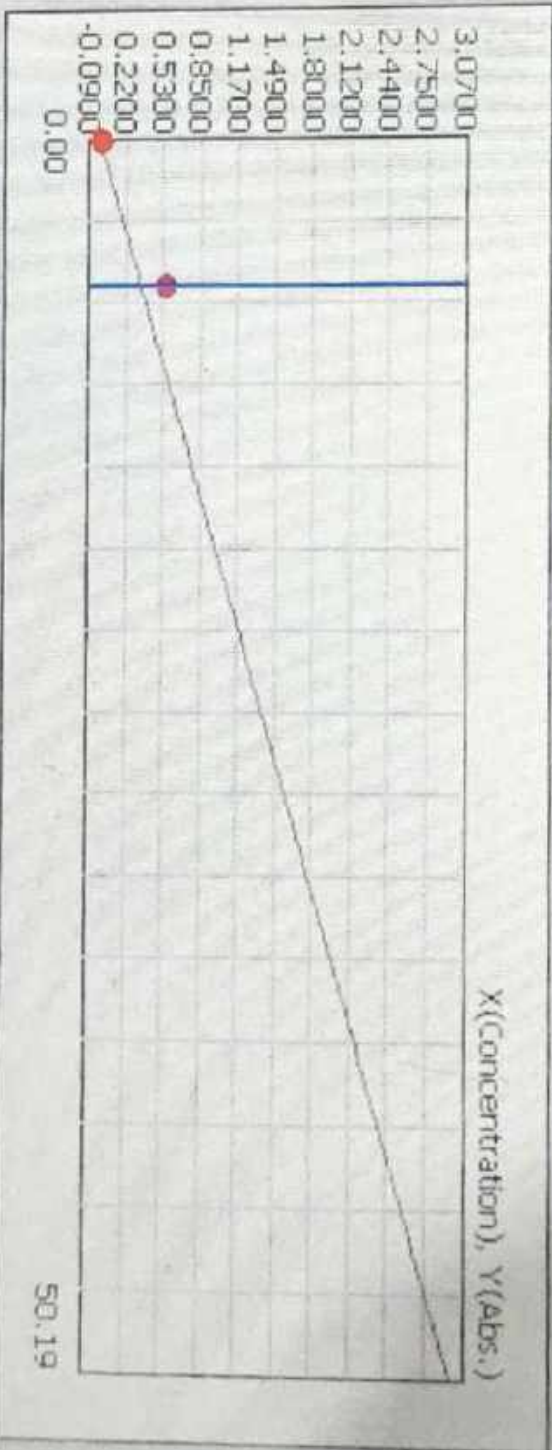
Calibration Data

Parameter

Type B K a b c

Point & Curve

- URICA
- ERCREAT
- ERURICA
- ERBCAL
- ERCHOL
- ERTRIG
- ERGLUC
- ERPROT**
- ERALBUM
- ERSGOT
- ERSGPT
- ERALKPH
- ERUREA



Calibration Data

- URICA
- ERCREAT
- ERURICA
- ERBCAL
- ERCHOL
- ERTRIG
- ERGLUC
- ERPROT
- ERALBUM**
- ERSGOT
- ERSGPT
- ERALKPH
- ERUREA

Parameter:

Type

B

K

a

b

c

2 Point Linear

0.0000

7.8200

Point & Curve

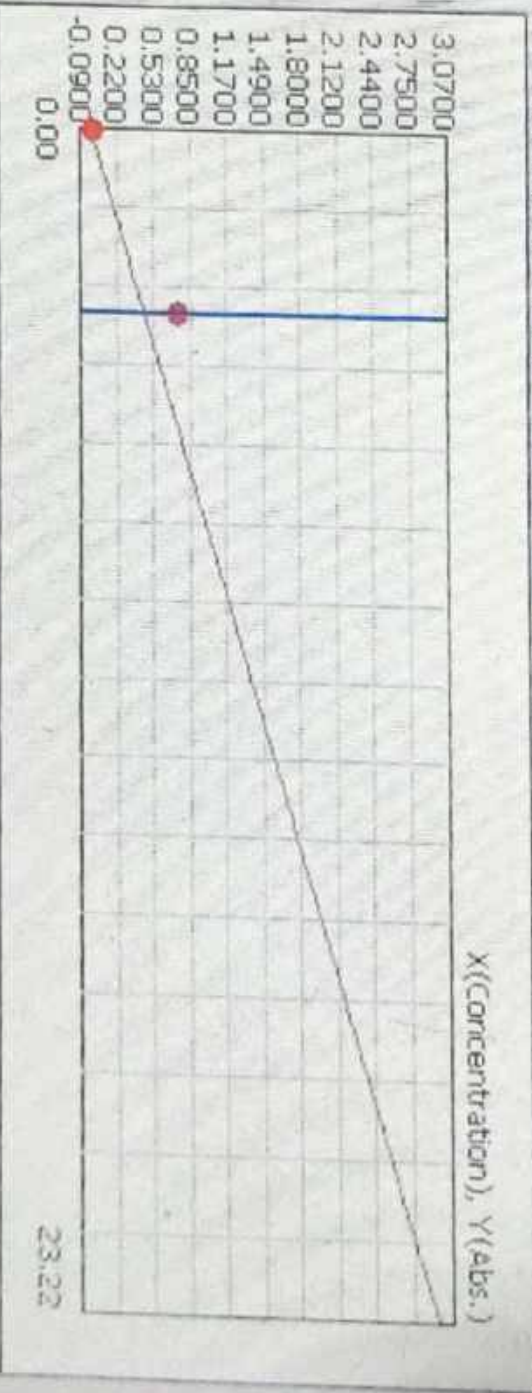
Point

2



Conc. / Abs.

3.60 / 0.7472



Return

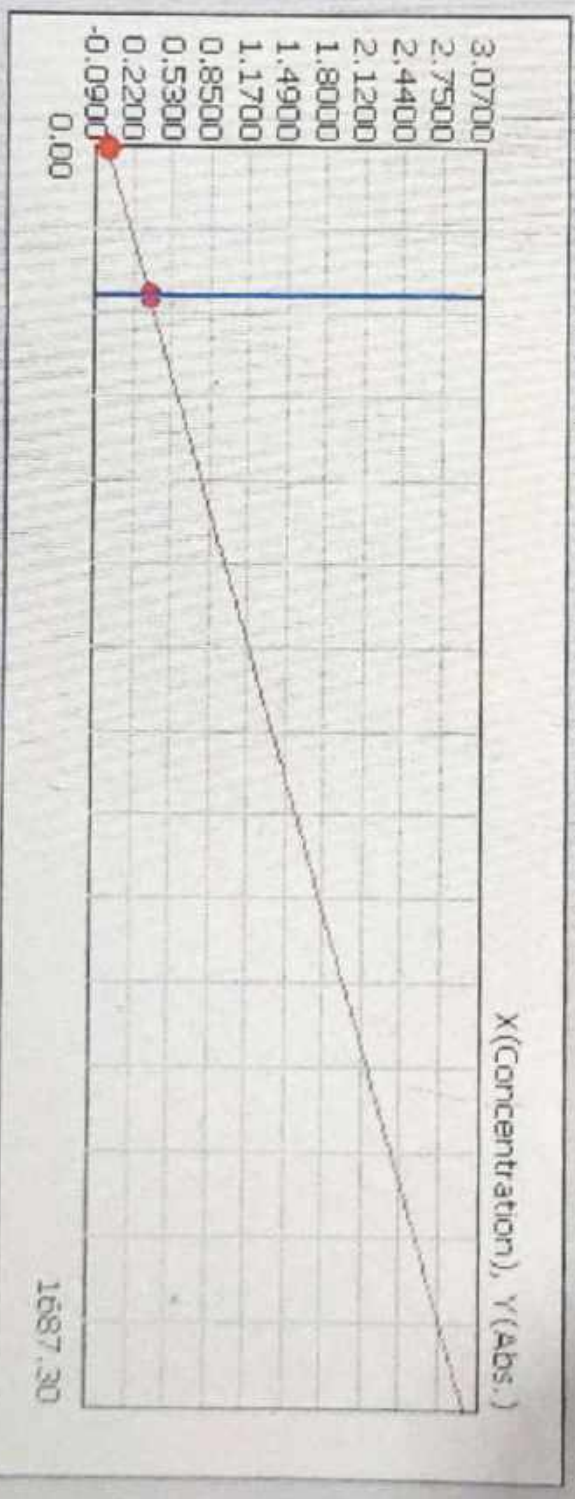
- URICA
- ERCREAT
- ERURICA
- ERBCAL
- ERCHOL
- ERTRIG**
- ERGLUC
- ERPROT
- ERALBUN
- ERSGOT
- ERSGPT
- ERALKPH
- ERUREA

Parameter

Type	B	K	a	b	c
2 Point Linear	0.0000	568.1173			

Point & Curve

Point	2	Conc. / Abs.	200 / 0.3520
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Return

Calibration Data

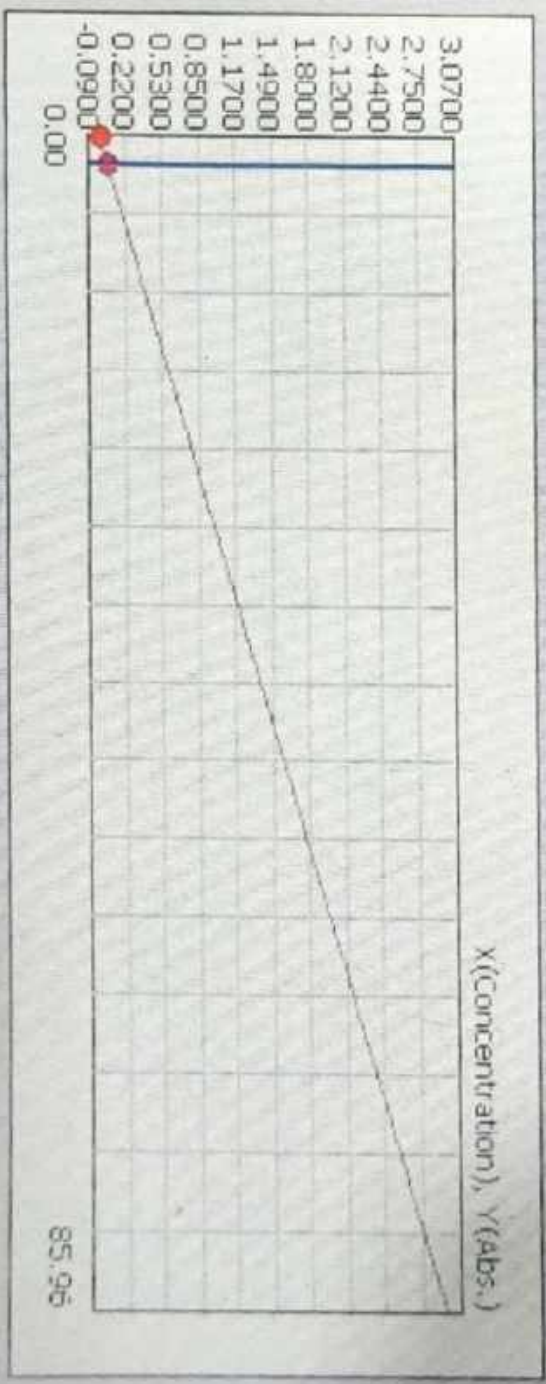
- URICA
- ERCREAT**
- ERURICA
- ERBCAL
- ERCHOL
- ERTRIG
- ERGLUC
- ERPROT
- ERALBUM
- ERSGOT
- ERSGPT
- ERALKPH
- ERUREA

Parameter

Type **2 Point Linear** B **0.0000** K **28.9436** a b c

Point & Curve

Point **2** Conc. / Abs. **2.00 / 0.0691**



Return

Calibration Data

- AGDCAL
- CKAGD
- G6pdp
- AMMONI
- ddimer
- EMGLU
- AMY
- LIPAGD
- HDL
- lipase
- RF
- ERBGPDI
- UAPRI

Parameter

Type

2 Point Linear

B

-0.0055

K

298.1900

a

b

c

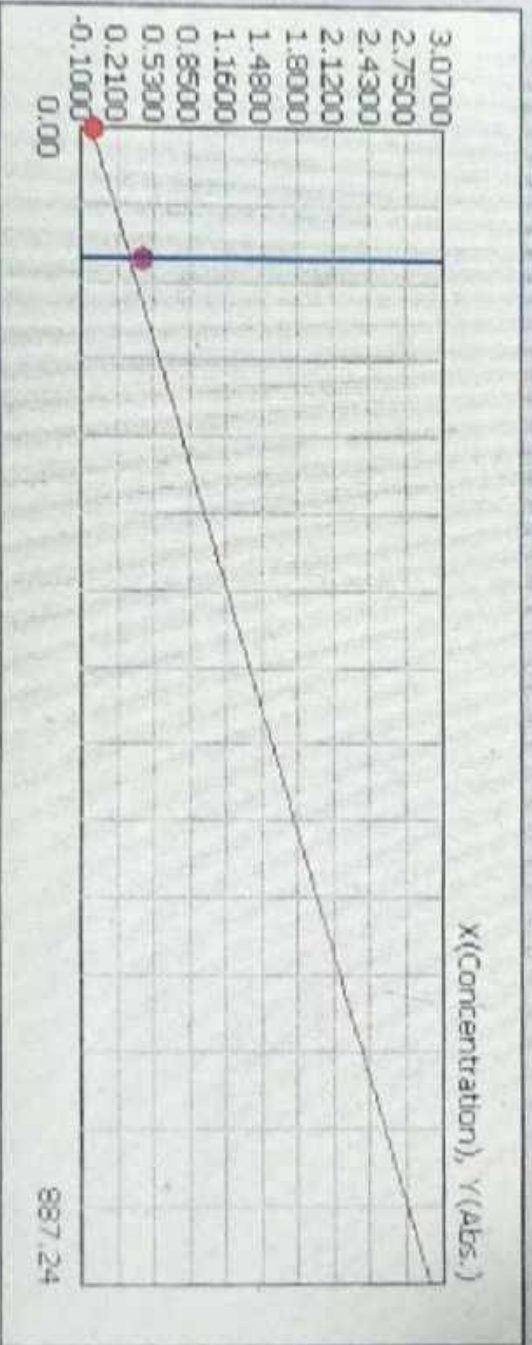
Point & Curve

Point

2

Conc. / Abs.

100.00 / 0.4179



Return