



MEDICARE
ENTERPRISE

ANNEXURE A

Installation Qualification

Name of the customer: **We care Diagnostic Centre.**
Instrument type: **Sami Auto Bio-Chemistry analyser**
Model name: **Curionix Bharat 88**
Date of receipt: **01.05.2024**
Serial number: **BA-CL-3927**
Date of installation: **02.05.2024**

Power checks:

Power supply: **AC 228V-50 Hz**
Plug top: **5 Amps**
Earth voltage: **0.5 Volt**

Environmental check:

Parameter	Working range	Site conditions
Room temperature	5-40°C	27°C
Humidity	10-90%	72%

Physical check of the equipment:

Check for damage	Checked	No damage found
Visual and functional inspection	Checked	OK.
No damage on internal assembly	Checked	No damage found

System Configuration check:

Positioning of the		
Equipment flat stable surface	Checked	Found OK
Adequate space around the BA88A	Checked	Found OK
Interference to other equipment	Checked	No interference

Result

Installed the **Bharat 88** satisfactorily and is ready for operational verification

Installed by: **Dipankar Basu Mallick**

Checked by: **Mr. NIRUPAM SARKAR**

Signature:

MEDICARE ENTERPRISE
Dipankar Basu Mallick
Authorized Signatory

Signature:

Nirupam Sarkar

Date: **02.05.2024**

Date: **02.05.2024**

40/1C, Sri Gopal Mallick Lane, Kolkata 700012, Call 9874602750

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Operational Qualification
Operational Verification Report

Name of the customer: Wecare Diagnostic Centre.
Instrument type: Sami Auto Bio-Chemistry analyser
Model name: Curionix Bharat 88 Serial number: BA-CL-3927
Date of receipt: 01/05/2024 Date of installation: 02/05/2024

Operational check:

1. System checks Procedure:

- i) Flow cell Check: Passed.
- ii) Photometer Check: Passed.
- iii) Flow cell Compartment cooling Temperature Check: OK
- iv) Home Sensor status Check: Passed.
- v) Aspiration Check: Passed

Result

Operational verification of Bharat 88 has been completed satisfactorily and it is ready for the performance verification.

Operations performed by: Dipankar Basu Mallick

Signature:

Dipankar Basu Mallick
MEDICARE ENTERPRISE
Authorised Signatory

Date: 02/05/2024

Checked by: Mr. NIRUPAM SARKAR

Signature: *Nirupam Sarkar*

Date: 02/05/2024

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Performance Qualification

Performance Verification Report

Name of the customer:

WeCare Diagnostic Centre.

Instrument type:

Sami Auto Bio-Chemistry analyzer

Model name: Bharat 88

Serial number: BA-CL-3927

Date of receipt: 01/05/2024

Date of installation: 02/05/2024

Performance check:

1. Linearity Check: OK
2. Precision Check: Passed.
3. Control Run: Passed.

Result

The performance verification of Bharat 88 has been completed satisfactorily and instrument is ready to be placed in service.

Performance check done in presence of:

Lab In charge: Mr. NIRUPAM SARKAR

Signature: *Nirupam Sarkar*

Date: 02/05/2024

Performance check:

Performance by: Dipankar Basu Mallick

(Service engineer)

Dipankar Basu Mallick
MEDICARE ENTERPRISE
Authorised Signatory

Checked by: Mrs. Animesh Bhangl

Date: 02/05/2024

Date: 02/05/2024

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CALIBRATION CERTIFICATE

Customer Name : Wecare Diagnostic Centre. Address : Madhubon, (Near Purna Cinema), Kalna, Burdwan, Pin code 713409 Phone : 7001463974	Equipment : Semi Auto Analyzer Model : Curionix Bharat 88 S.No : BA-CL-3927 Date of Calibration : 02/05/2024 Due Date : 01/11/2024 Calibrated by : D.Basu Mallick
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UPS Power Supply	Observed Reading	Remarks
Ground to Neutral	0V	Acceptable Range
Ground to Phase	225V	With in. range
Phase to Neutral	225V	With in range

Power Supply	Measured Reading	Remarks
+5V DC $\pm 1.0\%$	5.02V	Null
+3V DC $\pm 1.0\%$	24.05V	Null
+12V DC $\pm 1.0\%$	+ 12.02V	Null

	Passed	Not Passed
System Initialization Check	Passed	
Key Board Check	Passed	
Temperature Calibration Check	Passed	
Pump Calibration Check	Passed	
Filter Wheel Motor Check	Passed	
Filter Wheel Home Position Check	Passed	
Display & Character Check	Passed	

Photometric Calibration	Gain	ADC	Status	Remark
1) 340 nm	769	6.0	Passed	Null
2) 405 nm	202	6.0	Passed	Null
3) 450 nm	162	6.0	Passed	Null
4) 510 nm	229	6.0	Passed	Null
5) 546 nm	213	6.0	Passed	Null
6) 578 nm	199	6.0	Passed	Null
7) 630 nm	290	6.0	Passed	Null
Range	100-3000	5.7-6.3	Passed	Null

Comments

Instrument is calibrated as per manufacturer's Guidance and specifications. Instrument is working satisfactory

Regional Manager –Technical support

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Place: Kolkata
Date: 02/05/2024

Dipannoy Basu Mallick
Authorized Signatory

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REF: wecare /support/003

Date: 21/08/2024

Customer Name	Wecare Diagnostic Centre.
Instrument	Curionix Bharat 88
Serial Number	BA-CL-3927
Protocol	QC Study
Date	21/08/2024

QC L1 Study Done by ELETECH Control Elirol_1_Lot_01-1200-07.

Date	ALBUMIN	BIL-T	Chol	CREAT	Glucose	TG	TP	Urea	Uric acid
14/08/2024	3.37	1.82	122.29	0.79	83.01	110.89	4.52	43.51	5.57
15/08/2024	3.41	1.08	110.50	0.73	87.32	114.80	4.74	38.60	5.99
16/08/2024	3.53	1.81	115.40	0.72	91.19	110.13	4.27	39.45	5.74
17/08/2024	3.53	2.03	119.68	0.77	91.09	114.88	4.73	37.99	4.96
18/08/2024	3.38	1.85	116.38	0.78	91.59	110.30	4.52	36.44	5.54
19/08/2024	3.39	1.76	120.99	0.70	97.36	113.58	4.43	36.18	5.38
20/08/2024	3.35	1.96	113.07	0.74	88.47	108.55	4.62	37.70	5.60
UNIT	g/dl	mg/dl	mg/dl	mg/dl	mg/dl	mg/dl	g/dl	mg/dl	mg/dl
TARGET	3.08	1.75	116	0.72	91.5	101	4.81	40.2	4.87
RANGE	2.53-3.63	1.43-2.07	99-133	0.59-0.85	77.8-105.2	85-117	4.23-5.39	34.2-46.2	4.14-5.60
SD	0.08	0.10	3.31	0.03	4.43	2.54	0.17	2.47	0.32
CV %	2.20	5.40	2.81	4.49	4.92	2.27	3.68	6.40	5.75

QC L2 Study Done by ELETECH Control Elirol_2_Lot_02-2200-03.

Date	ALBUMIN	BIL-T	Chol	CREAT	Glucose	TG	TP	Urea	Uric acid
14/08/2024	4.67	6.15	166.01	3.13	198.46	178.74	7.76	121.97	9.59
15/08/2024	4.85	6.12	168.44	2.85	209.64	171.41	7.90	112.00	9.39
16/08/2024	4.62	5.59	170.38	2.76	210.20	180.18	7.84	106.14	10.28
17/08/2024	4.89	6.04	151.16	2.74	205.42	175.89	7.15	108.25	9.32
18/08/2024	4.78	6.16	163.54	2.80	214.65	181.62	7.29	108.29	9.77
19/08/2024	4.73	6.05	160.95	2.98	219.72	190.67	7.52	105.28	9.88
20/08/2024	5.02	6.10	169.42	2.97	203.29	180.91	7.66	112.33	10.23
UNIT	g/dl	mg/dl	mg/dl	mg/dl	mg/dl	mg/dl	g/dl	mg/dl	mg/dl
Target	4.96	6.14	162	2.95	221.5	195	7.54	120.3	9.63
Range	4.07-5.85	5.03-7.25	138-186	2.42-3.48	188.3-254.7	164-226	6.64-8.44	102.3-136.3	8.19-11.07
SD	0.14	0.20	6.68	0.14	7.13	8.53	0.28	5.68	0.38
CV	2.87	3.31	4.07	4.79	3.41	4.71	3.73	5.13	3.88

** ALL ORIGINAL INSTRUMENT PRINTOUT ATTACHED WITH THIS STUDY REPORT.

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Bipamar Basu Mallick
Authorised Signatory 21/08/2024



MEDICARE ENTERPRISE

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REF: wecare /support/002

Date: 21/08/2024

Customer Name	Wecare Diagnostic Centre.
Instrument Model / Type	Curionix Bharat 88 / Saml Auto Biochemistry Analyzer
Serial Number	BA-CL-3927
Protocol	Precision Study
Date	21/08/2024

	ALBUMIN	BIL-T	Chol	CREAT	Glucose	TG	TP	Urea	Uric acid
1	3.44	1.81	122.61	0.76	90.63	113.04	4.36	38.93	5.32
2	3.51	1.95	120.89	0.71	91.12	114.51	4.42	38.80	5.59
3	3.38	1.79	119.81	0.70	90.88	112.52	4.63	39.37	5.67
4	3.49	1.84	121.92	0.72	92.27	111.88	4.29	38.62	5.21
5	3.35	1.91	120.13	0.70	91.26	113.57	4.47	39.31	5.44
6	3.31	1.85	122.54	0.73	93.56	110.58	4.51	37.92	5.69
7	3.46	1.88	121.90	0.71	90.66	114.32	4.33	38.25	5.49
8	3.58	1.93	122.77	0.73	91.85	113.59	4.56	38.23	5.41
9	3.30	1.82	120.55	0.74	90.46	111.80	4.43	37.61	5.62
10	3.41	1.90	122.48	0.70	91.72	112.92	4.59	38.99	5.26
UNIT	g/dl	mg/dl	mg/dl	mg/dl	mg/dl	mg/dl	g/dl	mg/dl	mg/dl
MEAN	3.42	1.86	121.56	0.72	91.44	112.88	4.45	38.6	5.47
SD	0.09	0.05	1.12	0.02	0.95	1.21	0.11	0.59	0.17
CV	2.64%	2.90%	0.92%	2.78%	1.04%	1.07%	2.55%	1.52%	3.13%
TARGET	3.08	1.75	116	0.72	91.5	101	4.81	40.2	4.87
RANGE	2.53-3.63	1.43-2.07	99-133	0.59-0.85	77.8-105.2	85-117	4.23-5.39	34.2-46.2	4.14-5.60

Precision Study Done by ELETECH Control Elitrol_1_Lot_01-1200-07.

** ALL ORIGINAL INSTRUMENT PRINTOUT ATTACHED WITH THIS STUDY REPORT.

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REF : wecare/support/001

Date: 21/08/2024

Customer Name	Wecare Diagnostic Centre.
Instrument Model / Type	Curionix Bharat 88 / Sami Auto Biochemistry Analyzer
Serial Number	BA-CL-3927
Protocol	Linearity Study
Date	21/08/2024

	ALBUMIN	BIL-T	Chol	CREAT	Glucose	TG	TP	Urea	Uric acid
1:1	2.71	3.17	82.88	1.68	111.10	108.19	3.96	63.01	5.39
	5.42	6.34	165.76	3.36	222.20	216.38	7.92	126.02	10.78
1:5	1.02	1.16	32.56	0.65	44.89	43.10	1.43	24.21	2.19
	5.10	5.80	162.80	3.25	224.45	215.50	7.15	121.05	10.95
1:10	0.55	0.69	16.91	0.31	22.62	20.63	0.78	12.30	0.98
	5.50	6.90	169.10	3.10	226.20	206.30	7.80	123.00	9.80
UNIT	g/dl	mg/dl	mg/dl	mg/dl	mg/dl	mg/dl	g/dl	mg/dl	mg/dl
Target	4.96	6.14	162	2.95	221.5	195	7.54	120.3	9.63
Range	4.07-5.85	5.03-7.25	138-186	2.42-3.48	188.3-254.7	164-226	6.64-8.44	102.3-136.3	8.19-11.07

Linearity Study Done by ELETECH Control Elitrol_2_Lot__02-2200-03.

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Authorised Signatory 21/8/2024.



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Performance Qualification

Performance Verification Report

Name of the customer:

Wecare Diagnostic Centre.

Instrument type:

Sami Auto Bio-Chemistry analyzer

Model name: Bharat 88

Serial number: BA-CL-3927

Date of receipt: 01/05/2024

Date of installation: 02/05/2024

Performance check:

1. Linearity Check: OK
2. Precision Check: Passed.
3. Control Run: Passed.

Result

The performance verification of **Bharat 88** has been completed satisfactorily and instrument is ready to be placed in service.

Performance check done in presence of:

Lab In charge: Mr. NIRUPAM SARKAR

Signature:

Date: 02/05/2024

Performance check:

Performance by: Dipankar Basu Mallick

(Service engineer)

Checked by: Mrs. Animesh Bhangi

MEDICARE ENTERPRISE

Date: 21/08/2024

Authorised Signatory

Date: 21/08/2024

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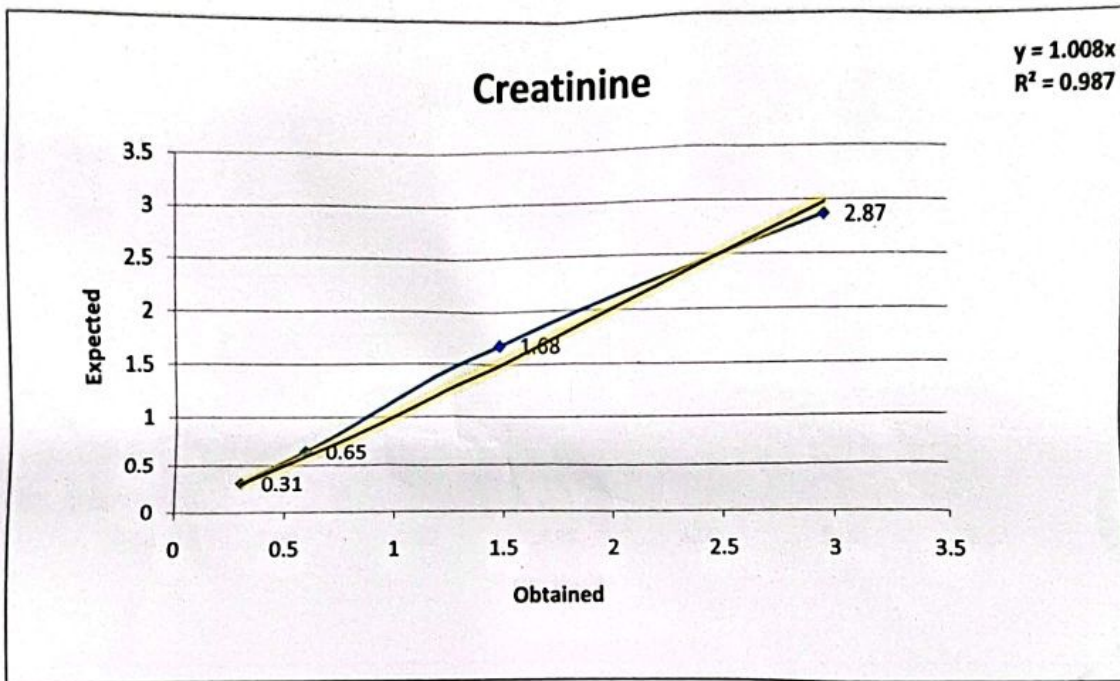
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Customer Name	Wecare Diagnostic Centre.
Instrument Model / Type	Curionix Bharat 88 / Saml Auto Biochemistry Analyzer
Serial Number	BA-CL-3927
Protocol	Linearity Graph Study Creatinine
Date	21/08/2024



Test Creatinine	Expected	Obtained
Neat	2.95	2.87
01:02	1.48	1.68
01:05	0.59	0.65
01:10	0.3	0.31

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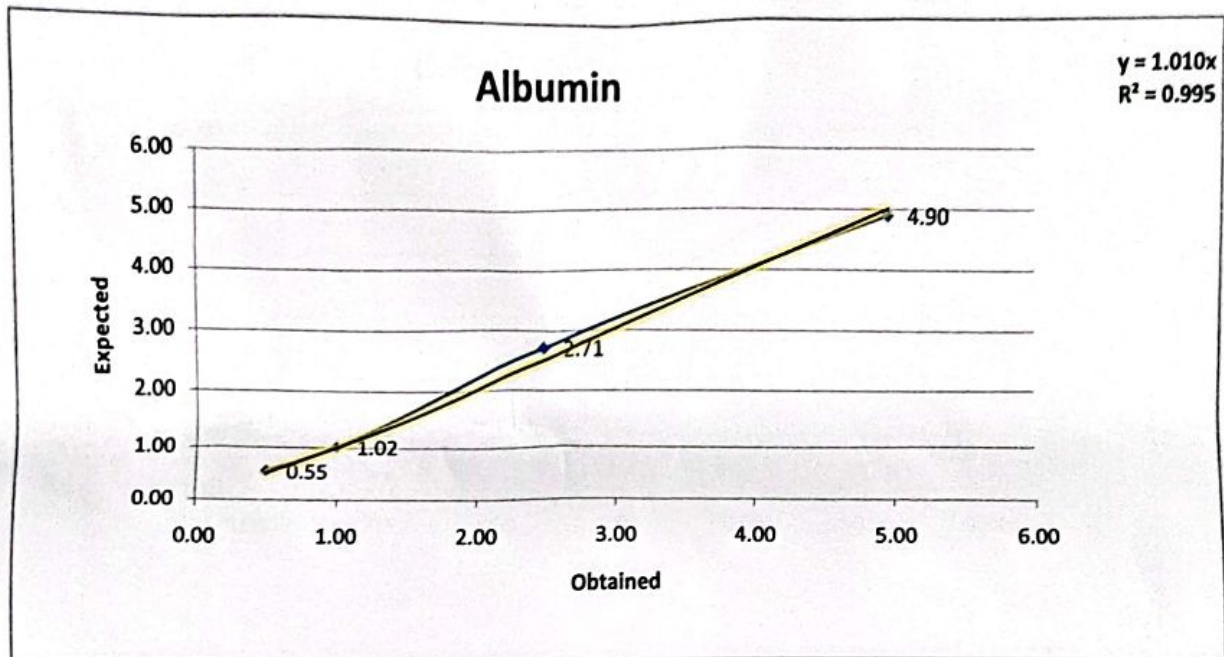
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Customer Name	Wecare Diagnostic Centre.
Instrument Model / Type	Curionx Bharat 88 / Sami Auto Biochemistry Analyzer
Serial Number	BA-CL-3927
Protocol	Linearity Graph Study Albumin
Date	21/08/2024

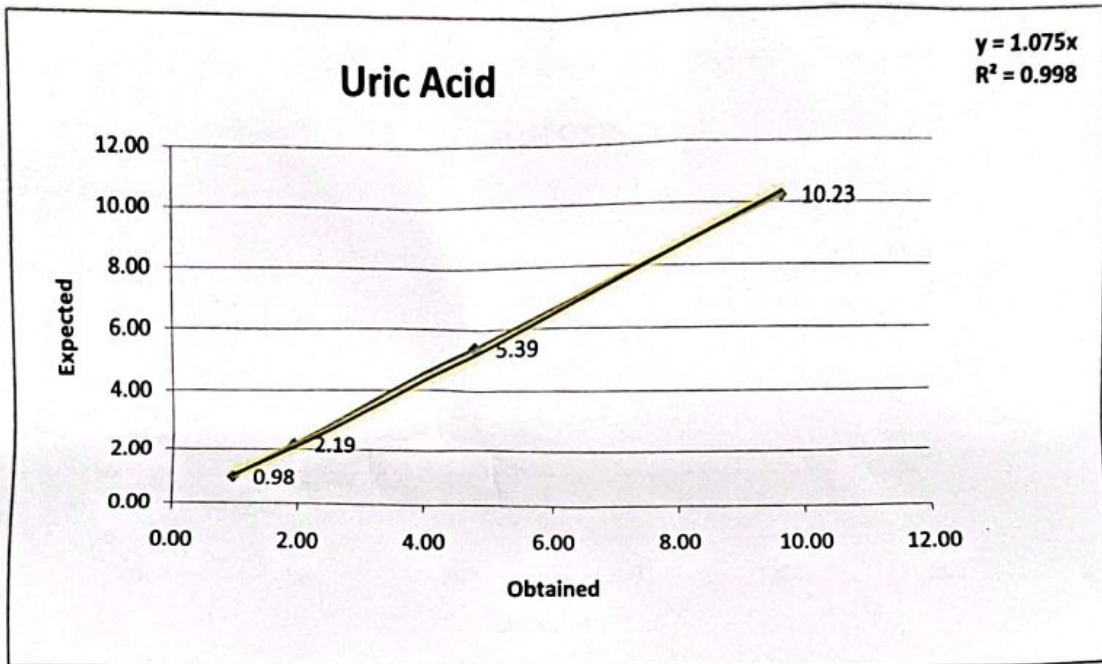


Test Albumin	Expected	Obtained
Neat	4.96	4.90
1:2	2.48	2.71
1:5	0.99	1.02
1:10	0.50	0.55

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Customer Name	Wecare Diagnostic Centre.
Instrument Model / Type	Curionix Bharat 88 / Sami Auto Biochemistry Analyzer
Serial Number	BA-CL-3927
Protocol	Linearity Graph Study Uric Acid
Date	21/08/2024



Test Uric Acid	Expected	Obtained
Neat	9.63	10.23
1:2	4.82	5.39
1:5	1.93	2.19
1:10	0.96	0.98

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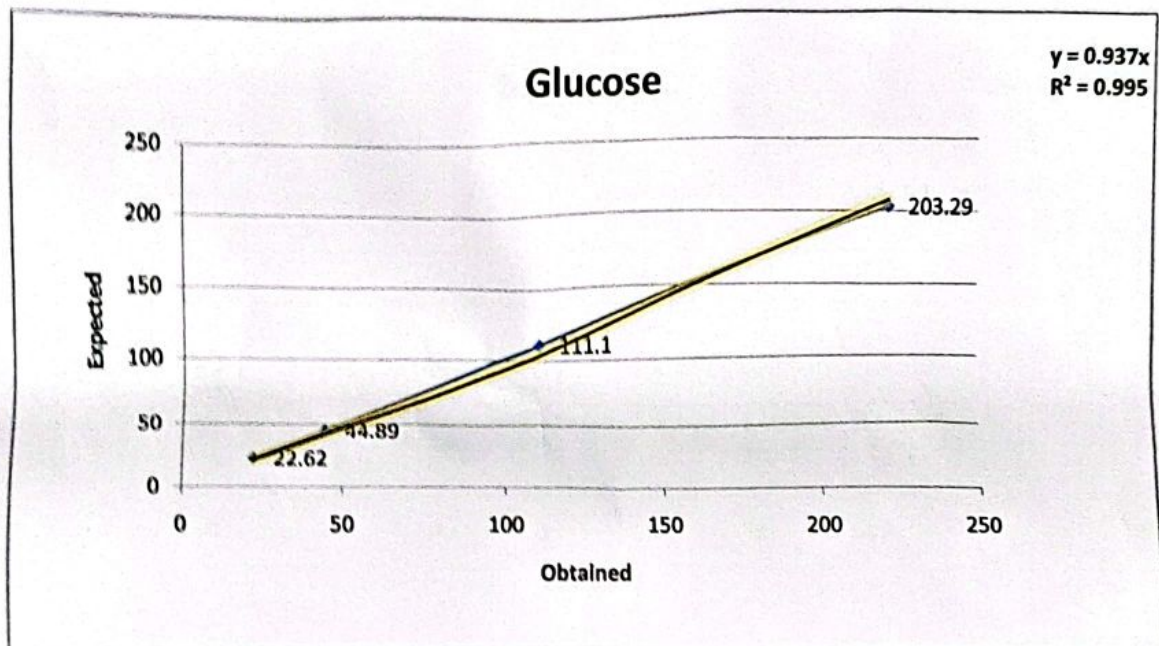
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Customer Name	Wecare Diagnostic Centre.
Instrument Model / Type	Curlonix Bharat 88 / Sami Auto Biochemistry Analyzer
Serial Number	BA-CL-3927
Protocol	Linearity Graph Study Glucose
Date	21/08/2024



Test Glucose	Expected	Obtained
Neat	221.5	203.29
01:02	110.75	111.1
01:05	44.3	44.89
01:10	22.15	22.62

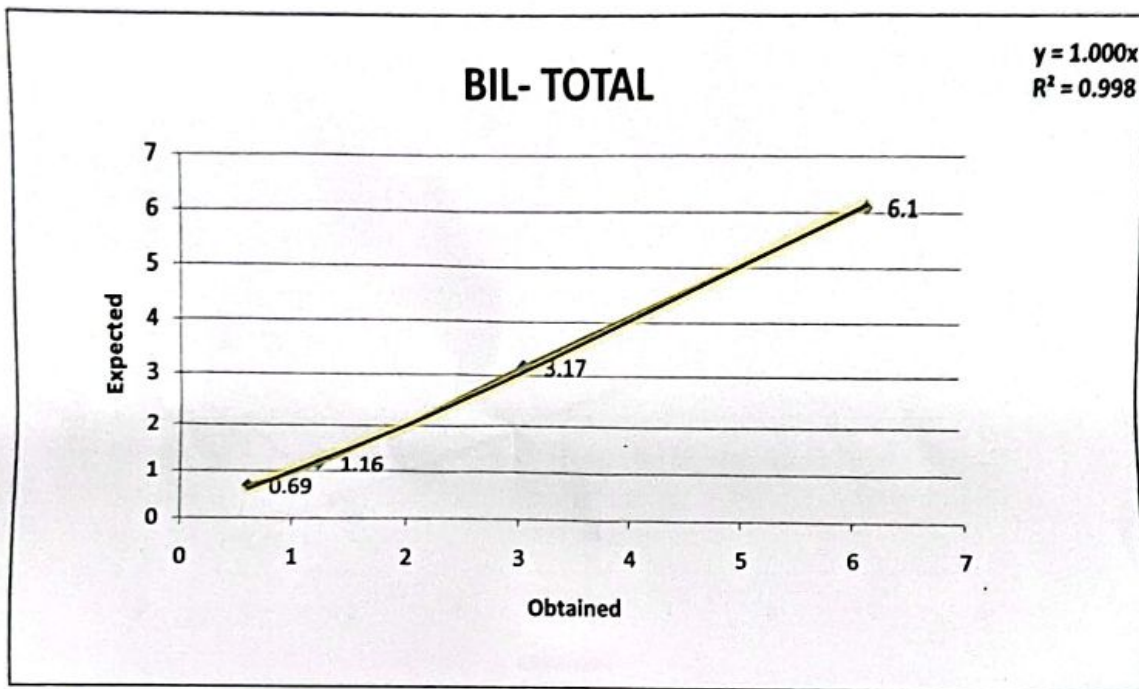
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Customer Name	Wecare Diagnostic Centre.
Instrument Model / Type	Curlonix Bharat 88 / Sami Auto Biochemistry Analyzer
Serial Number	BA-CL-3927
Protocol	Linearity Graph StudyBIL- TOTAL
Date	21/08/2024

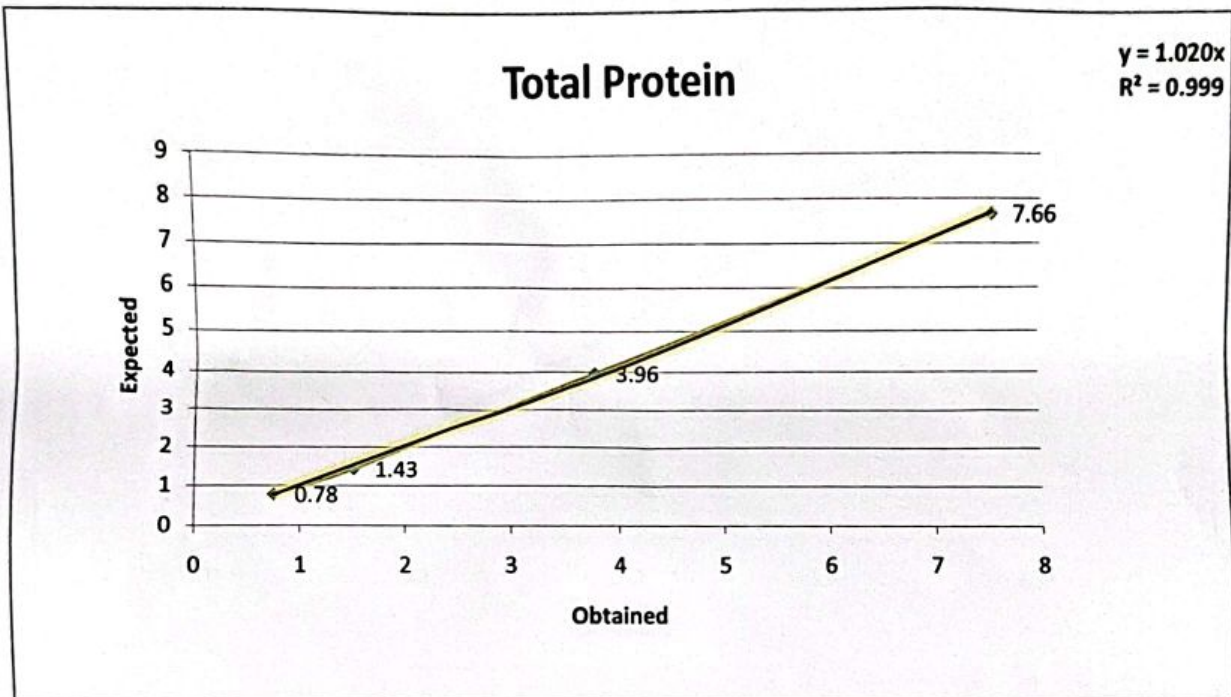


Test BIL- TOTAL	Expected	Obtained
Neat	6.14	6.1
01:02	3.07	3.17
01:05	1.23	1.16
01:10	0.61	0.69

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Customer Name	Wecare Diagnostic Centre.
Instrument Model / Type	Curlonix Bharat 88 / Sami Auto Biochemistry Analyzer
Serial Number	BA-CL-3927
Protocol	Linearity Graph Study Total Protein
Date	21/08/2024



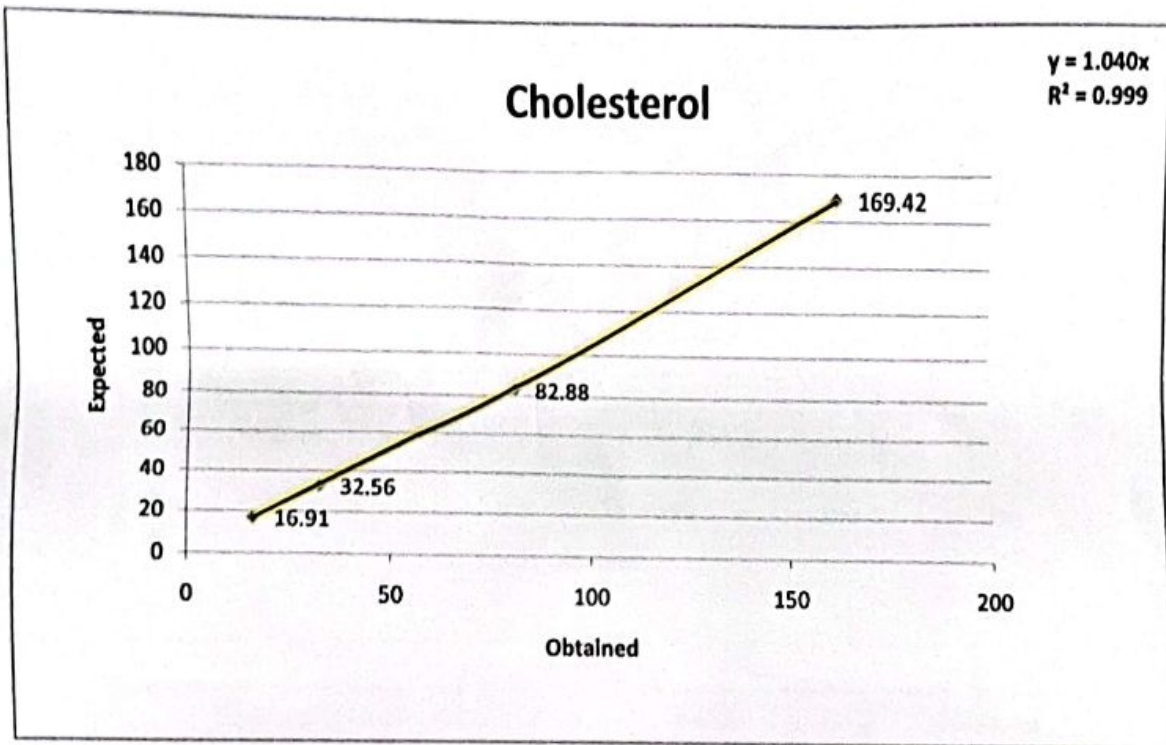
Test Total Protein	Expected	Obtained
Neat	7.54	7.66
01:02	3.77	3.96
01:05	1.51	1.43
01:10	0.75	0.78

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Customer Name	Wecare Diagnostic Centre.
Instrument Model / Type	Curlonlx Bharat 88 / Saml Auto Biochemistry Analyzer
Serial Number	BA-CL-3927
Protocol	Linearity Graph StudyCholesterol
Date	21/08/2024



Test Cholesterol	Expected	Obtained
Neat	162	169.42
01:02	81	82.88
01:05	32.4	32.56
01:10	16.2	16.91

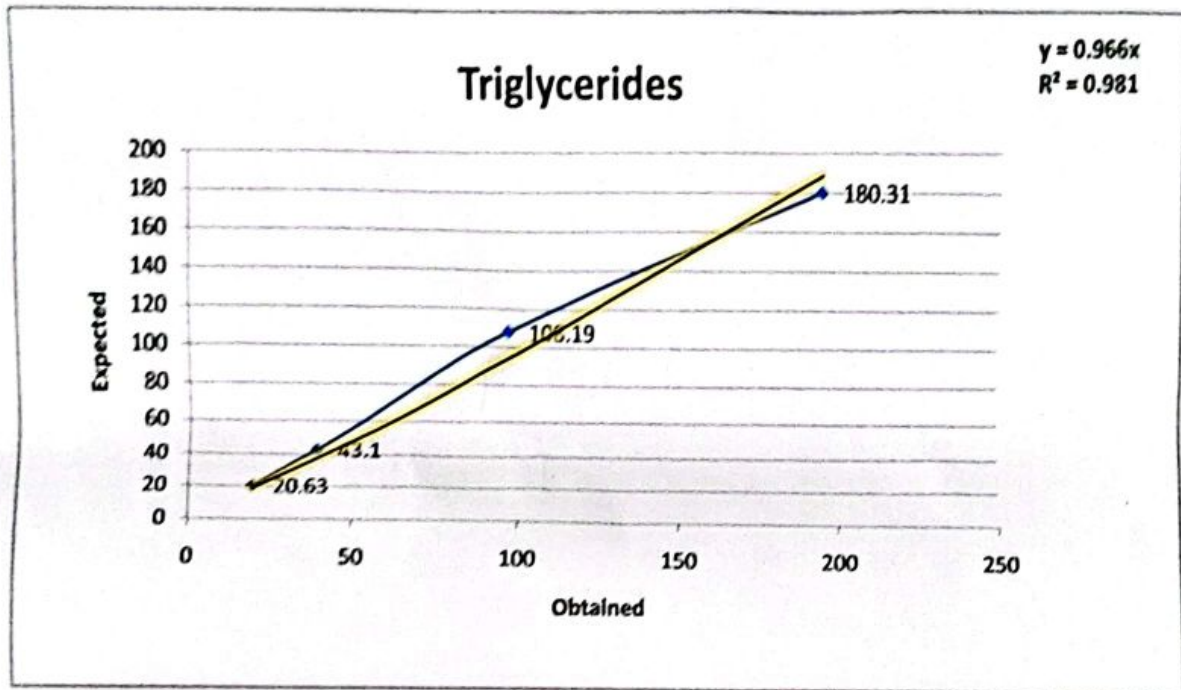
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Customer Name	We care Diagnostic Centre.
Instrument Model / Type	Curionix Bharat 88 / Sami Auto Biochemistry Analyzer
Serial Number	BA-CL-3927
Protocol	Linearity Graph Study Triglycerides
Date	21/08/2024

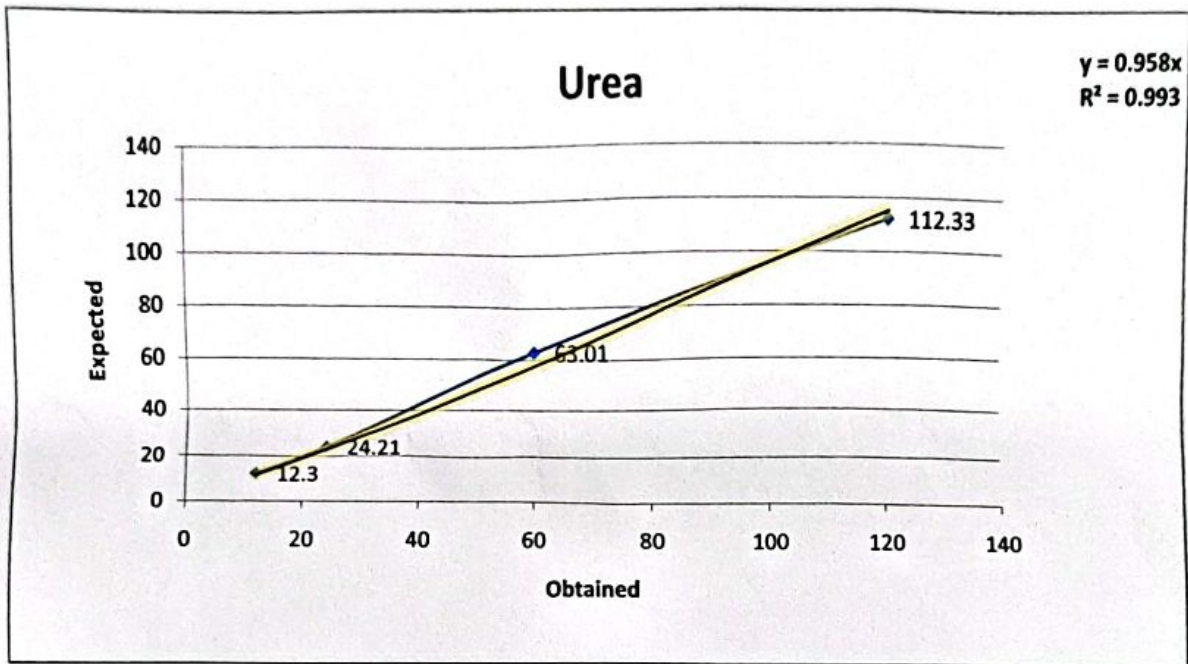


Test Triglycerides	Expected	Obtained
Heat	195	180.31
01:02	97.5	108.19
01:05	39	43.1
01:10	19.5	20.63

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Customer Name	Wecare Diagnostic Centre.
Instrument Model / Type	Curlonx Bharat 88 / Sami Auto Blochemistry Analyzer
Serial Number	BA-CL-3927
Protocol	Linearity Graph StudyUrea
Date	21/08/2024



Test Urea	Expected	Obtained
Neat	120.3	112.33
01:02	60.15	63.01
01:05	24.06	24.21
01:10	12.03	12.3

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