

Date: 21/06/2021

CALIBRATION CERTIFICATE

This is to certify that BTS – 350 Photometer bearing S.No: **801751324** installed at **Prem Clinical Lab,Cuddalore** has been calibrated on 21/06/2021.

Calibration Values: LIGHT INTENSITY TEST

LED	TINT	MAIN	REFERENCE
340	95	964159	290503
405	140	976943	843661
505	69	911963	970894
535	67	967907	825315
560	98	910798	970322
600	39	963602	770829
635	30	953995	706093
670	119	787900	977612

PERISTALTIC PUMP ADJUSTMENT TEST

VALUE	CURRENT	NEW
SAMPLE VOLUME	53449	53449
POSITIONING	2200	2200
PUMP DELAY	2	2

Next calibration is due on 20/06/2022

For **BIOSYSTEMS DIAGNOSTICS Pvt. Ltd.,**

A. P. S. Yadav


AUTHORISED SIGNATORY

Registered Office:

BioSystems Diagnostics Pvt. Ltd.,
A4, SIPCOT Industrial Park, Irungattukottai,
Thandalam Village, Sriperumbudur - 602105.
Ph: +91 - 44 - 3034 1911 / 12 /13
E-mail: customersupport@biosystems.in
Website: www.biosystems.in
CIN – U29297TN2003PTC051492



BTS 350 - Semi Auto BioChemistry Analyser

Installation Qualification Certificate

For

***PREM CLINICAL LAB,
CUDDALORE***

BioSystems Diagnostics Pvt. Ltd

Corporate Office:
BioSystems S.A. Costa Brava 30, 08030 Barcelona (Spain)
Tel +34-93 311 00 00, Fax+34-93 346 77 99
<http://www.biosystems.es>



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Website: www.biosystems.in
CIN - U29297TN2003PTC051492



CERTIFICATE OF INSTALLATION

Instrument Name : BTS 350 Semi Auto Biochemistry Analyser

Serial Number : 801751324

**Customer : Prem Clinical Lab,
No. 82-c, Main Road,
Pudupalayam, Cuddalore.607001.**

The undersigned performer certifies that the installation Qualification Protocol has been successfully completed for the instrument stated above.

Engineer

Signature :
Name : Mr.Ramesh.G
Designation : Asst Manager - Service
Company : BioSystems Diagnostics Pvt. Ltd

Quality Manager

Signature :
Name : R.JANAKIRAMAN
Designation : Quality Manager
Company : Prem Clinical Lab, Cuddalore.



Registered Office:

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Website: www.biosystems.in
CIN - U29297TN2003PTC051492



INSTALLATION REPORT

Customer Name : PREM CLINICAL LAB, CUDDALORE
Department : Quality Manager
Contact Person : R.JANAKIRAMAN
Instrument Model : BTS 350
Serial Number : 801751324
Date of Installation : 10/12/2010

The System was installed along with the necessary accessories. All basic requirements and adjustments were checked and are found to be satisfactory. Preliminary customer training was provided and standardization of a few parameters was done. The Instrument is found to be working satisfactorily.



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CIN – U29297TN2003PTC051492



INSTRUMENT SETUP:

- Instrument installed
- Printer Installed
- User software 1.42 installed
- All necessary checks done

OPERATION INSPECTION:

- No air bubbles found in the Tubing
- Temperature of the Flow cell Chamber are within range
- No unusual noises produced in the system
- Warm up procedure within time limit

For Biosystems Diagnostics Pvt. Ltd.,

For

A. Pulyadhi



Mr. Ramesh.G
Asst Manager – Service



Registered Office:
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Website: www.biosystems.in
CIN - U29297TN2003PTC051492



INSTALLATION QUALIFICATION

Customer Name : PREM CLINICAL LAB, CUDDALORE

Address : PREM CLINICAL LAB,
No. 82-c, Main Road,
Pudupalayam, Cuddalore.607001.

Instrument Model : BTS 350

Serial No. : 801751324

Operational requirement for the Instrument:

Requirement	Acceptable Range	Observed Range
Input Voltage	220 \pm 10 V	222 V
Line Frequency	50 or 60 Hz	50 Hz
Ambient Temperature	18 – 30 deg. C	23 deg. C

For Biosystems Diagnostics Pvt. Ltd.,

Pon
A. P. Pradyumnachandran

Mr. Ramesh. G
Asst Manager - Service



Registered Office:

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CIN – U29297TN2003PTC051492



BTS350 - Semi Auto BioChemistryAnalyser

Operational Qualification

For

***PREM CLINICAL LAB,
CUDDALORE***

BioSystems Diagnostics Pvt. Ltd.,

Corporate Office:
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Tel +34-93 311 00 00, Fax+34-93 346 77 99
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BTS350 – Semi Auto Biochemistry Analyser

OPERATIONAL QUALIFICATION

1. System Decontamination
2. Maintenance Procedures
3. System Performance check procedures
4. Customer Training Operation and Maintenance



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Website: www.biosystems.in
CIN - U29297TN2003PTC051492



CERTIFICATE OF OPERATION

Instrument Name : BTS350 - Semi Auto Biochemistry Analyser
Serial Number : 801751324
Customer : PREM CLINICAL LAB,
No. 82-c, Main Road,
Pudupalayam, Cuddalore.607001.

The undersigned performer certifies that the Operational Qualification Protocol has been successfully completed for the instrument stated above.

Engineer

For

A. P. Ramesh G



Signature :
Name : Mr. Ramesh. G
Designation : Asst Manager - Service
Company : BioSystems Diagnostics Pvt. Ltd.,

Quality Incharge

Signature :
Name : R. JANAKIRAMAN
Designation : Quality Manager
Company : Prem Clinical Lab, Cuddalore



Registered Office:

BioSystems Diagnostics Pvt. Ltd.,
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SYSTEM PERFORMANCE CHECK PROCEDURE

SYSTEM CHECK	PERFORMANCE
System Decontamination	Done
Photometer LED Check	Done
Start Up	Done
Pump Adjustments	Done
Temperature Check	Done

Customer Signature:

Corporate Office:
BioSystems S.A. Costa Brava 30, 08030 Barcelona (Spain)
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OPERATIONAL QUALIFICATION

System Certification:

Study data has determined that the System described in this document either meets all criteria outlined in this Operational Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any have been addressed. The system is ready for specified usage.

Protocol Performed By: BioSystems Diagnostics Pvt. Ltd
Name : Mr.Ramesh.G
Title : Asst Manager - Service
Company: BioSystems Diagnostics Pvt. Ltd

Customer Authorization PREM CLINICAL LAB, CUDDALORE
Name:R.JANAKIRAMAN
Title: Quality Manager

Pon
A. Pulyadhiswaran

ENGINEER SIGNATURE

CUSTOMER SIGNATURE

DATE:

DATE:

Corporate Office:
BioSystems S.A. Costa Brava 30, 08030 Barcelona (Spain)
Tel +34-93 311 00 00, Fax+34-93 346 77 99
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CIN - U29297TN2003PTC051492



BTS350 - Semi Auto BioChemistryAnalyser

Performance Qualification

For

***PREM CLINICAL LAB,
CUDDALORE***

BioSystems Diagnostics Pvt. Ltd

Corporate Office:
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BTS350 SEMIAUTO BIOCHEMISTRY ANALYSER

PERFORMANCE QUALIFICATION:

The following parameters were checked and found to be within acceptable limits.

<u>LED/Filters</u>	<u>Sensitivity (nA)</u> (Observed values)	<u>Minimum Value (nA)</u>	<u>Maximum Value (nA)</u>
340	30	12	40
405	25	12	60
505	23	12	100
535	60	12	100
560	173	150	450
600	23	12	100
635	12	12	30
670	32	12	120

DAC Analogic/Digital Converter

<u>Filters</u>	<u>Sensitivity (nA)</u> (Observed values)	<u>Minimum Value (nA)</u>	<u>Maximum Value (nA)</u>
340	67	50	90
405	95	75	140
505	98	75	140
535	88	75	140
560	117	60	120
600	78	75	140
635	92	75	140
670	84	75	140

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Website: www.biosystems.in
CIN - U29297TN2003PTC051492



CERTIFICATE OF PERFORMANCE

Instrument Name : BTS-350 Semi Auto Biochemistry Analyser
Serial Number : 801751324
Customer : PREM CLINICAL LAB,
No. 82-c, Main Road,
Pudupalayam, Cuddalore.607001.

The undersigned performer certifies that the Operational Qualification Protocol has been successfully completed for the instrument stated above.

Engineer

Pon

A. P. Polyaad



Signature :
Name : Mr. Ramesh. G
Designation : Asst Manager - Service
Company : BioSystems Diagnostics Pvt. Ltd

Quality Manager

Signature :
Name : R. JANAKIRAMAN
Designation : Quality Manager
Company : Prem Clinical Lab, Cuddalore



GLUCOSE - GOD-PAP Method

Kit Name : Agappe

Month / Year: March - 2022

Equip. Name:	Bio-System BTS-350
QC.Manufacturer	C.M.C

Lot.#	311110357
Exp. Date	2023-10

TARGET	
Mean	119.41
SD	1.28
CV(%)	1.07

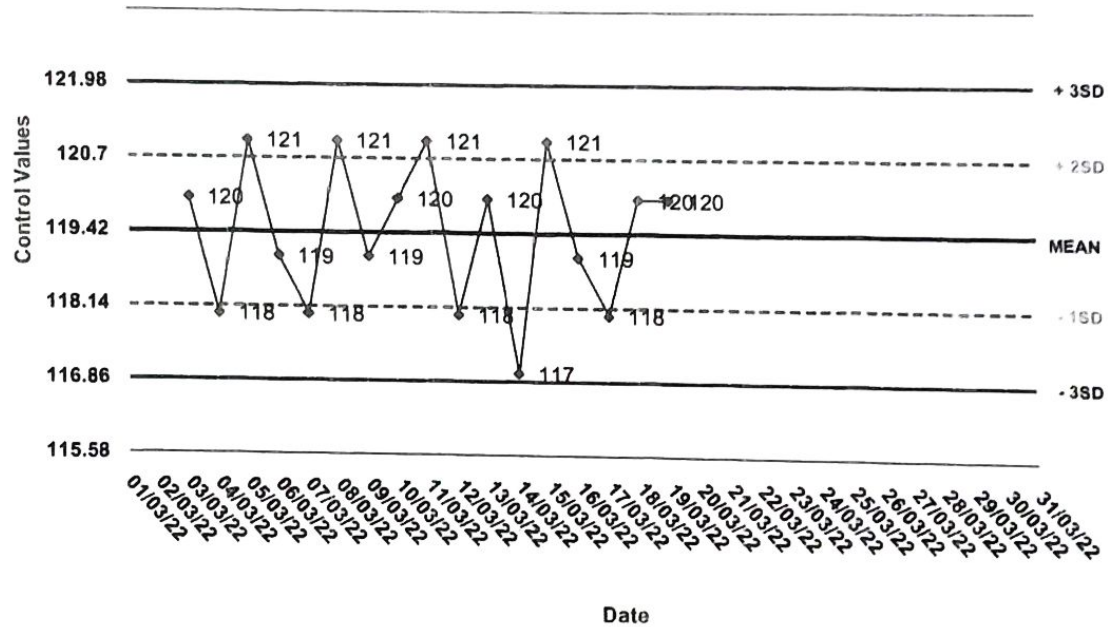
Day to Day	
Mean	119.41
SD	1.28
CV(%)	1.07
Mu	2.10

FORMAT AXIS SCALE	
Minimum	115.58
Maximum	123.24
Major Unit	1.28
Minor Unit	1.28
Horizontal X Axis	115.58

Days	Control Values
1-Mar	
2-Mar	
3-Mar	120
4-Mar	118
5-Mar	121
6-Mar	119
7-Mar	118
8-Mar	121
9-Mar	119
10-Mar	120
11-Mar	121
12-Mar	118
13-Mar	120
14-Mar	117
15-Mar	121
16-Mar	119
17-Mar	118
18-Mar	120
19-Mar	120
20-Mar	
21-Mar	
22-Mar	
23-Mar	
24-Mar	
25-Mar	
26-Mar	
27-Mar	
28-Mar	
29-Mar	
30-Mar	
31-Mar	

(+)3SD	(+)2SD	(+)1SD	MEAN	(-)1SD	(-)2SD	(-)3SD
123.24	121.97	120.69	119.41	118.13	116.86	115.58

Internal Quality Control - Levey Jennings Chart



Prepared BY : _____ Approved By: _____

PREM CLINICAL LAB PUDUPALAYAM CUDDALORE.

Equip. Name:	Bio-System BTS-350
QC.	
Manufacturer:	C.M.C

Lot.#	121B
Exp. Date	2024-10

TARGET	
Mean	31.26
SD	1.48
CV(%)	4.75

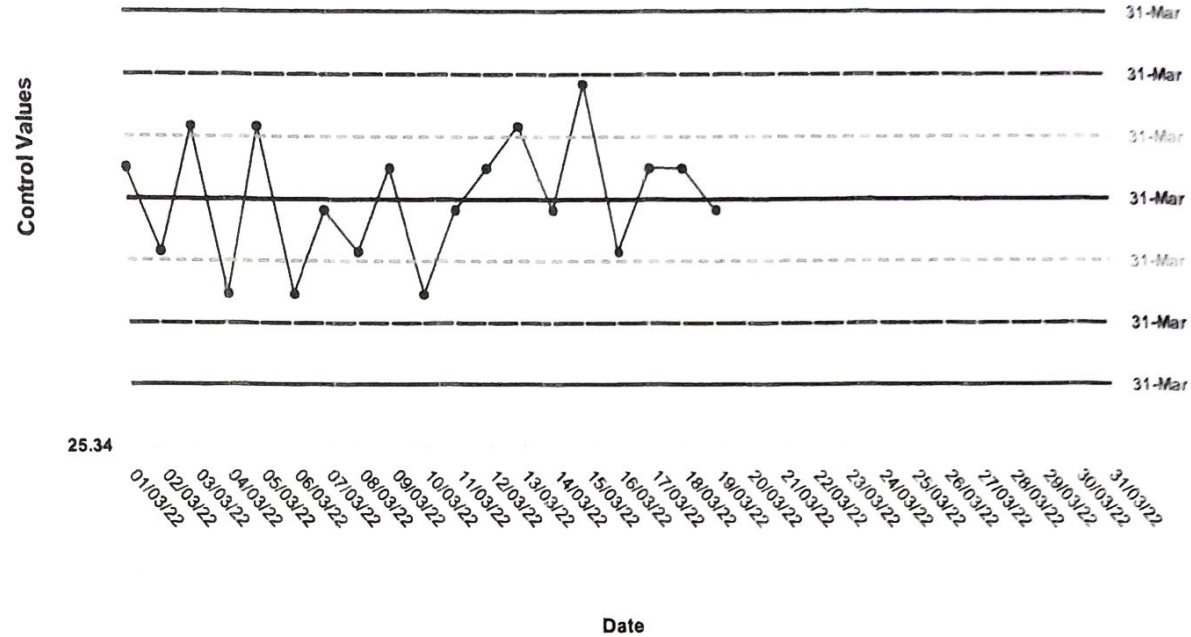
Day to Day	
Mean	31.26
SD	1.48
CV(%)	4.75
Mu	9.31

FORMAT AXIS SCALE	
Minimum	25.34
Maximum	37.18
Major Unit	1.48
Minor Unit	1.48
Horizontal X Axis	25.34

Days	Control Values
1-Mar	32
2-Mar	30
3-Mar	33
4-Mar	29
5-Mar	33
6-Mar	29
7-Mar	31
8-Mar	30
9-Mar	32
10-Mar	29
11-Mar	31
12-Mar	32
13-Mar	33
14-Mar	31
15-Mar	34
16-Mar	30
17-Mar	32
18-Mar	32
19-Mar	31
20-Mar	
21-Mar	
22-Mar	
23-Mar	
24-Mar	
25-Mar	
26-Mar	
27-Mar	
28-Mar	
29-Mar	
30-Mar	
31-Mar	

(+3SD)	(+2SD)	(+1SD)	MEAN	(-1SD)	(-2SD)	(-3SD)
35.70	34.22	32.74	31.26	29.78	28.30	26.82

Levey Jennings Chart



Prepared BY: _____

Approved By: _____

Internal Quality Control Data / Levey Jennings Chart

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CREATININE Jaffes Kinetic method

Month/Year: Mar-22

Equip. Name:	Bio Systems BTS - 350	Lot.#	149
	1.6	Exp. Date	2021 - 10
C.M.C			

TARGET	
Mean	1.60
SD	0.11
CV(%)	6.63

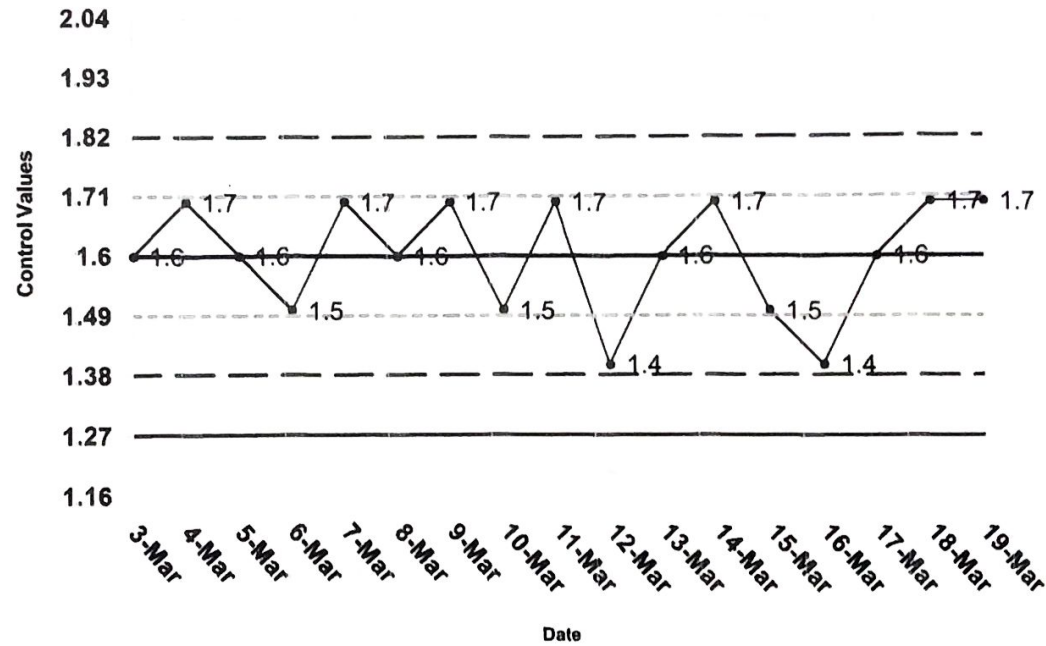
Day to Day	
Mean	1.60
SD	0.11
CV(%)	6.63
Mu	12.99

FORMAT AXIS SCALE	
Minimum	1.16
Maximum	2.04
Major Unit	0.11
Minor Unit	0.11
Horizontal X Axis	1.16

Days	Control Values
3-Mar	1.6
4-Mar	1.7
5-Mar	1.6
6-Mar	1.5
7-Mar	1.7
8-Mar	1.6
9-Mar	1.7
10-Mar	1.5
11-Mar	1.7
12-Mar	1.4
13-Mar	1.6
14-Mar	1.7
15-Mar	1.5
16-Mar	1.4
17-Mar	1.6
18-Mar	1.7
19-Mar	1.7

(+3SD)	(+2SD)	(+1SD)	(-1SD)	(-2SD)	(-3SD)
	1.82	1.71	1.49	1.38	1.27

Levey Jennings Chart



Internal Quality Control Data / Levey Jennings Chart

BILIRUBIN JENDRASSIK GROOF METHC

Month / Year: **Mar-22**

Equip. Name:	Bio Systems BTS - 350
QC. Manufacturer.:	C.M.C

Lot.#	149 A
Exp. Date	2024 - 08

TARGET	
Mean	1.83
SD	0.18
CV(%)	9.81

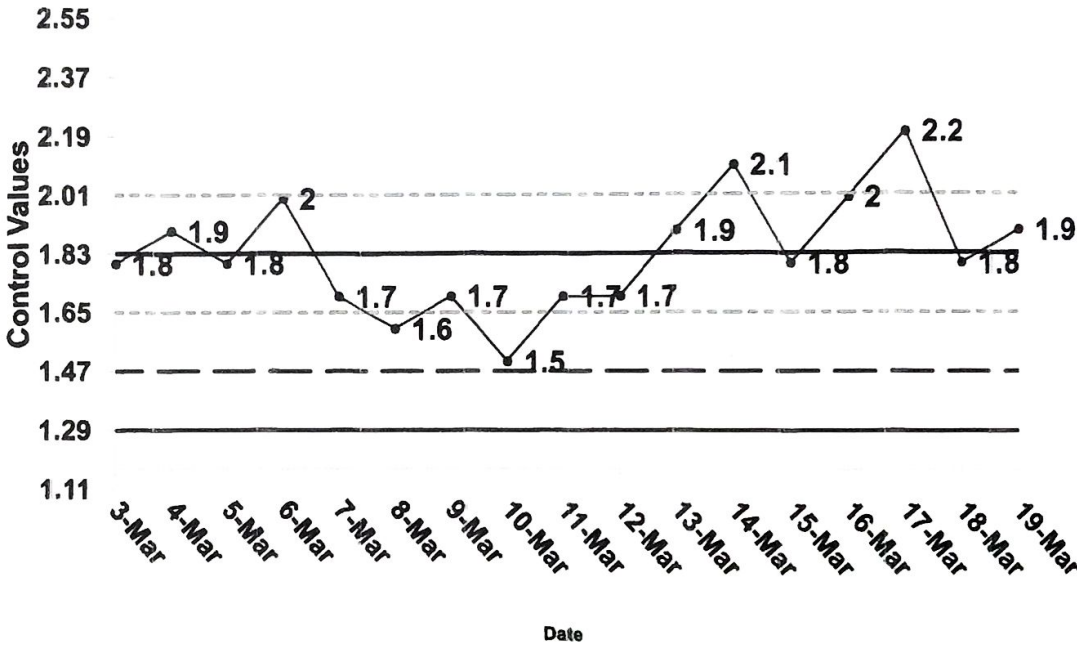
Day to Day	
Mean	1.83
SD	0.18
CV(%)	9.81
Mu	19.23

FORMAT AXIS SCALE	
Minimum	1.11
Maximum	2.55
Major Unit	0.18
Minor Unit	0.18
Horizontal X Axis	1.11

Days	Control Values
3-Mar	1.8
4-Mar	1.9
5-Mar	1.8
6-Mar	2
7-Mar	1.7
8-Mar	1.6
9-Mar	1.7
10-Mar	1.5
11-Mar	1.7
12-Mar	1.9
13-Mar	2.1
14-Mar	1.8
15-Mar	2
16-Mar	2.2
17-Mar	1.8
18-Mar	1.9
19-Mar	1.9

(+)3SD	(+)2SD	(+)1SD	(-)1SD	(-)2SD	(-)3SD
2.37	2.19	2.01	1.65	1.47	1.29

Levey Jennings Chart



Internal Quality Control Data / Levey Jennings Chart

T.PROTEIN BIURET METHOD

Month / Year: **Mar-22**

Equip. Name:	Bio Systems BTS - 350	Lot.#	147 C
QC. Manufacturer.:	C.M.C	Exp. Date	2024 - 09

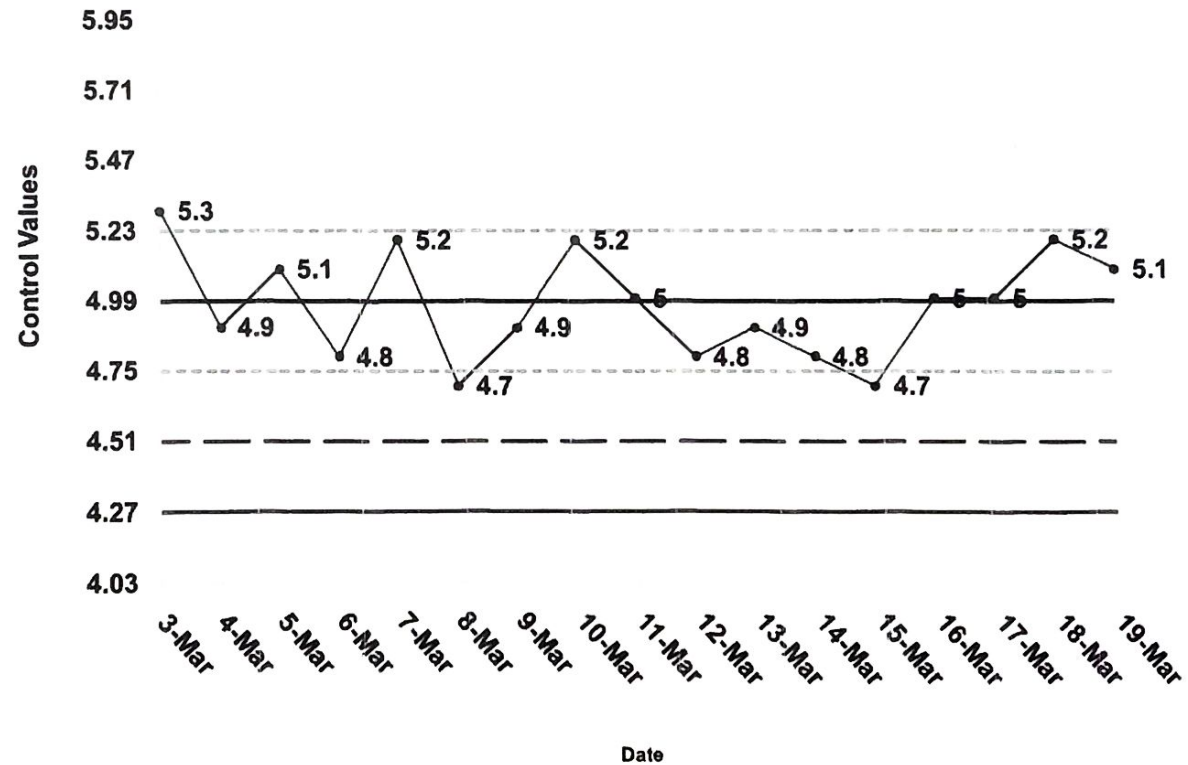
TARGET		Day to Day	
Mean	4.99	Mean	4.98
SD	0.24	SD	0.19
CV(%)	4.83	CV(%)	3.73
		Mu	7.31

FORMAT AXIS SCALE	
Minimum	4.03
Maximum	5.95
Major Unit	0.24
Minor Unit	0.24
Horizontal X Axis	4.03

Days	Control Values
3-Mar	5.3
4-Mar	4.9
5-Mar	5.1
6-Mar	4.8
7-Mar	5.2
8-Mar	4.7
9-Mar	4.9
10-Mar	5.2
11-Mar	5
12-Mar	4.8
13-Mar	4.9
14-Mar	4.8
15-Mar	4.7
16-Mar	5
17-Mar	5
18-Mar	5.2
19-Mar	5.1

(+3SD)	(+2SD)	(+1SD)	(-1SD)	(-2SD)	(-3SD)
5.71	5.47	5.23	4.75	4.51	4.27

Levey Jennings Chart



ALBUMIN BCG - Colorimetric II

Month/Year: Mar-22

Equip. Name:	Bio Systems BTS - 350
QC. Manufacturer.:	C.M.C

Lot.#	145 C
Exp. Date	2024 - 10

TARGET	
Mean	2.98
SD	0.13
CV(%)	4.37

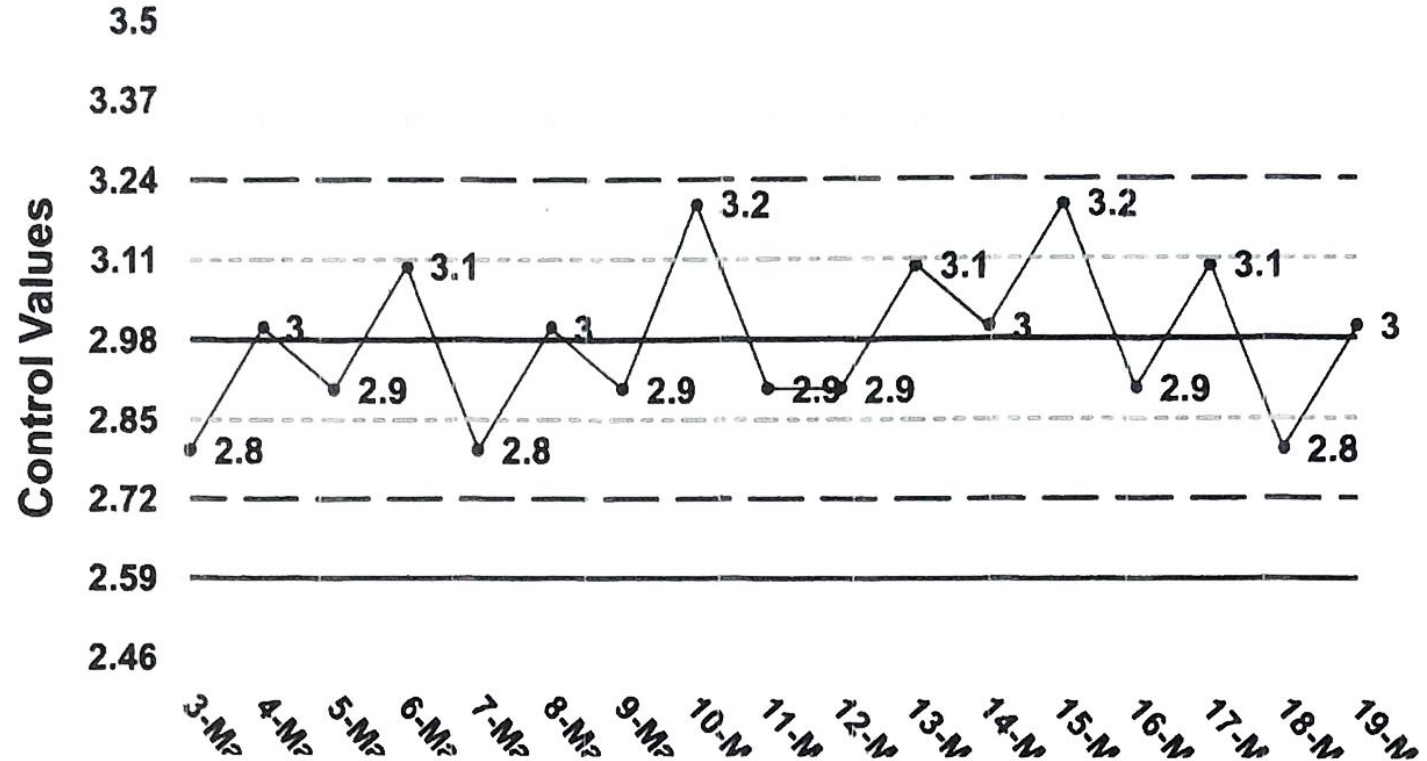
Day to Day	
Mean	2.98
SD	0.13
CV(%)	4.37
Mu	8.56

FORMAT AXIS SCALE	
Minimum	2.46
Maximum	3.50
Major Unit	0.13
Minor Unit	0.13
Horizontal X Axis	2.46

Days	Control Values
3-Mar	2.8
4-Mar	3
5-Mar	2.9
6-Mar	3.1
7-Mar	2.8
8-Mar	3
9-Mar	2.9
10-Mar	3.2
11-Mar	2.9
12-Mar	2.9
13-Mar	3.1
14-Mar	3
15-Mar	3.2
16-Mar	2.9
17-Mar	3.1
18-Mar	2.8
19-Mar	3

(+3SD)	(+2SD)	(+1SD)	(-1SD)	(-2SD)	(-3SD)
	3.24	3.11	2.85	2.72	2.59

Levey Jennings Chart



Uric Acid- Enzymatic Method

Month / Year: **Mar-22**

Equip. Name:	Bio Systems BTS-350
QC.	
Manufacturer:	C.M.C

Lot.#	31050456
Exp. Date	2024-09

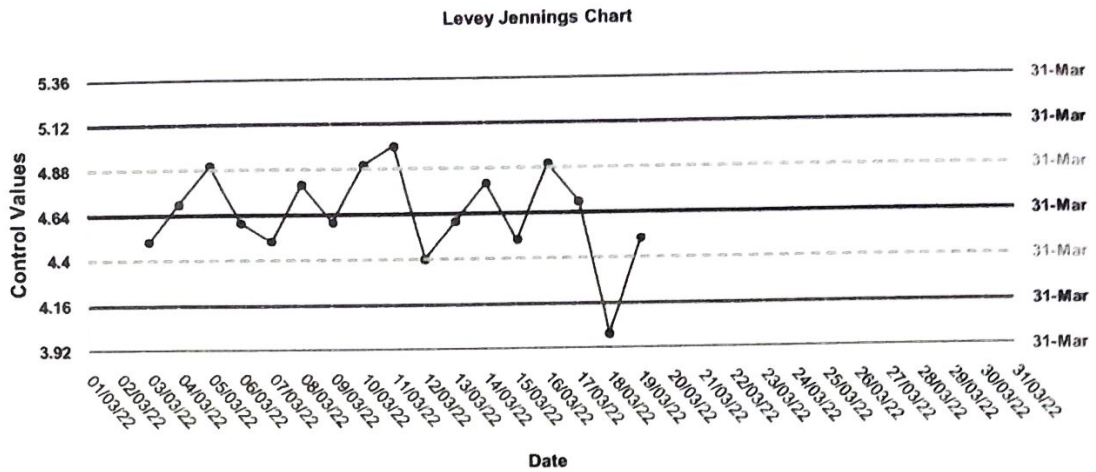
TARGET	
Mean	4.64
SD	0.24
CV(%)	5.23

Day to Day	
Mean	4.64
SD	0.24
CV(%)	5.23
Mu	10.24

FORMAT AXIS SCALE	
Minimum	3.92
Maximum	5.36
Major Unit	0.24
Minor Unit	0.24
Horizontal X Axis	3.92

Days	Control Values
1-Mar	
2-Mar	
3-Mar	4.5
4-Mar	4.7
5-Mar	4.9
6-Mar	4.6
7-Mar	4.5
8-Mar	4.8
9-Mar	4.6
10-Mar	4.9
11-Mar	5
12-Mar	4.4
13-Mar	4.6
14-Mar	4.8
15-Mar	4.5
16-Mar	4.9
17-Mar	4.7
18-Mar	4
19-Mar	4.5
20-Mar	
21-Mar	
22-Mar	
23-Mar	
24-Mar	
25-Mar	
26-Mar	
27-Mar	
28-Mar	
29-Mar	
30-Mar	
31-Mar	

(+3SD)	(+2SD)	(+1SD)	MEAN	(-1SD)	(-2SD)	(-3SD)
5.36	5.12	4.88	4.64	4.40	4.16	3.92



Prepared BY : _____ Approved By: _____

Cholesterol-CHOD-PAP METHC

Level: **L2**

Month/Year: **Mar-22**

Equip. Name:	Bio Systems BTS-350
QC.	
Manufacturer:	C.M.C

Lot.#	149
Exp. Date	2024-04

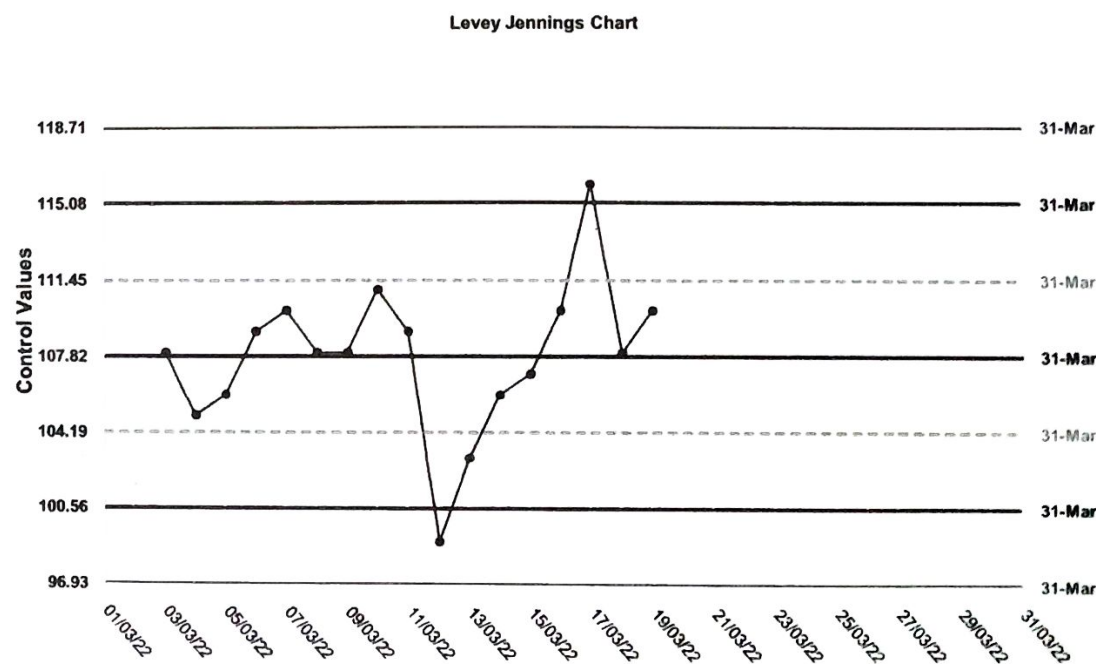
TARGET	
Mean	107.82
SD	3.63
CV(%)	3.36

Day to Day	
Mean	107.82
SD	3.63
CV(%)	3.36
Mu	6.59

FORMAT AXIS SCALE	
Minimum	96.93
Maximum	118.71
Major Unit	3.63
Minor Unit	3.63
Horizontal X Axis	96.93

Days	Control Values
1-Mar	
2-Mar	
3-Mar	108
4-Mar	105
5-Mar	106
6-Mar	109
7-Mar	110
8-Mar	108
9-Mar	108
10-Mar	111
11-Mar	109
12-Mar	99
13-Mar	103
14-Mar	106
15-Mar	107
16-Mar	110
17-Mar	116
18-Mar	108
19-Mar	110
20-Mar	
21-Mar	

(+3SD)	(+2SD)	(+1SD)	MEAN	(-1SD)	(-2SD)	(-3SD)
118.71	115.08	111.45	107.82	104.19	100.56	96.93



Triglycerides-GPO-PAP METHC

Level: L3

Month/Year:

Mar-22

Equip. Name:	Bio Systems BTS-350
QC.	
Manufacturer:	C.M.C

Lot.#	21226010901
Exp. Date	2023-08

TARGET	
Mean	134.82
SD	3.99
CV(%)	2.96

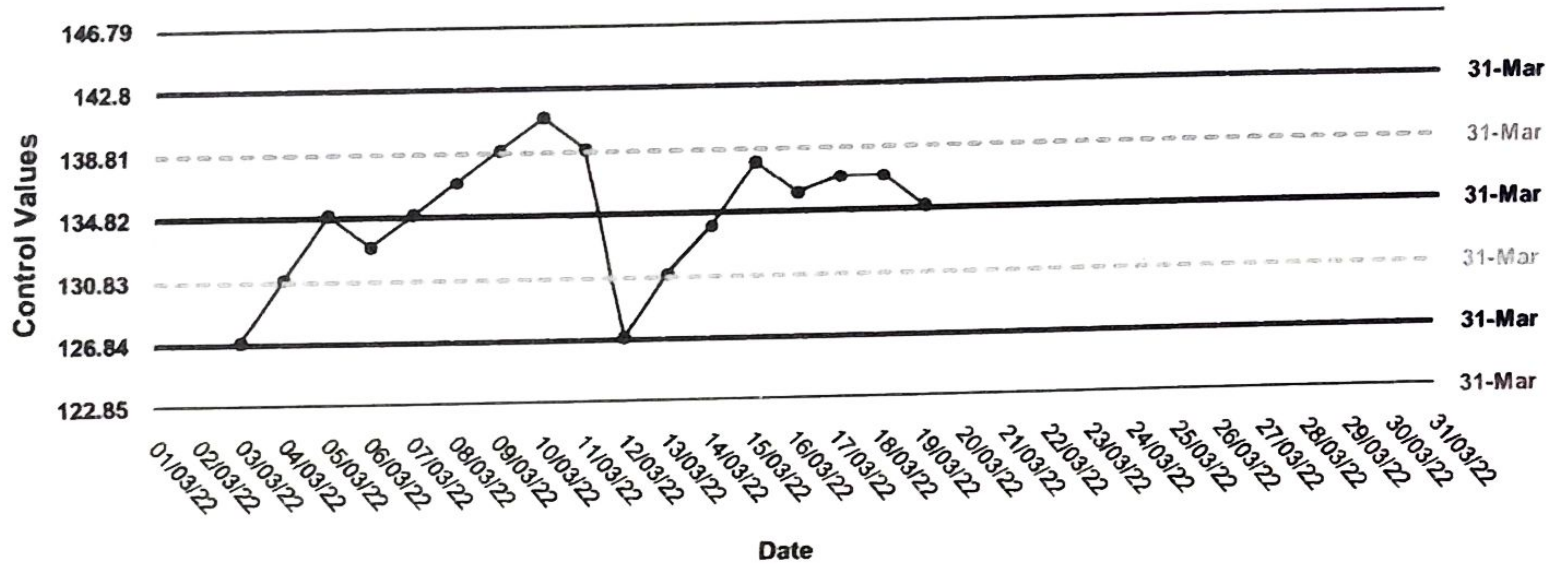
Day to Day	
Mean	134.82
SD	3.99
CV(%)	2.96
Mu	5.80

FORMAT AXIS SCALE	
Minimum	122.85
Maximum	146.79
Major Unit	3.99
Minor Unit	3.99
Horizontal X Axis	122.85

Days	Control Values
1-Mar	
2-Mar	
3-Mar	127
4-Mar	131
5-Mar	135
6-Mar	133
7-Mar	135
8-Mar	137
9-Mar	139
10-Mar	141
11-Mar	139
12-Mar	127
13-Mar	131
14-Mar	134
15-Mar	138
16-Mar	136
17-Mar	137
18-Mar	137
19-Mar	135
20-Mar	
21-Mar	
22-Mar	
23-Mar	
24-Mar	
25-Mar	
26-Mar	
27-Mar	
28-Mar	
29-Mar	
30-Mar	
31-Mar	

(+)3SD	(+)2SD	(+)1SD	MEAN	(-)1SD	(-)2SD	(-)3SD
146.79	142.80	138.81	134.82	130.83	126.84	122.85

Levey Jennings Chart



Prepared BY: _____

Approved By: _____

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