

Enabling Better Outcomes

CALIBRATION CERTIFICATE

This is to certify that Biochemistry Analyser SF-3000 PLUS bearing Serial No.4512-1493 which has been installed at ANNAI DIAGNOSTIC LAB, KULLANCHAVADI has been tested on the following aspects

1. LIGHT SOURCE :

Constant Light intensity for each filter.

2. CALIBRATION :

*The Absorbance Factor according to the Factory set calibration.
The Read Cell Temperature according to the Factory set calibration.*

3. FILTERS :

FILTERS(nm)	VOLTS(v)
340	3.90
405	5.00
505	5.90
545	6.30
580	6.30
630	6.50

Quality of the individual filters viz.340, 405, 505, 545, 580 and 630 were checked for calibration through the instrument software and calibrated.

On complete testing of the unit we found that the unit is working satisfactorily and used to carry out the necessary functions.

*Date of Calibration : 25-08-2021
Next Calibration Due : 24-08-2022*

For CPC DIAGNOSTICS PVT LTD

Authorised Signatory



Enabling Better Outcomes

INSTALLATION QUALIFICATION (IQ)

INSTRUMENT DESCRIPTION

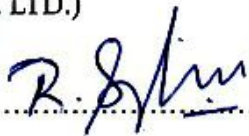
MODEL NO : Stat Fax 3000 Pjus
SERIAL NO : 4512-1493
MANUFACTURER : AWARENESS TECHNOLOGIES INC, USA
DISTRIBUTOR : CPC DIAGNOSTICS PVT. LTD
No. 324, KHADI GRAMMODYOG COMPLEX,
AVVAI SHANMUGAM SALAI, GOPALPURAM,
CHENNAI-86

CUSTOMER NAME : ANNAI DIAGNOSTIC LAB, KULLANCHAVADI

DATE OF INSTALLATION : 24/10/2017

ENGINEER (FOR CPC DIAGNOSTICS PVT. LTD.)

SIGNATURE





NAME

: Mr .R. SURAJ KUMAR

DESIGNATION

: DEPUTY GENERAL MANAGER

COMPANY

: CPC DIAGNOSTICS PVT. LTD.

CUSTOMER (ANNAI DIAGNOSTIC LAB, KULLANCHAVADI)

SIGNATURE



NAME

: M. LISA

DESIGNATION

: LAB. TECHNICIAN & PROPRIETOR

CORPORATE OFFICE

No.70/6, Old No.108/6, 4th floor, Westminster, Dr. Radhakrishnan Salai, Mylapore, Chennai - 600 004.

Phone No: 044-23460168/169

Enabling Better Outcomes

INSTALLATION REQUIREMENTS:

Installation Environment Conditions

Place should not be subjected to direct sunlight
Place should be flat and minimum of dust.

Power Supply

Voltage 220-240V AC
1.0 KVA Online UPS.

Temperature And Humidity Conditions

The temperature of the analyzer room should be between 18 - 30°C
The temperature fluctuation during the analysis should be $\pm 2^\circ\text{C}$

1. Dimensions Of System Main Units (Unit: mm)

40cm (L) X 37cm (W) X 14cm (H), (30 cm lid opened) 6.4 Kg

VERIFIED BY: MR.R.SURAJ KUMAR

REVIEWED BY:

(FOR ANNAI DIAGNOSTIC LAB, KULLANCHAVADI)


SIGNATURE: 


SIGNATURE:

Enabling Better Outcomes PERFORMANCE QUALIFICATION

FILTER VOLTAGES – All wave length voltage should be within 2 to 10 volts

Filters (nm)	Volts (v)
340	3.30
405	6.17
505	5.96
545	5.64
580	6.62
630	4.50

PRECISION CHECK

This module is highlighting the reproducibility and pipetting accuracy of the system. Measuring criteria

1. One end point chemistry
2. One kinetic chemistry
3. Large sample chemistry
4. Small sample chemistry
5. R1 only
6. R1 + R2

BY DOING PRECISION CHECK WITH GLUCOSE, ALT, CREATININE ABOVE REQUIREMENT WILL BE COMPLETED.

HERE BY I'm VERIFYING THAT THE CONTROL RESULT OF THE EXECUTED PARAMETERS ARE WITHIN THE SD RANGE AND CV RANGE.

VERIFIED BY: MR.R.SURAJ KUMAR

REVIEWED BY:
(FOR ANNAI DIAGNOSTIC LAB, KULLANCHAVADI)

SIGNATURE:



SIGNATURE:



everlife

CPC Diagnostics

CPC DIAGNOSTICS PVT LTD
REGISTERED OFFICE
No.9, 5th floor, Gokul Tower,
9 & 10, CP Ramaswamy Road,
Alwarpet, Chennai - 600 018
Tel: +91-44-24993989
Email: sales@cpodiagnosics.in
CIN: U52599TN1991PTC021095

Enabling Better Outcomes **OPERATIONAL QUALIFICATION**

ANALYSER CHECK

- FILTER VOLTAGES
- TEMPERATURE IN CUVET HOLDER
- TEMPERATURE IN INCUBATOR
- LAMP CONDITION

REMARK

OK
OK
OK
GOOD

VERIFIED BY: Mr.R.SURAJ KUMAR

REVIEWED BY:
(FOR ANNAI DIAGNOSTIC LAB, KULLANCHAVADI)

R. Suraj Kumar

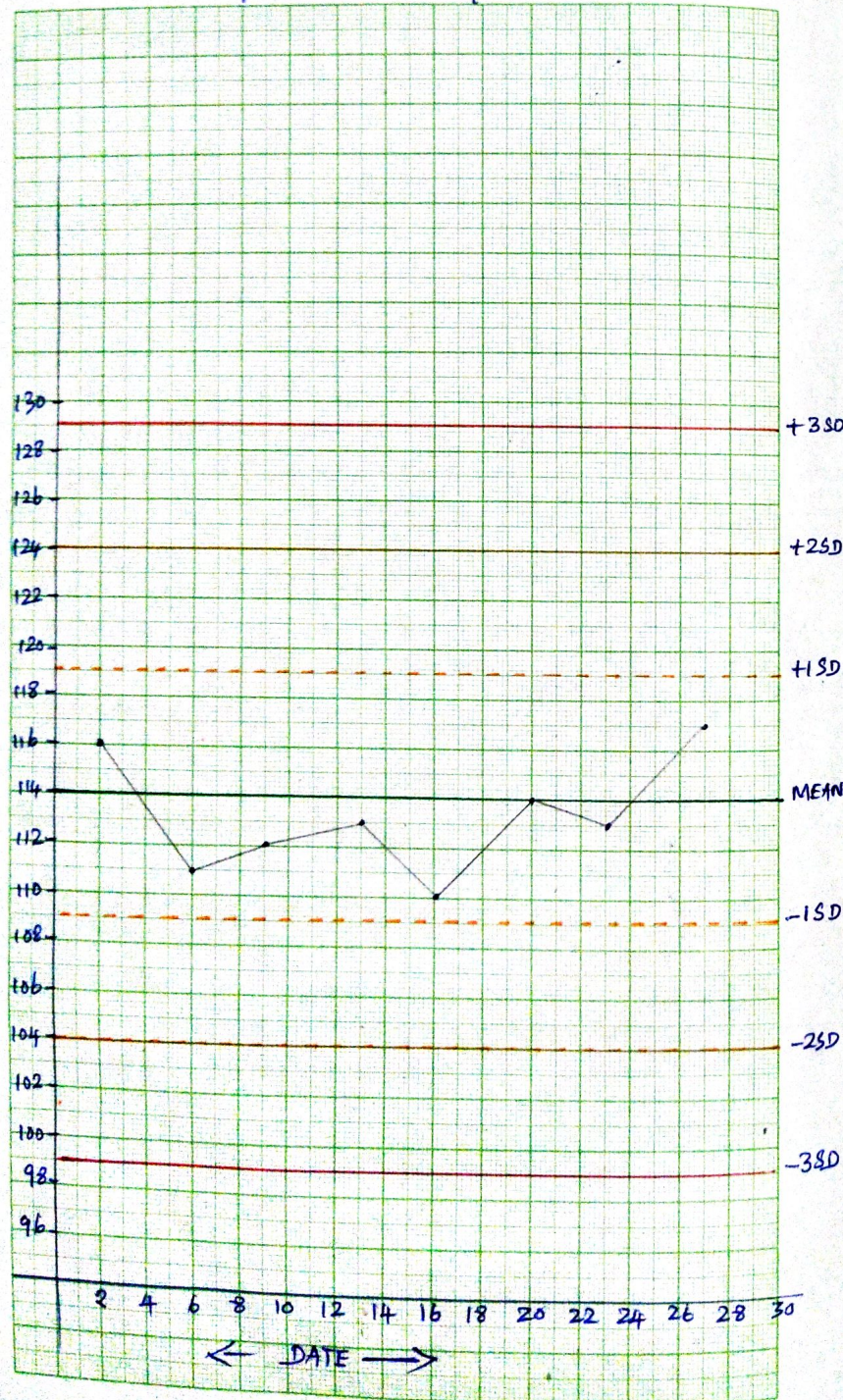
SIGNATURE:



[Signature]

SIGNATURE:

GLUCOSE - AUGUST - 2021



INTERNAL QUALITY CONTROL

GLUCOSE

AUGUST - 2021

Ex. No.

DATE

IQA'S SAMPLE PROVIDER: CMC - VELLORE

INSTRUMENT NAME: CPC STAT FAX 3000 PLUS

LOT KIT NAME : BIOSYSTEM DIAGNOSTICS PVT LTD.

KIT LOT No. : 175 A

KIT EXPIRY DATE : 30.08.2023

CMC MEAN VALUE : 114 mg/dl.

CMC RANGE VALUE : 104 - 124 mg/dl.

STANDARD DEVIATION : $\frac{124 - 104}{4} \Rightarrow \frac{20}{4} \Rightarrow 5$

1 SD = 1 x 5 = 5

2 SD = 2 x 5 = 10

3 SD = 3 x 5 = 15

+ 3 SD = MEAN VALUE + 3 SD $\Rightarrow 114 + 15 \Rightarrow 129$

+ 2 SD = MEAN VALUE + 2 SD $\Rightarrow 114 + 10 \Rightarrow 124$

+ 1 SD = MEAN VALUE + 1 SD $\Rightarrow 114 + 5 \Rightarrow 119$

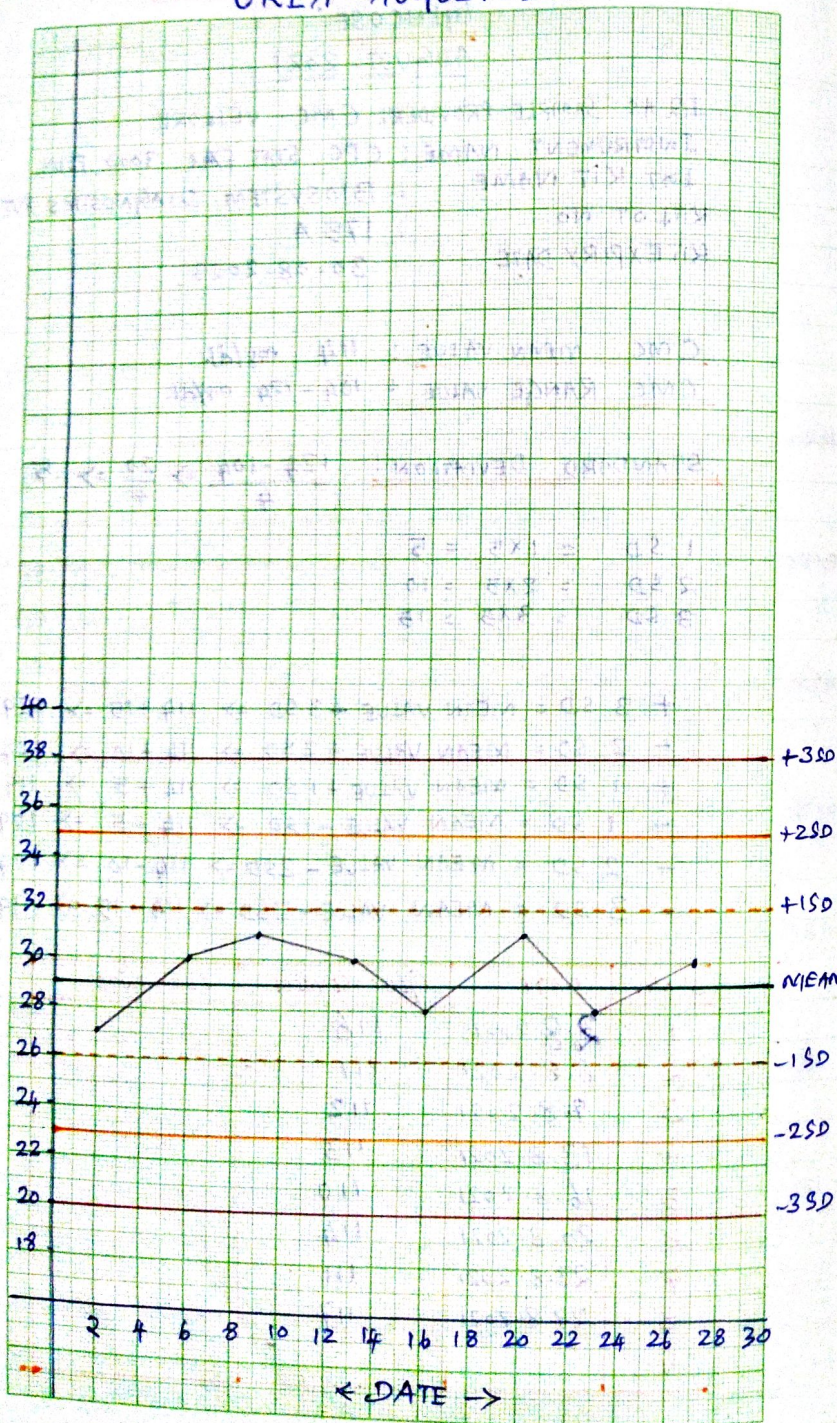
- 1 SD = MEAN VALUE - 1 SD $\Rightarrow 114 - 5 \Rightarrow 109$

- 2 SD = MEAN VALUE - 2 SD $\Rightarrow 114 - 10 \Rightarrow 104$

- 3 SD = MEAN VALUE - 3 SD $\Rightarrow 114 - 15 \Rightarrow 99$

S.No.	DATE	GLUCOSE VALUE	COMMENTS
1	2.8.2021	116	
2	6.8.2021	111	
3	9.8.2021	112	
4	13.8.2021	113	
5	16.8.2021	110	
6	20.8.2021	114	
7	23.8.2021	111	
8	27.8.2021	117	
9			

UREA - AUGUST - 2021



INTERNAL QUALITY CONTROL UREA

Ex. No. AUGUST - 2021

DATE

IQAS SAMPLE PROVIDER : CMC - VELLORE
 INSTRUMENT NAME : CPC STATFAX 3000 PLUS
 KIT NAME : BIOSYSTEM DIAGNOSTICS PVT.LTD
 KIT LOT NO. : 131
 KIT EXPIRY DATE : 31.3.2024

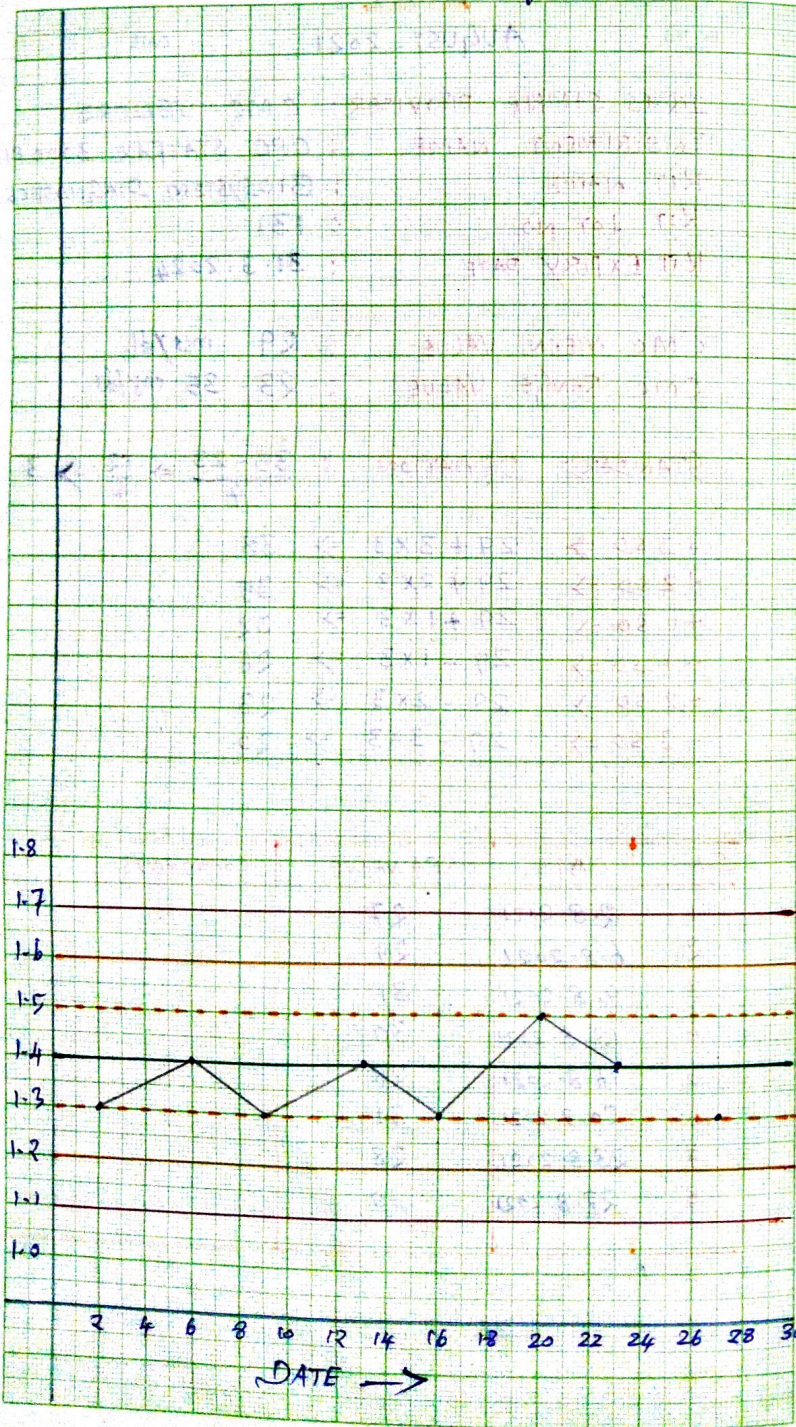
CMC MEAN VALUE : 29 mg/dl.
 CMC RANGE VALUE : 23 - 35 mg/dl.

STANDARD DEVIATION : $\frac{35-23}{4} \Rightarrow \frac{12}{4} \Rightarrow 3$

- +3 SD $\Rightarrow 29 + 3 \times 3 \Rightarrow 38$
- +2 SD $\Rightarrow 29 + 2 \times 3 \Rightarrow 35$
- +1 SD $\Rightarrow 29 + 1 \times 3 \Rightarrow 32$
- 1 SD $\Rightarrow 29 - 1 \times 3 \Rightarrow 26$
- 2 SD $\Rightarrow 29 - 2 \times 3 \Rightarrow 23$
- 3 SD $\Rightarrow 29 - 3 \times 3 \Rightarrow 20$

S.No.	DATE	UREA VALUE	COMMENTS
1	2.8.2021	27	
2	6.8.2021	29	
3	9.8.2021	31	
4	13.8.2021	30	
5	16.8.2021	28	
6	20.8.2021	31	
7	23.8.2021	28	
8	27.8.2021	30	

INTERNAL QUALITY CONTROL
CREATININE - AUGUST - 2021



INTERNAL QUALITY CONTROL
CREATININE

Ex. No. AUGUST - 2021

DATE

IQAS SAMPLE PROVIDER: CMC - VELLORE
INSTRUMENT NAME: CPC STATFAX 3000 PLUS
KIT NAME: BIOSYSTEM DIAGNOSTICS PVT LTD
KIT LOT No.: 154
KIT EXPIRY DATE: 31.03.2024

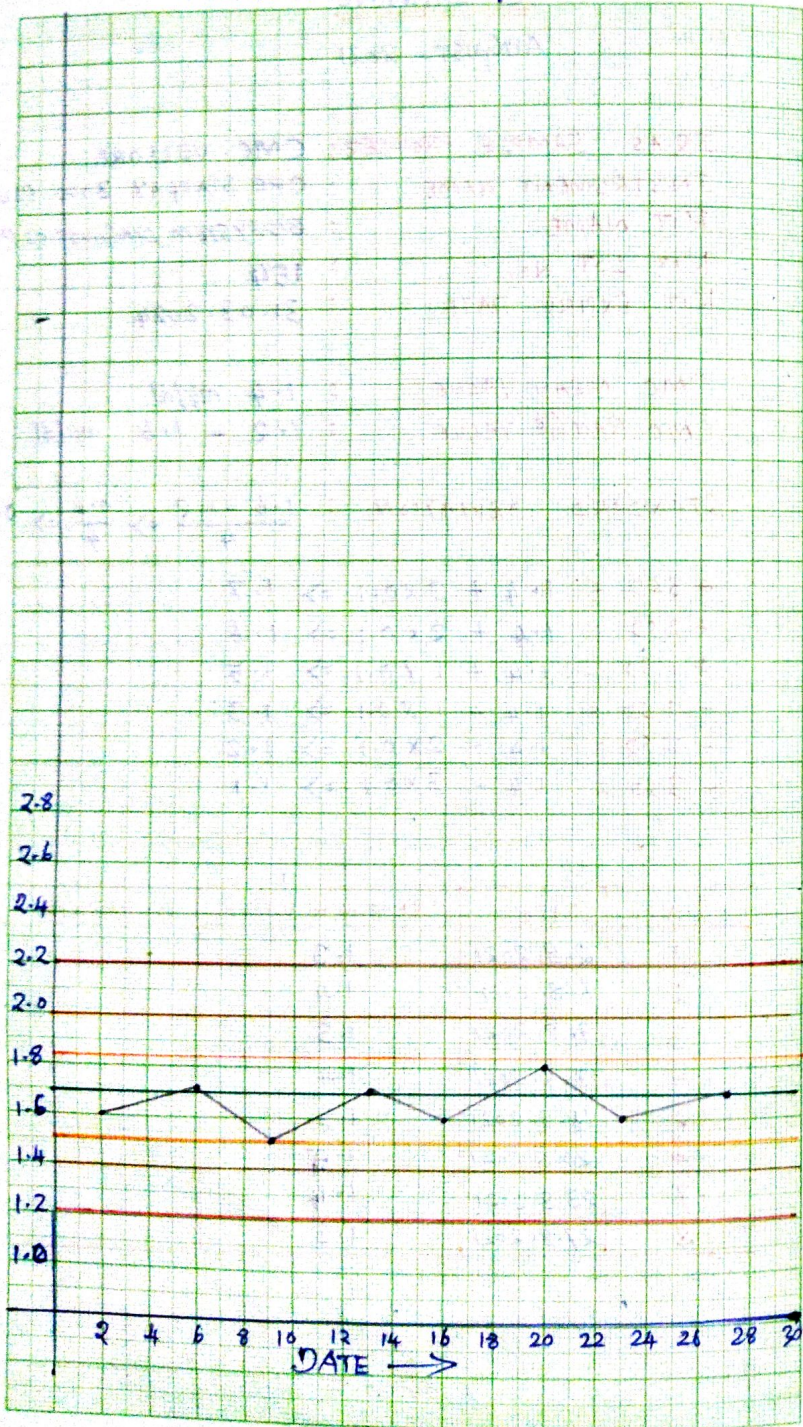
CMC MEAN VALUE: 1.4 mg/dl.
CMC RANGE VALUE: 1.2 - 1.6 mg/dl.

STANDARD DEVIATION: $\frac{1.6 - 1.2}{4} \Rightarrow \frac{0.4}{4} \Rightarrow 0.1$

- +3SD = 1.4 + 3 x 0.1 \Rightarrow 1.7
- +2SD = 1.4 + 2 x 0.1 \Rightarrow 1.6
- +1SD = 1.4 + 1 x 0.1 \Rightarrow 1.5
- 1SD = 1.4 - 1 x 0.1 \Rightarrow 1.3
- 2SD = 1.4 - 2 x 0.1 \Rightarrow 1.2
- 3SD = 1.4 - 3 x 0.1 \Rightarrow 1.1

S.No.	DATE	CREATININE VALUE	COMMENTS
1	2.8.2021	1.3	
2	6.8.2021	1.4	
3	9.8.2021	1.3	
4	13.8.2021	1.4	
5	16.8.2021	1.3	
6	20.8.2021	1.5	
7	23.8.2021	1.4	
8	27.8.2021	1.3	

T. BILIRUBIN - AUGUST - 2021



INTERNAL QUALITY CONTROL

T. BILIRUBIN

Ex. No. AUGUST - 2021

DATE

IQAS SAMPLE PROVIDER : CMC - VELLORE
 INSTRUMENT NAME : CPC STATFAX 3000 PLUS
 KIT NAME : BIOSYSTEM DIAGNOSTICS PVT LTD
 KIT LOT NO. : 16213
 KIT EXPIRY DATE : 31.10.2023

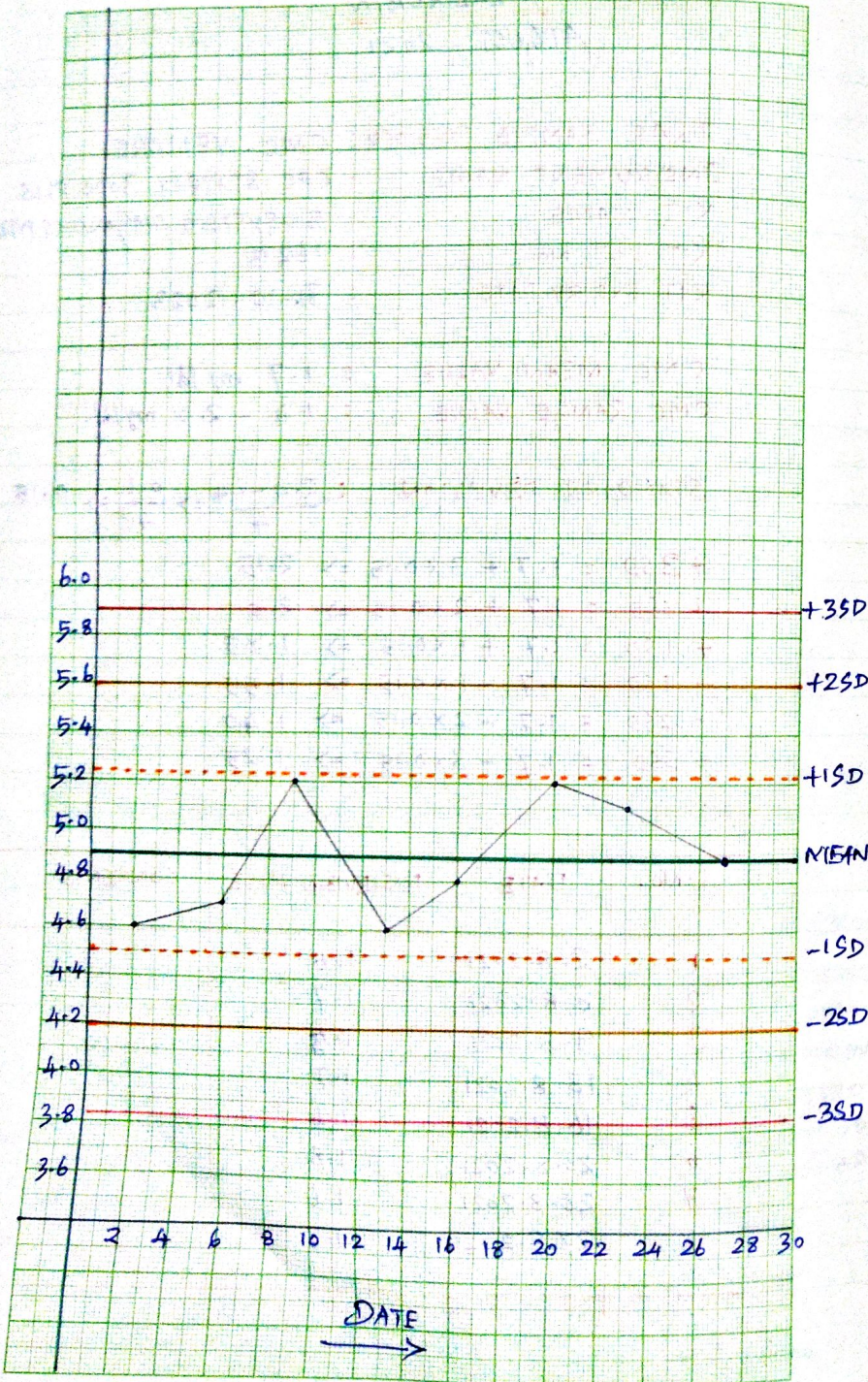
CMC MEAN VALUE : 1.7 mg/dl.
 CMC RANGE VALUE : 1.4 - 2.0 mg/dl.

STANDARD DEVIATION : $\frac{2.0 - 1.4}{4} \Rightarrow \frac{0.6}{4} \Rightarrow 0.15$

- +3SD = 1.7 + 3 x 0.15 \Rightarrow 2.15
- +2SD = 1.7 + 2 x 0.15 \Rightarrow 2.0
- +1SD = 1.7 + 1 x 0.15 \Rightarrow 1.85
- 1SD = 1.7 - 1 x 0.15 \Rightarrow 1.55
- 2SD = 1.7 - 2 x 0.15 \Rightarrow 1.40
- 3SD = 1.7 - 3 x 0.15 \Rightarrow 1.25

S.No.	DATE	BILIRUBIN VALUE	COMMENTS
1	2.8.2021	1.6	
2	6.8.2021	1.7	
3	9.8.2021	1.5	
4	13.8.2021	1.7	
5	16.8.2021	1.6	
6	20.8.2021	1.8	
7	23.8.2021	1.6	
8	27.8.2021	1.7	

T. PROTEIN - AUGUST - 2021



INTERNAL QUALITY CONTROL

T. PROTEIN

Ex. No.

AUGUST - 2021

DATE

IQAS SAMPLE PROVIDER : CMC-VELLORE
 INSTRUMENT NAME : CPC STATFAX 3000 PLUS
 KIT NAME : BIOSYSTEM DIAGNOSTICS ^{INTL}
 KIT LOT No. : 123
 KIT EXPIRY DATE : 30.11.2022

CMC MEAN VALUE : 4.9 mg/dl.

CMC RANGE VALUE : 4.2 - 5.6 mg/dl.

STANDARD DEVIATION : $\frac{5.6-4.2}{4} \Rightarrow \frac{1.4}{4} \Rightarrow 0.35$

+3SD : $4.9 + 3 \times 0.35 \Rightarrow 5.95$

+2SD : $4.9 + 2 \times 0.35 \Rightarrow 5.6$

+1SD : $4.9 + 1 \times 0.35 \Rightarrow 5.25$

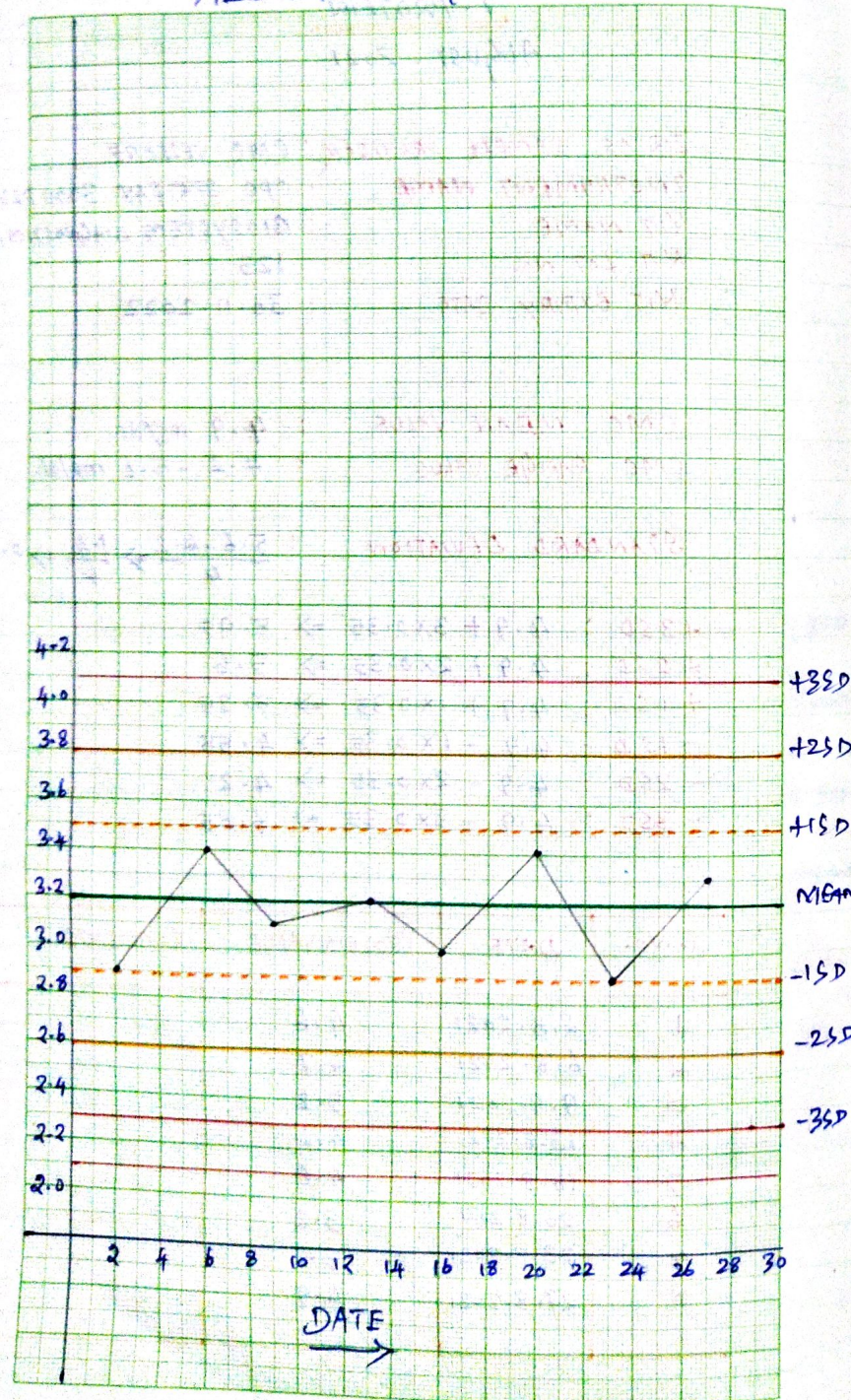
-1SD : $4.9 - 1 \times 0.35 \Rightarrow 4.55$

-2SD : $4.9 - 2 \times 0.35 \Rightarrow 4.2$

-3SD : $4.9 - 3 \times 0.35 \Rightarrow 3.85$

S. No.	DATE	PROTEIN VALUE	COMMENTS
1	2.8.2021	4.6	
2	6.8.2021	4.7	
3	9.8.2021	5.2	
4	13.8.2021	4.6	
5	16.8.2021	4.8	
6	20.8.2021	5.2	
7	23.8.2021	5.1	
8	27.8.2021	4.9	

ALBUMIN - AUGUST - 2021



INTERNAL QUALITY CONTROL

ALBUMIN

Ex. No. AUGUST - 2021

DATE

IQ AS SAMPLE PROVIDER : CMC - VELLORE
 INSTRUMENT NAME CPC : STAFFAX 3000 PLUS
 KIT NAME : ACCUREX BIOMEDICALS PVT LTD
 KIT LOT No. : 49020
 KIT EXPIRY DATE : 31. 01. 2022

CMC MEAN VALUE : 3.2 mg/dl.
 CMC RANGE VALUE : 2.6 - 3.8 mg/dl.

STANDARD DEVIATION : $\frac{3.8 - 2.6}{4} \Rightarrow \frac{1.2}{4} \Rightarrow 0.3$

+3SD = 3.2 + 3x0.3 \Rightarrow 4.1

+2SD = 3.2 + 2x0.3 \Rightarrow 3.8

+1SD = 3.2 + 1x0.3 \Rightarrow 3.5

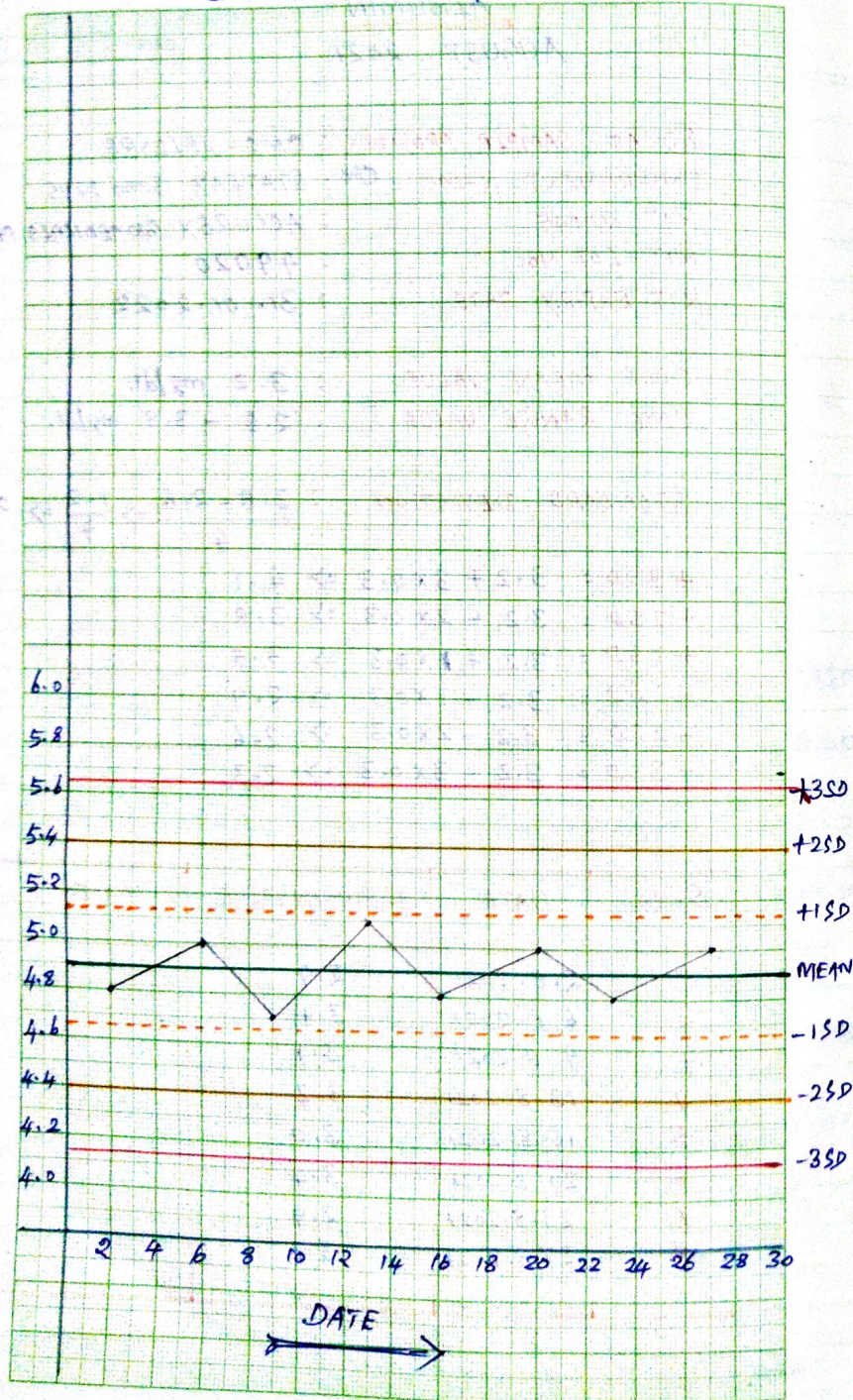
-1SD = 3.2 - 1x0.3 \Rightarrow 2.9

-2SD = 3.2 - 2x0.3 \Rightarrow 2.6

-3SD = 3.2 - 3x0.3 \Rightarrow 2.3

S.No.	DATE	ALBUMIN VALUE	COMMENTS
1	2.8.2021	2.9	
2	6.8.2021	3.4	
3	9.8.2021	3.1	
4	13.8.2021	3.2	
5	16.8.2021	3.0	
6	20.8.2021	3.4	
7	23.8.2021	2.9	
8	27.8.2021	3.3	

URIC ACID - AUGUST - 2021



INTERNAL QUALITY CONTROL

URIC ACID

Ex. No. AUGUST - 2021

DATE

IQ AS SAMPLE PROVIDER: CMC - VELLORE
 INSTRUMENT NAME : CPC STATFAX 3000 PLUS
 KIT NAME : BIOSYSTEM DIAGNOSTICS PVT LTD.
 KIT LOT No. : 147
 KIT EXPIRY DATE : 31.03.2023

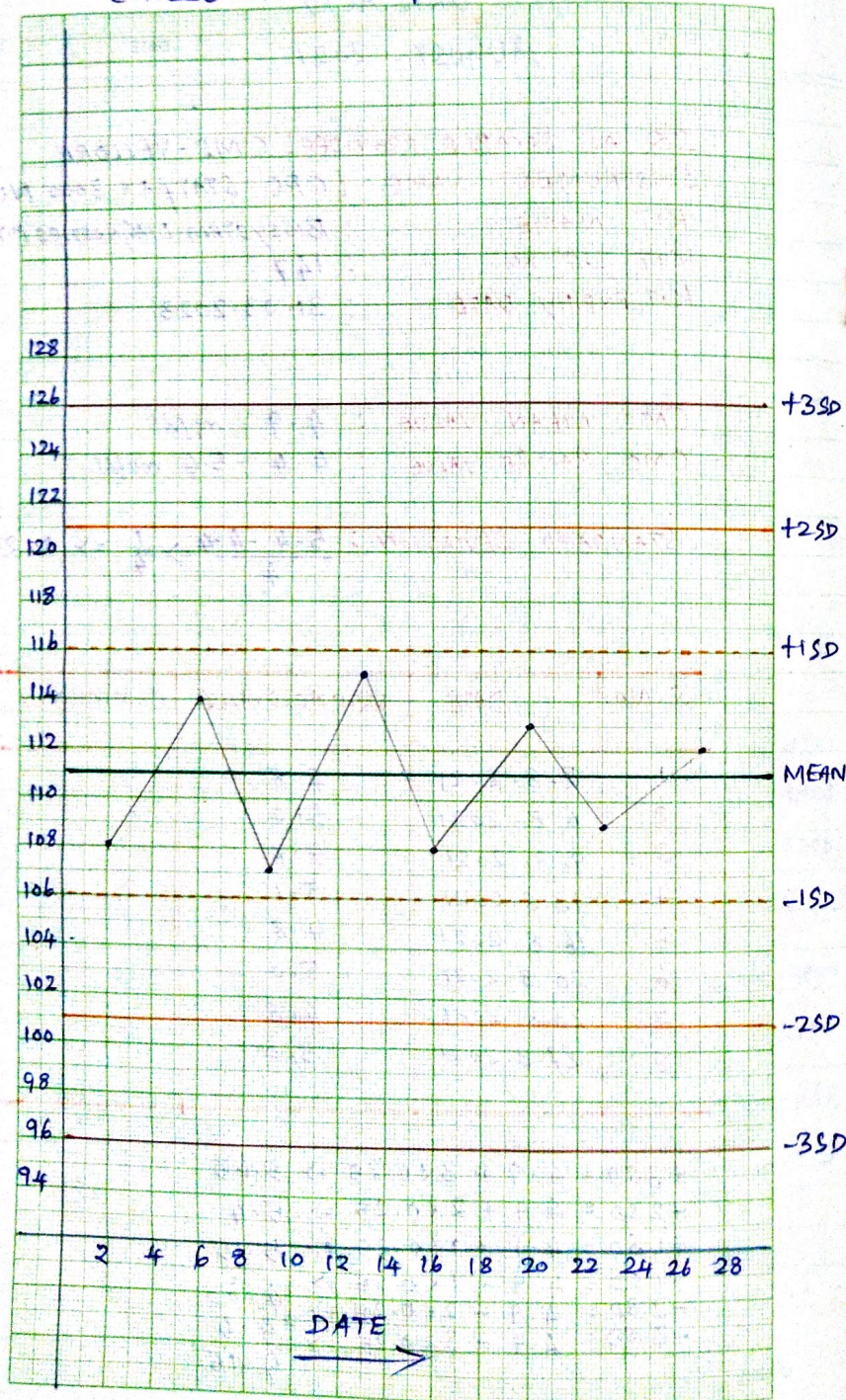
CMC MEAN VALUE : 4.9 mg/dl.
 CMC RANGE VALUE : 4.4 - 5.4 mg/dl.

STANDARD DEVIATION : $\frac{5.4 - 4.4}{4} \Rightarrow \frac{1}{4} \Rightarrow 0.25$

S.No.	DATE	URIC ACID VALUE	COMMENTS
1	2.8.2021	4.8	
2	6.8.2021	5.0	
3	9.8.2021	4.7	
4	13.8.2021	5.1	
5	16.8.2021	4.8	
6	20.8.2021	5.0	
7	23.8.2021	4.8	
8	27.8.2021	5.0	

+3SD = 4.9 + 3 × 0.25 ⇒ 5.65
 +2SD = 4.9 + 2 × 0.25 ⇒ 5.4
 +1SD = 4.9 + 1 × 0.25 ⇒ 5.15
 -1SD = 4.9 - 1 × 0.25 ⇒ 4.65
 -2SD = 4.9 - 2 × 0.25 ⇒ 4.4
 -3SD = 4.9 - 3 × 0.25 ⇒ 4.15

CHOLESTEROL - AUGUST - 2021



INTERNAL QUALITY CONTROL

CHOLESTEROL

AUGUST - 2021

Ex. No.

DATE

IQAS PROVIDER NAME : CMC - VELLORE

INSTRUMENT NAME : CPC STATFAX 3000 PLUS

KIT NAME : BIOSYSTEM DIAGNOSTICS PVT. LTD.

KIT LOT No. : 151

KIT EXPIRY DATE : 29.02.2024

CMC MEAN VALUE : 111 mg/dl.

CMC RANGE VALUE : 101 - 121 mg/dl.

STANDARD DEVIATION : $\frac{121-101}{4} \Rightarrow \frac{20}{4} \Rightarrow 5$

S.No.	DATE	CHOLESTEROL VALUE	COMMENTS
1	2.8.2021	108	
2	6.8.2021	114	
3	9.8.2021	107	
4	13.8.2021	115	
5	16.8.2021	108	
6	20.8.2021	113	
7	23.8.2021	109	
8	27.8.2021	112	

+ 3SD = 111 + 3x5 \Rightarrow 126

+ 2SD = 111 + 2x5 \Rightarrow 121

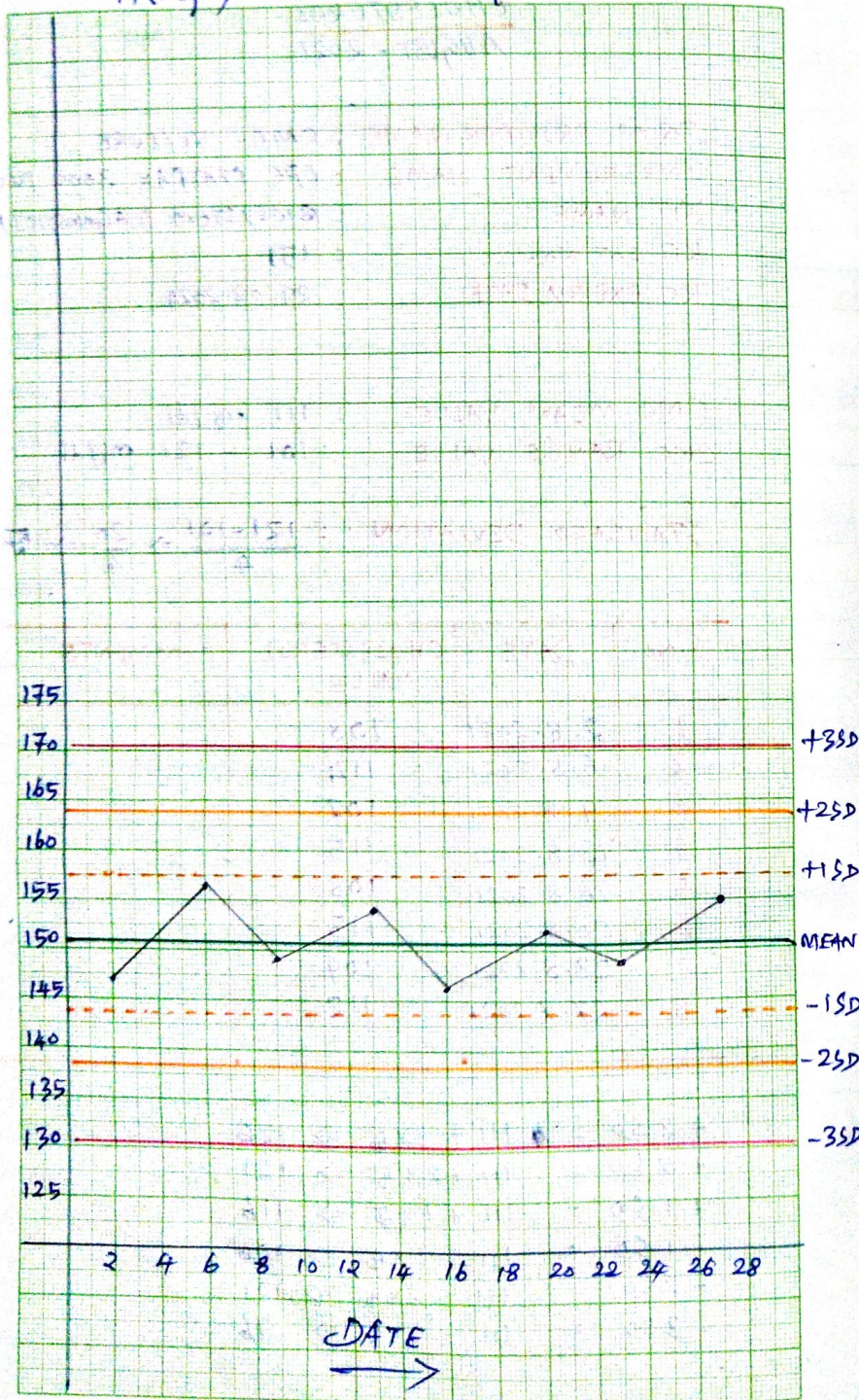
+ 1SD = 111 + 1x5 \Rightarrow 116

- 1SD = 111 - 1x5 \Rightarrow 106

- 2SD = 111 - 2x5 \Rightarrow 101

- 3SD = 111 - 3x5 \Rightarrow 96

TRIGLYCERIDES - AUGUST - 2021



INTERNAL QUALITY CONTROL

TRIGLYCERIDES

Ex. No.

DATE

AUGUST - 2021

IQA PROVIDER NAME : CMC - VELLORE

INSTRUMENT NAME : STATFAX 3000 PLUS

KIT NAME : BIOSYSTEM DIAGNOSTICS PRIVATE

KIT LOT No. : 147

KIT EXPIRY DATE : 28.02.2023

CMC MEAN VALUE : 151 mg/dl.

CMC RANGE VALUE : 138 - 164 mg/dl.

$$\text{STANDARD DEVIATION} = \frac{164 - 138}{4} \Rightarrow \frac{26}{4} \Rightarrow 6.5$$

S.No.	DATE	TRIGLYCERIDES VALUE	COMMENTS
1	2.8.2021	147	
2	6.8.2021	156	
3	9.8.2021	149	
4	13.8.2021	154	
5	16.8.2021	146	
6	20.8.2021	152	
7	23.8.2021	149	
8	27.8.2021	155	

$$+3SD = 151 + 3 \times 6.5 \Rightarrow 170.5$$

$$+2SD = 151 + 2 \times 6.5 \Rightarrow 164$$

$$+1SD = 151 + 1 \times 6.5 \Rightarrow 157.5$$

$$-1SD = 151 - 1 \times 6.5 \Rightarrow 144.5$$

$$-2SD = 151 - 2 \times 6.5 \Rightarrow 138$$

$$-3SD = 151 - 3 \times 6.5 \Rightarrow 131.5$$