



Tjan Sian Hwa
Nov 2021

SIGMA METRIC IN LABORATORY

SIGMA IN PRE-POST ANALYTIC PHASE

$$\text{Sigma} = (\text{No of non compliance} / \text{No of specimen/lab request}) \times 1.000.000$$

Turn Around Time indicator : < 60 min
 January : 3500 patients
 : 25.000 tests
 Result < 60 min : 3280 patients
 Non compliance : 220 patients =
 $220/3500 \times 1.000.000 = 62.857/\text{mill}$

Six Sigma Conversion Table

Yield	DPMO	Sigma	Yield	DPMO	Sigma	Yield	DPMO	Sigma
6.6%	934,000	0	69.2%	308,000	2	99.4%	6,210	4
8.0%	920,000	0.1	72.6%	274,000	2.1	99.5%	4,660	4.1
10.0%	900,000	0.2	75.8%	242,000	2.2	99.7%	3,460	4.2
12.0%	880,000	0.3	78.8%	212,000	2.3	99.75%	2,550	4.3
14.0%	860,000	0.4	81.6%	184,000	2.4	99.81%	1,860	4.4
16.0%	840,000	0.5	84.2%	158,000	2.5	99.87%	1,350	4.5
19.0%	810,000	0.6	86.5%	135,000	2.6	99.90%	960	4.6
22.0%	780,000	0.7	88.5%	115,000	2.7	99.93%	680	4.7
25.0%	750,000	0.8	90.3%	96,800	2.8	99.95%	480	4.8
28.0%	720,000	0.9	91.9%	80,800	2.9	99.97%	330	4.9
31.0%	690,000	1	93.3%	66,800	3	99.977%	230	5
35.0%	650,000	1.1	94.5%	54,800	3.1	99.985%	150	5.1
39.0%	610,000	1.2	95.5%	44,600	3.2	99.990%	100	5.2
43.0%	570,000	1.3	96.4%	35,900	3.3	99.993%	70	5.3
46.0%	540,000	1.4	97.1%	28,700	3.4	99.996%	40	5.4
50.0%	500,000	1.5	97.7%	22,700	3.5	99.997%	30	5.5
54.0%	460,000	1.6	98.2%	17,800	3.6	99.9980%	20	5.6
58.0%	420,000	1.7	98.6%	13,900	3.7	99.9990%	10	5.7
61.8%	382,000	1.8	98.9%	10,700	3.8	99.9992%	8	5.8
65.6%	344,000	1.9	99.2%	8,190	3.9	99.9995%	5	5.9
						99.99966%	3.4	6

SIGMA IN ANALYTIC PHASE

$$\text{Sigma} = (\text{TEa} - \text{Bias}) / S$$

CHOLESTEROL

- Tea (CLIA) 10%
- Bias 1%
- Presisi (CV) 3.0%

$$\text{Sigma} = (\text{Tea} - \text{Bias}) / S$$

$$= (10 - 1) / 3.0 = 3$$

$$= (66.000 \text{ errors} / 1 \text{ millions test})$$

BIAS

- Bias → Difference from true value
 - Reference method
 - Peer Group
- **Classification of peer group** → the same instrument and method
- **Number of peer group**
- **Availability of continuous bias data**

KNOW HOW YOUR EQAS PROVIDER ANALYSE AND REPORT THE EQAS DATA

- EQAS

Abbott ARCHITECT/Alinity (c, i, ci mo...		Comparative Statistics					Your Deviation			
Your Result		N	Mean	SD	CV	U ¹	Z-score	RMZ	%	
126.04 U/L		◆ Your Mode	4920	121	6.88	5.69	0.245	0.75	0.53	4.24
		■ Your Method	3517	120	7.11	5.92	0.300	0.83	0.55	4.93
		● Your Peer	453	122	4.47	3.66	0.525	0.84	0.34	3.08

IQC PEERGROUP

Analyte	Month	Mean	SD	N	CV	CVI	Diff.	BIAS	TE		SDI	LL.....UL
ALKALINE PHOSPHATASE - IFCC, ACC. TO SCHUMANN GEN.2 SERUM, PLASMA												
ALP [U/l]	2/2021	96.38	2.62	24	2.72%	0.49	-13.18%	-4.53%	9.01%	●	-0.81	
		-	-	-	-		-					Graphic not displayable
ALP [U/l]	1/2021	100.94	5.61	148/6	5.56%		-9.06%					
		98.05	2.65	21	2.71%	0.66	-11.67%	-0.69%	5.15%	●	-0.17	Graphic not displayable
ALP [U/l]	12/2020	-	-	-	-		-					Graphic not displayable
		98.72	4.06	141/6	4.11%		-11.06%					
ALP [U/l]	11/2020	97.47	2.51	32	2.58%	0.87	-12.19%	-0.21%	4.47%	●	-0.07	Graphic not displayable
		-	-	-	-		-					Graphic not displayable
ALP [U/l]	10/2020	97.67	2.91	124/5	2.98%		-12.01%					
		95.81	2.21	26	2.31%	0.62	-13.69%	-1.73%	5.54%	●	-0.46	Graphic not displayable
ALP [U/l]	9/2020	-	-	-	-		-					Graphic not displayable
		97.50	3.65	106/4	3.74%		-12.16%					
ALP [U/l]	10/2020	98.50	2.96	32	3.01%	0.92	-11.26%	0.50%	5.46%	●	0.15	Graphic not displayable
		-	-	-	-		-					Graphic not displayable
ALP [U/l]	9/2020	98.01	3.22	109/4	3.28%		-11.70%					
		96.89	3.27	28	3.37%	1.07	-12.71%	-0.81%	6.38%	●	-0.26	Graphic not displayable
		-	-	-	-		-					Graphic not displayable

PROTEIN

1

Kelompok Metode

Parameter	CCV(%)	Metode	Peserta	Hasil Anda	Nilai Target	VIS
Protein Total	3.90	Colorimetric (Biuret) Cu-protein complex	337	4.00	4.23	139
Albumin	7.50	Colorimetric (BCG) ,Monoreagent	329	2.90	2.83	33
AST/SGOT	12.50	IFCC without P5P, 37° C (& JSCC)	380	210.60	202.94	30
ALT/SGPT	17.30	IFCC without P5P, 37° C (& JSCC)	364	104.40	104.42	0
Gamma GT	7.80	Szasz, 37° C	112	138.60	155.72	141

Bias : $(4.00-4.23)/4.23*100=5.4\%$

Kelompok Alat

Parameter	CCV(%)	Alat	Peserta	Hasil Anda	Nilai Target	VIS
Protein Total	3.90	Cobas c501 / Roche	31	4.00	4.18	111
Albumin	7.50	Cobas c501 / Roche	30	2.90	2.85	23
AST/SGOT	12.50	Cobas c501 / Roche	29	210.60	207.07	14
ALT/SGPT	17.30	Cobas c501 / Roche	29	104.40	100.99	20
Gamma GT	7.80	Cobas c501 / Roche	31	138.60	154.11	129

Bias : $(4.00-4.18)/4.18*100=4.3\%$

Kelompok Reagen

Parameter	CCV(%)	Reagen	Peserta	Hasil Anda	Nilai Target	VIS
Protein Total	3.90	3183734190 / 4657586190 / 11553836316 / 11929917216 /	110	4.00	4.17	105
Albumin	7.50	3183688122 / 4657357190 / 11970569216/11970909216 / R	120	2.90	2.84	28
AST/SGOT	12.50	10851124216, 37° C / 11876848216, 37° C / 20764949322, :	146	210.60	203.69	27
ALT/SGPT	17.30	10851132216, 37° C / 11876805216, 37° C / 20764957322, :	146	104.40	100.90	20

Bias : $(4.00-4.17)/4.17*100=4.1\%$

BIAS DAN PRESISI

Bias & Imprecision Histogram

Immunoassay Plus • Lot 123450 • Exp 01-Dec-2018

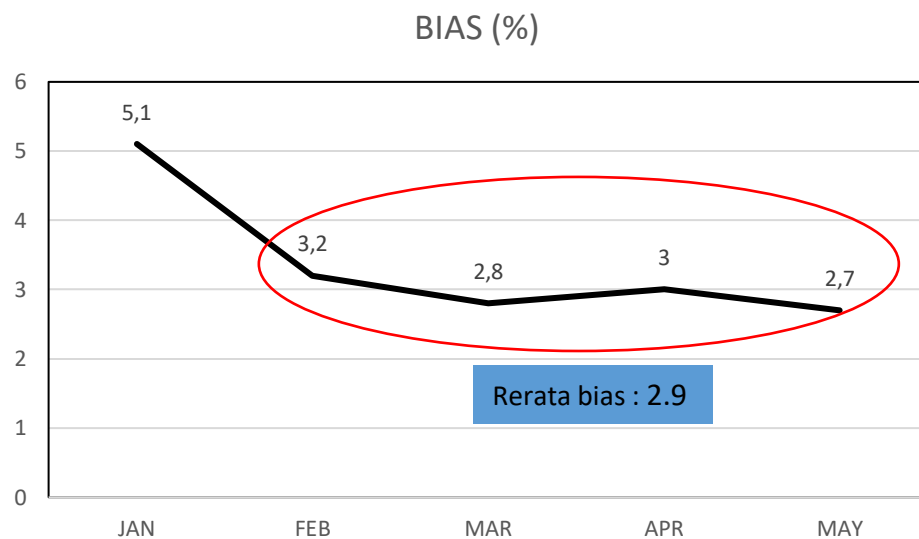
Associated Regional Laboratory
123 Main Street
Anytown, NY 12345-6789
Attention: Lab Supervisor



- Bias : mean of 3-4 EQAS result
- CV /SD : 3-6 months IQC result
- Monitor CV and Bias monthly to see any significant change

2

BIAS CALCULATION

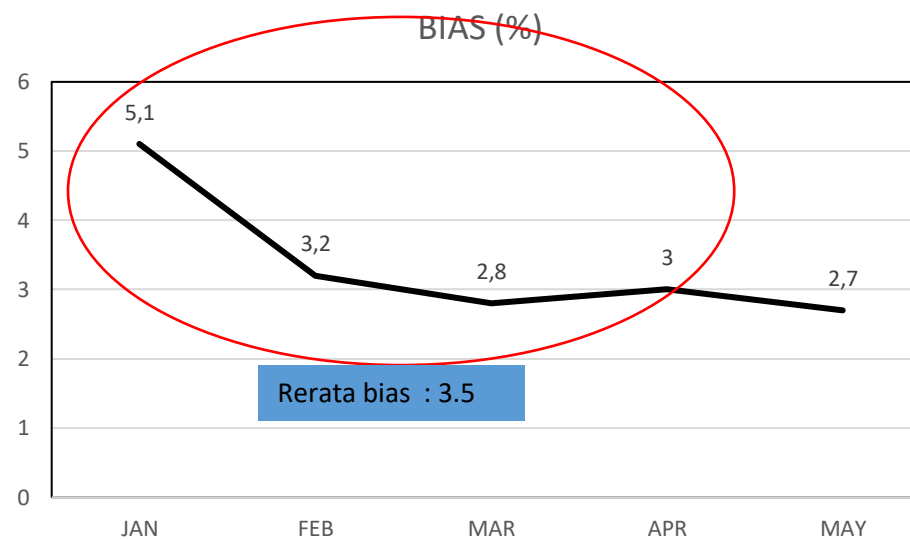


CHOLESTEROL:

TEA 10%

CV 1.7%

SIGMA (10-2.9)/1.7 = 4.2



CHOLESTEROL:

TEA 10%

CV 1.7%

SIGMA (10-3.5)/1.7 = 3.8

Table 5

Sigma metrics and QGI ratio all analytes for IQC - Level 2 and Level-3 using TEa values from CLIA guidelines and biological variation database specifications.

	CV%		BIAS%		TEa CLIA	TEa BVD	Sigma CLIA		Sigma BVD		QGI		Problem	
	L2	L3	L2	L3			L2	L3	L2	L3	L2	L3	L2	L3
AST	6.36	3.07	2.3	2.3	20	16.69	2.7	5.76	2.26	4.68	0.24	0.5	imp	imp
ALP	4.3	4.62	-0.64	-0.64	30	12.04	7.12	6.63	2.94	2.74	-0.09	-0.09	imp	imp
ALB	4.34	4.36	-5.82	-5.82	10	4.07	3.64	3.62	2.27	2.26	-0.89	-0.89	Imp,inac	Imp, inac
TP	3.45	2.45	0.85	0.85	10	3.63	2.65	3.73	0.80	1.13	0.16	0.23	imp	imp
GLU	3.74	2.99	-1.09	-1.09	10	6.96	2.96	3.71	2.15	2.69	-0.19	-0.24	imp	imp
BUN	6.02	4.99	-0.84	-0.84	9	15.55	1.63	1.97	2.7	3.28	-0.09	-0.11	imp	imp
URI	4.74	5.04	-3.35	-3.35	17	11.97	4.29	4.03	3.23	3.03	-0.47	-0.44	imp	imp
CRE	5.97	3.45	-2.88	-2.88	15	8.87	3.01	5.18	1.96	3.41	-0.32	-0.55	imp	imp
TBI	4.19	6.48	-0.14	-0.14	20	26.94	4.81	3.11	6.46	4.18	-0.02	-0.01	imp	imp
ALT	6.56	5.12	10.7	10.73	20	27.48	1.41	1.81	2.55	3.27	1.09	1.39	Imp,inac	inacc
CAL	4.27	2.87	-6.24	-6.24	11	2.55	4.03	6.01	2.05	3.06	-0.97	-1.44	Imp,inac	inacc
TGL	4.19	3.44	-7.64	-7.64	25	25.99	7.78	9.49	8.02	9.77	-1.21	-1.48	inac	inac
HDL	2.94	4.48	7.83	7.83	30	11.63	7.54	4.94	1.29	0.84	1.77	1.16	inac	imp inac
CHO	3.28	2.6	-15.6	-15.6	10	9.01	7.81	9.8	7.51	9.47	-3.17	-4.01	inac	Inac

$$\text{Sigma} : (10-15.6)/3.28 = < 1$$

$$\text{Sigma} : (10-15.6)/3.28 = 7.8$$

4

CHOOSING TEA

Parameter Sodium	CLIA	Rilibank	RCPA	RICOS BV
Quality Goal	+/- 4 mmol/L	+/- 5%	+/- 3 mmol/L ≤ 150 mmol/L or +/- 2 mmol/L > 150 mmol/L	+/- 0.73%
Group or Peer Mean	141.60	141.60	141.60	141.60
Lab mean	140.99	140.99	140.99	140.99
Bias (%)	0.4	0.4	0.4	0.4
CV (%)	1.1	1.1	1.1	1.1
Sigma	$(2.8-0.4)/1.1=$ 2.2	$(5-0.4)/1.1 =$ 4.2	$(2.1-0.4)/1.1 =$ 1.5	$(0.73-0.4)/1.1=$ 0.3

QUALITY SPECIFICATION:

1. Clinical Requirement
2. Biological variation (Ricos's goal) → www.westgard.com
3. Best State of the Arts → professional organization/ regulator (RCPA, Rilibak, **CLIA**)

CALCIUM

- EQA :
 - Lab result 12.14 mg/dL
 - Peer group 12.3 mg/dL
 - Bias : - 0.16 mg/dL →
: $-0.16/12.3 \times 100 = 1.3\%$
- PMI :
 - Mean 10.2 mg/dL
 - SD 0.46 mg/dL
 - CV 6.4%
- TEA : 1 mg/dL
: $1/10.2 \times 100 = 9.8\%$
- SIGMA = $(9.8 - 1.3) / 6.4 = 1.3$

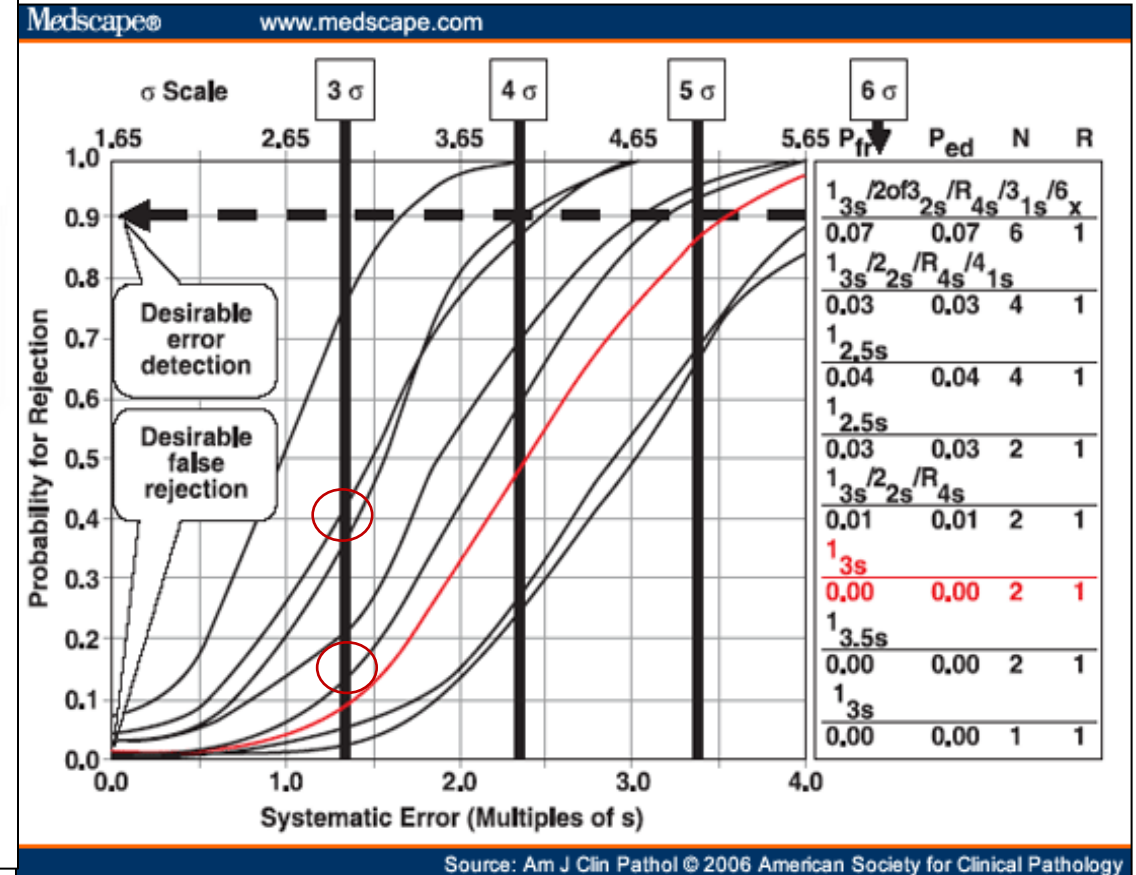
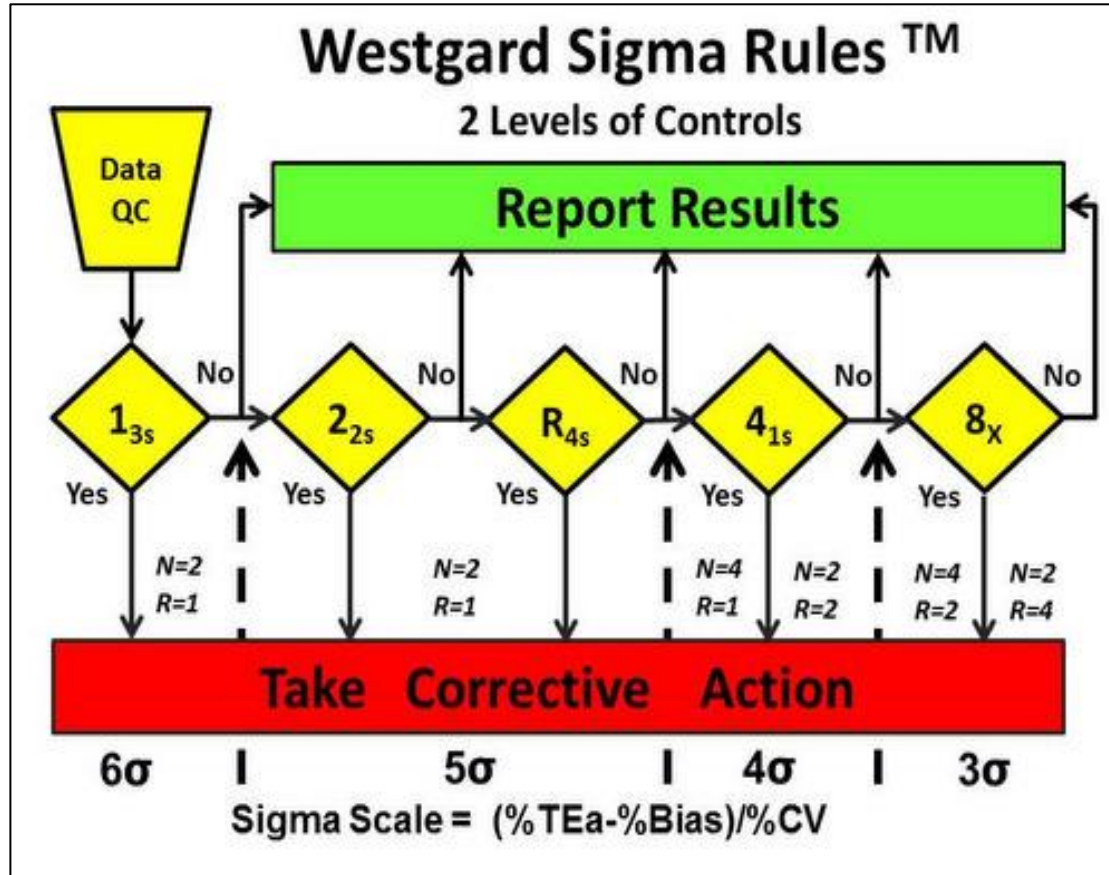
Test or Analyte	Acceptable Performance
Alanine aminotransferase	Target value $\pm 20\%$
Albumin	Target value $\pm 10\%$
Alkaline phosphatase	Target value $\pm 30\%$
Amylase	Target value $\pm 30\%$
Aspartate aminotransferase (AST)	Target value $\pm 20\%$
Bilirubin, total	Target value ± 0.4 mg/dL or $\pm 20\%$ (greater)
Blood gas pO ₂	Target value ± 3 SD
Blood gas pCO ₂	Target value ± 5 mm Hg or $\pm 8\%$ (greater)
Blood gas pH	Target value ± 0.04
Calcium, total	Target value ± 1.0 mg/dL
Chloride	Target value $\pm 5\%$
Cholesterol, total	Target value $\pm 10\%$
Cholesterol, high dens. lipoprotein	Target value $\pm 30\%$
Creatine kinase	Target value $\pm 30\%$

Table 5

Sigma metrics and QGI ratio all analytes for IQC - Level 2 and Level-3 using TEa values from CLIA guidelines and biological variation database specifications.

	CV%		BIAS%		TEa CLIA	TEa BVD	Sigma CLIA		Sigma BVD		QGI		Problem	
	L2	L3	L2	L3			L2	L3	L2	L3	L2	L3	L2	L3
AST	6.36	3.07	2.3	2.3	20	16.69	2.7	5.76	2.26	4.68	0.24	0.5	imp	imp
ALP	4.3	4.62	-0.64	-0.64	30	12.04	7.12	6.63	2.94	2.74	-0.09	-0.09	imp	imp
ALB	4.34	4.36	-5.82	-5.82	10	4.07	3.64	3.62	2.27	2.26	-0.89	-0.89	Imp,inac	Imp, inac
TP	3.45	2.45	0.85	0.85	10	3.63	2.65	3.73	0.80	1.13	0.16	0.23	imp	imp
GLU	3.74	2.99	-1.09	-1.09	10	6.96	2.96	3.71	2.15	2.69	-0.19	-0.24	imp	imp
BUN	6.02	4.99	-0.84	-0.84	9	15.55	1.63	1.97	2.7	3.28	-0.09	-0.11	imp	imp
URI	4.74	5.04	-3.35	-3.35	17	11.97	4.29	4.03	3.23	3.03	-0.47	-0.44	imp	imp
CRE	5.97	3.45	-2.88	-2.88	15	8.87	3.01	5.18	1.96	3.41	-0.32	-0.55	imp	imp
TBI	4.19	6.48	-0.14	-0.14	20	26.94	4.81	3.11	6.46	4.18	-0.02	-0.01	imp	imp
ALT	6.56	5.12	10.7	10.73	20	27.48	1.41	1.81	2.55	3.27	1.09	1.39	Imp,inac	inacc
CAL	4.27	2.87	-6.24	-6.24	11	2.55	4.03	6.01	2.05	3.06	-0.97	-1.44	Imp,inac	inacc
TGL	4.19	3.44	-7.64	-7.64	25	25.99	7.78	9.49	8.02	9.77	-1.21	-1.48	inac	inac
HDL	2.94	4.48	7.83	7.83	30	11.63	7.54	4.94	1.29	0.84	1.77	1.16	inac	imp inac
CHO	3.28	2.6	-15.6	-15.6	10	9.01	7.81	9.8	7.51	9.47	-3.17	-4.01	inac	Inac

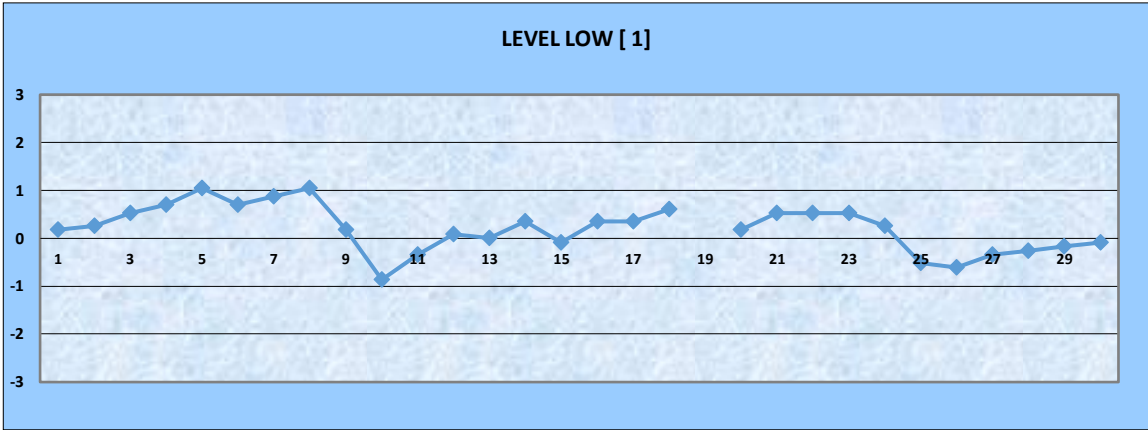
Sigma in L1 and L2 significantly differ



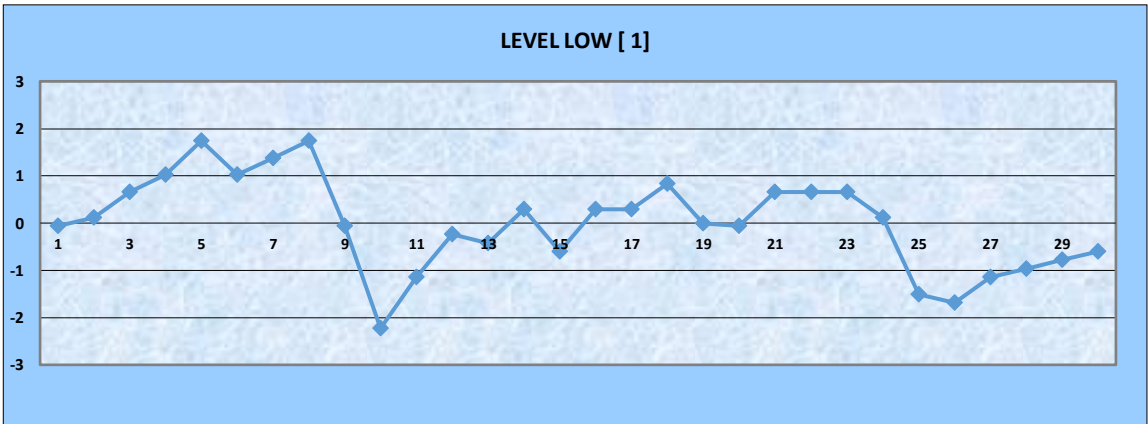
SIGMA 2,7
 SIGMA 5,76
 AVERAGE SIGMA : $2.7 + 5.76 = 4.2$

GOOD QC RULES :
 ❖ High error detection
 ❖ Low false rejection

KIT INSERT RANGE



LAB RANGE



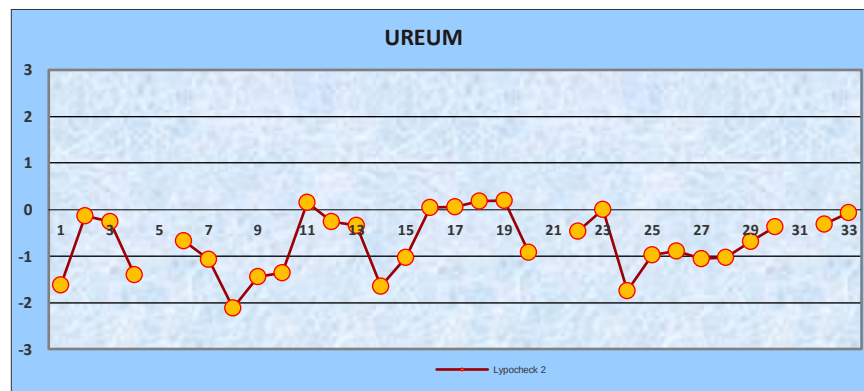
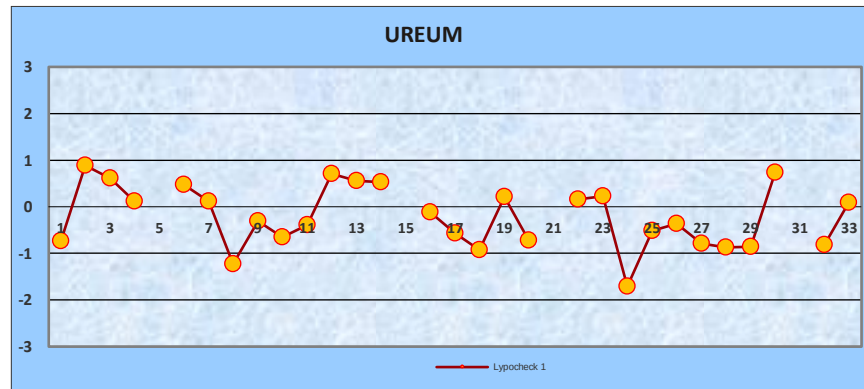
AST	
Mean lab	: 79.34
SD	: 4.54
CV	: 5.7 %
Bias	: 3.0%
TEA	: 20%

SIGMA : $(20-3.0)/ 5.7 = 3$

Take home message:
Calculate Lab own
mean and SD

UREUM

8



Lot No	26461	Lot No	26462
Level	Lypocheck 1	Level	Lypocheck 2
Exp.date	31.07.2022	Exp.date	31.07.2022
Batas Atas	16.90	CV (%)	3.7
Batas Bawah	13.60	Bias (%)	0.45%
Mean kit	15.25	TE (%)	9.5
Mean Alat	15.07	TEA (%)	9
SD kit	0.82	Source TEA	CLIA
SD Alat	0.56	SIGMA	2.3

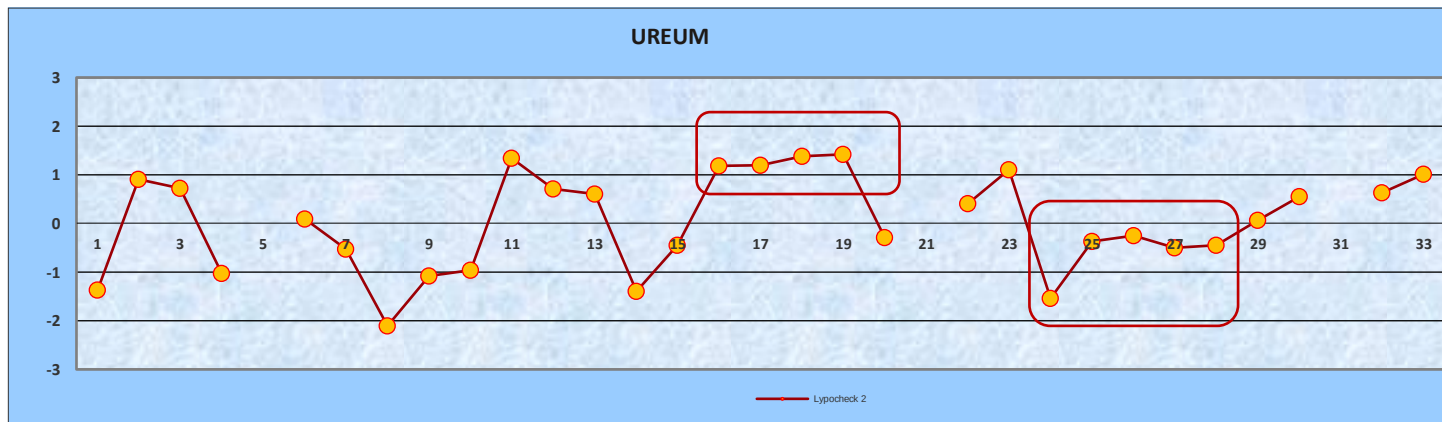
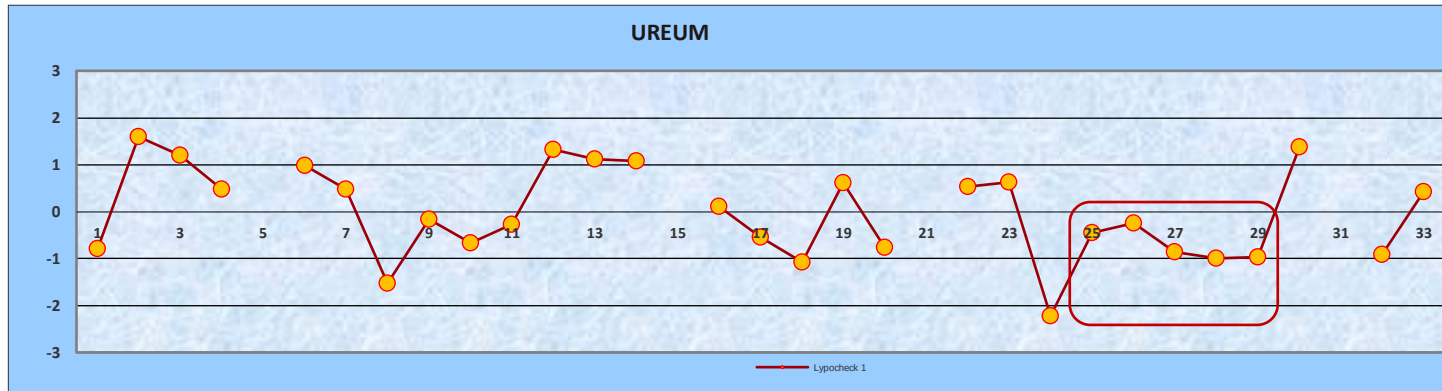
Batas Atas	52.40	CV (%)	3.2
Batas Bawah	43.30	Bias (%)	0.45%
Mean kit	47.85	TE (%)	9.0
Mean Alat	46.19	TEA (%)	9
SD kit	2.28	Source TEA	CLIA
SD Alat	1.49	SIGMA	2.7

Comparative Statistics					
	N	Mean	SD	CV	U'
◆ All Results	3528	53.8	4.06	7.55	0.171
▣ Your Method	2693	54.1	3.40	6.28	0.164
🕒 Your Peer	274	55.4	1.58	2.86	0.239

Your Result
55.65 mg/dL

$$\text{BIAS} : (55.65 - 55.4) / 55.4 * 100 = 0.45\%$$

LAB MEAN AND SD

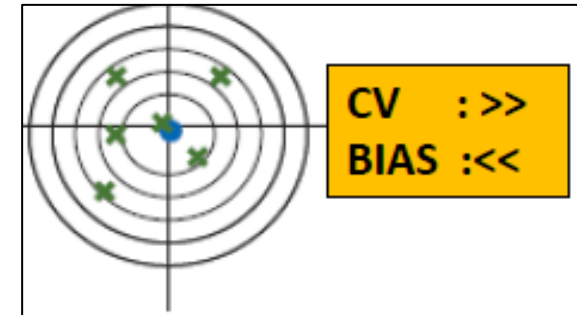
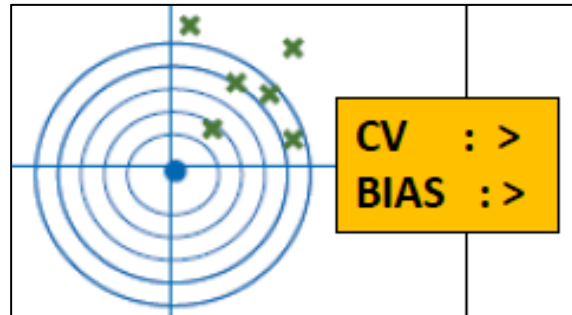
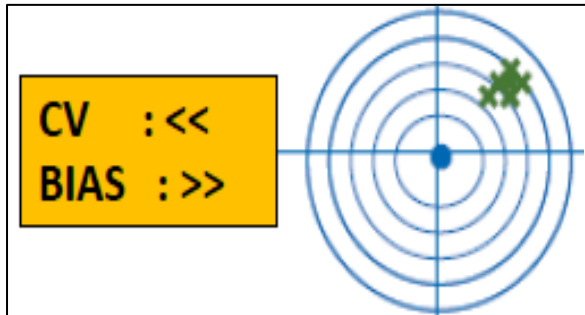


Take home message:

- ❖ Calculate Lab own mean and SD
- ❖ Use Westgard multi rules multi levels

$$\text{Sigma} = (\text{TEA} - \text{Bias}) / S$$

LOW SIGMA



- Random error
- Systematic error

$$\text{SIGMA} = (\text{TEA}-\text{BIAS})/\text{CV}$$

RICO'S OPTIMAL BIOLOGICAL VARIATION

imprecision	Bias
3	2.8

Lot No		26461		Lot No		26462	
Level		Lypocheck 1		Level		Lypocheck 2	
Exp.date		31.07.2022		Exp.date		31.07.2022	
Batas Atas	16.90	CV (%)	3.7	Batas Atas	52.40	CV (%)	3.2
Batas Bawah	13.60	Bias (%)	0.45%	Batas Bawah	43.30	Bias (%)	0.45%
Mean kit	15.25	TE (%)	9.5	Mean kit	47.85	TE (%)	9.0
Mean Alat	15.07	TEA (%)	9	Mean Alat	46.19	TEA (%)	9
SD kit	0.82	Source TEA	CLIA	SD kit	2.28	Source TEA	CLIA
SD Alat	0.56	SIGMA	2.3	SD Alat	1.49	SIGMA	2.7



Random Error or Systematic Error?

QUALITY GOAL INDEX (QGI)

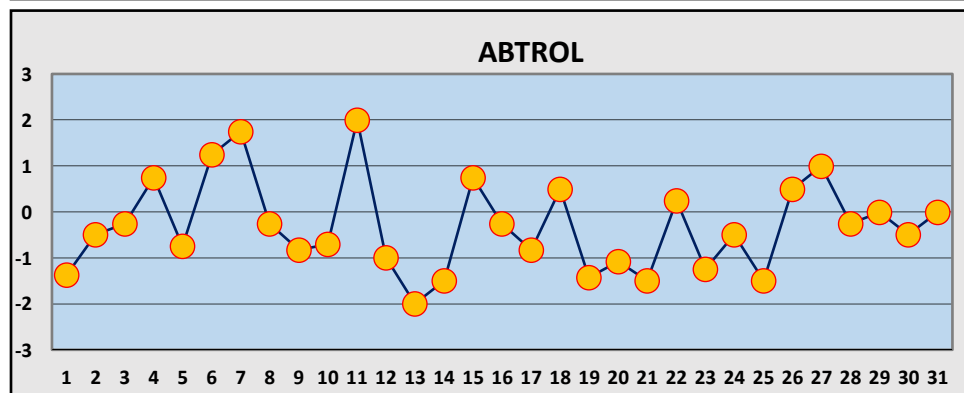
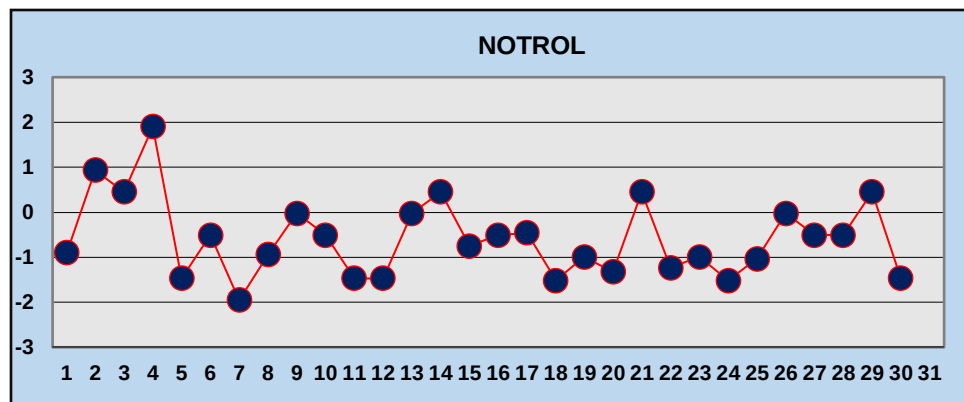
$$\text{QGI} = (\text{BIAS}/1.5\text{CV})$$

QGI	PROBLEM
< 0.8	Imprecision
0.8-1.2	Imprecision and Inaccuracy
> 1.2	Inaccuracy

$$\text{QGI} = 0.45 / (1.5 * 3.45) = 0.09$$

URIC ACID IQC

EQAS Z SCORE > 2



Your Result
7.1 mg/dL

	N	Mean	SD	CV	U'	BIAS
◆ Your Mode	7076	6.92	0.365	5.27	0.011	
▣ Your Method	6762	6.94	0.406	5.85	0.012	
⦿ Your Peer	461	6.70	0.164	2.36	0.019	2.4

CV level 1 = 3.6%

CV Level 2 = 4.2%

Average CV = $(3.6+4.2)/2 = 3.9\%$

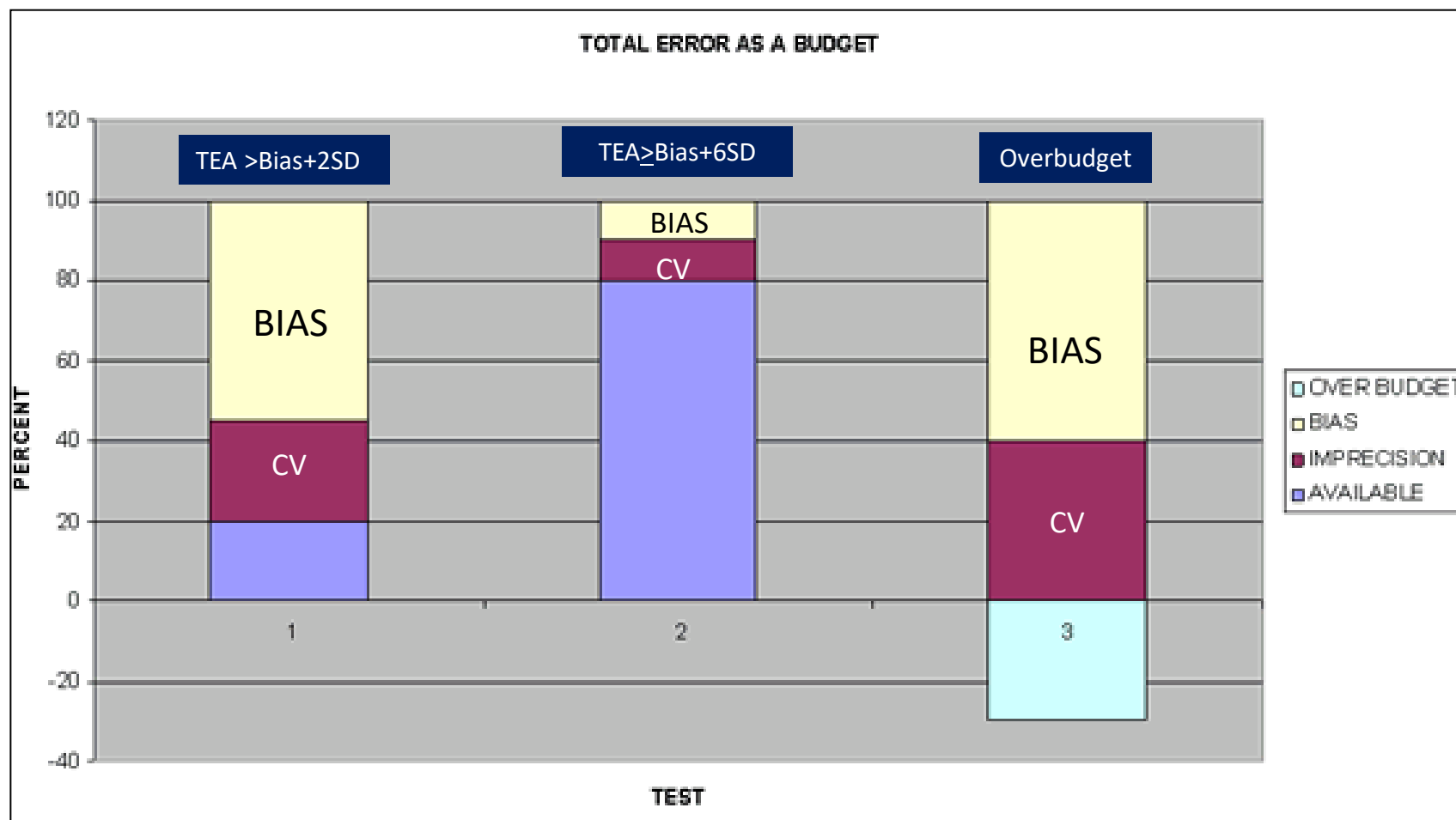
Bias = $(7.1-6.7)/6.7 = 6\%$

TE = $6 + (2 \times 3.9) = 13.8\%$

TEA uric acid = 17 %

SIGMA : $(17-2.4)/3.9 = 3.7$

Lot No	PB92	Lot No	PB93
Level	NORM	Level	ABNORM
Exp.date	31.07.2021	Exp.date	31.07.2021
Batas Atas	5.62	Batas Atas	10.60
Batas Bawah	4.79	Batas Bawah	9.00
Mean kit	5.21 SD kit 0.21	Mean kit	9.80 SD kit 0.40
Mean Lab	5.08 SD Lab 0.18	Mean Lab	9.67 SD Lab 0.41



CV 3.9%
BIAS 2.4%

RICO'S OPTIMAL BIOLOGICAL VARIATION	
imprecision	Bias
2.2	2.4

$$\text{QGI} = (\text{BIAS}/1.5\text{CV})$$

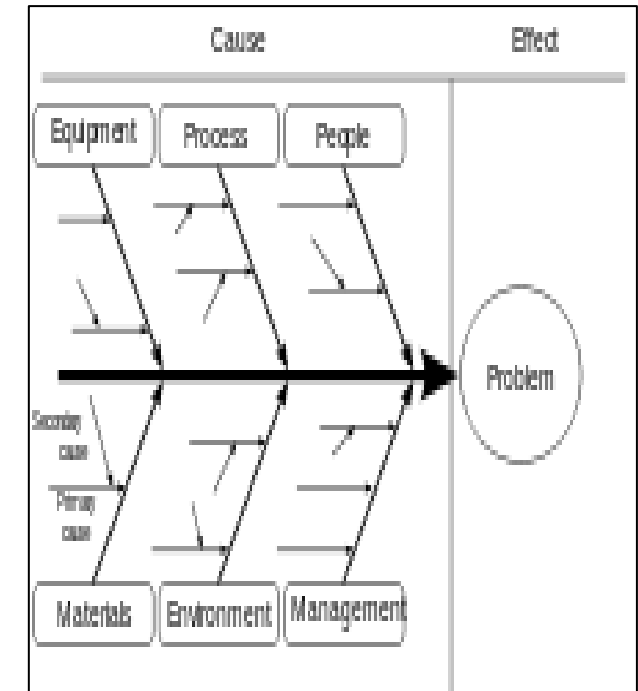
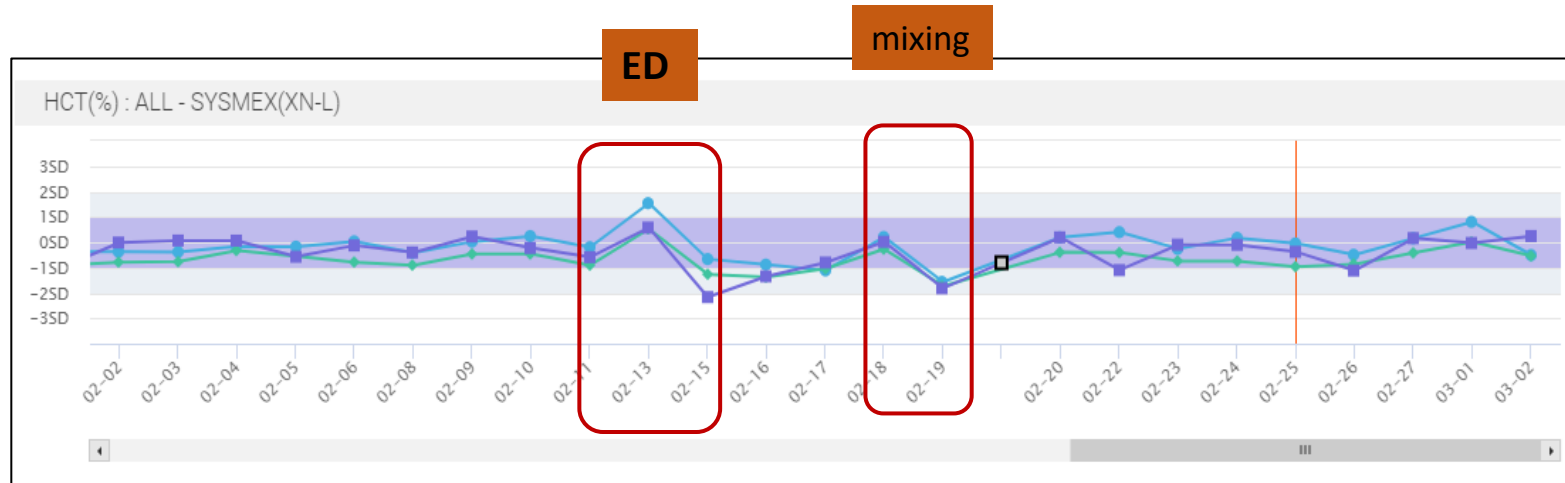
QGI	$2.4/(1.5*3.9) = 0.4$
-----	-----------------------

QGI	PROBLEM
< 0.8	Imprecision
0.8-1.2	Imprecision and Inaccuracy
> 1.2	Inaccuracy

INTERLABORATORY COMPARISON

			LABORATORY					
Bulan	Test	Level	A	B	C	D	E	F
Januari	Trombosit	Low	4.0	3.3	3.0	2.5	8.8	8.8
Januari	Trombosit	Normal	9.2	4.7	6.2	5.7	9.6	9.6
Januari	Trombosit	High	13.7	16.4	15.3	17.4	13.2	13.2
Januari	Hematokrit	Low	2.7	5.3	5.5	3.3	5.8	5.8
Januari	Hematokrit	Normal	1.9	5.0	6.4	4.0	4.2	4.2
Januari	Hematokrit	High	3.4	6.7	5.8	4.1	7.5	7.5
Januari	Eritrosit	Low	4.7	6.9	5.9	4.1	8.0	5.9
Januari	Eritrosit	Normal	7.9	10.2	7.9	4.4	5.9	7.4
Januari	Eritrosit	High	5.2	9.0	9.7	4.8	7.4	5.8
Januari	Lekosit	Low	5.7	4.6	6.8	7.7	7.1	13.3
Januari	Lekosit	Normal	11.6	11.2	11.1	9.3	8.6	8.0
Januari	Lekosit	High	14.2	18.7	15.8	12.2	13.3	5.9
Januari	Hemoglobin	Low	11.5	8.1	9.8	5.4	6.9	7.1
Januari	Hemoglobin	Normal	13.9	14.0	13.6	6.1	7.9	8.6
Januari	Hemoglobin	High	12.9	25.9	10.7	6.9	13.5	13.3

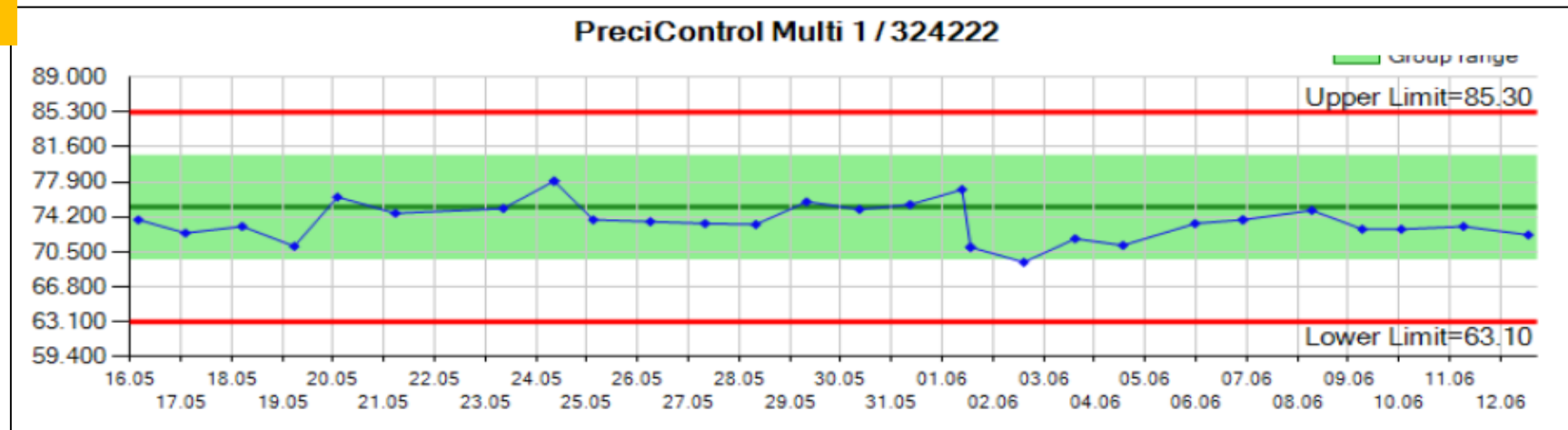
IQC DATA



AFTER CORRECTIVE ACTION

	A	B	C	D	E	F	G	H	I	J	K	L	M	N
1	REKAPITULASI KONTROL HEMATOLOGI													
2														
3	Bulan	: MARET 2021												
4	Alat	: Sysmex XN-550												
5														
6	Pemeriksaan	Level	Lot No Ctrl	N	SD	X kumulatif	Mean (pabrik)	Bias (%)	CV (%)	TE(a)%	TE(a)-source	TE (%)	TE%-OK? (Source)	Sigma
31	Hematokrit	Low	10431401		0.07	17.16	17.50	1.97	0.4	6	CLIA	2.8	TRUE	9.5
32	Hematokrit	Normal	10431402		0.20	36.80	37.80	2.65	0.5	6	CLIA	3.7	TRUE	6.2
33	Hematokrit	High	10431403		0.17	44.27	45.00	1.63	0.4	6	CLIA	2.4	TRUE	11.2

IQC PEER GROUP DATA

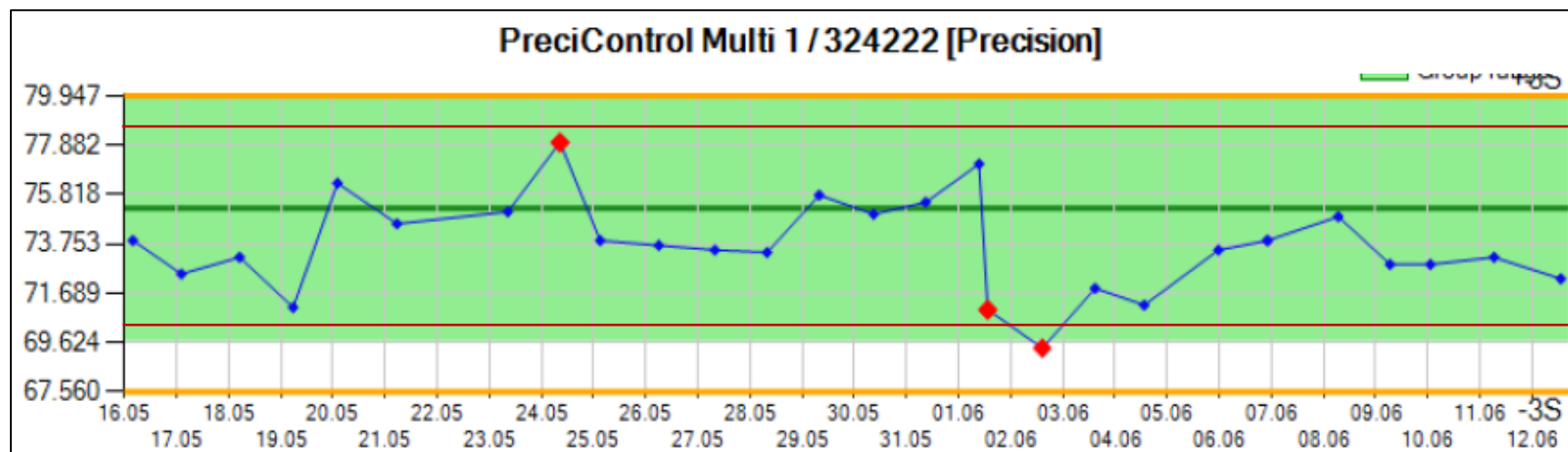


Kit Insert

Range: 63.1-85.3 mg/dL
Mean : 74.2 mg/dL
SD : 3.7 mg/dL

Lab Range

Range: 69.6-77.9 mg/dL
Mean : 73.75 mg/dL
SD : 2.06
CV : 3.2 %



Group Range

Range: 69.7-80.8 mg/dL
Mean : 75.25 mg/dL
SD : 2.77
CV 3.68 %

$$\text{BIAS} : (73.75 - 75.25) / 75.25 * 100\% = -1.99\%$$

$$\text{SIGMA} : (10 - 1.99) / 3.2 = 2.5$$

CV 3.2%
BIAS 1.99%

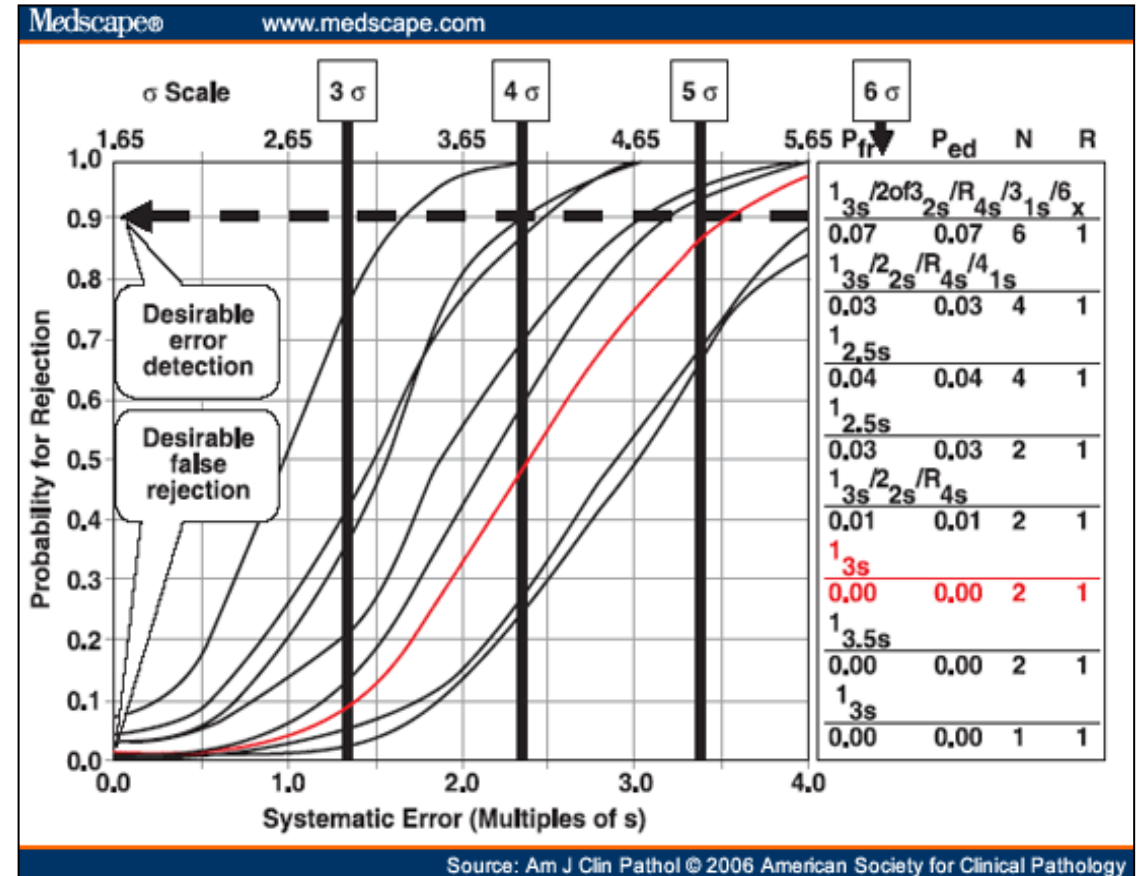
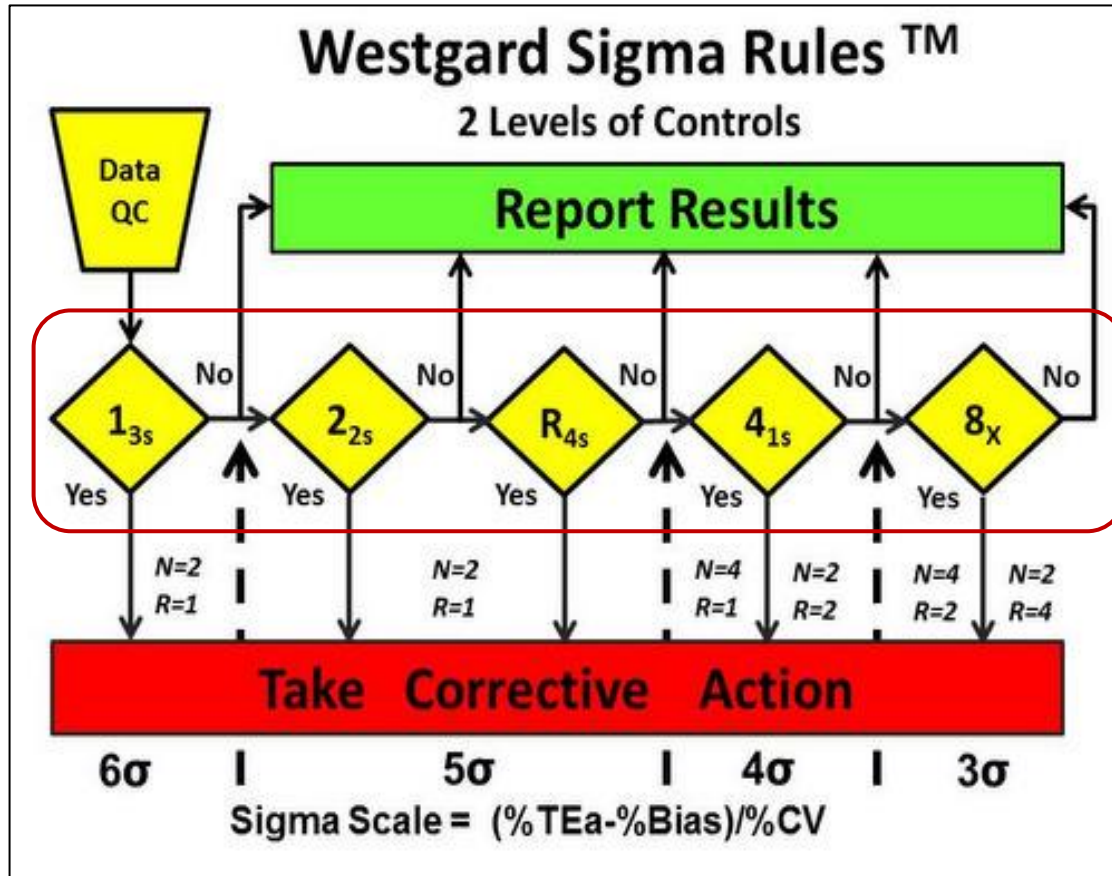
RICO'S OPTIMAL BIOLOGICAL VARIATION	
imprecision	Bias
2,98	4.1

$$\text{QGI} = (\text{BIAS}/1.5\text{CV})$$

QGI	$1.99 / (1.5 * 3.2) = 0.4$
-----	----------------------------

QGI	PROBLEM
< 0.8	Imprecision
0.8-1.2	Imprecision and Inaccuracy
> 1.2	Inaccuracy

$$\text{SIGMA} : (10-1.99)/3.2 = 2.5$$



TSH

	Lot No.: 85241	Lot No.: 85242	Lot No.: 85243
	LIQUICHEK 1 85241	LIQUICHEK 2 85242	LIQUICHEK 3 85243
Batas Atas	0.69	5.43	27.24
Batas Bawah	0.53	4.35	21.76
Mean Kit	0.61	4.89	24.50
Mean Alat	0.58	4.94	24.62
SD	0.02	0.14	0.80
CV	3.92	2.81	3.25

Mean CV = 3.3%

Instrument: Abbott Architect C Chemistry (c, i, or models)

Analyte	Unit	Result	Mean	Z-score	RMZ	Comparator
✓ CA 125	U/mL	73.7	73.5	0.04	0.59	Peer
✓ CEA	ng/mL	31.45	30.4	0.78	1.11	Peer
✓ T4, Total	µg/dL	4.62	4.59	0.11	1.04	Peer
✓ TSH	µIU/mL	0.549	0.538	0.31	0.59	Peer
✓ 25-OH-Vitamin D (Total)	ng/mL	12.6	11.3	1.71	0.12	Peer

$$\text{BIAS} = (0.549 - 0.538) / 0.538 * 100 = 2.04\%$$

RICOS DESIRABLE BIOLOGICAL VARIATION	Parameter	CVi	CVg	I(%)	BIAS(%)	TEA
	Thyroid stimulating hormone (TSH)	19.3	24.6	9.7	7.8	23.7

$$\text{SIGMA} = (23.7 - 2.04) / 3.3 = 6.6$$

https://biologicalvariation.eu/meta_calculations

TAKE HOME MESSAGE

- Sigma Metric in medical laboratory is used to measure lab performance, and also determine IQC rule, material and frequency
- Lab should choose appropriate TEA and determine CV and Bias from stable 3-4 cumulative data
- Bias should be calculate from the right peer group from EQAS or IQC peer group
- Do the right QC by calculating lab mean and SD and use Westgard multi rules multi levels
- Do DMAIC to improve Sigma

LET'S IMPLEMENT SIGMA