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Metrik Sigma

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- Metrik Sigma merupakan suatu metode penilaian kualitas dan program pengembangan yang digunakan dalam industri dan diterapkan pada laboratorium.

- Metrik Sigma merupakan metode yang dapat mengukur tampilan proses dan keluaran yang dihasilkan dalam proses pemeriksaan di laboratorium secara kuantitatif.

- Metrik Sigma adalah nilai numerik yang mencirikan kinerja metode dalam jumlah deviasi standar atau sigma s yang sesuai dalam batas toleransi atau persyaratan kualitas pemeriksaan.

Rumus Metrik Sigma :

$$\textbf{Metrik Sigma} = \frac{\textbf{TEa (\%) – bias (\%)}}{\textbf{CV (\%)}}$$

- TEa % : total kesalahan yang diperbolehkan
  TEa dapat diambil dari *Clinical Laboratories Improvement Act (CLIA) guidelines, European Biologic Test*

- Bias %: beda antara rerata hasil pemeriksaan suatu lab dengan rerata hasil pemeriksaan semua lab peserta uji profisiensi atau nilai referen (bias % dari uji PME= EQC)

- CV % : CV % hasil pemerikaan suatu lab (CV % dari uji PMI=IQC)

- Metrik sigma telah diadopsi sebagai pengukuran kualitas secara universal.

- Performansi dikarakterisasi menggunakan skala sigma, dengan nilai dari 2 sampai 6. Dalam performasi metrik Sigma, jika suatu metode mempunyai nilai kurang dari 3 maka metode tersebut dianggap tidak dapat dipercaya dan tidak seharusnya digunakan untuk pemeriksaan rutin.

- Hasil yang diharapkan adalah *six sigma* atau lebih.

- *Six sigma* menjamin hanya 3,4 *error* pada satu juta pemeriksaan dan merupakan *world class quality*.

Materials and Methods

This is a retrospective study, and data required for the study were extracted between July 2015 and June 2016 from a Secondary Care Government Hospital, Chennai. The data obtained for the study are IQC - coefficient of variation percent (CV%) and EQAS-Bias% for urea, creatinine, total bilirubin, serum glutamic oxaloacetic transaminase/aspartate aminotransferase (AST), serum glutamic pyruvic transaminase/alanine aminotransferase (ALT), alkaline phosphatase (ALP), total protein, albumin, calcium, phosphorus, magnesium, total cholesterol, triglycerides, high-density lipoprotein (HDL), sodium, and potassium. This study was done to assess the performance of these 16 biochemical parameters run on VITROS 4600 fully automated biochemistry analyzer on a Sigma Scale by calculating the sigma metrics for each parameter. Sigma metrics was calculated with the following formula:

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

Where, TEa is total error allowable, Bias and CV are the indicator of systematic and random errors, respectively.

Coefficient of variation

The CV is standard deviation (SD) expressed as a percentage and is a measure of the variability of an assay and is expressed as a percentage. CV was calculated from Biorad internal QC for the parameters.

$$CV = (SD/mean) \times (100)$$

Bias

Bias is the systematic difference between the expected results obtained by the laboratory test method and the results that would be obtained from an accepted reference method. Bias percentage for each parameter was calculated from the Biorad-EQAS.

$$\text{Bias}\% = \frac{\text{Our EQAS result - peer group mean (using the same instrument and method)}}{\text{Peer group mean (using the same instrument and method)}} \times 100$$

Table 3: The coefficient of variation percentage of level 1 internal quality control for 16 biochemical parameters from July 2015 to June 2016 and their average

Parameter	CV percentage of level 1												Average
	July 2015	August 2015	September 2015	October 2015	November 2015	December 2015	January 2016	February 2016	March 2016	April 2016	May 2016	June 2016	
Urea	2.30	1.70	2.00	2.20	1.80	3.00	2.70	3.80	2.70	3.10	3.50	2.90	2.64
Creatinine	1.50	1.30	2.70	2.00	1.70	3.70	2.10	3.90	1.30	1.60	1.50	3.40	2.23
Total bilirubin	8.50	7.80	4.98	7.80	4.80	5.40	9.00	11.30	6.60	5.60	5.60	4.80	6.85
AST/SGOT	3.90	3.42	3.40	4.90	4.01	3.00	4.60	4.00	4.80	3.80	4.30	4.40	4.04
ALT/SGPT	3.10	4.80	4.90	2.60	4.00	4.60	3.60	5.00	4.20	4.30	3.00	4.40	4.04
ALP	3.90	6.10	4.80	5.01	3.20	2.20	3.30	4.00	2.10	3.60	3.30	3.20	3.73
Total protein	1.80	2.90	8.20	1.50	1.30	3.01	2.90	1.60	1.30	2.50	1.80	1.80	2.55
Albumin	2.60	2.80	4.62	5.30	2.40	4.01	6.10	4.01	2.01	4.90	2.50	5.20	3.87
Calcium	1.70	1.70	0.70	1.40	1.50	1.60	2.00	4.50	1.80	2.80	1.60	3.60	2.08
Phosphorous	1.60	2.80	2.20	2.60	2.40	1.90	1.70	2.96	2.50	2.10	1.60	1.50	2.16
Magnesium	2.20	3.80	2.80	4.00	2.60	4.70	2.70	5.70	1.80	3.60	3.60	3.60	3.43
Cholesterol	2.10	3.10	2.30	2.40	2.50	4.00	2.70	1.60	2.80	2.50	2.30	3.80	2.68
Triglyceride	3.97	0.57	2.42	3.81	2.84	1.50	2.06	0.77	4.22	2.02	2.10	4.00	2.52
HDL-C	3.60	3.40	2.70	3.00	3.10	2.90	3.20	3.30	2.70	3.20	7.70	3.60	3.53
Sodium	0.90	1.24	1.02	2.00	0.88	0.94	0.87	1.37	1.65	1.54	1.67	0.97	1.25
Poatassium	1.20	0.98	1.04	1.34	2.11	2.70	1.90	2.10	1.83	2.01	1.94	1.79	1.75

AST = Aspartate aminotransferase, ALT = Alanine aminotransferase, ALP = Alkaline phosphatase, SGPT = Serum glutamic pyruvic transaminase, SGOT = Serum glutamic oxaloacetic transaminase, CV = Coefficient of variation, HDL-C = High-density lipoprotein cholesterol

Table 5: The Bias percentage obtained from Bio-Rad External Quality Assurance Scheme for 16 biochemical parameters from July 2015 to 2016 and their average

Parameter	Bias percentage												Average
	July 2015	August 2015	September 2015	October 2015	November 2015	December 2015	January 2016	February 2016	March 2016	April 2016	May 2016	June 2016	
Urea	1.23	12.20	1.92	1.58	0.22	0.70	4.80	1.04	4.52	5.80	1.12	4.84	3.33
Creatinine	3.83	3.12	0.37	2.63	4.61	4.03	3.10	2.09	0.76	2.70	2.11	0.86	2.52
Total bilirubin	5.85	4.09	1.12	10.80	9.71	1.60	3.71	5.97	3.66	4.60	2.46	3.78	4.78
AST/SGOT	1.99	5.35	0.48	3.11	1.89	1.29	0.44	0.78	0.02	2.82	2.72	1.80	1.89
ALT/SGPT	1.06	0.09	0.16	3.58	1.68	4.15	9.73	0.80	2.97	1.67	5.81	8.06	3.31
ALP	9.74	7.05	5.91	2.40	1.96	10.30	1.52	9.40	6.80	7.61	1.46	2.79	5.58
Total protein	4.60	4.70	0.38	2.66	0.68	5.73	2.44	2.29	3.12	0.80	2.50	1.60	2.62
Albumin	2.34	7.73	3.64	3.67	0.19	3.96	1.75	1.61	4.55	1.09	2.07	2.73	2.94
Calcium	5.32	2.65	2.59	2.70	2.20	0.90	4.42	2.58	0.84	0.15	0.63	0.90	2.16
Phosphorous	2.23	2.00	1.04	1.90	3.11	3.71	2.88	2.15	2.90	2.63	0.54	3.86	2.41
Magnesium	11.40	2.50	3.53	10.00	10.10	1.61	1.30	3.12	1.70	3.11	0.01	4.74	4.43
Cholesterol	2.30	1.78	7.23	8.46	6.40	2.74	9.50	3.46	0.76	8.73	6.72	3.43	5.13
Triglyceride	8.18	3.78	4.32	4.36	6.62	1.39	1.37	1.54	3.55	1.32	11.30	2.76	4.21
HDL-C	5.88	4.45	5.23	2.79	12.20	0.05	3.32	0.24	7.29	9.70	6.11	4.21	5.12
Sodium	1.07	1.00	1.94	2.07	0.20	0.09	0.08	0.20	1.52	1.82	1.74	1.39	1.09
Poatassium	0.82	1.77	1.17	0.69	0.96	2.53	0.46	3.12	4.01	2.53	3.44	3.49	2.08

AST = Aspartate aminotransferase, ALT = Alanine aminotransferase, ALP = Alkaline phosphatase, SGPT = Serum glutamic pyruvic transaminase, SGOT = Serum glutamic oxaloacetic transaminase, HDL-C = High-density lipoprotein cholesterol

- Contoh perhitungan Metrik Sigma

  a. Hitunglah Metrik Sigma TE pada parameter ALP dalam rentang waktu Juli 2015 s.d Juni 2016 dengan data hasil pemeriksaan serum kontrol pada IQC yang tertera pada Tabel 3. dan hasil pemeriksaan serum sampel pada EQC yang tertera pada Tabel 5

  Jawab :

  TEa = 30%

  Rerata CV = 3,73%

  Rerata bias = 5,58%

  $$\text{Metrik Sigma} = \frac{\text{TEa (\%)} - \text{bias (\%)}}{\text{CV (\%)}}$$

  $$= \frac{30 - 5,58}{3,73}$$

  $$= 6,54$$

Table 6: The sigma metrics and quality goal index ratio calculation from tea (Clinical Laboratory Improvement Amendment), average coefficient of variation percentage, and Bias percentage

Parameter	CV percentage		Bias percentage	Tea (CLIA)	Sigma		QGI		Problem
	Level 1	Level 2			Level 1	Level 2	Level 1	Level 2	
Urea	2.64	2.02	3.33	9.00	2.15	2.81	0.8	1.1	Imprecision
Creatinine	2.23	2.13	2.52	15.00	5.61	5.85	0.8	0.8	Imprecision
Total bilirubin	6.85	4.65	4.78	20.00	2.22	3.27	0.5	0.7	Imprecision
AST/SGOT	4.04	3.33	1.89	20.00	4.48	5.43	0.3	0.4	Imprecision
ALT/SGPT	4.04	3.08	3.31	20.00	4.13	5.43	0.5	0.7	Imprecision
ALP	3.73	3.72	5.58	30.00	6.55	6.57	1.0	1.0	None
Total protein	2.55	2.26	2.62	10.00	3.00	3.27	0.7	0.8	Imprecision
Albumin	3.87	3.60	2.94	10.00	1.82	1.96	0.5	0.5	Imprecision
Calcium	2.08	2.12	2.16	11.00	4.26	4.17	0.7	0.7	Imprecision
Phosphorous	2.16	2.13	2.41	10.00	3.51	3.56	0.7	0.8	Imprecision
Magnesium	3.43	2.38	4.43	25.00	6.01	8.63	0.9	1.2	None
Cholesterol	2.68	2.66	5.13	10.00	1.51	1.83	1.3	1.3	Inaccuracy
Triglyceride	2.52	1.99	4.21	25.00	8.24	10.45	1.1	1.4	None
HDL-C	3.53	3.28	5.12	30.00	7.04	7.60	1.0	1.0	None
Sodium	1.25	1.14	1.09	5.00	3.11	3.43	0.6	0.6	Imprecision
Potassium	1.75	1.74	2.08	5.00	1.67	1.67	0.8	0.8	Imprecision

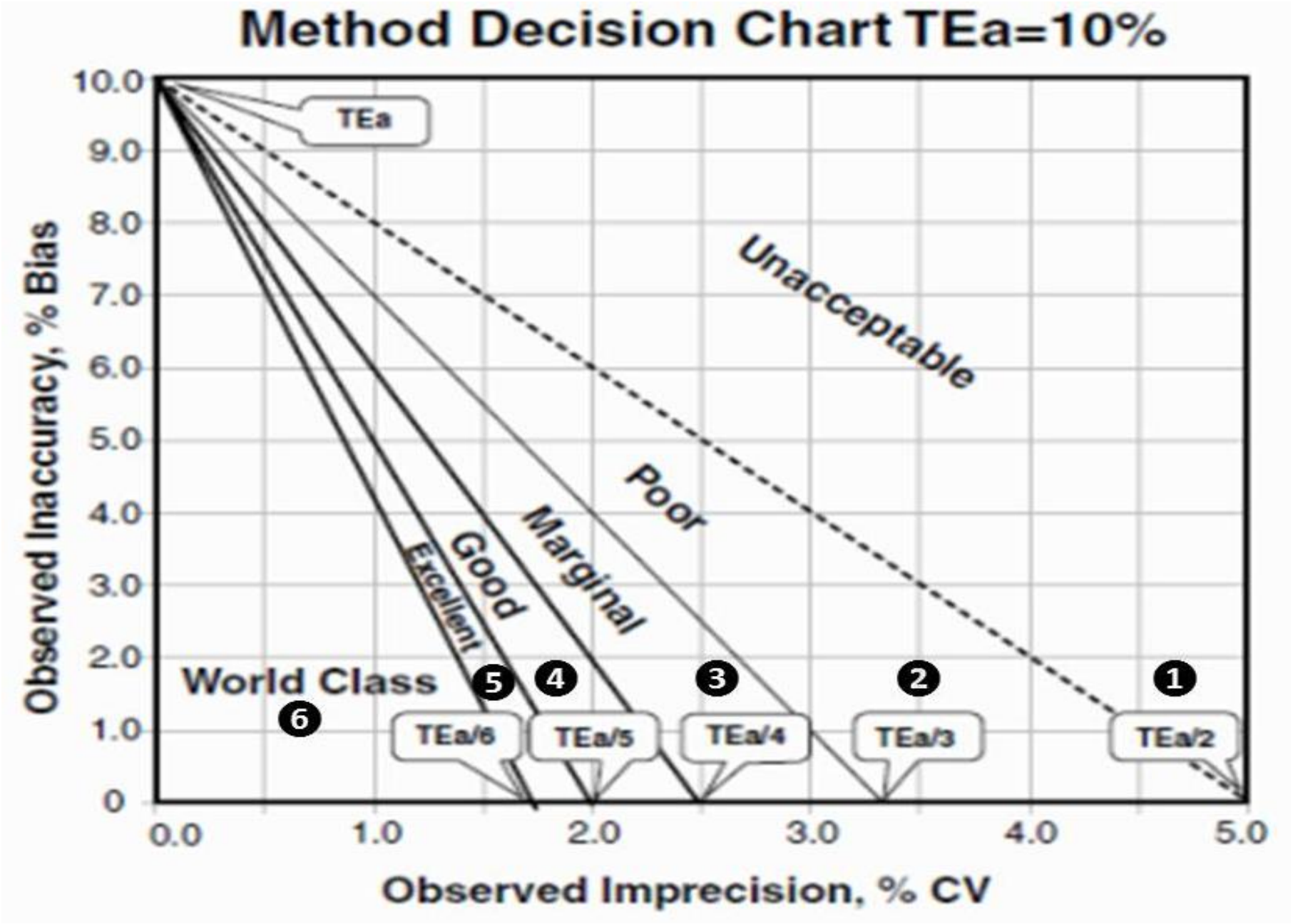
CLIA = Clinical Laboratory Improvement Amendment, AST = Aspartate aminotransferase, ALT = Alanine aminotransferase, ALP = Alkaline phosphatase, SGPT = Serum glutamic pyruvic transaminase, SGOT = Serum glutamic oxaloacetic transaminase, CV = Coefficient of variation, HDL-C = High-density lipoprotein cholesterol, QG = Quality Goal Index ratio

- Hasil *six sigma* dapat memberikan kepercayaan bagi klinisi dan pasien, meningkatkan efektivitas penggunaan kontrol dan kalibrator laboratorium, serta peningkatan kontrol kualitas laboratorium

- Metrik Sigma memberikan jumlah prosedur QC yang dibutuhkan oleh setiap parameter.

- Jika bias dan CV rendah, Metrik Sigma akan tinggi dan hanya dibutuhkan prosedur QC minimal.

- Sebaliknya jika bias dan CV besar, Metrik Sigma akan rendah , hal ini menunjukkan penampilan metode buruk dan membutuhkan lebih banyak prosedur QC

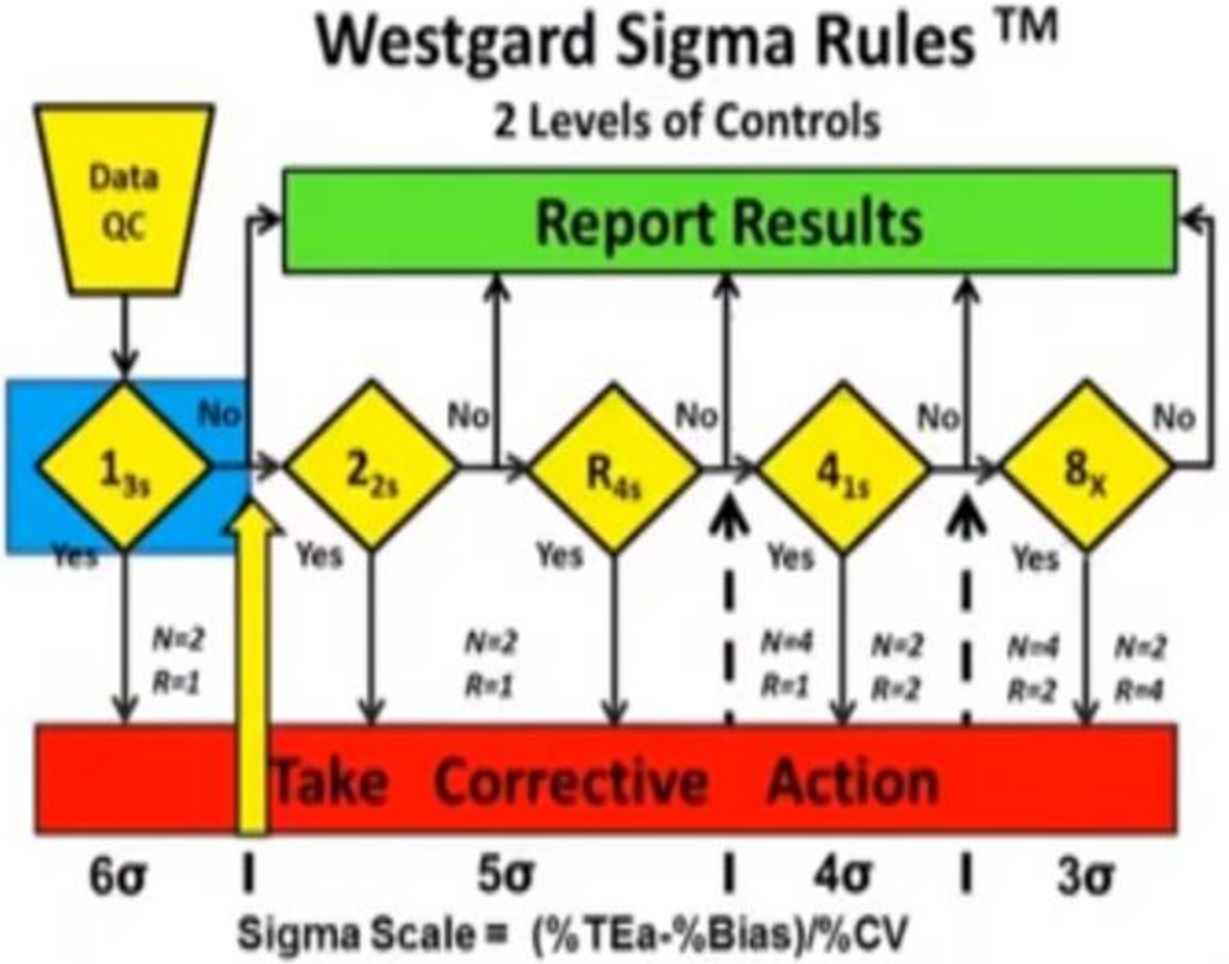


Gambar 4. Grafik *Normalized Method Decision*[9]

WESTGARD SIGMA RULE

Kualitas 6-sigma hanya membutuhkan aturan kontrol tunggal, 1-3s, dengan 2 pengukuran kontrol dalam setiap kali run

6σ



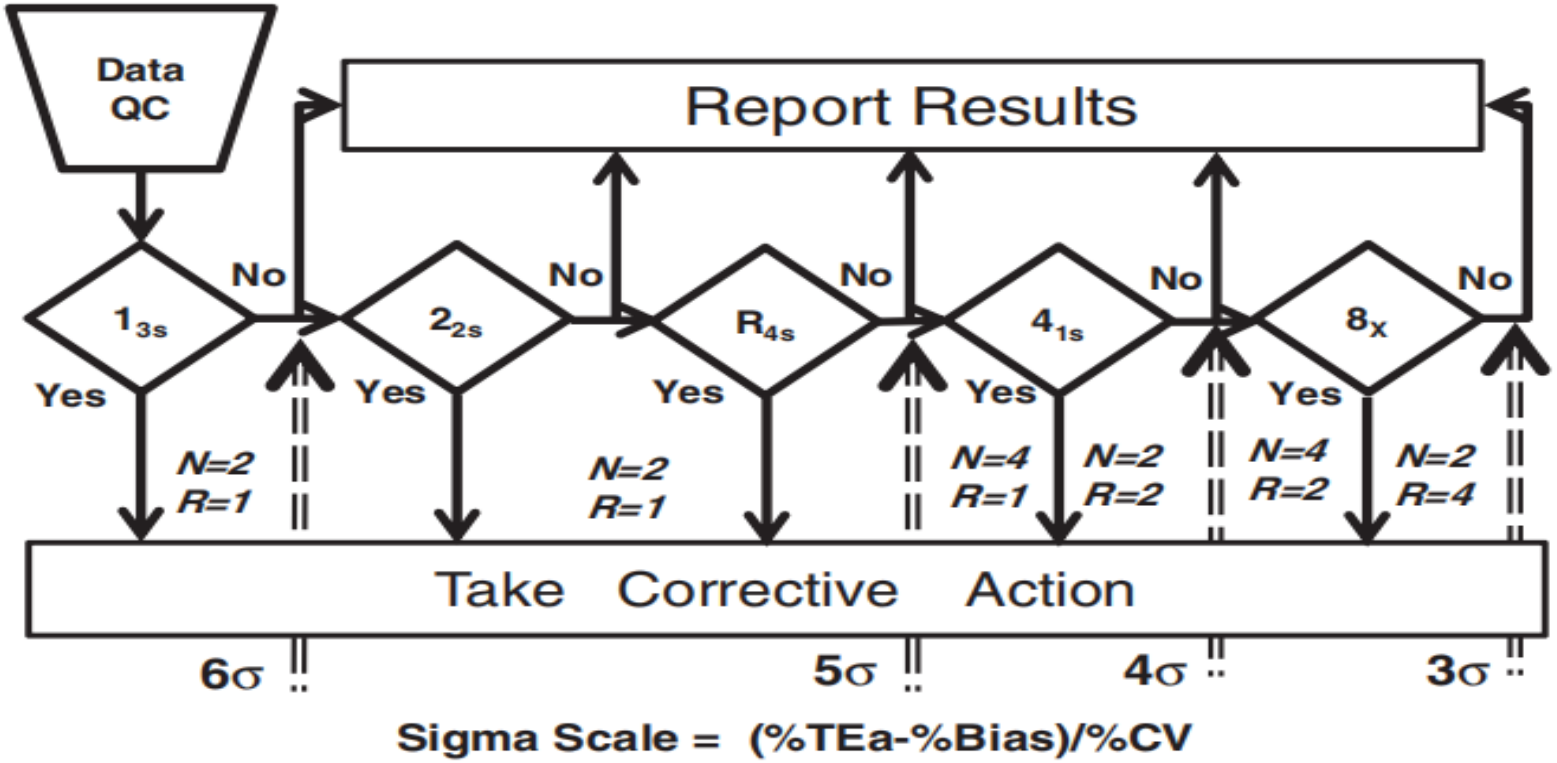


Figure 9. 'Westgard Sigma Rules' Graphic Tool for three levels of controls. Locate sigma-metric on scale at the bottom, read up and identify the control rules, number of control measurements (N), and number of runs (R) to the left of the arrow. For example, if the sigma-metric is five, then the appropriate SQC procedure is a 13s/22s/R4s with two control measurements in a single run.
QC: quality control.

QC Plan with Right-Sized Statistical QC

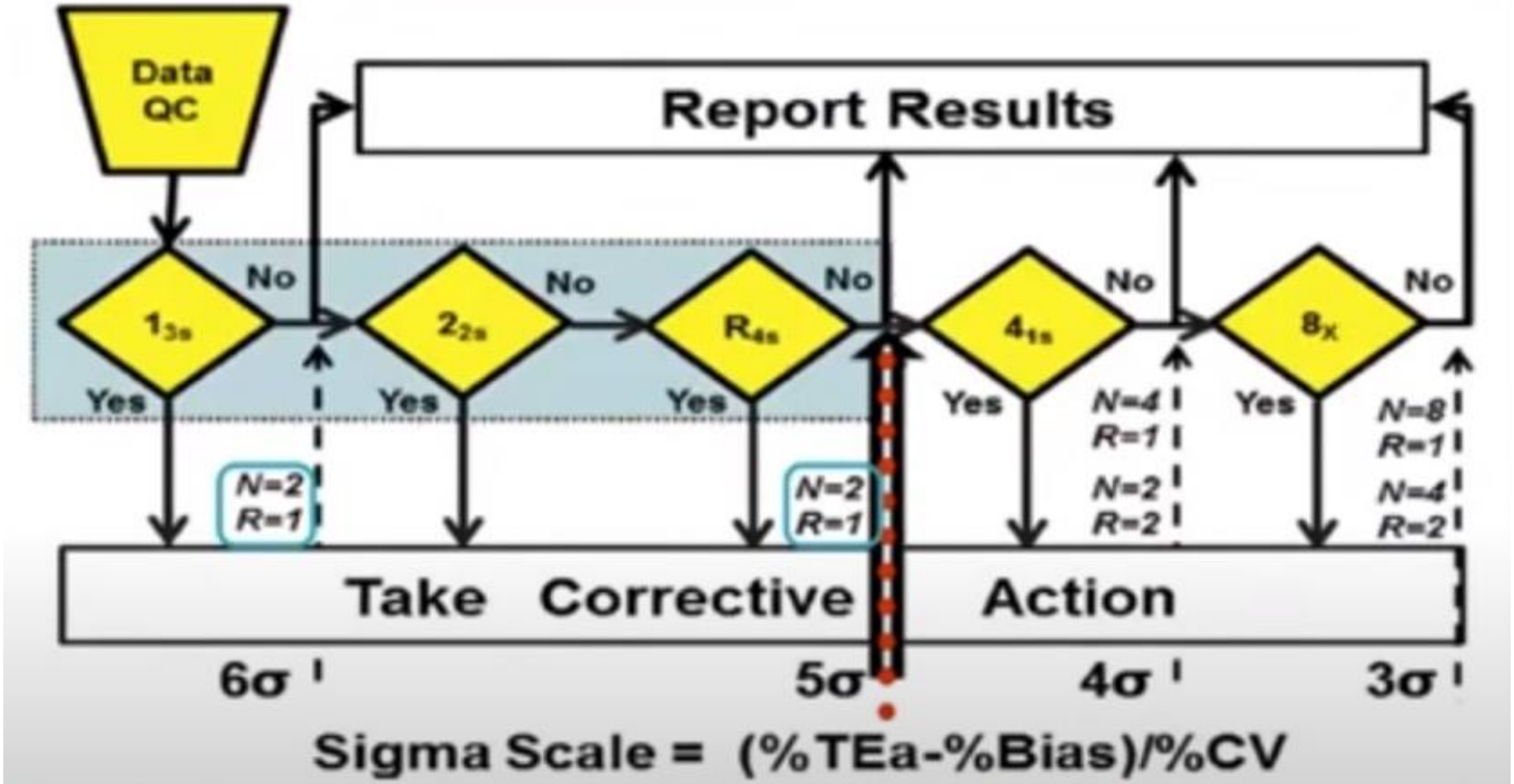


Fig. 4. Example of Cholesterol 5.0 sigma method, where TEa is 10%, bias is 0.0%, and CV (coefficient of variation) is 2.0%. Appropriate SQC procedure is $1_{3s}/2_{2s}/R_{4s}$ multirule procedure having a total of two control measurements per run (N = 2, R = 1).

KESIMPULAN

1. Pengukuran six sigma sangat penting untuk mengetahui kinerja operasional di laboratorium dari mulai tahapan preanalitik, analitik dan postanalitik

2. Hasil pengukuran six sigma dapat di jadikan sebagai salah satu dasar untuk mengevaluasi kualitas dan melakukan tindaklanjut sehingga kualitas dapat terus di tingkatkan

3. Pengukuran six sigma dalam QC dapat meningkatkan efisiensi dan efektifitas penggunaaan reagen dan kontrol di laboratorium

Conclusion

- Sigma metric, method decision charts and OPSpecs chart provide easy tools for laboratories to:
  - Determine the performance of their current methods
  - Validation protocols of a new instrument/method/reagent
  - Compare instruments/method/reagent performance
  - QC planning and QC design

Terimakasih