Sigma Matrix and 6 Sigma

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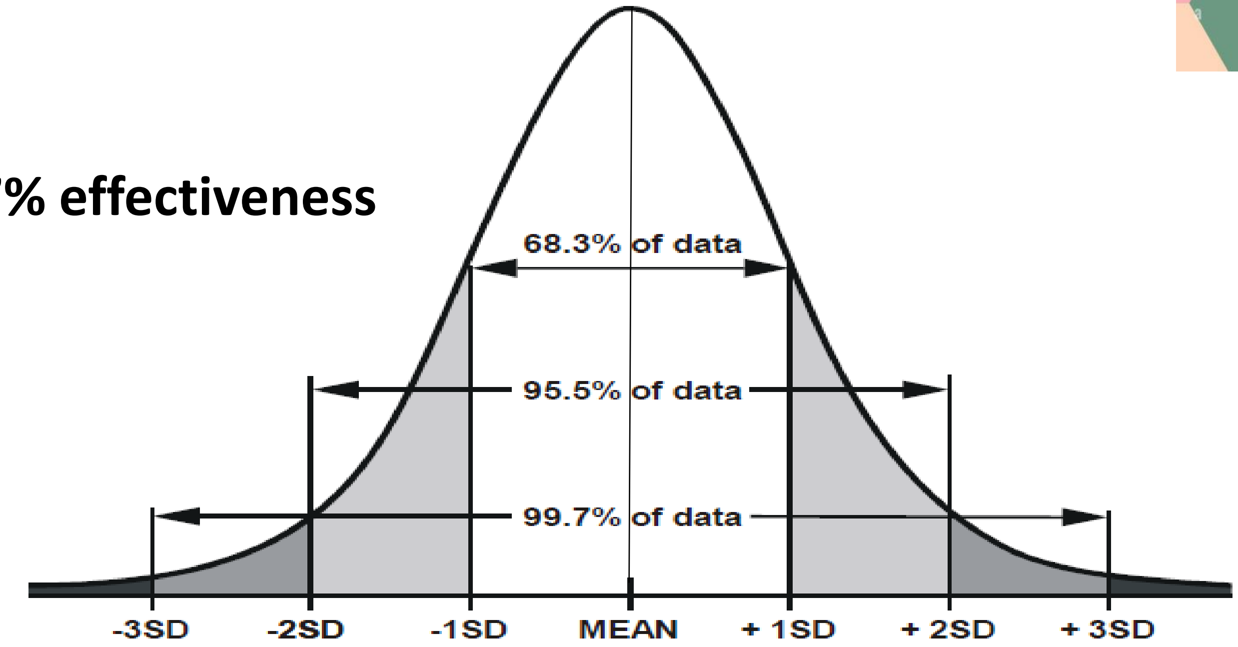
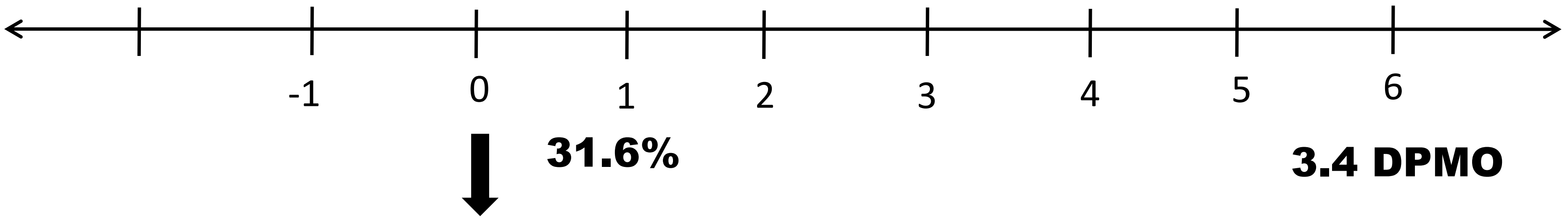
What is Six sigma?

- Six sigma is a statistical approach to reduce variations (defects) in order to "*Increase effectiveness*".
- Sigma (σ) – Standard Deviation

Six sigma = 99.99967% effectiveness



More than 50% defect rate <<< sigma will be negative



50% Defect rate

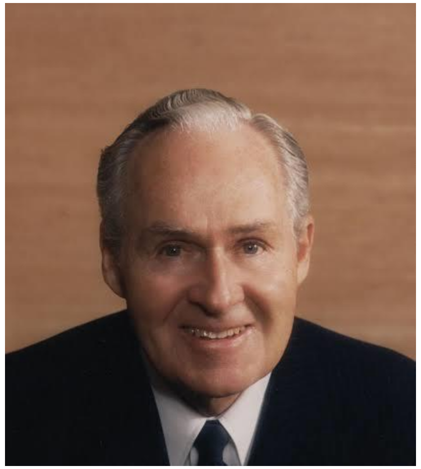
If defect reduces>>>>>>>> Sigma level increases

Lean

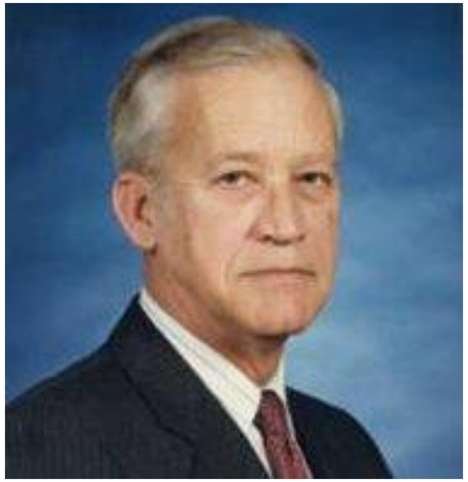
- Lean is identification and elimination of waste from the process to "Increase Efficiency" without compromizing on the quality.
- Example: Biomedical waste management

History of Six Sigma

- TOYOTA MOTORS
- MOTOROLA >>>>> 1986



CEO: Bob Galvin



Bill Smith
(Father of Six Sigma)

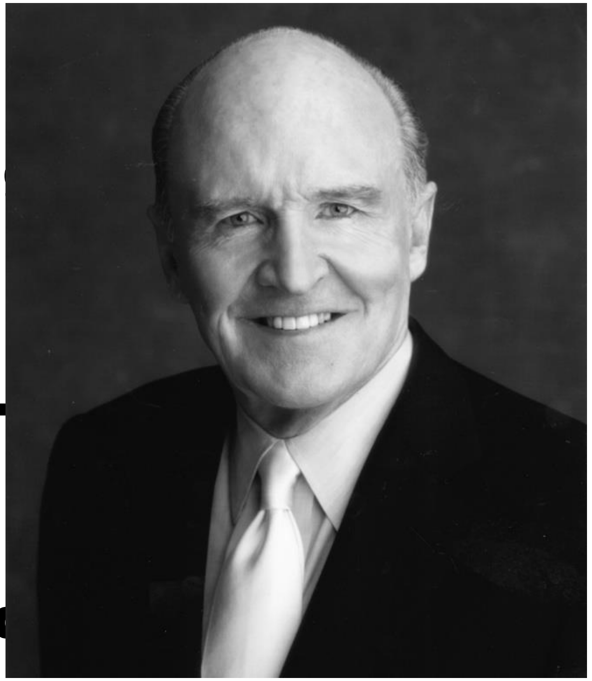
Dr. Mikel Harry

- **Dr. Mikel Harry started the first six sigma academy in 1996**

- **General Electric (GE): 1995**
- **He implemented 6 sigma in 5 different sta**

D M A I C

- **D (Define) : Selection of the right problem.**
- **M (Measure): Collecting reliable data.**
- **A (Analyze): To analyze Statistically to fin**
- **I (Improve) : strategies to improve the problrm.**
- **C (Control): Sustain the improvement.**

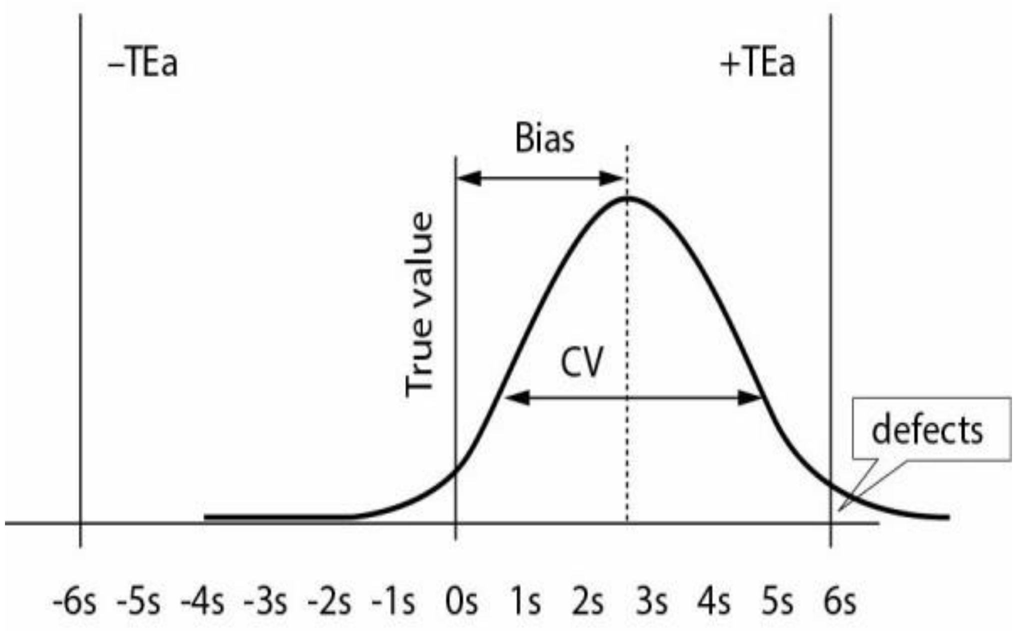


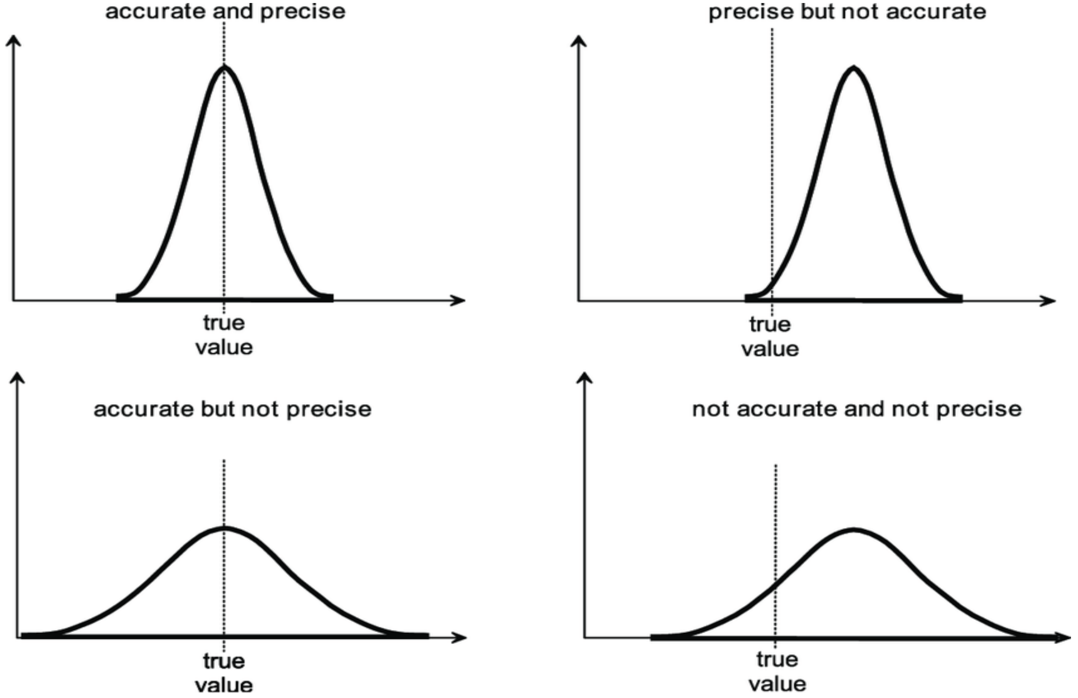
CEO: Jack Welch

How do we calculate Sigma metric?

$$\text{Sigma} = \frac{TE_a - |\textbf{Bias}|}{CV}$$

- Bias = Inaccuracy (Difference from reference value or peer group)
- CV (coefficient of variation) = Imprecision/ reproducibility
- TE_a = Total Allowable Error (or "Tolerance") required for that analyte. According to CLIA (Clinical Laboratory Improvement Amendment)





CLIA '88 PROFICIENCY TESTING LIMITS

ANALYTE	CLIA PROFICIENCY LIMIT
Lactate Dehydrogenase (LDH)	± 20%
LDH Isoenzymes	Target value ± 30% or (+ or -)
LDH Isoenzvmes 1	Target value ± 30% or (+ or -)
LDH Isoenzvmes 2	± 30%
LDH Isoenzvmes 3	± 30%
LDH Isoenzymes 4	± 30%
LDH Isoenzymes 5	± 30%
Lead	Target value ± 10% or ± 4 mcg/dL (greater)
Leukocyte Count WBC	± 15%
Lithium	Target value ± 20% or ± 0.3 mmol/L (greater)
Magnesium	± 25%
NAPA	± 25%
Partial Thromboplastin Time	± 15%
pC02	Target value ± 8% or ± 5 mm Hg (greater)
pH	Target value ± 0.04
p02	Target value ± 3 SD
Phenobarbital	± 20%
Phenytoin	± 25%
Platelet Count PLT	± 25%
Potassium	Target value ± 0.5 mmol/L
Primidone	± 25%
Procainamide (and metabolite)	± 25%
Prothrombin Time	± 15%
Quinidine	± 25%
Rheumatoid Factor	Target value ± 2 dilutions or positive/ negative
Rubella	Target value ± 2 dilutions or positive/ negative
Sodium	Target value ± 4 mmol/L
T3 Uptake	Target value ± 3 SD
Theophylline	± 25%
Thyroid-stimulating Hormone TSH	Target value ± 3 SD
Thyroxine T4 Total	Target value ± 20% or ± 1.0 mcg/dL (greater)
Tobramycin	± 25%
Total Protein Serum	± 10%
Triglycerides	± 25%
Triiodothyronine T3 Total	Target value ± 3 SD
Urea Nitrogen	Target value ± 9% or ± 2 mg/dL (greater)
Uric Acid	± 17%
Urine/Spinal	± 10%
Valproic Acid	± 25%
White Blood Cell Differential	Target value ± 3 SD based on the percentage of different types of white blood cells in the samples

CLIA '88 PROFICIENCY TESTING LIMITS

ANALYTE	CLIA PROFICIENCY LIMIT
Alcohol, Blood	± 25%
Alanine Aminotransferase (ALT/SGPT)	± 20%
Albumin	± 10%
Alkaline Phosphatase	± 30%
Alpha-1 Antitrypsin	Target value ± 3 SD
Alpha-Fetoprotein (Tumor Marker) AFP	Target value ± 3 SD
Amylase	± 30%
Antinuclear Antibody	Target value ± 2 dilutions or positive/ negative
Antistreptolysin 0	Target value ± 2 dilutions or positive/ negative
Anti-Human Immunodeficiency Virus	Reactive or nonreactive
Aspartate Aminotrasnferase (AST/SGOT)	± 20%
Bilirubin, Total	Target value ± 20% or ± 0.4 mg/dl (greater)
Calcium, Total	Target value ± 1.0 mg/dl.
Carbamazepine	± 25%
Cell Identification	90% or greater consensus on identification
Chloride	± 5%
Cholesterol, High Density Lipoprotein	± 30%
Cholesterol, Total	± 10%
Complement C3	Target value ± 3 SD
Complement C3C	Target value ± 3 SD
Complement C4	Target value + 3 SD
Cortisol	± 25%
Creatine Kinase	± 30%
Creatine Kinase CK-MB	Target value ± 3 SD or presence/ absence
Creatinine	Target value ± 15% or ± 0.3 mg/dl (greater)
Digoxin	Target value ± 20% or ± 0.2 ng/ml (greater)
Erythrocyte Count RBC	± 6%
Ethosuximide	± 20%
Fibrinogen	± 20%
Free Thyroxine Free T4	Target value ± 3 SD
Gentamicin	± 25%
Glucose	Target value ± 10% or ± 6 mg/dl (greater)
Hematocrit (Excluding Spun Hematocrits) HCT	± 6%
Hemoglobin Hgb, Total	± 7%
Hepatitis (HbsAg, anti-HBc, HbeAg)	Reactive (positive) or nonreactive (negative)
Human Chorionic Gonadotropin Beta	Target value ± 3 SD or positive/ negative
Human Chorionic Gonadotropin Intact	Target value ± 3 SD or positive/ negative
Human Chorionic Gonadotropin Qualitative	Target value ± 3 SD or positive/ negative
Human Chorionic Gonadotropin Total	Target value ± 3 SD or positive/ negative
IgA	Target value ± 3 SD
IgE	Target value ± 3 SD
IgG	± 25%
IgM	Target value ± 3 SD
Infectious Mononucleotides	Target value ± 2 dilutions or positive/ negative
Iron, Total	± 20%

- For Bias,

1. **Individual Deviations:**
   |*Measured Value−True Value* |
2. ***Average Deviation:***

$$\frac{\sum \text{Individual Deviations}}{\text{Number of Measurements}}$$

3. **Express Bias as a Percentage:**

$$\text{Bias (\%)} = \frac{\text{Average Deviation}}{\text{True Value}} \times 100$$

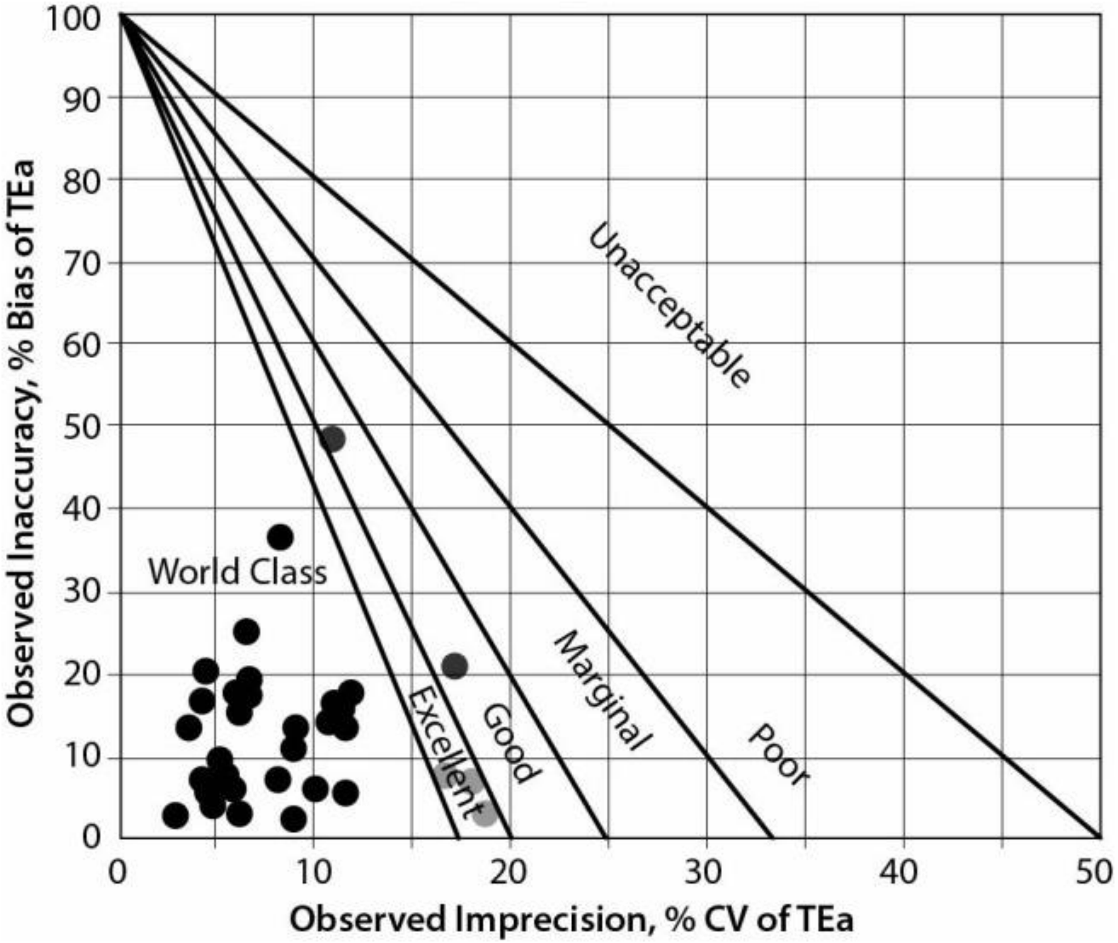
- For CV,

$$CV = \frac{\text{Standard Deviation (SD)}}{\text{Mean}} \times 100$$

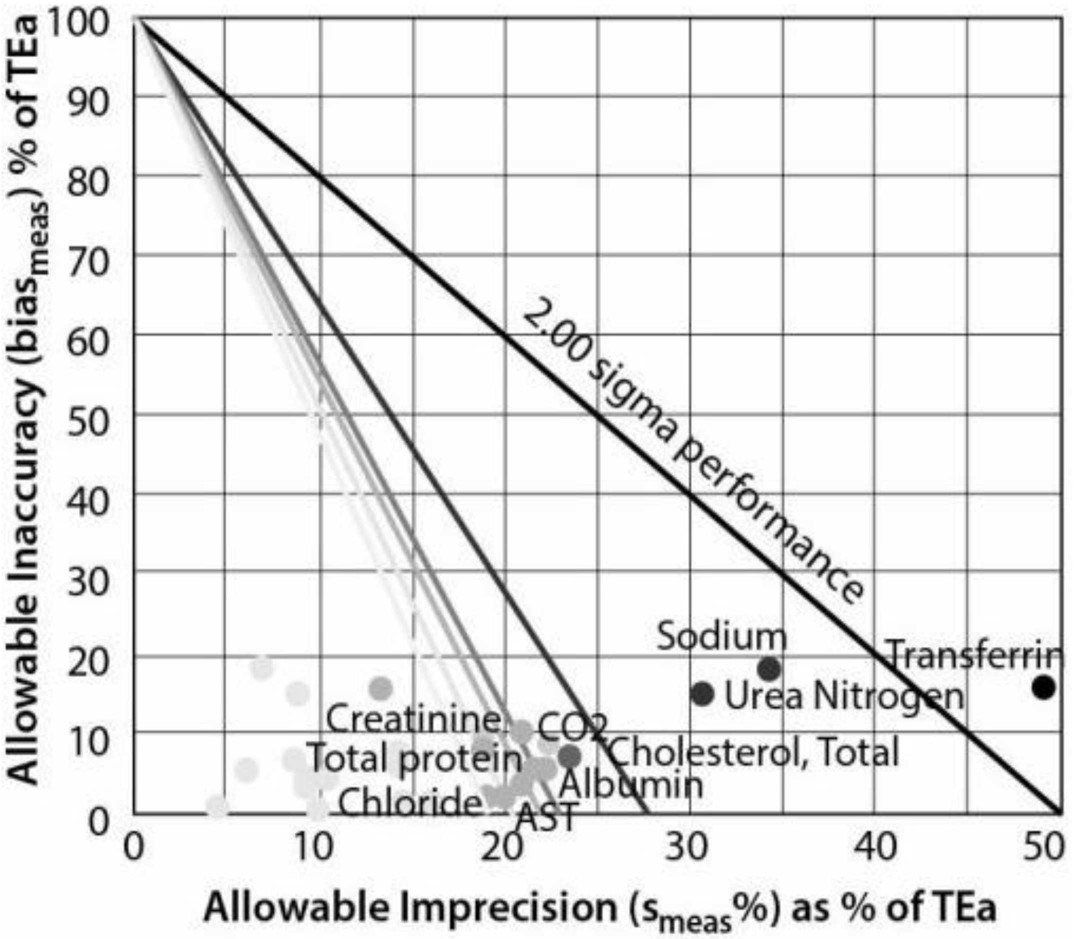
- For TE_a

The **Clinical Laboratory Improvement Amendments** of 1988 (CLIA) Guidelines has given TEa of 85 analytes as per the criticality of the analyte.

Method Decision chart



OPSpec Chart



Assessing a single analyte across multiple system

Analytical Sigma metrics: A review of Six Sigma implementation tools for medical laboratories

Sten Westgard*[1], Hassan Bayat[2], James O Westgard[1]

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[2]Immunogenetics Research Center, Mazandaran University of Medical Sciences, Sari, Iran

*Corresponding author: westgard@westgard.com

- The method decision chart is a tool used to assess a single analyte across multiple systems.
- It helps in evaluating the performance of a single analyte across different testing methods and determining the best method for testing that analyte.

Assessing multiple tests on one system across Labs

Taher *et. al., 2018* .

Multi-site study (11 Hospitals in 9 countries) evaluating 18 tests on the Alinity Assay System

Contents lists available at ScienceDirect

Clinical Biochemistry

journal homepage: www.elsevier.com/locate/clinbiochem

A novel Sigma metric encompasses global multi-site performance of 18 assays on the Abbott Alinity system

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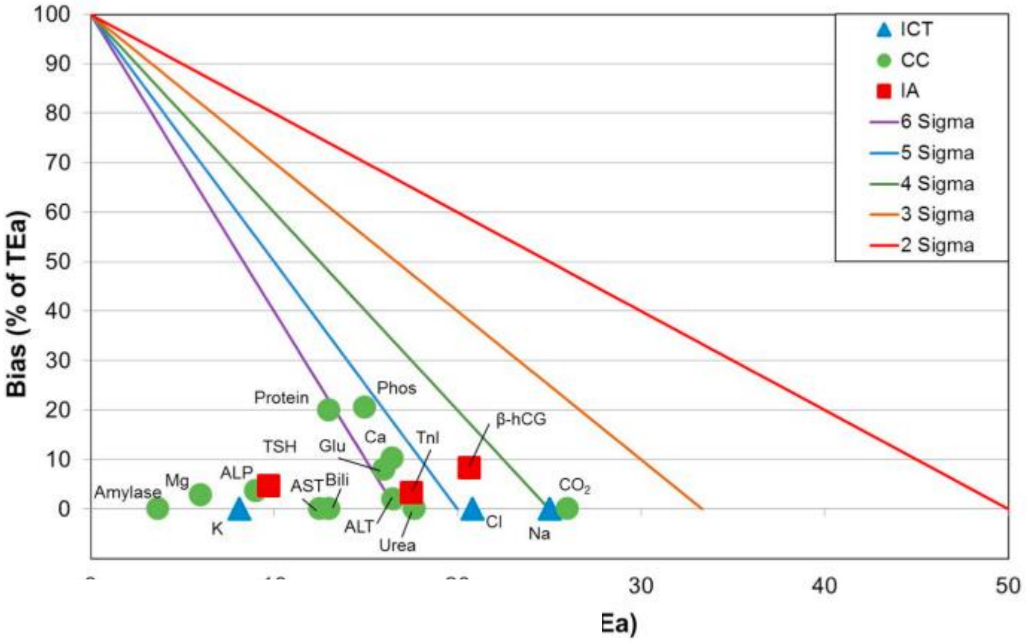
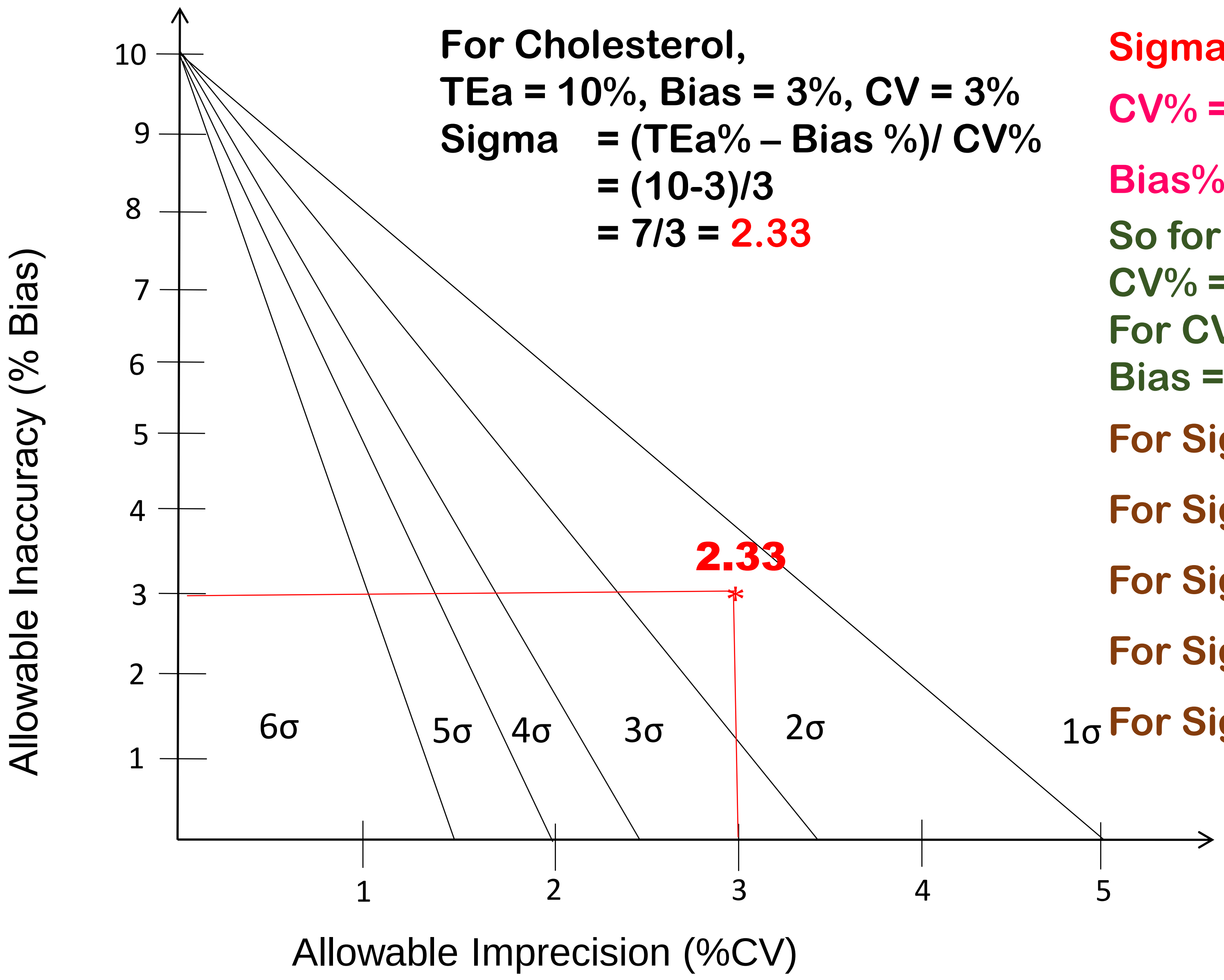
[b] Diagnostics Division, Abbott Laboratories, Abbott Park, IL, USA
[c] Department of Clinical Biochemistry, University Health Network, Toronto, ON, Canada

$$\frac{\%TEa - |\%bias|}{\%CV}$$

$$\frac{\%TEa - |\%pooled\ bias|}{\%CV}$$

$$\frac{\%TEa - |\%pooled\ bias|}{\%pooled\ CV}$$





Sigma = (TEa% – Bias %)/ CV%

CV% = (TEa% – Bias %)/ Sigma

Bias% = TEa% – (Sigma *CV%)

So for Bias = 0%,
CV% = TEa%/ Sigma
For CV% = 0,
Bias = TEa% - (Sigma* 0) = TEa = 10

For Sigma = 2, CV% = 10/2 = 5

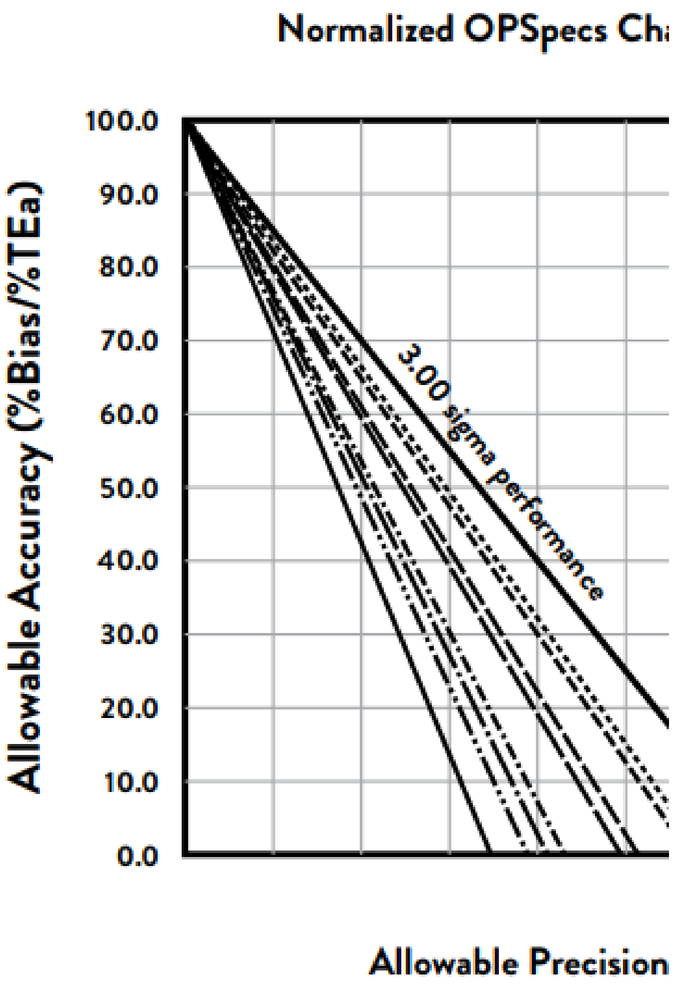
For Sigma = 3, CV% = 10/3 = 3.33

For Sigma = 4, CV% = 10/4 = 2.5

For Sigma = 5, CV% = 10/5 = 2

For Sigma = 6, CV% = 10/2 = 1.66

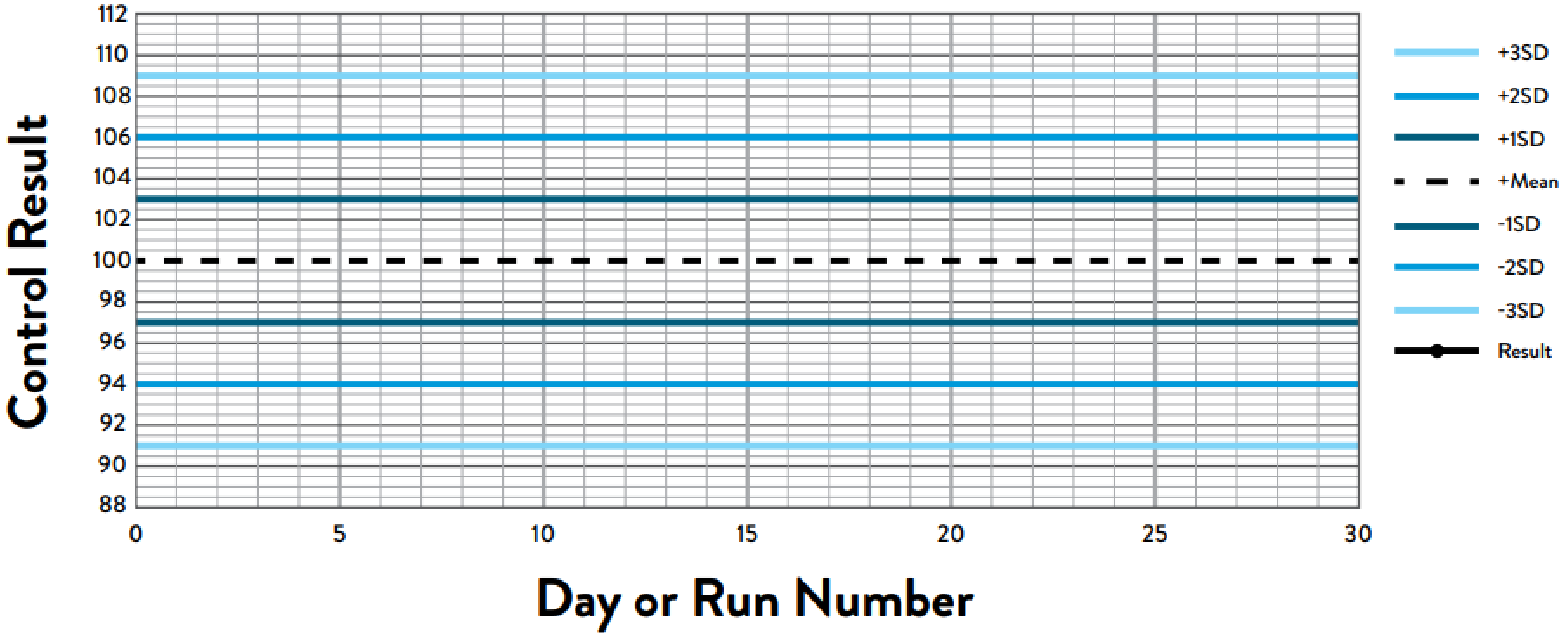
Normalized OPSpec Chart



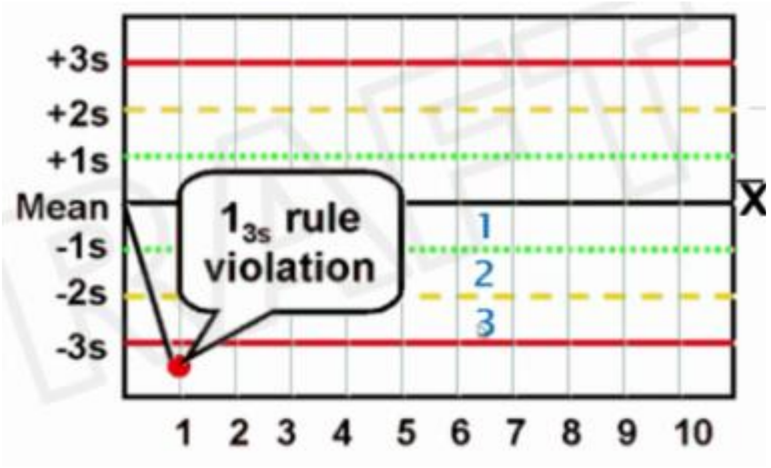
Rules	P_{fr}	N	R
$1_{3s}/2_{2s}/R_{4s}/4_{1s}/8_x$	0.08	8	1
$1_{3s}/2_{2s}/R_{4s}/4_{1s}/8_x$	0.03	4	2
$1_{3s}/2_{2s}/R_{4s}/4_{1s}$	0.03	4	1
$1_{2.5s}$	0.04	4	1
$1_{2.5s}$	0.03	2	1
$1_{3s}/2_{2s}/R_{4s}$	0.01	2	1
1_{3s}	0.00	2	1
$1_{3.5s}$	0.00	2	1

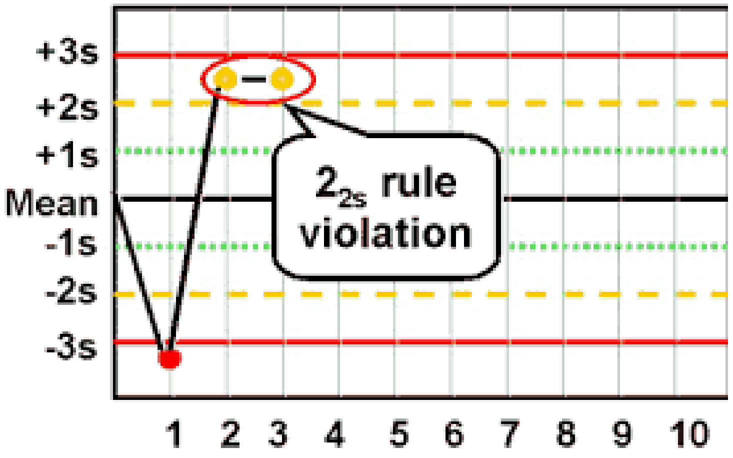
		N	R
$2_{2s}/R_{4s}/4_{1s}/8_x$	8	8	1
$2_{2s}/R_{4s}/4_{1s}/8_x$	3	4	2
$2_{2s}/R_{4s}/4_{1s}$	3	4	1
	4	4	1
	3	2	1
$2_{2s}/R_{4s}$	1	2	1
	0	2	1
	0	2	1

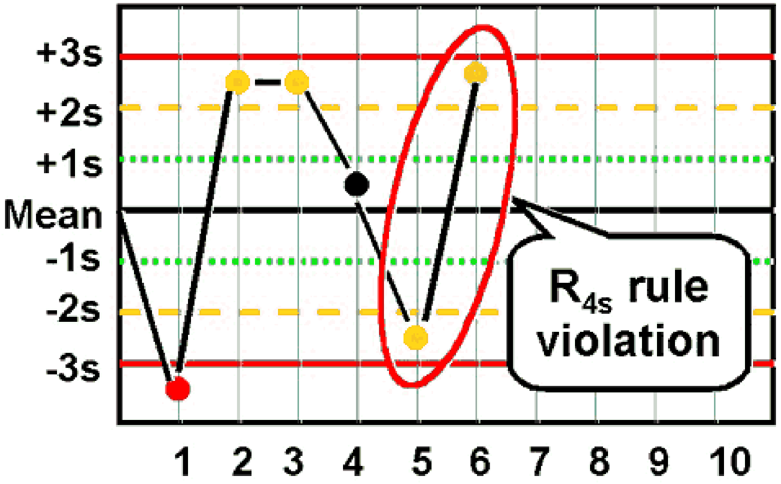
Levey-Jennings control chart

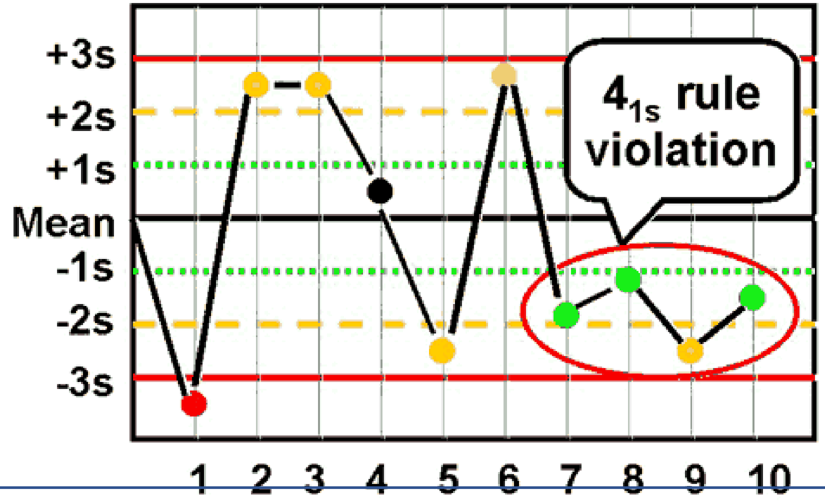


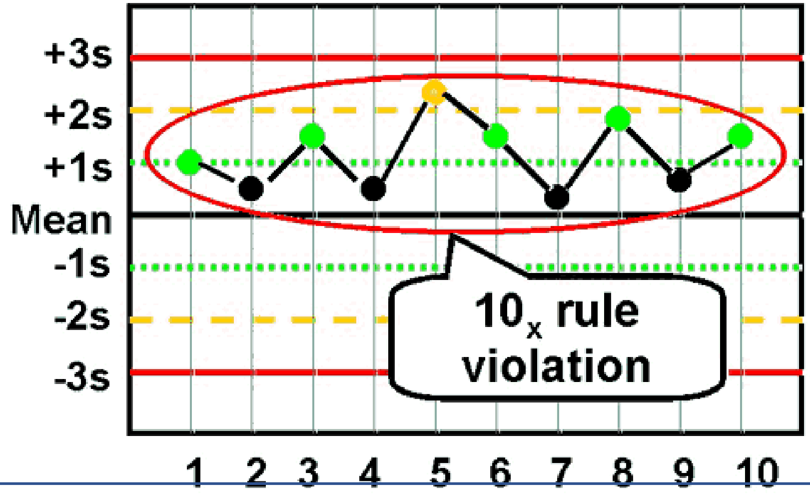
Westgard Rules







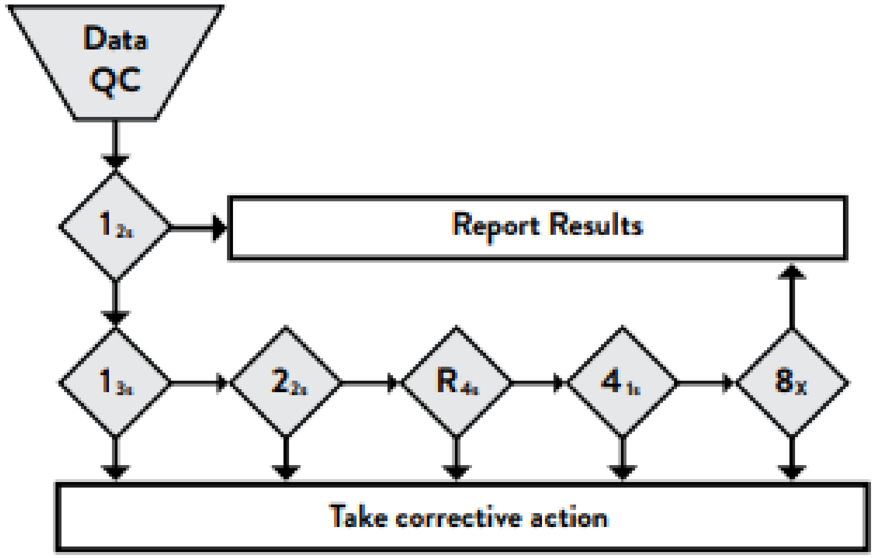




Evolution of Sigma Based QC

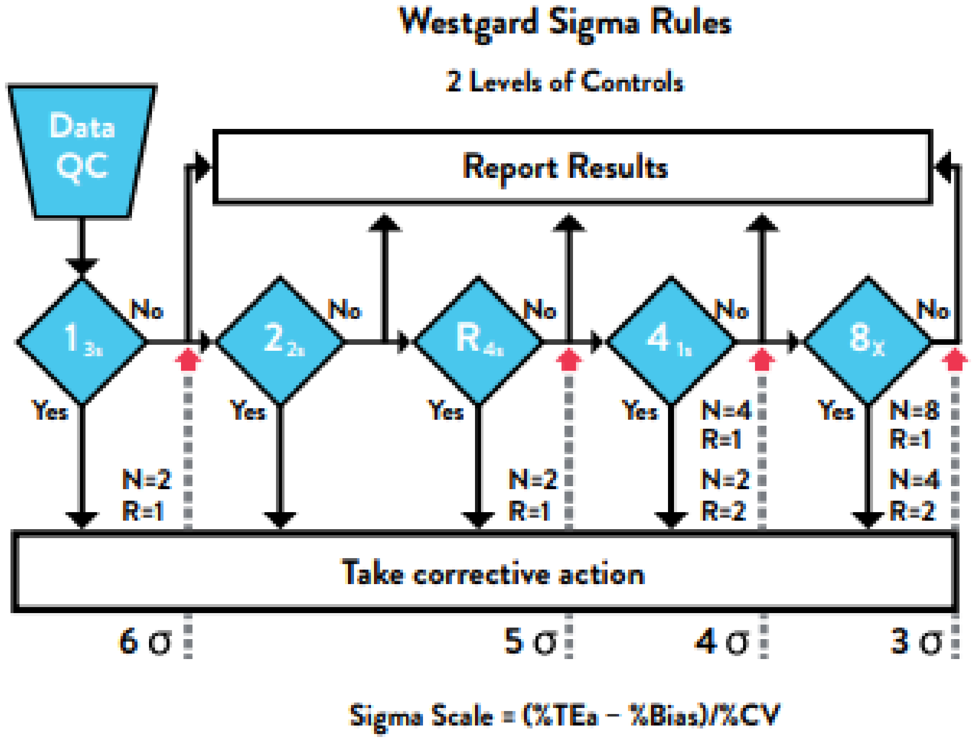
Original Westgard Rules, (March 1981)

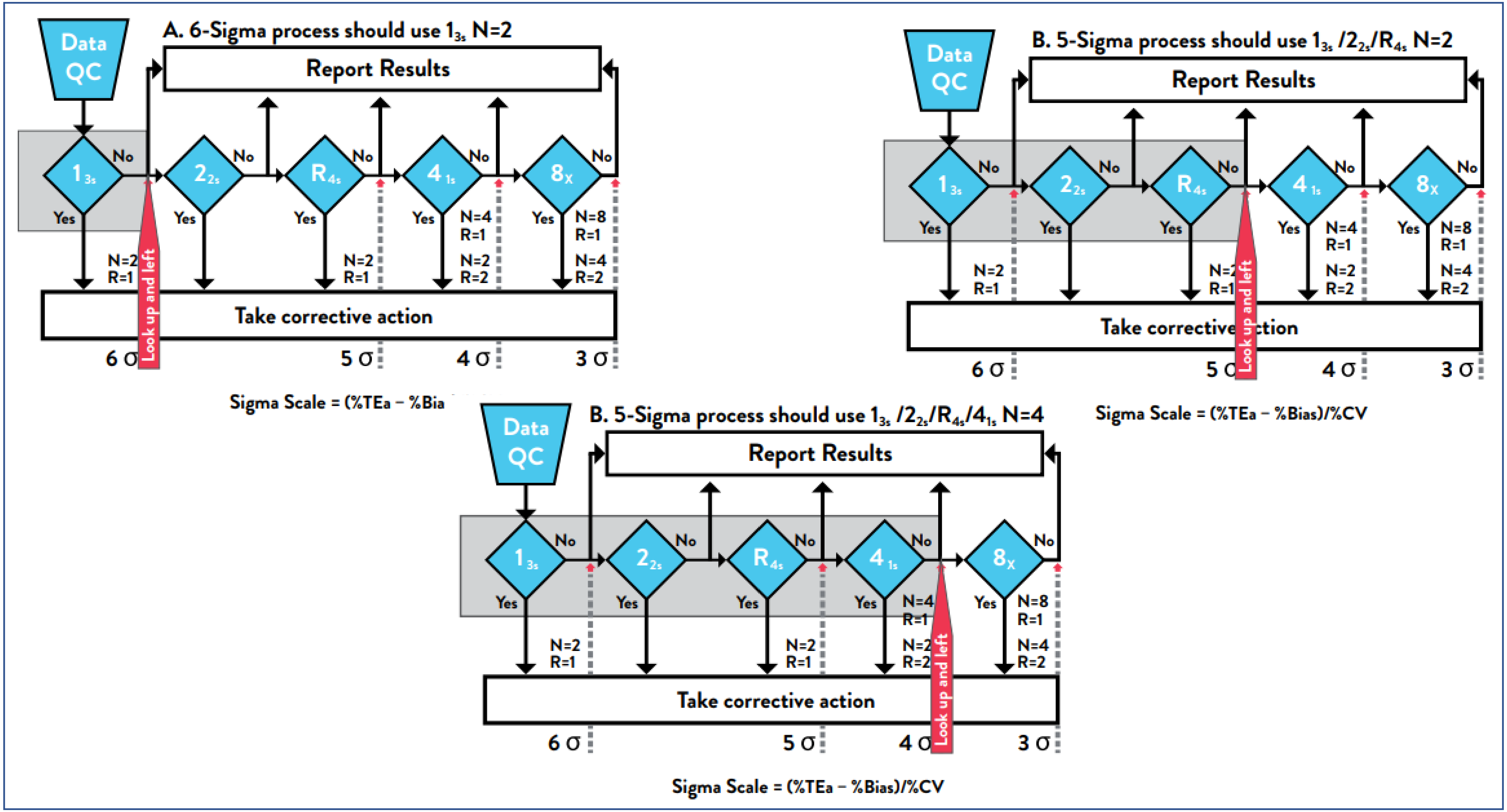
Westgard JO *et. al. Clin. Chem. Mar: 27(3); 493-501*



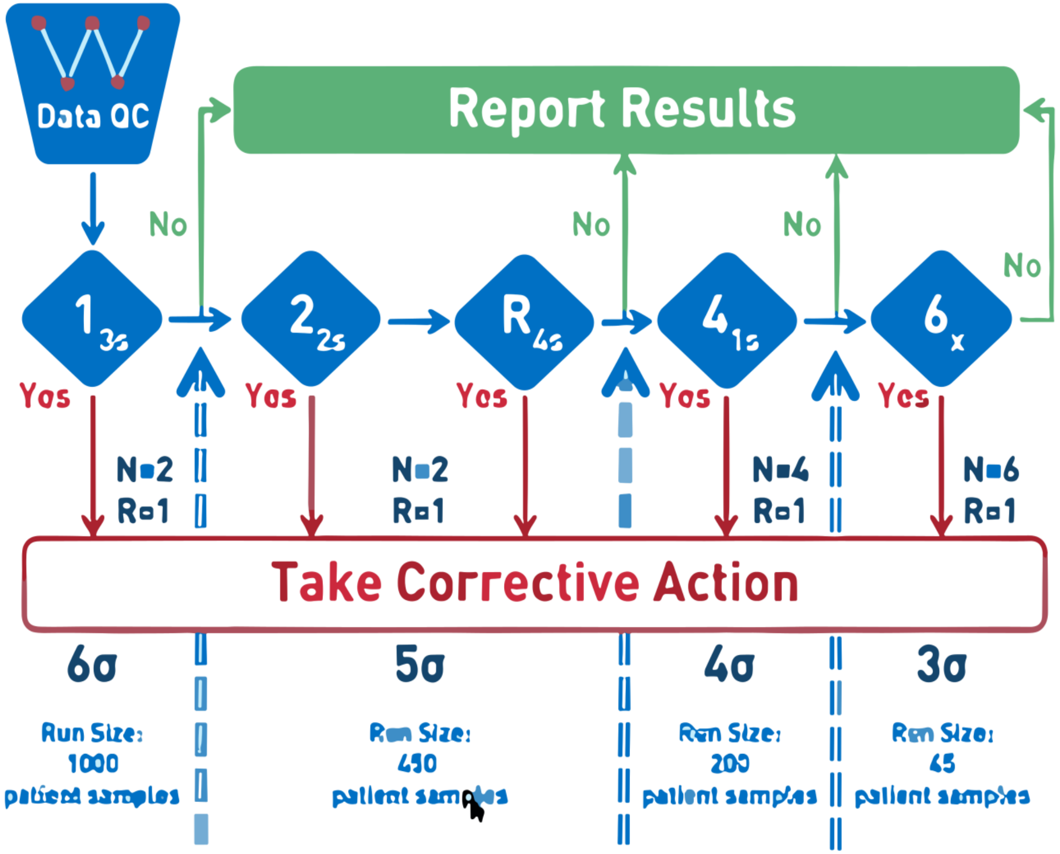
Westgard Sigma Rules, (2014)

Westgard JO, Westgard SA,
Basic Quality Management System, 2014




A. 6-Sigma process should use 1$_{3s}$ N=2
Data QC
Report Results
1$_{3s}$
2$_{2s}$
R$_{4s}$
4$_{1s}$
8$_{X}$
No
Yes
N=2 R=1
N=4 R=1
N=2 R=2
N=8 R=1
N=4 R=2
Look up and left
Take corrective action
6 σ
5 σ
4 σ
3 σ
Sigma Scale = (%TEa – %Bia
B. 5-Sigma process should use 1$_{3s}$ /2$_{2s}$/R$_{4s}$ N=2
Sigma Scale = (%TEa – %Bias)/%CV
B. 5-Sigma process should use 1$_{3s}$ /2$_{2s}$/R$_{4s}$/4$_{1s}$ N=4
Sigma Scale = (%TEa – %Bias)/%CV

Westgard Sigma Rules with run size (2018)



Sigma metric	Control rule	QC frequency
6	13s, n=2	1 per 1000 patients samples
5	13s/22s/r4s, n=2	1 per 450 patients samples
4	13s/22s/r4s/41s, n=4	1 per 200 patients samples
3	All “Westgard Rules”, n=6	1 per 45 patients samples

Measurement Uncertainty(MU)

- The International Vocabulary of Metrology (VIM) defines measurement uncertainty as a "non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used.“

- Measurement uncertainty is often expressed as a **Standard Deviation (SD) or Coefficient of variation (CV)**.

Measurement uncertainty using Sigma Matrix

- Sigma matrix = (TEa% - bias%)/ CV%
- CV% = (TEa% - bias%)/ Sigma matrix

If want to provide world class quality, Sigma matrix = 6

- CV% = (TEa% - bias%)/ 6

Sigma matrix 4.5 is for providing standard quality

- CV% = (TEa% - bias%)/ 4.5

Example: For Cholesterol, TEa = 10, Bias = 3

- CV% = (10-3)/6 = 1.166
- CV% = (10-3)/4.5 = 1.55

In the clinical laboratory, there are some test parameters like Bilirubin, Sodium, Potassium; where maintaining CV% at very low level is very difficult. For such parameters SD is targeted.

- SD = (TEa - bias)/ 4.5

Impact on the laboratory

Poor quality:

- More QC measurements and more rules to detect any deviation.
- More delay, more repeat, more results.
- Clinician and patient dissatisfaction.
- Financial impact.

Mahmood TS *et. al*. The Application of Six Sigma Methodology to Improve Service Quality: A Case Study in an Iraqi Retail Company. 2021 [cited 2024 Jan 15]

Sigma Level	DPMO	COPQ (Cost of Poor quality)
1	6,90,000	> 40% of Revenue
2	3,08,537	> 40% of Revenue
3	66,807	24 to 40% of Revenue
4	6,210	15 to 25% of Revenue
5	233	5 to 15% of Revenue
6	3.4	< 1% of Revenue

Status in India

Utilization of Lean & Six Sigma quality initiatives in Indian healthcare sector

Gaurav Suman, Conceptualization, Data curation, Methodology, Software, Writing – original draft# and
Deo Raj Prajapati, Conceptualization, Investigation, Project administration, Resources, Supervision, Validation, Writing – review & editing#*

Kingston Rajiah, Editor

‣ Author information ‣ Article notes ‣ Copyright and License information PMC Disclaimer

(Suman and Prajapati. Utilization of Lean & Six Sigma quality initiatives in Indian healthcare sector. Rajiah K, editor. PLOS ONE. 2021 Dec 23;16(12):e0261747)

- Nearly 40% of the hospitals surveyed did not apply any quality initiatives, and only 15 hospitals implemented Lean techniques, while 14 hospitals implemented Six Sigma techniques
- The major reasons for not implementing Lean and Six Sigma initiatives in Indian healthcare are a lack of knowledge and availability of resources.
- The implementation of Lean and Six Sigma in the Indian healthcare sector can lead to improved healthcare quality, reduced medical errors, and enhanced patient satisfaction.

Thank You