B-155

Sigma Metric Equation Proposed by James O. Westgard is Wrong

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Background

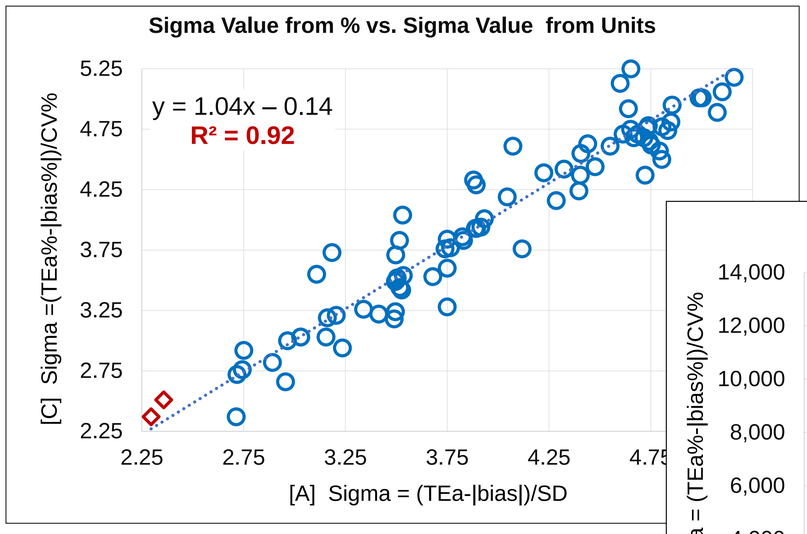
2022 AACC Poster #132 of the same title described how the Westgard sigma metric equation of **[A]** SM = (TEa - Bias)/SD proposed by James O. Westgard is NOT wrong when compared to the industrial practice of calculating sigma as **[B]** the difference between the mean and nearest upper or lower tolerance limit divided by the SD. Formulae [A] and [B] produce the same results.
The often-recommended practice of calculating sigma as [C] Sigma = (%TE -|%Bias|)/CV%, however, produces results that differ from either formulae described above whenever bias is not zero. This formula [C] using percentages is therefore wrong.

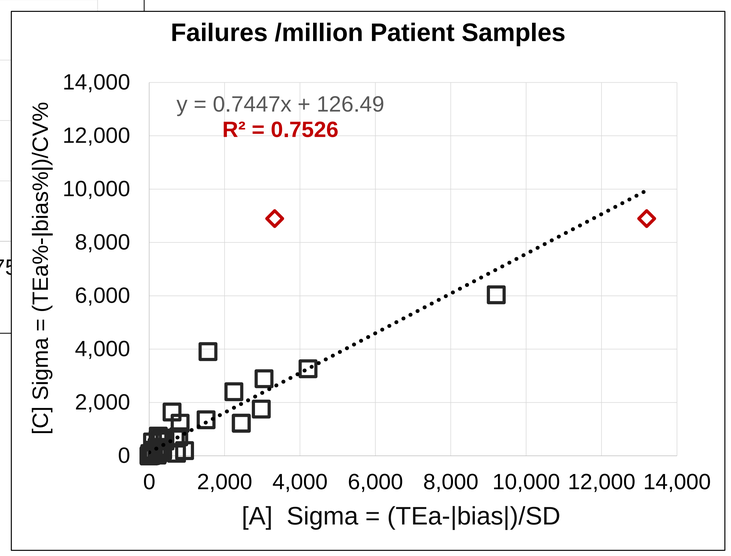
Methods

Sigma values were calculated as [A] (TEa - |Bias)|/SD and as [C] (%TE - |%Bias|)/CV% on fourteen routine chemistry analytes and four cardiac markers tested on two Ortho Vitros 5600 analysers from September to December 2022. CLIA TEa limits were selected as TEa limits for each analyte; bias was calculated as Current Mean - Peer Mean. Sigma tables were used to convert sigma to defects per million results. Eight-six of 320 data sets with sigma metrics from 2.25 to 5.25 were graphed to compare calculated sigma values and #failures/year.

Results

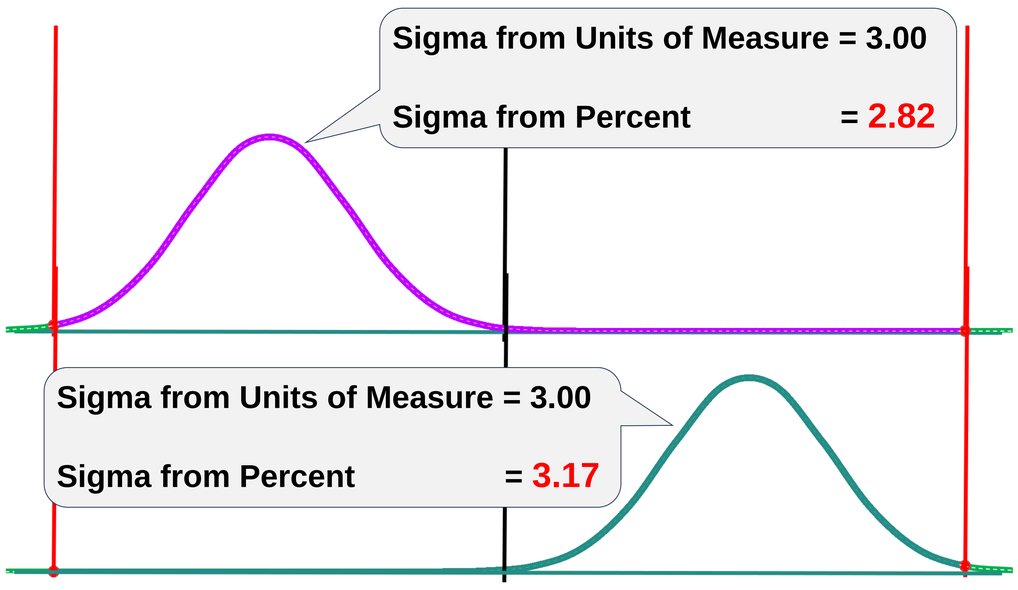
Comparison of sigma metrics calculated from formula [A] and [C] revealed
1. An R^2 = 1.00 if all 320 values with sigma metrics from 0.71 to 30.8;
2. An R^2 = 0.92 when the range was truncated to the 86 samples with sigma from 2.25 to 5.25; and
3. An R^2 value of only 0.75 when the same sigma values are converted to the number of results failing TEa limits per one million patent samples.



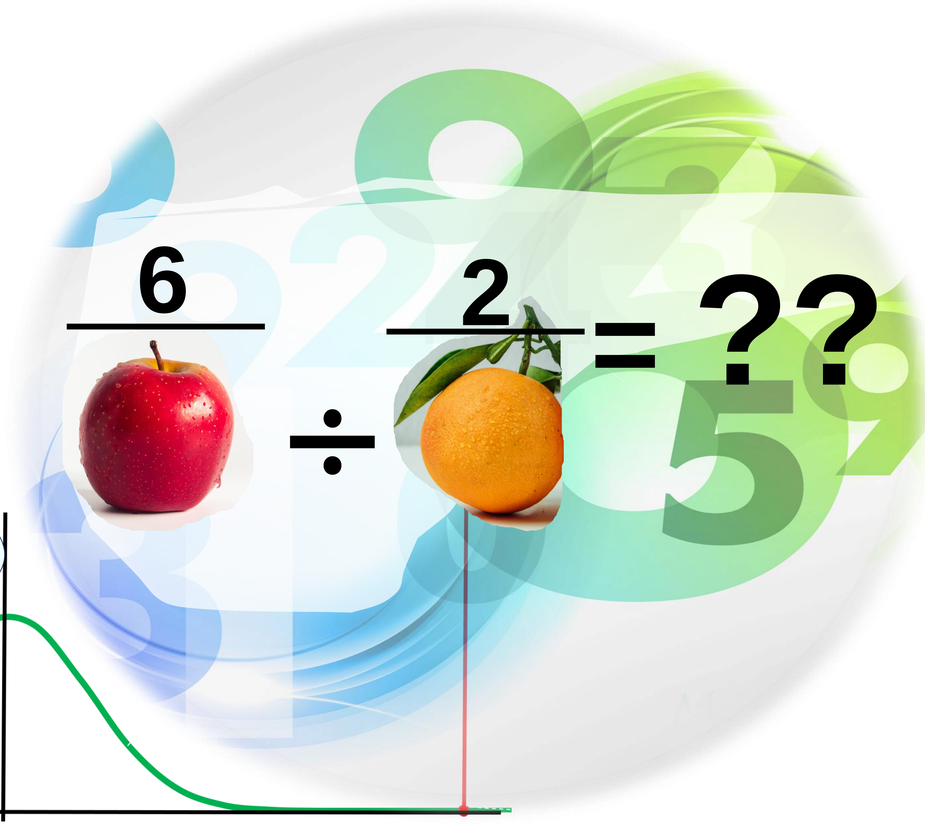


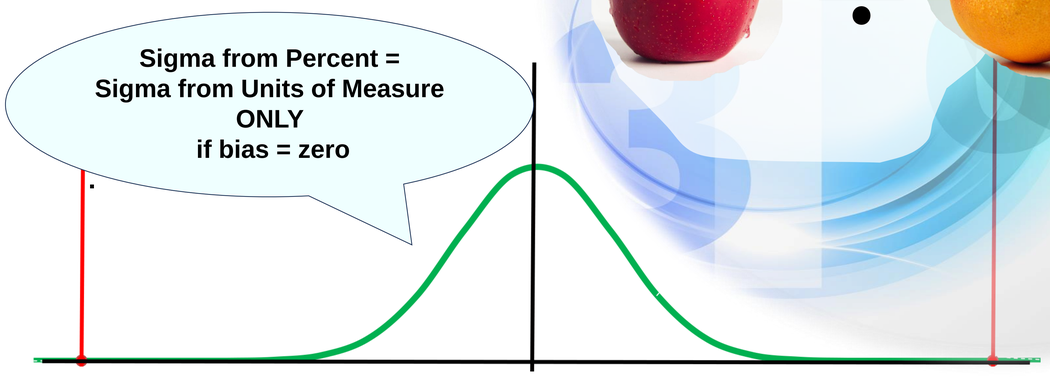
Conclusion:

Calculations of sigma metrics based on %Bias and %CV are incorrect. This is exacerbated when sigma is converted to the number of patient failures per million results









Compare calculations of Sigma and Total Error from units of measure and percent

	Formulae	Units/Result	Calculations	Units/Result	Calculations	Units/Result	Calculations
Measured Mean	FACT: Measured from individual QC results	100.00		106.00		94.00	
True Value	Opinion: Selected from Peer, Package insert or history	100.00		100.00		100.00	
Bias from Units	(Mean - True)	0.00	100 - 100	6.00	106 - 100	-6.00	94 - 100
Bias as Percent of True	Bias/True	0.0%	0 / 100	6.0%	6 / 100	-6.0%	-6 / 100
Medical Goal (TEa)	Opinion: Selected from Medical Goal or Proficiency	12.00		12.00		12.00	
Medical Goal (TEa)	TEa/True	12.0%	12 / 100	12.0%	12 / 100	12.0%	12 / 100
Measured SD	FACT: Measured from individual QC results	2.00		2.00		2.00	
CV%	CV% = SD/Mean	2.00%	2 / 100	1.89%	2 / 106	2.13%	2 / 94
Sigma (z-value to TEa)	(TEa-|Bias|)/SD	6.00	= (12 - |0|)/2	3.00	= (12 - |6|)/2	3.00	= (12 - |-6|)/2
Sigma metric from %	(TEa% - |Bias%|/CV%	6.00	=(12% - |0%|)/2%	3.17	=(12% - |6%|)/1.89%	2.82	=(12% - |6%|)/2.13%