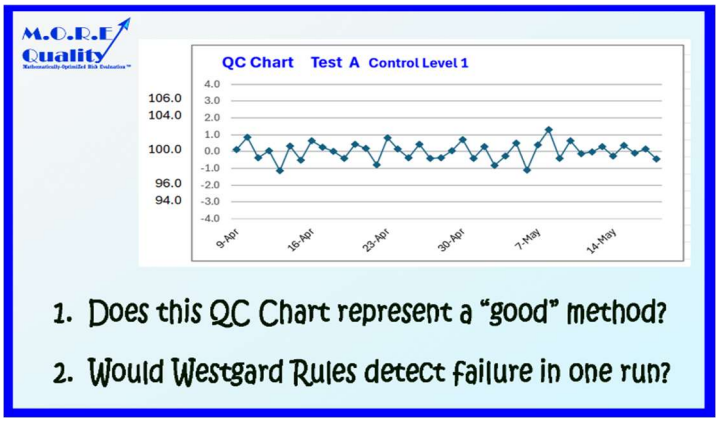
Repeat after me: "You cannot judge quality with only a QC Chart!"

Zoe C. Brooks, ElevateQC June 12,2025

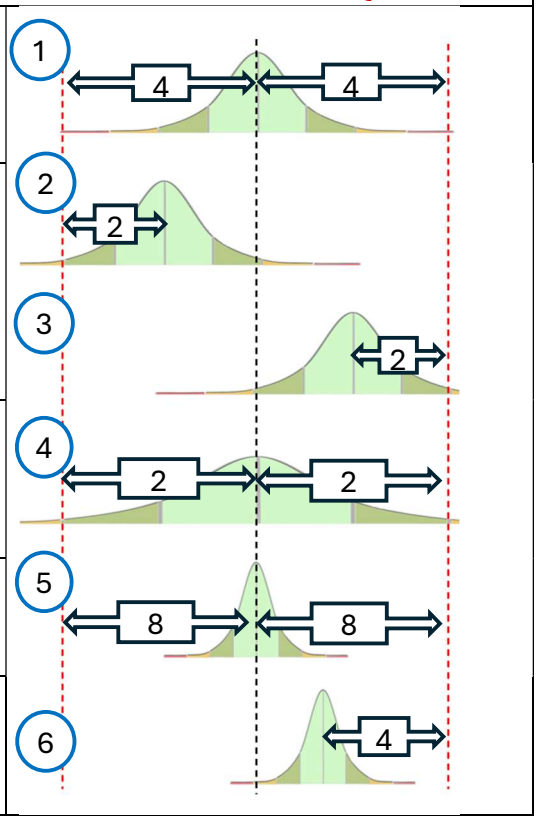


I posted this question recently on LinkedIn and finally, after several thousand views, someone asked:

"Dear Zoe. Would you please let us know what is the APS, Analytical Performance Specification selected for this test ? Or would you please let us know what test is to look for options of APS.

Without APS is almost impossible to know if the performance is good or bad."

The only information on this chart is that the assigned chart mean is 100.0 and chart SD is 2.0. From the pattern of data distribution you can see that the measured mean is also 100.0, the measured SD is probably 1.0, and the method accuracy and precision are stable. Polls over the years revealed that many laboratory professionals believe that "if the QC chart looks good, the method is good." In fact, the method represented in this QC chart may be "good" or "bad." You cannot judge analytical process quality with only a QC chart. In order to evaluate analytical process quality you need to know both the true value and allowable error limit (TEa), or Analytical Performance Standard (APS.)

These Risk Distribution curves have a measured mean of 100.0 and SD of 1.0 as on the QC chart.	
If the QC sample has a true value of 100.0 and TEa of 4.0, then bias is zero and sigma value = 4.0. Sigma is the number of SD from the mean to the nearest TEa limit and is calculated as calculated as [(TEa - |bias|)/SD] or [(4.0-0)/1.0].	
If the QC sample has a true value of 102 and TEa of 4.0, then bias is -2.0 and sigma value = 2.0. If the QC sample has a true value of 98.0 and TEa of 4.0, then bias is +2.0. Sigma is again 2.0. Sigma is insensitive to changes in bias as it uses the absolute bias for ease of calculation. Bias, however, can be clinically important.	
In Case 4, the measured mean and SD are the same as in other cases; the true value is 100.0 and the TEa is only 2.0. Bias and total error are the same as Case 1, but sigma is 2.0 (the same as in Cases 2 and 3.	
In Case 5, the true value remains at 100.0 but TEa is increased to 8.0. Bias and Total Error are the same as Case 1, but sigma (the number of SD to the nearest TEa) increases to 8.0.	
In Case 6, the true value is 96.0 and TEa is again 8.0. This method has an obvious positive bias and sigma becomes 4.0.	

The same measured mean and SD does not equate to the same method quality.

The same sigma value does not equate to the same clinical implication.

It is absolutely impossible to answer the question "Does this chart represent a good method " unless you know the true value and the allowable error limit. In fact you also need to know the acceptable risk level for this method, but that is a topic for deeper exploration in future posts and in online courses.

The Risk Distribution Curves display the measured mean and SD relative to the true value and allowable error limits or Analytical performance Standards. They allow you to visualize sigma as the number of SD to the nearest TEa limit and to see if the method has significant bias or imprecision.

Do you, or can you, evaluate acceptability of patient risk with only a sigma value? That is a topic to explore in more detail with other case studies, in online educational courses and at upcoming meetings of LabLogic Innovators https://lablogicinnovators.com.

The Measured Mean and SD alone cannot predict risk metrics such as bias, sigma or total error.							
		Case 1	Case 2	Case 3	Case 4	Case 5	Case 6
Risk Drivers	Measured Mean	100.0	100.0	100.0	100.0	100.0	100.0
	Measured SD	1.0	1.0	1.0	1.0	1.0	1.0
	True Value	100.0	102.0	98.0	100.0	100.0	96.0
	TEa	4.0	4.0	4.0	2.0	8.0	8.0
Statistical indicators vary with changes in risk drivers.	Bias	0.0	-2.0	2.0	0.0	0.0	4.0
	Sigma	4.0	2.0	2.0	2.0	8.0	4.0
	TE (2.0)	2.0	4.0	4.0	2.0	2.0	6.0
	TE (1.65)	1.65	3.65	3.65	1.65	1.65	5.65

Please repeat after me: **"You cannot judge quality with only a QC Chart!"** and stay tuned for a subsequent post where we'll answer the question "Would this chart detect would Westgard rules detect failure in a single run?"

I look forward to your comments. *Let's talk about managing patient risk, not just managing statistics!*

Prof Zoe

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