‘RISK ASSESSMENT’ QC METRICS MADE EASY

Verification of Statistics used in an Interactive PDF Application for Measuring Analytical Process Quality

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Preface:

- During the past years, I've attended several very excellent QC seminars, and collected numerous articles that discuss use of various tools or metrics for improving Clinical Laboratory QC processes. Calculations are explained along with descriptive charts and graphs. The user is then left to his own means to put this knowledge to good use.
- As a personal challenge, I took on creating a SmartLabTool to simplify those calculations, and make it available to the laboratory community.
- In order to validate the math, I needed to demonstrate that I could emulate math shown by the 'Experts'.

The Math is not always obvious

- The math I've used is shown on the next slide.
- Not everyone does the math the same way, as you will see in the examples shown.
- The following slides contain examples of use for the various metrics.
- The math is best reproduced when starting with the raw data.., of which I found few examples on the web.
- In some cases, I needed to take the math calculations to 4 decimal places, as this made a difference when reproducing others work.

Parameter	Terminology / Calculations
Mean(True)	As Published, Insert, Peer, Target
Mean(Obsv)	Observed Lab Mean from between day testing
SD(Obsv)	Lab Standard Deviation from between day testing
%CV	100 * SD / Mean(True), **or ? 100 * SD/ Mean(Obsv)**
Bias	Mean(True) – Mean(Obsv)
%Bias	100 * [(Mean(Obsv) – Mean(True)] / Mean(True) **or ? 100 * [Mean(Obsv) – Mean(True)] / Mean(Obsv)**
%TEa	Total Allowable Error (ATE), as with CLIA PT %CV
Imprecision	[SD(Obsv) * Zp] Zp is '2' for 2SD Limit
TE or TAE	Total Analytic Error = (Bias + Imprecision)
TEa or ATE	Total Error Allowed = Mean(True) * CLIA PT %CV
TE/TEa	Ratio: <1.0 is Acceptable, 0.33 or less desired
ME units	Margin for Error = (TEa – TE)
ME in SD	Margin for Error = (TEa – TE) / SD
Critical Systematic Error (ΔSE_{crit})	[(%TEa - %Bias) / CV%] – 1.65
Sigma, Sigma-Metric	(%TEa - %Bias) / %CV
TEB(%)	Total Error Budget = (TE/TEa) * 100, 33% or less desired

A Completed Template

- The following 2 pages demonstrate use of the template.
- The data was taken from a clients monthly QC summary report for illustration purposes only.
- **For Interpretation**, You will want to consult multiple references to decide how to best utilize this tool in your laboratory. Some uses include:
  - - Calculating Total Error and Comparing vs. Allowed Tolerance Limits
  - - Monitoring Accuracy (bias) and CV% (imprecision)
  - - For establishing QC Rules, and number of QC's to run
- Importantly consider the reference used for Total Allowable Error – Links to 3 sites for Allowable Error tables are on the 2nd page.

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Evaluate QC Performance vs. Allowable Error Limits 4.3

Reset Data | Reset Form

IMA - ACCESS-II Chemistry QC Evaluation BioRad Lot# 40841,43 03/15

Z = 2.0

Analyte & TEa Reference	Ctrl	True Mean	Obsv Mean	Obsv SD	Obsv %CV	Bias Units	%Bias	Imprec Units	TE Units	%TEa Limit	TEa Units	TE/TEa Ratio	%TE	ME Units	ME SD	Delta SEcrit	Sigma Metric
E2 - (CVb)	1	95.0	94.2	11.4	12.000	-0.80	0.8421	22.80	23.60	27.20	25.84	0.91	24.84	2.24	0.20	0.55	2.20
E2 - (CVb)	3	921.5	923.2	57	6.19	1.70	0.18	114.00	115.70	27.20	250.65	0.46	12.56	134.95	2.37	2.72	4.37
FERR - (CVb)	1	22.4	23.1	1.68	7.50	0.70	3.13	3.36	4.06	16.90	3.79	1.07	18.13	-0.27	-0.16	0.19	1.84
FERR - (CVb)	3	347	353	19.7	5.68	6.00	1.73	39.40	45.40	16.90	58.64	0.77	13.08	13.24	0.67	1.02	2.67
FOL - (CVb)	1	2.80	2.74	0.15	5.36	-0.06	2.14	0.30	0.36	39.00	1.09	0.33	12.86	0.73	4.88	5.23	6.88
FOL - (CVb)	3	13.45	13.1	0.61	4.54	-0.35	2.60	1.22	1.57	39.00	5.25	0.30	11.67	3.68	6.03	6.38	8.03
FSH - (CVb)	1	6.81	6.46	0.47	6.90	-0.35	5.14	0.94	1.29	21.20	1.44	0.89	18.94	0.15	0.33	0.68	2.33
FSH - (CVb)	3	38	37.6	1.97	5.18	-0.40	1.05	3.94	4.34	21.20	8.06	0.54	11.42	3.72	1.89	2.24	3.89
FT3 - (CVb)	1	2.29	2.31	0.09	3.93	0.02	0.87	0.18	0.20	11.30	0.26	0.77	8.73	0.06	0.65	1.00	2.65
FT3 - (CVb)	3	8.99	8.91	0.56	6.23	-0.08	0.89	1.12	1.20	11.30	1.02	1.18	13.35	-0.18	-0.33	0.02	1.67
FT4 - (CVb)	1	0.70	0.69	0.04	5.71	-0.01	1.43	0.08	0.09	11.20	0.08	1.15	12.86	-0.01	-0.29	0.06	1.71
FT4 - (CVb)	3	3.83	3.87	0.16	4.18	0.04	1.04	0.32	0.36	11.20	0.43	0.84	9.40	0.07	0.43	0.78	2.43
LH - (CVb)	1	1.8	1.74	0.11	6.11	-0.06	3.33	0.22	0.28	27.90	0.50	0.56	15.56	0.22	2.02	2.37	4.02
LH - (CVb)	3	54	53.8	3.43	6.35	-0.20	0.37	6.86	7.06	27.90	15.07	0.47	13.07	8.01	2.33	2.68	4.33
PRL - (CVb)	1	7.80	7.79	0.17	2.18	-0.01	0.13	0.34	0.35	29.40	2.29	0.15	4.49	1.94	11.43	11.78	13.43
PRL - (CVb)	3	39.3	38.7	1.7	4.33	-0.60	1.53	3.40	4.00	29.40	11.55	0.35	10.18	7.55	4.44	4.79	6.44
PSA - (CVb)	1	0.40	0.42	0.015	3.75	0.02	5.00	0.03	0.05	33.60	0.13	0.37	12.50	0.08	5.63	5.98	7.63
PSA - (CVb)	3	32.1	31.56	1.57	4.89	-0.54	1.68	3.14	3.68	33.60	10.79	0.34	11.46	7.11	4.53	4.88	6.53
TT3 - (3SD)	1	0.80	0.90	0.047	5.88	0.10	12.50	0.09	0.19	34.10	0.27	0.71	24.25	0.08	1.68	2.03	3.68
TT3 - (3SD)	3	2.79	2.84	0.15	5.38	0.05	1.79	0.30	0.35	23.80	0.66	0.53	12.54	0.31	2.09	2.44	4.09
T4 - (CLIA)	1	7.19	7.11	0.4	5.56	-0.08	1.11	0.80	0.88	20.00	1.44	0.61	12.24	0.56	1.40	1.75	3.40
T4 - (CLIA)	3	16.83	17.10	0.65	3.86	0.27	1.60	1.30	1.57	20.00	3.37	0.47	9.33	1.80	2.76	3.11	4.76
TSH - (CVb)	1	0.184	0.188	0.02	10.87	0.00	2.17	0.04	0.04	38.30	0.07	0.62	23.91	0.03	1.33	1.67	3.32
TSH - (CVb)	3	25.2	26.3	1.37	5.44	1.10	4.37	2.74	3.84	38.30	9.65	0.40	15.24	5.81	4.24	4.59	6.24

Mean(True) - as Published, Insert, Peer, Target
Mean(Obsv) - Observed Lab Mean from between day testing
SD(Obsv) - Lab Standard Deviation - between day testing
%CV(Obsv) - Calc. 100 * (SD / Mean(True))
Bias - Mean(True) - Mean(Obsv)
%Bias - 100 * ((Mean(Obsv) - Mean(True)) / Mean(True)
%TEa - Total Allowable Error (ATE), as with CLIA PT %CV
Imprecision - (SD(Obsv) * Zp), Zp is '2' for 2SD Limit

TE or TAE - Total Analytic Error = (Bias + Imprecision)
TEa or ATE - Total Error Allowed = (Mean(True) * CLIA PT %CV)
TE/TEa - <1.0 is Acceptable, .33 or Less Desired
%TE - %TE = %Bias + Zp * %CV
ME units - Margin for Error = (TEa - TE)
ME in SD - Margin for Error = (TEa - TE) / SD
Delta SEcrit - ((%TEa - %Bias) / CV%) - 1.65
Sigma Metric - (%TEa - %Bias) / CV%

Comments: ESTIMATED LEVEL RELATED 3SD LIMITS FOR T3 FROM API Q115

Reviewed by: 04/22/2015

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Quality Control Performance Limits (SD's) vs. TEa

BV (TEa Limits) | Rhoades (TEa) | CLIA PT Limits

IMA - ACCESS-II Chemistry QC Evaluation BioRad Lot# 40841,43 03/15

Analyte & TEa Reference	Ctrl	True Mean	Obsv Mean	Obsv SD	TEa Low	TEa High	2.0 SD Low	2.0 SD High	2.5 SD Low	2.5 SD High	3.0 SD Low	3.0 SD High	3.5 SD Low	3.5 SD High	4.0 SD Low	4.0 SD High	TEB %
E2 - (CVb)	1	95	94.2	11.4	69.16	120.84	71.40	117.00									91
E2 - (CVb)	3	921.5	923.2	57	670.85	1172.15	809.20	1037.20	780.70	1065.70	752.20	1094.20	723.70	1,122.70	695.20	1151.20	46
FERR - (CVb)	1	22.4	23.1	1.68	18.61	26.19	19.74	26.46	18.90								107
FERR - (CVb)	3	347	353	19.7	288.36	405.64	313.60	392.40	303.75	402.25	293.90						77
FOL - (CVb)	1	2.8	2.74	0.15	1.71	3.89	2.44	3.04	2.37	3.12	2.29	3.19	2.22	3.27	2.14	3.34	33
FOL - (CVb)	3	13.45	13.1	0.61	8.20	18.70	11.88	14.32	11.58	14.63	11.27	14.93	10.97	15.24	10.66	15.54	30
FSH - (CVb)	1	6.81	6.46	0.47	5.37	8.25	5.52	7.40		7.64		7.87		8.11			89
FSH - (CVb)	3	38	37.6	1.97	29.94	46.06	33.66	41.54	32.68	42.53	31.69	43.51	30.71	44.50		45.48	54
FT3 - (CVb)	1	2.29	2.31	0.09	2.03	2.55	2.13	2.49	2.09	2.54	2.04						77
FT3 - (CVb)	3	8.99	8.91	0.56	7.97	10.01	7.79	10.03									118
FT4 - (CVb)	1	0.7	0.69	0.04	0.62	0.78	0.61	0.77									115
FT4 - (CVb)	3	3.83	3.87	0.16	3.40	4.26	3.55	4.19	3.47								84
LH - (CVb)	1	1.8	1.74	0.11	1.30	2.30	1.52	1.96	1.47	2.02	1.41	2.07	1.36	2.13	1.30	2.18	56
LH - (CVb)	3	54	53.8	3.43	38.93	69.07	46.94	60.66	45.23	62.38	43.51	64.09	41.80	65.81	40.08	67.52	47
PRL - (CVb)	1	7.8	7.79	0.17	5.51	10.09	7.45	8.13	7.37	8.22	7.28	8.30	7.20	8.39	7.11	8.47	15
PRL - (CVb)	3	39.3	38.7	1.7	27.75	50.85	35.30	42.10	34.45	42.95	33.60	43.80	32.75	44.65	31.90	45.50	35
PSA - (CVb)	1	0.4	0.42	0.015	0.27	0.53	0.39	0.45	0.38	0.46	0.38	0.47	0.37	0.47	0.36	0.48	37
PSA - (CVb)	3	32.1	31.56	1.57	21.31	42.89	28.42	34.70	27.64	35.49	26.85	36.27	26.07	37.06	25.28	37.84	34
TT3 - (3SD)	1	0.8	0.9	0.047	0.53	1.07	0.81	0.99	0.78	1.02	0.76	1.04	0.74	1.06	0.71		71
TT3 - (3SD)	3	2.79	2.84	0.15	2.13	3.45	2.54	3.14	2.47	3.22	2.39	3.29	2.32	3.37	2.24	3.44	53
T4 - (CLIA)	1	7.19	7.11	0.4	5.75	8.63	6.31	7.91	6.11	8.11	5.91	8.31		8.51			61
T4 - (CLIA)	3	16.83	17.1	0.65	13.46	20.20	15.80	18.40	15.48	18.73	15.15	19.05	14.83	19.38	14.50	19.70	47
TSH - (CVb)	1	0.184	0.188	0.02	0.11	0.25	0.15	0.23	0.14	0.24	0.13	0.25	0.12				62
TSH - (CVb)	3	25.2	26.3	1.37	15.55	34.85	23.56	29.04	22.88	29.73	22.19	30.41	21.51	31.10	20.82	31.78	40

Comments:

TEB(%) = Total Error Budget = (TE/Tea)*100,
TEB(%) should not exceed 50%; 33% or less is desired.

Reviewed by: 04/22/2015

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Evaluate QC Performance vs. Allowable Error Limits

Check Calculations of TE, TE/TEa, SEc vs. P. Painter Presentation

Reset Data | Reset Form | Z = 1.96

Analyte & TEa Reference	Ctrl	True Mean	Obsv Mean	Obsv SD	Obsv %CV	Bias Units	%Bias	Imprec Units	TE Units	%TEa Limit	TEa Units	TE/TEa Ratio	%TE	ME Units	ME SD	Delta SEcrit	Sigma Metric
Example 1		200	210	5.0	2.50	10.00	5.00	9.80	19.80	10.00	20.00	0.99	9.90	0.20	0.04	0.35	2.00
Example 2		200	205	5.0	2.50	5.00	2.50	9.80	14.80	10.00	20.00	0.74	7.40	5.20	1.04	1.35	3.00

Source:

"How-Should-I" Guide to Laboratory Quality Control and Proficiency Testing

by Pennell C. Painter, PhD
COLA Symposium for Clinical Laboratories, 2007

Mean Pub:	200	SD Obs:	5	TEa:	20
-		X	1.96	-	
Mean Obs:	210			BIAS:	10
	---		---	/	
BIAS =	10	Imprecision =	9.8	SD Obs:	5
				-	
					1.65
TOTAL ERROR		**TOTAL Allowed ERROR**			---
BIAS:	10	Mean Pub:	200	Delta SEc	0.35
+		x			
Imprecision:	9.8	CMS PT %:	10		
	---		---		
TE =	19.8	TEa =	20		
TE/TEa =	0.99	Less than 1.0 is Acceptable			

△ **SEc is the Number of SD's the QC Mean Can Shift before 5% of Results Will Exceed the Defined TEa**

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Evaluate QC Performance vs. Allowable Error Limits

Check Calculations of TE, TE/TEa, SEc vs. P. Painter Presentation

Reset Data | Reset Form | Z = 1.96

Analyte & TEa Reference	Ctrl	True Mean	Obsv Mean	Obsv SD	Obsv %CV	Bias Units	%Bias	Imprec Units	TE Units	%TEa Limit	TEa Units	TE/TEa Ratio	%TE	ME Units	ME SD	Delta SEcrit	Sigma Metric
Example 1		200	210	5.0	2.50	10.00	5.00	9.80	19.80	10.00	20.00	0.99	9.90	0.20	0.04	0.35	2.00
Example 2		200	205	5.0	2.50	5.00	2.50	9.80	14.80	10.00	20.00	0.74	7.40	5.20	1.04	1.35	3.00

Source:

"How-Should-I" Guide to Laboratory Quality Control and Proficiency Testing

by Pennell C. Painter, PhD *COLA Symposium for Clinical Laboratories, 2007*

Mean Pub:	200	SD Obs:	5	TEa:	20
-		X	1.96	-	
Mean Obs:	205			BIAS:	5
	---		---	/	
BIAS =	5	Imprecision =	9.8	SD Obs:	5
				-	
					1.65
TOTAL ERROR		**TOTAL Allowed ERROR**			---
BIAS:	5	Mean Pub:	200	Delta SEc	1.35
+		X			
Imprecision:	9.8	CMS PT %:	10		
	---		---		
TE =	14.8	TEa =	20		
TE/TEa =	0.74	Less than 1.0 is Acceptable			

Bias decrease from 10 to 5 mg/dL decreased TE/TEa and increased Delta SEc

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Evaluate QC Performance vs. Allowable Error Limits

Plaut "Using Correct SDs and Means together with TE and TEa"

Reset Data | Reset Form | Z = 2.0

Analyte & TEa Reference	Ctrl	True Mean	Obsv Mean	Obsv SD	Obsv %CV	Bias Units	%Bias	Imprec Units	TE Units	%TEa Limit	TEa Units	TE/TEa Ratio	%TE	ME Units	ME SD	Delta SEcrit	Sigma Metric
Lab SD =		50	52	3.0	6.00	2.00	4.00	6.00	8.00	18.00	9.00	0.89	16.00	1.00	0.33	0.68	2.33
Arbitrary SD =		50	52	5.0	10.00	2.00	4.00	10.00	12.00	18.00	9.00	1.33	24.00	-3.00	-0.60	-0.25	1.40

TE > TEa, QC System is NOT in Control

"The TE must be less than the TEa for the QC system to be in control"

- **Not using lab measured SDs and Means – can have ramifications**
  - QC will appear in more often
  - Analytical system may develop an error missed by incorrect mean or SD
  - Lead to erroneous data reported to staff – potential missed diagnosis
- **Use both TE (Total Error) and TEa (Total Error allowed) with YOUR QC data**
- **Choose best QC rules based on both TE and TEa**
  - Select one or more QC rules that will detect an error that is larger than the TEa (that is when TE > TEa)

Source: Using correct SDs and Means together with TE and TEa;Lab and Risk Reduction, Part 6 D. Plaut, ADVANCE

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Evaluate QC Performance vs. Allowable Error Limits

Check Calculations vs. Zoe Brooks Article

Reset Data | Reset Form | Z = 2.0

Analyte & TEa Reference	Ctrl	True Mean	Obsv Mean	Obsv SD	Obsv %CV	Bias Units	%Bias	Imprec Units	TE Units	%TEa Limit	TEa Units	TE/TEa Ratio	%TE	ME Units	ME SD	Delta SEcrit	Sigma Metric
Example-1		100	100	1	1.00	0.00	0.00	2.00	2.00	10.00	10.00	0.20	2.00	8.00	8.00	8.35	10.00
Example-2		100	106	1	1.00	6.00	6.00	2.00	8.00	10.00	10.00	0.80	8.00	2.00	2.00	2.35	4.00
Example-3		100	100	2.5	2.50	0.00	0.00	5.00	5.00	10.00	10.00	0.50	5.00	5.00	2.00	2.35	4.00

Source: Quality Control: Save Money, Reduce Risks
on ADVANCE for Administrators of the Laboratory – by David Plaut, Zoe Brooks, and Kim Przekop – Nov. 27, 2014

Analyte	Ceramic
True	100.0
TEa =	10.0
Mean =	100.0
SD =	1.00
Acceptable?	Yes

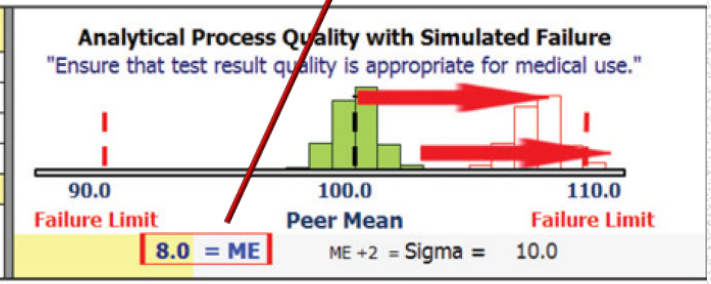

Fig 1. Ceramic Method 1

Analyte	Ceramic
True	100.0
TEa =	10.0
Mean =	106.0
SD =	1.00
Acceptable?	Yes

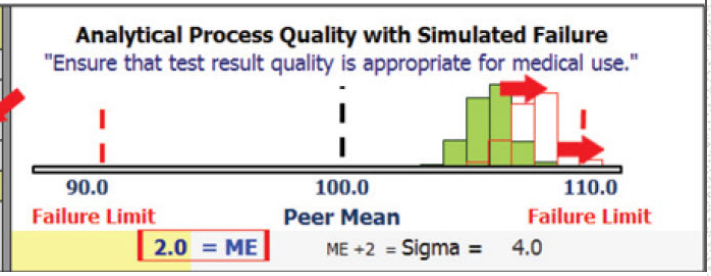

Fig 2. Ceramic Method 2

Analyte	Ceramic
True	100.0
TEa =	10.0
Mean =	100.0
SD =	2.50
Acceptable?	Yes

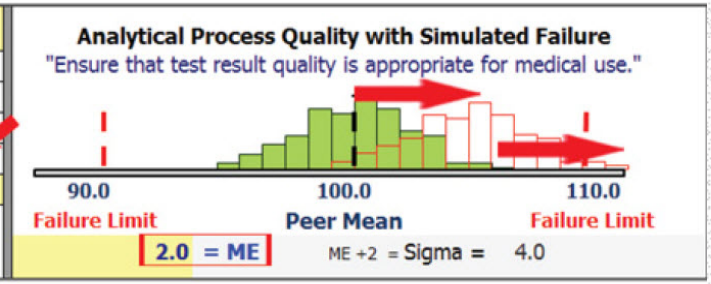

Fig 3. Ceramic Method 3

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Evaluate QC Performance vs. Allowable Error Limits

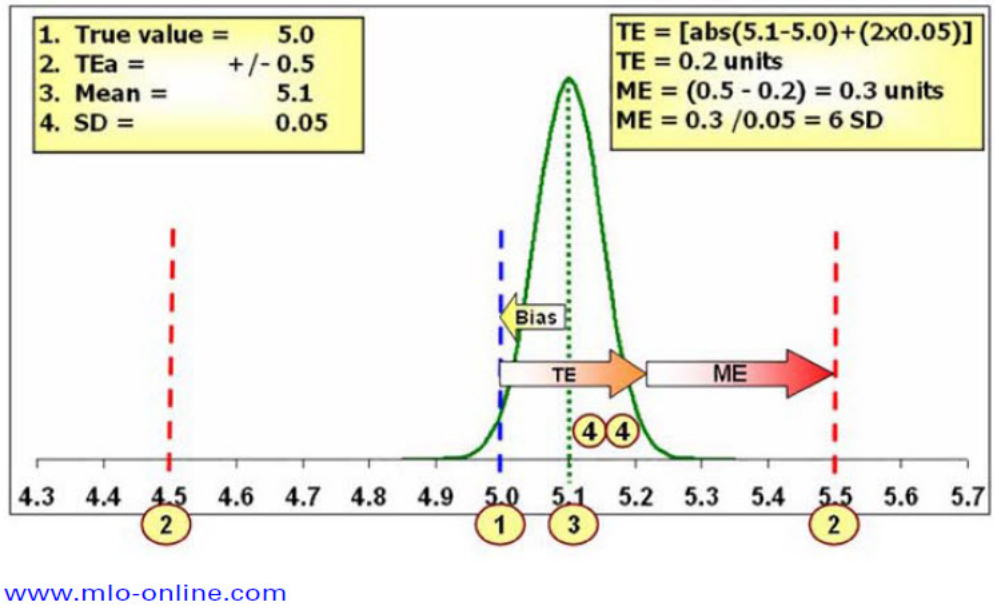
Reset Data | Reset Form | Z = 2.0

Check Calculations of TE, ME from Zoe Article MLO

Analyte & TEa Reference	Ctrl	True Mean	Obsv Mean	Obsv SD	Obsv %CV	Bias Units	%Bias	Imprec Units	TE Units	%TEa Limit	TEa Units	TE/TEa Ratio	%TE	ME Units	ME SD	Delta SEcrit	Sigma Metric
Example		5.0	5.1	0.05	1.00	0.10	2.00	0.10	0.20	10.00	0.50	0.40	4.00	0.30	6.00	6.35	8.00

*"The **Margin for Error** is simply the total allowable error minus the total error. Divide it by the SD to know how many SD the mean can shift before results will exceed allowable error limits."*

Figure 2: Illustration of concept of margin for error



Source: Use some horse sense with QC By Zoe Brooks and Carol Wambolt – MLO March, 2007

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Evaluate QC Performance vs. Allowable Error Limits

Check Calculations vs. BioRad Article for TE, TEB% and Sigma

Reset Data | Reset Form | Z = 1.645

Analyte & TEa Reference	Ctrl	True Mean	Obsv Mean	Obsv SD	Obsv %CV	Bias Units	%Bias	Imprec Units	TE Units	%TEa Limit	TEa Units	TE/TEa Ratio	%TE	ME Units	ME SD	Delta SEcrit	Sigma Metric
Example 1		100	102.5	4.5	4.50	2.50	2.50	7.40	9.90	10.00	10.00	0.99	9.90	0.10	0.02	0.02	1.67
Example 2		100	101.5	4.0	4.00	1.50	1.50	6.58	8.08	10.00	10.00	0.81	8.08	1.92	0.48	0.48	2.13
Example 3		100	101.0	2.5	2.50	1.00	1.00	4.11	5.11	10.00	10.00	0.51	5.11	4.89	1.96	1.95	3.60
Example 4		100	100.5	1.7	1.70	0.50	0.50	2.80	3.30	10.00	10.00	0.33	3.30	6.70	3.94	3.94	5.59

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Quality Control Performance Limits (SD's) vs. TEa

Check Calculations vs. BioRad Article for TE, TEB% and Sigma

BV (TEa Limits) | Rhoades (TEa) | CLIA PT Limits

Analyte & TEa Reference	Ctrl	True Mean	Obsv Mean	Obsv SD	TEa Low	TEa High	2.0 SD Low	2.0 SD High	2.5 SD Low	2.5 SD High	3.0 SD Low	3.0 SD High	3.5 SD Low	3.5 SD High	4.0 SD Low	4.0 SD High	TEB %
Example 1		100	102.5	4.5	90.00	110.00	93.50	111.50	91.25								99
Example 2		100	101.5	4	90.00	110.00	93.50	109.50	91.50								81
Example 3		100	101	2.5	90.00	110.00	96.00	106.00	94.75	107.25	93.50	108.50	92.25	109.75	91.00		51
Example 4		100	100.5	1.7	90.00	110.00	97.10	103.90	96.25	104.75	95.40	105.60	94.55	106.45	93.70	107.30	33

The total error budget (TEB) is a quantity that relates the laboratory's test system process capability (TE) to the laboratory's quality requirement (TEa):

*TEB = 100*TE / TEa*

TEB reflects the percentage of the TEa in patient results that is "consumed" by the laboratory's inherent test system

Table 2

TEB and Sigma With TEa = 10% as Bias and Imprecision Decrease

Bias	CV	TE	TEB	Sigma
2.5%	4.5%	2.5+1.645*4.5 = 9.9%	100*9.9/10 = 99%	(10-2.5)/4.5 = 1.67
1.5%	4.0%	1.5+1.645*4.0 = 8.1%	100*8.1/10 = 81%	(10-1.5)/4.0 = 2.12
1.0%	2.5%	1.0+1.645*2.5 = 5.1%	100*5.1/10 = 51%	(10-1.0)/2.5 = 3.60
0.5%	1.7%	0.5+1.645*1.7 = 3.3%	100*3.3/10 = 33%	(10-0.5)/1.7 = 5.59

Source: Sigma Metrics, Total Error Budgets & QC on ADVANCE for Administrators of the Laboratory By Curtis A. Parvin, PhD, John Yundt-Pacheco and Max Williams – 01/ 2012

Smart LabTools

Evaluate QC Performance vs. Allowable Error Limits

Plaut - "Six Sigma and the Laboratory - Part 3" ADVANCE March, 2015

Reset Data | Reset Form | Z = 2.0

Analyte & TEa Reference	Ctrl	True Mean	Obsv Mean	Obsv SD	Obsv %CV	Bias Units	%Bias	Imprec Units	TE Units	%TEa Limit	TEa Units	TE/TEa Ratio	%TE	ME Units	ME SD	Delta SEcrit	Sigma Metric
Example Data		100	103	1.5	1.50	3.00	3.00	3.00	6.00	10.00	10.00	0.60	6.00	4.00	2.67	3.02	4.67

sigma (SD)

The idea of six sigma (or standard deviation for us in this article) came from Motorola in the 1980s as a way to reduce shipping defective product. For us, that means reporting errors to the clinicians. One way to do this is during the analytical phase of the laboratory's work to reduce the SD or random error.

SDs from mean	Per million	Per thousand
6	0.0012	0.0000012
5	0.29	0.0002867
4.5	3.4	0.0033977
4	32	0.0316713
3	1350	1.3498981
2	52800	52.8
1	160000	160

Let's say that now your SD for glucose of 1.5 mg/dL and that your bias (your mean - group mean) is 3 mg/dL. The CLIA limit is 10 percent. So, if the group mean is 100, the CLIA limit is 10 mg/dL. Your total error is 3+2*(1.5) or 6. You are 4 units from the CLIA limit. That means that, given your SD of 1.5, you have a 2.7 sigma (SD) method (2.7 = 4/1.5). According to the chart below, you would report about 1 of 1000 runs that exceeded the CLIA limit before detecting the error and holding the patients' results. Keep in mind that this number of 1 in 1000 is runs - not patients.

Smart LabTools

Evaluate QC Performance vs. Allowable Error Limits

Q & A: Do I Need 4:1s and 10x rules - Westgard / verify sigma calcs.

Reset Data | Reset Form | Z = 2.0

Analyte & TEa Reference	Ctrl	True Mean	Obsv Mean	Obsv SD	Obsv %CV	Bias Units	%Bias	Imprec Units	TE Units	%TEa Limit	TEa Units	TE/TEa Ratio	%TE	ME Units	Margin for Error	Delta SEcrit	Sigma Metric
Westgard		1.24	1.2725	0.0165	1.297	0.03	2.55	0.03	0.07	8.74	0.11	0.60	5.15	0.04	2.60	3.12	4.77
Ricos Sigma		4.14	3.992	0.125	3.13	-0.15	3.71	0.25	0.40	8.74	0.36	1.10	9.97	-0.04	-0.29	-0.04	1.61

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Westgard Example - Same Example with Current Template

Z = 2.0

Analyte & TEa Reference	Ctrl	True Mean	Obsv Mean	Obsv SD	Obsv %CV	Bias Units	%Bias	Imprec Units	TE Units	%TEa Limit	TEa Units	TE/TEa Ratio	%TE	ME Units	ME SD	Delta SEcrit	Sigma Metric
Westgard		1.24	1.2725	0.0165	1.3306	0.03	2.6210	0.03	0.07	8.74	0.11	0.60	5.28	0.04	2.60	2.95	4.60
Ricos Sigma		4.14	3.992	0.125	3.02	-0.15	3.57	0.25	0.40	8.74	0.36	1.10	9.61	-0.04	-0.29	0.06	1.71

Comment: *math used for calculating the %Bias and %CV can potentially yield a different Sigma. Which math is more appropriate?*

Current Validated Template:

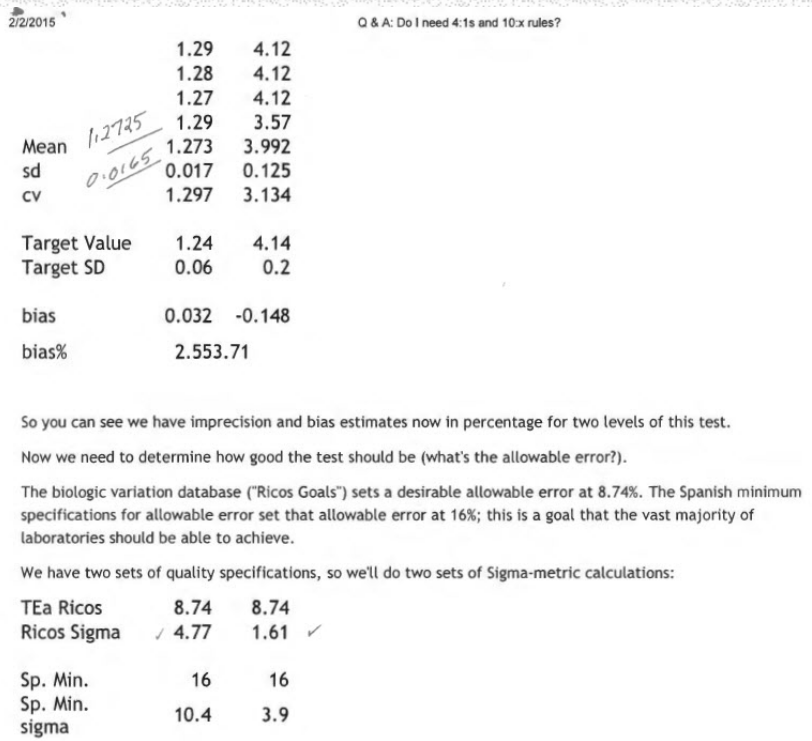
*%CV = 100 * (SD)/(True Mean)*

*%Bias = 100 * (Bias Units)/(True Mean)*

Modified Template to match Example:

%CV = 100 (SD)/(Obsv Mean)*

%Bias = 100 (Bias Units)/(Obsv Mean)*



2/2/2015

Q & A: Do I need 4:1s and 10:x rules?

	1.29	4.12
	1.28	4.12
	1.27	4.12
	1.29	3.57
Mean	1.273	3.992
sd	0.017	0.125
cv	1.297	3.134
Target Value	1.24	4.14
Target SD	0.06	0.2
bias	0.032	-0.148
bias%	2.553.71	

So you can see we have imprecision and bias estimates now in percentage for two levels of this test.

Now we need to determine how good the test should be (what's the allowable error?).

The biologic variation database ("Ricos Goals") sets a desirable allowable error at 8.74%. The Spanish minimum specifications for allowable error set that allowable error at 16%; this is a goal that the vast majority of laboratories should be able to achieve.

We have two sets of quality specifications, so we'll do two sets of Sigma-metric calculations:

TEa Ricos	8.74	8.74
Ricos Sigma	4.77	1.61
Sp. Min.	16	16
Sp. Min. sigma	10.4	3.9

References:

- **“How-Should-I” Guide to Laboratory Quality Control and Proficiency Testing** by Pennell C. Painter, PhD *COLA Symposium for Clinical Laboratories, 2007*
- **ADVANCE Magazine – Multitude of informative QC articles by David Plaut, Zoe Brooks, Curtis Parvin & many other contributers**
- **MLO Magazine – QC Articles**
- **BioRad qcnet.com – Informative publications, youtube QC videos**
- **ASCP – QC Seminars I’ve attended**
- **AACC – QC Seminars I’ve attended**
- **Westgard.com – The Ultimate Source of QC information**

- END -

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