



QUALITY CONTROL SYSTEM

‘A Simplified Approach to Meeting Basic Laboratory QC Requirements’

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Disclosures – Daniel Leighton, Consulting LLC

- I'm the creator and owner of SmartLabTools™ PDF applications & website; providing software solutions and education for assisting clinical laboratories in maintaining quality and regulatory compliance.
- By taking the '*Road Less Traveled*' Java-Scripted interactive PDF's for lab calculations, and other fill-in-the-blanks desktop tools have been created for ease of use in clinical laboratories.
- Many Tools are FREE and being downloaded all over the world; others support the website.
- Links connect to contributions by experts in the industry, and professional resources for which I have no financial interest

SmartLabTools™ Simplified Approach to Quality Control

For this workshop, participants will download templates, customize QC parameters, then enter QC results to demonstrate the interactive interpretation. Attendees will be provided links to FREE QC software to take back to their labs.

Following this workshop participants will be able to:

1. Set up Statistical Assessment Templates for Daily QC
2. Describe Statistical Tools used in QC data interpretation
3. Select QC Rules and Establish QC Limits
4. Set up Flagging sensitivity for alerting to potential Shifts or Trends..
(requires manual review of flagged() results)*
5. Recognize Control Outliers, and Trend Flag Alerts
6. Document Corrective Actions

(continued on slide 4)

SmartLabTools™ Simplified Approach to Quality Control

Following this workshop participants will be able to:

7. Define the QC Requirements of the Assay
8. Evaluate Published Mean and SD QC Limits
9. Use Tools to Calculate own Lab Mean and QC Limits
10. Use Tools to Calculate QC Limits using Historical CV
11. Understand the Basic Westgard Rules for QC Acceptance
12. Use of FREE QC Limits Conversion Calculator
13. Download and Customize QC Review Forms
14. Understand QC Compliance Responsibilities
15. Utilize Dropbox for QC Records and Reviews
16. Download SLT QC Procedure to Customize
17. Follow SLT Website Links to External QC Resources

'Hands-On' Workshop Housekeeping

THINGS YOU NEED TO KNOW ABOUT 'SLT INTERACTIVE PDF'S' ...

1. **CALCULATIONS** only work using 'FREE' Adobe Acrobat Reader

<https://acrobat.adobe.com/us/en/acrobat/pdf-reader.html>

2. Set Adobe Acrobat Reader as the 'DEFAULT READER' with Windows 10

<https://www.youtube.com/watch?v=w4J3a5Ps1uc>

3. Save First & Open PDF's From Your Computer, Not Mid-Way

4. Remove the Blue Highlighting.. [PowerPoint Instructions](#)

5. SLT PDF Templates can be filled in then 'Saved as', 'Copy/Paste' to duplicate.. or 'E-mailed', 'Reset' clears prior data

Smart LabTools™

Complex forms made simple.

DESCRIPTION

INSTRUCTION SESSION LINKS

SmartLabTools.com Website

<https://www.smartlabtools.com/>

SLT_105 Daily QC Assessment

https://www.smartlabtools.com/slt_105_quality_control_results_evaluation.html

SLT_100 Mean SD Calculator

https://www.smartlabtools.com/slt_100_mean_and_sd_calculator.html

SLT_111 Simple QC Range Calculator

https://www.smartlabtools.com/slt_111_simple_qc_calculator.html

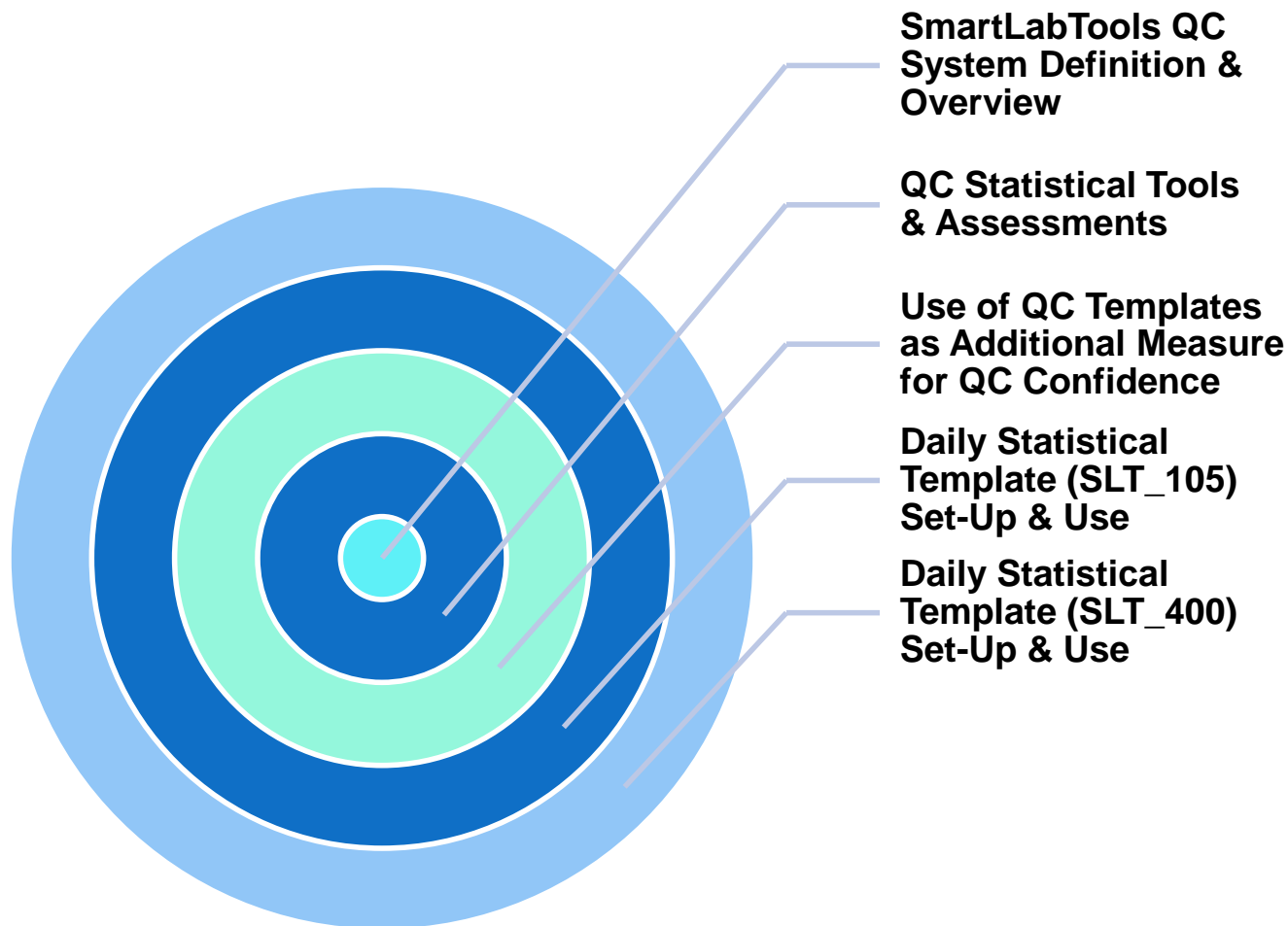
SLT QC Review Forms

https://www.smartlabtools.com/qc_review_forms.html

SLT Daily QC Written Procedure to modify

https://www.smartlabtools.com/slt_qc_procedure.html

(Section -1) QC System Overview



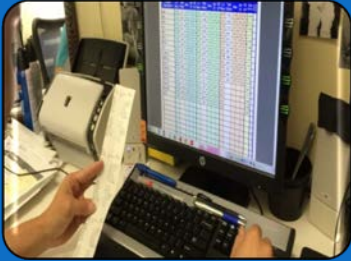
The SLT QC System

The SmartLabTools™ **Statistical Quality Control System** is comprised of a **collection of downloadable PDF templates** created to monitor the analytical performance of clinical laboratory testing. **There are NO programs to install.**

The simple to use, fill in the blanks **templates provide the immediate statistical information needed for decisions of accepting or rejecting test results** based on user defined QC limits and QC rules. The tools are widely applicable in the lab.

Analysts will require fundamental QC skills to competently implement the tools, set QC limits, use control rules, interpret QC results, and for troubleshooting. **Links to numerous educational resources are provided.**

IQCP or Regular QC ?



Whether you implement an Individualized Quality Control Program, or default CLIA regulated QC Program, you will want a means to verify that a measuring system is performing as expected.



SmartLabTools™ provides you with the resources needed to do just that with it's Statistical Calculators, L-J Charts, and QC Assessment Templates.



These downloadable PDF's require no programs to load, only the Free Adobe Acrobat PDF Reader



Definition and Overview

INSTITUTE FOR QUALITY SYSTEMS

HEMATOLOGY - ABX MICROS® 8

LOT# MX400L, MX400F, MX400H EXP: 09/05/2016

Instrument	Analyte	Low	High	CV	CV	CV	CV	CV	CV	CV	CV
17M CTL	WBC	1.00	2.41	2.41	0.20	2.00	0.00	0.00	0.00	0.00	QC
MX400L	RBC	2.21	2.31	2.31	0.00	2.21	0.17	2.27	0.00	0.00	QC
	HGB	5.70	0.50	0.50	0.20	5.70	0.10	0.00	0.00	0.00	QC
	HCT	14.00	10.00	10.00	1.00	14.00	0.10	0.10	0.00	0.00	QC
	PLT	50.00	50.00	70.00	10.00	50.00	0.00	0.00	0.00	0.00	QC
	GRAN%	10.00	10.00	20.00	2.00	10.00	0.00	0.00	0.00	0.00	QC
	LYMP%	50.00	10.00	40.00	0.00	50.00	0.00	0.00	0.10	0.00	QC
	MPO%	0.00	10.00	10.00	0.00	0.00	0.00	0.00	0.00	0.00	QC
17M CTL	WBC	0.70	0.50	0.50	0.00	0.70	0.00	0.00	0.00	0.00	QC
MX400H	RBC	4.40	4.62	4.61	0.00	4.40	0.00	0.00	0.00	0.00	QC
	HGB	13.10	14.10	13.70	0.30	13.00	0.10	0.00	0.00	0.00	QC
	HCT	35.10	40.10	37.40	1.20	32.00	0.20	0.10	0.00	0.00	QC
	PLT	70.00	200.00	100.00	10.00	70.00	0.00	0.00	0.00	0.00	QC
	GRAN%	10.00	20.00	17.00	2.00	10.00	0.00	0.00	0.10	0.00	QC
	LYMP%	50.00	40.00	35.00	0.00	50.00	0.00	0.00	0.20	0.00	QC
	MPO%	0.00	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	QC
17M CTL	WBC	0.50	1.10	1.10	0.00	0.50	0.00	0.00	0.00	0.00	QC
	HGB	15.40	17.00	16.00	0.10	15.00	0.00	0.00	0.00	0.00	QC
MX400H	RBC	5.00	6.00	5.00	0.10	5.00	0.00	0.00	0.00	0.00	QC
	HGB	17.00	19.00	18.00	0.30	16.00	0.40	1.14	0.00	0.00	QC
	HCT	48.00	54.00	50.00	1.50	50.00	0.10	0.10	0.00	0.00	QC
	PLT	60.00	170.00	100.00	10.00	60.00	0.00	0.00	0.00	0.00	QC
	GRAN%	11.00	85.00	20.00	10.00	10.00	0.00	0.00	0.00	0.00	QC
	LYMP%	11.00	71.00	16.00	0.00	10.00	0.00	0.00	0.20	0.00	QC
	MPO%	0.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	QC

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PROBING: BD Low Controls and High Controls, 1995 (see instructions)

100 - 1000 - 10000 - 100000 - 1000000 - 10000000 - 100000000 - 1000000000 - 10000000000 - 100000000000 - 1000000000000 - 10000000000000 - 100000000000000 - 1000000000000000 - 10000000000000000 - 100000000000000000 - 1000000000000000000 - 10000000000000000000 - 100000000000000000000 - 1000000000000000000000 - 10000000000000000000000 - 100000000000000000000000 - 1000000000000000000000000 - 10000000000000000000000000 - 100000000000000000000000000 - 1000000000000000000000000000 - 10000000000000000000000000000 - 100000000000000000000000000000 - 1000000000000000000000000000000 - 10000000000000000000000000000000 - 100000000000000000000000000000000 - 1000000000000000000000000000000000 - 10000000000000000000000000000000000 - 100000000000000000000000000000000000 - 1000000000000000000000000000000000000 - 10000000000000000000000000000000000000 - 100000000000000000000000000000000000000 - 1000000000000000000000000000000000000000 - 100 - 1000 - 100 - 1000 - 100 - 1000 - 100 - 1000 - 100 - 1000 - 100 - 1000 - 100 - 1000 - 100 - 1000 - 1000 - 100 - 1000 - 100 - 1000 - 100 - 1000 - 100 - 1000 - 100 - 1000 - 100 - 1000 - 100 - 1000 - 100 - 1000 - 100 - 1000 - 100 - 1000 - 100 - 1000 - 100 - 1000 - 100 - 1000 - 100 - 1000 - 100 - 1000 - 100 - 1000 - 100 - 1000 - 100 - 1000 - 100 - 1000 - 100 - 1000 - 100 - 1000 - 100 - 100 - 1000 - 100 - 1000 - 100 - 1000 - 100 - 1000 - 100 - 100 - 100 - 100 - 100 - 1000 - 1000 - 100 - 1000 - 100 - 1000 - 1000 - 100 - 1000 - 100 - 1000 - 100 - 1000 - 100 - 1000 - 100 - 100 - 1000 - 100 - 1000 - 1000

SmartLabTools™ Quality Control System provides a simplified practical approach to the immediate assessment of quality control data through the use of a collection of PDF™ templates programmed with statistical calculations necessary to assist the operator in determining if a quality control result is acceptable.

Patient	Test	Result	QC
17M CTL	WBC	1.00	QC
17M CTL	RBC	2.21	QC
17M CTL	HGB	5.70	QC
17M CTL	HCT	14.00	QC
17M CTL	PLT	50.00	QC
17M CTL	GRAN%	10.00	QC
17M CTL	LYMP%	50.00	QC
17M CTL	MPO%	0.00	QC

This provides the foundation for the justification of reporting patient results. The interactive QC software may be applied as the primary, or as a secondary QC measure; for detection of Biases, and alert to potential Shifts, or Trends that could immediately or eventually affect the accuracy or reliability of patient test results.

Basic QC Requirement

QC 16 R (COLA
ACCREDITATION
MANUAL)

- “For each quantitative test performed, are quality control data prepared and plotted with each testing event, or are statistical parameters calculated to permit the laboratory to assess continued accuracy and precision of the method?”

QC Statistics – The Calculations

Mean

SD

CV

QC Limits

Bias

SDI

Z-score

- SLT QC Statistical Assessment Templates each contain the following “expert” educational link that explains statistics used.
- QC - The Calculations
westgard.com/lesson14.htm

Statistical Tools & Assessments

QC STATISTIC	DEFINITION / MEASURES
Mean	<ul style="list-style-type: none"> • Sum of individual measurements / # of measurements • An estimate of central tendency of stable system distribution • Relates to accuracy or systematic error
Standard Deviation (SD)	$S = \sqrt{\sum (X_i - \bar{X})^2 / (n-1)}$ <ul style="list-style-type: none"> • Shows distribution of control results vs. expected mean • Measure of imprecision or random error • Greater the random error the more imprecise are the results
Coefficient of Variation (CV)	<ul style="list-style-type: none"> • $CV = (SD/Mean) * 100$ • Standard deviation as a % of mean • Measure of random error or imprecision

Statistical Tools & Assessments

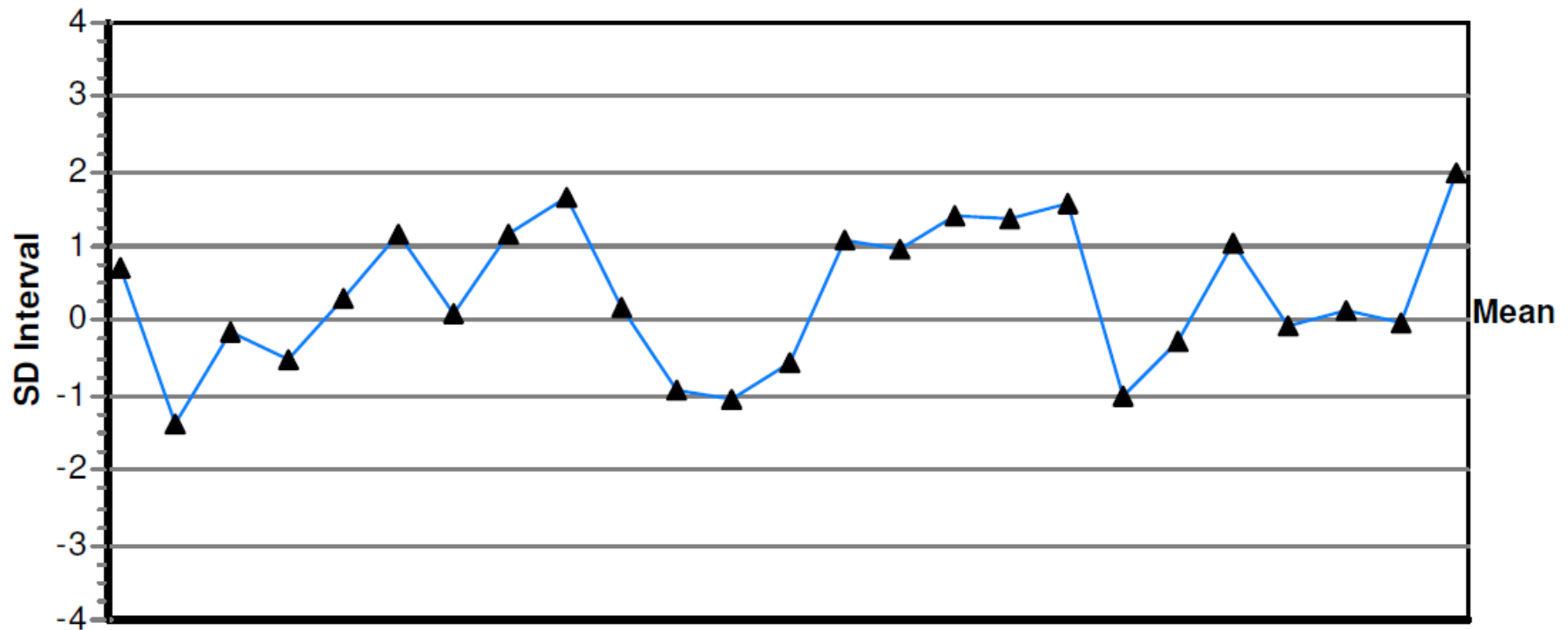
QC STATISTIC	DEFINITION / MEASURES
Bias (Observed QC Result) - (Target QC Result)	A measure of control result distance from the target mean in same units as the target. Statistical QC objective is to monitor change from the baseline (Target Mean)
SDI*(z-score) An Indicator of Bias $\frac{(Value - Target)}{Target\ SD}$ <i>Reference: Advance: Scott Warner, Blog 2014</i>	A “z-score” describes how many standard deviations a control result is from the mean expected for the material <ul style="list-style-type: none"> • The SDI (z-score) corresponds to where on a control chart a value falls • It is very helpful when you are looking at control results on different tests and different materials on a multi-test analyzer • A Tech can quickly see what's in, what's out, and what's trending • For example: If all levels of QC on an analyte have negative or have positive SDI(z-score), there may be a calibration bias

* The Standard Deviation Index (SDI) is used when analyzing PT data, or external QC Program data for bias. Z-score is used for internal QC program data. Both terms are used interchangeably in the SLT QC Templates.

Statistical Tools & Assessments

SD INTERVAL
QC GRAPH

GRAPH FOR VISUALIZING SDI (z-score)
graphs are not included in SLT QC Program



Statistical Tools & Assessments

QC STATISTIC

WESTGARD WEB – QC THE CALCULATIONS

What's a z-score?

A z-score is a calculated value that tells how many standard deviations a control result is from the mean value expected for that material. It is calculated by taking the difference between the control result and the expected mean, then dividing by the standard deviation observed for that control material. For example, if a control result of 112 is observed on a control material having a mean of 100 and a standard deviation of 5, the z-score is 2.4 $[(112 - 100)/5]$. A z-score of 2.4 means that the observed control value is 2.4 standard deviations from its expected mean, therefore this result exceeds a 2s control limit but not a 3s control limit.

Statistical Tools & Assessments

QC STATISTIC

WESTGARD WEB – QC THE CALCULATIONS

Why is a z-score useful?

It is very helpful to have z-scores when you are looking at control results from two or more control materials at the same time, or when looking at control results on different tests and different materials on a multitest analyzer. You can quickly see if any result exceeds a single control limit, for example, a z-score of 3.2 indicates that a 3s control limit has been exceeded. You can also look for systematic changes or trends occurring across different control materials, for example, consecutive z-scores of 2 or greater on two different control materials.

Statistical Tools & Assessments

QC ALERTS	DEFINITION / ACTION
SLT_105 Template SDI (z) Alert Flags	<p><i>* SDI > 'Trend Alert' Setting Warrants Attention</i> Appears in the 'actions' section whenever a QC value exceeds the Trend Flag Alert adjustable setting ..ie. 1.0,1.5 SDI an Asterisk(*) appears next to the QC Result.</p> <p><i>* SDI >2.0 Warrants Investigation</i> Appears in the 'actions' section whenever a QC value exceeds 2.0 SDI</p> <p><i>"QC Out"</i> In the <u>QC Out</u> column_when QC value exceeds 2.0 SDI</p>
SLT_400 Template SDI Adjustable Alert Flag	<p><i>* Trend Alert – Warrants Attention</i> Appears in the 'actions' section whenever a QC value exceeds the Trend Flag Alert Setting, which is adjustable.. (i.e. 1.0, 1.25, 1.5 SDI)</p> <p><i>* QC Out – Requires Investigation</i> Appears in the 'actions' section whenever a QC value exceeds 2.0 SDI</p> <p><i>"Out"</i> Appears in the <u>QC In?</u> column</p>

How Does QC Statistical Assessment Help?

My Analyzers have QC printouts...

QC is reviewed and released in LIS...

QC graphs are reviewed bi-weekly...

An Additional Measure of QC Confidence is provided when using SLT Statistical Assessment Templates:

QC problems are detected sooner when Statistical Assessment is performed on individual QC entries prior to releasing patient results

Printouts Summarize Analyzer QC for rapid review by Analyst, Supervisors, Consultants, and Director (**90 files in 9 Seconds**)

Provides **means for ensuring QC results are statistically evaluated** by Analyst & Supervisory Staff prior to releasing patient results

Serves as the '**Master**' **QC source**. Analyzer QC Limits and LIS QC limits follow those established for SLT QC template

Additional QC reviews still recommended bi-weekly or monthly, using L-J Charts & Statistical Summaries from Analyzer or LIS

Using The Daily QC Templates...

Set up for **Rapid Manual Data Entry** using [TAB] Key

Calculates QC Result Bias, Provides SDI Calculations, and **Flags Values that Exceed Defined QC Limits**

'QC O.K.' or **'QC Out'** Messages are Instantly generated, Alerting the analyst to when the method has a problem

One can **readily look down the column of SDI's for an Alert Flag** should a potential QC problem exist

When a QC problem exists, **provision is made on the same Template for Documenting the Remedial Actions**

Daily QC Results Evaluation (SLT105)

Example-1 (No QC Exceptions)

Example-2 (With a QC Exception)

Smart LabTools **QUALITY CONTROL RESULTS EVALUATION**
IPM LABORATORY

This Smart Lab Tool allows for comparison of Test Data to an Established QC Range. The difference, and Standard Deviation Index (SDI) are calculated. Any SDI-1.0 deserves special attention as in the future this bias may lead to QC failure. SDI-2.0 requires greater concern and is flagged as "Out".

HEMATOLOGY - ABX MICROS 60
LOT# MX016L, MX016N, MX016H - EXP. 03/05/2016

Specimen Source	Analyte Name	Low -2SD	High +2SD	Calc Mean	Calc 1SD	Test Value	Calc Bias	Calc SDI	QC In?	QC Out?
LOW CTL	WBC	1.60	2.40	2.00	0.20	2.10	0.10	0.50	QC In	
MX016L	RBC	2.27	2.57	2.42	0.08	2.36	-0.06	-0.80	QC In	
	HGB	5.60	6.40	6.00	0.20	6.10	0.10	0.50	QC In	
	HCT	14.50	18.50	16.50	1.00	16.00	-0.50	-0.50	QC In	
	PLT	55.00	95.00	75.00	10.00	72.00	-3.00	-0.30	QC In	
	GRAN %	17.50	31.50	24.50	3.50	24.50	0.00	0.00	QC In	
	LYMP %	57.50	73.50	65.50	4.00	65.9	0.40	0.10	QC In	
	MID %	4.00	16.00	10.00	3.00	9.60	-0.40	-0.13	QC In	
NORM CTL	WBC	6.60	8.20	7.40	0.40	7.60	0.20	0.50	QC In	
MX016N	RBC	4.46	4.82	4.64	0.09	4.58	-0.06	-0.67	QC In	
	HGB	12.90	14.10	13.50	0.30	13.40	-0.10	-0.33	QC In	
	HCT	34.60	39.60	37.10	1.25	36.50	-0.60	-0.48	QC In	
	PLT	216.00	296.00	256.00	20.00	247.00	-9.00	-0.45	QC In	
	GRAN %	52.00	66.00	59.00	3.50	61.20	2.20	0.63	QC In	
	LYMP %	27.00	39.00	33.00	3.00	31.70	-1.30	-0.43	QC In	
	MID %	3.00	13.00	8.00	2.50	7.10	-0.90	-0.36	QC In	
HIGH CTL	WBC	18.20	21.40	19.80	0.80	19.60	-0.20	-0.25	QC In	
MX016H	RBC	5.46	5.86	5.66	0.10	5.60	-0.06	-0.60	QC In	
	HGB	17.60	19.00	18.30	0.35	18.20	-0.10	-0.29	QC In	
	HCT	47.40	53.40	50.40	1.50	49.60	-0.80	-0.53	QC In	
	PLT	437.00	567.00	502.00	32.50	483.00	-19.00	-0.58	QC In	
	GRAN %	72.00	86.00	79.00	3.50	79.20	0.20	0.06	QC In	
	LYMP %	10.50	20.50	15.50	2.50	15.50	0.00	0.00	QC In	
	MID %	1.50	9.50	5.50	2.00	5.30	-0.20	-0.10	QC In	

QC item(s):
Problem:
Actions:

SLT_CW105a v.070212
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Daniel W. Leighton

1/6/2016 7:24 am

[Reset All](#) [Reset Data](#)

[Click for Link To QC Reference](#)

Kathy Analyst

DL Reviewed by

Smart LabTools **QUALITY CONTROL RESULTS EVALUATION**
IPM LABORATORY

This Smart Lab Tool allows for comparison of Test Data to an Established QC Range. The difference, and Standard Deviation Index (SDI) are calculated. Any SDI-1.0 deserves special attention as in the future this bias may lead to QC failure. SDI-2.0 requires greater concern and is flagged as "Out".

HEMATOLOGY - ABX MICROS 60
LOT# MX016L, MX016N, MX016H - EXP. 03/05/2016

Specimen Source	Analyte Name	Low -2SD	High +2SD	Calc Mean	Calc 1SD	Test Value	Calc Bias	Calc SDI	QC In?	QC Out?
LOW CTL	WBC	1.60	2.40	2.00	0.20	2.30	0.30	1.50*	QC In	
MX016L	RBC	2.27	2.57	2.42	0.08	2.36	-0.06	-0.80	QC In	
	HGB	5.60	6.40	6.00	0.20	6.10	0.10	0.50	QC In	
	HCT	14.50	18.50	16.50	1.00	16.00	-0.50	-0.50	QC In	
	PLT	55.00	95.00	75.00	10.00	64.00	-11.00	-1.10*	QC In	
	GRAN %	17.50	31.50	24.50	3.50	24.50	0.00	0.00	QC In	
	LYMP %	57.50	73.50	65.50	4.00	65.90	0.40	0.10	QC In	
	MID %	4.00	16.00	10.00	3.00	9.60	-0.40	-0.13	QC In	
NORM CTL	WBC	6.60	8.20	7.40	0.40	8.30	0.90	2.25*		QC Out
MX016N	RBC	4.46	4.82	4.64	0.09	4.50	-0.14	-1.55*	QC In	
	HGB	12.90	14.10	13.50	0.30	13.40	-0.10	-0.33	QC In	
	HCT	34.60	39.60	37.10	1.25	36.50	-0.60	-0.48	QC In	
	PLT	216.00	296.00	256.00	20.00	247.00	-9.00	-0.45	QC In	
	GRAN %	52.00	66.00	59.00	3.50	61.20	2.20	0.63	QC In	
	LYMP %	27.00	39.00	33.00	3.00	31.70	-1.30	-0.43	QC In	
	MID %	3.00	13.00	8.00	2.50	7.10	-0.90	-0.36	QC In	
HIGH CTL	WBC	18.20	21.40	19.80	0.80	21.30	1.50	1.88*	QC In	
MX016H	RBC	5.46	5.86	5.66	0.10	5.47	-0.19	-1.90*	QC In	
	HGB	17.60	19.00	18.30	0.35	18.20	-0.10	-0.29	QC In	
	HCT	47.40	53.40	50.40	1.50	49.60	-0.80	-0.53	QC In	
	PLT	437.00	567.00	502.00	32.50	483.00	-19.00	-0.58	QC In	
	GRAN %	72.00	86.00	79.00	3.50	79.20	0.20	0.06	QC In	
	LYMP %	10.50	20.50	15.50	2.50	15.50	0.00	0.00	QC In	
	MID %	1.50	9.50	5.50	2.00	5.30	-0.20	-0.10	QC In	

QC item(s): WBC outlier, RBC's biased low
Problem: WBC Control Out by >2SD, other 2 Levels Biased on High Side
Actions: Re-Calibrate Analyzer prior to running patient samples

SLT_CW105a v.070212
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Daniel W. Leighton

1/6/2016 7:19 am

[Reset All](#) [Reset Data](#)


[Click for Link To QC Reference](#)

Kathy Analyst

DL Reviewed by

* SDI >1.0 Warrants Attention
* SDI >2.0 Warrants Investigation


SLT_105 Setting up the QC Template



Smart LabTools
complex.com made simple

QUALITY CONTROL RESULTS EVALUATION

REPLACE WITH NAME OF LABORATORY



This Smart Lab Tool allows for comparison of Test Data to an Established QC Range. The difference, and Standard Deviation Index (SDI) are calculated. Any SDI>Alert() deserves special attention as in the future this bias may lead to QC failure. SDI>2.0 requires greater concern and is flagged as "Out".

1.0

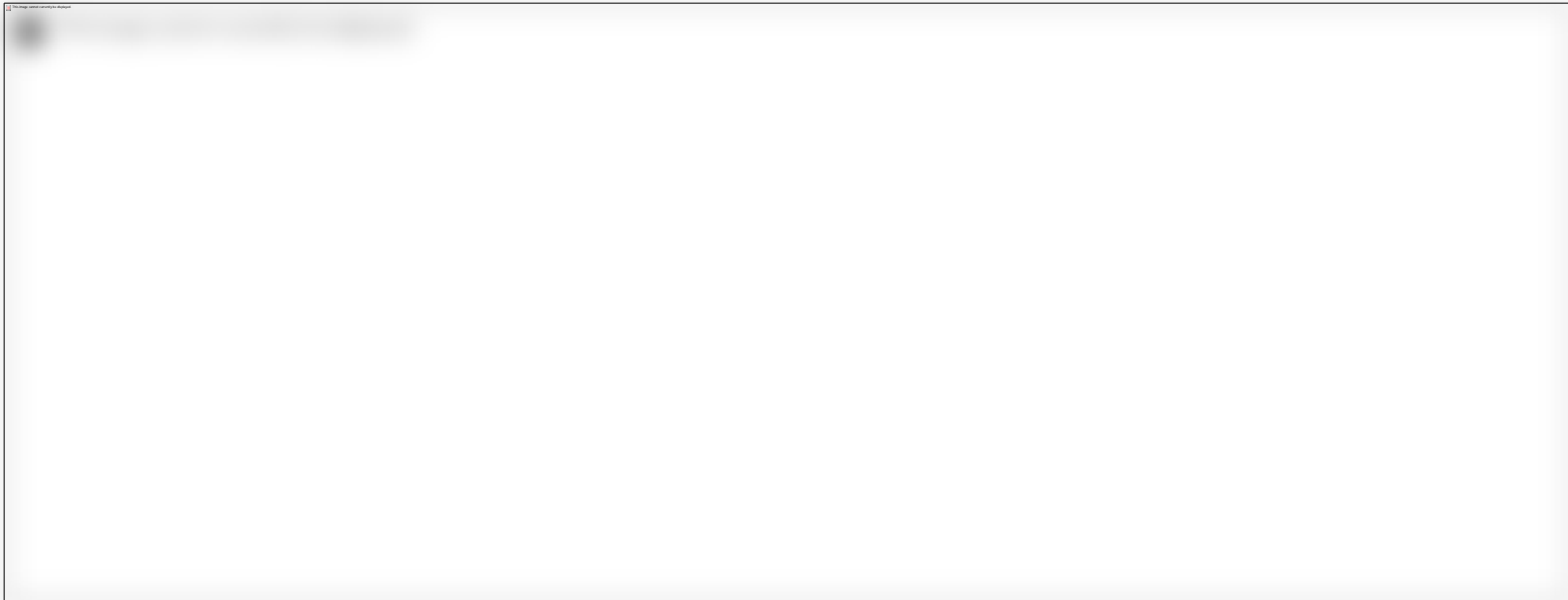
**Replace with Test System Description
& Control Information Here..**

Set SDI Bias Alert Here

Specimen Source	Analyte Name	Low -2SD	High +2SD	Calc Mean	Calc 1SD	Test Value	Calc Bias	Calc SDI	QC In?	QC Out?
L-1 Control	Glucose	100.00	110.00	105.00	2.50					
Enter -2SD and +2SD Limits Here										

- Enter Name of Laboratory in Header
- Define Test System.. Instrument (Method) & Control Info.
- By Line, Enter Control, Analyte, QC Limits for up to 24 Files
- Mean & 1SD are Automatically Calculated
- Setup QC Template Test Order to Match Analyzer Printout
- "Save As".. To Name Your Customized Template
- Enter Results in Test Value Column, Using [Tab] Key
- After each use.. 'Save' Adding Date to File Name
- Click [Reset Data] Prior to Next Use
- [Reset All] Clears Template Completely

SLT_105 Data Entry & Assessment



Data is rapidly entered in QC Results Column using [Tab] key

[Reset Data] button clears QC Results, Interpretations, and QC Actions

[Click Here for Link to Download Free Demo Template](#)

Statistical Assessment Template, SLT_105

Showing Bias Calculations & Interpretation

HEMATOLOGY - ABX MICROS 60										
LOT# MX400L, MX400N, MX400H - EXP. 09/05/2016										
Specimen Source	Analyte Name	Low -2SD	High +2SD	Calc Mean	Calc 1SD	Test Value	Calc Bias	Calc SDI	QC In?	QC Out?
LOW CTL	WBC	1.60	2.40	2.00	0.20	2.00	0.00	0.00	QC In	
MX400L	RBC	2.21	2.51	2.36	0.08	2.53	0.17	2.27 *		QC Out
	HGB	5.70	6.50	6.10	0.20	6.20	0.10	0.50	QC In	

Flagged Alerts & Corrective Actions on Lower Page

QC item(s): RBC Low Ctl Out, Normal and High Controls Near Mean Problem: RBC Low Control Out High >2SD, <3SD first occurrence Actions: Opened New Vial of Control & Repeated, Low Ctl Now In (2.38)		<input type="button" value="v"/> <input type="button" value="v"/> <input type="button" value="v"/>	* SDI >1.0 Warrants Attention * SDI >2.0 Warrants Investigation
SLT_CW105a v.082116 © SmartLabTools 2008-2016 Daniel W. Leighton	8/21/2016 4:02 pm	<input type="button" value="Reset All"/>	<input type="button" value="Reset Data"/>
<input type="button" value="Click for Link To QC Reference"/>		Morgan Analyst	DL Reviewed by

Multi-Level QC Statistical Assessment

Adjustable trend alert flagging and average SDI (z-score) statistic indices for up to 3-levels, 90 Files (SLT_400)

QC Data Entry & Assessment

QC Parameter Set-up Page

TO START - SCROLL DOWN TO SECOND PAGE FOR SET-UP INSTRUCTIONS

SmartLabTools **ACR LABORATORY** **DAILY Q.C. STATISTICAL ASSESSMENT**

TEST SYSTEM: INTEGRA 400+ INTEGRA 400+ INTEGRA 400+ Bias #CTLs
 CONTROLS: MULTITUAL 1 MULTITUAL 2 MULTITUAL 3 3
 LOT NUMBERS: 45681 45682 45683 Trend Flag =
 EXPIRATION: 06/30/16 06/30/16 06/30/16 1.5

Analyte Description	L-1 Mean	Test Value	Bias	SDI (Z)	QC In?	L-2 Mean	Test Value	Bias	SDI (Z)	QC In?	L-3 Mean	Test Value	Bias	SDI (Z)	QC In?	Ave SDI (Z)	Trend
ALP	33.20	31	-2.20	-0.60	In	132.50	120	-12.50	-1.43	In	297.50	281	-16.50	-0.93	In	-0.99	
ALT	22.35	19	-3.35	-1.38	In	88.30	80	-8.30	-1.42	In	170.00	168	-2.00	-0.19	In	-1.00	
AST	39.75	38	-1.75	-0.72	In	105.50	98	-7.50	-1.11	In	236.00	232	-4.00	-0.25	In	-0.69	
DBIL	0.21	0.2	-0.01	-0.32	In	1.17	1.1	-0.07	-0.35	In	2.09	2.0	-0.08	-0.26	In	-0.31	
TBIL	0.51	0.6	0.09	1.00	In	2.86	2.9	0.05	0.19	In	6.77	6.3	-0.47	-0.94	In	0.08	
ALB	2.53	2.5	-0.03	-0.18	In	3.49	3.4	-0.09	-0.47	In	4.27	4.2	-0.07	-0.33	In	-0.32	
TP	3.95	4.1	0.16	0.85	In	5.39	5.6	0.22	0.95	In	6.54	6.7	0.17	0.61	In	0.80	
CA	6.01	5.8	-0.21	-0.98	In	10.33	10.2	-0.13	-0.34	In	13.10	13.0	-0.10	-0.20	In	-0.50	
PHOS	2.04	2.0	-0.04	-0.27	In	4.62	4.5	-0.12	-0.59	In	7.98	7.8	-0.18	-0.64	In	-0.50	
CREA	0.59	0.58	-0.01	-0.28	In	1.70	1.72	0.02	0.19	In	5.83	5.66	-0.17	-0.47	In	-0.19	
BUN	14.55	15.2	0.65	0.67	In	39.15	39.1	-0.05	-0.02	In	69.85	67.2	-2.65	-0.66	In	-0.00	
NA	113.50	116	2.50	0.91	In	138.50	141	2.50	0.77	In	154.00	154	0.00	0.00	In	0.56	
K	2.57	2.6	0.04	0.45	In	4.08	4.1	0.02	0.18	In	7.67	7.6	-0.07	-0.33	In	0.10	
CL	76.00	78	2.00	0.80	In	95.40	98	2.60	0.93	In	119.50	123	3.50	0.93	In	0.89	
CO2	16.55	16	-0.55	-0.29	In	19.90	19	-0.90	-0.41	In	25.20	25	-0.20	-0.08	In	-0.26	
GLUC	59.50	58	-1.50	-0.49	In	122.50	119	-3.50	-0.67	In	366.00	349	-17.00	-1.17	In	-0.78	
GGT	27.20	26	-1.20	-0.42	In	75.45	72	-3.45	-0.62	In	126.00	119	-7.00	-0.82	In	-0.62	
UA	3.64	3.7	0.06	0.35	In	5.39	5.4	0.01	0.04	In	9.62	9.8	0.18	0.46	In	0.29	
MG	1.11	1.1	-0.01	-0.11	In	2.58	2.5	-0.08	-0.59	In	3.75	3.6	-0.15	-0.81	In	-0.50	
CK	83.00	80	-3.00	-0.40	In	287.00	267	-20.00	-1.21	In	677.00	645	-32.00	-0.93	In	-0.85	
CHOL	110.45	113	2.55	0.48	In	181.00	184	3.00	0.38	In	263.00	262	-1.00	-0.09	In	0.26	
TRIG	88.90	93	4.10	0.80	In	134.50	138	3.50	0.52	In	220.00	225	5.00	0.56	In	0.62	
HDL	28.90	35	6.10	2.30	Out	49.55	57	7.45	1.59	In	85.00	91	6.00	0.71	In	1.53	*
LDH	123.00	122	-1.00	-0.17	In	181.00	179	-2.00	-0.25	In	404.50	403	-1.50	-0.09	In	-0.17	
C3	89.65	89	-0.65	-0.09	In	120.00	126	6.00	0.67	In	152.50	151	-1.50	-0.13	In	0.15	
C4	16.45	15	-1.45	-0.95	In	21.60	20	-1.60	-0.82	In	28.15	25	-3.15	-1.30	In	-1.02	
IGA	114.00	127	13.00	1.63	In	155.50	160	4.50	0.51	In	201.00	203	2.00	0.20	In	0.78	*
IGG	599.50	579	-20.50	-0.62	In	817.50	813	-4.50	-0.11	In	983.00	963	-20.00	-0.48	In	-0.40	
IGM	54.15	54	-0.15	-0.03	In	81.25	80	-1.25	-0.25	In	93.40	88	-5.40	-1.12	In	-0.47	

Comments / Actions: HDL - L-1 >2SD, other 2 controls in, biased on high side
 Re-calibrate prior to next run. * Trend Alert - Warrants Attention
 * QC Out - Requires Investigation

1/6/16
 08:57 Reset Data MICHAEL ON/DL
 Analyst Reviewed by
 SLT_400.b ©2007-2014, SmartLabTools™ Daniel W. Leighton, MT(ASCP), CLB

SmartLabTools **ACR LABORATORY** **ESTABLISHED QUALITY CONTROL PARAMETERS** **QC Lesson** **Reset All**

TEST SYSTEM: INTEGRA 400+ INTEGRA 400+ INTEGRA 400+
 CONTROLS: MULTITUAL 1 MULTITUAL 2 MULTITUAL 3
 LOT NUMBERS: 45681 45682 45683
 EXPIRATION: 06/30/16 06/30/16 06/30/16

Analyte Description	L-1 -2SD	L-1 -1SD	L-1 Mean	L-1 +1SD	L-2 -2SD	L-2 -1SD	L-2 Mean	L-2 +1SD	L-3 -2SD	L-3 -1SD	L-3 Mean	L-3 +1SD
ALP	25.9	40.5	33.20	3.65	115	150	132.50	8.75	262	333	297.50	17.75
ALT	17.5	27.2	22.35	2.43	76.6	100	88.30	5.85	148.5	191.5	170.00	10.75
AST	34.9	44.6	39.75	2.43	92	119	105.50	6.75	204	268	236.00	16.00
DBIL	0.129	0.298	0.21	0.04	0.791	1.54	1.17	0.19	1.44	2.73	2.09	0.32
TBIL	0.325	0.692	0.51	0.09	2.37	3.34	2.86	0.24	5.78	7.75	6.77	0.49
ALB	2.24	2.81	2.53	0.14	3.12	3.85	3.49	0.18	3.84	4.70	4.27	0.22
TP	3.58	4.31	3.95	0.18	4.93	5.84	5.39	0.23	5.99	7.08	6.54	0.27
CA	5.58	6.44	6.01	0.22	9.56	11.1	10.33	0.39	12.1	14.1	13.10	0.50
PHOS	1.78	2.29	2.04	0.13	4.21	5.03	4.62	0.21	7.42	8.54	7.98	0.28
CREA	0.494	0.694	0.59	0.05	1.49	1.91	1.70	0.11	5.11	6.55	5.83	0.36
BUN	12.6	16.5	14.55	0.98	34.6	43.7	39.15	2.28	61.8	77.9	69.85	4.03
NA	108	119	113.50	2.75	132	145	138.50	3.25	147	161	154.00	3.50
K	2.41	2.72	2.57	0.08	3.86	4.3	4.08	0.11	7.27	8.06	7.67	0.20
CL	71	81	76.00	2.50	89.8	101	95.40	2.80	112	127	119.50	3.75
CO2	12.7	20.4	16.55	1.93	15.5	24.3	19.90	2.20	19.9	30.5	25.20	2.65
GLUC	53.4	65.6	59.50	3.05	112	133	122.50	5.25	337	395	366.00	14.50
GGT	21.5	32.9	27.20	2.85	64.4	86.5	75.45	5.53	109	143	126.00	8.50
UA	3.3	3.98	3.64	0.17	4.93	5.85	5.39	0.23	8.84	10.40	9.62	0.39
MG	0.938	1.28	1.11	0.09	2.31	2.85	2.58	0.14	3.38	4.12	3.75	0.19
CK	68.1	97.9	83.00	7.45	254	320	287.00	16.50	608	746	677.00	34.50
CHOL	99.9	121	110.45	5.28	165	197	181.00	8.00	240	286	263.00	11.50
TRIG	78.6	99.2	88.90	5.15	121	148	134.50	6.75	202	238	220.00	9.00
HDL	23.6	34.2	28.90	2.65	40.2	58.9	49.55	4.68	68	102	85.00	8.50
LDH	111	135	123.00	6.00	165	197	181.00	8.00	370	439	404.50	17.25
C3	75.3	104	89.65	7.18	102	138	120.00	9.00	129	176	152.50	11.75
C4	13.4	19.5	16.45	1.53	17.7	25.5	21.60	1.95	23.3	33.0	28.15	2.43
IGA	98	130	114.00	8.00	138	173	155.50	8.75	181	221	201.00	10.00
IGG	533	666	599.50	33.25	738	897	817.50	39.75	899	1067	983.00	42.00
IGM	42.2	66.1	54.15	5.98	71.2	91.3	81.25	5.03	83.8	103.0	93.40	4.80

Instructions on use of Multi-Level QC Assessment Template: be certain to use 'Save as' to re-name your template changes
 1) Pg.2 edit headers and set up test system demographics - changes will appear on Pg.1
 2) Pg.2 enter Analyte Descriptions, -2SD, +2SD QC limits - Mean & SD calculates on Pg.2, and Mean appears on Pg.1
 3) Pg.1 upper right enter # Control Levels - i.e. 1, 2, or 3
 4) Pg.1 upper right enter z-score Trend Flag Limit, i.e. 1.0, 1.2, 1.5 to establish alert flagging sensitivity
 5) Pg.1 enter QC results, click on entry box or use TAB key for vertical column data entry
 6) Observe: Bias (Mean-Result), z-score [(Mean-Result)/SD], AVE z-score [(sum of Z's)/#CTLs], QC "In", QC "Out"
 7) Trend Alert Flags: Occur when any one Control level's z-score exceeds user-defined Trend Flag Limit
 8) Observe and Document Actions in Comments section when Trend Alert message, or QC "Out" message appears

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SLT_400 Setting up the QC Template

Enter QC
Test Values
For
Statistical
Assessment
on Page-1

Smart LabTools		ACR LABORATORY																
		DAILY Q.C. STATISTICAL ASSESSMENT																
TEST SYSTEM:	INTEGRA 400+	INTEGRA 400+	INTEGRA 400+	Bias # CTLs														
CONTROLS:	MULTIQUAL 1	MULTIQUAL 2	MULTIQUAL 3	3														
LOT NUMBERS:	45731	45732	45733	Trend Flag =														
EXPIRATION:	02/28/18	02/28/18	02/28/18	1.5														
Analyte Description	L-1 Mean	Test Value	Bias	SDI (Z)	QC In?	L-2 Mean	Test Value	Bias	SDI (Z)	QC In?	L-3 Mean	Test Value	Bias	SDI (Z)	QC In?	Ave SDI (Z)	Alert	Trend
ALP	30.45	24	-6.45	-1.88	In	138.00	123	-15.00	-1.43	In	267.50	248	-19.50	-1.20	In	-1.50	*	
ALT	30.50	29	-1.50	-0.45	In	91.30	83	-8.30	-1.21	In	194.00	183	-11.00	-0.96	In	-0.87		

Define QC
System
Descriptions
& 2SD
Limits on
Page-2

Smart LabTools		ACR LABORATORY											
		ESTABLISHED QUALITY CONTROL PARAMETERS											
TEST SYSTEM:	INTEGRA 400+	INTEGRA 400+	INTEGRA 400+	QC Lesson									
CONTROLS:	MULTIQUAL 1	MULTIQUAL 2	MULTIQUAL 3	Reset All									
LOT NUMBERS:	45731	45732	45733										
EXPIRATION:	02/28/18	02/28/18	02/28/18										
Analyte Description	L-1 -2SD	L-1 +2SD	L-1 Mean	L-1 1SD	L-2 -2SD	L-2 +2SD	L-2 Mean	L-2 1SD	L-3 -2SD	L-3 +2SD	L-3 Mean	L-3 1SD	
ALP	23.6	37.3	30.45	3.43	117	159	138.00	10.50	235	300	267.50	16.25	
ALT	23.8	37.2	30.50	3.35	77.6	105	91.30	6.85	171	217	194.00	11.50	

SLT_400 Template Set-Up Instructions

• Page-2 for QC Parameter Set-up

Instructions on use of Multi-Level QC Assessment Template: be certain to use 'Save as' to re-name your template changes

- 1) Pg.2 edit headers and set up test system demographics - changes will appear on Pg.1
- 2) Pg.2 enter Analyte Descriptions, -2SD, +2SD QC limits - Mean & SD calculates on Pg.2, and Mean appears on Pg.1
- 3) Pg.1 upper right enter # Control Levels.. i.e. 1, 2, or 3
- 4) Pg.1 upper right enter z-score Trend Flag Limit, i.e. 1.0, 1.2, 1.5 to establish alert flagging sensitivity
- 5) Pg.1 enter QC results..click on entry box or use TAB key for vertical column data entry.
- 6) Observe: Bias (Mean-Result), z-score $[(\text{Mean-Result})/\text{SD}]$, AVE z-score $[(\text{sum of Z's})/\#\text{CTLs}]$, QC "In", QC "Out"
- 7) Trend Alert Flags: Occur when any one Control level's z-score exceeds user-defined Trend Flag Limit
- 8) Observe and Document Actions in Comments section when Trend Alert message, or QC "Out" message appears

• Page-1 Upper Right Settings

Bias # CTLs
3
Trend Flag =
1.5

- Set No. of Controls for Ave Bias Calc.
- Set Trend Flag for Alert Sensitivity

SLT_400 Help Icons & Buttons

Smart LabTools ?

Dan Leighton - Multi-Level QC Template Purpose:

User definable template for manual entry of QC results - instantly computes statistical indices, permitting the laboratory to assess continued accuracy and precision of test methods. QC Out, and Trend flags alert the analyst to significant biases (shifts or trends) for up to 3-levels of QC. Early actions may then be taken to address test system problems. Comments and remedial actions may be recorded below.

- SEE INSTRUCTIONS BOTTOM PG.2
MESSAGE AT TOP MAY BE ERASED

Dan Leighton

The z-score (SD Interval) statistic used with internal QC programs tells how many standard deviations a control value is from the mean value expected for that material. It is a calculation similar to the SDI (standard deviation index), used with External QC Programs and Proficiency Testing programs. SDI being the more familiar term is used here with z-score.

A z-score of +1.7 means that the test value was +1.7 standard deviations above the mean.
A z-score of -1.7 signifies a value below the mean.
Control results with (+/-) z-scores greater than the Trend Flag setting, trigger a Trend Alert flag.

19:55 **Reset Data**

Resets Only the Test Results 016, SmartLab

QUALITY CONTROL PARAMETERS **Reset All**

CAUTION!!! This Button Clears All Custom Parameters

OF LAB ON PAGE-2 ? **QC Lesson**

Link to Westgard.com for QC Lesson 14 **All**

SLT_400 Data Entry & Assessment

TEST SYSTEM:	INTEGRA 400+					INTEGRA 400+					INTEGRA 400+					Bias # CTLs	
CONTROLS:	MULTIQUAL 1					MULTIQUAL 2					MULTIQUAL 3					3	
LOT NUMBERS:	45731					45732					45733					Trend Flag =	
EXPIRATION:	02/28/18					02/28/18					02/28/18					1.5	
Analyte Description	L-1 Mean	Test Value	Bias	SDI (Z)	QC In?	L-2 Mean	Test Value	Bias	SDI (Z)	QC In?	L-3 Mean	Test Value	Bias	SDI (Z)	QC In?	Ave SDI (Z)	Trend Alert
ALP	30.45	27	-3.45	-1.01	In	138.00	134	-4.00	-0.38	In	270.00					-0.46	
ALT	30.50	29	-1.50	-0.45	In	91.30	88	-3.30	-0.48	In	194.00					-0.31	
AST	36.75	38	1.25	0.45	In	103.95	103	-0.95	-0.13	In	247.00					0.11	
DBIL	0.20	0.2	0.00	0.04	In	1.09	1.0	-0.09	-0.52	In	1.95					-0.16	
TBIL	0.47	0.5	0.03	0.33	In	2.83	2.8	-0.03	-0.11	In	6.41					0.07	
ALB	2.37	2.2	-0.17	-1.20	In	3.49	3.3	-0.19	-0.88	In	4.59					-0.69	

Data is rapidly entered in QC Results Column using [Tab] key

[Reset Data] button clears QC Results, Interpretations, and QC Actions

[Click Here for Link to Download Free Demo Template](#)

QC Out Flagging & Trend Alerts

TEST SYSTEM:	ABBOTT CELL-DYN 1800					ABBOTT CELL-DYN 1800					ABBOTT CELL-DYN 1800					Bias # CTLs	
CONTROLS:	ABBOTT					ABBOTT					ABBOTT					3	
LOT NUMBERS:	5327					5327					5327					Trend Flag =	
EXPIRATION:	03/11/16					03/11/16					03/11/16					1.0	
Analyte Description	L-1 Mean	Test Value	Bias	SDI (Z)	QC In?	L-2 Mean	Test Value	Bias	SDI (Z)	QC In?	L-3 Mean	Test Value	Bias	SDI (Z)	QC In?	Ave SDI (Z)	Trend Alert
WBC	2.10	2.3	0.20	1.00	In	7.20	7.9	0.70	1.40	In	15.90	16.1	0.20	0.16	In	0.85	*
RBC	2.36	2.10	-0.26	-2.60	Out	4.24	4.09	-0.15	-1.20	In	5.31	5.22	-0.09	-0.60	In	-1.47	*
HGB	5.70	5.8	0.10	0.40	In	11.50	11.7	0.20	0.57	In	16.20	16.6	0.40	0.80	In	0.59	

- RBC: **SDI(z) >2.0 (-2.60)** gives a '**QC Out**' Flag, as result is beyond **2SD**.
- *Note: Choice of QC rejection or acceptance rules must be defined by the user.
(A references link to Westgard.com is provided on each template to facilitate choice of QC rules.)*
- Observe: Calibration Bias for RBC... All 3 Levels on low side of mean with **Ave SDI(z) = -1.47** (on average, results are falling **1.5SD** below the mean)
- WBC: **SDI(z) value of 1.40** exceeded the **Trend Alert Flag setting of 1.0** for L-2 Control, therefore ****** appears in **Trend Alert** column. **Ave SDI(z) = 0.85** (Control on high side of mean warrants review of past & future QC for shifts or trends)

Creation of Interactive “Smart” PDF Forms

- 2 examples of Fields with JavaScript Calculations

☒ Custom calculation script:

```
((Math.abs((this.getField("FillText5").value)>
(this.getField("FillText1025").value)?"*":((Mat
h.abs((this.getField("FillText582").value)>
(this.getField("FillText1025").value)?"*":((Mat
h.abs((this.getField("FillText587").value)>
(this.getField("FillText1025").value)?"*":""))))
```

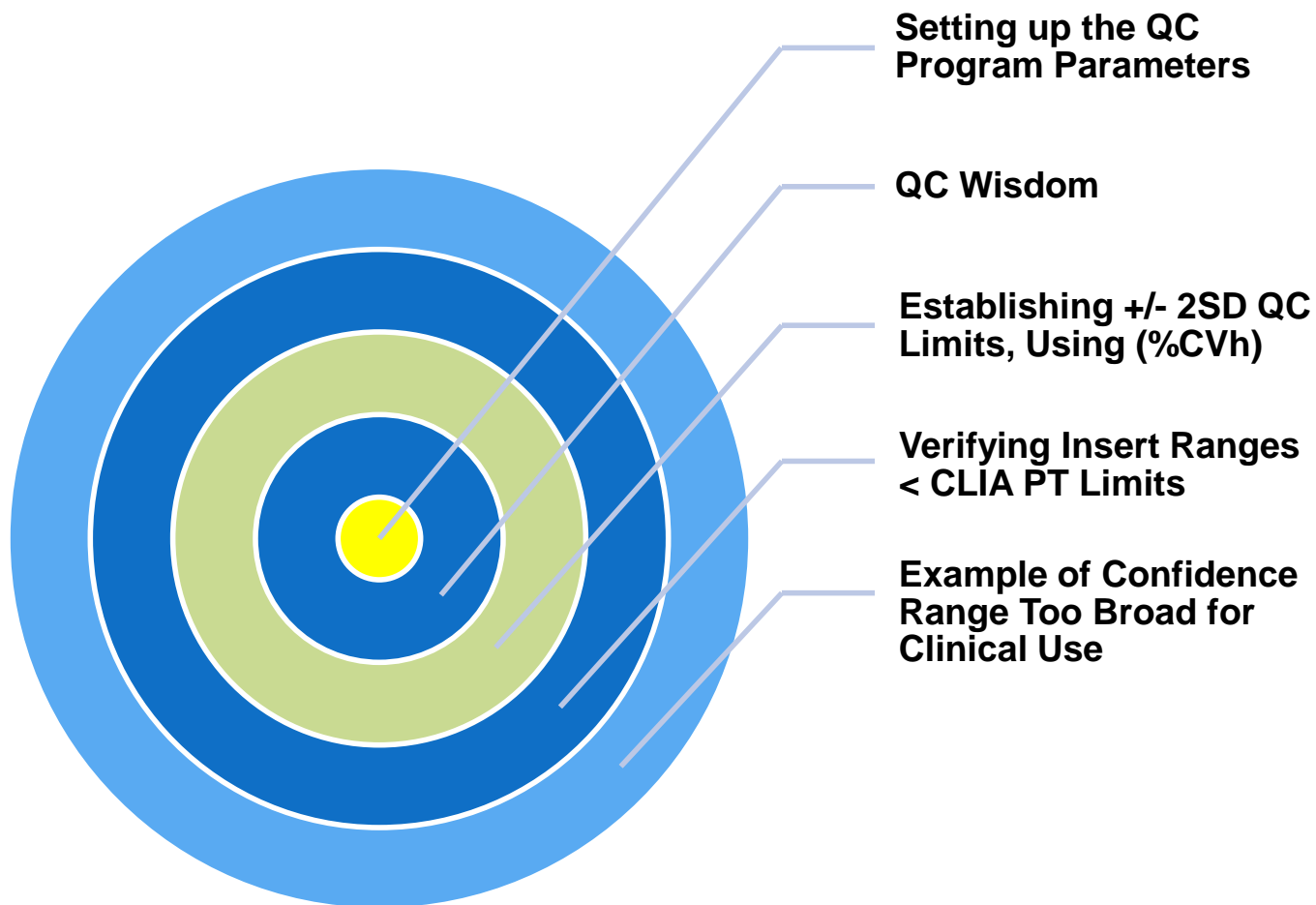
Determines QC Trend Flag Alert (*), or Not

☒ Custom calculation script:

```
(((((this.getField("FillText585").value<(this.get
Field("FillText206").value)&&((this.getField("
FillText585").value>0))?"Out":(((this.getField(
"FillText585").value>
(this.getField("FillText207").value)"Out":(((t
his.getField("FillText585").value>0)"In":"")))
```

Determines QC “Out” or QC “In”

(Section-2) Setting up the QC System




Setting up the Default QC Program

Step	Activity	Purpose
1.	Define the QC Requirements of the Assay (2 levels minimum)	Select the QC controls to use, Assayed, Un-assayed, 2 or 3 levels
2.	Locate published QC Means and Ranges when available	Package Insert Values, On-line Insert, or Peer Group data if un-assayed
3.	Perform replicate study on QC to confirm published ranges, or for establishing new limits	When initially validating an assay or parallel testing a new lot of control <u>SLT 413</u> <u>SLT 415</u> <u>or other SLT calculator</u>
4.	Determination of Mean & QC Limits for each level of control	Compare Mean, SD, CV%, to Insert values, Peer or Historical Statistics
5.	Determine Total Allowable Error limits for the Assay (TEa)	QC limits for the assay not to exceed allowable error limits (CLIA, CVb, etc.) <u>SLT 419</u> <u>SLT 110</u>
6.	Replicate study (within-run)	Ideal: $\leq 25\%$ of the TEa for the Assay
7.	Replicate study (between-run)	Ideal: $\leq 33\%$ of the TEa for the Assay

Some QC Wisdom...

	Advise	Comments
1	Do not accept without verification the analyte levels (insert limits) given on commercial QC Products	QC limits given with commercial QC products are often too broad for clinical use (<i>see example slide -32</i>)
2	Verify given insert limits are 2SD or 3SD, often they are 3SD	SLT Templates require 2SD limits , Verify SD with <u>SLT 111 Template</u>
3	Do not use limits that exceed the CLIA Proficiency Testing Limits, or risk failing PT	Analytical Allowable CLIA Error (TEa) Assay limits, and Calculator are available on the <u>SLT 110 Template</u> .
4	Biological Variation tables are another source of Error Limits	(CVb) limits tables may be found on the Westgard website
5	Read The Control Product Insert Instructions & disclaimers (Examiners will read them)	Adhering to stability claims is helpful for avoiding unnecessary rejections and troubleshooting
6	Examiners read QC Procedures	..and hold you to the written word

Establishing Your Lab's +/- 2SD QC Limits

	Resource	Comments / Reference Links
1	<p>“Chemistry Guideline for Establishing New Control Lot Means and Quality Control (QC) Ranges Through Parallel Testing and Historic Coefficient of Variation (%CVh)”</p> <p>Authored by Kurt Michael and Paul Richardson</p>	<p>Click on Reference Link: Establishing Chemistry QC Ranges</p> <div>  <p>pSMILE Patient Safety Monitoring & International Laboratory Evaluation</p> </div> <p>Link to pSMILE</p>
2	<p>“Best Practices in Establishing Quality Control Parameters”</p> <p>Authored by M. Laura Parnas, PhD Source: Clinical Laboratory News</p>	<p>Click on Reference Link: Best Practices in Establishing QC Parameters</p>
3	<p>“Planning a Statistical Quality Control Strategy”</p> <p>Authored by Greg Miller, PhD Source: AACC 2016 Workshop</p>	<p>Click on Reference Link: “Planning a Statistical Quality Control Strategy”</p>
4	<p>SmartLabTools Templates to Calculate +/- 2SD Limits using (%CVh)</p>	<p>Templates SLT_417, SLT_111.d</p>

SLT_111 to Calculate 2SD Limits (%CVh)

My eInserts target means, Bio-Rad QC <http://www.qcnet.com/>,

Glucose | mg/dL | 60 | 120 | 360

Glucose	Hexokinase	mg/dL							
Level	Mon	Cum	Level	Mon	Cum	Level	Mon	Cum	
Siemens Dimension Series									
Mean	1	62.83	63.00	2	126.4	126.6	3	364.8	366.5
SD		1.68	1.85		2.38	2.84		7.68	7.43
CV		2.7	2.9		1.9	2.2		2.1	2.0
# Points		8475	113K		1883	20102		8267	113K
# Labs		242	344		37	54		236	334

Peer Summary with Large User Data Base, for Most Accurate Estimate of the Method Control Means

Enter Mean and CV% to Calculate 1SD, and 2SD QC Limits

Control Level	Mean	CV%	1SD	- 2SD Limit	+2SD Limit
Level-1	63.00	2.70	1.70	59.60	66.40
Level-2	126.00	1.90	2.39	121.21	130.79
Level-3	365.00	2.10	7.67	349.67	380.33

Reset

Comments: Use to Calculate 2SD Limits based on Peer Historical CV%

Example Shows Calculation of Interim 2SD Limits using Peer Means & Prior Month's CV's

Using New Lot Parallel Testing Means, & Lab Prior CV's is Useful For Calculating Interim 2SD Limits

Verify QC Limits \leq CLIA PT Limits



Calculator for Evaluating Control Limits Based on Total Allowable Error Limits

EVALUATING GLUCOSE RANGES

TEa Limits				If use TEa (%)			If use TEa (Value)		
Control Level	Mean	Limit %	Limit Val	Low	High	1SD	Low	High	1SD
Level-1									
Level-2									
Level-3									

Reset

This simple calculator assists with evaluating QC Limits based on analytic quality requirements, such as Proficiency Testing (PT) allowable error limits.

The TABLE below lists information on CLIA proficiency testing criteria for acceptable analytical performance, as printed in the Federal Register February 28, 1992;57(40):7002-186.

Use CLIA PT limits as a guide, and not set your QC limits wider, else risk failing PT Challenges.

Laboratories are responsible for setting their own limits.

Example: Insert Limits (3SD), Range > CLIA

C	INSERT			U		Confidence range	1 SD
SODIUM-E				mmol/L	150	135 - 165	5
				mg/dL	345	309 - 381	12
				mEq/L (mval/L)	150	135 - 165	5

Enter Known Mean and SD to Calculate CV%, 2SD, 3SD Limits

(SLT_111)

“Confidence Range”
is 3SD Limits

Control Level	Mean	1SD	- 2SD	+2SD	- 3SD	+3SD	CV%
Level-1							
Level-2	150.00	5.00	140.00	160.00	135.00	165.00	3.33

(SLT_110 Calc. CLIA Limits) CLIA PT Limits

Control Level	Mean	Limit %	Limit Val
Level-1	150.00		4.00

If use CLIA PT (%)

Low	High	1SD
150.00	150.00	

If use CLIA PT (Value)

Low	High	1SD
146.00	154.00	2.00

Sodium (mmol/L) **

CH-01	133	127 - 136
CH-02	163	157 - 166
CH-03	199	195 - 204
CH-04	150	146 - 154
CH-05	174	169 - 178

Use of CLIA Limits in API PT Program

Manufacturer “Confidence range” SD is 2.5 x that allowed by CLIA

Beware – Manufacturer's QC Ranges

Current Worklist QC Results				Recommend set to 2SD 136-156	
<i>Field Engineer QC Guidance for Sodium</i>					
Lot	1703701	Expiration Date	04/10/2019	Context	
Last Run	01/18/2019 16:53:53				
Target	Confidence Range	CV	SD	Low	Target
146	142-150	0	0		

*Recommend set to 2SD
136-156*

The use of the manufacturer ranges, package insert ranges, and other externally imposed ranges is highly discouraged. No matter how the manufacturer sweet-talks you about using a wider range, the best practice is to use YOUR RANGE and YOUR MEAN. Whenever the manufacturer tries to get you to use a different mean or a different (wider) mean, they are not trying to control the method, they are trying to control you (and get you to stop asking for technical support).

Westgard: Questions and Answers on QC Frequency, and QC in Hematology

<https://www.westgard.com/questions-qc-hematology.htm>

Consequences of Wider QC Limits...

Few or No Flags on Instrument Tapes

5/01/07 14:09

RBC

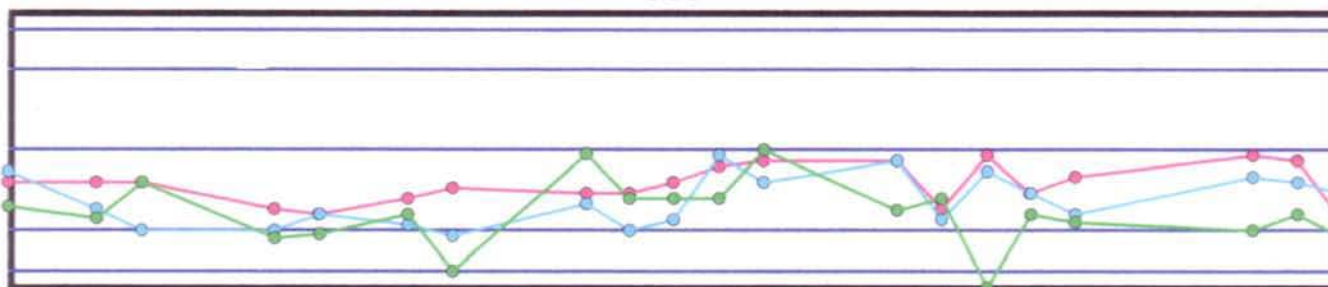
5/31/07 14:19

+3SD

+2SD

-2SD

-3SD



Level

-2SD

Mean

+2SD

Lot#

L: 2.320 2.47 2.620 16881

N: 4.100 4.25 4.400 16881

H: 5.03 5.23 5.43 16881

Exceptions

Run Date

Level

Value

5/07/07 14:27	H	5.01 >2
5/08/07 14:39	H	5.02 >2
5/11/07 14:25	N	4.09 >2
5/11/07 14:26	H	4.93 >2
5/23/07 14:39	H	4.89 >3
5/31/07 14:19	H	5.01 >2

All Levels RBC Biased to Low Side, Resulting in Unsuccessful PT 3x in a Row!



Severe Sanctions for Failing RBC PT

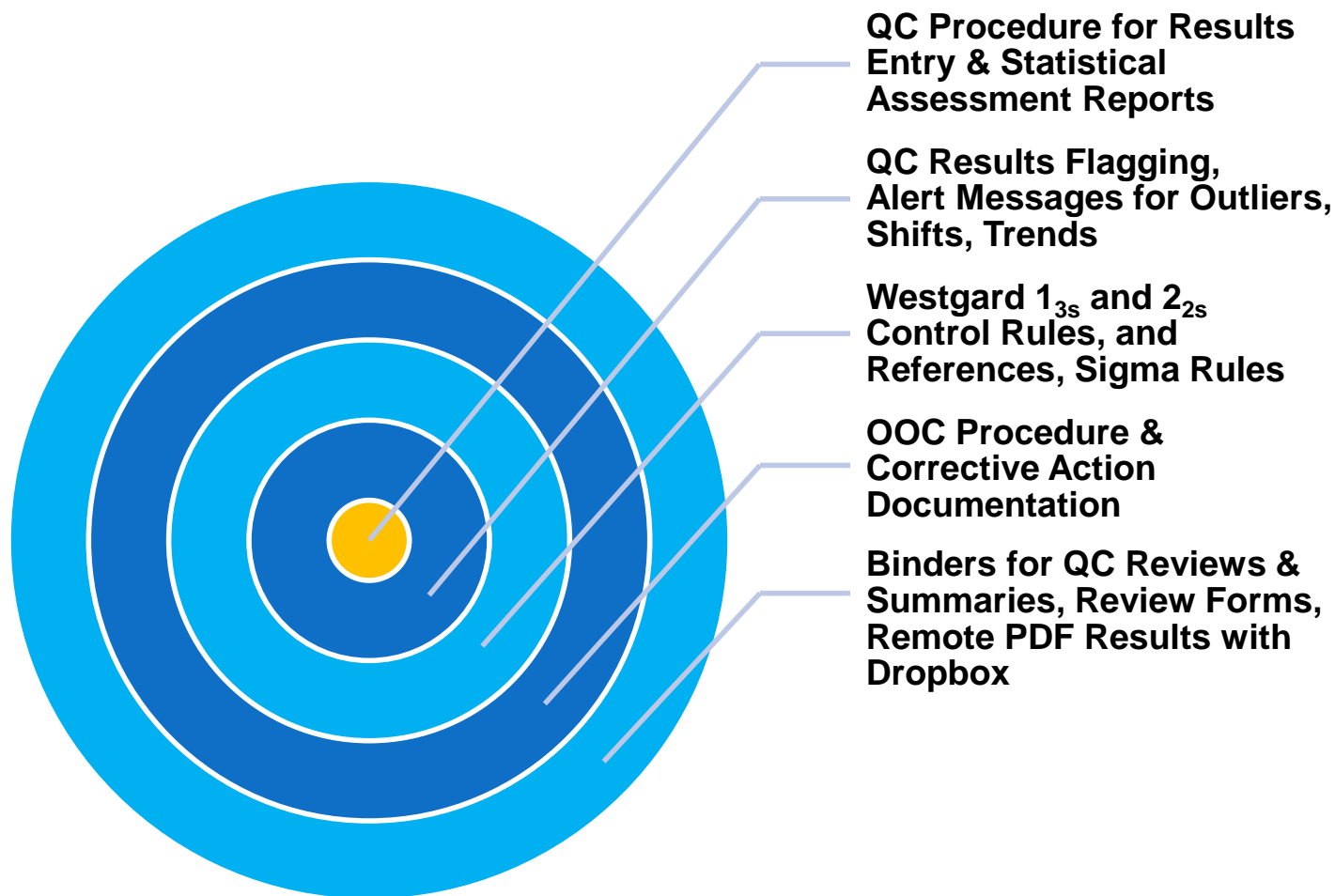
Following is a listing of the final sanctions against Laboratory's CLIA certificate as a result of the subsequent occurrence of unsuccessful participation in proficiency testing for the analyte erythrocyte count (RBC): Limitation of the laboratory's CLIA certificate for the analyte RBC for not less than six months effective October 13, 2006; a Directed Plan of Correction effective October 11, 2006; a Civil Money Penalty effective October 11, 2006 in the amount of \$3,000 per day of non-compliance until the Limitation of the laboratory's CLIA certificate in the analyte RBC for a total of \$6,000; Cancellation of the laboratory's approval to receive Medicare payments for all laboratory services effective October 13, 2006.

In accordance with 42 C.F.R. § 493.1850(a)(2), information regarding the above imposed sanctions against the laboratory's CLIA certificate will appear in the Laboratory Registry for the calendar year in which the actions are imposed. In addition, pursuant to 42 C.F.R. § 493.1844(g)(1), we will notify the general public by means of a notice published in a local newspaper.

CMS - Corrective Actions & Measures Directive (Submit with 2567 Response)

- Documentation showing what corrective action(s) have been taken for patients found to have been affected by the deficient practice;
- How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) have been taken;
- What measure has been put into place or what systemic changes have been made to ensure the deficient practice does not recur, and,
- How the corrective action(s) are being monitored to ensure the deficient practice does not recur.

(Section-3) Policies & Procedures



P&P-1: Results Entry & Statistical Assessment

1. QC Results from select instrument quality control printouts, or worksheets, are **manually entered** into the designated SmartLabTools™ QC template for instant statistical assessment and interpretation.
2. Entered **results are evaluated** against the assigned 2SD QC limits which may be verified product insert or user-defined ranges. The Analytical Bias and Standard Deviation Index (SDI) are calculated and displayed.
3. “QC In” interpretation appears when QC results are acceptable, else “QC Out”, and alarm messages appear to Alert the analyst when there is a method problem.

P&P-2: QC Results Flagging

4. An important element of the SLT QC System is the immediate flagging of results which have exceeded Trend Flag* setting, signaling and early warning to a potential QC Shift or Trend, and 'QC Out' flagging whenever user defined 2SD acceptance limits are exceeded.
5. An SDI of > Trend Flag setting is denoted with an asterisk (*), whereas an SDI of >2.0 is of greater concern and shows as 'Out' in the (QC In?) column. Flagged results are immediately recognizable for further interpretation against the laboratory's defined QC rules. Investigation or Corrective Action may be warranted, and can be documented at the bottom of the QC template.

P&P-3: Statistical Assessment (Trend Alert Flags)

6. With Alert Flagging (*), the following message appears at the bottom of the page when set SDI limits are exceeded for any single QC event:

“Trend Alert - Warrants Attention”

7. Trends are defined as a series of controls above or below the mean, remain within limits, and indicates systematic error.

Flagged (*) analytes need be reviewed further by the analyst for previously flagged results for the same control, and for flagged results of related controls (other levels).

(Alerts to results exceeding set SDI limits, but does not track QC results from consecutive runs)

8. The *“Ave SDI (z-score)”* helps when evaluating systematic error such as calibration bias.

P&P-4: Statistical Assessment (“QC Out”)

9. Results that exceed 2.0 SDI (>2.0 standard deviations) are flagged as “QC Out” and require the analyst to examine the condition to see which QC Rules may have been violated (see *Control Rules Guidelines*), and if warranted, take remedial measures to correct the condition.

The following alert message appears at lower page:

“QC Out - Requires Investigation”	SLT_400
“SDI >2.0 Warrants Investigation”	SLT_105

P&P-4: Statistical Assessment (“QC Out”)

Comment: *“An analytical run should not be rejected if a single quality control value is outside the $\pm 2s$ QC limits but within the $\pm 3s$ QC limits. Approximately 4.5% of all valid QC values will fall somewhere between ± 2 and ± 3 standard deviation limits. Laboratories that use a $\pm 2s$ limit frequently reject good runs. That means patient samples are repeated unnecessarily, labor and materials are wasted, and patient results are unnecessarily delayed.”*

Comment Source: BioRad – QC Education, QC Workbook 2008, Authored by: Greg Cooper, CLS, MHA

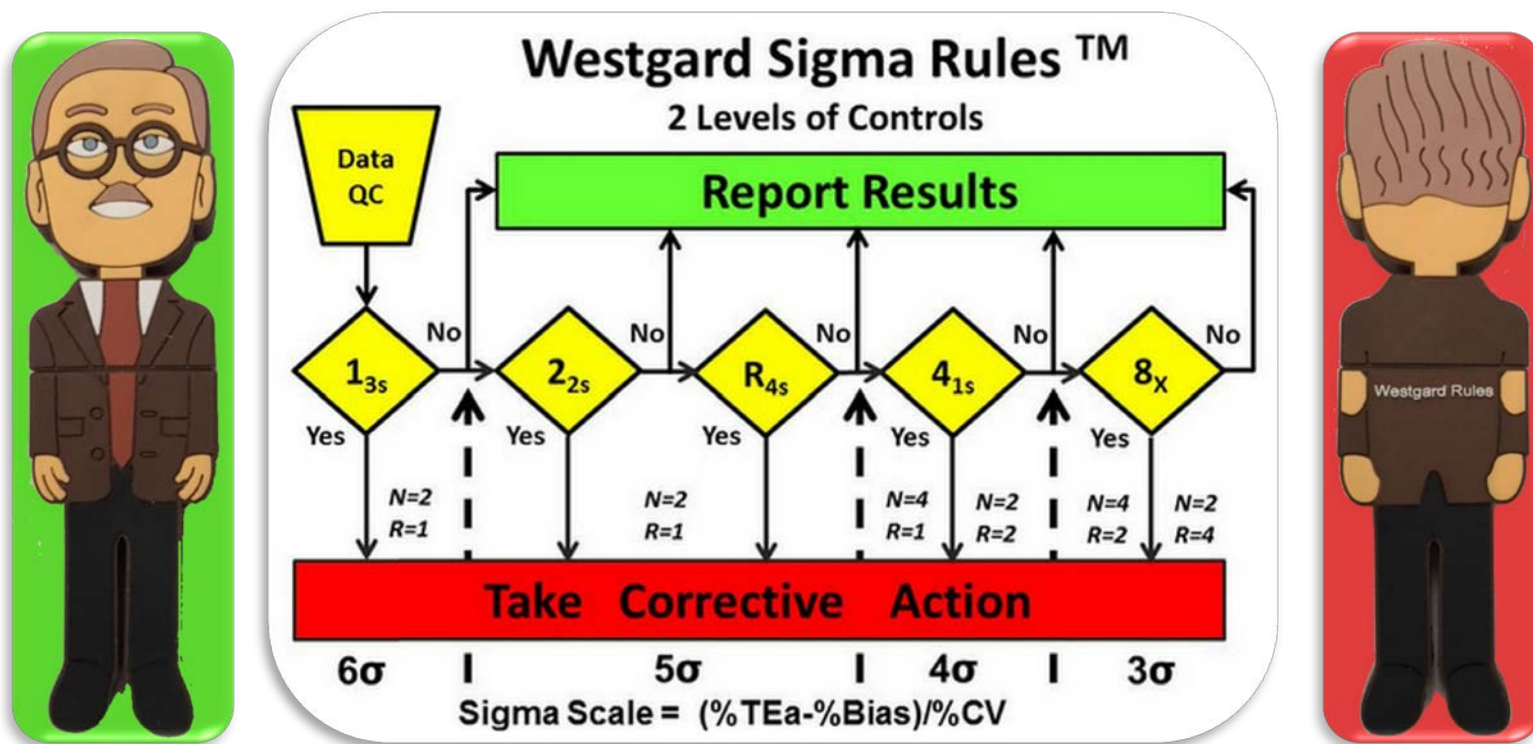
P&P-5:

Defining Lab's Own QC Rules

Rule	Some examples of Westgard Rules
* 1_{3s}	One QC event falls beyond either +3SD or -3SD
* 2_{2s}	Two consecutive QC events fall beyond the same 2SD limit (either +2SD or -2SD)
4_{1s}	Four consecutive QC events fall beyond the same 1SD line (either +1SD or -1SD)
R_{4s}	Two consecutive QC events fall a distance of 4SD from each other
10_x	Ten consecutive QC events fall to the same side of the mean (or target)

- Westgard Rules may refer to within a QC event (eg, comparing results of the high and the low QC material) or across QC events (eg, comparing the prior high QC material result with the current high QC material result).
- * **Suggested Control Rules** when evaluating SLT QC Statistical Assessment Templates
- *Each laboratory must establish it's own QC rules and practices, as approved by the Laboratory Director.*
- Refer to Westgard.com for QC Lessons and use of QC Rules <https://www.westgard.com/lesson74.htm>
<https://www.westgard.com/lesson18.htm>

Sigma Rules - Based on Assay Quality Performance



The Westgard Sigma Rules diagram(s) makes it easy to select the **right control rules** and the **right number of control measurements**.

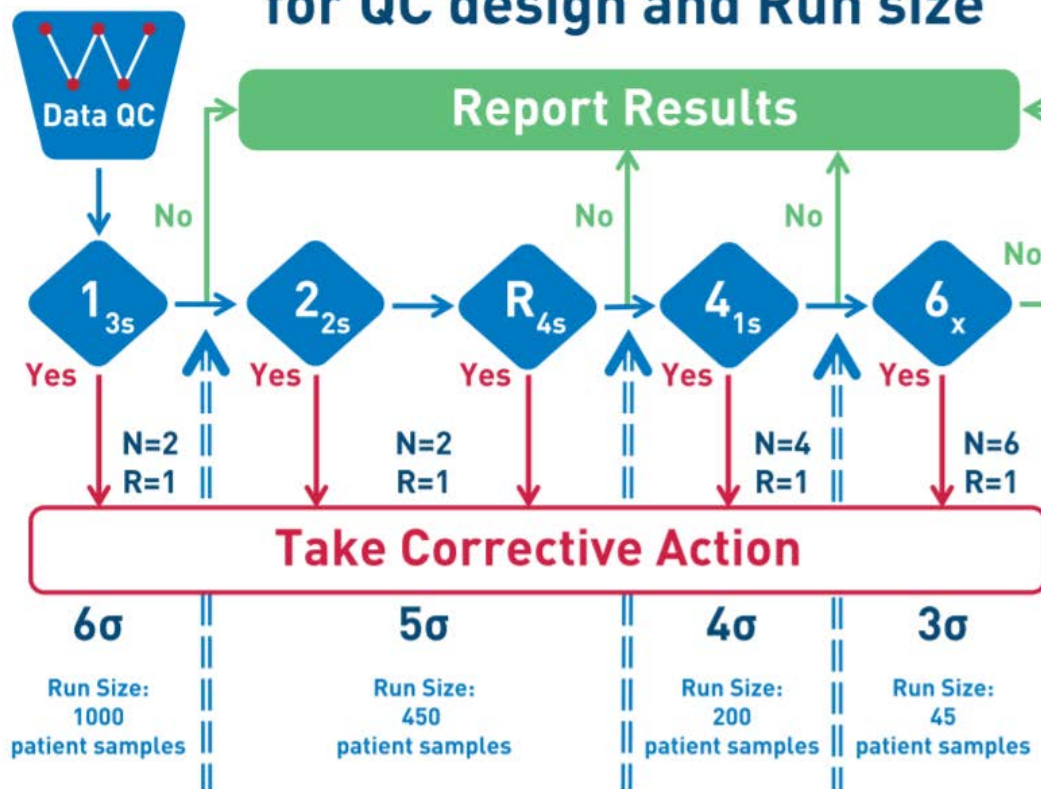
Link to : [westgard.com/westgard-sigma-rules](https://www.westgard.com/westgard-sigma-rules)

Link to : [westgard.com](https://www.westgard.com) for latest QC manual

Link to : [SLT Sigma Calculators & Resources](#)



Westgard Sigma Rules[®] for QC design and Run size



WESTGARD **QC**

Sigma Scale = $(\%TEa - \%Bias) / \%CV$

Ref: Clin Chem 2018; 64:289

P&P-6:

The 1_{2s} QC Rule not cause for rejection

Accept Run and Report Patient Results if:

1. All controls are within $\pm 2SD$ of the established mean.
2. (1_{2s}) One control is within $\pm 2SD$ second control $> 2SD$, but within $\pm 3SD$ ($< 3.0 SDI$), acceptable for first time only.

Treat the outlier as a warning, and be alert to potential 2_{2s} should same QC be $> 2SD$ next run.

P&P-7:

Using 1_{3s} and 2_{2s} QC Rules

Reject a run and Take Corrective Action If:

1. One control is greater than $\pm 3SD$ (3.0 SDI) from the established mean. (1_{3s}) rule violation.
2. Two controls for same analyte are greater than $\pm 2SD$ from the established mean. (2_{2s}) rule violation
3. Refer to the lab's Q.C. Corrective Action Procedure, and Documentation Procedure if run is rejected.
4. Flagged analytes * *Trend Alert*, will be monitored and used as a "warning" to investigate potential QC problems.
5. Shifts and Trends in control values are not suggested as criteria for rejecting or accepting control results.

P&P-8: Daily QC Statistical Assessment Report

1. The *'Daily QC Statistical Assessment Report'* is visually analyzed, any necessary actions taken, printed, signed by the analyst, and filed in the *Daily QC Review Binder* for further review by the Director or his designee.
2. The *'Daily QC Statistical Assessment Report'* is also 'Saved' to the designated folder in the web application 'Dropbox' for off-site review by the Technical Supervisor. QC Report is saved using file-name and testing date. *(examples to follow)*
3. For next run/day use, select prior run/day report, and use the *[Reset Data]* button to clear prior test data, interpretation, and corrective actions. Enter current data, and repeat process.

P&P-9: Out of Control Corrective Measures

1. If the results of the controls are beyond established limits as indicated by being flagged as '**Out**' by the analyzer or SmartLabTools™ QC software, and meet 2_{2s} or 1_{3s} run rejection criteria, then investigate the condition before repeating the controls. (Refer to Laboratory's own QC Rules and Repeat Criteria)
2. If QC is still out, corrective action should be taken and documented. Some examples of corrective action are preparation of fresh controls or reagents, checking expiration dates and lot numbers, checking calibration and proper operation of the instrument, cleaning the instrument, etc.

P&P-10: Out of Control Measures (Cont.)

3. If the problem is limited to the control only, no further steps need be taken other than to demonstrate satisfactory performance with another control. *The repeat value may be documented by typing into a blank section of the QC Template.*
4. If the problem is corrected, all specimens run from the time the problem was detected must be **re-run**. Specimens run before the problem was identified and when controls were “in control” need not be re-run. Careful investigation needs be done to identify the exact point when the problem occurred.


P&P-11: Out of Control Measures (Cont.)

5. If the problem cannot be identified, results cannot be released. Instrument should be shut down and technical support should be called for troubleshooting and service. Use the backup equipment when available. If alternate testing devices are not available, notify the Lab Director or Designee immediately.

P&P-12

Corrective Action - Documentation

Document Q.C. problems and corrective action on the '[Daily QC Statistical Assessment Report](#)' or a designated Instrument '[Corrective Action Form](#)', as below. [\(SLT 200\)](#)



CLINICAL LABORATORY

Corrective Action Form

[Print Form](#)
[Reset Form](#)

PENTRA-400 CHEMISTRY

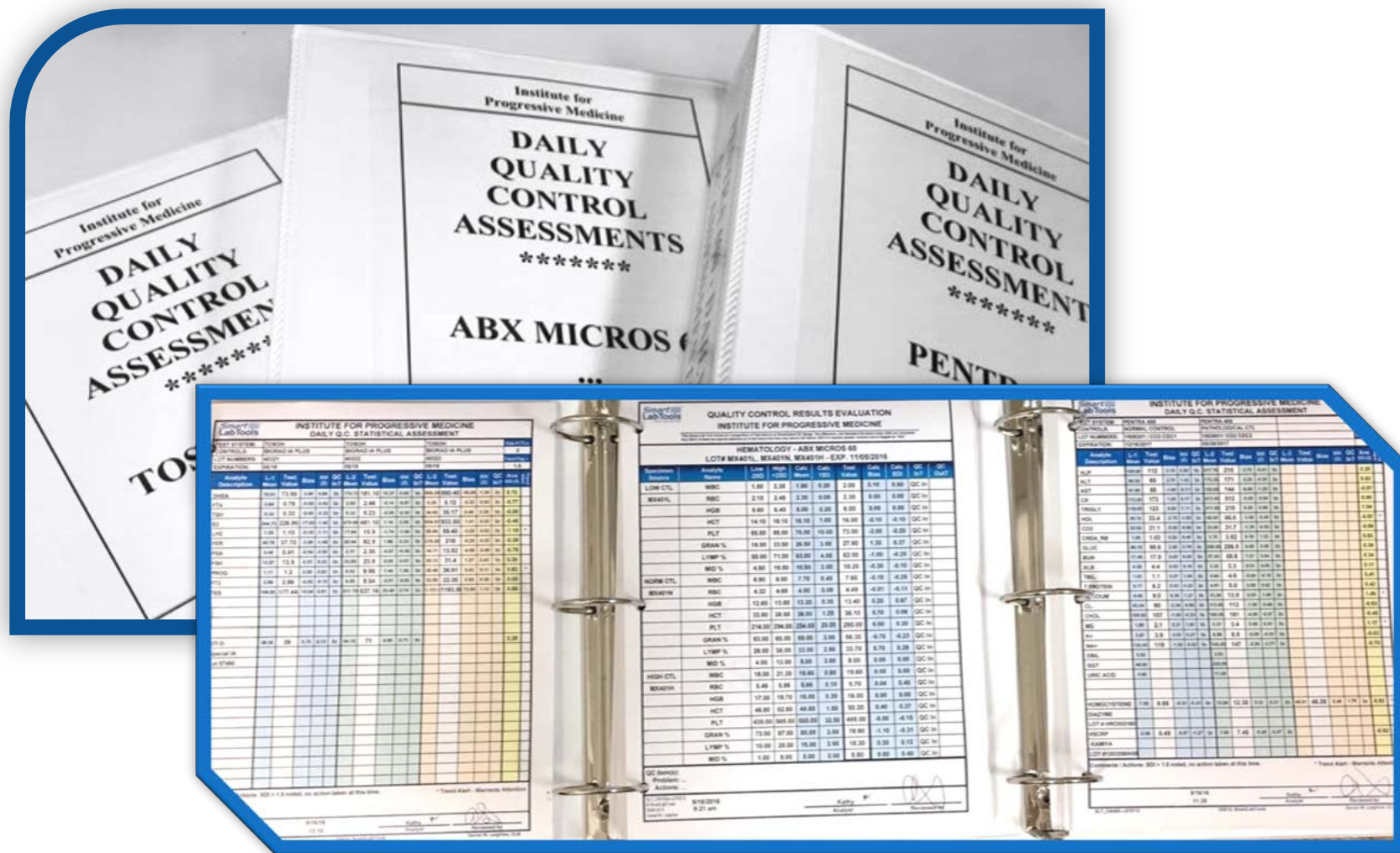
Date	Tech	Problem	Resolution
<div style="display: flex; align-items: center;"> <div style="border: 1px solid black; padding: 2px; margin-right: 5px;"> September 2016 Sun Mon Tue Wed Thu Fri Sat 28 29 30 31 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 1 2 3 4 5 6 7 8 <input type="checkbox"/> Today: 9/26/2016 </div> <div style="text-align: center;"> DL </div> </div>		RECORD CONTROL REPEATS AND MINOR QC ISSUES ON THE 'DAILY QC STATISTICAL INDICES EVALUATION FORM'.	DOCUMENT INSTRUMENT, AND OTHER OPERATIONAL PROBLEMS ON THIS FORM. PRINT CORRECTIVE ACTION FORM MONTHLY AND FILE IN THE DAILY QC BINDER.
	DL	ELECTRONIC CALENDAR	

P&P-13

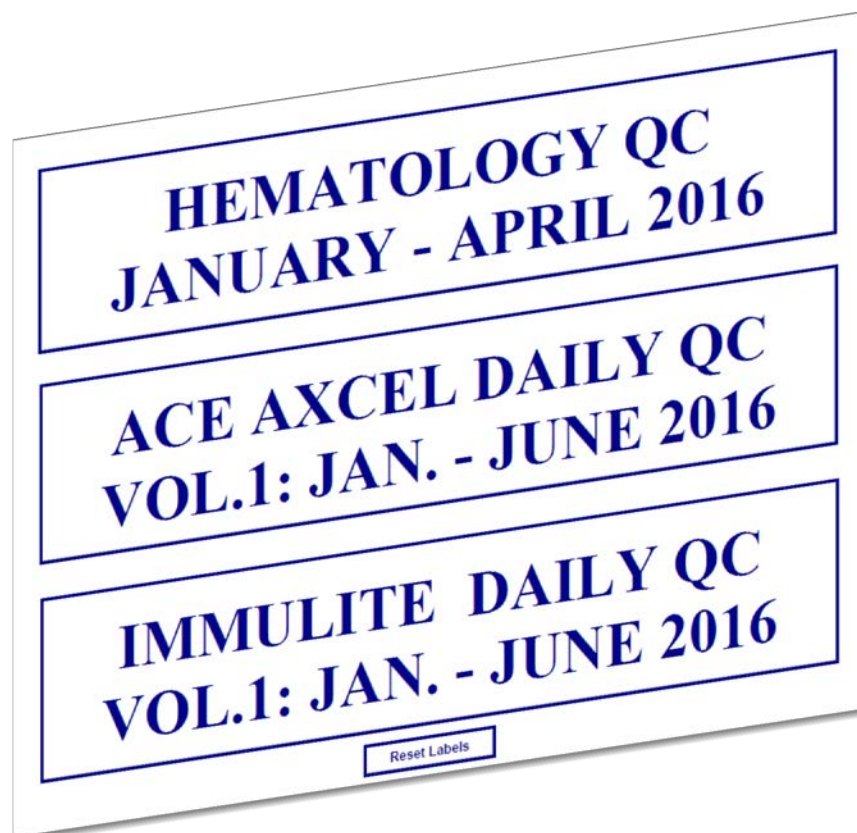
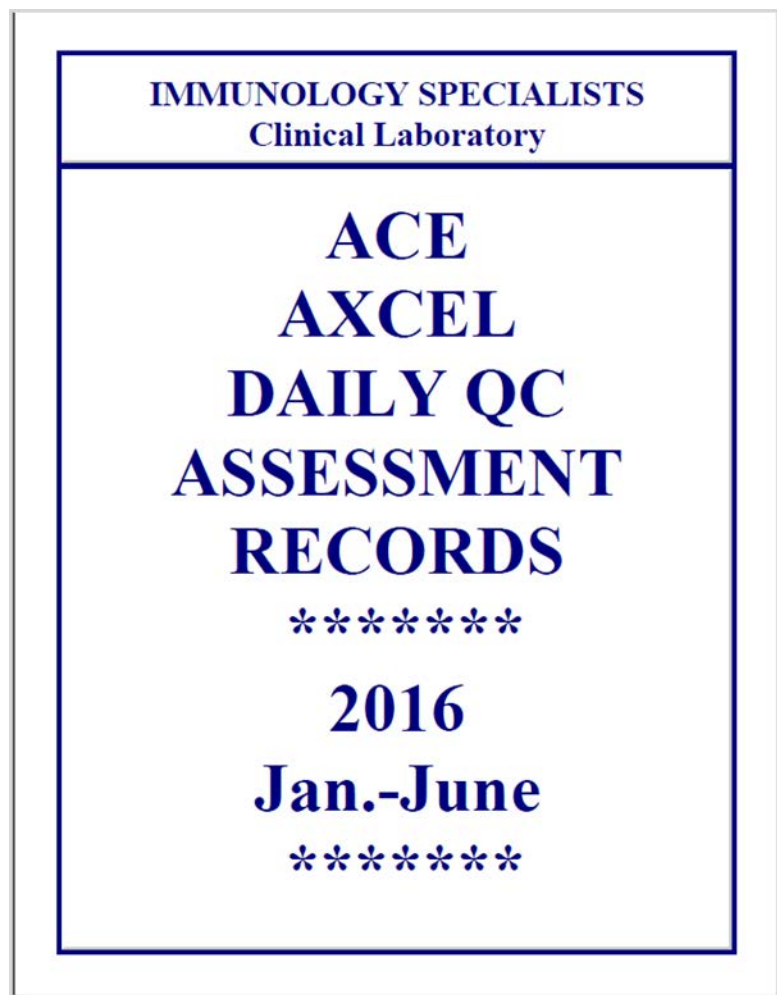
The Daily QC Review Binder Contents

1. 'Daily QC Review Binders' are prepared for each Test System, to contain the daily QC reports
2. 'Daily QC Assessment Reports' are hole-punched and saved in the month-tabbed 2"-3" Binders (See SLP 500 Binders)
3. Optionally include analyzer QC printouts with the Daily Reports
4. Include Corrective Actions, QC Inserts, Peer Reports, QC Parallel Testing Statistics, Service Reports, in this binder or other designated binder

Daily QC Signed & Filed in Binders

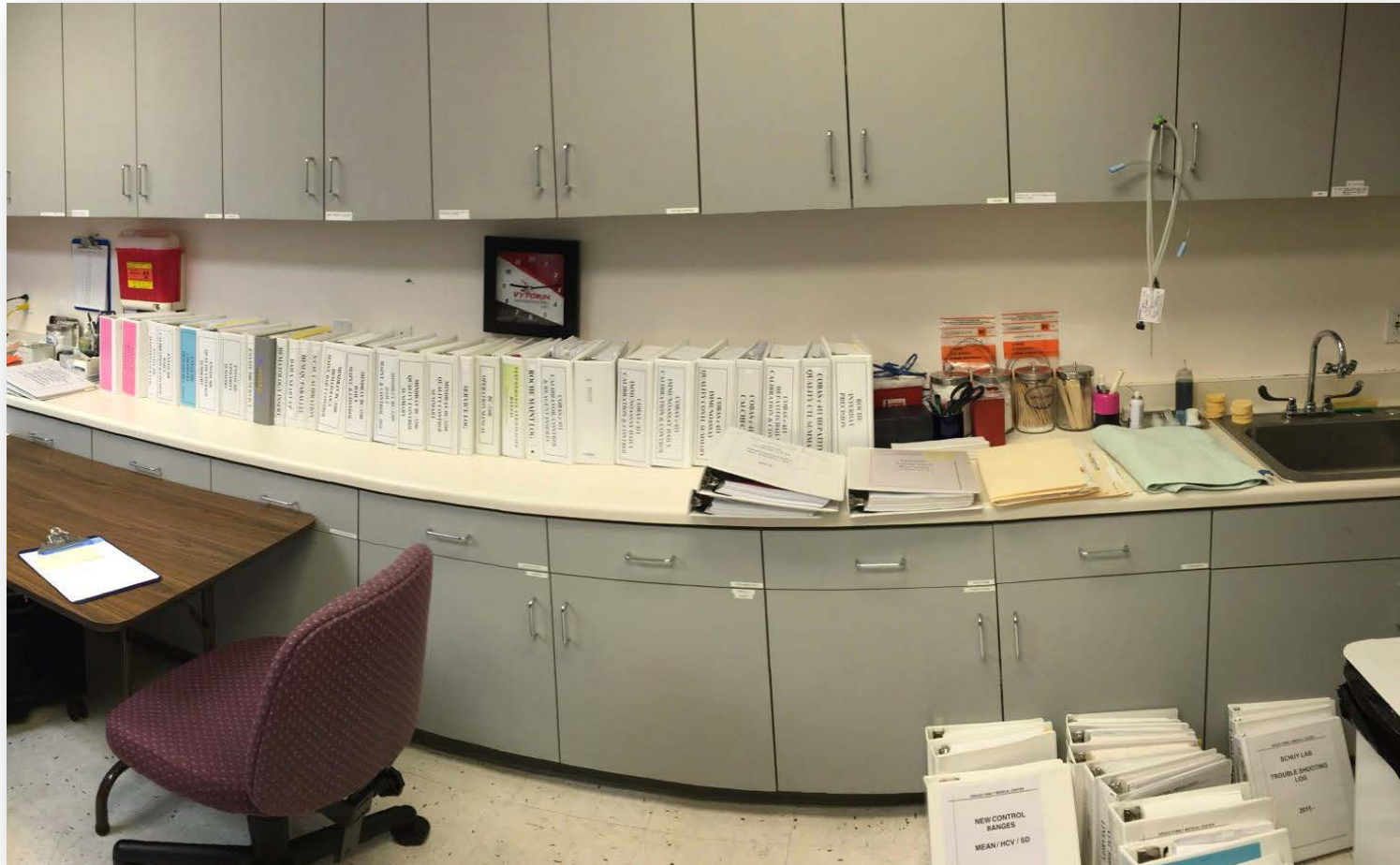


Templates – Binder Cover & 2" Spines



[Click Link For Free Download](#)

Binders Organized for an Inspection



P&P-14

Monthly QC Review - Summary

1. Be sure that EACH 'Daily QC Assessment Report' has been reviewed and initialed by the Testing Person & a responsible Lab Supervisor, TS, TC, or Director
2. Include an EOM 'Monthly QC Review Summary'_ describe the significant QC exceptions (if any) that occurred for that month. (See SLT 202)

P&P-15

L-J Graph – Screen Reviews

1. Weekly, L-J Graph Screen Reviews of Quality Control Files on the Clinical Analyzers or LIS are recommended when available.
2. Monthly, L-J Charts may be viewed only, selectively printed, or all printed.
3. Documentation of L-J reviews by Supervisory Staff may be recorded on the 'SLT 210 Levey-Jennings Review Log'.
4. Review logs may be kept in the *'Daily QC Review Binder'*.

P&P-16

Monthly QC Results Reviews

1. Monthly, or more frequently, as warranted, any additional QC information is gathered and reviewed alongside the accumulation of *'Daily QC Statistical Assessment Reports'*.
2. When available, include in the monthly review;
 - a) QC Statistical Summaries from instruments or LIS
 - b) Graphical representations from instruments or LIS
 - c) Peer reports from inter-laboratory QC programs (EQC)
 - d) Proficiency Results (EQA)
 - e) Updated QC product inserts and notices
3. Reviews should include evaluation of Control Mean and SD assignments, and updated when indicated.

(SLT 419 is a useful tool when evaluating QC limits)

P&P-17

QC Review & Approval Form

1. Monthly, an 'SLT 202 Quality Control Review and Approval Form' is attached to the front of each QC product's monthly collection of 'Daily QC Statistical Assessment Reports', as well as any additional QC documents.
2. Document monthly review comments, with notation of QC exceptions, and actions taken or recommended, & follow-ups.
3. Emphasis on maintenance of acceptable QC performance, and effectiveness of remedial measures taken for QC exceptions.
4. Reviewers should consist of Testing Personnel, Supervisor, Technical Supervisor, as well as Director and/or designee.

QC Review Forms

CLINICAL LABORATORY MONTHLY QC REVIEW



QUALITY CONTROL & INSTRUMENT MAINTENANCE RECORDS REVIEW AND APPROVAL

QC / Maintenance for the Month / Year: September, 2016

DEPARTMENT: General Laboratory

☐ ABX Hematology ☐ Affinion ☐ _____

☐ Pentra 400 ☐ Sysmex Coag ☐ _____

☐ Architect ☐ _____ ☐ _____

☐ No Exceptions Noted, QC O.K. ☐ No Exceptions Noted, Maintenance O.K.

☐ Exceptions Noted:

Comments/Overview:

[Click Here to download
Free QC Review Forms
from SmartLabTools.com](#)

CLS:		Date:	
Technical Supervisor:		Date:	
Staff / Other:		Date:	
Laboratory Director:		Date:	

SLT_202 SmartLabTools.com

RESET

REPLACE WITH NAME OF LABORATORY MONTHLY QUALITY CONTROL SUMMARY

LOCATION	MONTH AND YEAR	PREPARED BY
DAILY QUALITY CONTROL REVIEW: PROBLEMS NOTED THIS MONTH IN THIS SECTION:		<input type="checkbox"/> DAILY QC : NO PROBLEMS NOTED
Temperatures:		
Personnel Compliance:		
Controls (state test, control name, level):		
Standards (state test, manufacturer, level):		
Equipment verification checks (indicate instrument and serial number):		
Daily QC Statistical Assessments, L-J Quality Control Charts:		
Other quality control issues:		
Corrective action(s) taken:		
INTERLABORATORY COMPARISON REPORTS: <input type="checkbox"/> No problems noted on inter-laboratory comparison reports		
Problems noted (indicate test(s), method(s), control name(s)):		
Any QC problems noted which require further review by the Technical Consultant or Lab Director		
Director Review: _____ Dated: _____ TC Review: _____ Dated: _____		

SLT_205 SmartLabTools.com

Reset

QC Review Forms (cont.)

NAME OF LABORATORY GOES HERE
Quality Assurance / Quality Control
Review Form

Review: Monthly QA/QC Notes

Reviewer: _____

Month of Review: September ▼ Review Period: _____

Notes:

Use This Form To Comment on Monthly QC or QA Issues
'Save' your Notes to a Dropbox QA/QC Review Folder

Reviewed by: _____ Reset

Laboratory Staff: _____ Date: _____

Technical Consultant/Supervisor: _____ Date: _____

Director: _____ Date: _____

SLT_215 SmartLabTools.com

REPLACE WITH NAME OF LABORATORY
Quality Assurance
Review Form

Review: QC REVIEW PLAN EFFECTIVENESS

Reviewer: _____

Month of Review: December ▼ Review Period: 2018 YTD

Daily QC Statistical Assessment Reports have been reviewed and filed in the Monthly QC Binders, Monthly QC Reports, QC Logs, Statistical Summaries, Levey-Jennings charts and QC policies have been reviewed. Lab QC was submitted to vendors for Peer Reports,

Performance Measures Related to Method:

1. Quality Control Satisfactory & Performed per analyte procedure	<input checked="" type="checkbox"/> Met	<input type="checkbox"/> Not Met
2. QC is being documented in appropriate places	<input checked="" type="checkbox"/> Met	<input type="checkbox"/> Not Met
3. QC logs are being maintained in an organized manner	<input checked="" type="checkbox"/> Met	<input type="checkbox"/> Not Met
4. QC Inserts and other QC records maintained for 3 years	<input checked="" type="checkbox"/> Met	<input type="checkbox"/> Not Met
5. QC monthly reviews are being performed in a timely manner	<input checked="" type="checkbox"/> Met	<input type="checkbox"/> Not Met
6. QC Corrective Actions have been documented and reviewed	<input checked="" type="checkbox"/> Met	<input type="checkbox"/> Not Met
7. Instruments/Analytes are being Calibrated as required	<input checked="" type="checkbox"/> Met	<input type="checkbox"/> Not Met
8. Temperatures and Maintenance Logs are up-to-date	<input checked="" type="checkbox"/> Met	<input type="checkbox"/> Not Met
9. QC Rules are being followed	<input checked="" type="checkbox"/> Met	<input type="checkbox"/> Not Met
10. IQCP performed on schedule	<input checked="" type="checkbox"/> Met	<input type="checkbox"/> Not Met
11. Cal-Verification(s) are performed as needed or min. each 6mos.	<input checked="" type="checkbox"/> Met	<input type="checkbox"/> Not Met
12. Lab Personnel demonstrate competency with QC processes	<input checked="" type="checkbox"/> Met	<input type="checkbox"/> Not Met

Conclusion: /// Example of QC Review Plan Effectiveness Template ///

Reset

Reviewed by: _____

Laboratory Staff: _____ Date: _____

Technical Consultant/Supervisor: _____ Date: _____

Director: _____ Date: _____


SLT_236 SmartLabTools.com

Replace with name of Laboratory
Line 2
Line 3

[Clear Form](#)

Control	Lot Number	Expiration Date	Date in Use	Other
Reagent				
Calibrator				
Control				
CALIBRATORS,				
CONTROLS, OR				
REAGENTS				

(Section-4) Basic QC Statistics Calculators



Smart LabTools
Empowering Quality Control

CALCULATE QC MEAN(S), SD, CV%, QC RANGES

< REPLACE WITH NAME OF LABORATORY >

PRECISION STUDIES FOR NEW CONTROL LOT#

DESCRIPTION: GLUCOSE

INSTRUMENT: DIMENSION XPAND PLUS

METHOD: ENZYMATIC

CONTROL: BIORAD CHEMISTRY - NORMAL CONTROL

LOT #: 12345..

OTHER: EXP. 10/17

I.D.	1-20	I.D.	21-40	I.D.	41-60
1	102	21	97	41	98
2	103	22	95	42	101
3	99	23	104	43	104
4	95	24	101	44	100
5	104	25	105	45	99
6	107	26	100	46	106
7	103	27	96		
8	100	28	104		
9	98	29	103		
10	97	30	99		
11	101	31	107		
12	105	32	101		
13	96	33	104		
14	104	34	99		
15	110	35	103		
16	99	36	107		
17	103	37	99		

?

QUALITY CONTROL / METHOD VALIDATION


QC STATISTICS

N =	19
MEAN =	26.45
1 SD =	1.63
CV % =	6.15
GEO MEAN =	26.41

QUALITY CONTROL LIMITS	
1 STANDARD DEVIATION =	
2 STANDARD DEVIATIONS =	
3 STANDARD DEVIATIONS =	
Clear Data	

LOW	HIGH
24.83	28.08
23.20	29.71
21.57	31.33
Reset All	

QC Statistics – Multiple Analytes (8 x 20dp)



PRECISION AND ACCURACY STATISTICAL ASSESSMENT
 < Replace with Name of Laboratory >
 // PARALLEL TESTING NEW LOT OF CONTROLS FOR ABX MICROS 60 //

Analyte :	WBC	RBC	HGB	HCT	PLT	GRAN %	LYMP %	MID %
QC Material :	HORRIBA	HORRIBA	HORRIBA	HORRIBA	HORRIBA	HORRIBA	HORRIBA	HORRIBA
Lot Number :	MX401L	MX401L	MX401L	MX401L	MX401L	MX401L	MX401L	MX401L
Expiration :	11/05/16	11/05/16	11/05/16	11/05/16	11/05/16	11/05/16	11/05/16	11/05/16
Target Value :	1.90	2.30	6.0	16.1	75	26.5	63.0	10.5
Ranges :	1.5 - 2.3	2.15 - 2.45	5.6 - 6.4	14.1 - 18.1	55 - 95	19.5 - 33.5	55.0 - 71.0	4.5 - 16.5

Run	L-1	L-1	L-1	L-1	L-1	L-1	L-1	L-1
1	2.0	2.31	6.0	16.2	75	26.9	59.1	10.6
2	1.9	2.30	6.1	16.2	75	26.1	60.2	10.2
3	1.8	2.33	6.1	16.2	76	27.2	61.5	10.3
4	2.0	2.29	6.1	16.1	78	27.0	65.1	10.3
5	1.9	2.30	6.0	16.1	77	26.8	60.3	10.3
6	1.9	2.31	6.1	16.1	78	26.8	60.5	11.0
7	2.0	2.31	6.0	16.3	77	27.3	62.5	11.2
8	1.8	2.32	5.9	16.2	73	29.0	62.0	10.9
9	1.9	2.31	6.0	16.2	74	28.9	62.8	11.1
10	2.0	2.30	6.1	16.1	75	27.6	60.7	11.0

N :	10	10	10	10	10	10	10	10
Mean :	1.92	2.31	6.04	16.17	75.80	27.36	61.47	10.69
1 SD :	0.08	0.01	0.07	0.07	1.69	0.93	1.71	0.39
% CV :	4.11	0.49	1.16	0.42	2.23	3.38	2.79	3.65
Target Value :	1.90	2.30	6.00	16.10	75.00	26.50	63.00	10.50
% Recovery :	101.05	100.35	100.67	100.43	101.07	103.25	97.57	101.81

Clear Form
Reset
Reset
Reset
Reset
Reset
Reset
Reset

Comments : ACCEPTABLE PRECISION, ACCURACY PER INSERT LIMITS - OK FOR USE
 Analyst : KL 10/4/2016 Approved by : DL

Smart
LabTools

ESTABLISH QC MEAN(S), SD, CV%, QC RANGES

< Replace with Name of Laboratory >

DESCRIPTION: Establish Patient Mean of Normals for Use in the INR Calculation

INSTRUMENT: ACL-1000

ANALYTE: Prothrombin Time

METHOD: Coagulation Time (Seconds)

CONTROL: N/A

LOT #: Thromboplastin Lot# 123456

ID	1-20
9001	10.8
9002	11.1
9003	11.7
9004	11.5
9005	12.0
9006	13.1
9007	11.8
9008	10.8
9009	11.2
9010	13.5
9011	10.7
9012	9.5
9013	10.6
9014	10.9
9015	11.3
9016	11.8
9017	12.0
9018	12.1
9019	13.2
9020	10.8

ID	21-40
9021	12.8
9022	12.1
9023	12.0
9024	12.0
9025	12.7
9026	13.4
9027	10.8
9028	11.8
9029	10.0
9030	9.7
9031	9.8
9032	10.5
9033	10.8
9034	12.2
9035	13.3
9036	12.4
9037	9.4
9038	13.2
9039	13.0
9040	12.8

ID	41-60
9041	11.7
9042	10.1
9043	13.1
9044	12.6
9045	11.0
9046	12.0
9047	10.0
9048	9.0
9049	11.1
9050	10.5
9051	10.3
9052	11.8
9053	11.9
9054	13.2
9055	14.0
9056	9.7
9057	10.4

ID	61-80

ID	81-100

N	MEAN	1SD	CV%	-1SD	+1SD	-2SD	+2SD	-3SD	+3SD	Geom. Mean
57	11.54	1.22	10.56	10.32	12.75	9.10	13.97	7.88	15.19	11.47

COMMENTS: Patient Mean Study - Use Geometric Mean for INR Calculation

Reset

SLT_412 Mean SD Calc 100W
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Daniel W. Leighton, MT(ASCP), CLB

9/21/2015

DL
Analyst

Smart
LabTools

MULTI-ANALYTE QC STATISTICS CALCULATOR

< Replace with Name of Laboratory >

Description: INSTRUMENT XT-1800i PRECISION STUDIES
CONTROL SYSMEX L-1, LOT 10050810 CLOSED MODE

WBC	RBC	HGB	HCT	MCV	PLAT		
3.17	2.26	5.6	17.1	75.7	62		
3.02	2.29	5.6	17.3	75.5	57		
2.94	2.28	5.6	17.3	75.9	60		
3.01	2.28	5.6	17.3	75.9	62		
2.90	2.26	5.7	17.1	75.7	57		
3.00	2.27	5.7	17.3	76.2	60		
2.91	2.24	5.7	17.0	75.9	61		
3.09	2.28	5.7	17.4	76.3	52		
3.03	2.24	5.6	17.4	76.3	62		
3.02	2.28	5.7	17.1	76.3	59		
N =	10	10	10	10	10		
MEAN =	3.01	2.27	5.65	17.23	75.97	59.20	
1SD =	0.08	0.02	0.05	0.14	0.29	3.16	
CV% =	2.71	0.77	0.93	0.82	0.38	5.33	
-2SD =	2.85	2.23	5.54	16.95	75.39	52.89	
+2SD =	3.17	2.30	5.76	17.51	76.55	65.51	
Reset	Reset	Reset	Reset	Reset	Reset	Reset	Reset

Comments: CV% ARE WITHIN MANUFACTURER'S ALLOWABLE LIMITS.
CONTROL VALUES ARE WITHIN INSERT LIMITS.

Reset All

9/21/2015

Analyst: MaryAnn


QC Statistics

FREE Calculator (SLT_100)
Click Anywhere on Image for
Webpage Download Link

There are two formulas to calculate Standard Deviation. This form was programmed using the 'manual' calculation method, which necessitates clicking the check boxes so calculations 'catch-up'.

Newer forms use the 'computer' formula for immediate SD Calculation, and don't require the check boxes.

Check out the many QC Calculators on the SLT website.



Calculate Mean, SD, CV%, Reference Range

?

?

Document Test System Information

Method / Instrument	Test Description	Units
AU400 CHEMISTRY	GLUCOSE	MG/DL

Other Reagent / Q.C. Product Information

EVALUATING NEW LOT OF QC..

Enter Data

88.00	90.00	88.00	86.00	93.00	
89.00	92.00	87.00	87.00	94.00	
86.00	87.00	86.00	90.00	95.00	
84.00	86.00	84.00	91.00	96.00	
89.00	91.00	89.00	88.00	97.00	


CLICK ALL 3 BOXES ==>>> ☐ ☐ ☐ <<<= RE-CLICK WITH CHANGES

Calculated Statistics

N =	25	1 SD Range =		to	89.32
Arithmetic Mean =	89.32	2 SD Range =		to	
1 SD =		3 SD Range =		to	
CV% =					

Analyst: _____

SLT_100 Mean SD Calc 30dp
©2007-2013, SmartLabTools™



Daniel W. Leighton, MT(ASCP), CLB
Email: Dan@smartlabtools.com

Calculate QC Limits..

Smart LabTools **CALCULATE QC LIMITS USING HISTORICAL CV% (HCV)**

CLEAR FORM **< REPLACE WITH NAME OF LABORATORY >**

METHOD : OLYMPUS AU400E OLYMPUS AU400E OLYMPUS AU400E

CONTROLS : BIORAD L-1 BIORAD L-2 BIORAD L-3

LOT #s : 123451.. 123452.. 123453..

EXPIRATION : 08/31/17 08/31/17 08/31/17

ANALYTE	MEAN	HCV	SD	-2SD	+2SD	MEAN	HCV	SD	-2SD	+2SD	MEAN	HCV	SD	-2SD	+2SD
SODIUM	114.5	1.0	1.15	112.21	116.79	141.5	1.0	1.42	138.67	144.33	156.5	2.0	3.13	150.24	162.76
POTASSIUM	2.6	4.0	0.10	2.39	2.81	3.9	2.7	0.11	3.69	4.11	7.36	1.3	0.10	7.17	7.55
CHLORIDE	76.5	1.5	1.15	74.21	78.80	101	1.9	1.92	97.16	104.84	117	2.3	2.69	111.62	122.38
CO2	15.2	7.0	1.06	13.07	17.33	20.4	6.8	1.39	17.63	23.17	27	6.1	1.65	23.71	30.29
GLUCOSE	63	3.1	1.95	59.09	66.91	123	3.0	3.69	115.62	130.38	363	3.1	11.25	340.49	385.51
CREATININE	0.63	8.9	0.06	0.52	0.74	1.83	5.9	0.11	1.61	2.05	6.88	6.9	0.47	5.93	7.83
T. PROTEIN	4.0	3.5	0.14	3.72	4.28	5.3	3.1	0.16	4.97	5.63	6.9	4.1	0.28	6.33	7.47
ALBUMIN	2.5	4.0	0.10	2.30	2.70	3.3	3.0	0.10	3.10	3.50	4.3	3.4	0.15	4.01	4.59
CALCIUM	5.8	4.4	0.26	5.29	6.31	9.8	4.3	0.42	8.96	10.64	13.2	3.6	0.48	12.25	14.15
ALT	22	8	1.76	18.48	25.52	76.5	6.3	4.82	66.86	86.14	165	7.2	11.88	141.24	188.76
AST	40	5.7	2.28	35.44	44.56	94	5.4	5.08	83.85	104.15	226	7.8	17.63	190.74	261.26
ALP	29	12	3.48	22.04	35.96	139	7.6	10.56	117.87	160.13	289	8.6	24.85	239.29	338.71
T. BILI	0.74	2.3	0.02	0.71	0.77	3.1	2.8	0.09	2.93	3.27	7.1	2.4	0.17	6.76	7.44
GGT	24	5.6	1.34	21.31	26.69	65	7.4	4.81	55.38	74.62	111	8.3	9.21	92.57	129.43
BUN	14.7	4.3	0.63	13.44	15.96	40.5	3.2	1.30	37.91	43.09	73	3.2	2.34	68.33	77.67
URIC ACID	3.5	3.0	0.11	3.29	3.71	5.8	4.3	0.25	5.30	6.30	9.8	5.1	0.50	8.80	10.80
TOT. CHOL	109	5.1	5.56	97.88	120.12	174	3.5	6.09	161.82	186.18	263	3.8	9.99	243.01	282.99
HDL CHOL	37	3.4	1.26	34.48	39.52	65	2.8	1.82	61.36	68.64	90	3.1	2.79	84.42	95.58
TRIG	87	3.5	3.05	80.91	93.09	136	3.3	4.49	127.02	144.98	211	3.4	7.17	196.65	225.35

SLT_417 v.111613 ©2007-2015, SmartLabTools™ Daniel W. Leighton, MT(ASCP), CLB

SLT_417

Smart LabTools **Simple Q.C. Range Calculator**

DESCRIBE TEST SYSTEM HERE

Enter Known Mean and SD to Calculate CV%, 2SD, 3SD Limits

Control Level	Mean	1SD	-2SD	+2SD	-3SD	+3SD	CV%
Level-1	100.00	2.50	95.00	105.00	92.50	107.50	2.50
Level-2	200.00	3.50	193.00	207.00	189.50	210.50	1.75
Level-3	300.00	5.00	290.00	310.00	285.00	315.00	1.67

Enter Range to Calculate Mean and 1SD (If Range is 2SD) (If Range is 3SD)

Control Level	Range Low	Range High	Mean	1SD	Mean	1SD	CV%
Level-1	95.00	105.00	100.00	2.50	100.00	1.67	2.50
Level-2	193.00	207.00	200.00	3.50	200.00	2.33	1.75
Level-3	290.00	310.00	300.00	5.00	300.00	3.33	1.67

Enter Mean and CV% to Calculate 1SD, and 2SD QC Limits

Control Level	Mean	CV%	1SD	-2SD Limit	+2SD Limit
Level-1	100.00	2.50	2.50	95.00	105.00
Level-2	200.00	1.75	3.50	193.00	207.00
Level-3	300.00	1.67	5.01	289.98	310.02

Reset

Comments: Use this Simple Calculator to quickly Convert QC Limits from Inserts or other sources for use in your QC Program.

[Click Here for Free Download](#)

SLT_111.d Simple QC Range Calculator ©2007-2014, SmartLabTools™ Daniel W. Leighton, MT(ASCP), CLB Email: Dan@smartlabtools.com

SLT_111

Levey-Jennings Q.C. Chart & Mean, SD Calculator

INTERNAL MEDICINE ASSOCIATES

[illegible]

Normal Distribution Simulation

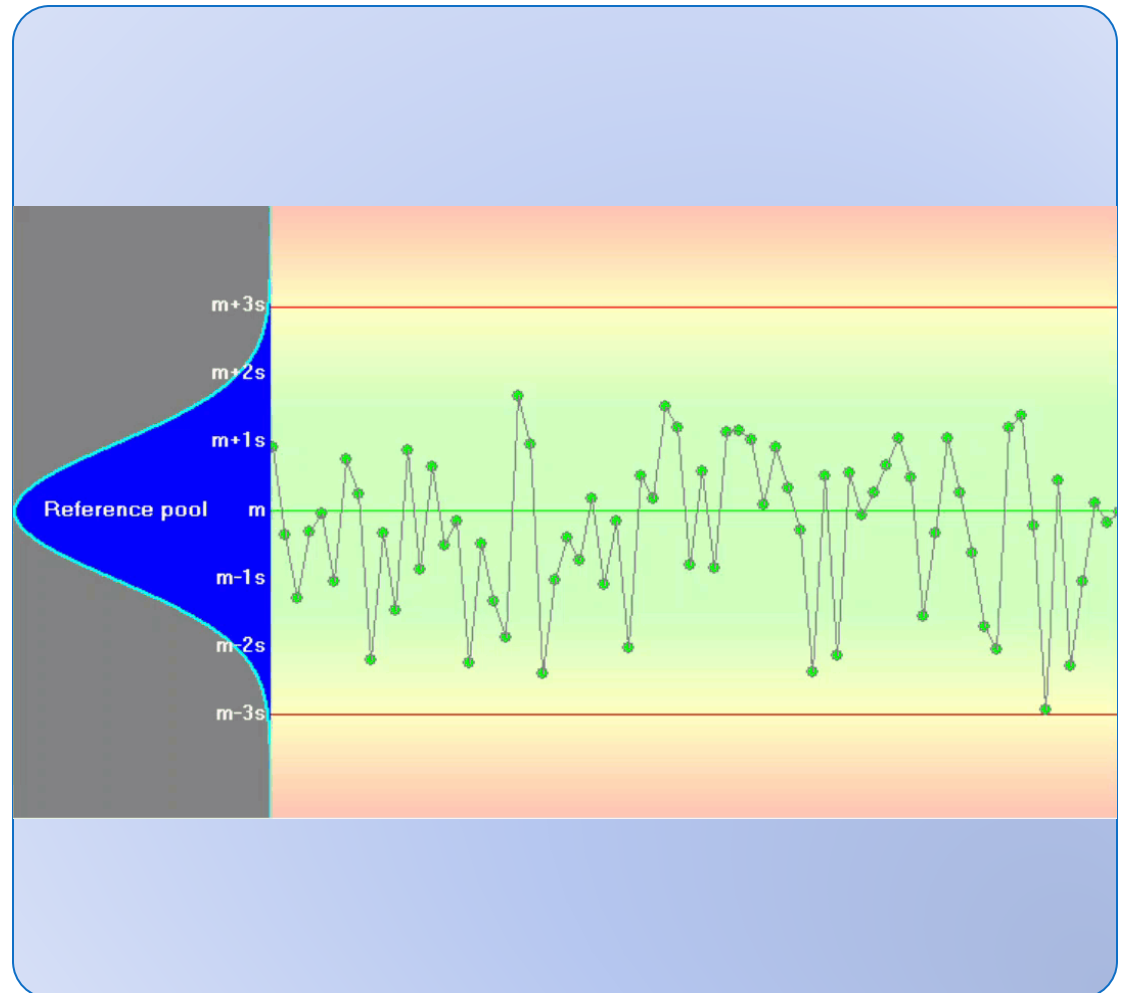
Zero Bias

+1SD Bias

+2SD Bias

CV x 2

CV x 2 , -1SD Bias



Bias Increased by +1SD Simulation

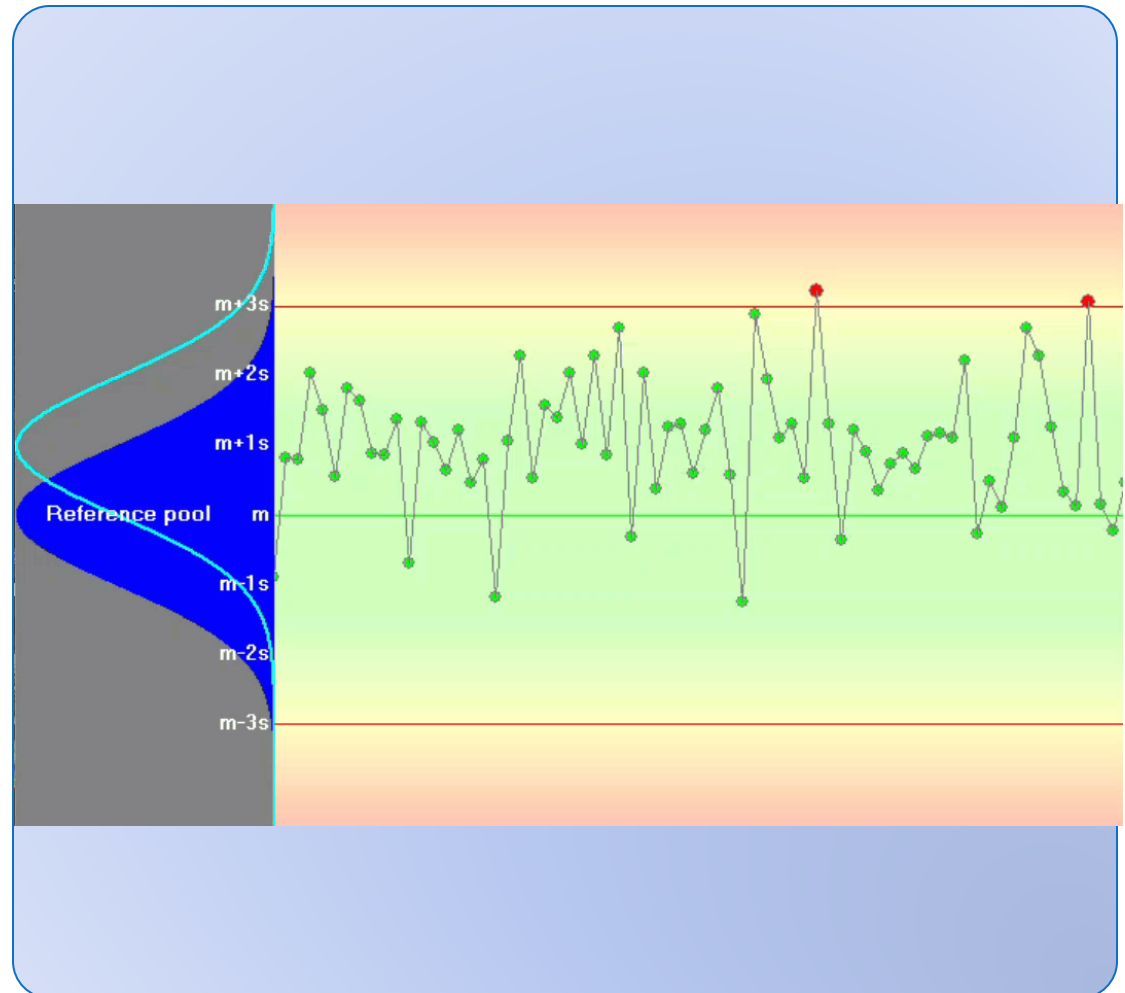
Zero Bias

+1SD Bias

+2SD Bias

CV x 2

CV x 2 , -1SD Bias



Bias Increased by +2SD Simulation

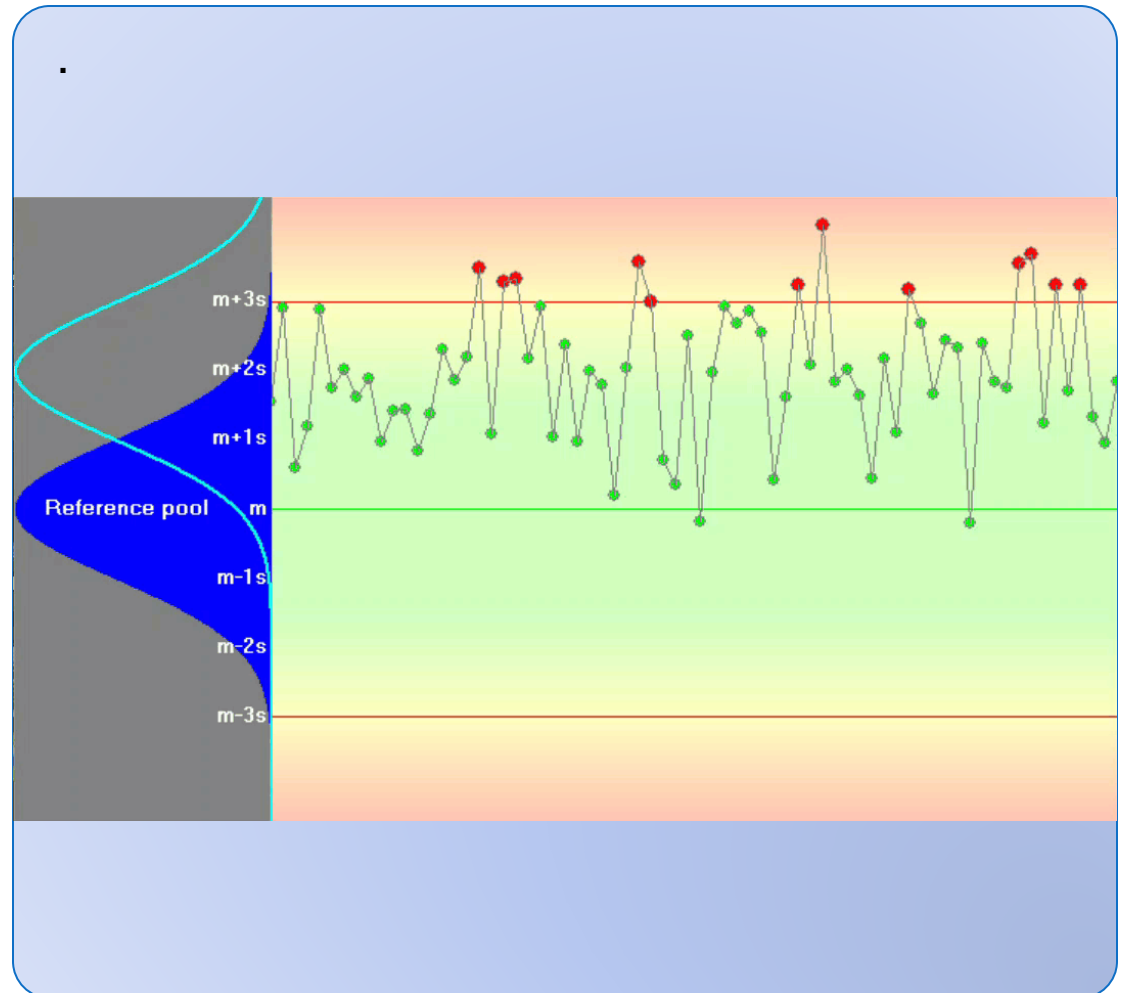
Zero Bias

+1SD Bias

+2SD Bias

CV x 2

CV x 2 , -1SD Bias



Imprecision Increased x 2 Simulation

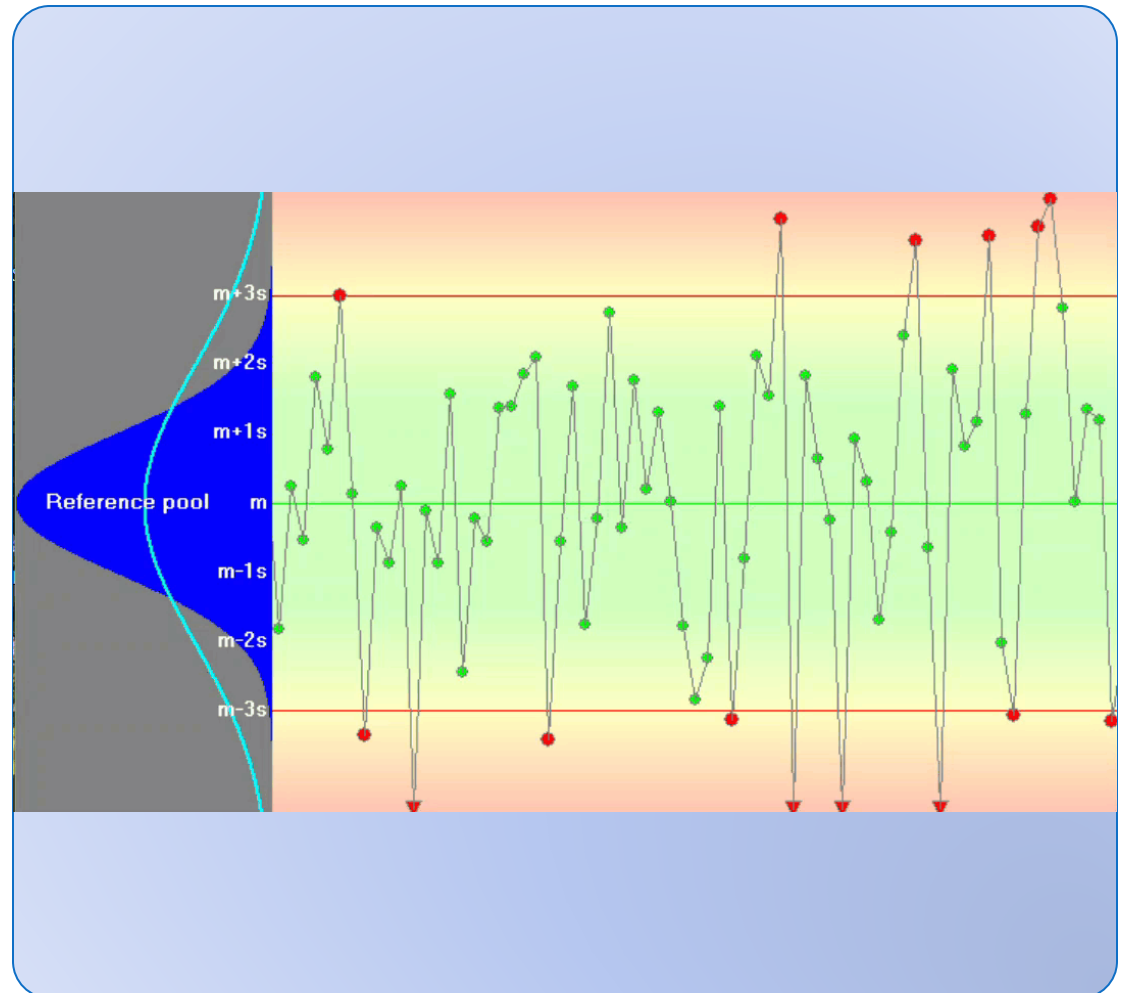
Zero Bias

+1SD Bias

+2SD Bias

CV x 2

CV x 2 , -1SD Bias



Bias & Imprecision Simulation

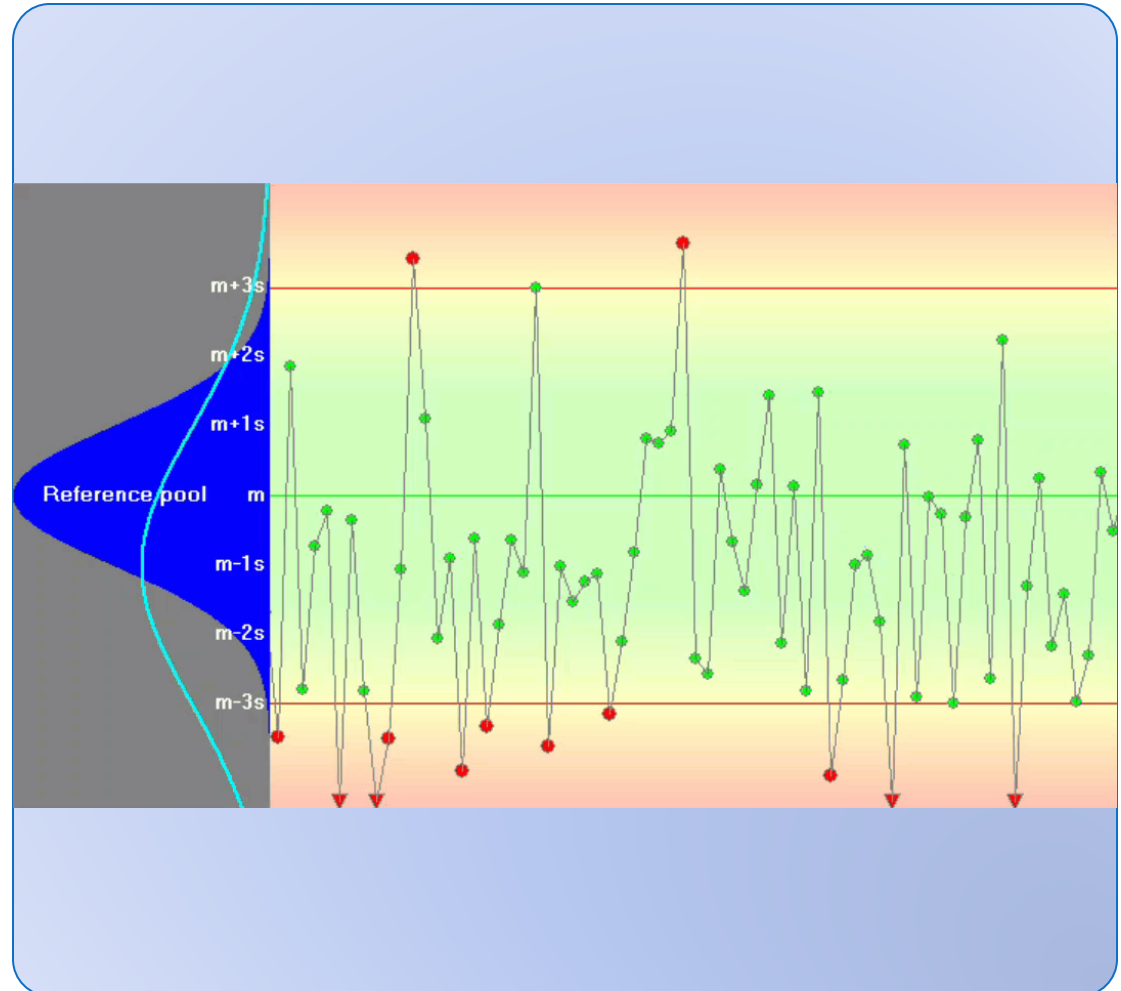
Zero Bias

+ 1SD Bias

+ 2SD Bias

CV x 2

CV x 2 , -1SD Bias



(Section-5) Cloud Storage and Sharing

Dropbox

Dropbox, Inc.

<https://www.dropbox.com/install>



The benefit of saving the electronic PDF files in a web folder is that they may be shared and viewed remotely.

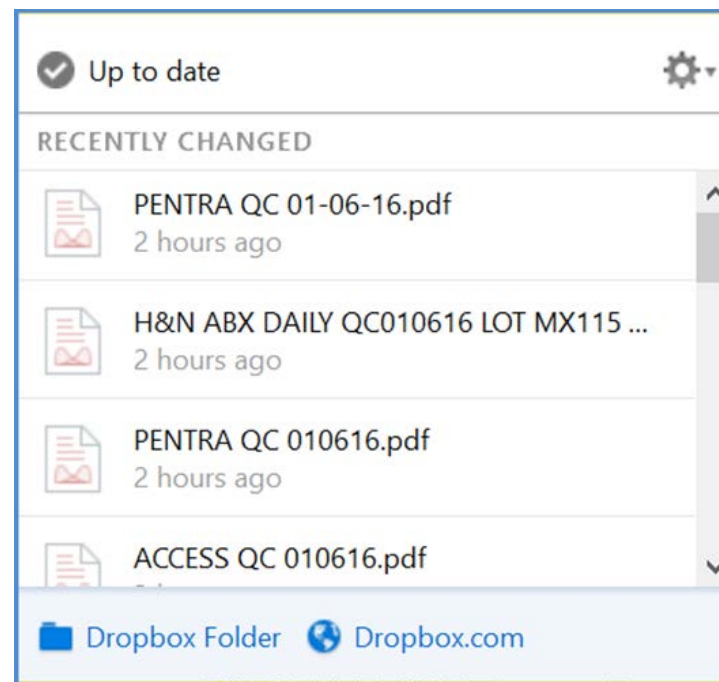
The following illustrates use of Dropbox for QC Files

Using Dropbox Folders (Web Application)

In Dropbox Create

- db folder for each Lab
- Subfolders by subject
- Subfolders by analyzer
- Subfolders by year
- Subfolders by month

Save QC Reports (files)
include date in filename

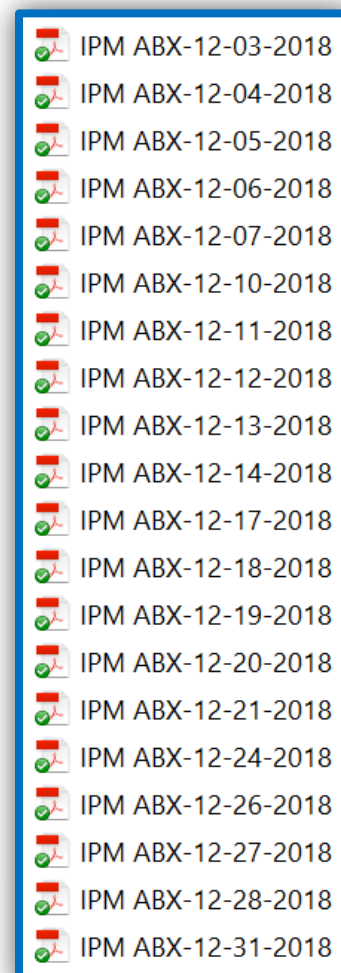
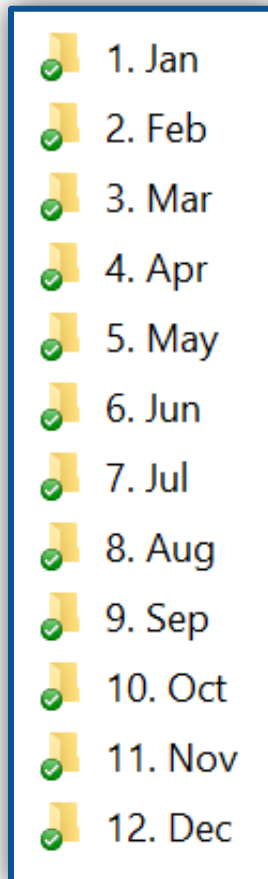
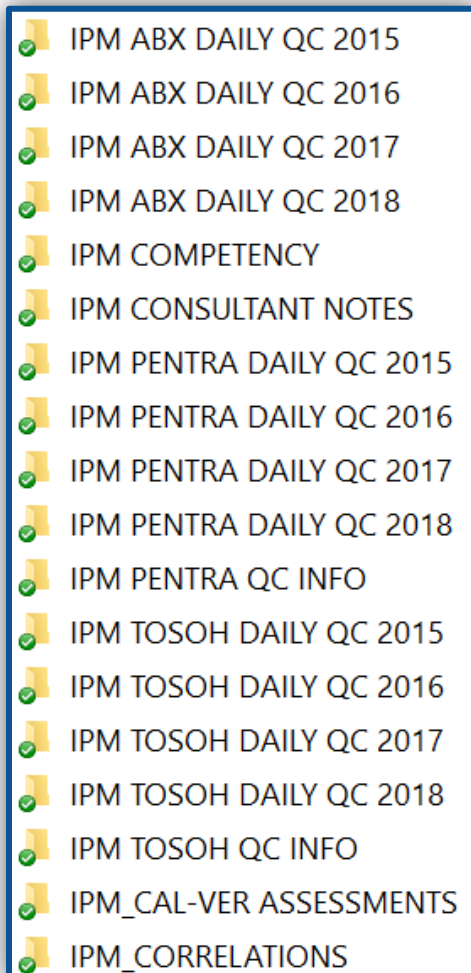


QC Activity as viewed from consultants desktop

Dropbox Folders with QC Reports (PDF's)

Filed by:

- Instrument
- Year
- Month
- Day



Dropbox.. QC Activity Reports emailed



IPM Lab Irvine_Folder



IPM ABX-08-15-2016.pdf

Added to 8. AUG 2016 by Kathy Monday 8/15/2016



PENTRA QC 08-12-16.pdf

Added to 8. AUG 2016 by Kathy Friday 8/12/2016



IPM_TOSOH QC 08-12-16.pdf

Added to 8. AUG 2016 by Kathy Friday 8/12/2016



IPM ABX-08-12-2016.pdf

Added to 8. AUG 2016 by Kathy Friday 8/12/2016



IPM ABX-08-11-2016.pdf

Added to 8. AUG 2016 by Kathy Thursday 8/11/2016

7 other events ...



ACR_Folder



INTEGRA 400 DAILY QC 08-15-16.pdf

Added to 8. AUG 2016 by Guillermo Monday 8/15/2016



INTEGRA 400 DAILY QC 08-11-16.pdf

Added to 8. AUG 2016 by Guillermo Thursday 8/11/2016



SYSMEX DAILY QC 07-27-16.pdf

Added to 7 SYSMEX D...016 by Guillermo Tuesday 8/9/2016



SYSMEX DAILY QC 07-26-16.pdf

Added to 7 SYSMEX D...016 by Guillermo Tuesday 8/9/2016



SYSMEX DAILY QC 07-25-16.pdf

Added to 7 SYSMEX D...016 by Guillermo Tuesday 8/9/2016

5 other events ...

FOLLOWING ARE SOME QC RELATED CITATIONS

Be Prepared:

One QC Out... can lead to 6 deficiencies

We were scheduled for a [REDACTED] inspection, and I wanted to wait it out before retiring. [REDACTED] surveyor came on [REDACTED] turned out to be not the usual [REDACTED] surveyor. She was not in a good mood; and proceeded to slam through our operations for the past 24 months with a laser... then any single deficiency got bundled with related up-line responsibilities. Sample in point - only one QC point recorded with Estradiol, on a particular day 2 years ago, got a QC citation; that triggered a Personnel Competency citation, and not following QC P&P, and Supervisory Lack of Training citation, and an Incompetent Tech Supv citation, finishing with a Director not Ensuring... citation. That was SIX citations from this ONE observation. Wow. So, SIX legit deficiencies exponentially became 36 citations. Frightful of [REDACTED] a giant Shift in our history.

***Examiners are highly experienced at finding QC deficiencies..
It's best the laboratory find and fix them first.***

***SmartLabTools™ QC Statistical Assessment system can help
provide that “additional measure” needed to ensure lab is
examining each QC result prior to reporting patient results.***

CMS - QC Citation Response Denied

D5469

The laboratory's allegation of compliance is not credible and evidence of correction is not acceptable.

Finding #1

Although the laboratory's submitted protocol indicates that the stated values of new commercially assayed CBC QC materials were to be verified through parallel testing against QC materials in use, the laboratory provided no documentation indicating that this protocol had been effectuated, no information as to how the results of the parallel testing will be documented, and no information as to whether laboratory staff has been trained on this new protocol.

Lesson here is that if you say your going to do something in your Policy & Procedure... Examiner's will hold you to it.

SLT_410 & SLT 413 were created for parallel testing Hematology QC and Chemistry QC.

CMS - QC Citation - Corrective Action

D5481

The laboratory's allegation of compliance is not credible and evidence of correction is not acceptable.

Finding #1

The submission references "Ex. I, Tabs 2-6." We located these tabs, but found no documentation in Tabs 2, 5 and 6.

Although the laboratory's submitted protocol requires that QC values be acceptable prior to reporting patient results, the submission states: "[REDACTED] reviewed all quality control (QC) data for PT/INR [Prothombin Time/International Normalized Ratio] for the time period that this lot of Dade Innovin was in use." The laboratory provided no documentation of this review other than stating it was performed. We also found no documentation to indicate that the revised standard operating procedures (SOPS) have been effectuated. That is, we found no documentation of PT/INR QC failure investigations and corrective actions taken based on the revised SOPS.

Documenting QC failure investigations & corrective actions is an essential part of any laboratory Quality Control program. Forms for documenting QC Corrective Actions & Reviews are provided in the SLT_QC System.

QC Citation – Follow Lab's QC Policy

a. The General Quality Control Policy, under "Control Processing" stated "The technologist performing the assay must check that control results are within acceptable limits before reporting patient's results. If control results are acceptable, proceed to run and report patient samples. " Under " Corrective Action if Control Results are Not Acceptable (i.e. exceed +/- 2 SD are rejected by Westgard rules ...) " the policy stated, "Do not report patient results if QC is unacceptable."

b. Quality control results did not meet the laboratory's criteria for acceptability for Total Bilirubin on 9/10/15 when the Day to Day Chart (Levey Jennings Chart) showed that 1 of 2 results (Multiquel Level 3) exceeded 2 standard deviations from the mean.

g. There were no corrective actions documented when quality control results failed to meet the criteria for acceptability, including assessment of patient test results in the unacceptable run and since the last acceptable test run to determine if patient test results had been adversely affected.

Statistically, 1 in 20 results may exceed 2SD limits for each control

The 1-2s Rule can be too restrictive, and should be used as a 'Warning' and not for 'Rejection'

Set 2-2s, and 1-3s for Rejection Rules with SLT QC



Daniel W. Leighton, Bioanalyst
dan@smartlabtools.com