SMARTLABTOOLS™ QUALITY CONTROL SYSTEM

A Collection of PDF Templates for Creating an Effective Statistical Quality Control Program

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Ver.122616

Introduction to 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.
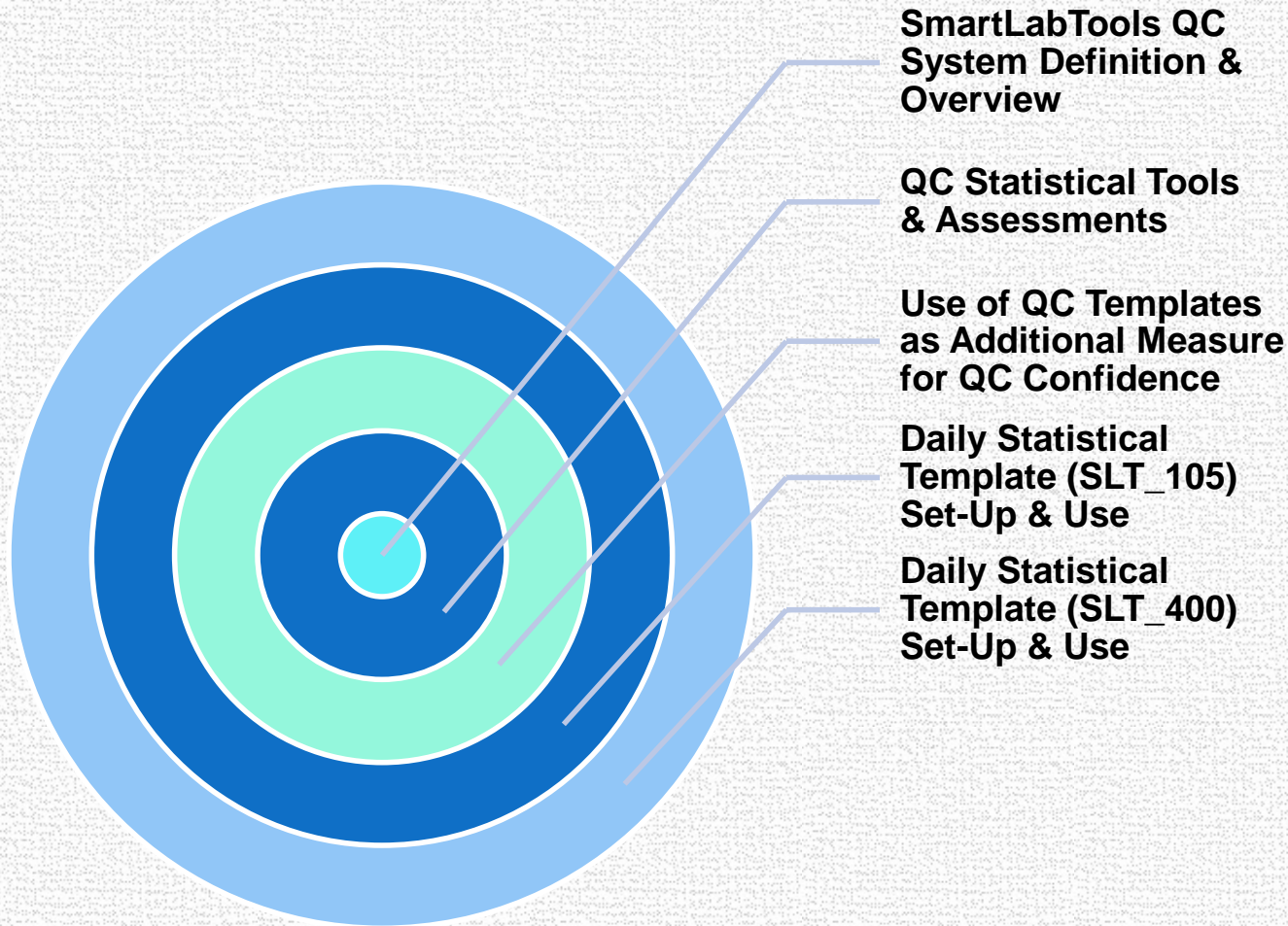
This presentation is meant as a teaching tool, for use of the QC System.

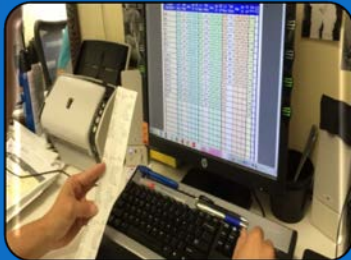Analysts will require fundamental QC skills to competently implement the software, use control rules, interpret QC results, and for troubleshooting. Links to numerous educational resources are provided.

Disclosure: The author has no financial relationships with any of the references mentioned.

(Section -1) QC System Overview

SmartLabTools QC System Definition & Overview

QC Statistical Tools & Assessments

Use of QC Templates as Additional Measure for QC Confidence

Daily Statistical Template (SLT_105) Set-Up & Use

Daily Statistical Template (SLT_400) Set-Up & Use
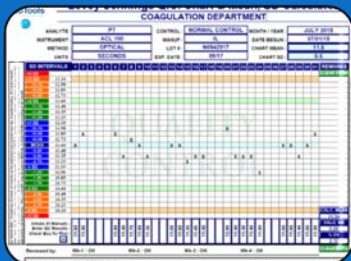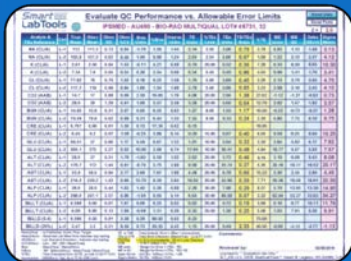
IQCP or Regular QC ?

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

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.

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	• Sum of individual measurements / # of measurements • An estimate of central tendency of stable system distribution • Relates to accuracy or systematic error
Standard Deviation (SD)	$$S = \sqrt{\Sigma(Xi - X)^2 \ / \ (n-1)}$$ • 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)	• 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. <u>QC objective</u>: **monitor change**
SDI*(z-score) An Indicator of Bias *(Value – Target) / Target SD* AVE SDI (z) 2 or 3 controls	A "z-score" describes how many standard deviations a control result is from the mean expected for the material • 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 *Reference: Advance: Scott Warner, Blog 2014*

* 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

QC ALERTS	DEFINITION / ACTION
SLT_105 Template SDI Adjustable Alert Flag	** Trend Alert - Warrants Attention* 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) An Asterisk(*) appears next to the QC Result. ** SDI >2.0 Warrants Investigation* Appears in the 'actions' section whenever a QC value exceeds 2.0 SDI *"QC Out"* In the <u>QC Out </u>column when QC value exceeds 2.0 SDI
SLT_400 Template SDI Adjustable Alert Flag	** Trend Alert – Warrants Attention* 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) ** QC Out – Requires Investigation* Appears in the 'actions' section whenever a QC value exceeds 2.0 SDI *"Out"* Appears in the <u>QC In?</u> column

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:

Allows for the immediate data analysis needed to make a decision on the acceptance or rejection of an analytical run, and reporting patient results

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 *(Review 90 files in 9 Seconds)*

Serves as the 'Master' QC source. Analyzer QC limits and LIS QC limits follow those established and managed with SLT QC template

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

Using the Daily QC Templates…

Set up for Rapid Manual Data Entry using [Tab] key

Calculates QC Result Bias, Provides SDI Calculations & 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 to see if a potential QC problem exists

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)*

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

Example-1 (No QC Exceptions)

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]   Kathy — **Analyst**   DL — **Reviewed by**

Click for Link To QC Reference

Example-2 (With a QC Exception)

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

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

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1/6/2016 7:19 am   [Reset All] [Reset Data]   Kathy — **Analyst**   DL — **Reviewed by**

Click for Link To QC Reference

SLT_105 Setting up the QC Template

- 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

HIGH CTL	WBC	18.30	22.30	20.30	1.00					
61930424	RBC	5.08	5.68	5.38	0.15					
	HGB	14.80	16.40	15.60	0.40					
	HCT	43.50	50.50	47.00	1.75					
	PLT	464.00	564.00	514.00	25.00					
	GRAN %	73.20	85.20	79.20	3.00					
	LYMP %	7.30	17.30	12.30	2.50					
	MONO %	4.40	12.40	8.40	2.00					

QC item(s):
Problem: ...
Actions: ...

Please Refer to website for
Interactive Demo of Data Entry

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 occurance
Actions: Opened New Vial of Control & Repeated, Low Ctl Now In (2.38)

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

SLT_CW105a v.082116
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Daniel W. Leighton

8/21/2016
4:02 pm

Reset All | Reset Data

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

SLT_400 Setting up the QC Template

Enter QC Test Values For Statistical Assessment on Page-1

Smart LabTools — Complex Forms made Simple

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)	Trend Alert
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 — Complex Forms made Simple

ACR LABORATORY
ESTABLISHED QUALITY CONTROL PARAMETERS

QC Lesson | Reset All

TEST SYSTEM:	INTEGRA 400+	INTEGRA 400+	INTEGRA 400+
CONTROLS:	MULTIQUAL 1	MULTIQUAL 2	MULTIQUAL 3
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 [(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

- 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

Please Refer to website for Interactive Demo of Data Entry

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	0.20	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: <u>Calibration Bias for RBC</u>… 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)?"*":"")))
```

◉ 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 Trend Flag Alert (*), or Not   Determines QC "Out" or QC "In"

(Section-2) Setting up the QC System

Setting up the QC Program Parameters

QC Wisdom

Establishing +/- 2SD QC Limits, Using (%CVh)

Verifying Insert Ranges < CLIA PT Limits

Example of Confidence Range Too Broad for Clinical Use
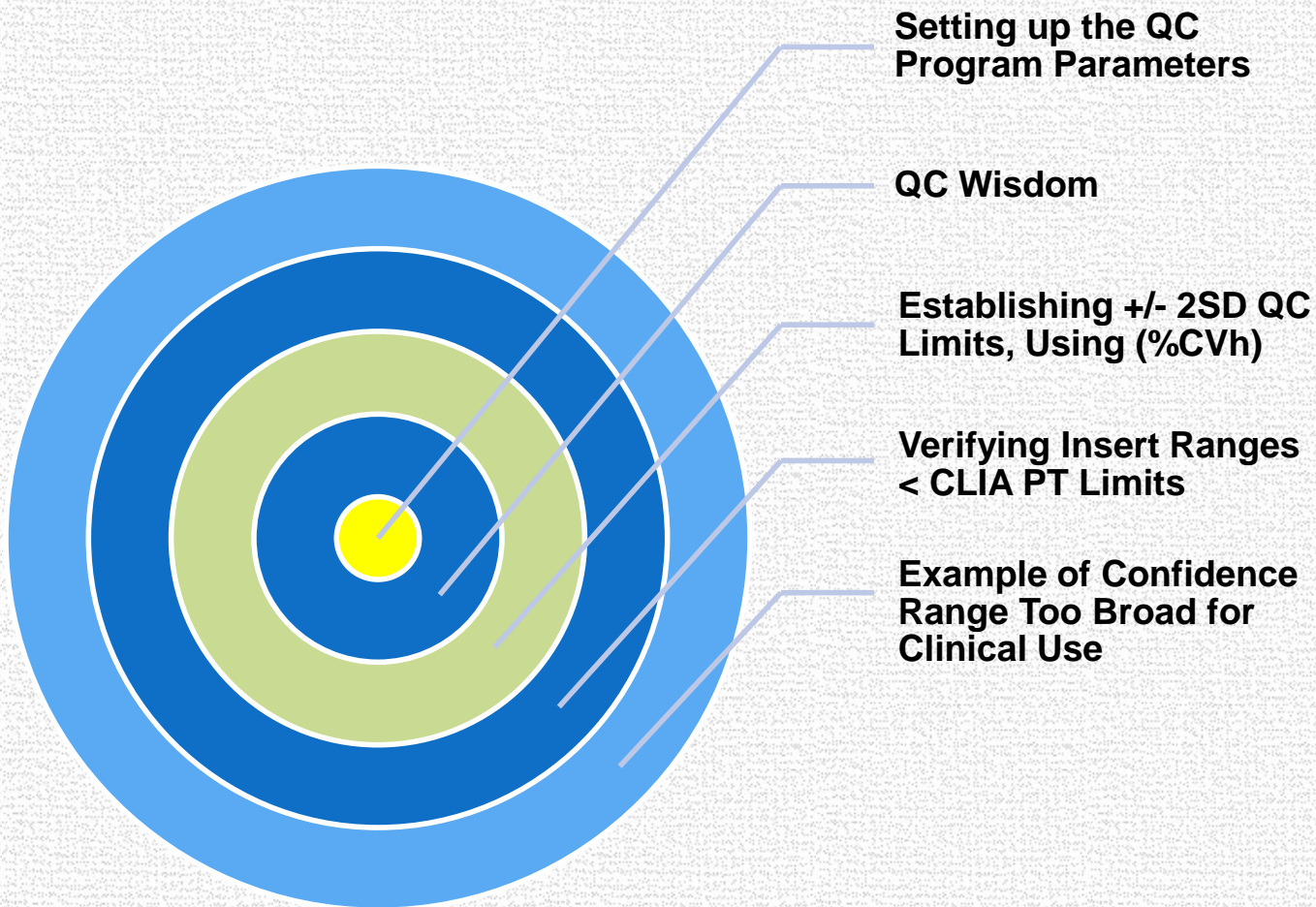
Setting up the Default QC Program

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 *(SLT_413), (SLT_415), other SLT calculator*
4.	Determination of Mean & QC Limits for each level of control	Compare Mean, SD, CV%, to Insert values, Peer, Lab Historical Statistics
5.	Determine Total Allowable Error limits for the Assay (TEa)	QC limits for the assay not to exceed TEa .. (CLIA, CVb, etc.) *(SLT_110, 419)*
6.	Select Control Rules	Refer to Westgard Rules
7.	Use 1_{2s} as Warning Rule	2_{2s} / 1_{3S} suggested as Rejection Rules

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 *(see example slide -31)*
2	Verify given insert limits are 2SD or 3SD, often they are 3SD	SLT Templates require 2SD limits, Verify SD with *SLT_111 Template*
3	Do not use limits that exceed the CLIA Proficiency Testing Limits, or risk failing PT, and Ineffective QC	Analytical Allowable CLIA Error (TEa) Assay limits, and Calculator are available on the *SLT_110 Template*.
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	"Chemistry Guideline for Establishing New Control Lot Means and Quality Control (QC) Ranges Through Parallel Testing and Historic Coefficient of Variation (%CVh)" Authored by Kurt Michael and Paul Richardson	Click on Reference Link: Establishing Chemistry QC Ranges pSMILE — Patient Safety Monitoring & International Laboratory Evaluation Link to pSMILE
2	"Best Practices in Establishing Quality Control Parameters" Authored by M. Laura Parnas, PhD Source: Clinical Laboratory News	Click on Reference Link: Best Practices in Establishing QC Parameters
3	"Planning a Statistical Quality Control Strategy" Authored by Greg Miller, PhD Source: AACC 2016 Workshop	Click on Reference Link: "Planning a Statistical Quality Control Strategy"
4	SmartLabTools Templates to Calculate +/- 2SD Limits using (%CVh)	Templates SLT_417, SLT_111.d

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 Preferred For Calculating Interim 2SD Limits

Verify QC Limits ≤ CLIA PT Limits

Smart LabTools
Complex Forms made Simple

Calculator for Evaluating Control Limits Based on Total Allowable Error Limits

EVALUATING GLUCOSE RANGES

Control Level	TEa Limits			If use TEa (%)			If use TEa (Value)		
	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.

SLT_110

Click Here For Link To Download Free Calculator

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

(SLT_111)

"Confidence Range" is 3SD Limits

Enter Known Mean and SD to Calculate CV%, 2SD, 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			If use CLIA PT (%)			If use CLIA PT (Value)		
Control Level	Mean	Limit %	Limit Val	Low	High	1SD	Low	High	1SD
Level-1	150.00		4.00	150.00	150.00		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

(Section-3) Policies & Procedures

QC Procedure for Results Entry & Statistical Assessment Reports

QC Results Flagging, Alert Messages for Outliers, Shifts, Trends

Westgard 1_{3s} and 2_{2s} Control Rules, and References, Sigma Rules

OOC Procedure & Corrective Action Documentation

Binders for QC Reviews & Summaries, Review Forms, QC Calculators, Remote PDF Results with Dropbox
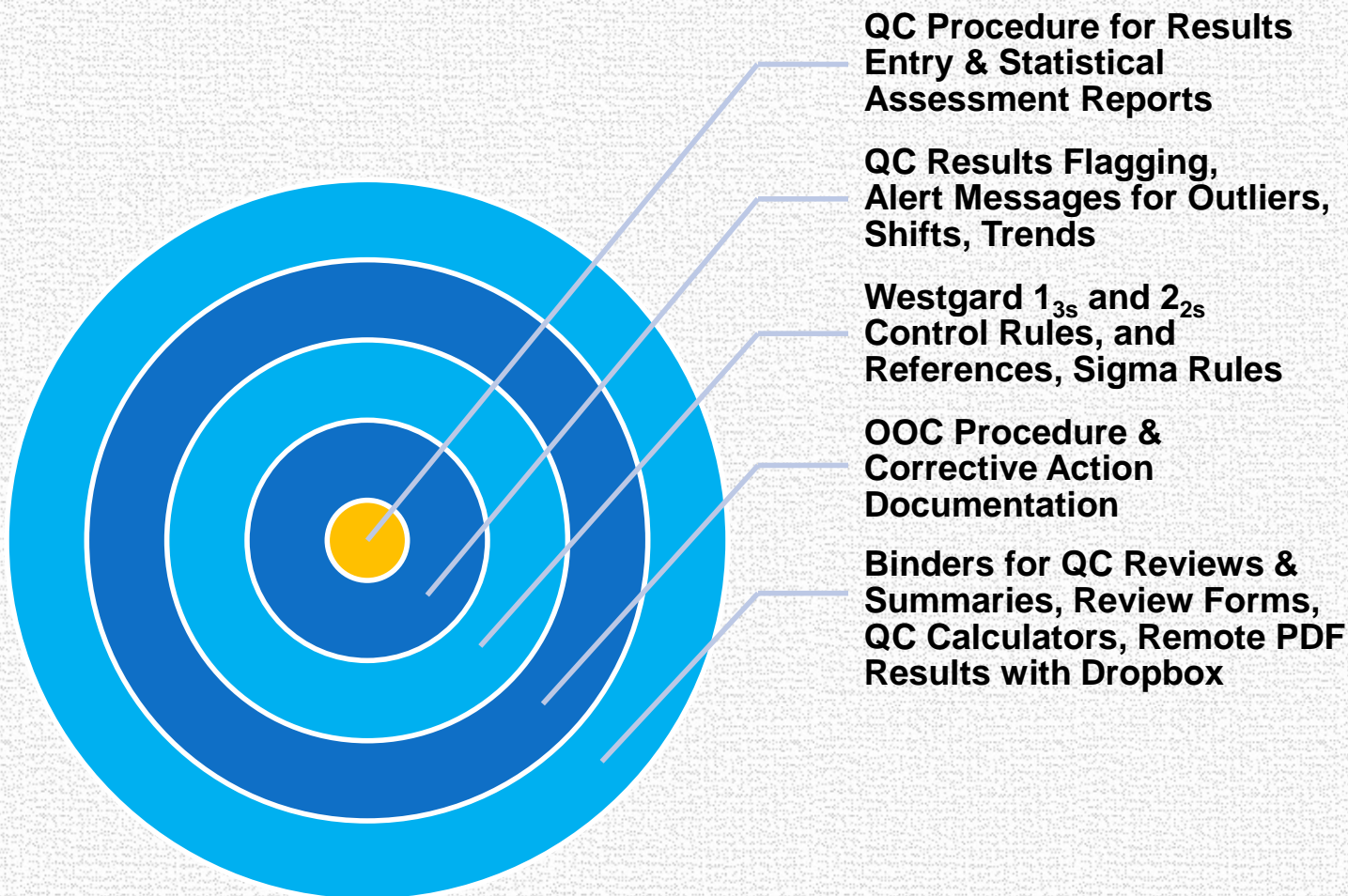
P&P-1:
Results Entry & Statistical Assessment

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 Alert Flag* setting, signaling an 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 the adjustable set <u>SDI Alert limits are exceeded for any single QC event</u>:

   "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 examined further by the analyst for previously flagged results for the same control, and for flagged results of related controls (other levels). The "*Ave SDI (z-score)*" helps when evaluating systematic error such as calibration bias.

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

8. Acknowledgement of review or investigation of the flagged condition can be made by placement of the operator initials on the printout, adjacent to the flagged results.

P&P-4:
Statistical Assessment ("QC Out")

9. **Results that exceed 2SDI (>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

Comment: "*An analytical run should not be rejected if a single quality control value is outside the ±2s QC limits but within the ±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 ±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 Link : 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)
* 2 of 3_{2s}	Two of three results for same QC event/analyte beyond 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

- 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.

- The 1_{2s} rule (not shown) is generally considered as a 'warning rule'.

- *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

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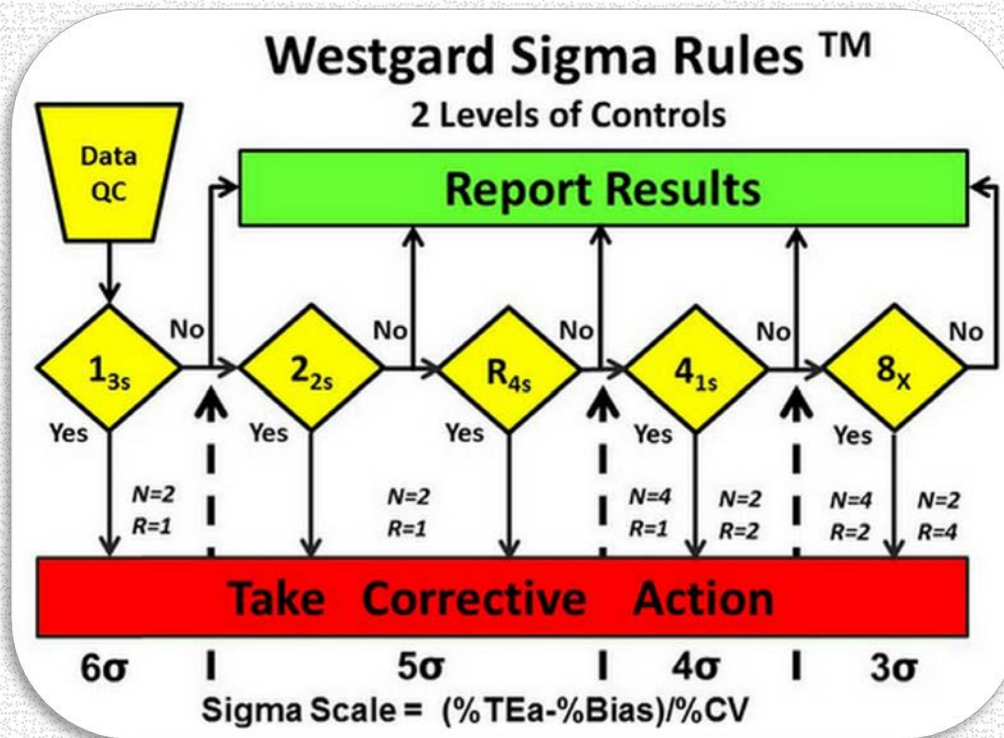
The Westgard Sigma Rules diagram(s) makes it easy to select the **right control rules** and the **right number of control measurements.**

Link to : westgard.com/westgard-sigma-rules

Link to : westgard.com for latest QC manual

Link to : SLT_419 Sigma Calculator

P&P-6:
The 1_{2s} QC Rule not cause for rejection

Accept Run and Report Patient Results if:

1. All controls are within ±2SD of the established mean.

2. **(1_{2s})** One control is within ±2SD second control >2SD, but within ±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 ±3SD *(3.0 SDI)* from the established mean. **(1_{3s})** rule violation.

2. Two controls for same analyte are greater than ±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 <u>re-run</u>. 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)

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

IMMUNOLOGY SPECIALISTS
Clinical Laboratory

ACE
AXCEL
DAILY QC
ASSESSMENT
RECORDS

****

2016
Jan.-June

****

HEMATOLOGY QC
JANUARY - APRIL 2016

ACE AXCEL DAILY QC
VOL.1: JAN. - JUNE 2016

IMMULITE DAILY QC
VOL.1: JAN. - JUNE 2016

Reset Labels

Click Link For Free Download

Binders Organized for an Inspection
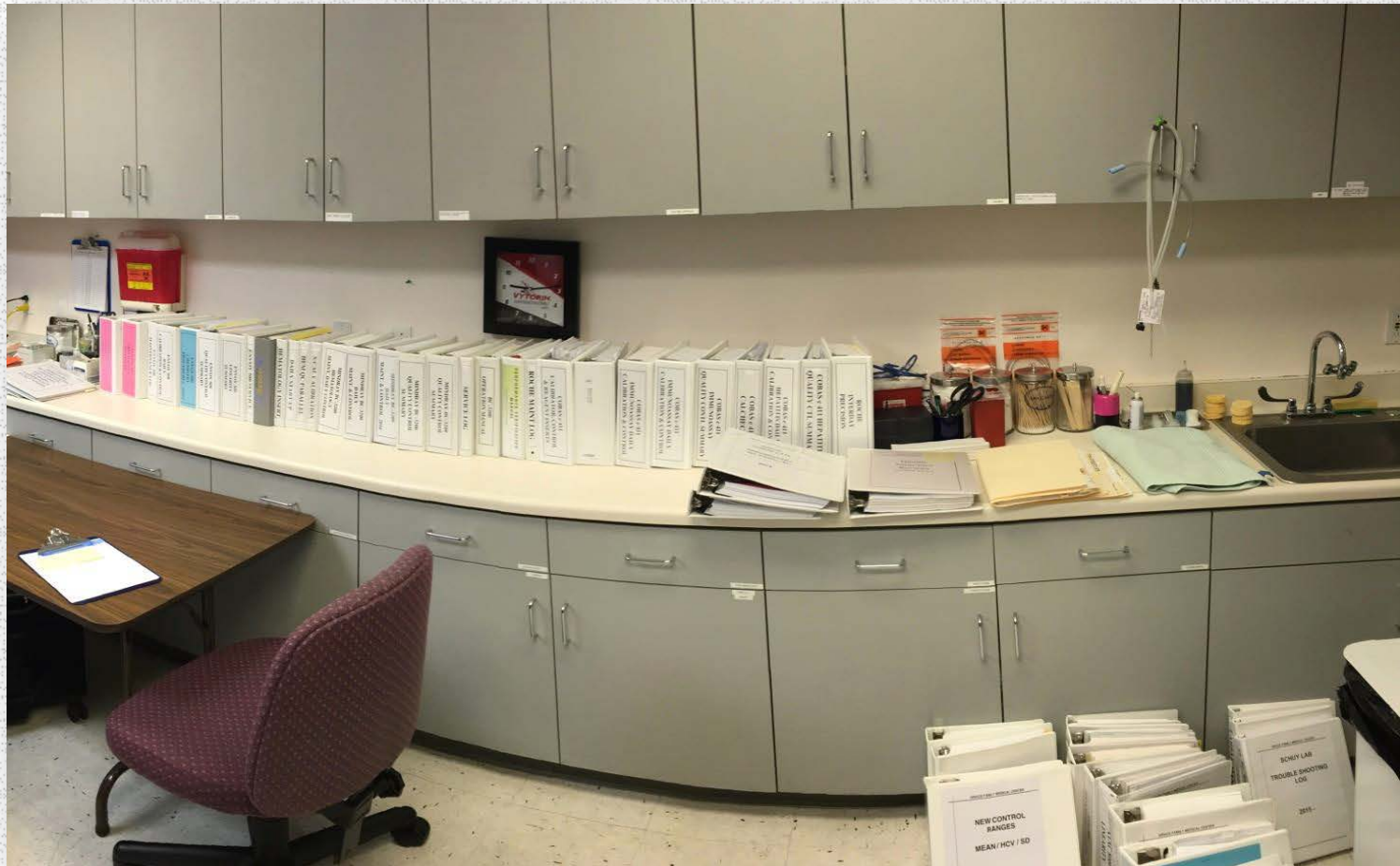
P&P-14
Monthly QC Review - Summary

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 <u>Screen Reviews</u> 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 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

Left form

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:

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

SLT_202 SmartLabTools.com   RESET

Click Here to download Free QC Review Forms from SmartLabTools.com

Right form

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: ☐ 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: ☐ 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

Reset

Reviewed by:

Laboratory Staff: _____ Date: _____

Technical Consultant/Supervisor: _____ Date: _____

Director: _____ Date: _____

SLT_215 SmartLabTools.com

NAME OF LABORATORY GOES HERE
Quality Assurance
Review Form

Review: QC REVIEW PLAN EFFECTIVENESS

Reviewer: D. LEIGHTON, CLB

Month of Review: October ▾ | **Review Period:**

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

Standards:

	Met	Not Met
1. QC is being performed according to protocol.	☐	☐
2. QC is being documented in appropriate places.	☐	☐
3. QC logs are being maintained in a organized manner.	☐	☐
4. QC review is being performed in a timely manner.	☐	☐
5. QC Corrective Actions have been documented and reviewed.	☐	☐
6. Instruments/Analytes are being Calibrated as required.	☐	☐
7. Policies and procedures accurately reflect the activities of the lab.	☐	☐

Conclusion:

Customize this Template for documenting QA Reviews

Reset

Reviewed by:

Laboratory Staff: _____ Date: _____

Technical Consultant/Supervisor: _____ Date: _____

Director: _____ Date: _____

SLT_220 SmartLabTools.com

QC Review Forms (cont.)

NAME OF LABORATORY / Analyzer
WEEKLY QC L-J SCREEN REVIEW LOG SHEET

Date/ By CLS	Review Period	QC L-J Screen Review Findings Indicate Any Tests / QC Files requiring Supervisor Attention
DWL	9/25 - 9/30	You can type text here..... [Reset] Clears the Form

USE THIS FORM TO NOTE ANY ANALYTES THAT REQUIRE ATTENTION BY THE LABORATORY SUPERVISOR. DOCUMENT CORRECTIVE ACTIONS ON THE INSTRUMENT SPECIFIC CORRECTIVE ACTION FORMS LOCATED IN THE CORRECTIVE ACTIONS BINDER.

    line-1
    You can type more text here...
    line-3

Reset

SLT_210 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				

SLT_225 SmartLabTools.com

(Section-4) Basic QC Statistics Calculators

SLT_415

QC Statistics – Multiple Analytes (8 x 20dp)

Smart LabTools

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	Reset

Comments : ACCEPTABLE PRECISION, ACCURACY PER INSERT LIMITS - OK FOR USE

Analyst : KL   10/4/2016   Approved by : DL

SLT_413

QC Statistics Calculators (cont.)

CALCULATE 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	ID	21-40	ID	41-60	ID	61-80	ID	81-100
9001	10.8	9021	12.8	9041	11.7				
9002	11.1	9022	12.1	9042	10.1				
9003	11.7	9023	12.0	9043	13.1				
9004	11.5	9024	12.0	9044	12.6				
9005	12.0	9025	12.7	9045	11.0				
9006	13.1	9026	13.4	9046	12.0				
9007	11.8	9027	10.8	9047	10.0				
9008	10.8	9028	11.8	9048	9.0				
9009	11.2	9029	10.0	9049	11.1				
9010	13.5	9030	9.7	9050	10.5				
9011	10.7	9031	9.8	9051	10.3				
9012	9.5	9032	10.5	9052	11.8				
9013	10.6	9033	10.8	9053	11.9				
9014	10.9	9034	12.2	9054	13.2				
9015	11.3	9035	13.3	9055	14.0				
9016	11.8	9036	12.4	9056	9.7				
9017	12.0	9037	9.4	9057	10.4				
9018	12.1	9038	13.2						
9019	13.2	9039	13.0						
9020	10.8	9040	12.8						

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

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

Reset

DL
9/21/2015   Analyst

SLT_412

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		

	WBC	RBC	HGB	HCT	MCV	PLAT		
N =	10	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   Analyst: MaryAnn
9/21/2015

Form: SLT_410 v.111613   ©2007-2015, SmartLabTools™   Daniel W. Leighton, MT(ASCP), CLB

SLT_410

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.

See other QC Calculators on the SLT website.

Smart LabTools

Calculate Mean, SD, CV%, Reference Range

TYPE YOUR LAB NAME HERE

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% =			

Reset

Analyst: _____

SLT_100 Mean SD Calc 30dp
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SmartLabTools.com

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

Calculate QC Limits..

SLT_417

SLT_111

L-J Chart – Simple to Create

WATCH...

INSTRUCTION DEMO

1. *QC ENTERED LOWER SCREEN*

2. *MEAN & SD ARE CALCULATED*

3. *USER UPDATE CHART MEAN & SD*

4. *CHART IS AUTO-SCALED*

5. *CLICK BOX TO PLOT DATA*

6. *SAVE OR PRINT PDF QC CHART*

SLT_416

(Section-5) Cloud Storage and Sharing

Dropbox

Dropbox, Inc.

https://www.**dropbox**.com/install
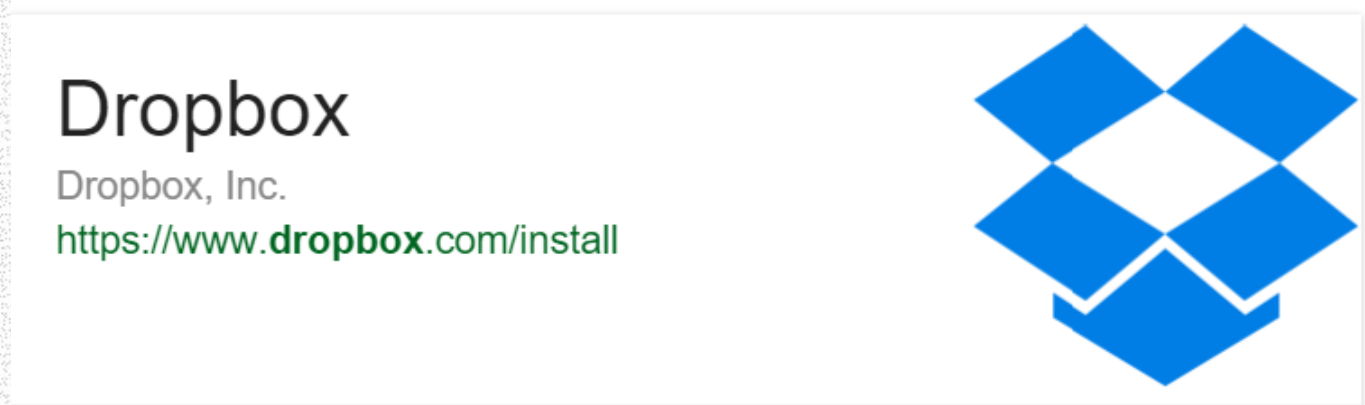
The benefit of saving the electronic PDF files in a web folder is that they may be shared and viewed remotely.

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
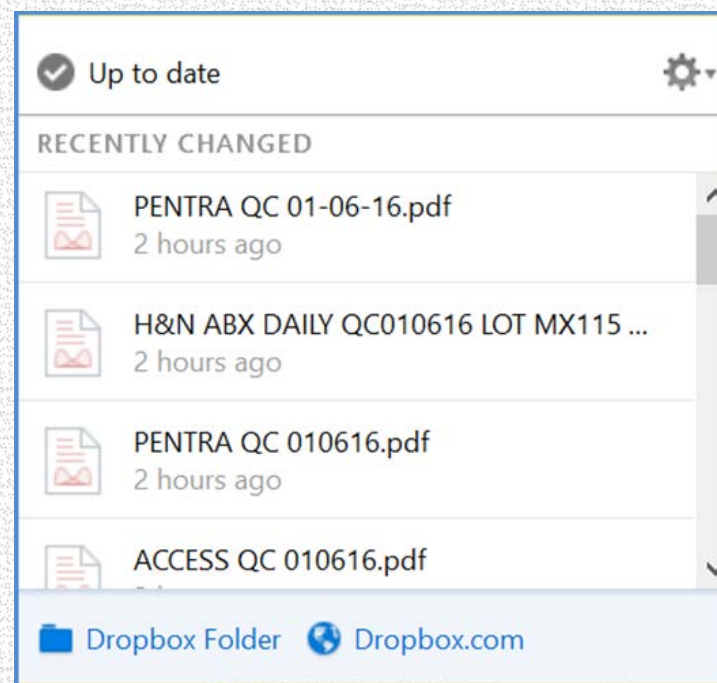
QC Activity as viewed from consultants desktop

Dropbox Folders with QC Reports (PDF's)

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 with an Effective QC Program: One QC Out… can lead to 6 deficiencies

We were scheduled for a ▓▓▓▓ inspection, and I wanted to wait it out before retiring.
▓▓▓▓ surveyor came on �_____ turned out to be not the usual ▓▓▓▓ 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 ▓▓▓▓ 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 and every QC result prior to reporting patient results.

CMS - QC Citation – Parallel Testing

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_413 was created to meet the parallel testing requirement for Hematology QC.

CMS - QC Citation - Corrective Action

D5481

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

<u>Finding #1</u>
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: "_____ 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 (Multiqual 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'

At minimum set 2-2S, and 1-3S Rules

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