# Templates with brief descriptions

# SLT\_100 Mean and SD Calculator

This form simplifies calculation of QC Statistics for up to 30 data points.

# SLT\_101 Mean & SD Calc. 60 & ID

Calculate Arithmetic & Geometric Means with SD, CV%, SD Ranges for up to 60 data points. User may include an ID, or date to accompany each data point. N, Mean(s), SD, CV%, and SD Limits are provided.

#### SLT\_102 PT Reagent Validation & INR Calculator

Calculates Normal Protime Reference Range & Geometric Mean for use in the INR formula. Form includes and INR calculator.

# SLT\_102.5 PT Reagent Validation

Calculates Normal Protime Reference Range & Geometric Mean for use in the INR formula. Use for validating a new of PT reagent.

#### SLT\_103 Protime Seconds to INR Conversion Table

Enter ISI and Normal PT Mean to generate chart. Use to validate calculations from analyzer & LIS.

# SLT\_104 Protime-INR Calculation Validation

This SmartLabTool allows you to validate coagulation instrument and/or lab computer calculations for Protime - INR. Enter 'ISI', 'Patient Mean of Normal Range', and 'Patient PT Seconds'. PT Ratio and INR will be calculated, as well as % difference of INR derived from instrument and/or lab computer (LIS).

# SLT\_125 Coagulation Worksheet

An editable Coagulation worksheet

# SLT\_105 Quality Control Results Evaluation – for up to 24 QC Files

Use daily for statistical evaluation of QC Results. Simple setup: user defines 2 SD limits; Mean and 1SD are calculated on form. Test Results may be entered rapidly via TAB key for INSTANT QC data assessment. Bias, SDI, Trend Alert Flags, QC In or QC Out interpretations are given. Drop down box simplifies documentation of QC Corrective Actions. Automatic Date/Time Stamp.

# SLT\_105CV Calibration Verification

Adaptation of SLT\_105 Template to evaluate Calibration Verification Data.

Templates v. 07/07/2018

# SLT\_105PT Self Evaluation of PT Results

Adaptation of SLT\_105 Template to Self-Evaluate Proficiency Testing Data.

# SLT\_106 Method Comparison of Split Samples

Validation Tool for Initial Method Correlation or CLIA required Twice-Annual Comparison of different methods for same analyte. Compare 1 or 2 analytes/page, biases vs. CLIA Limits. Dropdown box has CLIA Limits. Correlation & Linear Regression Statistics provided.

# SLT\_107 Proficiency Testing Investigation and Corrective Action

This form enables a standardized approach to documenting investigation and corrective actions for proficiency testing failures. Enter the PT graded results for calculation / analysis of systematic error (biases). Enter repeated or self-graded results to demonstrate quantitative accuracy improvement.

Interactive form provides a format for documenting PT investigation findings and corrective actions.

# SLT\_110 CLIA PT QC Limits Calculator (Simple Version)

Enter known Mean and CLIA 'PT Total Allowable Error', or user designated limits to calculate QC limits. Includes attached table of CLIA 'Proficiency Testing (PT) Allowable Error Limits.

# SLT\_111 Simple QC Range Calculator

Enter known Mean & SD to calculate 2SD, 3SD limits & CV%. 2) Enter QC range to calculate Mean, SD, CV%. 3) Enter Mean and CV% to calculate 1SD, and 2SD QC limits.

# SLT\_112 CLIA TEa QC Limits Calculator

Chart for calculation of QC limits based on CLIA 'PT Total Allowable Error' or user designated limits. Includes a dropdown box with CLIA '88 Proficiency Testing Limits. Enter Limit (±%) or Limit (± value) to generate Low and High QC limits.

# SLT\_113 Test Parameters Chart

Colorful chart for posting Analyte, Units, Reference Range, Critical Value, Panic Value, Stated Linearity, Lab Linearity (Analyte Measurement Ranges), Repeat Ranges. Signature line for Director approval.

# SLT\_114 Precision Studies Evaluation Calculator

Chart evaluates criteria for acceptable performance of replication studies with standard deviations obtained during short-term imprecision studies and long-term imprecision studies.

# SLT\_126 Temp Record v.1.5b, SLT\_126 Temp Record v.15e

User editable multi-purpose 12-Month Temperature Charts, Blue or Green. Use for monitoring daily temperatures. Record temperature, user initials, and supervisor review.

Templates v. 07/07/2018

#### SLT\_127 Min-Max Temperature Charts

Customizable Min-Max Temperature Charts with Corrective Action Log

#### SLT\_130 Multi-Analyte 2-Method Comparison

Simplifies comparing results from analyzers that produce multiple analytes, for ensuring they produce similar results. Useful tool for meeting the CLIA requirement for 6-month cross-instrument correlation studies. Dropdown box with CLIA PT Accuracy Limits facilitates use for acceptance criteria. Form is quick and simple to set-up and use. User may enter review comments on form.

# SLT\_200 Corrective Action Form

Corrective Action Form that may be customized for use as a printed form, or electronically. Form includes drop down calendar for recording date, as well as documenting Tech, Problem, Resolution and Supervisor review.

#### SLT\_400 Daily QC Statistical Assessment – for up to 90 QC Files

Use daily for statistical evaluation of QC Results. Form provides a dashboard view of QC interpretation of up to 90 QC Results for 3-levels of Controls. 2-page form with built in instructions simplifies setup. Test Results may be entered rapidly via TAB key (vertical column) for INSTANT QC data assessment.

Form automatically calculates Bias, SDI (z-score), SDI average, QC In vs. QC Out. It provides Trend Alert based on user defined action limits. Form allows for documentation of Corrective Actions and Time/Date.

# SLT\_410 Multi-Analyte QC Statistics x8

User Customizable for INSTANT QC Calculations: MEAN, SD, CV%, 2SD LIMITS - 8 Separate Files (Columns), with up to 20 Data Points each.

This form simplifies analyses of QC Statistics for multiple analytes.

# SLT\_412 Calculate QC Statistics 100N

User Customizable form for INSTANT Calculation of QC Statistics, Including GEOMETRIC MEAN (for up to 100 QC RESULTS) with optional ID - *Results may be entered in any order on this form*. This form is useful for analyzing few to a 100 QC values, or for establishing or validating a patient reference range. The Geometric Mean calculation may be utilized when determining 'normal' patient mean (seconds), a parameter used in the prothrombin-time INR calculation formula.

#### SLT\_413 Multi-Analyte Precision and Accuracy QC Statistics x8

User Customizable for INSTANT QC Calculations : MEAN, SD, CV%, %RECOVERY- 8 Separate Files (Columns), with up to 20 Data Points each. *Enter Target (Mean) for % Recovery* 

Templates v. 07/07/2018

This form simplifies the assessment of Precision and Accuracy for multiple analytes. It is useful for parallel testing of new lots of QC material, a CLIA requirement. For Accuracy evaluation, the Calculated Mean is compared to the Target Value.

#### SLT\_415 Calculate QC Statistics 60N

User Customizable form for INSTANT Calculation of QC Statistics, Including GEOMETRIC MEAN (for up to 60 QC RESULTS) with optional ID.

This form is useful for analyzing few to 60 QC values, or for establishing or validating a patient reference range. The Geometric Mean calculation may be utilized when determining 'normal' patient mean (seconds), a parameter used in the prothrombin-time INR calculation formula

# SLT\_416 L-J Chart with SD Calc. and Plot

Dynamic-Levey-Jennings (LJ) Chart

- Auto Scales SD Limits, - Auto QC Statistics, - Plots QC Graph

User Customizable Form Simplifies creation of L-J Charts for manual entry of monthly QC data, with optional electronic entry of QC results, to generate QC Statistics, and Graph Data.

Form may be printed for manual charting of QC data, or results entered electronically.

This form is also useful for assessing Accuracy and Precision during validation studies.

# SLT\_417 Calculate QC Limits using Historical CV% (HCV)

ESTABLISH YOUR OWN QC LIMITS AND AVOID THE PITFALLS OF USING MANUFACTURER'S QC LIMITS WHICH ARE MOST OFTEN TOO WIDE.

This tool assists with determination of appropriate 2SD QC limits for up to 90 QC Files. User enters estimated QC Mean (based on replicate testing), and (%CVh) based on previous QC Lot, or Peer Lot-to-date statistics. Calculations occur automatically. Re-evaluate QC limits ongoing as appropriate.

# SLT\_420 External QA PT, SLT\_421 Calibration Verification, SLT\_422 Compare Internal Methods

A <u>Multi-purpose Calculator</u> adapted for results comparisons between labs, within lab, and vs known calibrators, or other such materials used for verifying calibration.

Each adaptation may employ as allowable error limits; 1) a percent difference, 2) absolute difference, or 3) Standard Deviation (based on Proficiency Error). Results are compared vs. the defined error limits, and interpretation of 'acceptable' or 'unacceptable' given. Form accommodates 5 Levels.

# SLT\_424 CalVer Assessment

Enter Target Value and Allowable Error Limit %, and Target Limits are calculated. After entering up to 5 Observed Values, a Mean is calculated and compared to the Target Limits where an Interpretation of 'Within Range' or 'Exceeds Range' is given.

Templates v. 07/07/2018

#### SLT\_426 Correlation Calculator Worksheet

Worksheet is particularly useful when comparing 2 internal multi-analyte methods which perform the same tests. The 'Means' of both methods are calculated and compared to the 'Grand Mean'. A statistical ratio is generated when biases are compared to lab historical CV's. Interpretation of 'Acceptable' or 'Unacceptable' for calculated method bias is provided.

#### SLT\_430, 431, 432 Free & Bioavailable Testosterone Calculator Worksheet

Enter ID, Patient Name and results for Albumin, SHBG, and Total Testosterone for up to 20 patient's results. Built in formulas provide instant calculation of Free Testosterone, % of Total T., Bioavailable T., and Bioavailable % of Total T.

Calculations mimic those at <u>http://www.issam.ch/freetesto.htm</u>. A link is provided on the form.

**3 variations** of the worksheet have been devised based on units of Total Testosterone and units for expressing calculated Free Testosterone.

#### SLT\_419 Calculate TE and Sigma Metric

Calculates Bias and Imprecision, Total Error, TE/Tea ratio, Total Error Budget, Margin for Error, Sigma Metric, QC Limits.

#### SLT\_433 Calculate Sigma Metrics

Simplified calculator for Assay Quality Performance Indicator.

#### SLT\_433 Calculate Measurement Uncertainty (MU)

Calculates QC confidence limits when using SD derived from 'Measurement of Uncertainty' calculations, per reference article.

#### SLT\_414 Calculate 2SD Limits from Insert

Calculate 2SD Limits using Mean and 1SD

#### SLT\_414.5 Convert 3SD QC Limits to 2SD

Useful when converting Insert 3SD limits to 2SD limits

#### SLT\_435 General PT Investigation Checklist

Interactive Investigation Form adapted from Johns Hopkins website (psmile.org)

#### SLT\_436 Proficiency Test Corrective Action

4-page form for PT Investigation

Templates v. 07/07/2018

#### SLT\_437 Continuous Quality Improvement

Document self-grading of those "un-graded" proficiency test scores.

#### SLT\_450 Laboratory Report

Create a 2-page chartable Laboratory Report, with user defined Headers, Test Descriptions, up to 4 Reference Ranges. Enter patient test results quickly using the tab key. Abnormal values are flagged Low or High. Report includes provision for including a custom Logo.

# SLT\_460 Schedule Status Report

Flexible form for creating schedules for lab activities such as equipment maintenance, employee competency assessments, calibration verification & other upcoming events. Days Left, and Status is calculated when a Date Due is entered (this updates each time file is opened).

#### SLT\_500, 501, 502 Binder Covers, Spines, Tabs

Simplifies creation of uniform labeling of Procedure Binders

#### SLT\_150 Verify Common Lab Calculations

Verify some of the common calculations made in the Lab Information System or coming from the analyzer.

#### SLT\_160 eGFR Calculation 3 Equations

Use to confirm which calculation used in your analyzer

#### **Other Useful Forms:**

QA Review Forms

**IQCP QA Review Forms** 

**Competency Assessment Forms**