Tips & Tools from a consultant for laboratory compliance

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Kim Irwin, MT(ASCP), COLA Examiner

1.5 PACE credits

Disclosures – Daniel Leighton, Consulting LLC

- **I'm the creator and owner of SmartLabTools™ PDF applications & website; providing software solutions and education to assist clinical laboratories in meeting quality requirements, and maintaining 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.**

Tips & Tools for Laboratory Compliance

Experienced Laboratory Consultant and COLA Examiner will provide an overview of the inspection process and discuss common citations. Solutions in the form of downloadable software will be demonstrated and provided as measures for how these citations can be avoided or resolved.

Participants will be introduced to ‘fill-in-the-blanks’ PDF™ Templates that may be used directly from laboratory desktop computers. Once downloaded, these tools do not require program experience or an internet connection.

Following this workshop you will be able to:

1. Discuss components of the Laboratory Inspection Process
2. Understand the Deficiency Remedial Process
3. Become aware of Common Pitfalls that result in Citations
4. Download and use PDF Tools to meet Compliance Requirements

Presentation Roadmap (pg-1)

What are SmartLabTools?

- Downloading via hyperlinks
- Using Interactive (Smart) PDF's

The Laboratory Inspection Process

- COLA an Accrediting Agency
- State / CLIA

QC & PT Issues

- Citation Examples
- Tips & Tools to Fix QC & PT via (SmartLabTools.com)
- Demonstrate QC Calculators
- L-J Chart vs. Daily QC Assessments (Templates)

Other Tips & Tools:

- Coagulation ISI, PT Mean
- Environmental (Temperature & Humidity)
- Method Validation – Verify Reference Range

Presentation Roadmap (pg-2)

Other Tips & Tools (cont.)

- Proficiency Testing Tools
- Competency Assessments Tools
- Scheduled Events Tools
- Calibration Verification Tools
- Verify LIS Calculations Tools
- Prepare Binder Covers Tools

- **More.. Free Software**
- **Other Resources**
- **Dropbox for Compliance Monitoring**

Smart LabTools™
Complex Forms made Simple

- Adobe PDF™ *(Portable Document Files)*
- Java-Scripted Lab Calculations
- Interactive Tools for Laboratories
- Customizable Forms (Templates)
- May be Saved, Duplicated, Printed
- Enables Laboratories' Regulatory Compliance
- Templates for A Comprehensive QC Program
- Enables QC Monitoring via Cloud Applications

‘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**

DESCRIPTION	INSTRUCTION SESSION LINKS
SmartLabTools.com Website	https://www.smartlabtools.com/
Getting Started….. Practice Templates	
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

Double Inspection for POL

COLA
Lab Accreditation Through Education

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Hutchinson, Kansas
CHIEF EXECUTIVE OFFICER
Douglas A. Beigel

Attn: Lab

COLA ID: Redacted
05/24/13

Dear _____ MD:

Your laboratory was recently surveyed by COLA on 05/22/2013 by **Leigh Ann Smith**. We're pleased to assist you in maintaining quality lab practices.

During the survey of your lab, there were serious or systemic issues identified, requiring that your lab be referred to our Staff Technical Accreditation Team (STAT) for additional review. Once the STAT team has met to discuss the issues in your lab, you will receive a separate STAT letter (typically within one-two weeks) that will detail any additional actions required for accreditation. In the meantime, we are providing a Plan of Required Improvement (PRI) so that you may begin working on resolutions to the COLA criteria citations identified by the surveyor. A series of reports have been included to review the laboratory's citations at different levels and indicates the actions you will need to take to correct citations. This customized plan shows each required improvement prioritized for your convenience. In fact, you may have already begun to implement some of these improvements as the result of the summary conference conducted by the COLA surveyor.

Included as part of this report are:

- Laboratory Information – This is a listing of stored information in our database observed at the time of the survey. This information should be accurate and up-to-date. If it is not, please submit corrections either through COLAcentral™ (www.colacentral.com) or with your Agreement to the Plan of Required Improvement.
- Peer Review Comparison - This report has a statistical analysis showing your lab's performance compared to other laboratories with a similar number of annual tests.
- Plan of Required Improvement (PRI) - This report has specific instructions regarding the actions that must be taken to correct your citations. This customized plan is sorted as follows:
  - Improvements needed within 30 days, documentation required; then
  - Improvements to be completed in a timely manner, no documentation required.

  Note: Repeat citations (citations that you also received during the prior COLA survey) are denoted with an asterisk (*).
- Agreement to the PRI – This document states that you agree to correct and maintain corrections to all citations noted at the time of survey.

9881 Broken Land Parkway Suite 200 Columbia, Maryland 21046-1195 *Phone* 410.381.6581 *Fax* 410.381.8611 www.cola.org
Information Resource Center: 800-981-9883
ISODOC 24-128

CDPH

State of California—Health and Human Services Agency
California Department of Public Health

RON CHAPMAN, MD, MPH
Director

EDMOND G. BROWN JR
Governor

Certified-Return Receipt:
(Confirmation of successful transmission by email or fax constitutes proof of receipt of this letter)

May 28, 2013

LAB NAME // REDACTED

State License #: CNCXXXXX
CLIA#: 05DXXXXXX

RE: STATE OF CALIFORNIA CONDITION-LEVEL DEFICIENCIES - NOT IMMEDIATE JEOPARDY

Dear Laboratory Director/Owner:

A survey of your laboratory was conducted on 5/22/2013 and completed on 5/22/2013 by Victoria Y. Maxwell, Examiner of the Department of Public Health, Laboratory Field Services. As a result of that survey it was determined that your laboratory was not in compliance with the requirements specified in Chapter 3 (commencing with Section 1200) of Division 2 of the Business and Professions Code (BPC) and/or Title 17 California Code of Regulations (CCR).

Enclosed is the Statement of Deficiencies found during this review. The following condition level deficiencies were not met:

1) 42 CFR 493.1101 Patient Test Management as incorporated at CBPC 1220(a)(2)(A).

2) 42 CFR 493.1201 (a)(b) General Quality Control as incorporated at CBPC 1220(d)(2)(B).

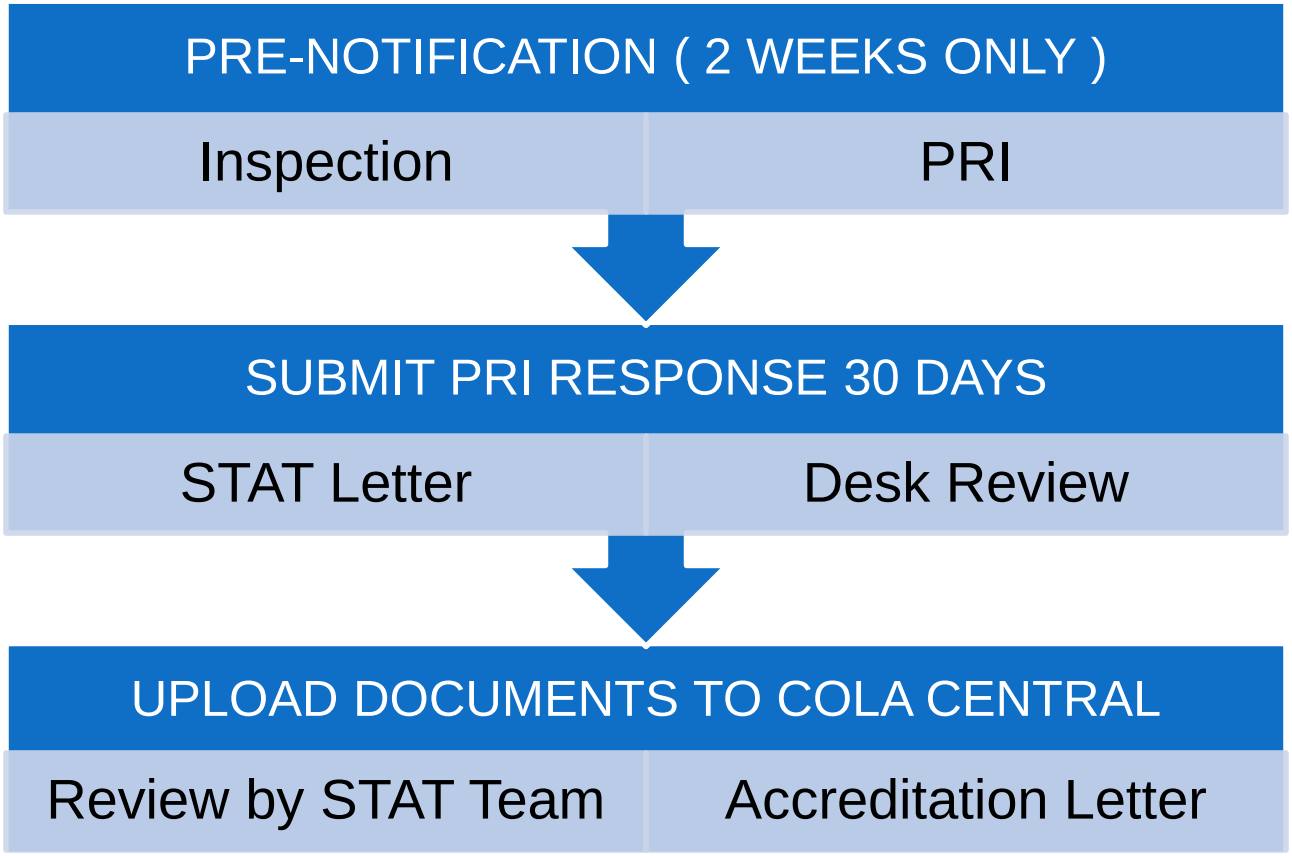
3) 42 CFR 493.1403 Laboratory Director-Moderate Complexity as incorporated at CBPC 1209(a), CBPC 1209(b)(1), and CBPC 1209(d)(1)(2).

4) 42 CFR 493.1701 Quality Assurance as incorporated at BPC 1220 (d)(2)(C)

The Statement of Deficiencies describes the violations that were identified. You are required to submit an allegation of compliance and evidence of correction for each

Laboratory Field Services, California Department of Public Health, 850 Marina Bay Parkway, Richmond CA 94804-6403
(510) 620-3800
Internet Address: http://cdph.ca.gov/lfs

COLA Accreditation Survey



COLA – PRI

COLA ID:
05/24/13

Dear

Your laboratory was recently surveyed by COLA on 05/22/2013 by **Leigh Ann Smith**. We're pleased to assist you in maintaining quality lab practices.

During the survey of your lab, there were serious or systemic issues identified, requiring that your lab be referred to our Staff Technical Accreditation Team (STAT) for additional review. Once the STAT team has met to discuss the issues in your lab, you will receive a separate STAT letter (typically within one-two weeks) that will detail any additional actions required for accreditation. In the meantime, we are providing a Plan of Required Improvement (PRI) so that you may begin working on resolutions to the COLA criteria citations identified by the surveyor. A series of reports have been included to review the laboratory's citations at different levels and indicates the actions you will need to take to correct citations. This customized plan shows each required improvement prioritized for your convenience. In fact, you may have already begun to implement some of these improvements as the result of the summary conference conducted by the COLA surveyor.

COLA - STAT Letter & Cease Testing

June 3, 2013

Dear Laboratory Director: **FedEx 2nd Day Tracking:**

At the time of survey, you were informed that the laboratory was being referred to the Staff Technical Accreditation Team (STAT) for decisions on serious problems identified by the surveyor. The decision of the Team and additional requirements for accreditation are conveyed in this letter. The documents required should be marked with your COLA ID and sent to COLA as soon as possible.

Your laboratory was required to cease all patient testing for every analyte performed on the Access Immunoassay Analyzer due to Quality Control (QC) issues.

During your survey performed May 22, 2013, the surveyor noted that the acceptable limits for the QC material used on the Access Immunoassay analyzer was not entered correctly, resulting in out of range QC not being identified and corrected, prior to patient testing. In addition, it was noted that the laboratory failed to establish its own mean and Standard Deviation (SD) for the QC material, failed to perform two levels of QC everyday of patient testing, and failed to review statistical data (Levy-Jennings graphs) at each testing event to assess continued accuracy and precision of the method. Lastly, the surveyor noted that weekly maintenance and system checks were not being performed on the Access analyzer. As a result of these findings, the laboratory was required to cease all patient testing performed on the Access Immunoassay Analyzer.

COLA – Desk Review

COLA ID:
CLIA ID:
September 11, 2013 **FedEx 2nd Day Tracking:**

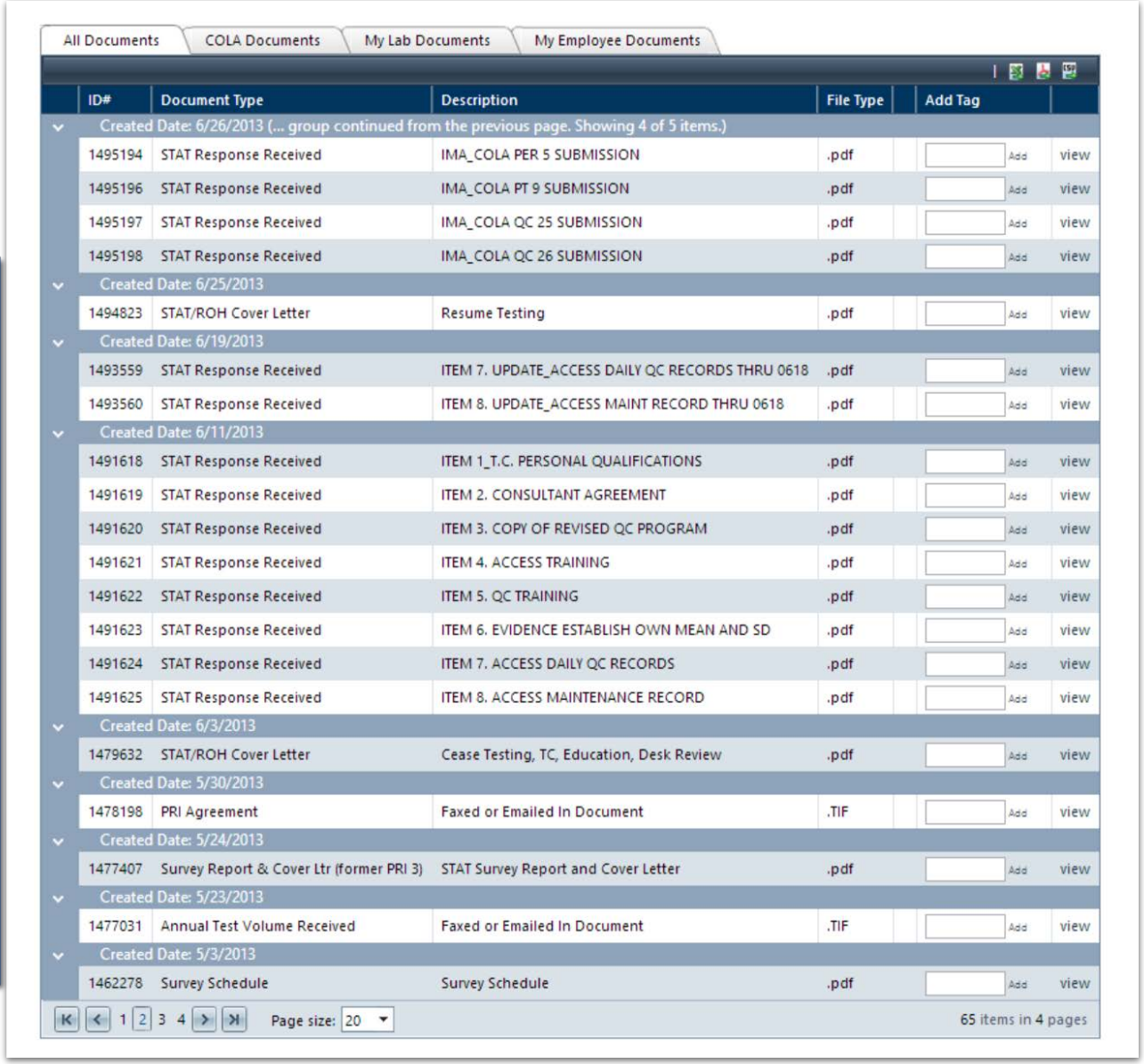
Dear Laboratory Director:

On June 3, 2013, COLA sent the laboratory a letter regarding the decision of the Staff Technical Accreditation Team (STAT) on serious issues identified by the surveyor at the time of the survey. It was stated in that letter that COLA would request additional documentation to ensure continued compliance. At this time we are requesting the following additional documents:

COLA CENTRAL ON-LINE DOCUMENTS

COLA Central lab document depository, where documents may conveniently be downloaded by Client/Consultant,

Documents such as responses may be uploaded electronically



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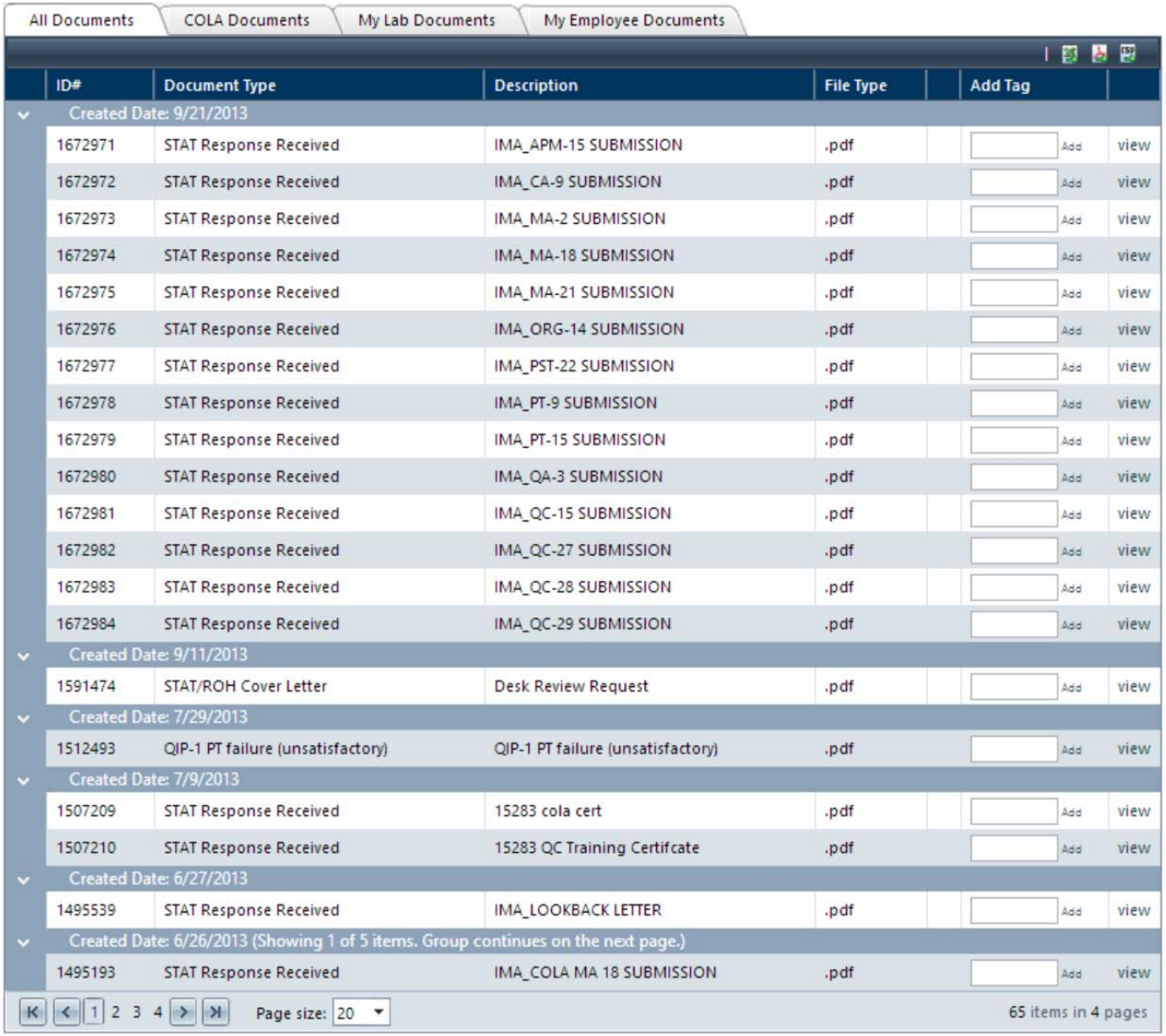
Created Date: 6/26/2013 (... group continued from the previous page. Showing 4 of 5 items.)					
1495194	STAT Response Received	IMA_COLA PER 5 SUBMISSION	.pdf	Add	view
1495196	STAT Response Received	IMA_COLA PT 9 SUBMISSION	.pdf	Add	view
1495197	STAT Response Received	IMA_COLA QC 25 SUBMISSION	.pdf	Add	view
1495198	STAT Response Received	IMA_COLA QC 26 SUBMISSION	.pdf	Add	view
Created Date: 6/25/2013					
1494823	STAT/ROH Cover Letter	Resume Testing	.pdf	Add	view
Created Date: 6/19/2013					
1493559	STAT Response Received	ITEM 7. UPDATE_ACCESS DAILY QC RECORDS THRU 0618	.pdf	Add	view
1493560	STAT Response Received	ITEM 8. UPDATE_ACCESS MAINT RECORD THRU 0618	.pdf	Add	view
Created Date: 6/11/2013					
1491618	STAT Response Received	ITEM 1_T.C. PERSONAL QUALIFICATIONS	.pdf	Add	view
1491619	STAT Response Received	ITEM 2. CONSULTANT AGREEMENT	.pdf	Add	view
1491620	STAT Response Received	ITEM 3. COPY OF REVISED QC PROGRAM	.pdf	Add	view
1491621	STAT Response Received	ITEM 4. ACCESS TRAINING	.pdf	Add	view
1491622	STAT Response Received	ITEM 5. QC TRAINING	.pdf	Add	view
1491623	STAT Response Received	ITEM 6. EVIDENCE ESTABLISH OWN MEAN AND SD	.pdf	Add	view
1491624	STAT Response Received	ITEM 7. ACCESS DAILY QC RECORDS	.pdf	Add	view
1491625	STAT Response Received	ITEM 8. ACCESS MAINTENANCE RECORD	.pdf	Add	view
Created Date: 6/3/2013					
1479632	STAT/ROH Cover Letter	Cease Testing, TC, Education, Desk Review	.pdf	Add	view
Created Date: 5/30/2013					
1478198	PRI Agreement	Faxed or Emailed In Document	.TIF	Add	view
Created Date: 5/24/2013					
1477407	Survey Report & Cover Ltr (former PRI 3)	STAT Survey Report and Cover Letter	.pdf	Add	view
Created Date: 5/23/2013					
1477031	Annual Test Volume Received	Faxed or Emailed In Document	.TIF	Add	view
Created Date: 5/3/2013					
1462278	Survey Schedule	Survey Schedule	.pdf	Add	view

1 2 3 4 Page size: 20 65 items in 4 pages

COLA CENTRAL ON-LINE DOCUMENTS

Page-2 of Discussion example…

Approval for Certificate of Accreditation Pending..



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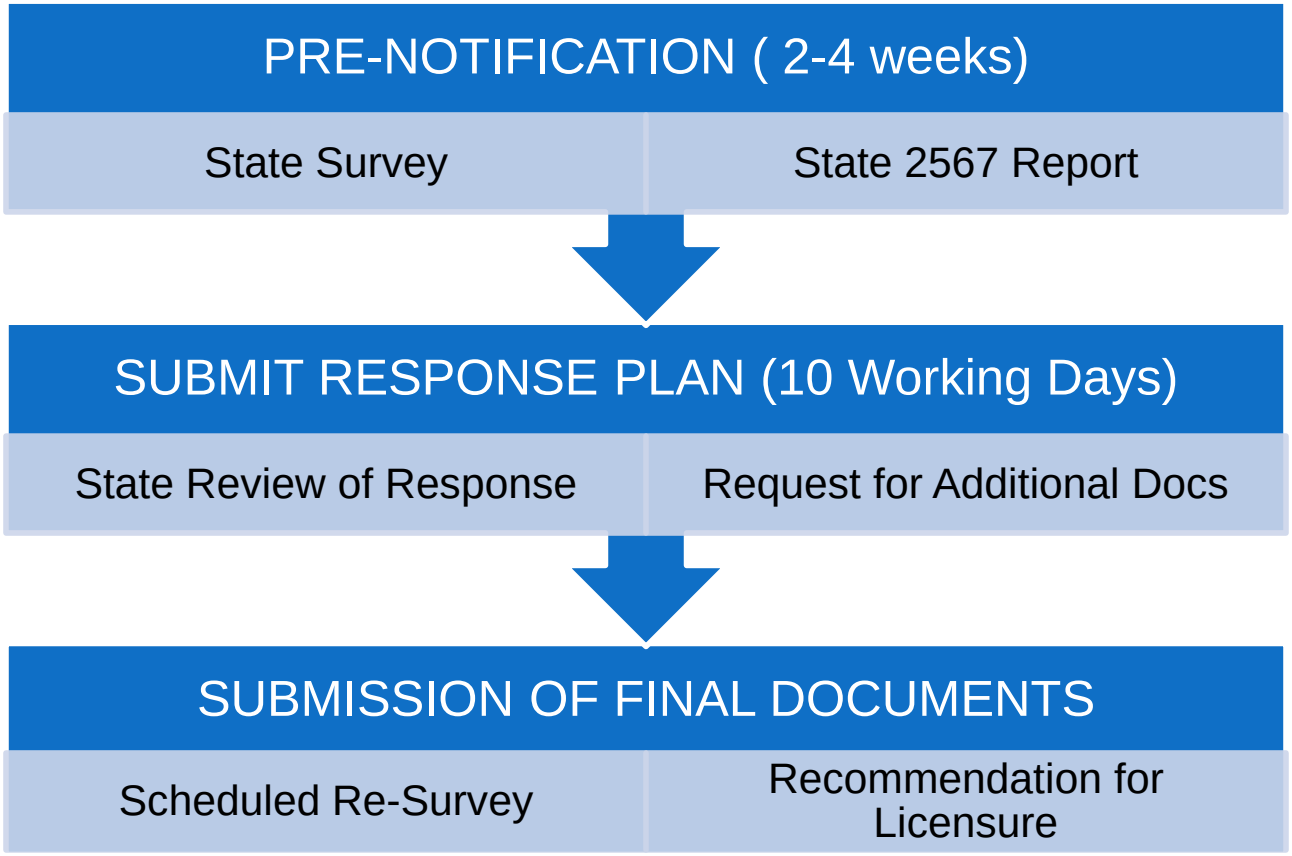
1672972	STAT Response Received	IMA_CA-9 SUBMISSION	.pdf	Add	view
1672973	STAT Response Received	IMA_MA-2 SUBMISSION	.pdf	Add	view
1672974	STAT Response Received	IMA_MA-18 SUBMISSION	.pdf	Add	view
1672975	STAT Response Received	IMA_MA-21 SUBMISSION	.pdf	Add	view
1672976	STAT Response Received	IMA_ORG-14 SUBMISSION	.pdf	Add	view
1672977	STAT Response Received	IMA_PST-22 SUBMISSION	.pdf	Add	view
1672978	STAT Response Received	IMA_PT-9 SUBMISSION	.pdf	Add	view
1672979	STAT Response Received	IMA_PT-15 SUBMISSION	.pdf	Add	view
1672980	STAT Response Received	IMA_QA-3 SUBMISSION	.pdf	Add	view
1672981	STAT Response Received	IMA_QC-15 SUBMISSION	.pdf	Add	view
1672982	STAT Response Received	IMA_QC-27 SUBMISSION	.pdf	Add	view
1672983	STAT Response Received	IMA_QC-28 SUBMISSION	.pdf	Add	view
1672984	STAT Response Received	IMA_QC-29 SUBMISSION	.pdf	Add	view
Created Date: 9/11/2013					
1591474	STAT/ROH Cover Letter	Desk Review Request	.pdf	Add	view
Created Date: 7/29/2013					
1512493	QIP-1 PT failure (unsatisfactory)	QIP-1 PT failure (unsatisfactory)	.pdf	Add	view
Created Date: 7/9/2013					
1507209	STAT Response Received	15283 cola cert	.pdf	Add	view
1507210	STAT Response Received	15283 QC Training Certifcate	.pdf	Add	view
Created Date: 6/27/2013					
1495539	STAT Response Received	IMA_LOOKBACK LETTER	.pdf	Add	view
Created Date: 6/26/2013 (Showing 1 of 5 items. Group continues on the next page.)					
1495193	STAT Response Received	IMA_COLA MA 18 SUBMISSION	.pdf	Add	view

1 2 3 4 Page size: 20 65 items in 4 pages

State Initial Survey for CA License



CDPH-LFS -Correspondence

Dear Laboratory Director/Owner(s):

The Department of Public Health, Laboratory Field Services (DPH-LFS) has received your Plan of Correction (POC)/ allegation of compliance and some supporting evidence in response to our letter dated 5/28/2013 and the Statement of Deficiencies notifying your laboratory of condition level deficiencies. You were directed to submit your plan of correction / a credible allegation of compliance. For your information, a Plan of Correction /credible allegation of compliance is a statement or documentation that is:

1.Made by a representative of a laboratory with a history of having maintained a commitment to compliance and taking corrective action when required;
2.Realistic in terms of the possibility of the corrective action being accomplished between the date of the survey and the date of the allegation; and
3.Indicates resolution of the problems.

Please be reminded that you also must submit documented evidence that verifies that the corrections were made. **Acceptable evidence of correction must include:**

1) Documentation showing what corrective action(s) has been taken for patients found to have been affected by the deficient practice.

CDPH-LFS-Correspondence

You were notified in our previous letter dated May 28, 2013, that failure to meet the condition level requirements and/or **failure to return the allegation of compliance and evidence of correction within the ten-day time period may result in sanctions** against the clinical laboratory license, clinical laboratory director, and owners, suspension from the Medi-Cal and/or Medi-Care program in addition to civil money penalties and recovery of costs associated with the investigation:

1) Civil money penalties of $3000/day and/or violation (CBPC 1310 and Title 17 CCR 1067.5)
2) Exclusion from Ownership or Operation (CBPC 1324 and Title 17 CCR 1065.30)
3) Revocation and/or suspension of the license to the facility (CBPC 1320 and Title 17 CCR 1062.5)

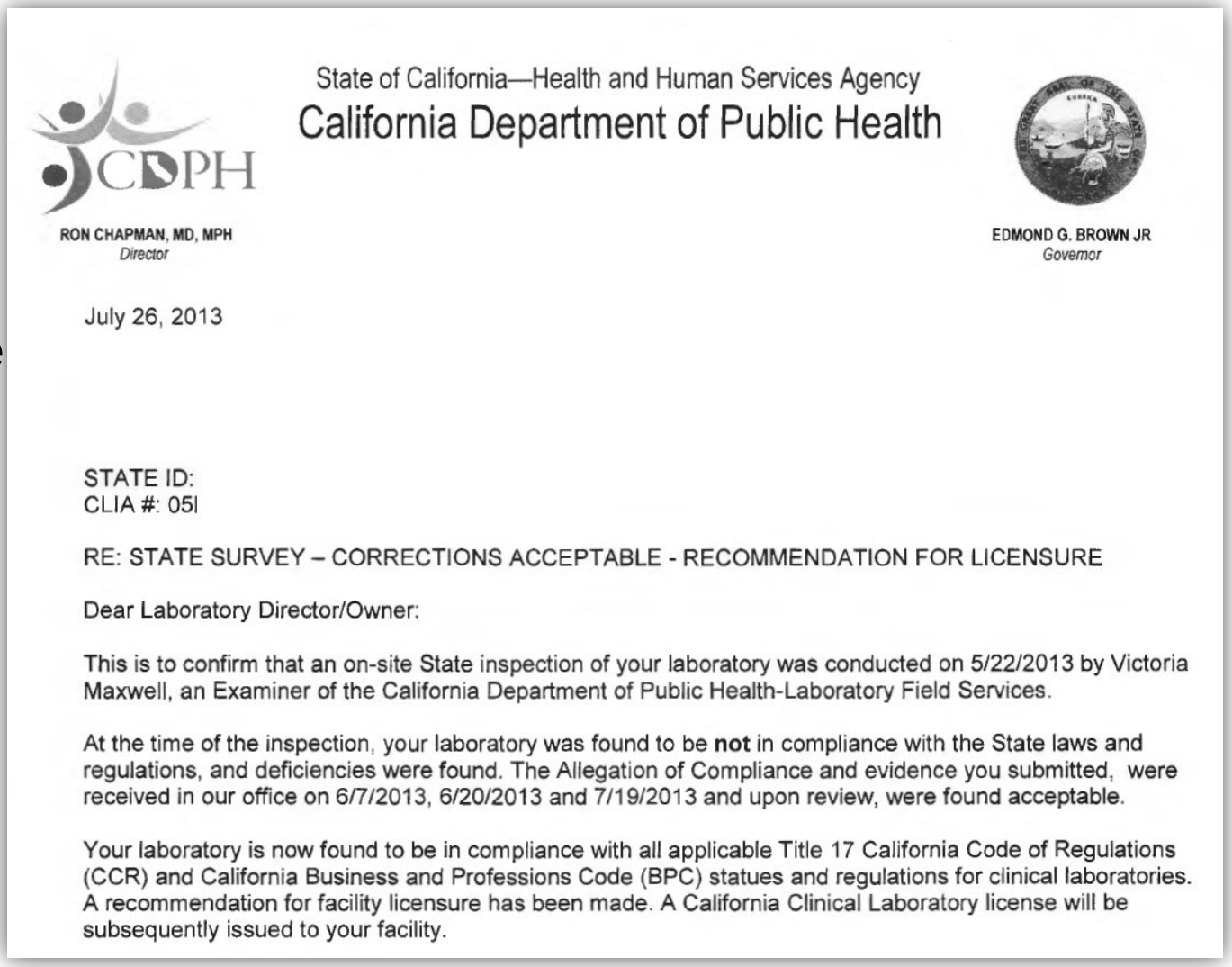
You have 10 working days from the date of receipt of this notice to submit a credible allegation of compliance and evidence of correction for the condition level deficiencies.

If we do not hear from you, or if we do not receive your acceptable evidence of compliance within the timeframe specified above, we may initiate enforcement actions including principal and or alternative sanctions.

CDPH SURVEY PROCESS FINALIZED

Corrections found Acceptable and License Issued

2 MONTH PROCESS..



State of California—Health and Human Services Agency
California Department of Public Health

RON CHAPMAN, MD, MPH
Director

EDMOND G. BROWN JR
Governor

July 26, 2013

STATE ID:
CLIA #: 05I

RE: STATE SURVEY – CORRECTIONS ACCEPTABLE - RECOMMENDATION FOR LICENSURE

Dear Laboratory Director/Owner:

This is to confirm that an on-site State inspection of your laboratory was conducted on 5/22/2013 by Victoria Maxwell, an Examiner of the California Department of Public Health-Laboratory Field Services.

At the time of the inspection, your laboratory was found to be **not** in compliance with the State laws and regulations, and deficiencies were found. The Allegation of Compliance and evidence you submitted, were received in our office on 6/7/2013, 6/20/2013 and 7/19/2013 and upon review, were found acceptable.

Your laboratory is now found to be in compliance with all applicable Title 17 California Code of Regulations (CCR) and California Business and Professions Code (BPC) statues and regulations for clinical laboratories. A recommendation for facility licensure has been made. A California Clinical Laboratory license will be subsequently issued to your facility.

Some Proficiency Citations

CITATIONS	ACTIONS
• Lab failed to perform detailed investigation of PT failures	• Revised PT procedure, and PT Action Form • Trained Personnel on new PT procedures & forms
• PT Records were not maintained for 2 years	• Save all analyzer Tapes & Printouts 3 years in Calif.
• Director failed to sign all PT attestations	• Put on QA Review List of Proficiency Testing documentation

Some QA/QC Citations

CITATION TO DO'S	ACTIONS
• Document all Function Checks	• Updated forms for PM
• Retaining Function Check printouts	• Save Function Checks, along with QC printouts
• Use latest version of Preventive Maintenance forms	• Manufacturer on-site training on maintenance, instrument QC functions
• Director's Name on LIS Report	• Updated LIS Report
• Update the QA Plan	• Updated QA Plan & Schedule

Some QA/QC Citations (continued)

CITATION TO DO'S	ACTIONS
• QC Printouts not saved for at least 2 years	• Printouts & Tapes now being saved
• Critical Values not defined for INR	• Updated Critical Values Procedures & List
• Not keeping a Critical Value Notification Log	• Critical Values Notification Log implemented & personnel trained
• Frequent QC Failures & No Records of Remedial Action	• Implemented Corrective Action Logs
• Failure to Establish Lab QC Limits	• Implemented New QC Program, Trained Personnel

Citation: Postanalytic

TIP: ENSURE 'NAME OF LABORATORY' IS ON ALL LAB DOCUMENTS
CBPC 1220(d)(2)(B) Quality Control as incorporated at 42 CFR 493.1250 Analytic and 493.1290 Postanalytic
Systems –Condition Reason for Rejection: Update the name of the laboratory in all laboratory documents submitted. The initial application stated that the name of the laboratory should be "_____ Medical Laboratory".
The laboratory submitted a maintenance log on ACE Axcel and Access 2 instruments without identifying the serial number of the instrument. Also, indicate the name of the laboratory in all laboratory forms.

Quality Control Specific Issues & Solutions to Improve the Sensitivity of QC by Developing useful Quality Control Ranges

COLA PRI – QC 10

REQUIREMENT

Are manufacturer's instructions for the use of reagents, controls, and kits followed?

- Altering the manufacturer's instructions is considered a modification of the test procedure which could change the complexity of the test.

COLA PRI – QC 10

CITATION & REQUIREMENT
The lab has not followed manufacturer's requirements with the use of controls. The lab is using Bio Rad Immunoassay QC, they have not established their own mean and SD, They have adopted the range of means as their QC range.

The range is to be used as a guide and does not provide a meaningful range to assess QC acceptability.

Required: Use your historic QC data and submit documentation demonstrating establishment of your own mean and 2SD range for… analytes

QC – Establish Own Limits

493.1218(d) Control Procedures

When calibration or control materials are used, **statistical parameters (e.g., mean and standard deviation)** for each lot number of calibration material and **each lot of control material must be determined through repetitive testing**. This Standard is not met as evidenced by: Based on review of quality control records, interview and direct observation, it was determined that the **laboratory failed to determine or establish statistical parameters** (e.g., mean, standard deviation, and acceptable limits) for **each lot of control** materials used for testing in the specialty of **Chemistry** and **Hematology**.

Findings included: (continued)

QC – Establish Own Limits

493.1218(d) Control Procedures (Continued)

The laboratory utilized Biorad Liquichek Immunoassay Plus Control levels 1, 2, and 3, lot numbers 40791, 40792, and 40793, respectively. These controls were tested on the Beckman Coulter Access 2 instrument to monitor the accuracy of few routine chemistry and some endocrinology tests performed on the instrument. The laboratory had been utilizing these specific control lots since December 2012 and to this day had not established their limits of acceptability.

QC - Insert Disclaimers

493.1218(d) Control Procedures (Continued)

In addition, as stated in the Biorad control package insert, section "Assignment of Values", that it was recommended that each laboratory to establish its own means and acceptable ranges and use the Manufacturer's given means and ranges only as a guide.

Note: Read the disclaimers on the insert! Examiners do.

QC Insert Limits – 3SD ?

493.1218(d) Control Procedures (Continued)

Biorad Liquichek Immunoassay Plus Control levels 1, 2, and 3, lot numbers 40791, 40792, and 40793, respectively, expiration date 9/30/2013 were utilized as controls.

Since the laboratory has not yet established their own values for all the control materials they use for testing, **the manufacturer's means and ranges, which was at 3SD (standard deviation) were utilized for acceptance criteria.**

Note: Commercial Control limits are potentially 3SD according to insert disclaimer

QC Corrective Action Log

493.1219(b) Remedial Actions

The laboratory must document all remedial actions taken when results of control and calibration materials fail to meet the laboratory's established criteria for acceptability.

This Standard is not met as evidenced by: Based on review of quality control records, interview and direct observation, it was determined that the **laboratory failed to document remedial actions** taken when results of control materials fail to meet the laboratory's established criteria for acceptability.

QC TIP #1

- *Beware of So-Called Instrument Specific Assayed Control Limits*
  - See following example where excessive QC limits have been published for assayed controls that equate to exactly 2x the CLIA Total Allowable Error Limits, & SD 3x the inter-lab peer SD

QC Insert Limits – Excessive

Assayed Controls Glucose and Cholesterol ranges set at 2x the CLIA Allowable PT Limits…

CLIA TEa = ±10%
Insert Limits = ±20%

	Units	Mean	Range	Mean	Range	Mean	Range
SIEMENS DIMENSION SERIES							
Acetaminophen (Enzymatic, colorimetric)	µg/mL	21.6	17.3 – 26.0	48.6	38.9 – 58.3	151	121 – 182
Albumin (Bromcresol Purple (BCP))	g/dL	2.41	1.93 – 2.90	3.23	2.58 – 3.87	4.09	3.27 – 4.91
Alkaline Phosphatase (PNPP, AMP Buffer) (2)	U/L	47.9	38.3 – 57.5	151	121 – 181	298	238 – 357
Alkaline Phosphatase (PNPP, AMP Buffer) (RG# FB 4084)	U/L	37.3	29.8 – 44.8	135	108 – 162	270	216 – 324
ALT/SGPT (UV with P5P) (2)	U/L	39.8	31.8 – 47.7	99.3	79.4 – 119	195	156 – 234
ALT/SGPT (UV with P5P) (ALTI) (2)	U/L	25.3	20.2 – 30.4	89.0	71.2 – 107	192	153 – 230
Amylase (CNP-triose/CNPG3) (2)	U/L	44.2	35.3 – 53.0	149	119 – 178	332	265 – 398
AST/SGOT (UV with P5P) (2)	U/L	42.0	33.6 – 50.4	109	86.8 – 130	263	211 – 316
AST/SGOT (UV with P5P) (IFCC 2002 Correlated) (2)	U/L	42.1	33.6 – 50.5	109	87.2 – 131	263	210 – 316
Bilirubin (Direct) (Diazotization) (DBI)(DF125)	mg/dL	0.200	0.160 – 0.240	1.11	0.887 – 1.33	1.89	1.51 – 2.26
Bilirubin (Direct) (Diazotization) (DBIL)(DF25A)	mg/dL	0.283	0.226 – 0.340	1.18	0.943 – 1.41	1.90	1.52 – 2.28
Bilirubin (Total) (Jendrassik Grof) (TBI)(DF167)	mg/dL	0.581	0.465 – 0.698	3.02	2.41 – 3.62	7.28	5.83 – 8.74
Bilirubin (Total) (Jendrassik Grof) (TBIL)(DF67A)	mg/dL	0.591	0.473 – 0.709	3.08	2.46 – 3.69	7.29	5.84 – 8.75
Calcium (o-cresolphthalein complexone)	mg/dL	5.71	5.14 – 6.28	9.36	8.43 – 10.3	12.5	11.3 – 13.8
Carbamazepine (Immunoturbidimetric)	µg/mL	3.93	3.15 – 4.72	8.85	7.08 – 10.6	12.8	10.3 – 15.4
Carbon Dioxide (CO2) (Enzymatic)	mEq/L	17.0	13.6 – 20.4	21.9	17.5 – 26.3	28.2	22.6 – 33.8
Chloride (ISE indirect) (EXL/Xpand)	mEq/L	73.8	68.5 – 79.1	97.5	93.8 – 101	123	113 – 133
Chloride (ISE indirect) (RxL)	mEq/L	72.0	57.6 – 86.4	94.8	75.9 – 114	121	96.7 – 145
Cholesterol (HDL) (Direct measure, polymer-polyanion) (DF48A)	mg/dL	34.7	27.7 – 41.6	52.3	41.8 – 62.7	84.3	67.5 – 101
Cholesterol (HDL) (Direct measure-PEG) (DF48B)	mg/dL	31.1	24.9 – 37.3	48.8	39.0 – 58.5	73.6	58.9 – 88.3
Cholesterol (LDL) (Direct measure) (ALDL)	mg/dL	59.4	47.5 – 71.3	86.1	68.9 – 103	137	110 – 165
Cholesterol (Total) (Cholesterol oxidase, esterase, peroxidase)	mg/dL	104	83.4 – 125	167	133 – 200	261	209 – 313
Cholinesterase (Butyrylthiocholine (Trinder)) (PCHE) (2)	U/L	7760	6210 – 9310	9530	7630 – 11440	12610	10090 – >14000
Complement C3 (Immunoturbidimetric)	mg/dL	85.2	68.1 – 102	118	94.7 – 142	154	123 – 185
Complement C4 (Immunoturbidimetric)	mg/dL	14.7	11.7 – 17.6	19.0	15.2 – 22.8	25.5	20.4 – 30.6
Creatine Kinase (CK) (NAC activated) (IFCC 2002)(CKI) (2)	U/L	88.2	70.5 – 106	276	221 – 331	654	523 – 785
Creatinine (Alkaline picrate-kinetic)	mg/dL	0.700	0.560 – 0.839	1.90	1.52 – 2.28	6.78	5.43 – 8.14
Creatinine (Alkaline picrate-kinetic, IFCC-IDMS Standardized) (IDMS Correlated)	mg/dL	0.532	0.425 – 0.638	1.73	1.39 – 2.08	6.62	5.29 – 7.94
Creatinine (Enzymatic IFCC-IDMS Standardized) (EZCR)	mg/dL	0.650	0.400 – 0.900	1.89	1.51 – 2.26	6.64	5.31 – 7.97
Digoxin (EIA)	ng/mL	0.443	0.355 – 0.532	1.65	1.32 – 1.98	3.22	2.57 – 3.86
Ethanol (Enzymatic UV)	mg/dL	19.2	15.3 – 23.0	70.8	56.7 – 85.0	174	139 – 209
Ferritin (EIA)	ng/mL	37.0	29.6 – 44.4	43.9	35.1 – 52.7	56.9	45.5 – 68.3
Gamma Glutamyltransferase (GGT) (2)	U/L	36.8	29.5 – 44.2	96.8	77.5 – 116	159	127 – 191
Gamma Glutamyltransferase (GGT) (IFCC 2002 Correlated) (2)	U/L	31.3	25.0 – 37.5	83.0	66.4 – 99.6	137	109 – 164
Gentamicin (Immunoturbidimetric)	µg/mL	2.03	1.63 – 2.44	6.12	4.89 – 7.34	10.5	8.41 – >12.0
Glucose (Hexokinase)	mg/dL	60.5	48.4 – 72.6	122	97.6 – 146	366	293 – 439

Detail Next Slide

QC Insert Limits vs. Peer Limits

Glucose Values – Insert, CV=10%

1SD = 6.0		1SD = 12.1		1SD = 36.5	
60.5	48.4 – 72.6	122	97.6 – 146	366	293 – 439

Peer / Monthly / Lot-To-Date, CV=3%

Mean	60.80	61.08	121.7	121.8	358.5	359.3
SD	1.88	1.88	5.14	3.58	9.30	9.62
CV	3.1	3.1	4.2	2.9	2.6	2.7
# Points	6698	37914	2914	17203	5393	31362
# Labs	219	277	83	109	197	255

QC Limits using Peer CV%

MEAN	HCV	SD	-2SD	+2SD	MEAN	HCV	SD	-2SD	+2SD	MEAN	HCV	SD	-2SD	+2SD
61	3.1	1.89	57.22	64.78	122	4.2	5.12	111.75	132.25	359	2.7	9.69	339.61	378.39

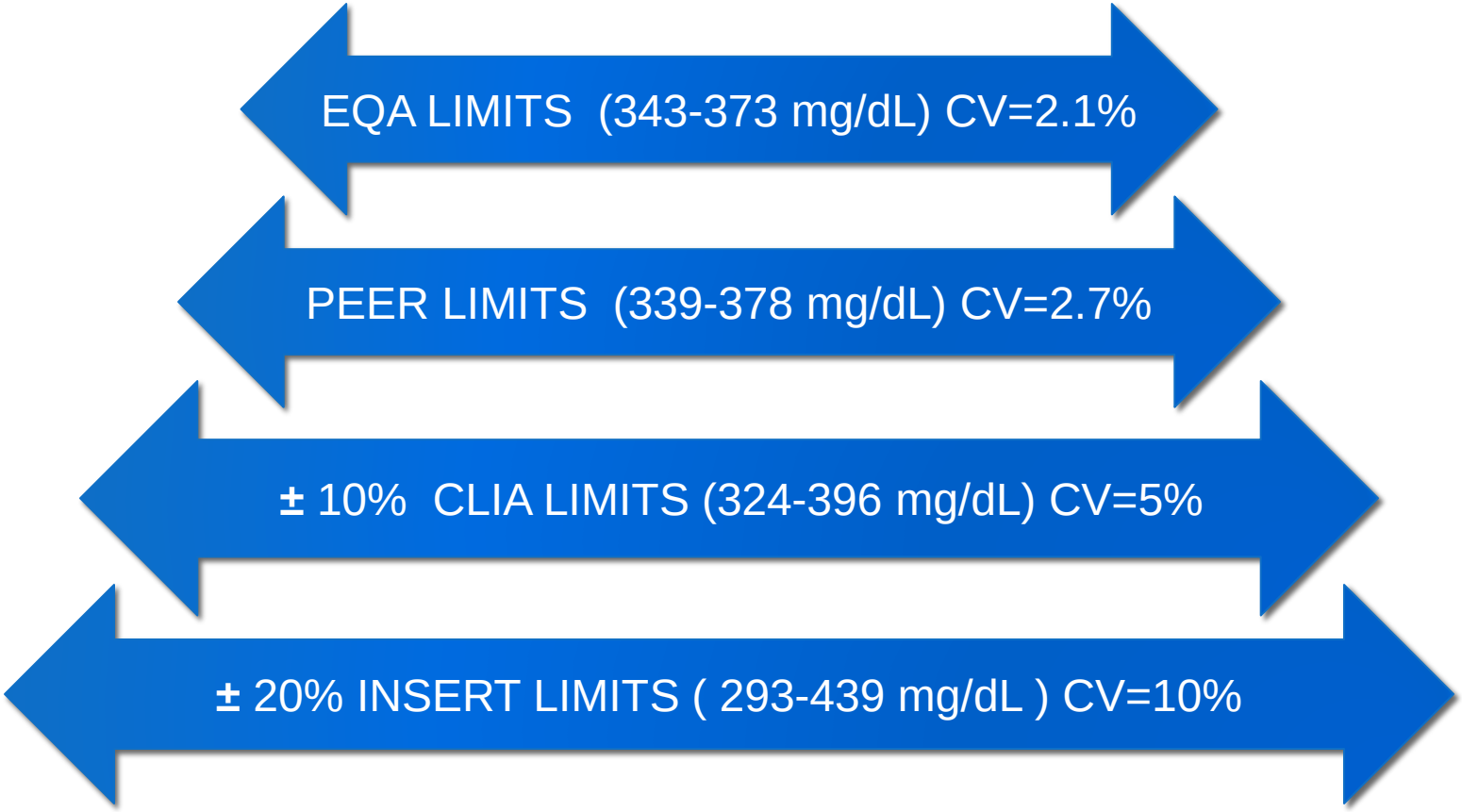
CV derived from External Proficiency Peer Data Referred to as CV_{EQA}

API PROFICIENCY Q213							
GLUCOSE DIMENSION			#LABS	MEAN	SD	CV%	RANGE
		SPEC 1	1153	147.3	2.9	2.0	132-163
		SPEC 2	1153	204.2	3.8	1.9	183-225
		SPEC 3	1153	88.7	1.9	2.1	79-98
		SPEC 4	1153	77.3	1.8	2.3	69-86
		SPEC 4	1153	101.6	2.2	2.2	91-112
				AVERAGE CV% =		**2.1**	

PT Total Allowable Error for Glucose is **± 10%, or ± 6**

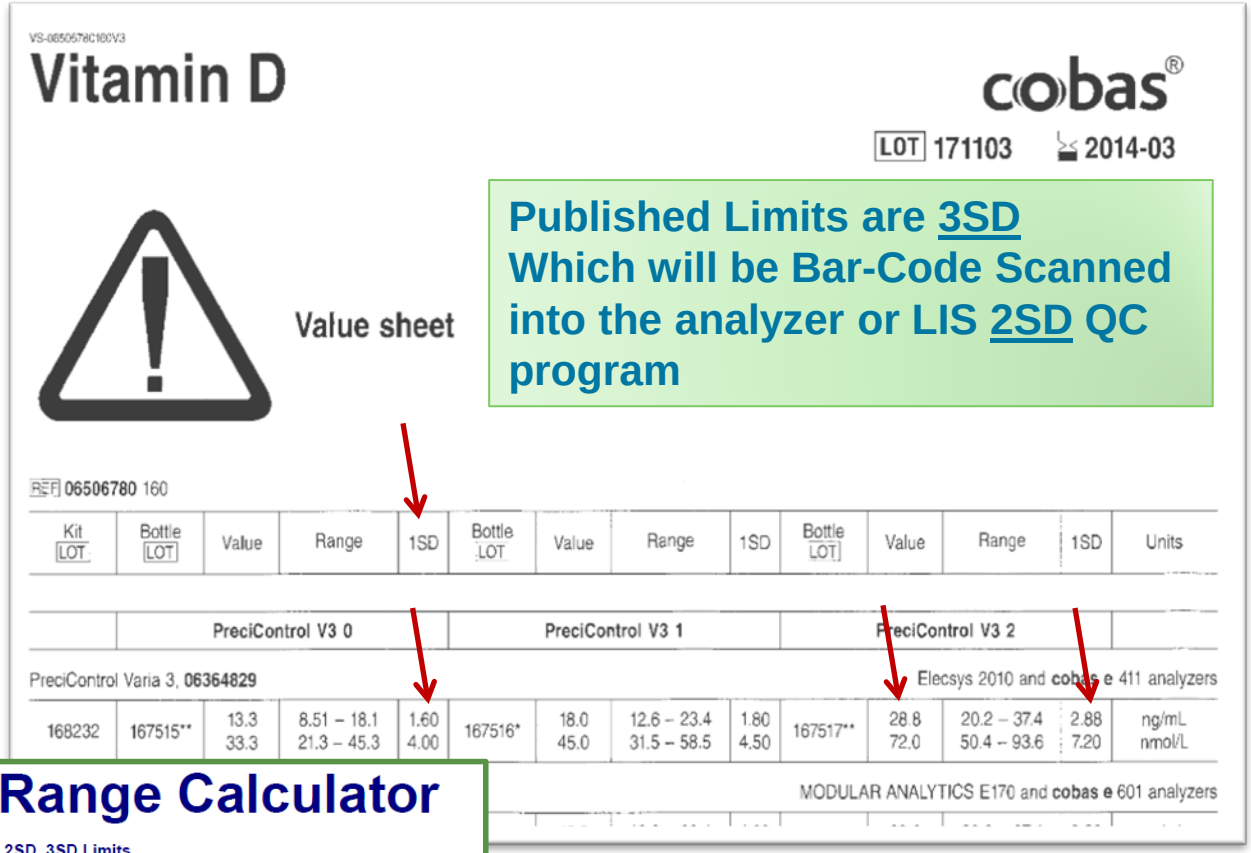
The CV% is not provided by the PT agency, so must be calculated:
CV = (SD/Mean) x 100, expressed as a percent (%)

QC Limits Comparison
Glucose, Level-3 Control



QC Tip #2

- *Beware of Assayed Control QC Limits that are 3SD , and may be introduced into analyzers (Bar-Code Scanned) or Manual input into an Instrument or LIS QC program that assumes 2SD limits.* ***Do the Math!***
  (Hint: Use Dan's Simple QC Range Calculator)



VS-06506780160V3

Vitamin D

cobas®

LOT 171103 2014-03

Value sheet

Published Limits are 3SD Which will be Bar-Code Scanned into the analyzer or LIS 2SD QC program

REF 06506780 160

Kit LOT	Bottle LOT	Value	Range	1SD	Bottle LOT	Value	Range	1SD	Bottle LOT	Value	Range	1SD	Units
	PreciControl V3 0				PreciControl V3 1				PreciControl V3 2				
PreciControl Varia 3, 06364829										Elecsys 2010 and cobas e 411 analyzers			
168232	167515**	13.3 33.3	8.51 – 18.1 21.3 – 45.3	1.60 4.00	167516*	18.0 45.0	12.6 – 23.4 31.5 – 58.5	1.80 4.50	167517**	28.8 72.0	20.2 – 37.4 50.4 – 93.6	2.88 7.20	ng/mL nmol/L
										MODULAR ANALYTICS E170 and cobas e 601 analyzers			

Simple Q.C. Range Calculator

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

Control Level	Mean	1 SD	- 2SD	+2SD	- 3SD	+3SD
Level-1	13.30	1.60	10.10	16.50	8.50	18.10
Level-2	18.00	1.80	14.40	21.60	12.60	23.40
Level-3	28.80	2.88	23.04	34.56	20.16	37.44

Enter Range to Calculate Mean and 1SD

Control Level	Range Low	Range High	(If Range is 2SD) Mean	1SD	(If Range is 3SD) Mean	1SD
Level-1	8.51	18.1	13.31	2.40	13.31	1.60
Level-2	12.6	23.4	18.00	2.70	18.00	1.80
Level-3	20.2	37.4	28.80	4.30	28.80	2.87

QC Product – Analyte Stability

The laboratory had been using the same Biorad control lots since December 2012 or maybe even much earlier. Review of the Biorad control package insert showed the manufacturer's disclosure of control value limitations. It stated that Folate and Estradiol values may gradually decrease over the product shelf life. Thus, individual laboratory means may eventually fall outside of the corresponding accepatable ranges printed in the insert. It is possible that the laboratory may be experiencing this now and this may necessitate an investigation.

Analyte Stability Insert Claims

STORAGE AND STABILITY

This product will be stable until the expiration date when stored unopened at -20 to -70°C.

Thawed and Unopened: When the control material is thawed and stored unopened at 2 to 8°C, all analytes will be stable for 30 days with the following exceptions: Folate will be stable for 4 days. Estradiol will be stable for 8 days. Free PSA, PSA and Prolactin will be stable for 14 days (date of thaw should be noted).

Thawed and Opened: Once the control material is thawed and opened, all analytes will be stable for 14 days when stored tightly capped at 2 to 8°C, with the following exceptions: Folate will be stable for 4 days. Estradiol will be stable for 5 days.

Once thawed, do not refreeze the control; discard the remaining material.

This product is shipped under frozen conditions.

LIMITATIONS

1. This product should not be used past the expiration date.
2. If there is evidence of microbial contamination or excessive turbidity in the product, discard the vial.
3. This product is not intended for use as a standard.
4. Folate and Estradiol values may gradually decrease over the product shelf life. Individual laboratory means may eventually fall outside of the corresponding acceptable ranges printed in this insert.

QC Assignments may Vary over Time …
Check Vendor Site & Participate in Peer Programs

ASSIGNMENT OF VALUES

The mean values printed in this insert were derived from replicate analyses and are specific for this lot of product. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of control. Individual laboratory means should fall within the corresponding acceptable range; however, laboratory means may vary from the listed values during the life of this control. Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation and reagents, or by manufacturer test method modifications. It is recommended that each laboratory establish its own means and acceptable ranges and use those provided only as guides.

Refer to *www.qcnet.com* for insert update information.

Dehydroepiandrosterone-Sulfate (DHEA-Sulfate)	µg/dL	86.6	72.8 – 101	122	102 – 142	526	442 – 610
Digoxin	ng/mL	0.760	0.640 – 0.880	2.06	1.72 – 2.40	3.26	2.74 – 3.78
Estradiol, E2 (E2, Re-standardization)	pg/mL	67.7	47.8 – 87.7	370	301 – 440	938	776 – 1100
Estriol, Free (Unconjugated)	ng/mL	1.32	1.11 – 1.54	2.96	2.49 – 3.44	>6.95	
Ferritin	ng/mL	23.8	20.0 – 27.6	119	100 – 138	269	226 – 312
Folate (Improved)	ng/mL	2.47	2.07 – 2.87	7.55	5.85 – 9.25	11.1	9.11 – 13.2
Folate (Re-standardization, FOLW)	ng/mL	3.37	2.83 – 3.91	9.83	8.11 – 11.6	14.4	12.1 – 16.7

Folate

Chemiluminescence ng/mL

Beckman Coulter Access, LXi 725, DxC 600i IA Systems

Beckman Coulter Access Folate (REF A14208)	Mean	3.13	3.22	9.78	9.76	14.20	14.51
	SD	0.180	0.253	0.346	0.495	1.01	1.36
	CV	5.7	7.9	3.5	5.1	7.1	9.4
	# Points	45	201	22	56	46	161
	# Labs	3	5	1	2	3	5
Beckman Coulter Access Folate (REF A98032)	Mean	3.28	3.36	10.28	10.63	14.61	15.13
	SD	0.249	0.252	0.721	0.729	1.03	1.11
	CV	7.6	7.5	7.0	6.9	7.1	7.3
	# Points	985	3544	587	2130	1003	3501
	# Labs	38	44	27	29	39	44

Using Historical CV to Set QC Ranges (1)

Establishing Chemistry QC Ranges

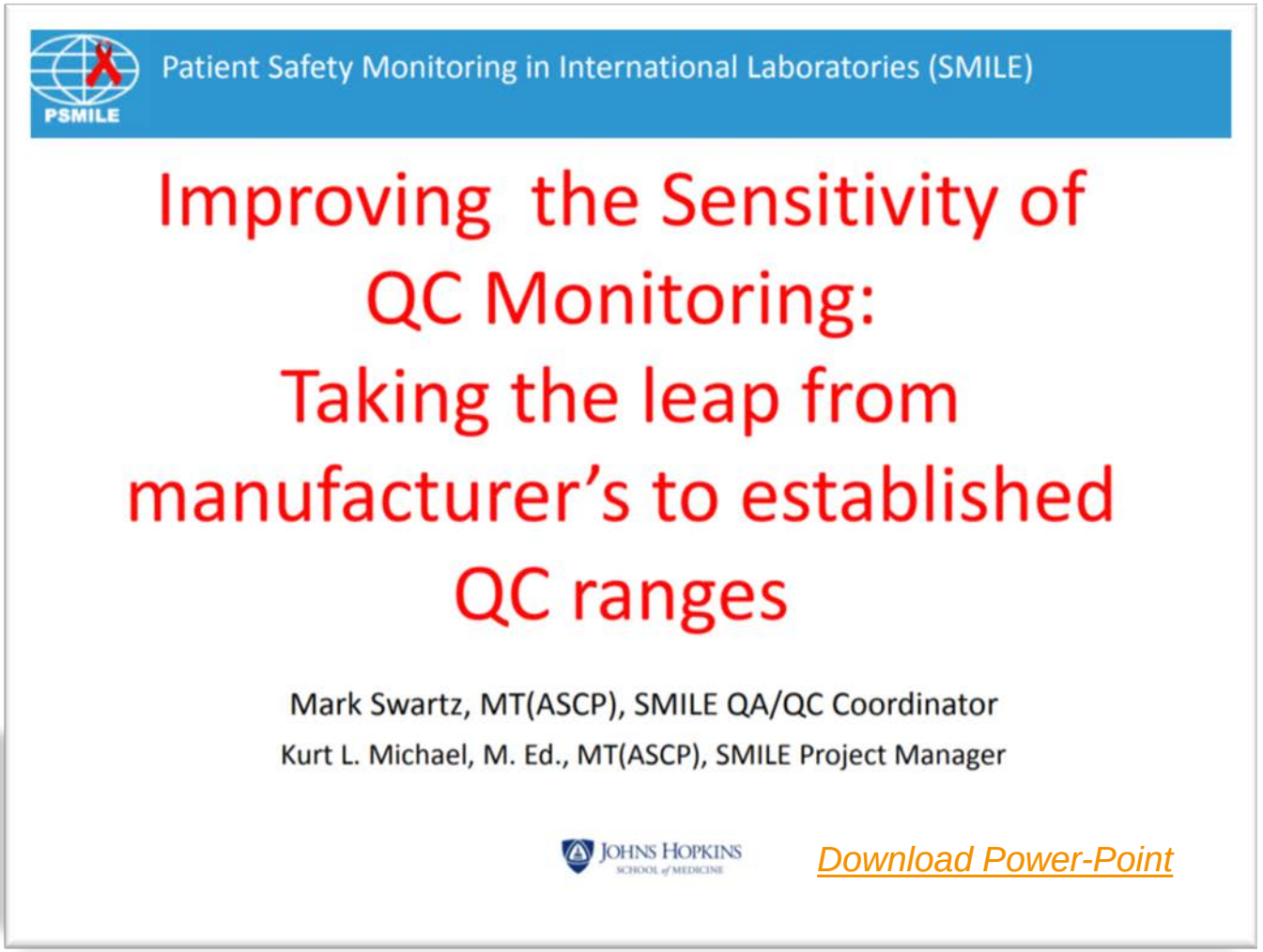
Chemistry Guideline for Establishing New Control Lot Means and Quality Control (QC) Ranges Through Parallel Testing and Historic Coefficient of Variation ($\%CV_h$)

Authored by Kurt Michael and Paul Richardson

In order to optimize controls, it is important for clinical laboratories to establish their own means and QC ranges for each new control lot number. Using the manufacturer's QC ranges will waste you QC money, as the ranges will be too wide to provide an appropriate level of warning value. Assay ranges for new control lot numbers should be confirmed prior to the expiration of the old lot. The means for all analytes of the new lot should fall within the assay ranges provided by the manufacturer. If they do not, then something in the system needs corrective action.

Click to Download 5-page Article

Using Historical CV to Set QC Ranges (2)



Summary: Calculating New Mean

1. Ensure that your old lot of QC material is within your current range with no bias, shifts, or trends
2. Run new QC material for at least 20 data points with old QC material for at least 5 days.
3. Ensure that your old QC material is within acceptable range for each run.
4. Calculate MEAN, SD & CV from data
5. Is the CV's < or = CV_H CV_{MAN} (INSERT) ?

Summary: Determine QC Limits

6
- Use Historical (Cumulative CV) to establish sensitive SD limits and QC Ranges

7
- CVh allows you to set your QC Limits based on your instruments precision capability

8
- Use CV from prior lot's to calculate preliminary QC limits for new lot
- Calculate using Tools next 3 slides

9
- Compare your CVh with Manufacturer's CVs and Peer CVs

10
- Review provided Article and PPT for best guidance on use of CVh for setting QC Limits

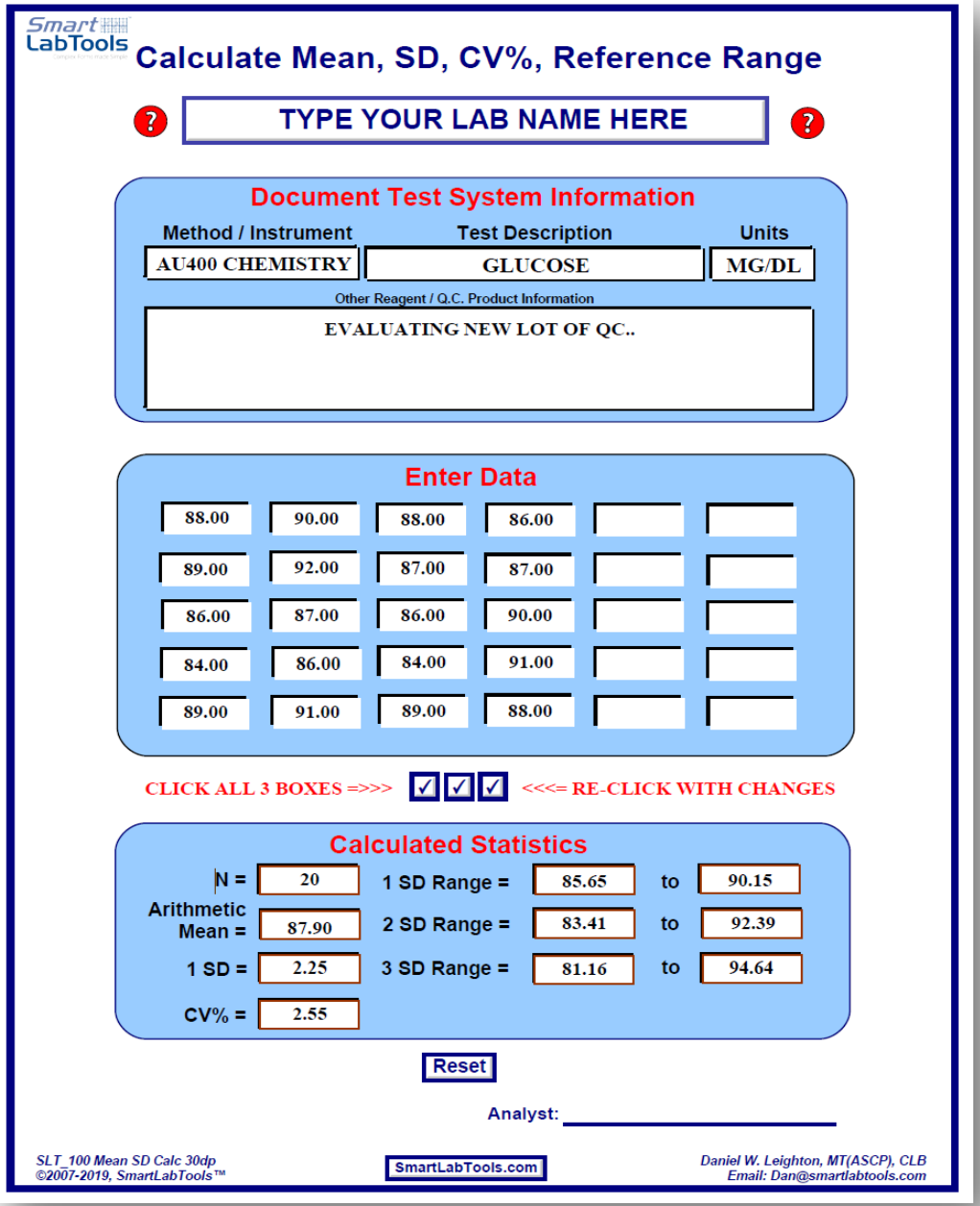
SLT_100 Calculate QC Statistics

SESSION EXERCISE: DOWNLOADING AND USING THIS CALCULATOR

****

LINK TO OTHER SLT QC CALCULATORS..

FREE SLT 100 QC Tool Click Here



Smart LabTools
Complex Forms made Simple

Simple Q.C. Range Calculator

GLUCOSE EXAMPLE

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

Control Level	Mean	1SD	- 2SD	+2SD	- 3SD	+3SD	CV%
Level-1	63.00	2.08	58.84	67.16	56.76	69.24	3.30
Level-2	123.00	3.69	115.62	130.38	111.93	134.07	3.00
Level-3	363.00	11.25	340.50	385.50	329.25	396.75	3.10

Enter Range to Calculate Mean and 1SD

Control Level	Range Low	Range High
Level-1	58.84	67.16
Level-2	115.62	130.38
Level-3	340.49	385.51

(If Range is 2SD)

Mean	1SD
63.00	2.08
123.00	3.69
363.00	11.26

(If Range is 3SD)

Mean	1SD	CV%
63.00	1.39	3.30
123.00	2.46	3.00
363.00	7.50	3.10

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

Control Level	Mean	CV%
Level-1	63.00	3.30
Level-2	123.00	3.00
Level-3	363.00	3.10

1SD	- 2SD Limit	+2SD Limit
2.08	58.84	67.16
3.69	115.62	130.38
11.25	340.49	385.51

FREE Tool Click Here

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Calculator for Evaluating Control Limits Based on Total Allowable Error Limits

GLUCOSE EXAMPLE

	TEa Limits			If use TEa (%)			If use TEa (Value)		
Control Level	Mean	Limit %	Limit Val	Low	High	1SD	Low	High	1SD
Level-1	60.00	10.00	6.00	54.00	66.00	3.00	54.00	66.00	3.00
Level-2	120.00	10.00	6.00	108.00	132.00	6.00	114.00	126.00	3.00
Level-3	280.00	10.00	6.00	252.00	308.00	14.00	274.00	286.00	3.00

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.

FREE Tool Click Here

COLA PRI – QC 16

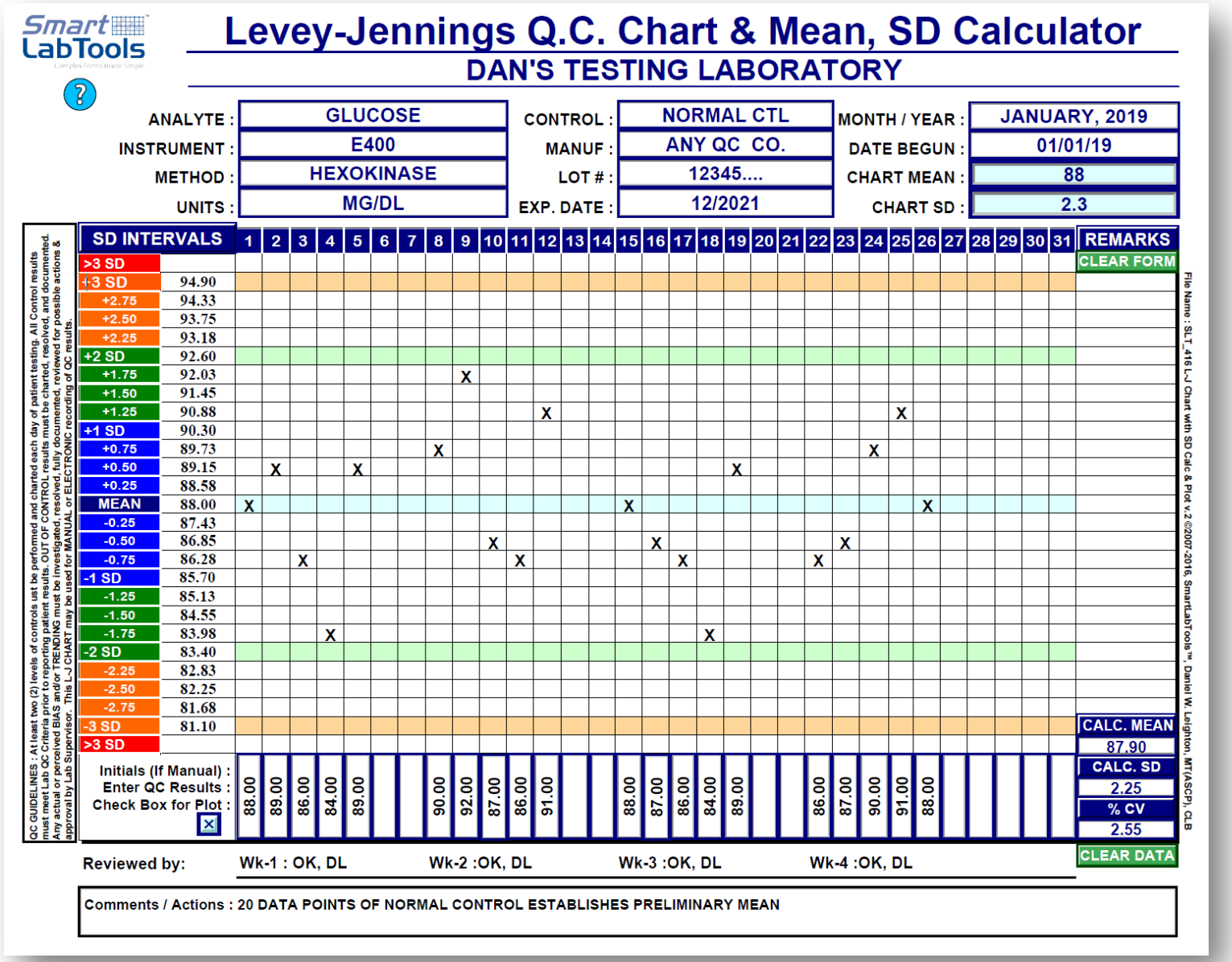
REQUIREMENT

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?

- Prepare conventional *Levey-Jennings QC Charts*, review weekly, monthly **and / or**……

- ***SmartLabTools™*** *Daily QC Statistical Assessments*

Data Plot with Calculated Mean, SD – High Sensitivity



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

DAN'S TESTING LABORATORY

ANALYTE :	GLUCOSE	CONTROL :	NORMAL CTL	MONTH / YEAR :	JANUARY, 2019
INSTRUMENT :	E400	MANUF :	ANY QC CO.	DATE BEGUN :	01/01/19
METHOD :	HEXOKINASE	LOT # :	12345....	CHART MEAN :	88
UNITS :	MG/DL	EXP. DATE :	12/2021	CHART SD :	2.3

QC GUIDELINES : At least two (2) levels of controls ust be performed and charted each day of patient testing. All Control results must meet Lab QC Criteria prior to reporting patient results. OUT OF CONTROL results must be charted, resolved, and documented. Any actual or perceived BIAS and/or TRENDING must be investigated, resolved, fully documented, reviewed for possible actions & approval by Lab Supervisor. This L-J CHART may be used for MANUAL or ELECTRONIC recording of QC results.

SD INTERVALS		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	31	REMARKS
>3 SD																																	CLEAR FORM
+3 SD	94.90																																
+2.75	94.33																																
+2.50	93.75																																
+2.25	93.18																																
+2 SD	92.60																																
+1.75	92.03									X																							
+1.50	91.45																																
+1.25	90.88												X													X							
+1 SD	90.30																																
+0.75	89.73								X																X								
+0.50	89.15		X			X														X													
+0.25	88.58																																
MEAN	88.00	X														X											X						
-0.25	87.43																																
-0.50	86.85										X						X							X									
-0.75	86.28			X								X						X					X										
-1 SD	85.70																																
-1.25	85.13																																
-1.50	84.55																																
-1.75	83.98				X														X														
-2 SD	83.40																																
-2.25	82.83																																
-2.50	82.25																																
-2.75	81.68																																
-3 SD	81.10																																
>3 SD																																	CALC. MEAN
Initials (If Manual) :																																	87.90
Enter QC Results :		88.00	89.00	86.00	84.00	89.00			90.00	92.00	87.00	86.00	91.00			88.00	87.00	86.00	84.00	89.00			86.00	87.00	90.00	91.00	88.00						CALC. SD
Check Box for Plot :		☒																															2.25
																																	% CV
																																	2.55
																																	CLEAR DATA

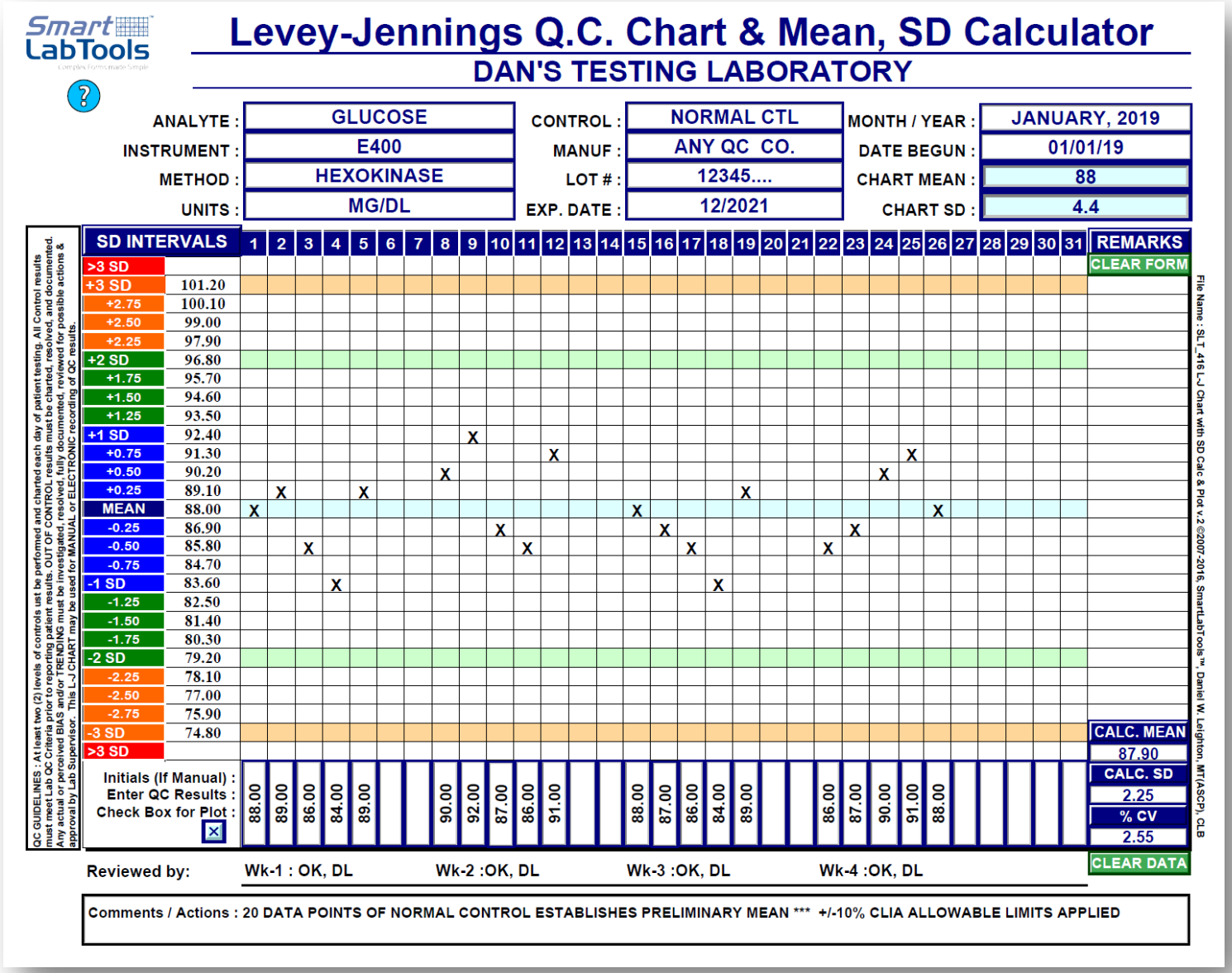
Reviewed by: Wk-1 : OK, DL Wk-2 :OK, DL Wk-3 :OK, DL Wk-4 :OK, DL

Comments / Actions : 20 DATA POINTS OF NORMAL CONTROL ESTABLISHES PRELIMINARY MEAN

File Name : SLT_416 L-J Chart with SD Calc & Plot v.2 ©2007-2016, SmartLabTools™, Daniel W. Leighton, MT(ASCP), CLB

SLT416

Data Plot with Calc. Mean, TEa% - Lower Sensitivity



Smart LabTools

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

DAN'S TESTING LABORATORY

ANALYTE :	GLUCOSE	CONTROL :	NORMAL CTL	MONTH / YEAR :	JANUARY, 2019
INSTRUMENT :	E400	MANUF :	ANY QC CO.	DATE BEGUN :	01/01/19
METHOD :	HEXOKINASE	LOT # :	12345....	CHART MEAN :	88
UNITS :	MG/DL	EXP. DATE :	12/2021	CHART SD :	4.4

QC GUIDELINES : At least two (2) levels of controls ust be performed and charted each day of patient testing. All Control results must meet Lab QC Criteria prior to reporting patient results. OUT OF CONTROL results must be charted, resolved, and documented. Any actual or perceived BIAS and/or TRENDING must be investigated, resolved, fully documented, reviewed for possible actions & approval by Lab Supervisor. This L-J CHART may be used for MANUAL or ELECTRONIC recording of QC results.

SD INTERVALS		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	31	REMARKS
>3 SD																																	CLEAR FORM
+3 SD	101.20																																
+2.75	100.10																																
+2.50	99.00																																
+2.25	97.90																																
+2 SD	96.80																																
+1.75	95.70																																
+1.50	94.60																																
+1.25	93.50																																
+1 SD	92.40									X																							
+0.75	91.30												X													X							
+0.50	90.20								X																X								
+0.25	89.10		X			X														X													
MEAN	88.00	X														X											X						
-0.25	86.90										X						X							X									
-0.50	85.80			X								X						X					X										
-0.75	84.70																																
-1 SD	83.60				X														X														
-1.25	82.50																																
-1.50	81.40																																
-1.75	80.30																																
-2 SD	79.20																																
-2.25	78.10																																
-2.50	77.00																																
-2.75	75.90																																
-3 SD	74.80																																CALC. MEAN
>3 SD																																	87.90
Initials (If Manual) :																																	CALC. SD
Enter QC Results :		88.00	89.00	86.00	84.00	89.00			90.00	92.00	87.00	86.00	91.00			88.00	87.00	86.00	84.00	89.00			86.00	87.00	90.00	91.00	88.00						2.25
Check Box for Plot :	☒																																% CV
																																	2.55
																																	CLEAR DATA

Reviewed by: Wk-1 : OK, DL Wk-2 :OK, DL Wk-3 :OK, DL Wk-4 :OK, DL

Comments / Actions : 20 DATA POINTS OF NORMAL CONTROL ESTABLISHES PRELIMINARY MEAN *** +/-10% CLIA ALLOWABLE LIMITS APPLIED

File Name : SLT_416 L-J Chart with SD Calc & Plot v.2 ©2007-2016, SmartLabTools™, Daniel W. Leighton, MT(ASCP), CLB

SLT416

Daily QC Assessment in current use

Daily QC is being saved to cloud storage application 'Dropbox' where TC can review remotely to observe:

1) QC Compliance
2) Shifts or Trends
3) QC Out
4) Corrective Action

Click here for link to SLT_105 demo template

Smart LabTools

QUALITY CONTROL RESULTS EVALUATION

AFC / URGENT CARE RIVERSIDE

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

HEMATOLOGY-MEDONIC-
CDS BOULE CON-DIFFTRI-LEVEL 2180601-K EXP 10/26/2018

Specimen Source	Analyte Name	Low -2SD	High +2SD	Calc Mean	Calc 1SD	Test Value	Calc Bias	Calc SDI	QC In?	QC Out?
ABN LOW	WBC	3.30	3.90	3.60	0.15	3.40	-0.20	-1.33*	QC In	
21803-01	LYMP%	40.00	54.00	47.00	3.50	47.60	0.60	0.17	QC In	
	MID%	0.20	10.20	5.20	2.50	4.90	-0.30	-0.12	QC In	
	GRAN%	40.80	54.80	47.80	3.50	47.50	-0.30	-0.09	QC In	
	RBC	2.00	2.24	2.12	0.06	2.12	0.00	0.00	QC In	
	HCT	11.70	16.70	14.20	1.25	15.00	0.80	0.64	QC In	
	HGB	5.00	5.60	5.30	0.15	5.30	0.00	0.00	QC In	
	PLAT	69.00	99.00	84.00	7.50	88.00	4.00	0.53	QC In	
NORMAL	WBC	7.90	9.10	8.50	0.30	8.90	0.40	1.33 *	QC In	
21803-2	LYPM%	45.30	55.30	50.30	2.50	50.90	0.60	0.24	QC In	
	MID%	1.20	11.20	6.20	2.50	6.20	0.00	0.00	QC In	
	GRAN%	38.50	48.50	43.50	2.50	42.90	-0.60	-0.24	QC In	
	RBC	3.79	4.15	3.97	0.09	4.03	0.06	0.67	QC In	
	HCT	29.90	35.90	32.90	1.50	34.70	1.80	1.20 *	QC In	
	HGB	11.30	12.10	11.70	0.20	11.70	0.00	0.00	QC In	
	PLAT	211.00	271.00	241.00	15.00	245.00	4.00	0.27	QC In	
ABN HIGH	WBC	19.20	22.80	21.00	0.90	20.90	-0.10	-0.11	QC In	
21803-03	LYMP%	58.80	68.80	63.80	2.50	62.60	-1.20	-0.48	QC In	
	MID%	0.70	10.60	5.65	2.48	6.10	0.45	0.18	QC In	
	GRAN%	25.60	35.60	30.60	2.50	31.30	0.70	0.28	QC In	
	RBC	4.65	5.09	4.87	0.11	4.88	0.01	0.09	QC In	
	HCT	41.20	48.20	44.70	1.75	45.70	1.00	0.57	QC In	
	HGB	15.10	16.10	15.60	0.25	15.50	-0.10	-0.40	QC In	
	PLAT	467.00	587.00	527.00	30.00	520.00	-7.00	-0.23	QC In	

QC item(s): Normal and High Qc

Problem: ... WBC: Measurement statistics warning- re-analyze

Actions: ...ran Prime cycle and repeated controls

* *Trend Alert Warrants Attention*

SLT_105a v.102616
© SmartLabTools™ 2008-2016
Daniel W. Leighton, CLB

10/2/2018 9:07 am

Reset All | Reset Data

Click for Link To QC Reference

Samantha Lyons — Analyst

DL — Reviewed by

Daily QC Assessment Template in current use

Daily QC is being saved to cloud storage application 'Dropbox' where TC can review remotely to observe:

1) QC Compliance
2) Shifts or Trends
3) QC Out
4) Corrective Action

Click here for link to SLT_400 Website & Demo Template

Smart LabTools

IMPERIAL VALLEY FAMILY CARE
DAILY Q.C. STATISTICAL ASSESSMENT

TEST SYSTEM:	VITROS 4600			Bias # CTLs
CONTROLS:	PERF. VERIFIER I	PERF. VERIFIER II		2
LOT NUMBERS:	B6272	C6274		Trend Flag =
EXPIRATION:	1/31/2020	1/31/2020		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
GLU	78.30	80.3	2.00	0.96	In	287.95	289.7	1.75	0.20	In						0.58	
TP	3.77	3.94	0.17	1.13	In	6.92	7.05	0.13	0.76	In						0.95	
URIC	3.87	3.75	-0.12	-0.80	In	10.85	10.61	-0.24	-0.96	In						-0.88	
ALB	2.37	2.46	0.09	1.00	In	4.61	4.67	0.06	0.55	In						0.77	
TRIG	122.10	124	1.90	0.63	In	250.60	255	4.40	0.70	In						0.67	
CHOL	151.20	152.8	1.60	0.37	In	235.70	237.9	2.20	0.37	In						0.37	
AMYL	77.00	71.5	-5.50	-0.92	In	322.00	313.4	-8.60	-0.41	In						-0.66	
CL-	80.70	80	-0.70	-0.64	In	107.00	106.7	-0.30	-0.21	In						-0.43	
K+	2.87	2.93	0.06	0.60	In	5.53	5.62	0.09	0.56	In						0.58	
NA+	119.80	118.7	-1.10	-0.79	In	142.70	142.6	-0.10	-0.07	In						-0.43	
ECO2	25.70	25.6	-0.10	-0.08	In	14.90	15.2	0.30	0.30	In						0.11	
PHOS	3.20	3.23	0.03	0.21	In	7.22	7.39	0.17	0.74	In						0.48	
CREA	0.81	0.84	0.03	0.38	In	5.16	5.15	-0.01	-0.07	In						0.15	
UREA	18.00	18.2	0.20	0.33	In	54.90	55.2	0.30	0.21	In						0.27	
BU	0.45	0.48	0.03	0.25	In	8.90	8.89	-0.01	-0.03	In						0.11	
CA	8.73	8.80	0.07	0.27	In	11.82	11.87	0.05	0.19	In						0.23	
TBIL	1.58	1.5	-0.08	-0.50	In	16.00	16.06	0.06	0.13	In						-0.18	
AST	36.00	36.8	0.80	0.53	In	166.00	168.8	2.80	0.56	In						0.55	
ALKP	112.50	111.1	-1.40	-0.11	In	495.00	486.5	-8.50	-0.14	In						-0.12	
ALT	36.00	36.8	0.80	0.16	In	187.00	187.2	0.20	0.02	In						0.09	
LDH	422.00	416.5	-5.50	-0.18	In	1,441.0	1477	36.00	0.58	In						0.20	
CK	148.00	150.8	2.80	0.13	In	780.00	798	18.00	0.21	In						0.17	
LIPA	146.00	152.5	6.50	0.86	In	586.00	603	17.00	1.20	In						1.03	
GGT	66.00	63.8	-2.20	-1.29	In	400.00	414	14.00	0.44	In						-0.43	
BC	0.46	0.33	-0.13	-0.96	In	3.32	3.39	0.07	0.28	In						-0.34	
MG	1.95	1.95	0.00	0.00	In	4.55	4.3	-0.25	-2.50	Out						-1.25	*
FE	100.22	104	3.78	0.87	In	221.90	226.9	5.00	0.60	In						0.73	
dHDL	48.20	47.9	-0.30	-0.19	In	61.60	59.6	-2.00	-0.85	In						-0.52	
dLDL	72.10	70.5	-1.60	-0.50	In	115.00	119.7	4.70	0.61	In						0.06	

Comments / Actions: MG Level-2 on the low side (1-2s), Level-1 on Mean.
OK to report this run

* Trend Alert - Warrants Attention
* QC Out - Requires Investigation

1/4/19
16:09

Reset Data

ANITA ROMO
Analyst

DL
Reviewed by

Prothrombin Time – Normal Patient Mean

COLA	COLA Requirement:
CO 2E	Does the laboratory determine the normal patient reference range and mean, with each change in lot number of thromboplastin reagent prior to use, and with any change in methodology?

"This range is method, instrument, and reagent specific. The lab must perform a normal patient mean study with every change in lot number of thromboplastin and with any change in methodology, using a sufficient number (minimum = 20) of normal patient specimens. It is not acceptable to use the daily normal control value or the mean of the normal control in place of your normal patient reference mean as the denominator in the INR calculations. You may not borrow a normal patient mean from any other facility."

Reference: Cola Laboratory Accreditation Manual 2018

Prothrombin Time – Normal Patient Mean

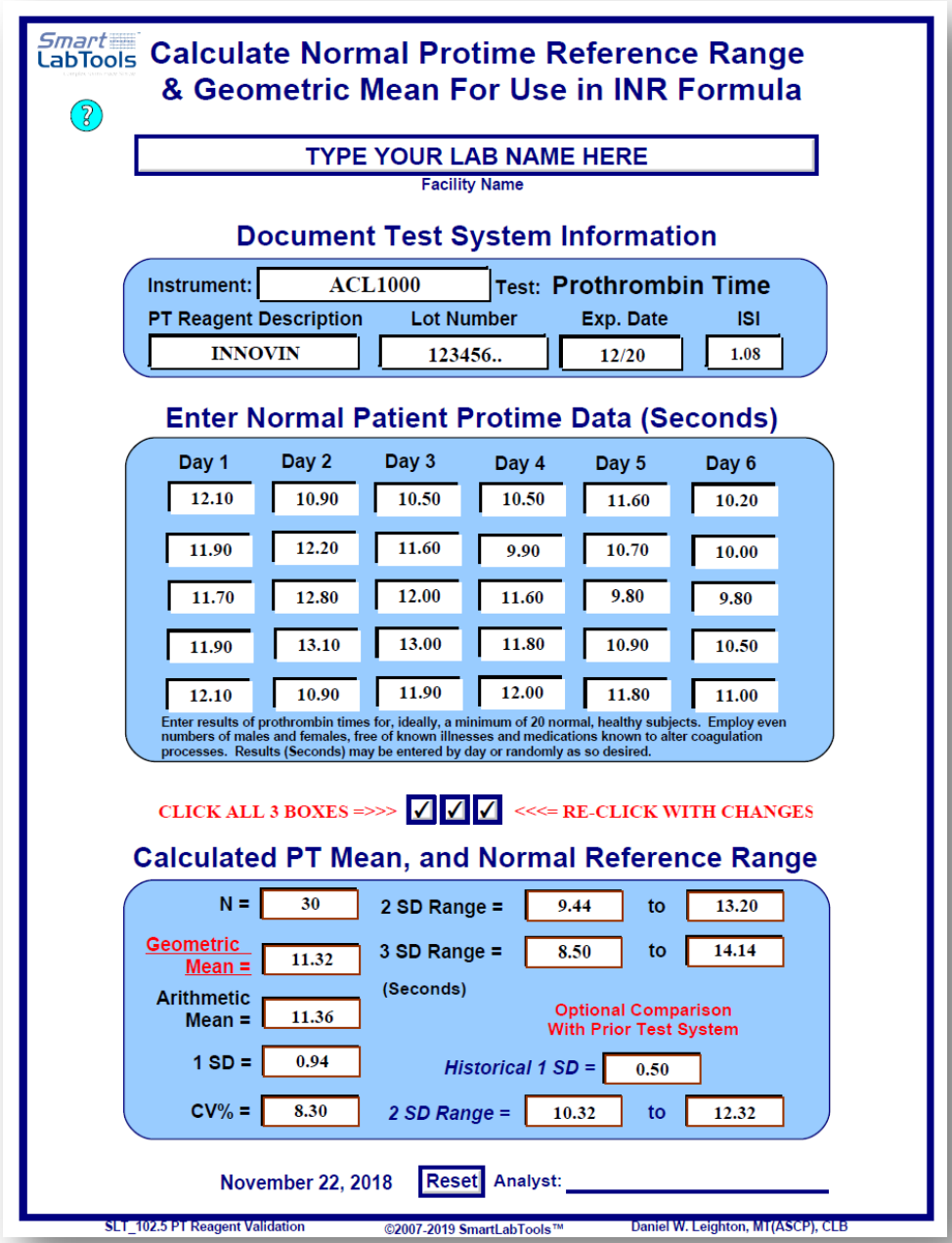
COLA	COAGULATION CITATION & ACTION REQUIRED
CO 2	***'The lab has determined the normal patient mean value for the current lot of thromboplastin to be 11.48. The labs has a value currently programmed in of 12.0. This lot of thromboplastin was started in August 2017'***
Action	Submit a process that will be used by the laboratory to ensure the correct normal patient mean value for each new lot of thromboplastin will be updated when new reagent is put into use.
QA 20.2	Perform an incident management investigation for PT INR to demonstrate any impact on patient results from use of the incorrect normal patient range value which was in use from August 2017 until May 2018.

Prothrombin Time Patient Mean & Range Calculator

Document Thromboplastin Lot#, Exp., ISI value

Geometric Mean is the preferred Mean for use in the INR calculation

Click Here or image for link to website where you may now download this ***FREE*** calculator



SmartLabTools

Calculate Normal Protime Reference Range & Geometric Mean For Use in INR Formula

TYPE YOUR LAB NAME HERE
Facility Name

Document Test System Information

Instrument: ACL1000 Test: Prothrombin Time

PT Reagent Description	Lot Number	Exp. Date	ISI
INNOVIN	123456..	12/20	1.08

Enter Normal Patient Protime Data (Seconds)

Day 1	Day 2	Day 3	Day 4	Day 5	Day 6
12.10	10.90	10.50	10.50	11.60	10.20
11.90	12.20	11.60	9.90	10.70	10.00
11.70	12.80	12.00	11.60	9.80	9.80
11.90	13.10	13.00	11.80	10.90	10.50
12.10	10.90	11.90	12.00	11.80	11.00

Enter results of prothrombin times for, ideally, a minimum of 20 normal, healthy subjects. Employ even numbers of males and females, free of known illnesses and medications known to alter coagulation processes. Results (Seconds) may be entered by day or randomly as so desired.

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

Calculated PT Mean, and Normal Reference Range

N =	30	2 SD Range =	9.44	to 13.20
Geometric Mean =	11.32	3 SD Range =	8.50	to 14.14
Arithmetic Mean =	11.36	(Seconds)		
1 SD =	0.94	Optional Comparison With Prior Test System		
CV% =	8.30	*Historical 1 SD* =	0.50	
		2 SD Range =	10.32	to 12.32

November 22, 2018 Reset Analyst: _____

SLT_102.5 PT Reagent Validation ©2007-2019 SmartLabTools™ Daniel W. Leighton, MT(ASCP), CLB

Prothrombin Time – ISI & INR

COLA	COLA Requirement:
CO 1E	Does the laboratory have a mechanism to ensure that the correct activity of the Thromboplastin, as indicated by the ISI, (corresponding to the current lot number of tissue thromboplastin in use) is used to calculate the INR prior to the use of each new lot number?

"The ISI is the International Sensitivity Index value that is determined by the thromboplastin reagent manufacturer for your particular instrument or method. The ISI is an indication of how sensitive the thromboplastin reagent is in relation to the standard set by the World Health Organization."

*"**NOTE**: Frequently ISI values differ from batch to batch or lot to lot of Thromboplastin. When values change, the new value must be updated and used in calculating the INR."*

Reference: Cola Laboratory Accreditation Manual 2018

Verify INR Calculations

COLA	COLA Requirement:
QA 23R	Does the laboratory's QA Plan include at least annual verification of the accuracy of the INR calculation? This includes: • Verification that the correct ISI value for the lot number in use is included in the calculation; • Verification that the current normal patient mean is included in the calculation; and • Verification that the calculation of the INR is accurate.

"Incorrect INR values can have potentially harmful effects on patients. A patient's medication dosage may be adjusted to a level that is dangerous for the patient if the INR calculation is reported incorrectly. As part of the QA Plan, at least annually, confirm that the correct values for ISI and normal patient mean are being utilized, and that the calculation, whether performed by your staff, or by a computer, yields the correct results."

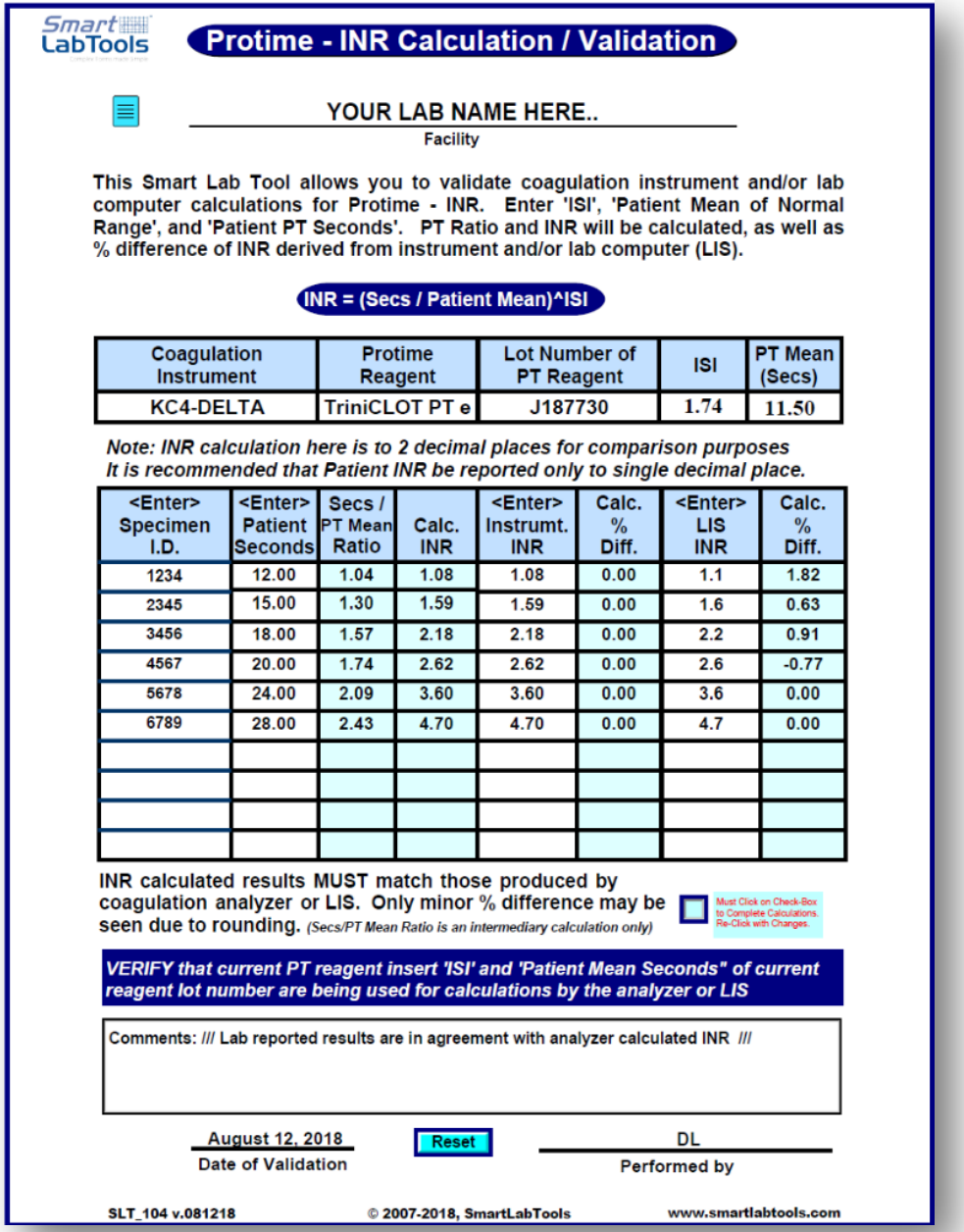
Reference: Cola Laboratory Accreditation Manual 2018

Protime - INR Calculation Validation Tool

Tip:

Form calculates INR based on ISI and Patient Mean, then compares to INR calculated by analyzer or LIS

Click Here or on image for link to website where you may now download this ***FREE*** Calculator.



Smart LabTools

Protime - INR Calculation / Validation

YOUR LAB NAME HERE..
Facility

This Smart Lab Tool 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).

INR = (Secs / Patient Mean)^ISI

Coagulation Instrument	Protime Reagent	Lot Number of PT Reagent	ISI	PT Mean (Secs)
KC4-DELTA	TriniCLOT PT e	J187730	1.74	11.50

Note: INR calculation here is to 2 decimal places for comparison purposes
It is recommended that Patient INR be reported only to single decimal place.

<Enter> Specimen I.D.	<Enter> Patient Seconds	Secs / PT Mean Ratio	Calc. INR	<Enter> Instrumt. INR	Calc. % Diff.	<Enter> LIS INR	Calc. % Diff.
1234	12.00	1.04	1.08	1.08	0.00	1.1	1.82
2345	15.00	1.30	1.59	1.59	0.00	1.6	0.63
3456	18.00	1.57	2.18	2.18	0.00	2.2	0.91
4567	20.00	1.74	2.62	2.62	0.00	2.6	-0.77
5678	24.00	2.09	3.60	3.60	0.00	3.6	0.00
6789	28.00	2.43	4.70	4.70	0.00	4.7	0.00

INR calculated results MUST match those produced by coagulation analyzer or LIS. Only minor % difference may be seen due to rounding. *(Secs/PT Mean Ratio is an intermediary calculation only)*

Must Click on Check-Box to Complete Calculations. Re-Click with Changes.

VERIFY that current PT reagent insert 'ISI' and 'Patient Mean Seconds" of current reagent lot number are being used for calculations by the analyzer or LIS

Comments: /// Lab reported results are in agreement with analyzer calculated INR ///

August 12, 2018
Date of Validation

Reset

DL
Performed by

SLT_104 v.081218 © 2007-2018, SmartLabTools www.smartlabtools.com

Coagulation Worksheet

provisional QC Limits for new control lot

100 PLAZA CLINICAL LABORATORY
CA-600 COAGULATION ANALYZER

Reagent	Lot Number	Exp. Date	Reagent	Lot Number	Exp. Date	Reagent	Lot Number	Exp. Date
PROTIME	549717	09/21/20				NORMAL CTL	548040	04/2019
PTT	538528	04/10/19				ABNORMAL CTL	548465	04/2018
CACL	539798	11/02/21						

Shift	Date	Time	Tech	Shift	Date	Time	Tech	Shift	Date	Time	Tech
1				2				3			

Control	PT	PTT	Fibrinogen	Control	PT	PTT	Fibrinogen	Control	PT	PTT	Fibrinogen
NORMAL CTL	9.9-10.8	22.9-27.7	n/a	NORMAL CTL				NORMAL CTL			
Result =			n/a								
ABNORMAL CTL	48.6-56.6	62.5-68.5	n/a	ABNORMAL CTL				ABNORMAL CTL			
Result =			n/a								

Accession Number	Patient Name	PT Seconds	PT INR	PTT Seconds	Fibrinogen	FDP	Tech / Initials	Comments / Review

Document Reagent & Control Lot #’s in Use, QC Limits, QC Results & Patient Results.
‘SAVE’ ALL REAGENT & QC INSERTS

Click on Link to SmartLabTools.com Forms & Resources

Coagulation Tools

Coagulation Tips

	Tips
1.	Examiner will want to verify ‘ISI’ used for each lot of thromboplastin used for the previous 2 years. Have records organized & available.
2.	Be prepared to demonstrate how and where ‘ISI’ setting is made in the coagulation analyzer. If not familiar with this task ..Practice!
3.	Be prepared to show how ‘Patient Mean’s’ were calculated for the past and present lots of PT reagent.
4.	Verify correct settings frequently, as you cannot undo potential patient harm should incorrect settings and calculations be used.
5.	Pay attention to pre-analytical requirements for coagulation samples such as fill volume and added centrifugation time for platelet poor plasma .. 15 minutes @ 1500xg (~2500-3500 rpm depending on rotor).

Coagulation Tips

Tips (Pre-Analytical)

6. Examiners can make mistakes.. What is wrong with the following citation?

ORG 14	General	ORG 14 Do personnel follow all procedures as written in the procedure manual?	The laboratory does not follow specimen processing procedures for Coagulation. The lab centrifuges for 10 minutes at 2500 rpm. The lab uses the package insert as the procedure and the insert states 15 minutes at 1500 rpm.

SPECIMEN COLLECTION AND TREATMENT

Nine volumes of blood are to be collected in one volume of 3.2% (0.109M) sodium citrate. Immediately after blood collection, samples are centrifuged at 1500 x g for 15 minutes. Storage at 2-8°C is not recommended as it may result in cold activation of Factor VII. Refer to the most recent version of the CLSI document H21-A5 for further instructions regarding specimen collection and treatment.[7]

Plasma storage: 8 hours at 20 ± 5°C. [8]

Do not store plasma at 2-8°C.[9]

Coagulation Tips

Tips (Pre-Analytical)

7. Helpful Chart to understand the relationship between Centrifugal G-Force RCF, and RPM

Centrifuge Reference Guide

Centrifuges with Horizontal Rotors

Model	Urine	Sodium Citrate (Coag) PPP	Plasma Serum (Chemistry)	PRP PRF	STAT	Mobile Care	Max RPM	Max G-Force RCF	Settings	Control	Digital Display	Up to 17 x 75 or 100 mm or 10 mL
	Cycle Time (Minutes)											
642B*		15	10				3380	1600	One	Knob		6
642E		15	10				3380	1600	One	Button		6
642M		15	10			✓	3400	1600	One	Button		6
HORIZON 6	5	15	10	✓			3800	2000	Three	Button		6
HORIZON 6 Flex	5	15	10	✓			3800	2000	Ten	Button	✓	6

I Am Too Hot!

What To Do When Your Temperatures are Out of Range

Lynh Rowe, CLS

Objectives

1. Understand why temperature documentation is critical
2. Know how to correctly read a digital thermometer and document temperatures
3. Know the steps to take when the temperature is out of range: Corrective Action
4. Review the supervisor responsibilities
5. Train ourselves to become critical document auditors

2 Temperature and Humidity Monitoring

Have you ever encountered a temperature log that seemed forgotten, with the last readings entered months before? What about a recorded temperature that is outside of the acceptable range with no corrective action to be found?Temperature records are not kept just for CAP compliance, though this is a requirement. The intent of monitoring temperature is to ensure that reagents, supplies, equipment, kits and specimens are stored at appropriate, validated temperatures to ensure integrity of testing for the patient.

In order to ensure proper temperatures are maintained, all items to be stored in a refrigerator, freezer or room must first be evaluated for proper storage temperature. This fundamental step is often overlooked. Do not just assume that refrigerated means 2 to 8 degrees Celsius or frozen means -10 to -30 degrees Celsius. Manufacturers establish temperature specifications based on their own stability studies, and laboratories are obligated to follow these requirements.

Just as temperature monitoring is often ignored or done poorly, humidity monitoring is often overlooked. When humidity is found to be outside of acceptable ranges, often, no corrective action is implemented as potential solutions are seemingly too costly or complex. Has your laboratory performed a thorough evaluation of manufacturer and best practice stability specifications of temperature and humidity requirements for all reagents, kits, equipment and specimens? If not, your laboratory may have a serious compliance and patient safety risks lurking. Jennifer Dawson, MHA, DLM(ASCP)SLS, QLC, QIHC

Humidity Records

COLA	COLA Requirement:
MA 6R	If your laboratory's instrumentation is affected by humidity, is the humidity in the laboratory monitored and corrective action taken if it exceeds the manufacturer's acceptable limits?

To determine if this criterion is applicable to your instrument, check for environmental conditions or specifications in the operator's manual generally found in the section marked "Set Up" or "Installation." Most instruments have an acceptable operating range that is easily met and maintained. However others may have a narrow range, as humidity can affect instrument performance or accuracy and sensitivity of the test method. The more restrictive the range, the more critical it is to monitor humidity when testing is performed.

Reference: Cola Laboratory Accreditation Manual 2018

Check Humidity Requirements

Instrument Manual Stated: 40-80%
Unrealistic for this lower desert community lab

Thank you for contacting Technical Support regarding the humidity requirements for the Tosoh G8 Analyzer. The environmental specification for humidity is intended to eliminate static electricity. Discharge of static electricity has potential to cause damage to analyzer components, cause plastic parts to attract or repel each other, and cause minor static shock to the operator.

The Tosoh G8 Analyzer environmental specification for humidity can be modified as follows:

Humidity	20 % to 80 %; non-condensing

When using this modified specification, an anti-static floor mat must be placed in the workspace in front of the analyzer. A rubber floor mat would be suitable for this purpose.

LABORATORY HUMIDITY RECORD

REPLACE WITH NAME OF LABORATORY

EQUIPMENT IDENTIFICATION	SERIAL NUMBER	DEPARTMENT	ACCEPTABLE LIMITS	OTHER	*SUPERVISORY REVIEW*
n/a	n/a	Lab	30 - 70 %	n/a	

YEAR 2019	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	31	DATE	INITIALS
JANUARY																																	
FEBRUARY																																	
MARCH																																	
APRIL																																	
MAY																																	
JUNE																																	
JULY																																	
AUGUST																																	
SEPTEMBER																																	
OCTOBER																																	
NOVEMBER																																	
DECEMBER																																	

Adjust Limits according to your Lab instruments specifications

FREE Tool Click Here

SmartLabTools.com

HUMIDITY % RECORDED BY

NU = NOT IN USE

NR = NOT RECORDED

Temperature Records

COLA	COLA Requirement:
MA 7-13	**Are temperatures recorded each day of testing and corrective action taken and documented when out of range?**

Each day of testing temperatures should be recorded. When the temperature is outside of the established range corrective action should be taken to ensure the integrity of the reagents, specimens, instruments and kits. Temperature problems can adversely affect patient results. Always document the actions taken whenever a temperature problem is detected.

Remember to record temperatures of refrigerators and freezers any time reagents or specimens are stored in them.

Reference: Cola Laboratory Accreditation Manual 2018

Temperature Ranges Established?

COLA	COLA Requirement:
MA 14 R	**Have acceptable ranges for temperature been established for each of the following: Refrigerators, Freezers, Room Temperature, Incubators, Water Baths, Dry Bath, & other temperature dependent equipment ?**

An acceptable range should be established for the above temperature checks by consulting information that comes with the instruments and kits in use in your laboratory.

When a temperature is out of range, corrective action should be recorded.

Reference: Cola Laboratory Accreditation Manual 2018

Temperature Certification

COLA	COLA Requirement:
MA 15R	**Are thermometers verified for accuracy prior to use?**

Thermometers can be checked by comparing them to a National Institute for Standards and Technologies (NIST) standard thermometer or other ***certified thermometer****. If the thermometer is found to be inaccurate, a correction factor may be applied.*

NIST standard thermometers may be bought from your laboratory supply company.

Reference: Cola Laboratory Accreditation Manual 2018

Consultants Certified Thermometer

ICC INSTRUMENT COMPANY INCORPORATED

ANAB ACCREDITED ISO/IEC 17025 CALIBRATION LABORATORY

Certificate of Calibration
575814
Page 1 of 2

Instrument Identification

ccount #: 15604
aniel W. Leighton, Consulting LLC
51 S. Ladan Lane
naheim Hills, CA 92808

PO# : COD

SO#: 32497

Instrument Id: 114463
Mfr: FLUKE
Model: 51
Accuracy: ±0.1% of reading + 0.7°C (+1.3°F)

Serial #: 4710393
Noun: Digital Thermometer (Single Input)

Certification Information

Reason For Service: Calibration
Type Of Calibration: Normal
As Found Condition: In Tolerance
As Left Condition: In Tolerance
Procedure: 33K5-4-275-1 R03 : Digital Thermometer (51 or equiv)
Remarks: Measurement Uncertainty @ k=2: ± 0.09°C/0.16°F

Technician: Kevin Halloran
Cal Date: 29 NOV 18
Cal Due: 29 NOV 20
Temperature: 24.0 °C
Humidity: 51.0 %

Traceability at ICC Instrument Co., Inc. is obtained through an unbroken chain of measurements with known uncertainties to the International Systems of Units (SI) through the National Institute of Technology (NIST) or other recognized national or international standards bodies (NMI's). ICC Instrument Co., Inc's calibration system is accredited to ISO/IEC 17025 and ANSI Z-540-1.

The results contained within relate only to the item(s) calibrated. Pass/Fail or In/Out of tolerance statements are the opinions of ICC Instrument Co., Inc., where decisions are based on test results falling within specified limits with no reduction by the uncertainty of the measurement.

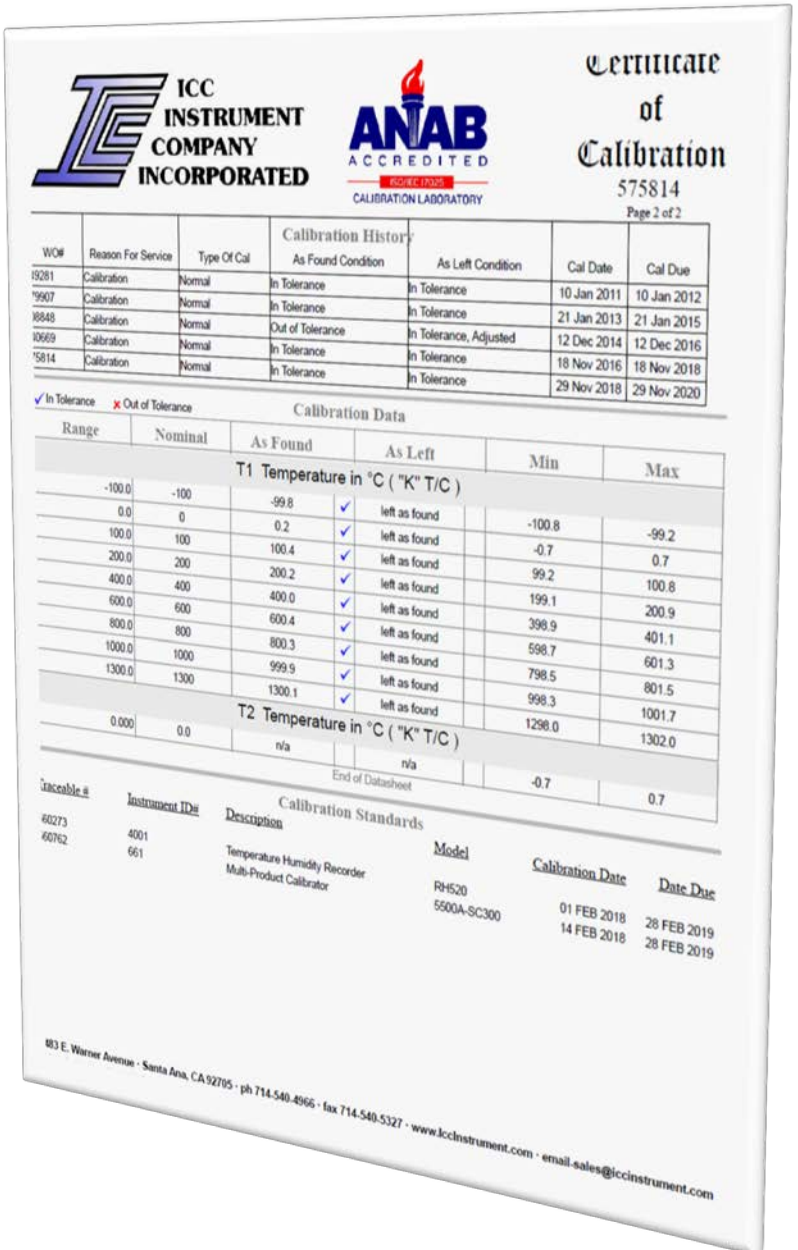
Reported uncertainties are expressed as expanded uncertainty at approximately the 95% confidence level using the coverage factor of k=2.

Due dates appearing on the certificate of calibration and labels are determined by client for administrative purposes and do not imply continued conformance to specifications. This certificate shall not be reproducted except in full, without the written approval of ICC Instrument Co., Inc.

Guillermo H. Arias, Technical Manager

Mark V. Halloran, President

483 E. Warner Avenue · Santa Ana, CA 92705 · ph 714-540-4966 · fax 714-540-5327 · www.iccinstrument.com · email-sales@iccinstrument.com



ICC INSTRUMENT COMPANY INCORPORATED

ANAB ACCREDITED ISO/IEC 17025 CALIBRATION LABORATORY

Certificate of Calibration
575814
Page 2 of 2

Calibration History

WO#	Reason For Service	Type Of Cal	As Found Condition	As Left Condition	Cal Date	Cal Due
9281	Calibration	Normal	In Tolerance	In Tolerance	10 Jan 2011	10 Jan 2012
9907	Calibration	Normal	In Tolerance	In Tolerance	21 Jan 2013	21 Jan 2015
8848	Calibration	Normal	Out of Tolerance	In Tolerance, Adjusted	12 Dec 2014	12 Dec 2016
0669	Calibration	Normal	In Tolerance	In Tolerance	18 Nov 2016	18 Nov 2018
5814	Calibration	Normal	In Tolerance	In Tolerance	29 Nov 2018	29 Nov 2020

✓ In Tolerance x Out of Tolerance

Calibration Data

Range	Nominal	As Found		As Left	Min	Max
T1 Temperature in °C ("K" T/C)						
-100.0	-100	-99.8	✓	left as found	-100.8	-99.2
0.0	0	0.2	✓	left as found	-0.7	0.7
100.0	100	100.4	✓	left as found	99.2	100.8
200.0	200	200.2	✓	left as found	199.1	200.9
400.0	400	400.0	✓	left as found	398.9	401.1
600.0	600	600.4	✓	left as found	598.7	601.3
800.0	800	800.3	✓	left as found	798.5	801.5
1000.0	1000	999.9	✓	left as found	998.3	1001.7
1300.0	1300	1300.1	✓	left as found	1298.0	1302.0
T2 Temperature in °C ("K" T/C)						
0.000	0.0	n/a		n/a	-0.7	0.7

End of Datasheet

Calibration Standards

Traceable #	Instrument ID#	Description	Model	Calibration Date	Date Due
60273	4001	Temperature Humidity Recorder	RH520	01 FEB 2018	28 FEB 2019
60762	661	Multi-Product Calibrator	5500A-SC300	14 FEB 2018	28 FEB 2019

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Temperature Corrective Action

COLA	COLA Requirement:
MA 16 R	**Does the laboratory take and document all corrective actions taken when storage conditions are not maintained within established limits?**

"If proper storage conditions are not maintained, the integrity of reagents, controls, calibrators, and patient specimens cannot be assured. When such events occur the lab should document when the condition was identified, the action taken to correct the problem or relocate supplies to maintain appropriate storage conditions."

Reference: Cola Laboratory Accreditation Manual 2018

REPLACE WITH NAME OF LABORATORY

MAIN LABORATORY REFRIGERATOR UNIT ID#_____ RANGE: 2.0 - 8.0 'C

CORRECTIVE ACTION LOG

DATE	RACK OR UNIT ID *	PATIENT EFFECT YES	PATIENT EFFECT NO	1. DESCRIBE FINDINGS 2. DESCRIBE IMMEDIATE CORRECTIVE ACTION 3. WHAT WAS PATIENT EFFECT, HOW WAS IT ADDRESSED OR WHY IS IT NOT AN ISSUE.	INITIAL
				1. . 2. 3.	
				1. YOU MAY TYPE INTO THIS FORM.... 2. 3.	
				1. 2. 3.	
				1. 2. 3.	
				1. 2. 3.	
				1. 2. 3.	

FREE Tool Click Here

Code 1 = Routine activity causing rise in temperature. Monitor unit and keep door closed until unit recovers.
Code 2 = Unit undergoing routine maintenance
Code 3 = Large # of specimens placed into/removed from freezer tables, causing rise in temperature.
Code 4 = Wires accidentally disconnected. Reconnected wires. Samples not compromised (Explain)
Code 5 = Reason could not be determined
Code 6 = Power failure
Code 7 = Other (Explain)
Code 8 = Temperature was still rising. Monitor unit and keep door closed until unit recovers.
Code 9 = Person notified that service is needed or electronic work order submitted (Describe who was notified and when)
Code 10 = Reagents / Controls / Calibrators or Specimens not compromised (Explain)

* Where applicable

Review _____ Date _____

Temperature / Humidity Tips

Tips (page 1 of 2)
1. Recording Temperatures is an important task that requires training and competency
2. ALL persons recording temperatures should first review the training Power-Point *"I'm too hot"*
3. Read the insert instructions that came with the digital thermometer to ensure knowledge of settings: F to C, Min-Max Alarms, Re-Set, if dual probes 'IN' and 'OUT'.. Knowing which is which
4. Remember to ***'Read', 'Record', 'Reset'*** when using Min-Max thermometers
5. Citations will occur when materials stored in freezers are not within product required Temperatures
6. Frozen controls often require storage of -20 ºC or colder

Temperature / Humidity Tips

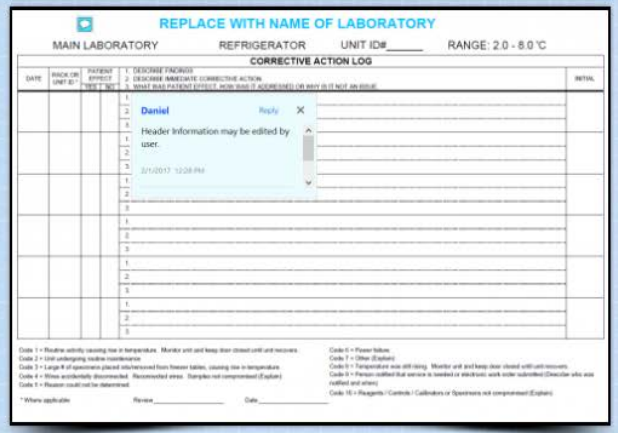
	Tips (page 2 of 2)
7.	Purchase **certified** thermometers.. Be sure to check expiration date, some are good for 2 years, otherwise validate at least annually against an NIST certified device.
8.	If using an outside service to certify onsite annually, be sure a copy of the current reference thermometer certificate is provided.
9.	For annual temperature / humidity forms print on heavier paper to endure the entire year.
10	Use of larger screen digital thermometers make the process easier and more likely obtain a correct reading.
11	Supervisors should frequently review logs,.. be certain ‘Outliers’ have supporting corrective actions. Document on SLT Corrective Action Log.
12	Also refer to *SOP Checklist for Temperature Monitoring*

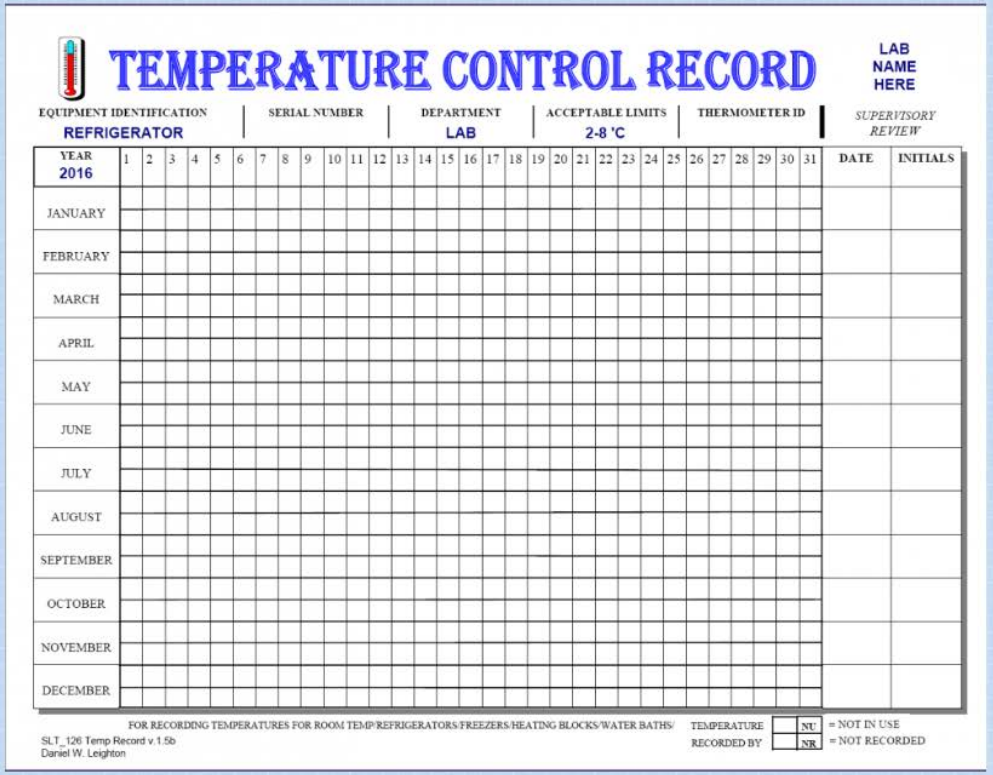
SLP_126 Temperature Record Portfolio

Includes Temperature Control, Laboratory Humidity, and a Miscellaneous Monthly record.

These templates are FREE. Click on BLUE TAB links below to download and save individual PDF charts.

Also see 'Min-Max' temperature charts





Click Here

Download Temperature Chart - Blue

Download Temperature Chart - Green

Download Temperature Chart - Misc.

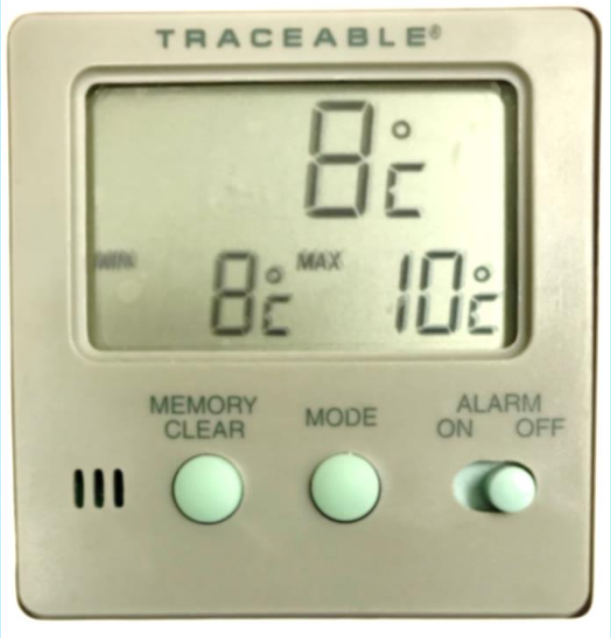
Download Humidity Chart

Download Temp. Corrective Action Log

Minimum-Maximum Thermometer…

- If a **minimum/maximum thermometer** is used to perform continuous monitoring of temperatures between daily temperature readings or following a laboratory downtime (e.g. laboratory closure for weekend or holiday), both the low and high temperatures must be recorded. To ensure correct temperature readings, the minimum/maximum thermometer **device must be reset prior to the monitoring period**

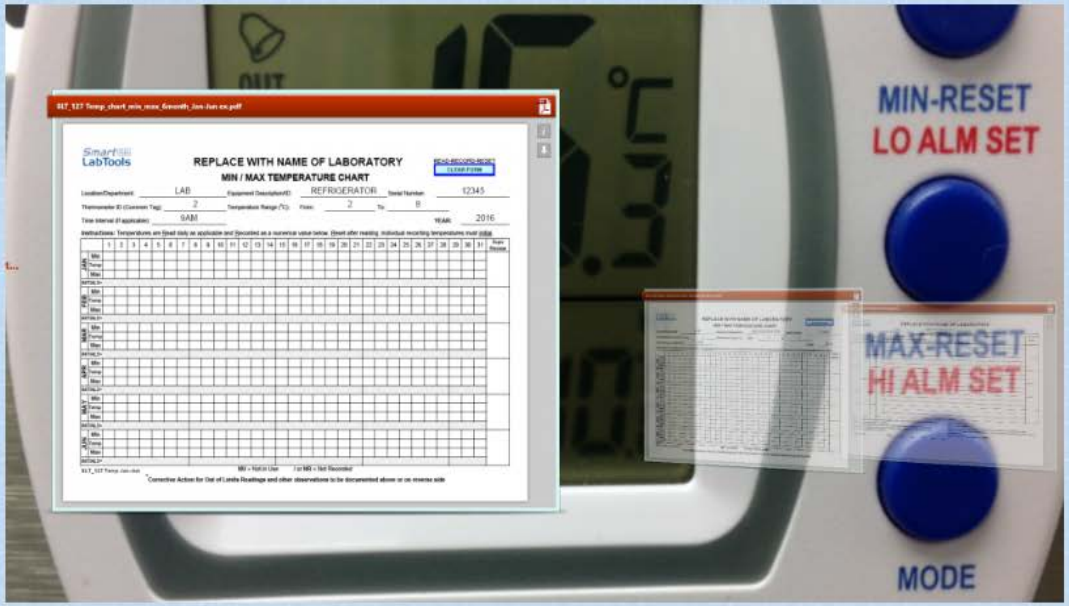
Read, Record, Reset



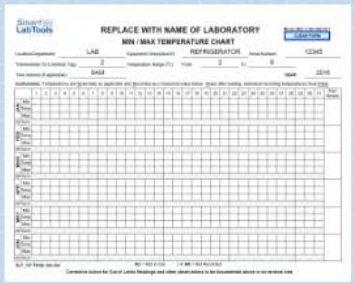
SLP_127 Min-Max Temperature Charts

Includes:

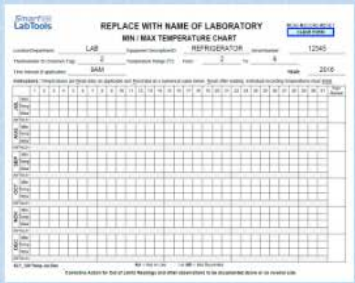
- SLT_127 6-month Temperature Chart (January - June)
- SLT_128 6-month Temperature Chart (July - December)
- Corrective Action Log
- These Charts are **FREE**



[Click Link to Webpage for Free Charts]



Download



Download

Download

Smart LabTools
Complex Forms made Simple

REPLACE WITH NAME OF LABORATORY

READ-RECORD-RESET
CLEAR FORM

MIN / MAX TEMPERATURE CHART

Location/Department: General Lab Equipment Description/ID: Refrigerator Serial Number: 123466

Thermometer ID (Common Tag): 101 Temperature Range (°C): From: 2.0 To: 8.0

Time Interval (If applicable): am YEAR: 2019

Instructions: Temperatures are Read daily as applicable and Recorded as a numerical value below. Reset after reading. Individual recording temperatures must initial.

		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	31	Supv Review
JAN	Min																																
	Temp																																
	Max																																
INITIALS=																																	
FEB	Min																																
	Temp																																
	Max																																
INITIALS=																																	
MAR	Min																																
	Temp																																
	Max																																
INITIALS=																																	
APR	Min																																
	Temp																																
	Max																																
INITIALS=																																	
MAY	Min																																
	Temp																																
	Max																																
INITIALS=																																	
JUN	Min																																
	Temp																																
	Max																																
INITIALS=																																	

FREE Tool Click Here

SLT_127 Temp Jan-Jun

NU = Not in Use / or **NR** = Not Recorded

*Corrective Action for Out of Limits Readings and other observations to be documented above or on reverse side

Method Validation – Reference Range (1)

COLA	COLA Requirement:	May Trigger Citation
VER4	Prior to patient testing, have each of the following performance specifications been verified and documented for each non-waived test or method: Reference range?	When laboratory did not validate the Reference Ranges for tests being performed.

"The span of values for a particular test that represents the results you would expect to see in a healthy (normal) patient population. Initially, you may use the manufacturer's suggested reference range. The laboratory is required to monitor the applicability of this range and make adjustments as necessary."

Reference: COLA LabGuide 13 'How to Verify Performance Specifications'

Method Validation – Reference Range (2)

COLA	COLA Requirement:	May Trigger Citation
VER 13 R	Are the established reference (normal) ranges for all patient tests appropriate for the laboratory's patient population?	When laboratory did not validate the Reference Ranges for tests being performed.

"As part of the validation process for implementation of non-waived tests and/or methods, the laboratory will need to verify the appropriateness of reference ranges. Consider the patient population served by your laboratory."

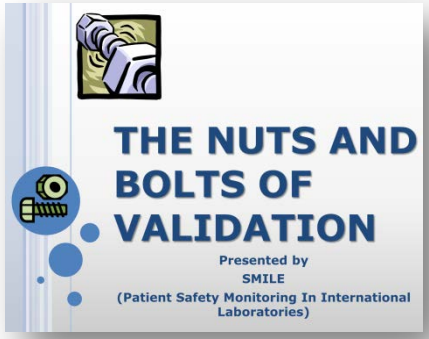
"Once reference ranges are established, the laboratory will want to monitor the ranges as part of its quality assessment program"

Reference: COLA Laboratory Accreditation Manual

Reference Range Verification 'Tool'

Spreadsheet Tools Available from pSMILE.org

Click Link for Free Tools & PowerPoint Instructions



Reference Interval Analysis

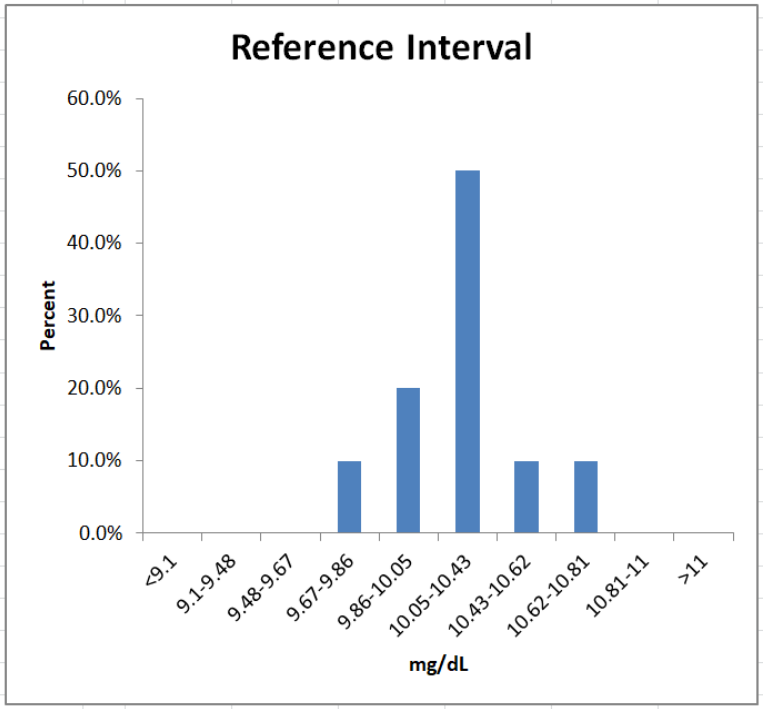
Method being evaluated:	Horiba Pentra 400+			Date:	10/28/2018
Analyte	CALCIUM				
Proposed Reference Range:	9.1	to	11	Units:	mg/dL

ENTER RESULTS IN CELLS AT RIGHT

10.5	10.3	10	10.2	10.1
10.6	10.2	10.2	10.3	10
10	10	10.1	10.1	10.7
10.1	10.1	9.8	9.7	10.8

mg/dL	*Frequency*	*%*
<9.1	0	0.0%
9.1-9.48	0	0.0%
9.48-9.67	0	0.0%
9.67-9.86	2	10.0%
9.86-10.05	4	20.0%
10.05-10.43	10	50.0%
10.43-10.62	2	10.0%
10.62-10.81	2	10.0%
10.81-11	0	0.0%
>11	0	0.0%

Mean:	10.19
SD:	0.28
Median:	10.1
Range:	9.7-10.8
Obs Outside:	0.0%
Grade:	Acceptable

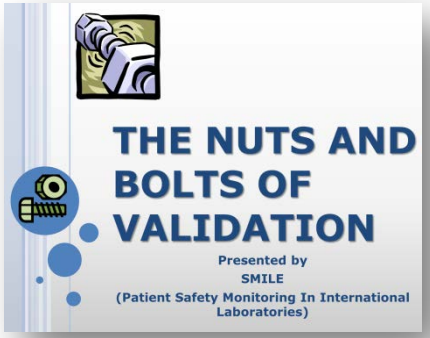


Reference Range Verification | Reference Range Establishment

Reference Range Establishment 'Tool'

Spreadsheet Tools Available from pSMILE.org

Click Link for Free Tools & PowerPoint Instructions



Reference Interval Analysis

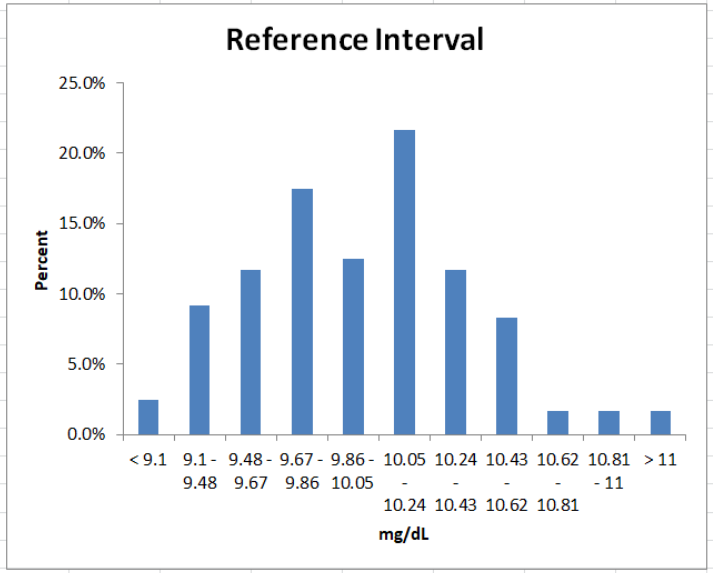
Method being evaluated:	Horiba Pentra 400+
Analyte	CALCIUM
Reference Range:	9.1 to 11
Date:	12/28/2018
Units:	mg/dL

ENTER RESULTS IN CELLS BELOW

10.5	10.1	9.7	11	10.5	10	10.1	9.3	9.9	9.8	9.8	10.2
10.6	9.8	11.3	10.9	10.2	9.5	10.5	12.2	8.9	9.8	9.8	9.7
10	10.2	10.3	10.5	10.2	10.3	9.4	9.5	9.9	10.4	10.4	9.2
10.1	10.3	10.2	10.3	10.4	9.4	9.7	10.2	9.7	9.6	9.6	9.3
10.3	10.1	10.2	9.5	9.7	9.8	9.4	10.4	9.9	10	10	9.7
10.2	9.7	10.3	10.2	9.4	10	10	10.1	9.6	9.1	9.1	9.9
10	10.1	10.2	10.3	9.3	9.8	9.6	9.5	9.5	9.7	9.7	9.6
10.1	10	10.2	9.8	9.9	10.6	9.6	9.7	9.4	10.4	9.6	9.5
10	10.7	10.4	10.2	9.7	10.6	9.5	9.8	10.6	10.1	9.7	9.4
10.2	10.8	10.4	10.5	9.9	10.1	9.4	10.1	10.1	10.1	10.2	10.6

Mean:	9.99
SD:	0.47
Minimum:	8.9
Maximum:	12.2
Median:	10

mg/dL	*Frequency*	Percent
< 9.1	3	2.5%
9.1 - 9.48	11	9.2%
9.48 - 9.67	14	11.7%
9.67 - 9.86	21	17.5%
9.86 - 10.05	15	12.5%
10.05 - 10.24	26	21.7%
10.24 - 10.43	14	11.7%
10.43 - 10.62	10	8.3%
10.62 - 10.81	2	1.7%
10.81 - 11	2	1.7%
> 11	2	1.7%



Reference Range Verification | Reference Range Establishment

Proficiency Testing (1 of 4)

COLA	COLA Requirement:	May Trigger Citation
PT2	PT2 For each regulated analyte tested in your laboratory, do you perform and report PT results to the PT Provider for all events, unless you have been granted an exemption by the PT Program and COLA for voluntarily ceasing to test an analyte	Missed PT event
PT5	Do you follow the same procedures for testing PT samples as you do for patient specimens?	Not rotating challenges among all testing personnel; repeating samples when it does not meet repeat criteria; calibrating right before running samples

Proficiency Testing (2 of 4)

COLA	COLA Requirement	May Trigger Citation
PT9	When results are unsatisfactory, do you evaluate the results and take appropriate corrective action	No corrective action documented; corrective action only includes repeats but no evaluation of patient impact or investigation into root cause
PT10	Does your laboratory verify the accuracy of any analyte specialty, or subspecialty that is assigned a PT score that does not reflect the accuracy of the laboratory's actual performance?	No evaluation of non graded PT results

Proficiency Testing (3 of 4)

COLA	COLA Requirement	May Trigger Citation
PT8	Are all PT results reviewed and evaluated by the laboratory director or other qualified designee in a timely manner?	No review by LD or qualified individual; no date of review; date of review greater than 30 days after receipt of results
PT15	A copy of the attestation form signed by the director and testing personnel?	Attestations either missing or not signed
PT16	An indication of the review of the graded results by the director as well as the testing personnel?	No indication that PT results are reviewed by laboratory staff such as Consultant, Supervisors, or testing personnel

Proficiency Testing Tools (4 of 4)

Click on Links to SmartLabTools.com Forms & Resources
Link to SLT Proficiency Testing Resources
Proficiency Testing Checklist
Investigation of Ungraded Proficiency Testing
Proficiency General Investigation Checklist
Proficiency Testing Corrective Action Checklist

Non-Regulated Analytes

COLA	COLA Requirement	May Trigger Citation
PT4E	For each unregulated analyte tested in your laboratory that you have not enrolled in a COLA-approved PT program, do you perform and compare the results of external split-specimen testing on at least five specimens twice a year in periodic intervals?	Not verifying the accuracy of non-regulated analytes by participation in a PT program, or by other means such as Split Specimen Analysis • 5 specimens, twice per year • 4 of 5 (80%) meet acceptance criteria
Click on Links to SmartLabTools.com Forms & Resources		
Link to SLT Correlation Testing, Split Samples		
Link to SLT PT Self Assessment Tool		
COLA LabGuide 9— “Split Specimen Analysis.”		

Competency Assessment (1 of 2)

COLA	COLA Requirement	May Trigger Citation
PER 5	Does your director or Technical Supervisor, Technical Consultant follow written policies and procedures to periodically evaluate personnel performance and competency of all staff involved in pre-analytical, analytic, and post-analytic phases of testing, as well as those responsible for supervision and consultation?	Competency assessments not performed; not done at six months, one year, and annual frequency; performed by individuals not qualified as TC or higher; ineffective reviews

Competency Assessment (2 of 2)

COLA	COLA Requirement	May Trigger Citation
PER6	Do the personnel reviews include the person's continuing education	No continuing education performed

Click on Link to SmartLabTools.com Forms & Resources

Competency Assessment Tools

Calibration Frequency

COLA	COLA Requirements	May Trigger a Citation
CA1	For all non-waived tests and methods, applicable, is calibration performed at the frequency recommended by the manufacturer or at the frequency determined by the laboratory if more stringent than the manufacturer?	Calibration not performed at required frequency; very common with hematology analyzers

Calibration Schedule Example

Smart LabTools

IMPERIAL VALLEY FAMILY CARE - LABORATORY

CALIBRATION VERIFICATION SCHEDULE

☑ 12/01/2018 Clear Form

#	Assay	Analyzer	Materials	Date Done	Date Due	Days Left	Status	Action
1	25-Hydroxyvitamin D (25-OH-D)	LIASON	DIASORIN	06/13/2018	12/13/2018	12	Almost Due	
2	CRP(HS)	VITROS	MICROAUDIT	09/02/2018	03/02/2019	91	O.K.	
3	DIRECT LDL	VITROS	MICROAUDIT	09/02/2018	03/02/2019	91	O.K.	
4	DIRECT TIBC	VITROS	MICROAUDIT	09/02/2018	03/02/2019	91	O.K.	
5	LYTES	VITROS	MICROAUDIT	09/02/2018	03/02/2019	91	O.K.	
6	TSH	ARCHITECT	MICROAUDIT	09/02/2018	03/02/2019	91	O.K.	
7	FREE T3	ARCHITECT	MICROAUDIT	09/02/2018	03/02/2019	91	O.K.	
8	FREE PSA	ARCHITECT	MICROAUDIT	09/02/2018	03/02/2019	91	O.K.	
9	FSH	ARCHITECT	MICROAUDIT	09/02/2018	03/02/2019	91	O.K.	
10	TOTAL PSA	ARCHITECT	MICROAUDIT	09/02/2018	03/02/2019	91	O.K.	
11	FERRITIN	ARCHITECT	MICROAUDIT	09/02/2018	03/02/2019	91	O.K.	
12	XN-550 HEMATOLOGY	SYSMEX	SYSMEX	11/04/2018	05/04/2019	154	O.K.	
13	GLYCOHEMOGLOBIN	TOSOH G8	BIO RAD	12/01/2018	06/01/2019	182	O.K.	

Click on Link to SmartLabTools.com Forms & Resources

SLT_460 Schedule Status Report

Some Lab Scheduled Events

1. Competency Assessment of Staff @ 6 months initially, 12 months thereafter
2. Calibration Verification for quantitative analytes with <3 calibrators @ 6 months
3. PT twice/yr for non-regulated analytes
4. Annual Equipment PM, Thermometer & Centrifuge Calibrations
5. Annual Director Review/Sign Lab P&P

Calibration Verification

COLA	COLA / CLIA Requirements
CA 2R	Is calibration verification performed, according to the manufacturer's instructions including: • the number, type and concentration of materials to be used, • use of materials at low, medium and high values within the reportable range, as determined by the laboratory, • acceptable limits for calibration verification, once every six months or more often if required by laboratory procedures?

Calibration Verification - Samples

USE MATERIALS OF KNOWN CONCENTRATION: REF: LAB GUIDE 15

- Commercially available calibration materials or linearity sets
- Same lot number of calibration materials that you are using for calibration of the instrument, provided that calibration is performed in calibration mode and calibration verification is performed in patient testing mode
- Previously Tested Proficiency testing samples with known results CLIA-defined acceptability limits are listed in the PT summary
- Control materials with known results; (You must use a different lot number of QC material for calibration verification than you use for your routine quality control.)
  Acceptability limits are established by the manufacturer
- Patient specimens with known results Use limits that are reasonable for the analyte, i.e., ± 2SD, or ± a set amount or percentage.

Calibration Verification Assessment

CALIBRATION VERIFICATION
WORKSHEET AND DOCUMENTATION FORM

Date _____ Analyte _____

Instrument _____ Serial # _____

Reagent/strip/cassette Lot # _____ Expiration Date _____

Calibration Materials Used _____

Source of Acceptable Limits _____

	Low Level	Mid Level	High Level
Lot Number			
Expiration Date			
Expected Result			
Acceptable Limits			

Calibration Verification Results

	Low Level	Mid Level	High Level
Repetition #1			
Repetition #2			
Repetition #3			
Mean			
Results acceptable?			

Comments and/or Corrective Actions _____

Performed by _____

LD Review _____ Date _____

Source: Cola Accreditation Manual

Smart LabTools

CALIBRATION VERIFICATION ASSESSMENT

INSTITUTE FOR PROGRESSIVE MEDICINE

		Analyte Measurement Range	
Analyte:	GLUCOSE		
Date of Verification:	11/21/18	Stated:	1.98 - 900
Instrument:	PENTRA 400	Verified:	7.57 - 801.97
Serial Number:			
Cal-Ver Material:	AUDIT LOT# 06636	Exp. Date:	05/16/20
Reagent Lot No.:	CURRENT LOT	Exp. Date:	
Performed by:	KATHY	%TEa:	10

Specimen:	A	C	E		
Target Range Low:	6.30	393.30	710.10	0.00	0.00
Target Value:	7.00	437.00	789.00		
Target Range High:	7.70	480.70	867.90	0.00	0.00
Observed Value 1:	7.70	438.50	818.50		
Observed Value 2:	7.20	441.00	791.00		
Observed Value 3:	7.80	433.80	796.40		
Observed Value 4:					
Observed Result Mean:	7.57	437.77	801.97		
Interpretation:	Within Range	Within Range	Within Range		
Percent Recovery:	108%	100%	102%	0%	0%

☑ *Check Box to Complete Calculations, or when Data Changes Made*

Comments:

TEa = CLIA // CAL-VERIFICATION ACCEPTABLE

Reviewed by & date:

SLT_424 CalVer Assessment
©2007-2014, SmartLabTools™

Reset Form Reset Data

Source: SmartLabTools.com/calibration verification

Verification of Accuracy of Calculations

COLA	COLA Requirement:
LIS 2.4	**Validation of the accuracy of data entry and verification of accuracy of any calculations performed?**
	This should be verified initially prior to the LIS being put into use and then assessed periodically as part of a quality assessment review.

Reference: Cola Laboratory Accreditation Manual 2018

Tool to Verify Common Lab Calculations

Click Link For *FREE* Calculation Verification Tool

L.I.S. Verify Calculations

Report ID : 12345

BUN	Creatinine	BUN/Crea (calc.)
20	1.9	10.53

BUN/Creatinine Ratio = (BUN/Creatinine)

Albumin	Total Protein	Globulin (calc.)	A/G ratio
3.5	7.2	3.70	0.95

Globulin = (T.Protein - Albumin) A/G ratio = Albumin / (T.Protein - Albumin)

Na+	K+	Cl-	HCO3- (CO2)	Anion Gap (calc.)
135	5.5	105	30	5.50

Anion Gap = (Na + K) - (HCO3 + CL) *Note: Verify same formula for Anion Gap is being used*

Cholesterol	Triglycerides	HDL	Chol/HDL ratio	LDL (calc.)	VLDL (calc.)
155	200	55	2.82	60.00	40.00

Chol / HDL ratio = (Chol / HDL) VLDL = (Trigl / 5) LDL = Chol - (Trigl / 5) - HDL

Tool to Verify eGFR Calculations

Do you know which equation your laboratory reports?

Simultaneously calculate results for three equations.

Click Link For FREE eGFR Verification Tool

To Calculate GFR, INPUT the following 2 variables:

Serum Creatinine mg/dL	Age* (Years)	
1.30	71	Reset
2 decimal pts. is preferred	* For > 18 yrs	

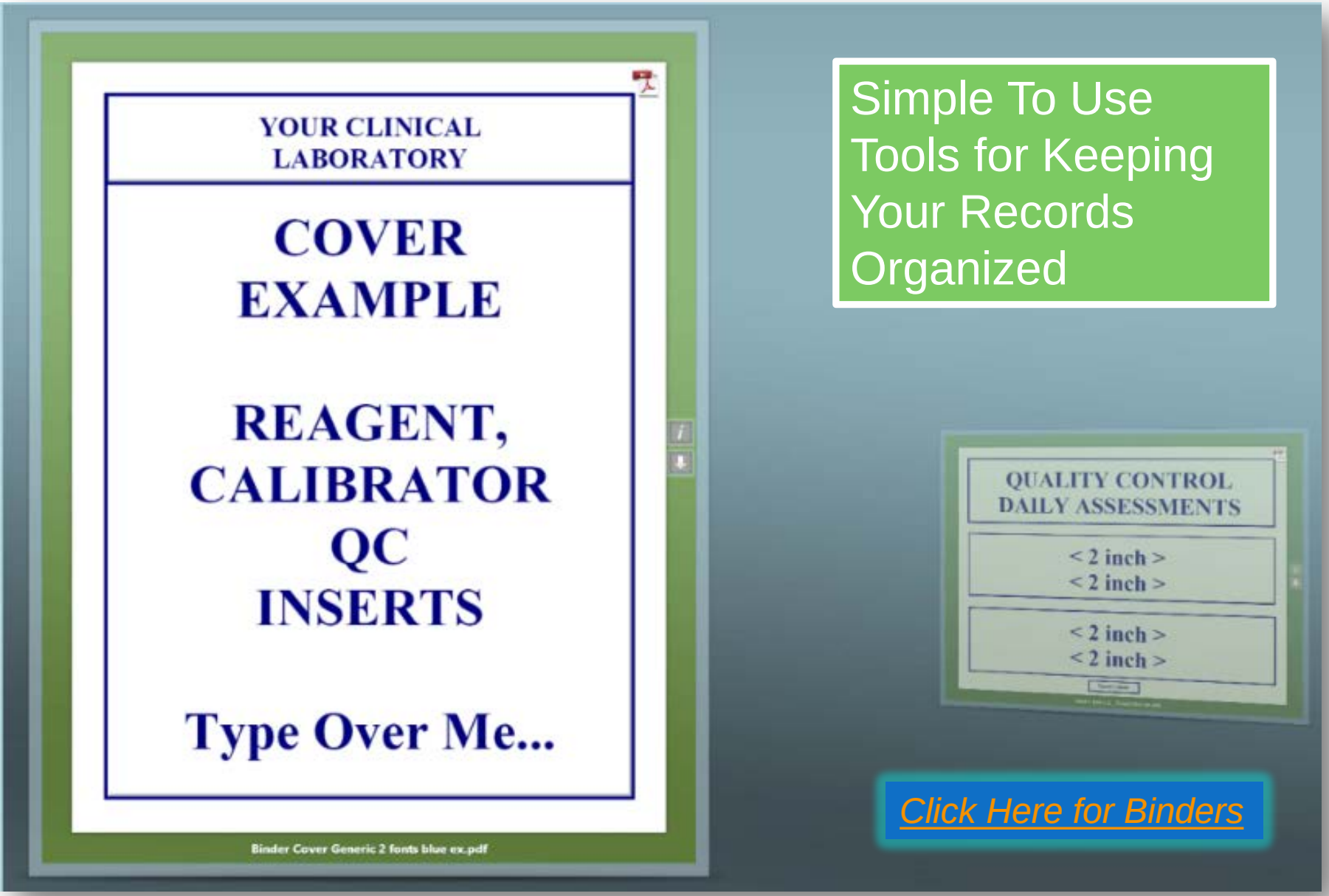
Traditional Calibration 4 variable MDRD Study Equation			
Non-Black Male	Non-Black Female	Black Male	Black Female
58	43	70	52

Calibration Traceable to IDMS Re-expressed 4 variable MDRD Study Equation			
Non-Black Male	Non-Black Female	Black Male	Black Female
54	40	66	49

CKD-EPI GFR Newer Equation by Levey, et. al.			
Non-Black Male	Non-Black Female	Black Male	Black Female
55	41	64	48

CKD-EPI equation by Levey, et. al.

eGFR = 141 x min(Scr/k,1)^a x max(Scr/k,1)^-1.209 x 0.993^Age [x 1.018 if female] [x 1.159 if Black]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QUALITY CONTROL DAILY ASSESSMENTS
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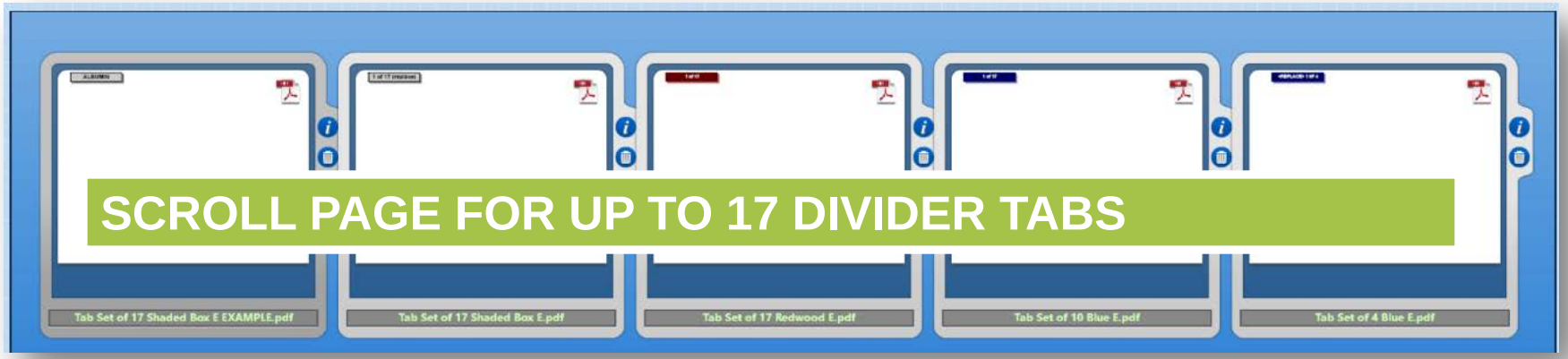
ASSORTED BINDER COVERS & TABS

SUGGESTIONS:

1. Use Heavier Stock Paper when available

2. Use Colored Paper for different sections or years



SCROLL PAGE FOR UP TO 17 DIVIDER TABS

PRINT COLORED TABS – PUT IN SHEET PROTECTORS TO STAND OUT BEYOND HOLE-PUNCHED DOCUMENTS

Customizable Signature Form

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< LINE 2 >

< LINE 3 >
< LINE 4 >
< LINE 5 >

DATE	NAME	TITLE	SIGNATURE

FREE Form Click Here

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Reset

EXAMPLE LABORATORY

QUALITY CONTROL TRAINING - D.W. LEIGHTON, CLB
OBJECTIVE: Q.C. TROUBLESHOOTING, CORRECTIVE ACTIONS

Testing Personnel have received in-service training regarding Q.C. Troubleshooting using the Quality Control Corrective Action Flow-sheet, and instructed on the use of labs Corrective Action Forms.

DATE	NAME	TITLE	SIGNATURE

The trainer has discussed, demonstrated, and coached the employee in extensive in-service training regarding topics related to Quality Control, Troubleshooting, Corrective Actions, and Documentation. The Employee has reviewed and has been trained in the above topics areas and agrees to abide by the regulated policy, procedure and/or guideline for all Testing and Quality Control procedures at EXMPLE Laboratory.

Discussion of Presentation…
Questions….

SLT Website Tour Time Permitting..

Thank You,

Dan Leighton
Dan@SmartLabTools.com