TIPS & TOOLS FOR ADDRESSING QC AND PT CITATIONS

California Association for Medical Laboratory Technology
Conference March 18, 2018

Presented By:
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Presentation Roadmap

- Inspection Process
  - COLA an Accrediting Agency
  - State / CLIA
- QC & PT Issues
  - Citation Examples
  - Tips
  - Tools To Fix QC (SmartLabTools.com)
  - Statistical QC Demonstration
  - DropBox for Compliance Monitoring
  - Free QC Software
  - Website Analytics

Double Inspection for POL

COLA
Lab Accreditation Through Education

Attn: Lab

COLA ID: 05/24/13 Redacted

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

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).

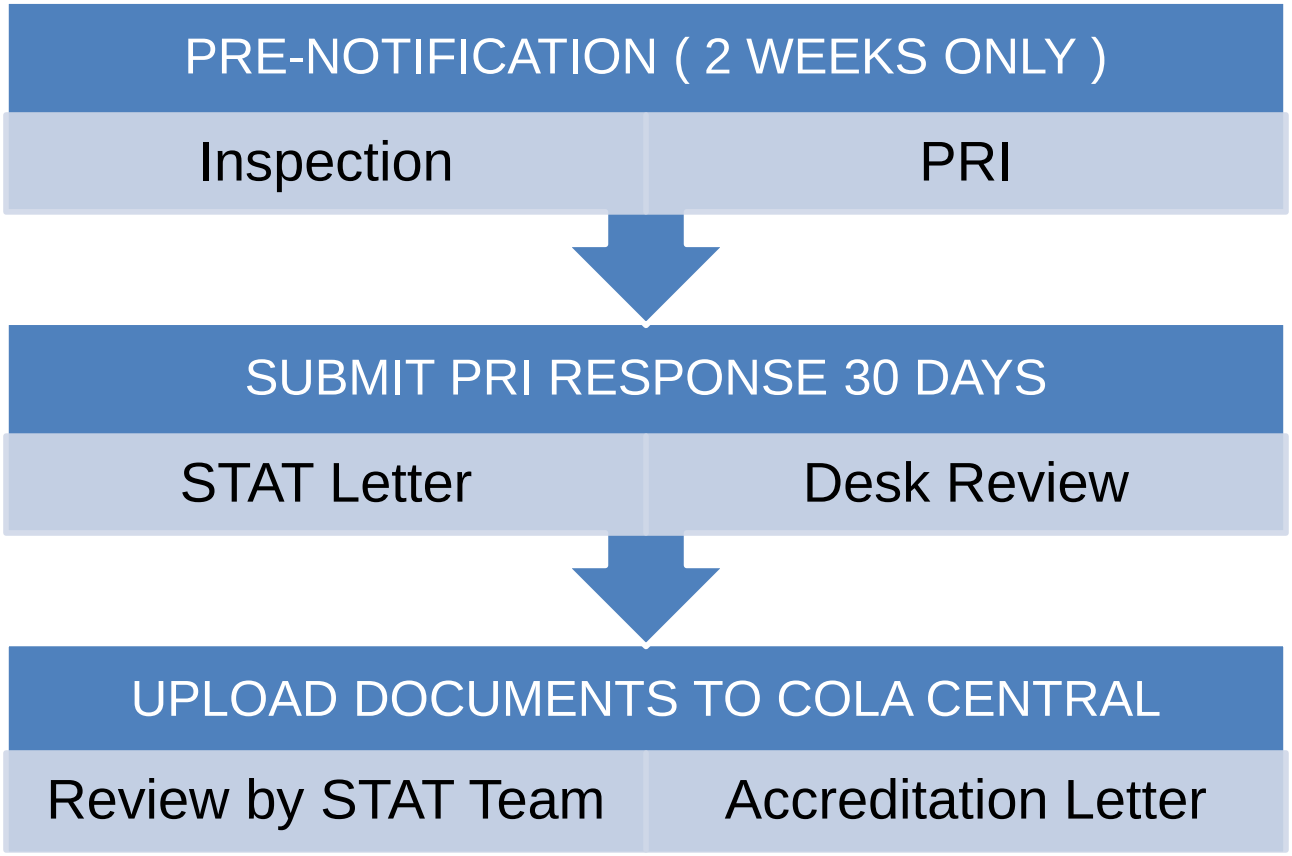
3) 42 CFR 493.1403 Laboratory Director-Moderate Complexity as incorporated at CBPC 1209(a), CBPC 1209(b)(1), and CBPC 1209(d)(1)(2).

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

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:

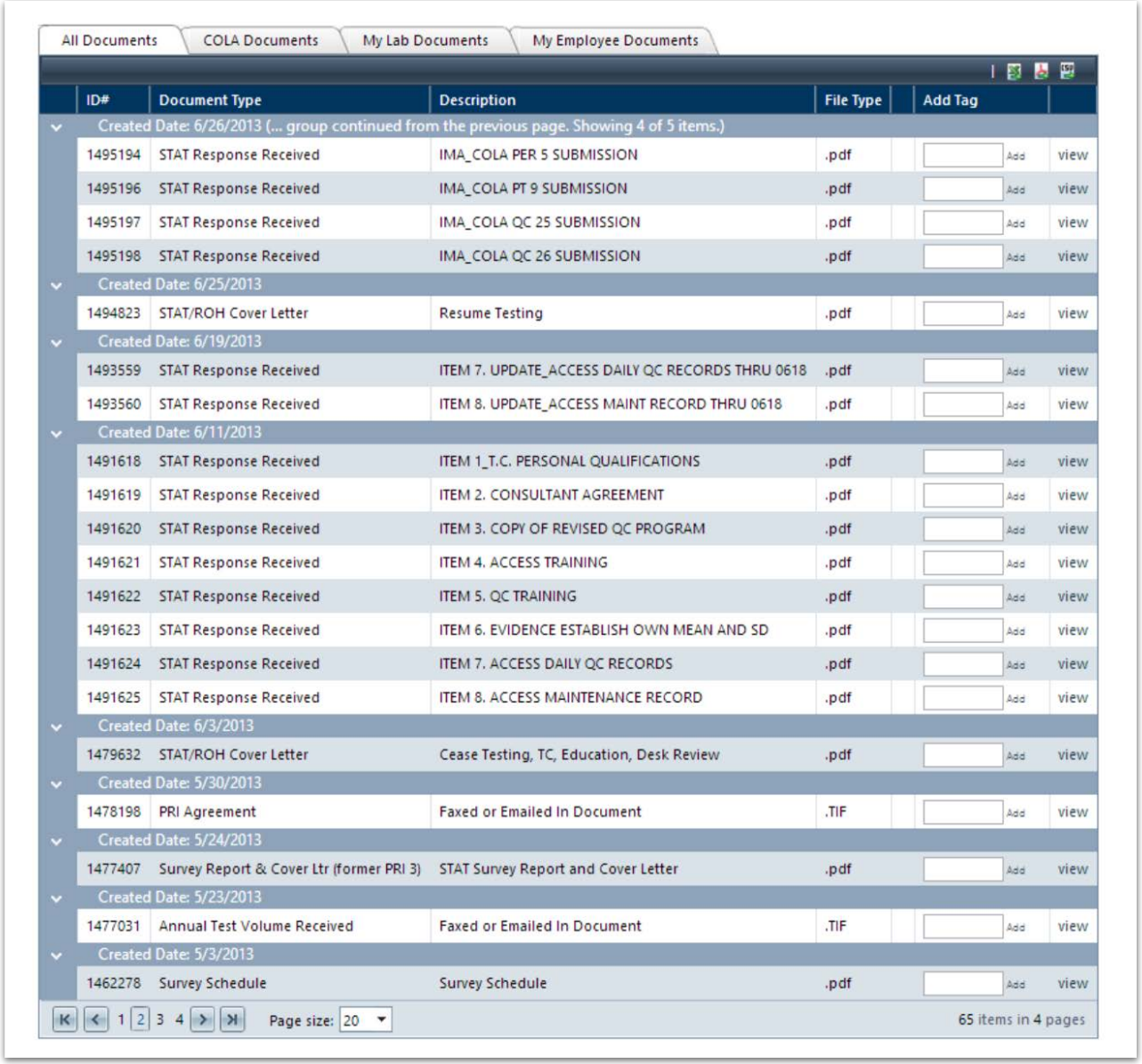
On June 3, 2013, COLA sent the laboratory a letter regarding the decision of the Staff Technical Accreditation Team (STAT) on serious issues identified by the surveyor at the time of the survey. It was stated in that letter that COLA would request additional documentation to ensure continued compliance. 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 from COLA by Client/Consultant

and

Documents such as responses may be uploaded electronically



All Documents | COLA Documents | My Lab Documents | My Employee Documents

ID#	Document Type	Description	File Type	Add Tag	
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…

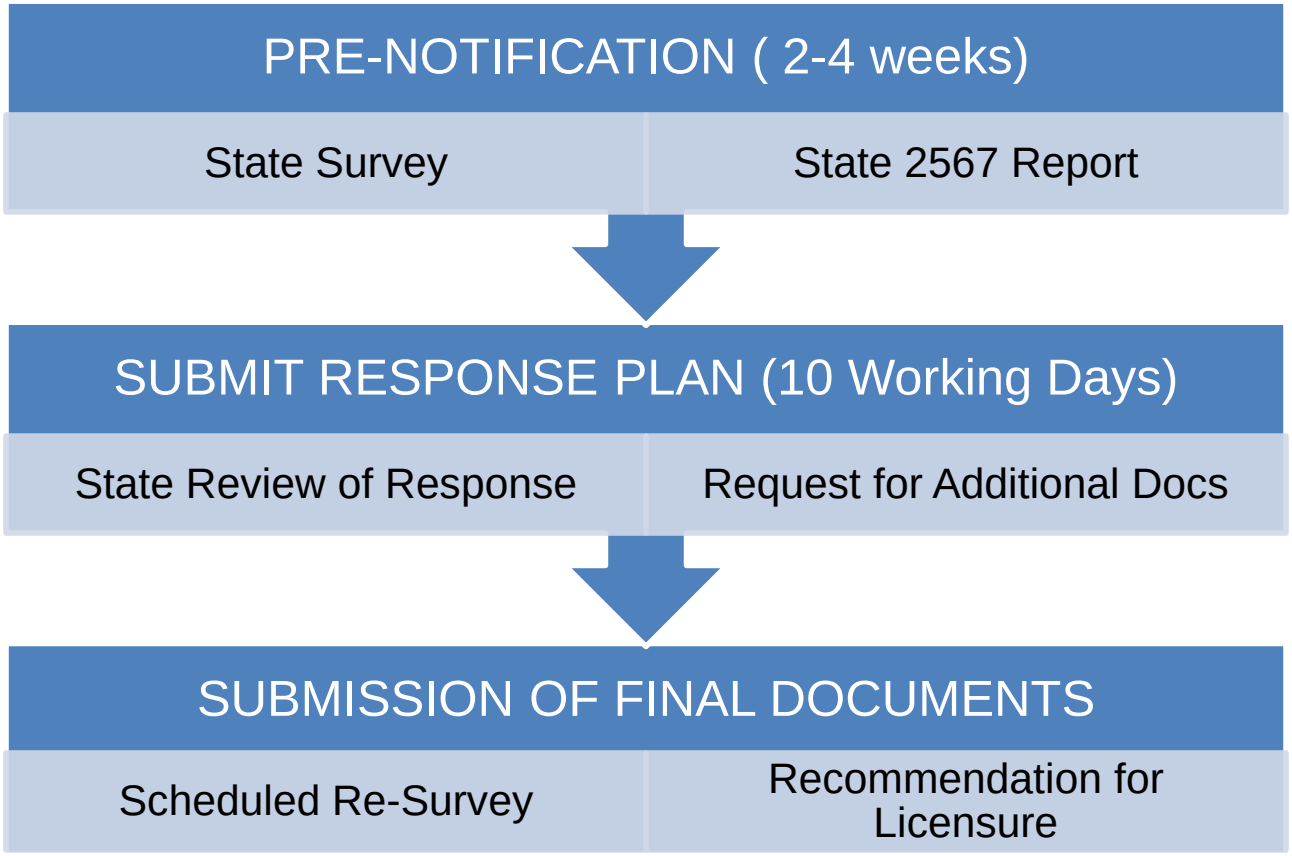
Approval for Certificate of Accreditation Pending..

All Documents | COLA Documents | My Lab Documents | My Employee Documents

ID#	Document Type	Description	File Type	Add Tag	
Created Date: 9/21/2013					
1672971	STAT Response Received	IMA_APM-15 SUBMISSION	.pdf	Add	view
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)

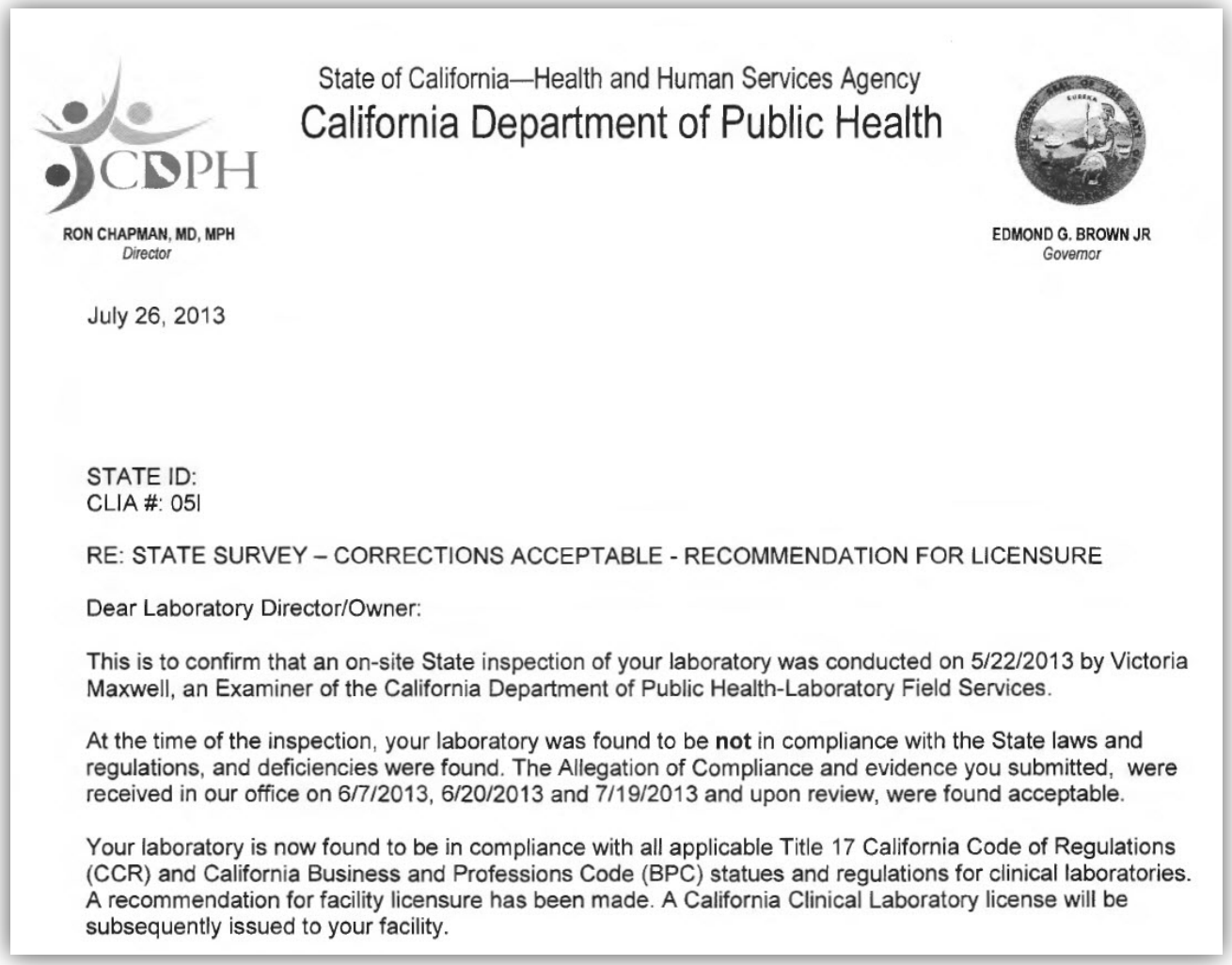
You have 10 working days from the date of receipt of this notice to submit a credible allegation of compliance and evidence of correction for the condition level deficiencies.

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

- Performed detailed investigation of PT failures
- Director to sign PT attestation
- PT Records retention – 2yrs

Actions

- Revise PT Procedure
- Revise PT Action Form
- Save Tapes, Printouts
- Train Personnel on new procedures, forms

Some QA/QC Citations

Citations

- Document all Function Checks
- Use latest version of PM forms
- Retain Function Check printouts
- Director's Name on LIS Report
- Update the QA Plan

Actions

- Update Forms for PM
- Manufacturer on-site Training on maintenance, instrument QC functions
- Save Function Checks along with QC printouts
- Updated LIS Report
- Updated QA Plan with Schedule
- Trained Personnel

QA/QC Citations (cont.)

Citations

- QC tapes, printouts not saved for at least 2 years
- Critical Values not defined for INR
- Not keeping a Critical Value Notification Log
- Frequent QC Failures, & No Documentation of Remedial Action
- Failure to Establish Lab QC Limits

Actions

- Printouts and Tapes now being saved
- Updated Critical Values Procedure & List
- Critical Values Notification Log implemented and personnel trained
- Implemented Corrective Action Logs
- Implemented New QC Program & Trained Testing Personnel

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

PRI – QC 10 Regulation

- QC 10 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.
- Use your historic QC data and submit documentation demonstrating establishment of your own mean and 2SD range for… analytes

COLA PRI – QC 16

QC 16 For each quantitative test performed, are quality control data prepared and plotted with each testing event, or are statistical parameters calculated to permit the laboratory to assess continued accuracy and precision of the method?

QC Statistical Parameters

- 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:

QC – Establish Own Limits

1. 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

- 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.**

QC Insert Limits – 3SD ?

- 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.**

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

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

CLIA TEa = ±10%
Insert Limits = ±20%

BIO-RAD

Liquid Assayed Multiqual®
Levels 1, 2 and 3

REF 694 Level 1 12 x 3 mL
695 Level 2 12 x 3 mL
696 Level 3 12 x 3 mL
695X MiniPak 3 x 3 mL

CE IVD EXP 2015-01-31 LOT 45650

Level 1 45651
Level 2 45652
Level 3 45653

http://www.myeinserts.com/45650

INSTRUMENT (1)

	Units	Level 1 - 45651		Level 2 - 45652		Level 3 - 45653	
		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

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

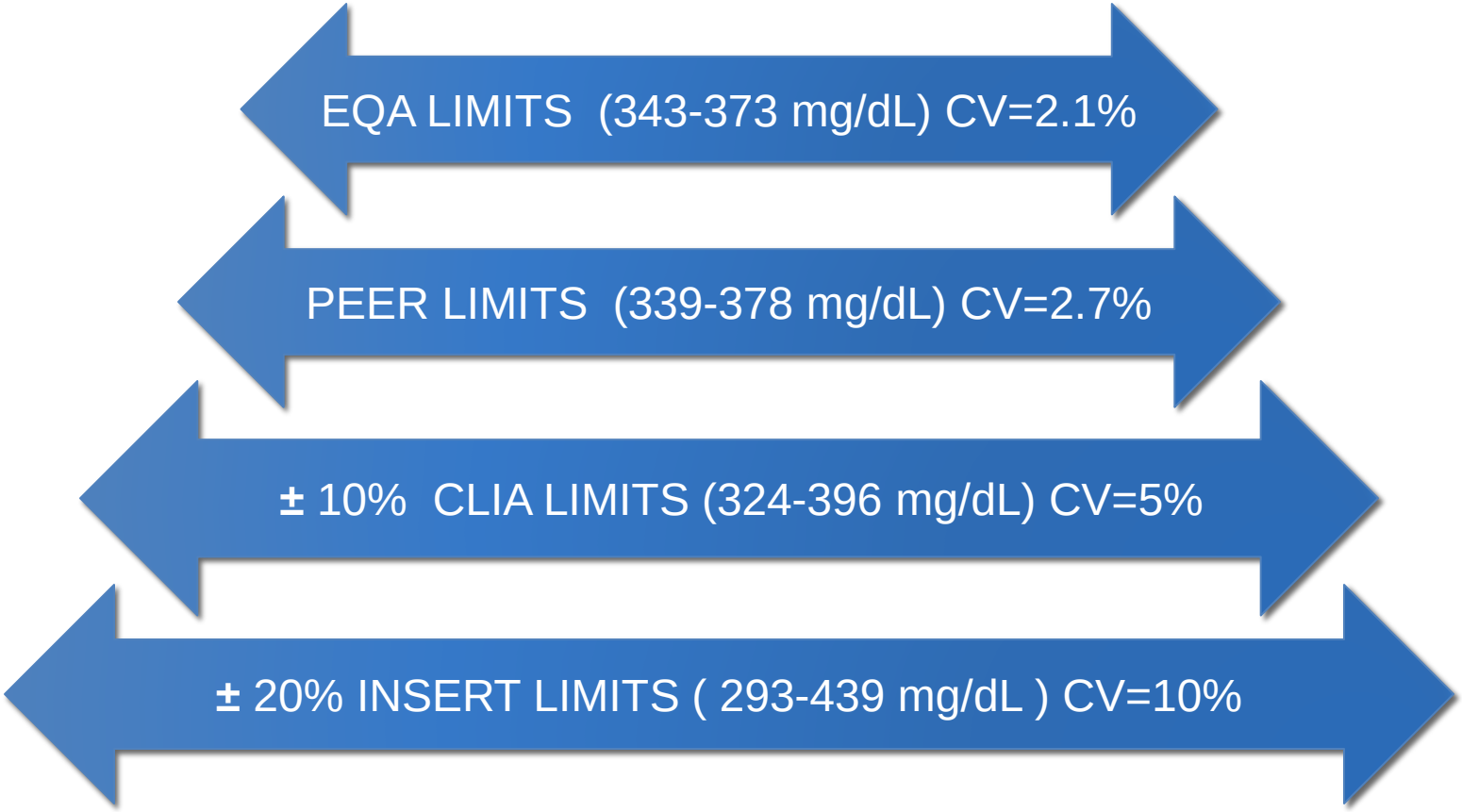
CV derived from External Proficiency peer data Referred to as CV_{EQA}

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 PDF QC Calculator)***

VS-06505780100V3

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 Insert Limitations – 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

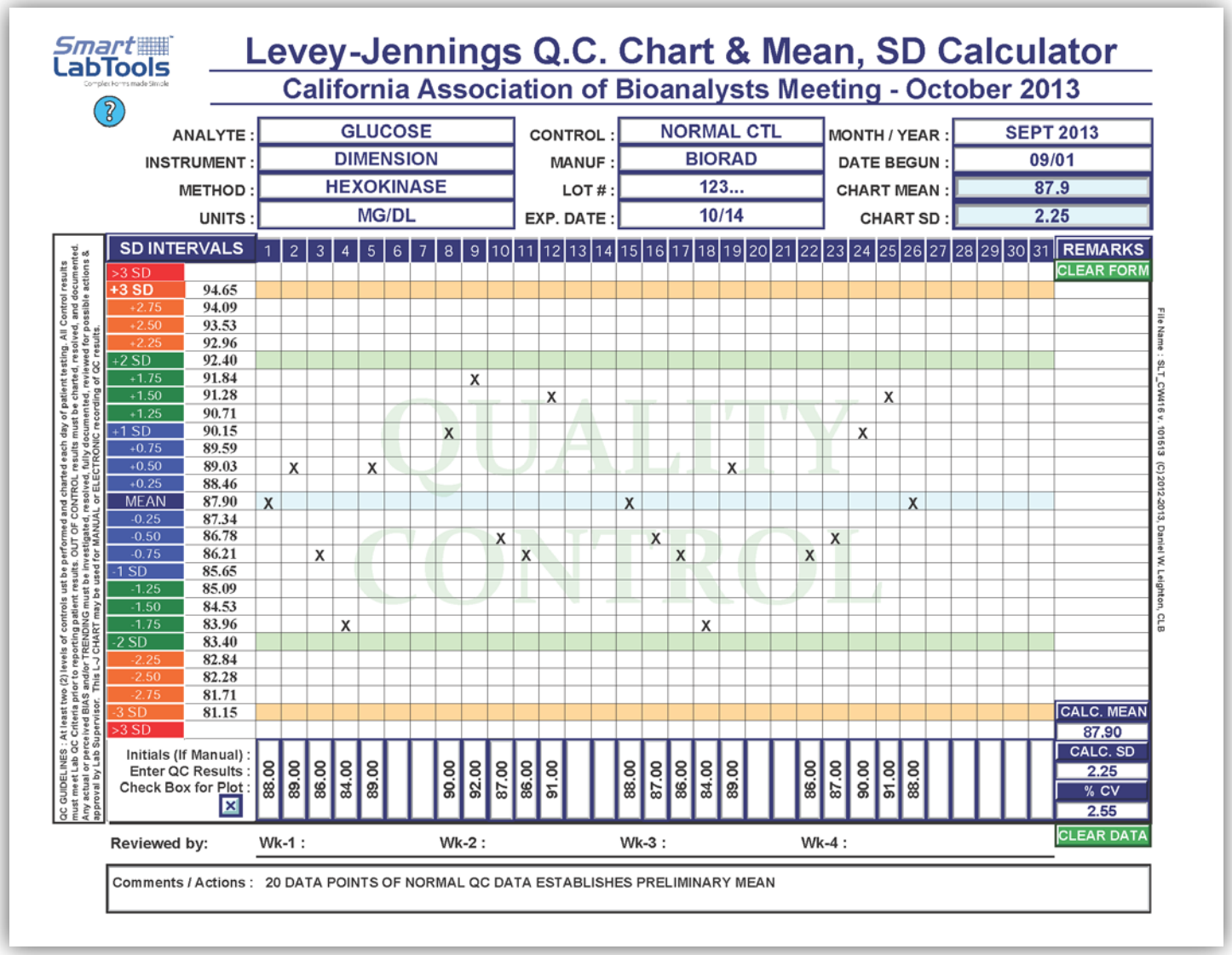
Read the Manuals, Inserts, Notices

- Examiners DO READ & quote labeling & Inserts
- Examiners DO READ & quote Instrument Manuals
- Reagent Re-formulations do occur / may be stated on Insert, Peer Reports with own limits
- Calibrator Set-points may be re-stated and Control Limits updated by manufacturer
  (Take appropriate actions & SAVE notices)

Establishing Your new Mean

1. Ensure that your old lot of QC material is running inside of 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. Ensure that your old QC material is within acceptable range for each run.
3. Calculate SD, MEAN & CV from data
4. Is the CV's < or = CV_H $CV_{MAN\ (INSERT)}$?

Data Plot with Calculated Mean, SD – High Sensitivity



Smart LabTools
Complex Forms made Simple

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

California Association of Bioanalysts Meeting - October 2013

ANALYTE :	GLUCOSE	CONTROL :	NORMAL CTL	MONTH / YEAR :	SEPT 2013
INSTRUMENT :	DIMENSION	MANUF :	BIORAD	DATE BEGUN :	09/01
METHOD :	HEXOKINASE	LOT # :	123...	CHART MEAN :	87.9
UNITS :	MG/DL	EXP. DATE :	10/14	CHART SD :	2.25

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	94.65																																
+2.75	94.09																																
+2.50	93.53																																
+2.25	92.96																																
+2 SD	92.40																																
+1.75	91.84									X																							
+1.50	91.28												X													X							
+1.25	90.71																																
+1 SD	90.15								X																X								
+0.75	89.59																																
+0.50	89.03		X			X														X													
+0.25	88.46																																
MEAN	87.90	X														X											X						
-0.25	87.34																																
-0.50	86.78										X						X							X									
-0.75	86.21			X								X						X					X										
-1 SD	85.65																																
-1.25	85.09																																
-1.50	84.53																																
-1.75	83.96				X														X														
-2 SD	83.40																																
-2.25	82.84																																
-2.50	82.28																																
-2.75	81.71																																
-3 SD	81.15																																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

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.

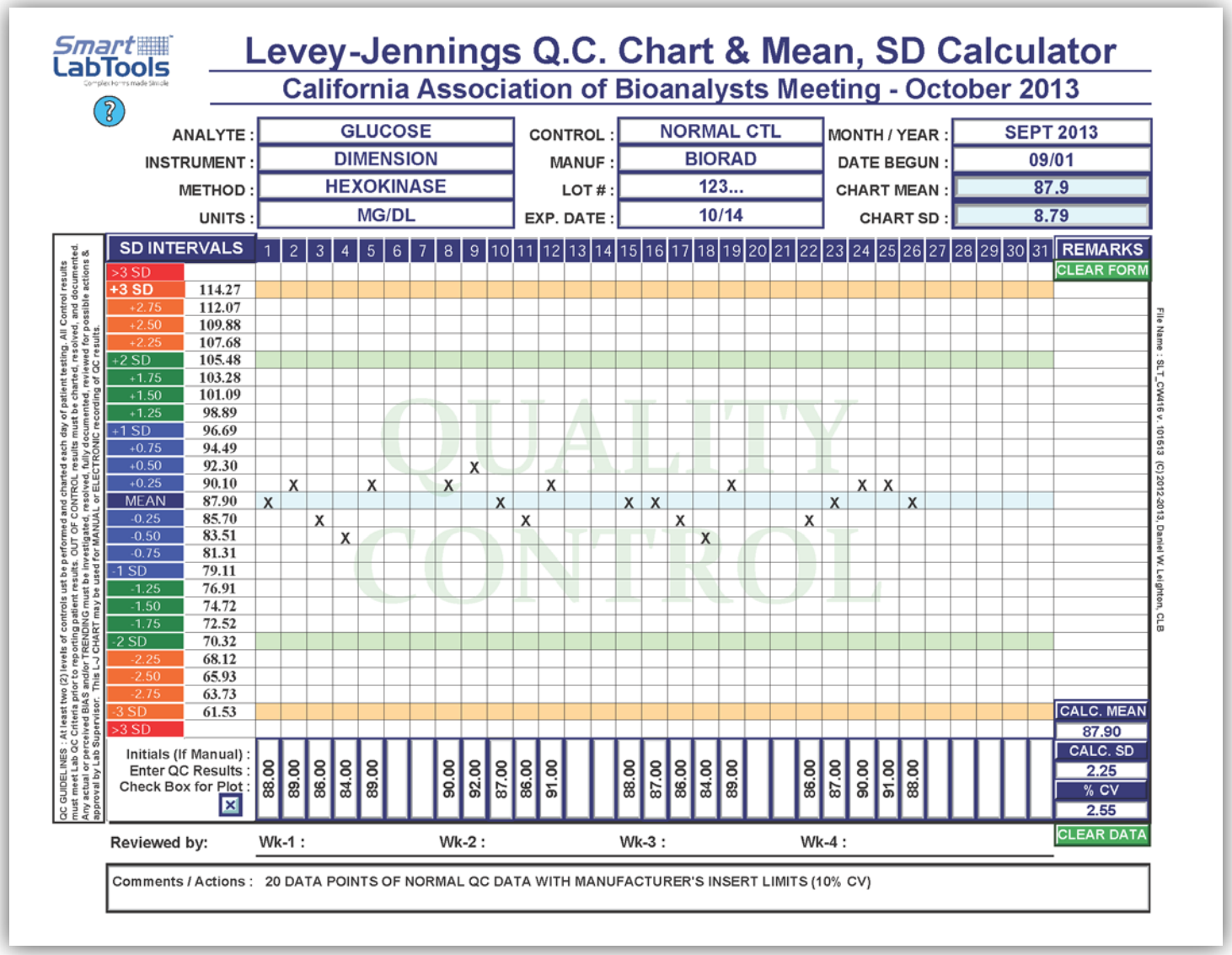
QUALITY CONTROL

File Name : SLT_CW416 v. 101513 (C) 2012-2013, Daniel W. Leighton, CLS

Reviewed by: Wk-1 : Wk-2 : Wk-3 : Wk-4 :

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

Data Plot with Insert Mean, CV% - Low Sensitivity



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

California Association of Bioanalysts Meeting - October 2013

ANALYTE :	GLUCOSE	CONTROL :	NORMAL CTL	MONTH / YEAR :	SEPT 2013
INSTRUMENT :	DIMENSION	MANUF :	BIORAD	DATE BEGUN :	09/01
METHOD :	HEXOKINASE	LOT # :	123...	CHART MEAN :	87.9
UNITS :	MG/DL	EXP. DATE :	10/14	CHART SD :	8.79

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	114.27																																
+2.75	112.07																																
+2.50	109.88																																
+2.25	107.68																																
+2 SD	105.48																																
+1.75	103.28																																
+1.50	101.09																																
+1.25	98.89																																
+1 SD	96.69																																
+0.75	94.49																																
+0.50	92.30									X																							
+0.25	90.10		X			X			X				X							X					X	X							
MEAN	87.90	X									X					X	X							X			X					
-0.25	85.70			X								X						X					X										
-0.50	83.51				X														X														
-0.75	81.31																																
-1 SD	79.11																																
-1.25	76.91																																
-1.50	74.72																																
-1.75	72.52																																
-2 SD	70.32																																
-2.25	68.12																																
-2.50	65.93																																
-2.75	63.73																																
-3 SD	61.53																																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 : Wk-2 : Wk-3 : Wk-4 :

Comments / Actions : 20 DATA POINTS OF NORMAL QC DATA WITH MANUFACTURER'S INSERT LIMITS (10% CV)

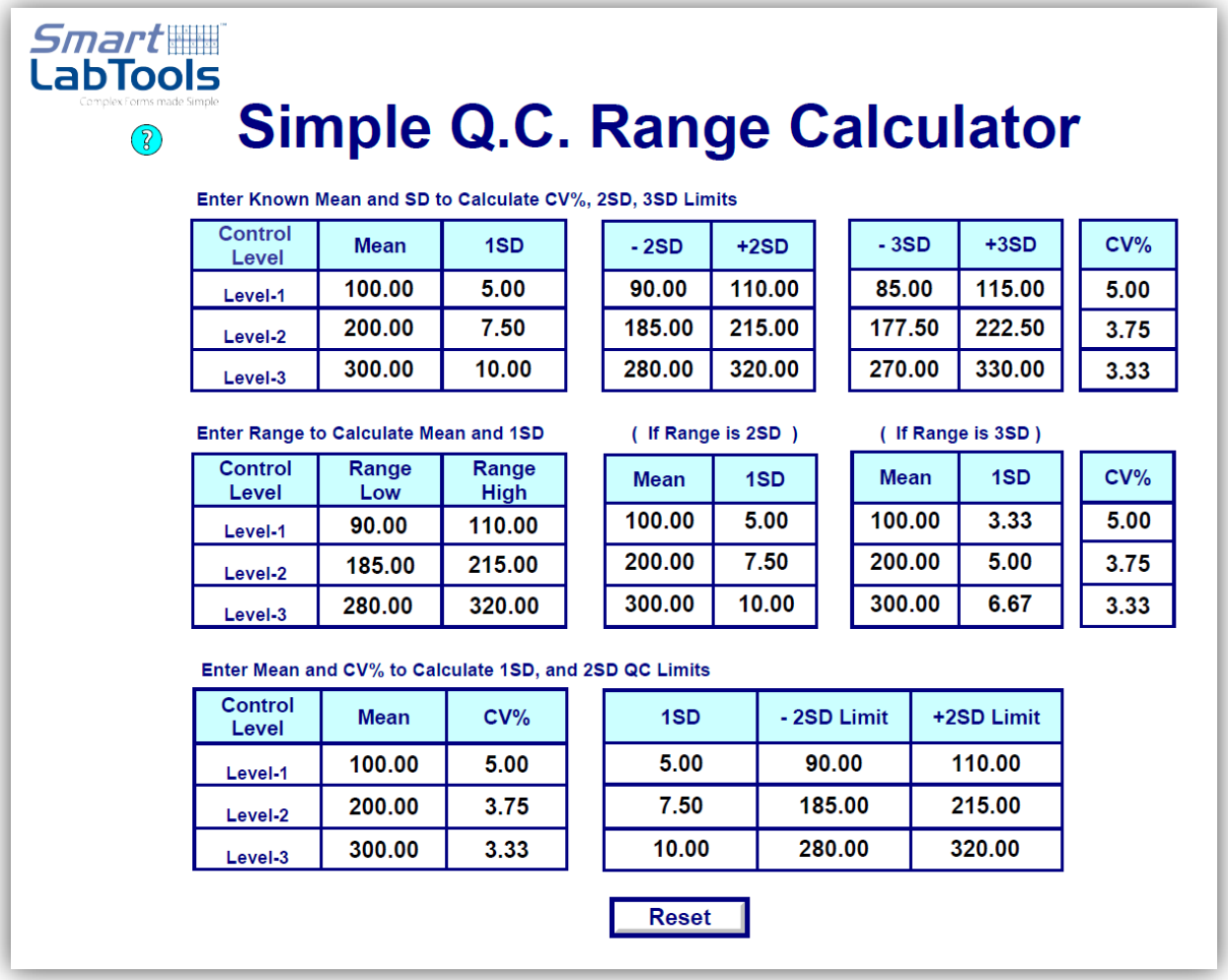
QUALITY CONTROL

File Name : SLT_CV416 v. 101513 (C) 2012-2013, Daniel W. Leighton, CLS

SmartLabTools Interactive PDF Calculators

Let this PDF Calculator assist you with determination of QC Limits

This PDF Calculator is a free download at www.SmartLabTools.com



SmartLabTools
Complex Forms made Simple

Simple Q.C. Range Calculator

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

Control Level	Mean	1SD	- 2SD	+2SD	- 3SD	+3SD	CV%
Level-1	100.00	5.00	90.00	110.00	85.00	115.00	5.00
Level-2	200.00	7.50	185.00	215.00	177.50	222.50	3.75
Level-3	300.00	10.00	280.00	320.00	270.00	330.00	3.33

Enter Range to Calculate Mean and 1SD

Control Level	Range Low	Range High
Level-1	90.00	110.00
Level-2	185.00	215.00
Level-3	280.00	320.00

(If Range is 2SD)

Mean	1SD
100.00	5.00
200.00	7.50
300.00	10.00

(If Range is 3SD)

Mean	1SD	CV%
100.00	3.33	5.00
200.00	5.00	3.75
300.00	6.67	3.33

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

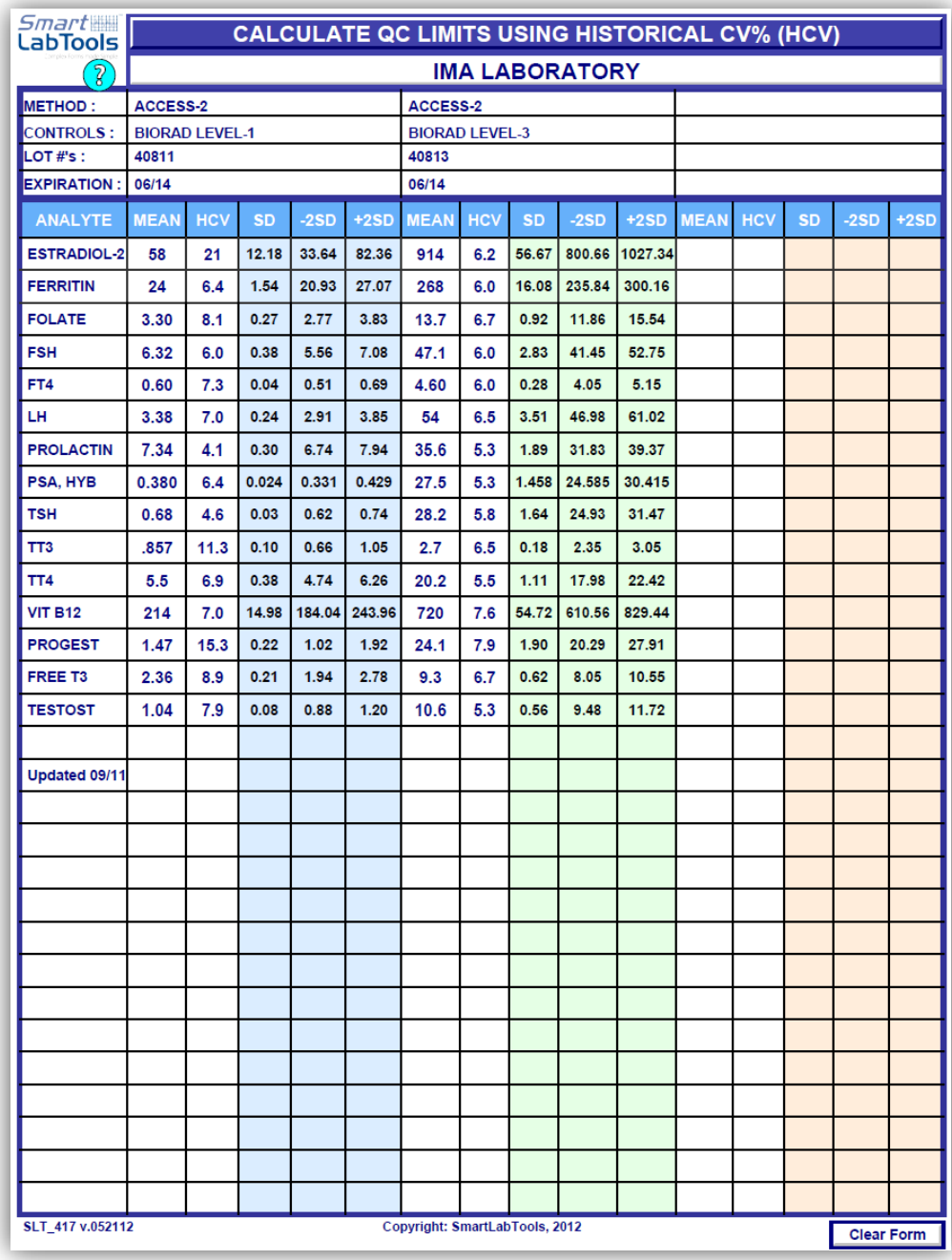
Control Level	Mean	CV%
Level-1	100.00	5.00
Level-2	200.00	3.75
Level-3	300.00	3.33

1SD	- 2SD Limit	+2SD Limit
5.00	90.00	110.00
7.50	185.00	215.00
10.00	280.00	320.00

Reset

Calculator for QC Limits using CV%

Calculate 2SD Limits using Lab determined **Mean** based on parallel testing data for this lot & **HCV** (Historical CV) from cumulative statistics of prior lot.



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CALCULATE QC LIMITS USING HISTORICAL CV% (HCV)

IMA LABORATORY

METHOD :	ACCESS-2					ACCESS-2									
CONTROLS :	BIORAD LEVEL-1					BIORAD LEVEL-3									
LOT #'s :	40811					40813									
EXPIRATION :	06/14					06/14									
ANALYTE	MEAN	HCV	SD	-2SD	+2SD	MEAN	HCV	SD	-2SD	+2SD	MEAN	HCV	SD	-2SD	+2SD
ESTRADIOL-2	58	21	12.18	33.64	82.36	914	6.2	56.67	800.66	1027.34					
FERRITIN	24	6.4	1.54	20.93	27.07	268	6.0	16.08	235.84	300.16					
FOLATE	3.30	8.1	0.27	2.77	3.83	13.7	6.7	0.92	11.86	15.54					
FSH	6.32	6.0	0.38	5.56	7.08	47.1	6.0	2.83	41.45	52.75					
FT4	0.60	7.3	0.04	0.51	0.69	4.60	6.0	0.28	4.05	5.15					
LH	3.38	7.0	0.24	2.91	3.85	54	6.5	3.51	46.98	61.02					
PROLACTIN	7.34	4.1	0.30	6.74	7.94	35.6	5.3	1.89	31.83	39.37					
PSA, HYB	0.380	6.4	0.024	0.331	0.429	27.5	5.3	1.458	24.585	30.415					
TSH	0.68	4.6	0.03	0.62	0.74	28.2	5.8	1.64	24.93	31.47					
TT3	.857	11.3	0.10	0.66	1.05	2.7	6.5	0.18	2.35	3.05					
TT4	5.5	6.9	0.38	4.74	6.26	20.2	5.5	1.11	17.98	22.42					
VIT B12	214	7.0	14.98	184.04	243.96	720	7.6	54.72	610.56	829.44					
PROGEST	1.47	15.3	0.22	1.02	1.92	24.1	7.9	1.90	20.29	27.91					
FREE T3	2.36	8.9	0.21	1.94	2.78	9.3	6.7	0.62	8.05	10.55					
TESTOST	1.04	7.9	0.08	0.88	1.20	10.6	5.3	0.56	9.48	11.72					
Updated 09/11															

SLT_417 v.052112

Copyright: SmartLabTools, 2012

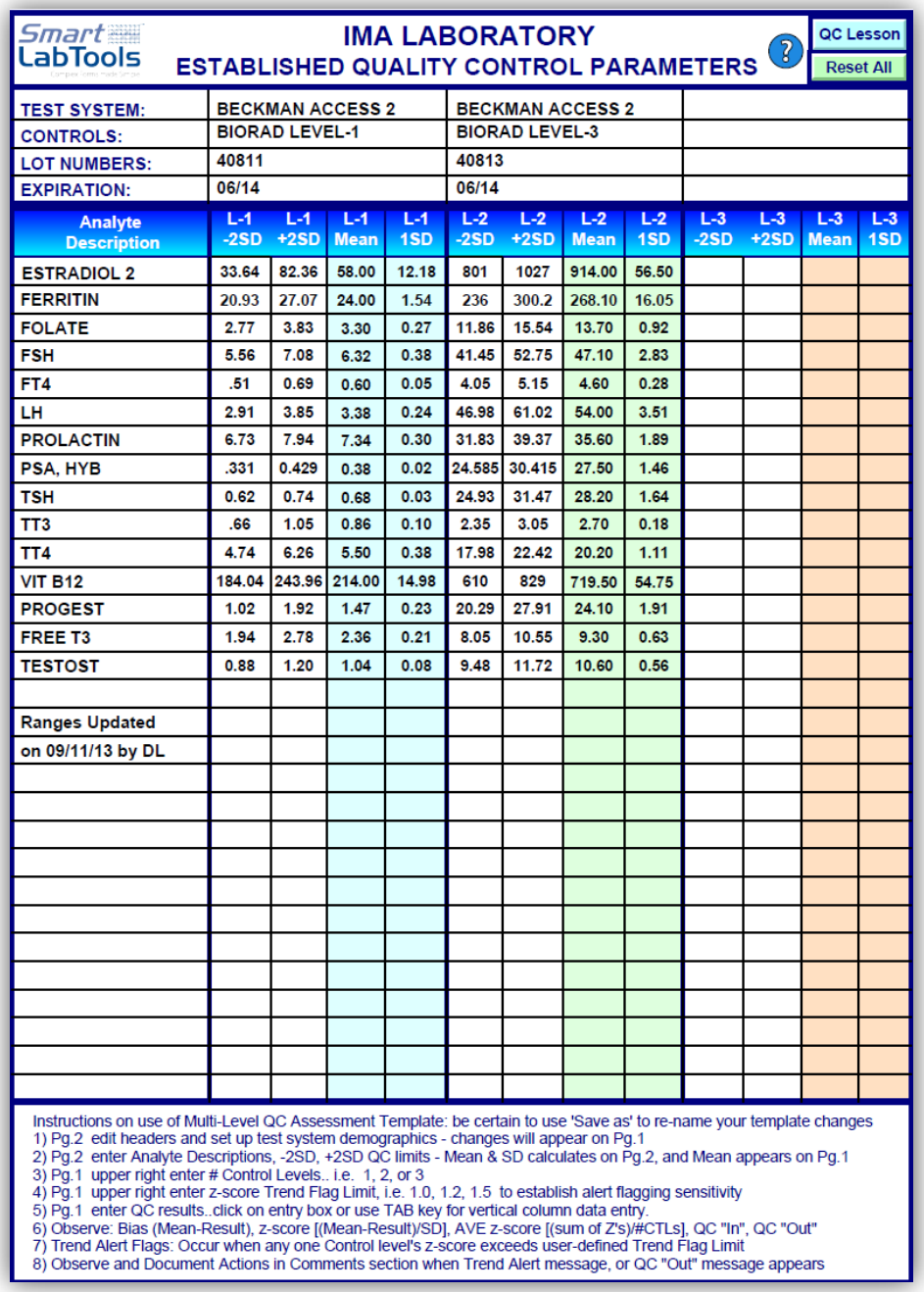
Clear Form

Set-up Page for Daily QC Assessment Program

Demographics and 2SD Limits are entered … Mean & SD are Calculated for Use by Daily QC Assessment Program

This form is also used as master for setting up QC files in Instruments and LIS programs

p.s. These tools are all PDF forms for Adobe Reader.. They are programmed with Java Script coding to perform the desired calculations.



Smart LabTools

IMA LABORATORY
ESTABLISHED QUALITY CONTROL PARAMETERS

QC Lesson | Reset All

TEST SYSTEM:	BECKMAN ACCESS 2				BECKMAN ACCESS 2							
CONTROLS:	BIORAD LEVEL-1				BIORAD LEVEL-3							
LOT NUMBERS:	40811				40813							
EXPIRATION:	06/14				06/14							
Analyte Description	L-1 -2SD	L-1 +2SD	L-1 Mean	L-1 1SD	L-2 -2SD	L-2 +2SD	L-2 Mean	L-2 1SD	L-3 -2SD	L-3 +2SD	L-3 Mean	L-3 1SD
ESTRADIOL 2	33.64	82.36	58.00	12.18	801	1027	914.00	56.50				
FERRITIN	20.93	27.07	24.00	1.54	236	300.2	268.10	16.05				
FOLATE	2.77	3.83	3.30	0.27	11.86	15.54	13.70	0.92				
FSH	5.56	7.08	6.32	0.38	41.45	52.75	47.10	2.83				
FT4	.51	0.69	0.60	0.05	4.05	5.15	4.60	0.28				
LH	2.91	3.85	3.38	0.24	46.98	61.02	54.00	3.51				
PROLACTIN	6.73	7.94	7.34	0.30	31.83	39.37	35.60	1.89				
PSA, HYB	.331	0.429	0.38	0.02	24.585	30.415	27.50	1.46				
TSH	0.62	0.74	0.68	0.03	24.93	31.47	28.20	1.64				
TT3	.66	1.05	0.86	0.10	2.35	3.05	2.70	0.18				
TT4	4.74	6.26	5.50	0.38	17.98	22.42	20.20	1.11				
VIT B12	184.04	243.96	214.00	14.98	610	829	719.50	54.75				
PROGEST	1.02	1.92	1.47	0.23	20.29	27.91	24.10	1.91				
FREE T3	1.94	2.78	2.36	0.21	8.05	10.55	9.30	0.63				
TESTOST	0.88	1.20	1.04	0.08	9.48	11.72	10.60	0.56				
Ranges Updated												
on 09/11/13 by DL												

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

Daily QC Statistical Assessment

1) Manually entered QC results are compared to user-defined parameters
2) Bias, SDI (z-score) are calculated
3) SDI > 1.5 (Trend Flag) for result triggers (*)
4) SDI > 2.0 (greater than 2SD) will show as 'Out', else 'In'.
5) 'Trend Alert' or 'QC OUT' Message appears on lower screen
6) Comments, Corrective Actions may be documented.
7) Date/Time/Analyst recorded
8) This example is actual client data viewed by TC using Cloud application 'Dropbox'

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IMA LABORATORY
DAILY Q.C. STATISTICAL ASSESSMENT

TEST SYSTEM:	BECKMAN ACCESS 2	BECKMAN ACCESS 2		Bias # CTLs
CONTROLS:	BIORAD LEVEL-1	BIORAD LEVEL-3		2
LOT NUMBERS:	40811	40813		Trend Flag =
EXPIRATION:	06/14	06/14		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
ESTRADIOL 2	58.00	48	-10.00	-0.82	In	914.00	919	5.00	0.09	In						-0.37	
FERRITIN	24.00	26.05	2.05	1.34	In	268.10	286.8	18.70	1.17	In						1.25	
FOLATE	3.30	3.30	0.00	0.00	In	13.70	13.46	-0.24	-0.26	In						-0.13	
FSH	6.32	6.48	0.16	0.42	In	47.10	48.85	1.75	0.62	In						0.52	
FT4	0.60	0.67	0.07	1.56	In	4.60	4.78	0.18	0.65	In						1.11	*
LH	3.38	3.82	0.44	1.87	In	54.00	55.33	1.33	0.38	In						1.13	*
PROLACTIN	7.34	7.51	0.18	0.58	In	35.60	37.13	1.53	0.81	In						0.70	
PSA, HYB	0.38	0.40	0.02	0.82	In	27.50	28.11	0.61	0.42	In						0.62	
TSH	0.68	0.73	0.05	1.67	In	28.20	30.72	2.52	1.54	In						1.60	*
TT3	0.86	0.85	-0.01	-0.05	In	2.70	2.98	0.28	1.60	In						0.77	*
TT4	5.50	6.22	0.72	1.89	In	20.20	22.23	2.03	1.83	In						1.86	*
VIT B12	214.00	226	12.00	0.80	In	719.50	767	47.50	0.87	In						0.83	
PROGEST	1.47	1.44	-0.03	-0.13	In	24.10	26.94	2.84	1.49	In						0.68	
FREE T3	2.36	2.29	-0.07	-0.33	In	9.30	9.72	0.42	0.67	In						0.17	
TESTOST	1.04	1.12	0.08	1.00	In	10.60	11.45	0.85	1.52	In						1.26	*
Ranges Updated																	
on 09/11/13 by DL																	

Comments / Actions: BIORAD HIGH PRL(40.30) AND TSH(32.71) OUT. RERAN AND CONTROL IN.

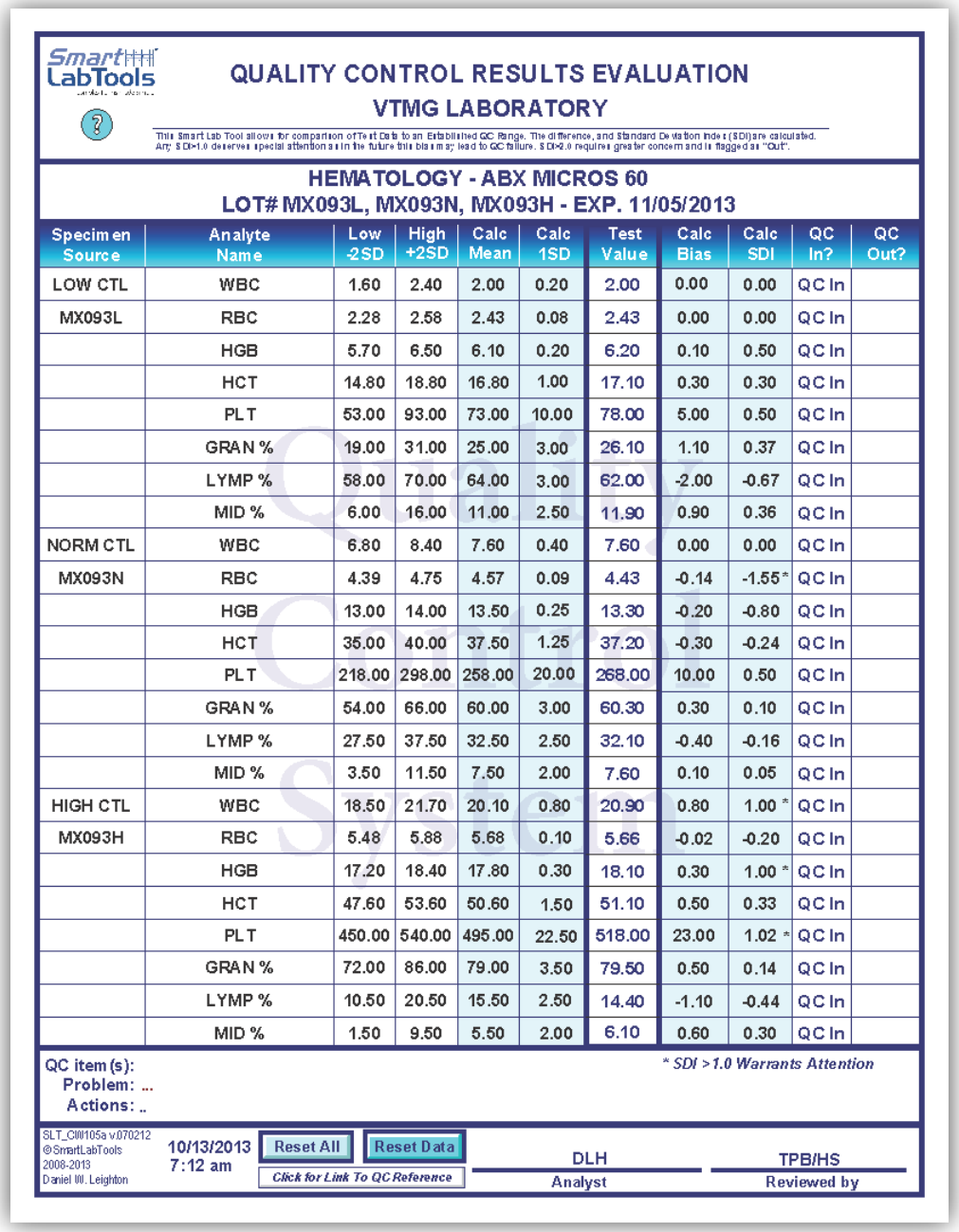
* Trend Alert - Warrants Attention

10/13/13 07:36 | Reset Data | BRITTANY Analyst | DL Reviewed by

Daily QC Assessment in current use with a COLA Client

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



SmartLabTools

QUALITY CONTROL RESULTS EVALUATION

VTMG LABORATORY

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

HEMATOLOGY - ABX MICROS 60
LOT# MX093L, MX093N, MX093H - EXP. 11/05/2013

Specimen Source	Analyte Name	Low -2SD	High +2SD	Calc Mean	Calc 1SD	Test Value	Calc Bias	Calc SDI	QC In?	QC Out?
LOW CTL	WBC	1.60	2.40	2.00	0.20	2.00	0.00	0.00	QC In	
MX093L	RBC	2.28	2.58	2.43	0.08	2.43	0.00	0.00	QC In	
	HGB	5.70	6.50	6.10	0.20	6.20	0.10	0.50	QC In	
	HCT	14.80	18.80	16.80	1.00	17.10	0.30	0.30	QC In	
	PLT	53.00	93.00	73.00	10.00	78.00	5.00	0.50	QC In	
	GRAN %	19.00	31.00	25.00	3.00	26.10	1.10	0.37	QC In	
	LYMP %	58.00	70.00	64.00	3.00	62.00	-2.00	-0.67	QC In	
	MID %	6.00	16.00	11.00	2.50	11.90	0.90	0.36	QC In	
NORM CTL	WBC	6.80	8.40	7.60	0.40	7.60	0.00	0.00	QC In	
MX093N	RBC	4.39	4.75	4.57	0.09	4.43	-0.14	-1.55 *	QC In	
	HGB	13.00	14.00	13.50	0.25	13.30	-0.20	-0.80	QC In	
	HCT	35.00	40.00	37.50	1.25	37.20	-0.30	-0.24	QC In	
	PLT	218.00	298.00	258.00	20.00	268.00	10.00	0.50	QC In	
	GRAN %	54.00	66.00	60.00	3.00	60.30	0.30	0.10	QC In	
	LYMP %	27.50	37.50	32.50	2.50	32.10	-0.40	-0.16	QC In	
	MID %	3.50	11.50	7.50	2.00	7.60	0.10	0.05	QC In	
HIGH CTL	WBC	18.50	21.70	20.10	0.80	20.90	0.80	1.00 *	QC In	
MX093H	RBC	5.48	5.88	5.68	0.10	5.66	-0.02	-0.20	QC In	
	HGB	17.20	18.40	17.80	0.30	18.10	0.30	1.00 *	QC In	
	HCT	47.60	53.60	50.60	1.50	51.10	0.50	0.33	QC In	
	PLT	450.00	540.00	495.00	22.50	518.00	23.00	1.02 *	QC In	
	GRAN %	72.00	86.00	79.00	3.50	79.50	0.50	0.14	QC In	
	LYMP %	10.50	20.50	15.50	2.50	14.40	-1.10	-0.44	QC In	
	MID %	1.50	9.50	5.50	2.00	6.10	0.60	0.30	QC In	

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

** SDI >1.0 Warrants Attention*

SLT_CWI105a v.070212
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Daniel W. Leighton

10/13/2013
7:12 am

Reset All | Reset Data

Click for Link To QC Reference

DLH — Analyst

TPB/HS — Reviewed by

Demonstration of Dropbox Application using Daily Q.C. Assessment Program

Discussion of Presentation…
Questions….
Acknowledgement
www.psmile.org/resources

END…
Thank You.