

Laboratory Advisory Committee (LAC) Meeting

September 10, 2012
Portland Marriott at Sable Oaks
Portland, ME

1. Call to Order – Jere High, Chair, LAC
2. Agenda Review and Repair
3. Minutes from 2011 LAC Meeting - attached
4. QCS Laboratory Program Update – Steven Sievert, QCS
 - a. Auditing Schedule - attached
 - b. Samples Unknown Program
 - i. Unknowns Failures and Solutions – Paul Sauvé
 - ii. Late Submission of Data - Steven Sievert
 - iii. Data Entry Errors – Steven Sievert
 - iv. 2012 Unknowns Schedule – Steven Sievert
 - c. Questions on current 'Auditing Guidelines for Laboratories'
5. New Business
6. Adjourn

Laboratory Advisory Committee (LAC) Meeting

September 10, 2012

Portland Marriott at Sable Oaks, Portland, ME

1. LAC meeting called to order by Chairman, Jere High at 1:20 p.m.
2. Hearing no opposition from attendees, Jere High appointed Steven Sievert to take minutes for the 2012 meeting.
3. It was moved, seconded and passed to approved the minutes from the 2011 LAC meeting as printed and distributed.
4. Lab QC Program presentation (attached to minutes) by Steven Sievert, QCS Program Manager
 - a. Current auditing schedule distributed and discussed.
 - b. Review of procedural steps following on-site laboratory audits.
 - c. Report on the late data submission by laboratories.
 - d. Discussion on data entry errors in the Samples Unknown program.
5. Samples Unknown – Failures and Solutions – presentation (attached to minutes) by Paul Sauvé, QCS-contracted Laboratory Auditor.
6. Skip Vierra (Central Counties DHIA) asked for clarification on the changes (SCC MD $\pm 5\%$ and SDD $<10\%$) approved in 2011 for the SCC calibration check tolerances. It was clarified that these changes (*Auditing Procedures for Laboratories*, page 20) were for SCC calibration check tolerances and did not affect the tolerances for conformance (*Auditing Procedures for Laboratories*, page 9) in the Samples Unknown program (SCC MD $\pm 10\%$, RMD $\pm 5\%$, and SDD $<10\%$).
7. Paul Sauvé commented on the scheduled unknowns program and introduced the idea of periodically having the monthly unknown samples sent to participating labs unannounced. After discussion, there was no action taken.
8. There were no other changes to the *Auditing Procedures for Laboratories* proposed during the meeting.
9. Adjourned at 2:25 p.m.

Recorded by:

Steven Sievert
QC Program Manager
Quality Certification Services Inc.

Laboratory Advisory Committee (LAC) Meeting

September 12, 2011

Sheraton Wall Centre Hotel, Vancouver, BC, Canada

1. LAC meeting called to order by Chairman, Jere High at 4:14 p.m.
2. It was moved, seconded and passed to approved the minutes from the 2010 LAC meeting as printed and distributed.
3. Jere High appointed Steven Sievert to take minutes for the 2011 meeting.
4. Lab QC Program presentation (attached to minutes) by Steven Sievert, QCS Program Manager
 - a. Current auditing schedule distributed and discussed.
 - b. Report on the late data submission by laboratories.
 - c. Discussion on data entry errors in the Samples Unknown program.
5. Requirements for water testing were brought back from the table and discussed. This topic was brought to the floor by Dixie Stauffer (Dairy One Cooperative – Pennsylvania Lab) at the 2010 LAC meeting. It was concluded that while each lab should be monitor their respective water quality, no changes in the 'Auditing Guidelines for Laboratories' were needed.
6. Jackie Avery (Dairy Lab Services) asked for clarification on the range of pilot samples for SCC. After a brief discussion, it was concluded that the range in the auditing guidelines was adequate. Laboratories should make sure they are using the most current version of the 'Auditing Guidelines for Laboratories.'
7. Skip Vierra (Central Counties DHIA) asked for clarification on the acceptable range for IR calibration checks.
 - a. The current range for milk fat and protein is a MD of +/- 0.05% and SDD within 0.06% (page 12 of auditing guidelines)
 - b. Discussion related to MA tolerances in certain areas and instrument performance capabilities ensued.
 - c. It was moved and seconded to change the acceptable range for fat and protein to MD of +/- 0.04% and SDD within 0.04%.
 - d. Further discussion centered on whether the acceptable range for SCC should be adjusted.
 - e. Based on the recommendation of the QCS-contracted lab auditor, the motion was amended to include the acceptable range for SCC is a MD within 5% and SDD within 10%.
 - f. Both the amendment and the amended motion were passed.
8. There was no other new business.
9. Adjourned at 5:09 p.m.

Recorded by:

Steven Sievert
QC Program Manager
Quality Certification Services Inc.

Centering Period Months for Laboratories – Even Years

Laboratories are subject to biennial, on-site audits. Below is a schedule of target months for the on-site audits scheduled to occur during even-numbered years.

January Dairy Lab Services
..... Stearns DHIA Central Laboratory
..... Minnesota DHIA - Zumbrota

February Fresno DHIA
..... Kings County DHIA
..... Central Counties DHIA
..... Southern Counties DHIA
..... Tulare DHIA

March Puerto Rico DHIA

April Lancaster DHIA
..... Dairy One Cooperative Inc. – Hagerstown
..... Dairy One Cooperative Inc. – State College
..... United Federation of DHIAs

August Asociación Holstein de México, Santiago de Querétaro, Querétaro, México
..... Alpura, Edo. de México, México, México
..... Alpura, Cd. Delicias, Chihuahua, México
..... Alpura, Gómez Palacio, Durango, México
..... Texas DHIA – Stephenville
..... The Dairy Authority LLC
..... Langston Laboratory

October Integrated DHI – Dimmitt
..... Integrated DHI – Dumas
..... Texas DHIA – Canyon
..... Circle H Headquarters LLC
..... ADM Laboratories LLC

Centering Period Months for Laboratories – Odd Years

Laboratories are subject to biennial, on-site audits. Below is a schedule of target months for the on-site audits scheduled to occur during odd-numbered years.

JanuaryHeart of America DHIA
.....Mid-South Dairy Records

FebruaryDodge County DHIA
.....Eastern Wisconsin DHIC
.....Gallenberger Dairy Records
.....NorthStar Cooperative DHI Services – Wisconsin

MarchSoutheast Milk, Inc.
.....Tennessee DHIA

AprilAgSource Cooperative Services/CRI – Menomonie Laboratory
.....Barron – Washburn DHIC
.....Marathon County DHIA

JuneDHI Cooperative Inc.
.....Eastern Lab Services
.....Universal Lab Services

SeptemberTillamook DHIA
.....Willamette DHIA
.....Washington State DHIA

OctoberAgSource Cooperative Services/CRI – North West Labs
.....High Desert Dairy Lab
.....Rocky Mountain DHIA
.....Arizona DHIA

DecemberDairy One Cooperative Inc. – Ithaca



QCS Sample Unknown Schedule for 2013

<u>Batch Number</u>	<u>Week Starting</u>	
182	January 14	
183	February 11	
184	March 18	One week later due to National DHIA Annual Meeting March 12-14
185	April 8	
186	May 13	
187	June 10	
188	July 8	
189	August 12	
190	September 16	
191	October 14	
192	November 11	
193	December 9	

Samples Unknown

--- Failures and Solutions ---

NALMA, September 10, 2012

Portland, Maine

Paul Sauvé, CLS



Outline

- Tolerances and nonconformances (examples)
- Enforcement (examples)
- Historical record of performance (statistics)
 - fat, protein, somatic cell count
- Primary cause of failures (examples and solutions)
 - hardware issues (mechanical)
 - software issues (calibration, instrument settings)
 - sample issues (quality, handling)



Tolerances and Nonconformances - Definitions

Tolerances:

The statistical indicators and associated limits used to assess performance in an individual trial.

Nonconformance:

Condition where defined performance guidelines (C.D.C.B.) are not satisfied.

Tolerances for an individual trial can be exceeded WITHOUT resulting in a nonconformance (failure).



Tolerances and Nonconformances - Examples

Fat and Protein:

tolerances:

mean difference (md) < +/- .04%

standard deviation of differences (sdd) < .04%

nonconformance:

A nonconformance (failure) exists if the md or sdd exceeds tolerances in two or more of the last four trials or if the rolling mean difference over the previous six trials exceeds +/- .02%.



Tolerances and Nonconformances - Examples

Butterfat

Sample Number	Lab/Instrument Avg			Instr Results		Prec Stats		Accuracy Stats	
	Ref	Inst	Diff	Rep1	Rep2	Range	SD Reqs	IR Mean	Diff
1	3.887	3.900	0.013	3.89	3.93	0.040	0.028	3.910	0.023
2	4.018	4.037	0.019	4.07	4.09	0.020	0.014	4.080	0.062
3	3.493	3.516	0.023	3.52	3.52	0.000	0.000	3.520	0.027
4	4.758	4.588	0.010	4.62	4.64	0.020	0.014	4.630	0.052
5	3.631	3.642	0.011	3.65	3.66	0.010	0.007	3.655	0.024
6	3.961	3.966	0.005	3.99	4.00	0.010	0.007	3.995	0.034
7	3.449	3.478	0.029	3.53	3.54	0.010	0.007	3.535	0.086
8	4.307	4.328	0.021	4.36	4.37	0.010	0.007	4.365	0.058
9	3.673	3.684	0.011	3.71	3.72	0.010	0.007	3.715	0.042
10	4.911	4.907	-0.004	4.97	4.98	0.010	0.007	4.975	0.064
11	3.149	3.156	0.007	3.18	3.18	0.000	0.000	3.180	0.031
12	2.877	2.865	-0.012	2.90	2.90	0.000	0.000	2.900	0.023
		MD	0.011			SDA	0.008	MD	0.044
		SDD	0.011					SDD	0.020

Does this represent a nonconformance (failure)?



Tolerances and Nonconformances - Examples

Butterfat

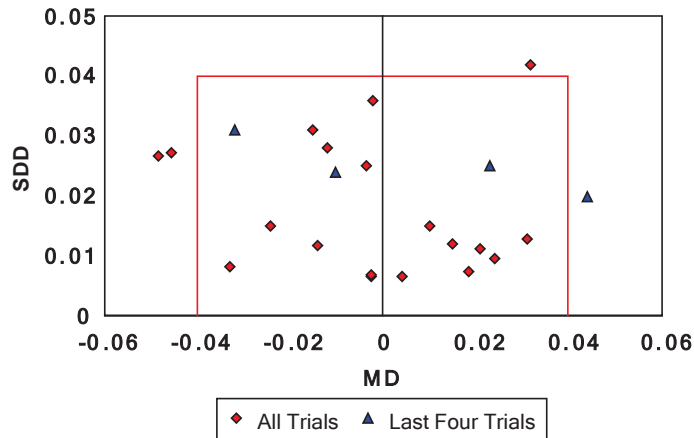
Sample Number	Lab/Instrument Avg			Instr Results		Prec Stats		Accuracy Stats	
	Ref	Inst	Diff	Rep1	Rep2	Range	SD Reqs	IR Mean	Diff
1	3.887	3.900	0.013	3.89	3.93	0.040	0.028	3.910	0.023
2	4.018	4.037	0.019	4.07	4.09	0.020	0.014	4.080	0.062
3	3.493	3.516	0.023	3.52	3.52	0.000	0.000	3.520	0.027
4	4.758	4.588	0.010	4.62	4.64	0.020	0.014	4.630	0.052
5	3.631	3.642	0.011	3.65	3.66	0.010	0.007	3.655	0.024
6	3.961	3.966	0.005	3.99	4.00	0.010	0.007	3.995	0.034
7	3.449	3.478	0.029	3.53	3.54	0.010	0.007	3.535	0.086
8	4.307	4.328	0.021	4.36	4.37	0.010	0.007	4.365	0.058
9	3.673	3.684	0.011	3.71	3.72	0.010	0.007	3.715	0.042
10	4.911	4.907	-0.004	4.97	4.98	0.010	0.007	4.975	0.064
11	3.149	3.156	0.007	3.18	3.18	0.000	0.000	3.180	0.031
12	2.877	2.865	-0.012	2.90	2.90	0.000	0.000	2.900	0.023
		MD	0.011			SDA	0.008	MD	0.044
		SDD	0.011					SDD	0.020

MD < +/- .04

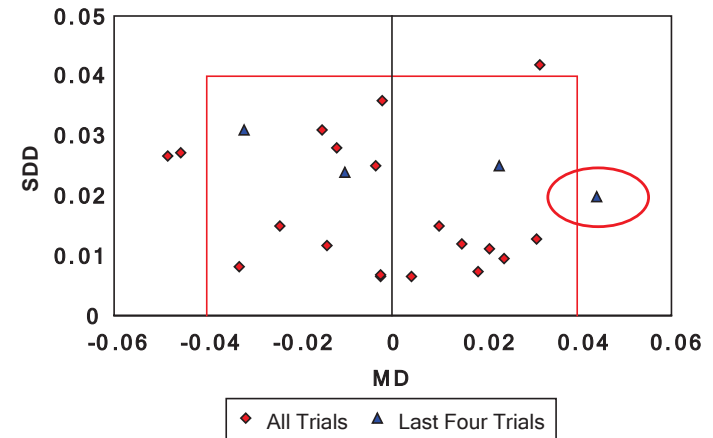
Does this represent a nonconformance (failure)?



Tolerances and Nonconformances - Examples



Tolerances and Nonconformances - Examples



Tolerances and Nonconformances - Examples

Somatic Cell Count:

tolerances:

mean percent difference (m%d) < +/-10%

standard deviation of percent differences (sd%d) < 10%

nonconformance:

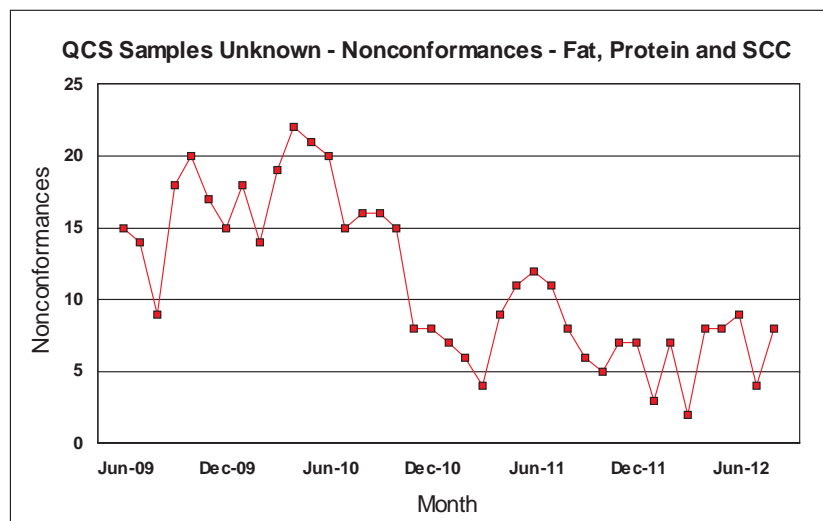
A nonconformance (failure) exists if the m%d or sd%d exceeds tolerances in two or more of the last four trials or if the rolling mean percent difference over the previous six trials exceeds +/-5%.

Nonconformances - Enforcement

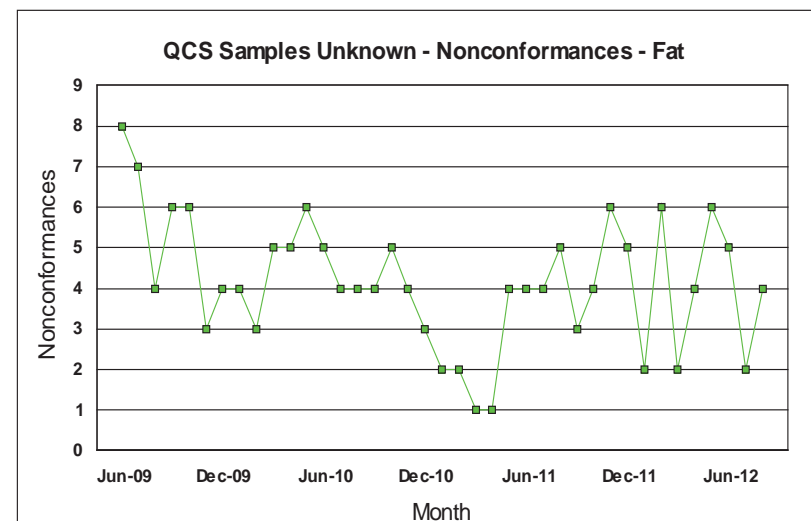
Upon completion of the data analysis each month, every nonconformance is reviewed in detail. The Auditor makes recommendations to QCS regarding follow-up activities.

- No immediate action recommended. (minor concerns, issues already addressed by lab staff)
- No immediate action recommended. Review next month and follow up if necessary. (borderline nonconformance)
- Recommend contact with lab regarding this issue.
- **RECOMMEND IMMEDIATE CONTACT WITH LAB REGARDING THIS ISSUE.** (ongoing test results are compromised)
- **CHANGE OF STATUS** (conditional, provisional, etc.)

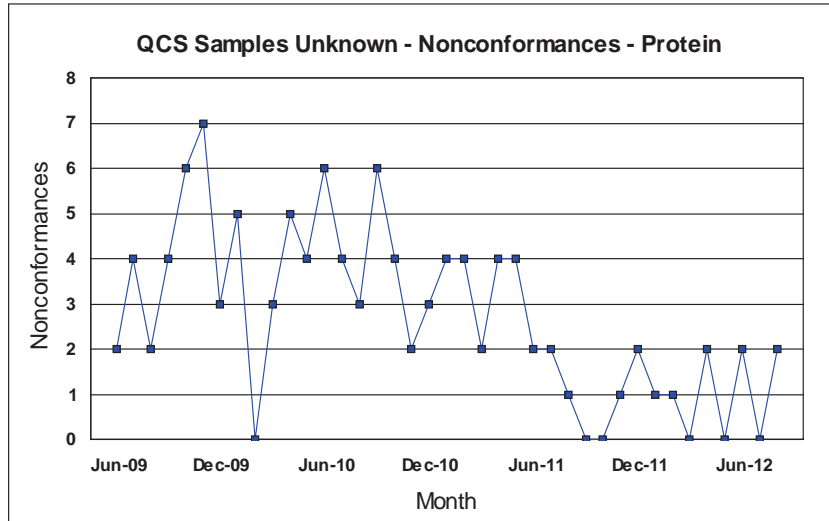
Samples Unknown – Record of Performance (All)



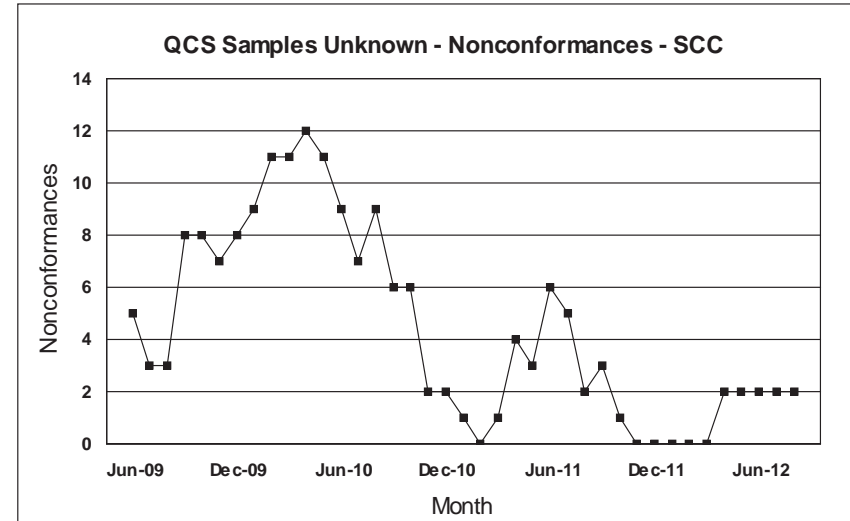
Samples Unknown – Record of Performance (Fat)



Samples Unknown – Record of Performance (Protein)



Samples Unknown – Record of Performance (SCC)



Samples Unknown – Compliance Rates (2012)

Date	Fat	Protein	SCC	All
Jan-12	98%	99%	100%	99%
Feb-12	94%	99%	100%	98%
Mar-12	98%	100%	100%	99%
Apr-12	96%	98%	98%	97%
May-12	94%	100%	98%	97%
Jun-12	95%	98%	98%	97%
Jul-12	98%	100%	98%	99%
Aug-12	96%	98%	98%	97%
Average	96%	99%	99%	98%

Samples Unknown – Failures (Causes, Solutions)

- Hardware issues (mechanical)
- Software issues (calibration, instrument settings)
- Sample issues (quality, handling)

Samples Unknown – Failures (Hardware)

- Homogenizer valve deficiency
- Flow system deficiency
- Temperature instability
- Voltage instability
- Pump failure
- Source failure
- Detector failure
- Worn cell
- Etc.

Samples Unknown – Failures (Hardware)

Solutions:

- Proper and regular QC diagnostics (homo check, purge check, repeatability, zero drift, etc.)
- Regular on-site preventative maintenance
- Manufacturer's PM program
- Replace worn parts as required
- Properly document all breakdowns and repairs
- Replace old, worn or outdated analyzers

Samples Unknown – Failures (Software)

- Instrument settings
 - gain
 - linearity
 - intercorrection factors
 - block temperature
 - pump strokes
 - proper measurement channel
- Calibration
 - slope
 - intercept

Samples Unknown – Failures (Software)

- Instrument settings
 - gain
 - linearity
 - intercorrection factors
 - block temperature
 - pump strokes
 - proper measurement channel
- Calibration
 - slope
 - intercept

Factory Settings

Samples Unknown – Failures (Software)

- Instrument settings
 - gain
 - linearity
 - intercorrection factors
 - block temperature
 - pump strokes
 - proper measurement channel
- Calibration
 - slope
 - intercept

User Settings

Common Errors in Instrument Calibration

Reference	Infrared	Difference
3.95	3.85	-0.09
4.40	4.26	-0.14
4.52	4.37	-0.15
3.57	3.51	-0.06
3.61	3.55	-0.06
3.75	3.68	-0.08
3.52	3.47	-0.05
4.16	4.04	-0.12
4.29	4.16	-0.13
3.48	3.43	-0.05
3.86	3.77	-0.09
3.76	3.68	-0.08
	MD	-0.09
	SDD	0.04

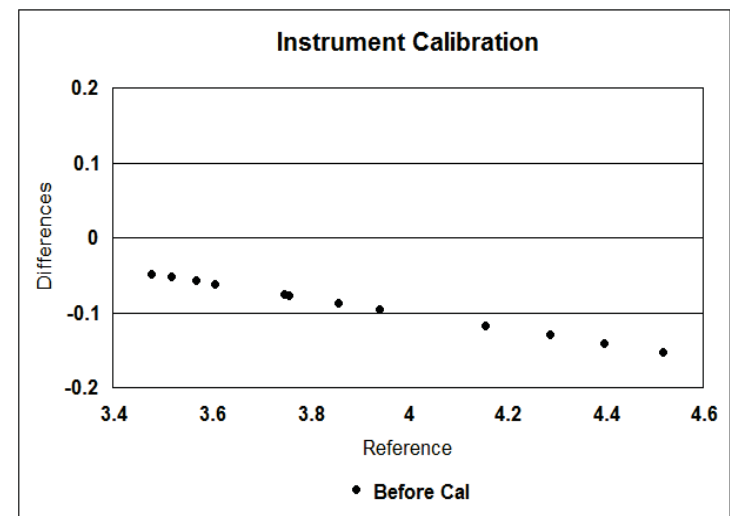
The Lab Manager reviews the data and adjusts the intercept by 0.09%.

Common Errors in Instrument Calibration

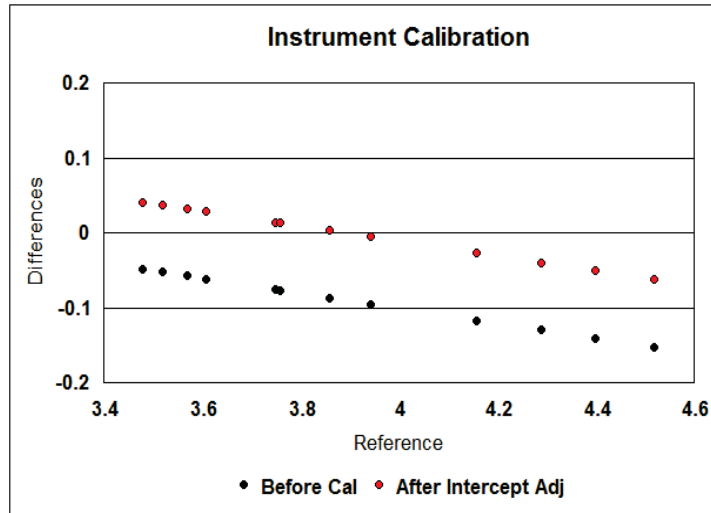
Reference	Adjusted Infrared	Difference
3.95	3.94	-0.01
4.40	4.35	0.05
4.52	4.46	-0.06
3.57	3.60	0.03
3.61	3.64	0.03
3.75	3.77	0.01
3.52	3.56	0.04
4.16	4.13	-0.03
4.29	4.25	-0.04
3.48	3.52	0.04
3.86	3.86	0.00
3.76	3.77	0.01
	MD	0.00
	SDD	0.04

The mean difference looks good but the standard deviation has not changed.

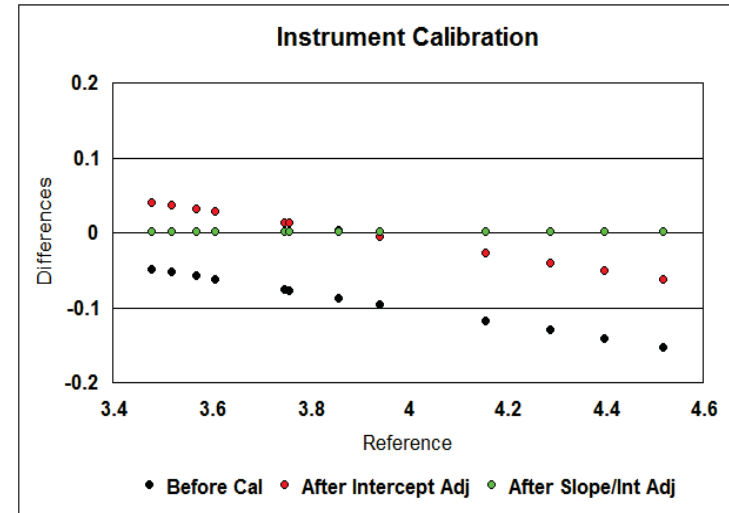
Common Errors in Instrument Calibration



Common Errors in Instrument Calibration



Common Errors in Instrument Calibration



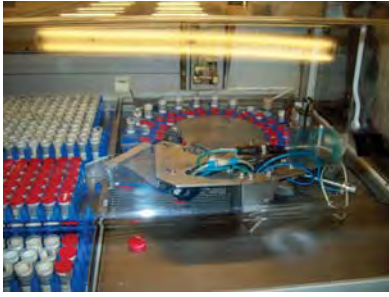
Common Errors in Instrument Calibration

Reference	Adjusted Infrared	Difference
3.95	3.95	0.00
4.40	4.40	0.00
4.52	4.52	0.00
3.57	3.57	0.00
3.61	3.61	0.00
3.75	3.75	0.00
3.52	3.52	0.00
4.16	4.16	0.00
4.29	4.29	0.00
3.48	3.48	0.00
3.86	3.86	0.00
3.76	3.76	0.00
	MD	0.00
	SDD	0.00

With a proper slope/intercept adjustment, both the md and sdd are reduced.

Samples Unknown – Failures (Sample Issues)

- Spoiled samples (delayed, abused on shipping)
- Splitting samples (use of one set on multiple lines)
- Frozen samples (in transit or on-site)
- Overheating (temperature, time in bath)
- Improper agitation (manual testing)
- Temperature cycling



QCS Laboratory Program Update

Steven J. Sievert
Manager, Quality Certification Services, Inc.
Technical Director, National DHIA



Lab Advisory Committee Meeting
September 10, 2012



QCS SIEVERT-LAC-09.10.2012

Components of Laboratory Certification



QCS SIEVERT-LAC-09.10.2012

General Auditing Guidelines

- Service providers are required to notify the auditor of:
 - Changes in business name, address, phone, email, contacts
 - Changes in authorized personnel – i.e. lab managers
 - Changes in equipment/instrumentation
- Notification within 30 days of change. Improvement since last meeting.
- Send changes to QCS Program Manager – Steven Sievert, not to Lab Auditor.
- Assures accuracy in billing, website listings, and monitoring instrument performance.



QCS SIEVERT-LAC-09.10.2012

Auditing Procedures for Laboratories

- Auditing schedule is periodically updated to reflect the current participating laboratories.
 - Balanced schedule, but some labs may move to balance work load in certain geographic regions.
 - 25 labs in even-numbered years
 - 22 labs in odd-numbered years
- QCS and Lab Auditor work cooperatively on schedule.



QCS SIEVERT-LAC-09.10.2012

Auditing Procedures for Laboratories

- Availability of Samples
 - Laboratory must have samples to run the day of the audit.
 - If not, audit is terminated and will be rescheduled.
- Laboratory is responsible for all costs associated with the subsequent audit.
- Will affect your certification status.

After your lab audit...

1. Paul provides a summary list to lab with non-compliance items, usually before leaving the laboratory.
2. Paul sends summary, audit report and certification status recommendation to QCS for review.
3. QCS reviews recommendation along with payment history, on-time submission requirements and other factors.
4. QCS prepares summary letter and full report and sends to laboratory, general manager and board president (as applicable).
5. QCS updates web-site with certification status.
6. QCS places follow-up items on calendar based on timetable (30 days, 6 months, etc.) stated in audit report.
7. QCS and Paul work cooperatively to secure required follow-up if laboratory does not respond in a timely fashion.
8. Failure to respond, either partly or fully, will negatively affect your certification status.

Procedure for New Instruments

- Notify QCS Program Manager of new instrument:
 - Make, Model and In-Service Date
 - Components to be analyzed
 - Instrument to be taken off-line (if applicable)
- Laboratory then adds instrument on Samples Unknown website.
- Samples Unknown website will create a new history file for the instrument.
- Enter data as normal during the next Samples Unknown trial.

Renaming of Instruments/Line Identification

- Notify QCS Program Manager of desire to rename instrument:
 - Has to be done by QCS to merge history files
 - If you only change the name on the Samples Unknown Website, it will create a new instrument and start a new history file
 - Please make changes prior to Samples Unknown test week, not during the week
- QCS will link the history files and email confirmation to lab.
- Enter data as normal during the next Samples Unknown trial.

Late Entry of Samples Unknown Results

- Laboratory Guidelines changed in 2009 – any lab submitting data late (unexcused) twice in a 12 month period will have certification status changed to **PROVISIONAL**
 - 4 Labs have been made provisional, 12 labs have 'one strike'
- There has been improvement in on-time submission and communication with QCS Program Manager
- What are valid excuses?
 - **Acceptable Reasons** – Instrument problems; Samples out of condition; Samples arrived late
 - **Unacceptable Reasons** – Vacation; Did not get around to running the samples; Forgot to enter the results

Samples Unknown – Data Entry Errors

- Increase in number of data entry errors in Samples Unknown:
 - Transpositions – 3.18 instead of 3.81
 - Minor data entry errors – 4.30 instead of 3.30
 - Switching rows & results – i.e. fat results entering for protein
 - Major data entry errors – entered the wrong data set
- Paul corrects obvious errors – but should he?
 - Labs should be responsible for the data they submit
 - If QCS does not correct the labs' mistakes, more labs may potentially be 'out of compliance.'
- Bottom Line – Please proof your data entry for accuracy.

Review of monthly samples unknown results

1. Paul provides a list of labs not satisfying the guidelines and recommendation each month:
 - Immediate contact with laboratory
 - Watch closely next month
 - Out of tolerance, but issue has been addressed
2. QCS sends an email to each lab listed as immediate contact requesting a response with 7 days to both Paul and QCS.
3. QCS and Paul work cooperatively to secure required follow-up if laboratory does not respond in a timely fashion.
4. Failure to respond will negatively affect your certification status.

Quality Certification Services Inc.

- Performance & Quality Standards
- Compliance Auditing of Providers
- Education, Training, & Development

A simple, yet vital mission....

Providing a reliable source of information to people interested in the U.S. dairy records industry.