

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.

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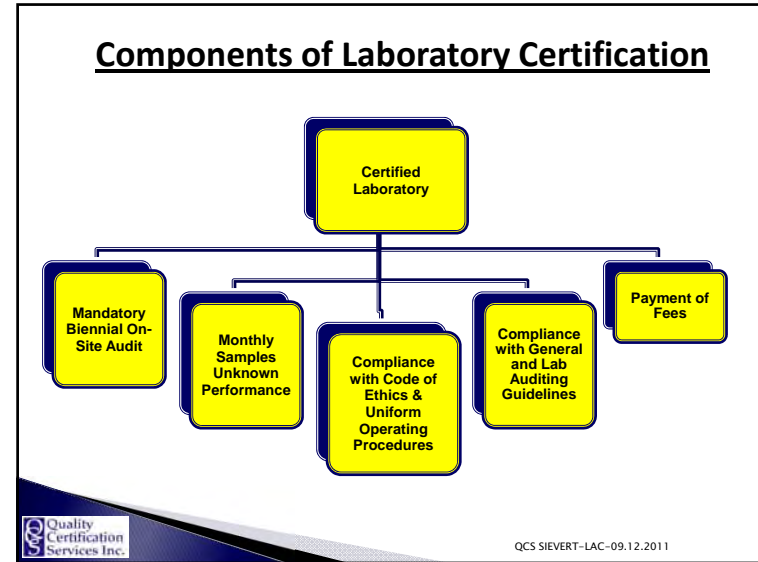
1. Call to Order – Jere High, Chair, LAC
2. Agenda Review and Repair
3. Minutes from 2010 LAC Meeting (attached)
4. QCS Laboratory Program Update – Steven Sievert, QCS
  - a. Auditing Schedule
  - b. Samples Unknown Program
    - i. Late Submission of Data
    - ii. Data Entry Errors
  - c. Questions from participating labs during last year
    - i. Water quality requirements – Dixie Burris, Dairy One Cooperative
    - ii. Pilot samples for SCC – Jackie Avery, Dairy Lab Services
    - iii. Acceptable range for IR calibration checks – Skip Vierra, Central Counties DHIA
5. New Business
6. Adjourn



## QCS Laboratory Program Update

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


Lab Advisory Committee Meeting  
 September 12, 2011

### Auditing Procedures for Laboratories

- Auditing schedule is periodically updated to reflect the current participating laboratories
  - *Continuing need to balance the schedule*
    - 23 labs in even-numbered years
    - 24 labs in odd-numbered years
  - *New laboratories and consolidations/closures in the future?*
  - *QCS and Lab Auditor work cooperatively on schedule*


QCS SIEVERT-LAC-09.12.2011



### 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*
  - *May affect your certification status*

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## 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
- Send changes to QCS Program Manager – Steven Sievert, not to Lab Auditor
- Assures accuracy in billing, website listings, and monitoring instrument performance



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## 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



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## 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



QCS SIEVERT-LAC-09.12.2011

## 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**
  - *2 Labs were made provisional, 13 labs have 'one strike'*
- 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; Forgetting to enter the results*



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### Late Entry of Samples Unknown Results

| Month          | Laboratories Submitting Late | Laboratories Excused | Laboratories Unexcused |
|----------------|------------------------------|----------------------|------------------------|
| September 2010 | 1                            | 0                    | 1                      |
| October 2010   | 4                            | 2                    | 2                      |
| November 2010  | 3                            | 1                    | 2                      |
| December 2010  | 5                            | 4                    | 1                      |
| January 2011   | 4                            | 3                    | 1                      |
| February 2011  | 0                            | 0                    | 0                      |
| March 2011     | 6                            | 4                    | 2                      |
| April 2011     | 5                            | 4                    | 1                      |
| May 2011       | 1                            | 0                    | 1                      |
| June 2011      | 1                            | 1                    | 0                      |
| July 2011      | 11                           | 7                    | 4                      |
| August 2011    | 2                            | 2                    | 0                      |



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### 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*
  - *Major data entry errors – entered the wrong data set*
  
- Paul corrects the 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.



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### Samples Unknown Data Entry Errors by Month

| Month          | Laboratories With Data Entry Errors | Number of Data Points Corrected |
|----------------|-------------------------------------|---------------------------------|
| September 2010 | 0                                   | 0                               |
| October 2010   | 3                                   | 25                              |
| November 2010  | 1                                   | 40                              |
| December 2010  | 3                                   | 12                              |
| January 2011   | 2                                   | 3                               |
| February 2011  | 0                                   | 0                               |
| March 2011     | 0                                   | 0                               |
| April 2011     | 3                                   | 22                              |
| May 2011       | 2                                   | 2                               |
| June 2011      | 2                                   | 22                              |
| July 2011      | 1                                   | 2                               |
| August 2011    | 2                                   | 49                              |



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### Samples Unknown–Batch Entry Confirmation

- Print a copy of your Batch Entry Confirmation Report
  - *Record/proof of your data entry*
  - *Check for accuracy – have noticed periodic data entry errors*

Lab Options

- Select Batch
- Change Lab Info
- Manage Email Accounts
- Test Instrument Identification
- Sample Unknown Entry
- OffLine Sample Unknown Entry
- Batch Entry Confirmation
- Batch Certification Report
- Email Batch Certification Report
- Batch Comparison Report
- Test Instrument History
- LogOff

Batch 141  
Lab Code 896

**Batch Entry Confirmation**

| Altera<br>Comb/Pass FT Plus | Fat    |        | Pro    |        | SCC   |       | MUN    |        |
|-----------------------------|--------|--------|--------|--------|-------|-------|--------|--------|
|                             | Rep1   | Rep2   | Rep1   | Rep2   | Rep1  | Rep2  | Rep1   | Rep2   |
| 1                           | 3.180  | 3.180  | 2.850  | 2.870  | 119   | 115   | 14.00  | 13.70  |
| 2                           | 3.450  | 3.450  | 2.830  | 2.830  | 125   | 120   | 7.60   | 8.20   |
| 3                           | 3.590  | 3.590  | 2.780  | 2.790  | 237   | 221   | 15.10  | 15.20  |
| 4                           | 4.480  | 4.470  | 2.960  | 2.970  | 389   | 387   | 9.50   | 10.30  |
| 5                           | 3.870  | 3.870  | 2.800  | 2.810  | 225   | 234   | 7.40   | 7.50   |
| 6                           | 3.620  | 3.630  | 3.000  | 3.010  | 1,138 | 1,117 | 8.80   | 9.10   |
| 7                           | 4.880  | 4.890  | 3.230  | 3.220  | 574   | 564   | 12.00  | 12.20  |
| 8                           | 3.670  | 3.670  | 2.890  | 2.890  | 309   | 310   | 8.60   | 8.90   |
| 9                           | 2.900  | 2.910  | 2.900  | 2.910  | 157   | 151   | 11.50  | 11.60  |
| 10                          | 4.050  | 4.050  | 3.480  | 3.480  | 270   | 264   | 4.80   | 4.70   |
| 11                          | 3.320  | 3.330  | 2.940  | 2.940  | 274   | 279   | 6.60   | 7.30   |
| 12                          | 4.520  | 4.510  | 2.950  | 2.950  | 290   | 306   | 9.30   | 9.90   |
| Hash Totals                 | 45.530 | 45.530 | 35.620 | 35.660 | 4,105 | 4,008 | 115.20 | 118.90 |



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**Have you checked out the QCS Website?**

**[www.quality-certification.com](http://www.quality-certification.com)**

**Your source for...**

- *Current versions of all Auditing Guidelines*
  - *includes periodic schedule updates*
  - *Laboratories are responsible for having the most current version*
- *Samples Unknown schedule*
- *List of Certified Providers*



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**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.*



QCS SIEVERT-LAC-09.12.2011

## How Your QC Data Can Help You

--- A Case Study ---

NALMA, September 11, 2011

Vancouver, Canada

Paul Sauvé, CLS



The laboratory receives a customer inquiry (complaint):

A dairy producer contacts the DHI laboratory with a concern.

Somatic cell count results for his entire herd are up more than 15% since the previous test.

There have been no significant changes in herd management practices and instances of mastitis are down.

The herd owner believes that the lab tests are incorrect and has requested a refund.



The Lab Manager refers to the SOP for addressing complaints:

Investigation / Resolution of Customer  
Complaints – Lab Tests  
SOP #C023

XYZ DHI Laboratory  
Anytown, North America  
Version 2.01, June 23, 2011

1. Title:  
Investigation / Resolution of Customer Inquiries and Complaints – Lab Tests.
2. Scope:  
This standard operating procedure is to be used to investigate and resolve customer inquiries and/or complaints related to test results on incoming DHI samples. Complaints may be received in person, by telephone, mail or email.
3. Responsibility:  
Any Lab employee may receive and document a customer inquiry or complaint.



The Lab Manager refers to the SOP for addressing complaints:

Investigation / Resolution of Customer  
Complaints – Lab Tests  
SOP #C023

XYZ DHI Laboratory  
Anytown, North America  
Version 2.01, June 23, 2011

- The Lab Manager (or appointed Deputy) is responsible for investigating all complaints and for reporting the results of the investigation to Lab Management. The General Manager (or appointed Deputy) is responsible for communicating the results of the investigation to the customer and for coordinating any corrective action. Any lab employee may contribute to the investigation.
4. Records:  
All customer inquiries and/or complaints as well as the results of the associated investigation and details of corrective actions undertaken are to be thoroughly documented using Form #C132 (Customer Inquiries and Complaints).



The Lab Manager refers to the SOP for addressing complaints:

Investigation / Resolution of Customer  
Complaints – Lab Tests  
SOP #C023

XYZ DHI Laboratory  
Anytown, North America  
Version 2.01, June 23, 2011

5. Procedure:

Any investigation into suspect laboratory results is to proceed as follows:

- Identify the date and time of testing and the instrument(s) used.
- Identify the instrument Operator at the time of testing.
- Identify the batch number of all reagents in use on the instrument in question at the time of testing. Verify lot numbers and expiration dates where applicable.
- Confirm that the Operator has been appropriately trained and authorized to conduct the testing.
- Review results of start-up diagnostics and QC checks on the day of testing.

The Lab Manager refers to the SOP for addressing complaints:

Investigation / Resolution of Customer  
Complaints – Lab Tests  
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XYZ DHI Laboratory  
Anytown, North America  
Version 2.01, June 23, 2011

- Review equipment maintenance records and note any recent malfunctions and/or repairs. If there have been repairs, ensure that the instrument has been calibrated prior to being returned to service.
- Review results of all zero checks and/or control samples tested before and after the sample(s) in question.
- Review results of calibration checks and/or adjustments prior to analysis of the sample(s) in question.
- Thoroughly review any additional contributing factors, abnormal situations, or circumstances that may have contributed to incorrect test results.

**Note: For each of the steps listed above, ensure that thorough records are maintained.**

The Lab Manager refers to the SOP for addressing complaints:

Investigation / Resolution of Customer  
Complaints – Lab Tests  
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XYZ DHI Laboratory  
Anytown, North America  
Version 2.01, June 23, 2011

6. Follow-Up:

If the investigation fails to turn up any potential situations which call into question the validity of the test results AND if the Lab Manager and General Manager are satisfied that the reported test results are accurate, the General Manager is to advise the customer, in writing, of the results of the investigation.

If the investigation identifies a situation calling into question the validity of the test results, the General Manager is to advise the client, in writing, of the situation and is to coordinate corrective action (revised test report, refund, resampling and retesting).

The Lab Manager refers to the SOP for addressing complaints:

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Anytown, North America  
Version 2.01, June 23, 2011

6. Follow-Up:

If the investigation identifies a situation calling into question the validity of the test results, the Laboratory Manager is to review all associated SOP's, identify the deficiency or deficiencies which lead to the release of incorrect test data, and take corrective action revising the associated SOP accordingly. In such cases, all lab staff are to be advised immediately of the revision and appropriate training on the revised procedure is to be delivered as necessary.

The Investigation:



Investigation / Resolution of Customer  
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- Confirm that the Operator has been appropriately trained and authorized to conduct the testing.
- Review results of start-up diagnostics and QC checks on the day of testing.

Traceability:



By referring to the “Herd Log-In” records, the Lab Manager was able to determine that the samples in question were tested on August 15, 2011 between 2:00pm and 3:00pm.

The same report showed that the samples were tested using the cell counter on “Line 3”.

These details were recorded on Form #C132 (Customer Inquiries and Complaints).

The Investigation:



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Complaints – Lab Tests  
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Version 2.01, June 23, 2011

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- Confirm that the Operator has been appropriately trained and authorized to conduct the testing.
- Review results of start-up diagnostics and QC checks on the day of testing.

Traceability:



Through work schedules and the “Daily Start-Up Log” the Lab Manager was able to determine that the Operator who logged in and tested the samples was John Smith.

John was a fairly new employee but seemed to be performing at a high level even though the Lab Manager had not been directly involved in his training.

The identity of the Operator involved in the testing was recorded on Form #C132 (Customer Inquiries and Complaints).

## The Investigation:

Investigation / Resolution of Customer  
Complaints – Lab Tests  
SOP #C023

XYZ DHI Laboratory  
Anytown, North America  
Version 2.01, June 23, 2011

### 5. Procedure:

Any investigation into suspect laboratory results is to proceed as follows:

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- Identify the instrument Operator at the time of testing.
- **Identify the batch number of all reagents in use on the instrument in question at the time of testing. Verify lot numbers and expiration dates where applicable.**
- Confirm that the Operator has been appropriately trained and authorized to conduct the testing.
- Review results of start-up diagnostics and QC checks on the day of testing.

## Traceability:

By referring to the “Daily Start-Up Log” the Lab Manager was able to identify the batch number, date and time of preparation of all chemicals in use on Line 3 at the time of the suspect testing.

The reagent logs indicated that all chemicals were prepared by authorized personnel and that none of the batches had exceeded the expiration dates.

These details were recorded on Form #C132 (Customer Inquiries and Complaints).

## The Investigation:

Investigation / Resolution of Customer  
Complaints – Lab Tests  
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Version 2.01, June 23, 2011

### 5. Procedure:

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- Identify the batch number of all reagents in use on the instrument in question at the time of testing. Verify lot numbers and expiration dates where applicable.
- **Confirm that the Operator has been appropriately trained and authorized to conduct the testing.**
- Review results of start-up diagnostics and QC checks on the day of testing.

## Training Records:

The Lab Manager reviewed the training records for John Smith. John had been trained by the Lab Supervisor and the training checklist indicated that he was authorized to log-in and process samples but was not yet trained or authorized to calibrate the analyzers.

These details were recorded on Form #C132 (Customer Inquiries and Complaints).

The Investigation:



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- Confirm that the Operator has been appropriately trained and authorized to conduct the testing.
- **Review results of start-up diagnostics and QC checks on the day of testing.**

Quality Control:



The “Daily Start-Up Log” for the cell counter on Line 3 showed that it passed the purge volume check, zero check and the repeatability check on the day in question.

The Operator did not note any abnormalities on the “Comments” field of the report.

This information was recorded on Form #C132 (Customer Inquiries and Complaints).

The Investigation:



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Anytown, North America  
Version 2.01, June 23, 2011

- **Review equipment maintenance records and note any recent malfunctions and/or repairs. If there have been repairs, ensure that the instrument has been calibrated prior to being returned to service.**
- Review results of all zero checks and/or control samples tested before and after the sample(s) in question.
- Review results of calibration checks and/or adjustments prior to analysis of the sample(s) in question.
- Thoroughly review any additional contributing factors, abnormal situations, or circumstances that may have contributed to incorrect test results.

**Note: For each of the steps listed above, ensure that thorough records are maintained.**

Equipment Maintenance:



A review of the “Equipment Maintenance Logs” showed that the cell counter on “Line 3” had been serviced by the manufacturer two months previously. A new cell had been installed and all lines in the flow system had been replaced. This was a regularly scheduled preventative maintenance visit and there were no concerns noted before or after the visit. There had been no recent malfunctions or repairs to the instrument.

This information was recorded on Form #C132 (Customer Inquiries and Complaints).

The Investigation:



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**Note: For each of the steps listed above, ensure that thorough records are maintained.**



Quality Control:



XYZ DHI Laboratory tests a low and high count control sample before and after every herd processed. Tolerances for this check are +/-5%. The results of these checks were as follows:

|              | BEFORE HERD | AFTER HERD |
|--------------|-------------|------------|
| Low Control  | +2%         | +1%        |
| High Control | +1%         | +1%        |

This information was recorded on Form #C132 (Customer Inquiries and Complaints).



The Investigation:



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Version 2.01, June 23, 2011

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**Note: For each of the steps listed above, ensure that thorough records are maintained.**



Instrument Calibration:



The calibration of the cell counter was checked the same morning that the samples were analyzed. Tolerances for mean percent difference and standard deviation of percent differences were satisfied and no adjustments were made.

The slope coefficient on the cell counter was 0.923.

This information was recorded on Form #C132 (Customer Inquiries and Complaints).



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- **Thoroughly review any additional contributing factors, abnormal situations, or circumstances that may have contributed to incorrect test results.**

**Note: For each of the steps listed above, ensure that thorough records are maintained.**

## Preliminary Conclusions:

The Lab Manager was now convinced that there were no lab errors or equipment malfunctions and suggested that the herd owner be told that the test results were valid.

The General Manager was not convinced. He know the herd owner well and could not believe that his cell counts would have increased so significantly in a one month period.

An external consultant was hired to take a closer look at the data.

## Coincidental Factors:

The Consultant looked at all of the same QC data that the Lab Manager reviewed. He also took a close look at the order of activities leading up to the analysis of the herd in question.

August 15, 2011

- 8:00 am – Machine is started up. All start-up checks pass.
- 8:10 am – Routine analysis of samples begins.
- 9:00 am – High and low control sample are in tolerance. Testing continues.
- 9:30 am – Calibration standards are analyzed. Results are good. The calibration is not adjusted. Routine testing continues.
- 9:45 am – The dye is replaced with a new batch.
- 10:00 am – New batches of high and low controls are received. Target values are assigned by analyzing 10 times each. Routine testing continues.
- 11:10 am – High and low control samples are in tolerance. Testing continues.

## Coincidental Factors:

The Consultant looked at all of the same QC data that the Lab Manager reviewed. He also took a close look at the order of activities leading up to the analysis of the herd in question.

August 15, 2011

- 8:00 am – Machine is started up. All start-up checks pass.
- 8:10 am – Routine analysis of samples begins.
- 9:00 am – High and low control sample are in tolerance. Testing continues.
- 9:30 am – Calibration standards are analyzed. Results are good. The calibration is not adjusted. Routine testing continues.**
- 9:45 am – The dye is replaced with a new batch.**
- 10:00 am – New batches of high and low controls are received. Target values are assigned by analyzing 10 times each. Routine testing continues.**
- 11:10 am – High and low control samples are in tolerance. Testing continues.**

What Happened:

[Redacted]

The dye was changed immediately before a new batch of control samples was put into service.

Since the machine calibration had been checked only 30 minutes earlier, the Operator only needed to assign target values for the new controls.

BUT...the new batch of dye was not prepared properly! Since new controls were put in service immediately afterwards, it was not obvious that the machine was testing 15% high.



Conclusions:

[Redacted]

An excellent set of QC procedures were in place.

An unlikely coincidence revealed a weakness in the system. This weakness lead to a customer complaint and subsequent investigation by lab staff.

The weakness was identified thanks to detailed procedures and excellent record keeping.

Both the customer and Lab Management were satisfied with the outcome.

BUT...there is more work to do!!!



Corrective Action:

[Redacted]

Investigation / Resolution of Customer  
Complaints – Lab Tests  
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6. Follow-Up:

If the investigation identifies a situation calling into question the validity of the test results, the Laboratory Manager is to review all associated SOP's, identify the deficiency or deficiencies which lead to the release of incorrect test data, and take corrective action revising the associated SOP accordingly. In such cases, all lab staff are to be advised immediately of the revision and appropriate training on the revised procedure is to be delivered as necessary.



Corrective Action:

[Redacted]

The Lab Manager determined how many other herds had been affected by this problem. All of the herd owners were contacted and advised of the situation.

The Lab Manager and General Manager revised the SOP's related to dye preparation and control sample preparation to ensure that these activities never again took place simultaneously.

Staff were provided with copies of the revised SOP's and appropriate training was delivered.





*Thank-You*

**CAPITAL**  
Laboratory Services