



How Your QC Data Can Help You

--- A Case Study ---

NALMA, September 11, 2011

Vancouver, Canada

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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	XYZ DHI Laboratory Anytown, North America
SOP #C023	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:

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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	XYZ DHI Laboratory Anytown, North America
SOP #C023	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

SOP #C023

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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.

The Lab Manager refers to the SOP for addressing complaints:

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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).

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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.

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.

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).

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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).

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- 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.

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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.

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- **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).

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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.

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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%

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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.

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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.

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What Happened:

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:

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:

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Corrective Action:

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