



Guidelines and Procedures for ELISA Proficiency Testing

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**Approved by:
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Program Overview

Quality Certification Services Inc. (QCS)

Quality Certification Services Inc. is a wholly owned subsidiary of National DHIA and provides certification services to the various providers segments of the Milk Recording/DHI industry. Quality Certification Services Inc. does not own any laboratory, milk recording entity or processing center - rather serves as an independent auditor of the services offered by the audited provider. Further, QCS does not endorse specific instruments, devices, tests, or software programs used in the DHI industry.

ELISA Testing of Milk Samples

DHI Field Technicians routinely collect individual milk samples from visually identified lactating cows. The certification of the activities of field service providers in the United States is described in the Council on Dairy Cattle Breeding (CDCB) auditing guidelines. Both dairy producers and industry personnel have recognized the value of ELISA testing on individual cows for a variety of measures.

QCS ELISA Proficiency Program

The core purpose of this program is to identify laboratories proficient in performing ELISA testing of milk samples. This program will consist of a monthly set (description on Page 7 of this document) of 'Samples Unknown' that will be distributed to participating laboratories for analysis.

This program is designed to:

- Promote standardization among labs conducting ELISA on milk samples
- Demonstrate and identify proficiency among laboratories that perform ELISA testing

Eligibility of Laboratories

This program is open to any laboratory using ELISA on milk samples. There are no limitations on the following:

- Test kit manufacturer – Identification of manufacturer of test kit required on application.
- ELISA tests run – Identification of assays performed required on application.
- Participation in other certification programs offered by QCS and/or other entities.

Program Entry

All laboratories wishing to participate in the ELISA Proficiency Testing Program must submit a signed application (Page 12) to the QCS Manager prior to entry. All fields in the application must be completed or the application will be returned to the laboratory for resubmission. Parties unknown to Quality Certification Services Inc. may be asked to submit a credit application along with the program application.

Program Overview (continued)

Voluntary Nature of Program

Participation in this program is voluntary and independent from other certification and proficiency programs, offered either by Quality Certification Services, Inc. and/or other entities. Though this program is voluntary; all program participants are expected to adhere to the guidelines and procedures as described in this document and its successors.

Training of Personnel

The scope of this program is limited to the assessment of individual laboratory technician's ability to accurately and reliably perform ELISA tests on a routine basis. As this program is vendor neutral, all participants are encouraged to follow manufacturer's recommendations and procedures at all times. In addition, there are numerous third parties that offer qualified training in the collection, handling and ELISA analysis of milk samples. While QCS may offer direct and indirect suggestions for training, such training will not be reviewed or required under this proficiency program.

Notification of QCS in Changes at Participating Laboratories

All participants are required to notify the QCS Manager of changes in laboratory name, ownership, contact information, assays performed, test kit manufacturers/suppliers, and technicians performing the assays. These changes are to be reported within 30 days via electronic or written means.

Proficiency Results

Laboratories that meet all requirements of this program, including but not limited to: accuracy, repeatability and interpretation of assay results will be listed as proficient in the ELISA analysis of milk samples. Those laboratories that meet all requirements of this program and demonstrate assay proficiency will be listed on the Quality Certification Services Inc. website.

References to External Programs

The 'Guidelines and Procedures for DHI ELISA Testing' reference other laboratory auditing guidelines approved by the Council on Dairy Cattle Breeding. These guidelines have been established for the quality certification of service providers in the DHI industry. The CDCB certification program exists to assure the accuracy of the data being submitted to genetic evaluation programs. While the DHI ELISA testing guidelines reference the CDCB program, this does not imply an endorsement – rather recognition of that program as it exists today.

Changes in the Guidelines

These guidelines are subject to review and revision at any time. It is the responsibility of the program participants to ensure that they have the most current version of the guidelines. Comments on these guidelines and/or procedures should be directed to the QCS Manager.

Program Administration and Contacts

Quality Certification Services Contacts

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Program Participation Fees

2010 Fee Structure

The fee structure for the ELISA Proficiency Testing program is based on assay(s) run and number of technicians. A laboratory's total annual fee will be calculated using the information provided in the program application based on the following fee schedule.

- Annual Samples Unknown Fee per ELISA test conducted (includes one technician).....\$360.00
- Annual Fee for Additional Technician (per ELISA test conducted).....\$120.00

For example, a laboratory conducting antibody tests for two different assays using two technicians would have an annual program fee of \$960.00 (two tests @ \$360.00 plus additional technician conducting each test @ 120.00).

Please note that the cost of the Samples Unknown Monthly Test Panels is not included in these fees and is the responsibility of each participating laboratory.

Invoicing of Certification Fees

Laboratories entering the program will be invoiced on a pro-rated annual basis, using the month of the application for the computation of fees. All participating laboratories will automatically renew on the first business day of the new calendar year unless the laboratory provides a written request indicating a desire to exit the program. This request must be received by the QCS Manager on or before December 1 of the current calendar year.

Annual program fees for all laboratories will be billed on January 1 (or the first business day) of each calendar year. The terms are 'NET 30' for all program participants.

Refund of Certification Fees

There will be no refund of certification fees for laboratories that leave the program during the year.

Payment of Certification Fees

Results, interpretation and publication of 'qualified' labs will not be released until the annual program fees are paid in full.

Description of the Monthly Samples Unknown Test Panel(s)

Composition of Samples Unknown Panel(s)

Each month the Samples Unknown Panel will consist of 10 samples in duplicate. The proportion of the negative and positive samples may vary by month. The positive samples will be scaled to achieve examples of low, medium and high reactivity in each test month.

Two blinded sets will be constructed for each set of Samples Unknown in the event that a retest is required.

Samples Unknown Program Schedule

Once a fully completed program application has been received by Quality Certification Services, Inc., QCS will contact the Samples Unknown supplier with each laboratory's specific needs for the monthly trial. Please note that the cost of the Samples Unknown Panels is the responsibility of each participating laboratories. The Samples Unknown supplier can provide an estimate of the cost.

During the third calendar week of each month, each participating laboratory will receive a panel of 20 'unknown' samples. The submission of results will be due on or before the last business day of the month the unknowns were received.

A detailed schedule of 'ship-dates' and 'due-dates' for the monthly Samples Unknown test panels can be found on the QCS website at www.quality-certification.com.

Analysis of the Samples Unknown Panel

Upon receipt, participating laboratories are urged to analyze the Samples Unknown Test Panel as soon as possible. All samples must be analyzed according the manufacturer's instruction. The following data needs to be collected and reported as part of the submission of monthly test results.

- Laboratory Name
- Laboratory Technician
- Test Manufacturer (i.e. IDEXX, Prionics, etc.)
- Lot Number of ELISA Kit
- Lot Number of Unknowns
- Test Date
- Raw Data (unknown samples and kit standards)
- Interpretation of Results

All labs are encouraged to maintain either a paper and/or digital backup of all test results that includes the aforementioned data points.

Guidelines for Submission of Samples Unknown Data

Electronic Submission of Data

Based on the information provided in the program application, Quality Certification Services Inc. will set up an on-line account for submission of data. All results must be submitted using this program. Data submitted by email, phone, fax, or postal mail will not be accepted.

When using the on-line submission program, all fields must be filled out in order for the data to be accepted. A user name and login will be provided to each participating laboratory upon application.

Deadline for Submission of Results

All results are required to be entered using the on-line program by the last business day of each calendar month. The on-line system will not accept any data after midnight central time on that day.

Late Submission of Results

Laboratories that do not submit results on time must notify the QCS manager via email with an explanation for the late submission. A high-quality scan of all results, saved in a PDF format, must be attached to this email.

The QCS manager will make the final determination on acceptance of these results. Any laboratory that does not submit samples (either unexcused late submission or non-submission) by the deadline will be removed from the list of qualified laboratories until such time that the laboratory demonstrates proficiency and compliance with these guidelines.

Batch Entry Confirmation

All participating laboratories are encouraged to use the 'Batch Entry Confirmation' option within the on-line program. A confirmation report with all data entered will be generated and provide documentation of time and data submitted.

Analysis and Interpretation of Samples Unknown Data

Quantitative Analysis

Raw data submitted by participating laboratories will be used to determine ELISA scores based on respective manufacturer's instructions

The target value for each sample will be determined by consensus among participating laboratories. This consensus (target) value will be the mean value of all reported values with the exclusion of statistical outliers. The mean difference (MD) will be calculated as the mean of the differences between target value and reported laboratory value. The standard deviation of the differences (SDD) will also be calculated based on the calculated differences.

Qualitative Analysis

Interpretive results (submitted as positive or negative) will be compared to values set by provider of the Samples Unknown panel(s).

Exclusion of Results

Results submitted by participating laboratories that are noted as 'Laboratory Error' or 'Sample Problem' will be excluded from both quantitative and qualitative analysis for the test period. The final decision on the exclusion of any or all data points lies with the QCS manager.

Compliance Criteria

For each assay analyzed, participating laboratories are required to achieve and maintain the following compliance levels:

- Quantitative Analysis
 - MD (mean difference) less than or equal to 0.40
 - SDD (standard deviation of differences) less than or equal to 0.40
- Qualitative Analysis
 - Correct Interpretation Level of 90% or higher

Qualification

Each participating laboratory will be required to maintain a passing criteria each month, each technician, and each assay. As previously described, the QCS website will maintain a current list of all qualified technicians and proficient laboratories.

Analysis and Interpretation of Samples Unknown Data – Test Proficiency Report

Test Proficiency Report

Upon completion of data analysis by QCS, a 'Test Proficiency Report' will be made available to all program participants. This report can be obtained by selecting this option within the QCS on-line system will contain the following information:

- Test information including Assay, Date, Laboratory, Technician
- Target and Reported numerical values, along with calculated MD and SDD
- Correct and Reported interpretive results
- Plot of target values versus reported laboratory values
- Plot of target values versus MD
- Summary compliance table including overall compliance level



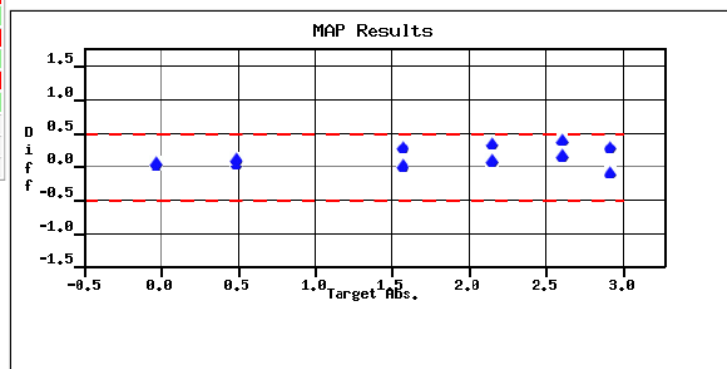
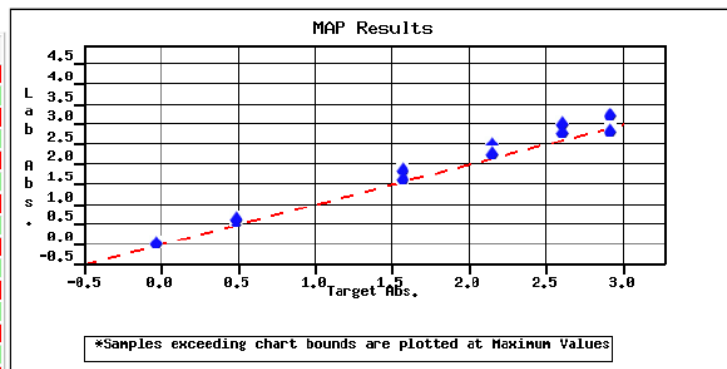
ELISA Proficiency Program
Samples Unknown
Trial 101 On 1/18/2010

ANTELBIO
Heather Donohue
MAP - PRIONICS

Sample	Target	Lab #	Diff	+/-
1	2.623	3.171	0.248	Pos
2	-0.028	-0.022	0.006	Neg
3	2.610	2.724	0.114	Pos
4	-0.023	-0.021	0.002	Neg
5	2.154	2.451	0.297	Pos
6	-0.028	-0.025	0.003	Neg
7	1.674	1.554	-0.020	Pos
8	-0.026	-0.023	0.002	Neg
9	0.495	0.505	0.010	Pos
10	-0.027	-0.027	0.000	Neg
11	2.923	2.780	-0.143	Pos
12	-0.023	-0.024	-0.001	Neg
13	2.610	2.957	0.347	Pos
14	-0.028	-0.023	0.005	Neg
15	2.154	2.207	0.053	Pos
16	-0.026	-0.024	0.001	Neg
17	1.574	1.511	-0.237	Pos
18	-0.028	-0.026	0.002	Neg
19	0.495	0.582	0.087	Pos
20	-0.027	-0.021	0.006	Neg
		MD	0.062	
		SDD	0.124	
		Dist	0.138	

Compliance Rates:	
Correct Negatives	100%
Correct Positives	100%
Overall Compliance	100%

Excluded from Results	Count
Lab/Tech Error	0
Sample Quality Problem	0



Analysis and Interpretation of Samples Unknown Data – Laboratory Comparison Report

Laboratory Comparison Report

In addition to an individual laboratory's test proficiency report, a 'Laboratory Comparison Report' will be made available to all program participants on a monthly basis.

This report will provide a plot the MD versus the SDD for all participating labs. A separate comparison report will be available for each assay. For laboratories with more than one technician performing the assay, all technicians from that lab will appear on one report. Each lab will know their performance, but will not know the identity of other program participants.

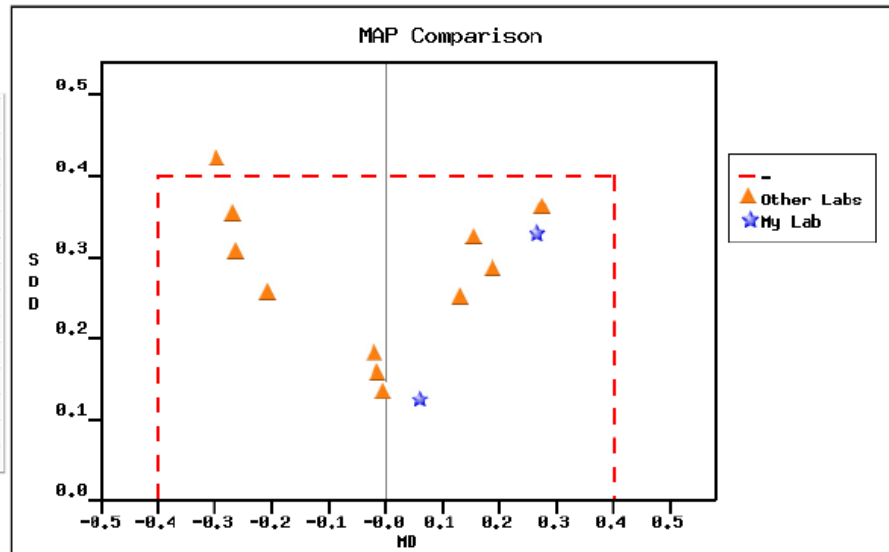
An example of the comparison report is illustrated below.



ELISA Proficiency Program
Samples Unknown
Trial 101 On 1/18/2010

ANTELBIO

Lab Tech	MD	SDD	D	Comp.
	-0.005	0.134	0.134	100%
Heather Donohue	0.062	0.124	0.138	100%
	-0.015	0.157	0.158	100%
	-0.020	0.182	0.183	100%
	0.133	0.251	0.284	100%
	-0.207	0.257	0.330	100%
	0.188	0.286	0.342	100%
	0.155	0.324	0.359	100%
	-0.284	0.307	0.405	100%
Jessica Houseman	0.267	0.328	0.423	100%
	-0.289	0.354	0.445	100%
	0.276	0.363	0.456	100%
	-0.295	0.422	0.515	100%



Application to ELISA Proficiency Testing Program

Date: _____ Customer No: _____ (assigned by QCS)

Laboratory Name: _____

Primary Contact: _____ Title: _____

Mailing Address: _____ Shipping Address: _____

City: _____ City: _____

State: _____ Zip Code: _____ State: _____ Zip Code: _____

Please complete the following:

ASSAYS PERFORMED AT YOUR LAB

LABORATORY TECHNICIAN NAME	MAP	BVD	LEUKOSIS	PROGESTERONE
		FUTURE AVAILABILITY	FUTURE AVAILABILITY	FUTURE AVAILABILITY
		FUTURE AVAILABILITY	FUTURE AVAILABILITY	FUTURE AVAILABILITY
		FUTURE AVAILABILITY	FUTURE AVAILABILITY	FUTURE AVAILABILITY
		FUTURE AVAILABILITY	FUTURE AVAILABILITY	FUTURE AVAILABILITY
<u>TEST MANUFACTURER (I.E. IDEXX, PRIONICS, ETC)</u>		FUTURE AVAILABILITY	FUTURE AVAILABILITY	FUTURE AVAILABILITY

I, acting as authorized representative, hereby apply for entry in the Quality Certification Services Inc. ELISA Proficiency Testing Program. I understand that this program is voluntary in nature and is separate from other certification programs offered by QCS and/or other entities. I further acknowledge that I have reviewed and understand the 'Guidelines and Procedures for ELISA Proficiency Testing' and agree to comply with all aspects, now and as they may exist in the future. I also agree to release Quality Certification Services Inc., along with its owners, successors and employees from any liability associated with this program.

 Signature (Authorized Representative)

 Printed Name of Signer

 Date Signed

PLEASE COMPLETE AND FAX TO QCS MANAGER AT 608.848.7675 OR EMAIL TO: sjsievert@dhia.org