Guidelines and Procedures for ELISA Proficiency Testing

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Quality Certification Services Inc.

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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 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.

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 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 various ELISA assays.

Eligibility of Laboratories

This program is open to any laboratory performing ELISA assays 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 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. While 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, Performance related to qualitative calls on samples identified as suspect or recheck will not affect certification status, rather these results are used for continuous improvement in technician/laboratory performance. Those laboratories that meet all requirements of this program and demonstrate assay proficiency will be listed on the Quality Certification Services Inc. website.

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

Fee Structure for 2021

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 Proficiency Test Fee per laboratory (includes first technician)……..$360.00
- Annual Fee for each additional technician……..$120.00

For example, a laboratory conducting tests for one assay using two technicians would have an annual program fee of $480.00 (annual fee @ $360.00 plus additional technician conducting the test @ $120.00).

Please note that the cost of the Unknown Monthly PT 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 an annual basis. 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 – MAP Assay

Composition of Samples Unknown Panel(s)

Each month the Samples Unknown Panel for MAP will consist of 20 samples. The panel with consist of 3 negative samples in duplicate, 3 positive samples in duplicate, and 8 additional samples as selected by the unknowns supplier. 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

Please note that the ordering and 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 second calendar week of odd-numbered months, each participating laboratory will receive a panel of 20 'unknown' samples. For laboratories participating in the QCS Samples Unknown program for components, these samples will be shipped at the same time. For the remaining laboratories, samples will be shipped 2nd day priority U.S. mail (next day priority to Canada via FedEx).

The submission of results will be due on or before the last calendar 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, etc.)
- Lot Number of ELISA Kit
- Lot Number of Unknowns
- Test Date
- Raw Data (unknown samples and kit standards)
- Interpretation of Results (negative, positive)

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

Description of the Monthly Samples Unknown Test Panel – Milk Pregnancy Assay

Composition of Samples Unknown Panel(s)

Each month the Samples Unknown Panel for Milk Pregnancy will consist of 12 samples. The panel with consist of 3 'open' samples, and 3 'pregnant' samples, and 6 samples that are potentially in the 'recheck' range as selected by the unknowns supplier. The 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

Please note that the ordering and 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 second calendar week of even-numbered months, each participating laboratory will receive a panel of 12 'unknown' samples. For laboratories participating in the QCS Samples Unknown program for components, these samples will be shipped at the same time. For the remaining laboratories, samples will be shipped 2nd day priority U.S. mail (next day priority to Canada via FedEx).

The submission of results will be due on or before the last calendar 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 encouraged 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, Conception, etc.)
- Lot Number of ELISA Kit
- Lot Number of Unknowns
- Test Date
- Raw Data (unknown samples and kit standards)
- Interpretation of Results (open, recheck, pregnant)

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 without prior approval.

When using the on-line submission program, all fields must be filled out in order for the data to be accepted. This data includes test kit lot, samples unknown lot, and the O.D. for each of the controls and unknown samples.

To be eligible for full certification,

- **Each laboratory is required to submit unknown PT results for each technician performing the assay on a monthly basis.**

A login (email address provided) and password 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.

Entry Confirmation

All participating laboratories are encouraged to use the '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.