Guidelines and Procedures for ELISA Proficiency Testing

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National DHIA Board of Directors
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Quality Certification Services Inc.

Guidelines and Procedures for ELISA Proficiency Testing

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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 Pages 7-8 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 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 (Page 13) 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

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Program Participation Fees

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 laboratory (includes one assay/technician) $360.00
- Annual Fee for each additional assay /technician combination $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). Another example would be a laboratory conducting two assays with two technicians conducting each test would have annual fee of $720.00.

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 – MAP Assay

Composition of Samples Unknown Panel(s)

Each month the Samples Unknown Panel for MAP will consist of 25 samples. The panel with consist of 4 negative samples in duplicate, 4 positive samples in duplicate, and 9 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

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 second calendar week of each month, each participating laboratory will receive a panel of 25 '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 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 (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 2 'open' samples in duplicate and 4 'pregnant or recheck' samples in duplicate 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

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 second calendar week of each month, 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 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 (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 results for each assay on a monthly basis.** These results may be from any technician performing the assay.
- **Each technician within the laboratory is required to submit data at least once per quarter for each assay performed.** In the event that more than one technician is submitting results for the laboratory in a given month, the laboratory must designate which set of results is the 'official' submission of that laboratory for each assay.

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 and Certification

Compliance Criteria - MAP

For each assay analyzed, participating laboratories are required to achieve and maintain the following compliance levels in at least three (3) of the previous four (4) months for full certification:

- **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.

Compliance Criteria – Milk Pregnancy

For each assay analyzed, participating laboratories are required to achieve and maintain the following compliance levels in at least three (3) of the previous four (4) months for full certification:

- **Quantitative Analysis**
  - MD (mean difference) less than or equal to 0.50.
  - SDD (standard deviation of differences) less than or equal to 0.50.

- **Qualitative Analysis**
  - Correct Interpretation Level of 90% or higher.

Certification

The QCS website will maintain a current list of all certified laboratories. The following status designations will be assigned to laboratories based on compliance and submission frequency.

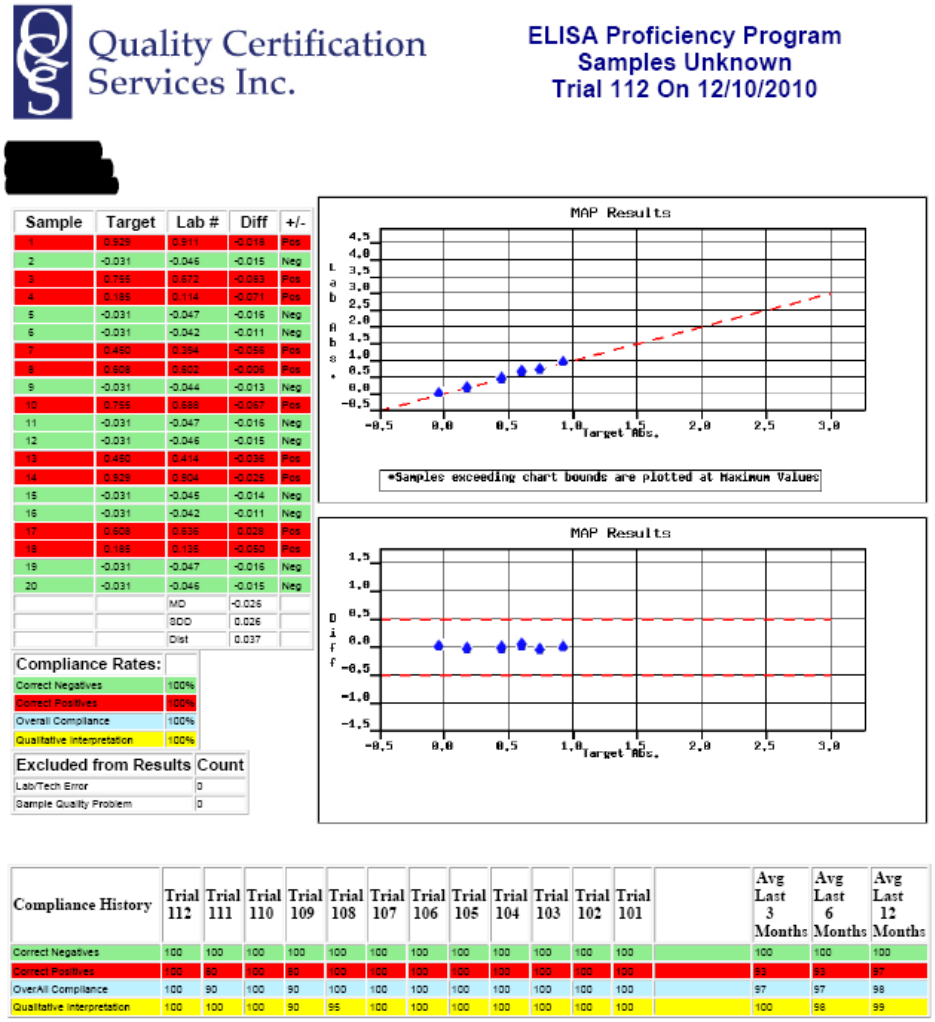
- **Certified** Laboratory meets all compliance criteria and technician submission frequency**.**
- **Conditional** Laboratory meets all compliance criteria but does not submit data each month.
- **Probationary** Laboratory does not meet certain aspects of the compliance criteria.
- **Decertified** Laboratory fails to demonstrate compliance after a probationary period.

Analysis and Interpretation of Samples Unknown Data – Test Proficiency Report

Test Proficiency Report

Upon completion of data analysis by QCS, a 'Test Proficiency Report' for each assay conducted 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



Quality Certification Services Inc.

ELISA Proficiency Program
Samples Unknown
Trial 112 On 12/10/2010

[redacted]

Sample	Target	Lab #	Diff	+/-
1	0.929	0.911	-0.018	Pos
2	-0.031	-0.046	-0.015	Neg
3	0.765	0.672	-0.093	Pos
4	0.185	0.114	-0.071	Pos
5	-0.031	-0.047	-0.016	Neg
6	-0.031	-0.042	-0.011	Neg
7	0.450	0.394	-0.056	Pos
8	0.808	0.802	-0.006	Pos
9	-0.031	-0.044	-0.013	Neg
10	0.765	0.698	-0.067	Pos
11	-0.031	-0.047	-0.016	Neg
12	-0.031	-0.046	-0.015	Neg
13	0.450	0.414	-0.036	Pos
14	0.929	0.904	-0.025	Pos
15	-0.031	-0.045	-0.014	Neg
16	-0.031	-0.042	-0.011	Neg
17	0.808	0.636	0.028	Pos
18	0.185	0.135	-0.050	Pos
19	-0.031	-0.047	-0.016	Neg
20	-0.031	-0.046	-0.015	Neg
		MD	-0.026	
		SDD	0.026	
		Dist	0.037	

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

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

Compliance History	Trial 112	Trial 111	Trial 110	Trial 109	Trial 108	Trial 107	Trial 106	Trial 105	Trial 104	Trial 103	Trial 102	Trial 101		Avg Last 3 Months	Avg Last 6 Months	Avg Last 12 Months
Correct Negatives	100	100	100	100	100	100	100	100	100	100	100	100		100	100	100
Correct Positives	100	80	100	80	100	100	100	100	100	100	100	100		93	93	97
OverAll Compliance	100	90	100	90	100	100	100	100	100	100	100	100		97	97	98
Qualitative Interpretation	100	100	100	90	95	100	100	100	100	100	100	100		100	98	99

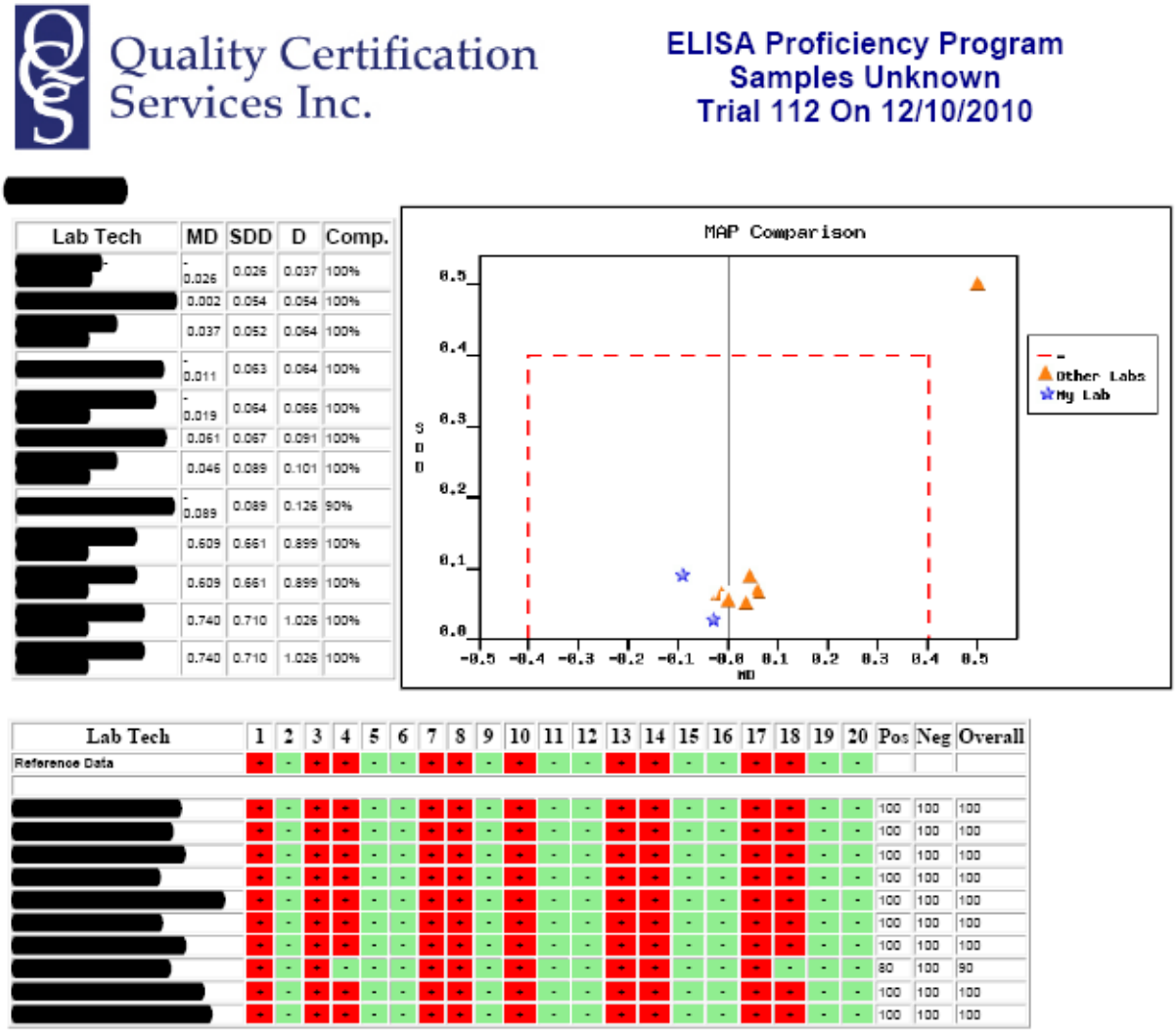
Analysis and Interpretation of Samples Unknown Data – Laboratory Comparison Report

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 for each assay conducted 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.



Quality Certification Services Inc.

Guidelines and Procedures for ELISA Proficiency Testing

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:

ELISA ASSAYS PERFORMED AT YOUR LAB

LABORATORY TECHNICIAN NAME	MAP	MILK PREGNANCY	LEUKOSIS	BVD
			FUTURE AVAILABILITY	FUTURE AVAILABILITY
			FUTURE AVAILABILITY	FUTURE AVAILABILITY
			FUTURE AVAILABILITY	FUTURE AVAILABILITY
			FUTURE AVAILABILITY	FUTURE AVAILABILITY
TEST MANUFACTURER (I.E. IDEXX, PRIONICS, ETC)			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