QCS Laboratory Program Update

Laboratory Advisory Committee Meeting
September 9, 2019

Steven Sievert
Manager, Quality Certification Services Inc.
Technical Director, National DHIA
Chair, ICAR Subcommittee for Recording and Sampling Devices

NATIONAL DHIA
Quality Certification Services Inc.

Housekeeping

Auditing Schedules

Current list of labs with respective centering months included

- **22 labs in even years**
- **21 labs in odd years**

- **Lab audits conducted within 60 days of centering month based on auditor's schedule**

Schedule modifications

- **QCS works with lab auditor to determine the most efficient use of resources – time, travel**

NATIONAL DHIA
Quality Certification Services Inc.

Availability of Samples During On-Site Audit

Laboratory MUST have samples to run the day of the on-site audit. If there are no samples available, the on-site audit will be terminated and will have to be rescheduled.

Laboratory is responsible for all costs (time and travel) associated with the subsequent audit.

Will negatively affect your certification status (i.e. Provisional).

Note that the certification expiration date cannot be extended and the auditor's schedule may push subsequent audit date past the existing expiration date. The net result is decertification of the laboratory until the on-site audit can be completed. Decertified laboratories may not send data to the CDCB.

Non-Compliant Issues from Previous On-Site Audit

It is normal that certain noncompliant items identified during the course of the on-site audit are designated with a completion timeline of 'by the next audit'

If a laboratory fails to address these noncompliant items by the subsequent audit, the laboratory will have its certification status changed to 'Conditional.'

May bypass the 'Conditional' status if additional serious noncompliant issues are identified during the course of the subsequent audit.

The auditor will recommend to QCS a time-frame for completion that will not exceed six (6) months.

Failure to address these items within the time-frame designated will result in the laboratory certification status to be changed to 'Provisional.' If a laboratory continues to fail to address the noted noncompliant issues, the laboratory may be decertified.

NATIONAL DHIA
QCS Quality Certification Services Inc.

Proposed Changes to

Auditing Procedures for Laboratories

NATIONAL DHIA

Quality Certification Services Inc.

Addition of Full Spectral Fat Calibration to Guidelines

Proposed by Dairy One Cooperative Inc.

- **Either 'B' wavelength or full spectral calibration**
- **Supporting documentation circulated to all labs on August 31, 2018**

Changes to text of Guidelines include:

Butterfat Analysis~~and "B" Filter~~

All IR analyzers must use either a "B" wavelength or full spectral calibration.~~.~~

New Instrument Approval Protocol

1. As outlined in the *General Auditing Guidelines*, the new instrument(s) must be reported to QC Program Manager and subsequently enrolled in the monthly Samples Unknown program. For each new instrument, the following information should be provided:

    a. Manufacturer,
    b. Model,
    c. Condition (new, used, refurbished),
    d. Serial number,
    e. Components to be analyzed (fat, protein, SCC, MUN, other),
    ~~e.~~f. Fat analysis (if applicable) using "B" wavelength or full spectra,
    ~~f.~~g. Instrument(s) to be replaced/taken out of service (where applicable).

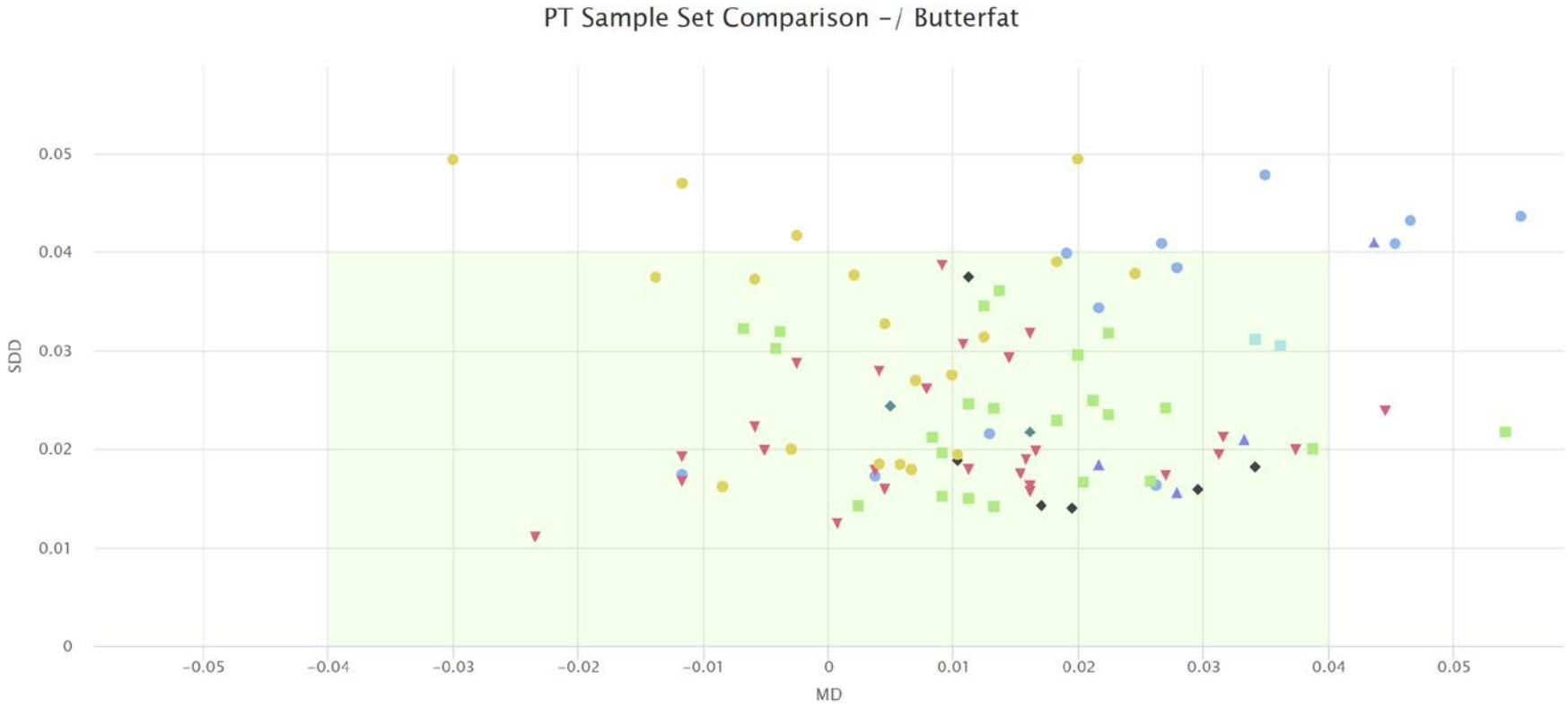
NATIONAL DHIA | QSC Quality Certification Services Inc.

Quantitative PT Programs

Samples Unknown

February 2019 Fat PT Results

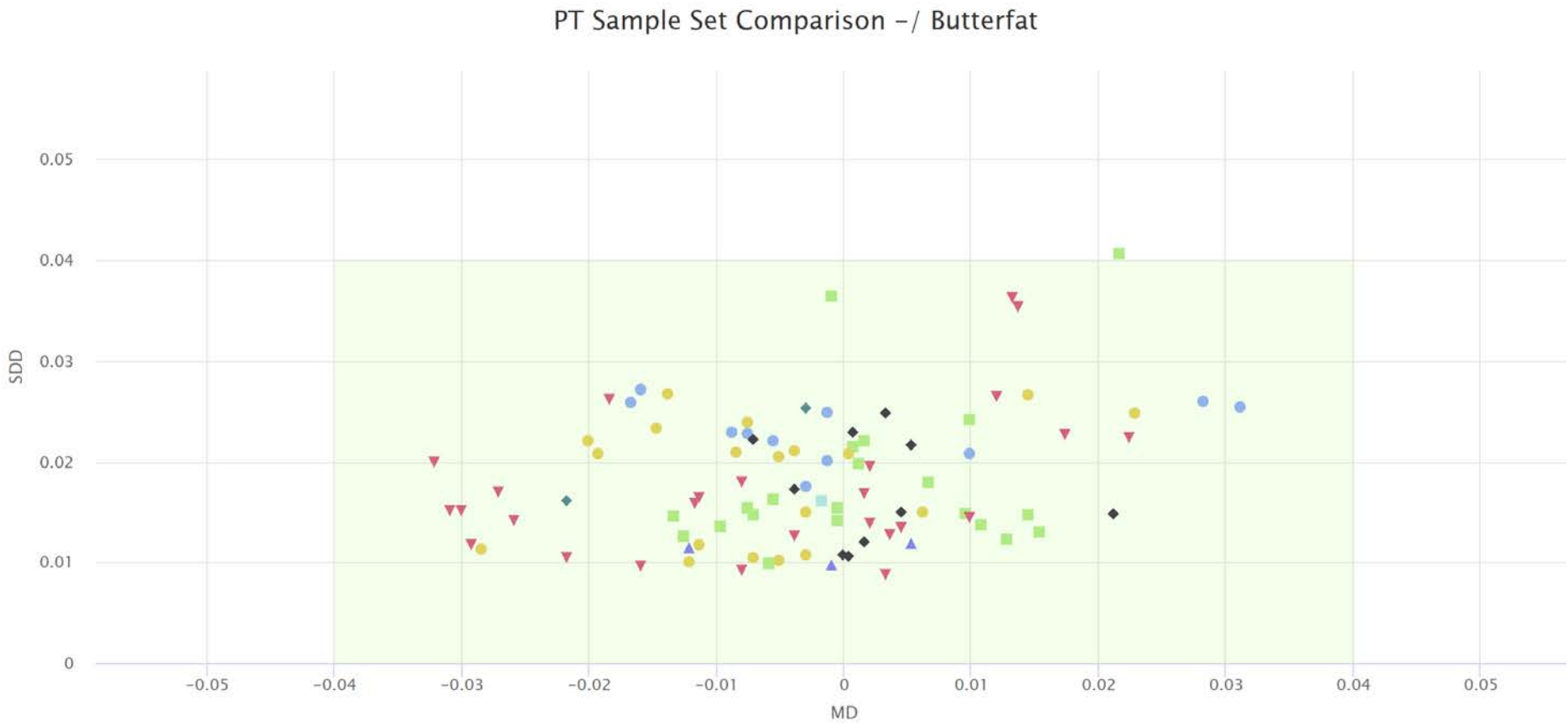
- Disagreement between reference chemistry and instrument results
- Different models of instruments provided clustered results
- Most likely related to fatty acid profile of sample sets (calibration/PT)



NATIONAL DHIA

Quality Certification Services Inc.

August 2019 Fat PT Results

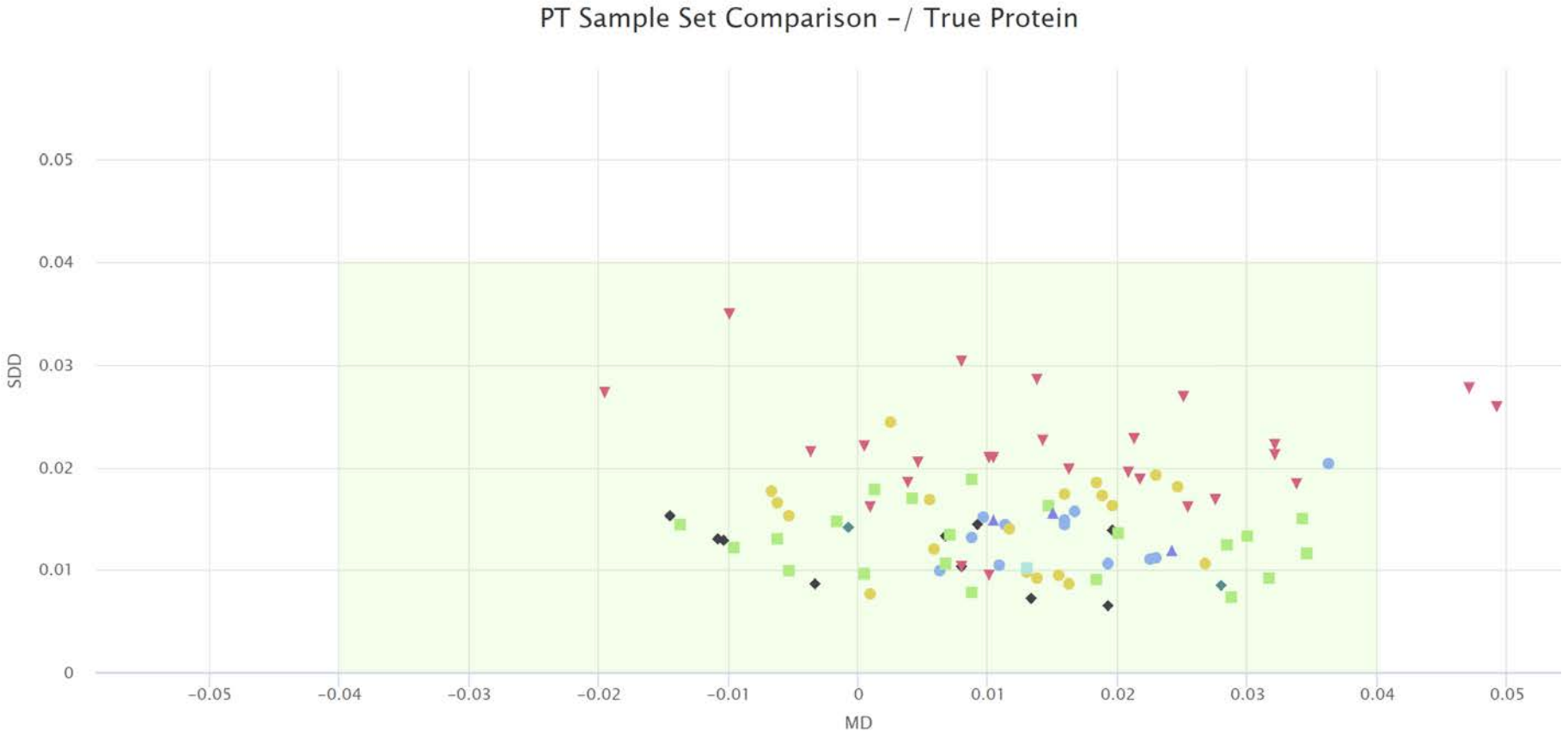


NATIONAL DHIA

Quality Certification Services Inc.

August 2019 True Protein PT Results

- **Slight bias (0.012) on protein results**
- **Bias most likely introduced by calibration samples prior to PT sample week – most laboratories did not notice the shift**

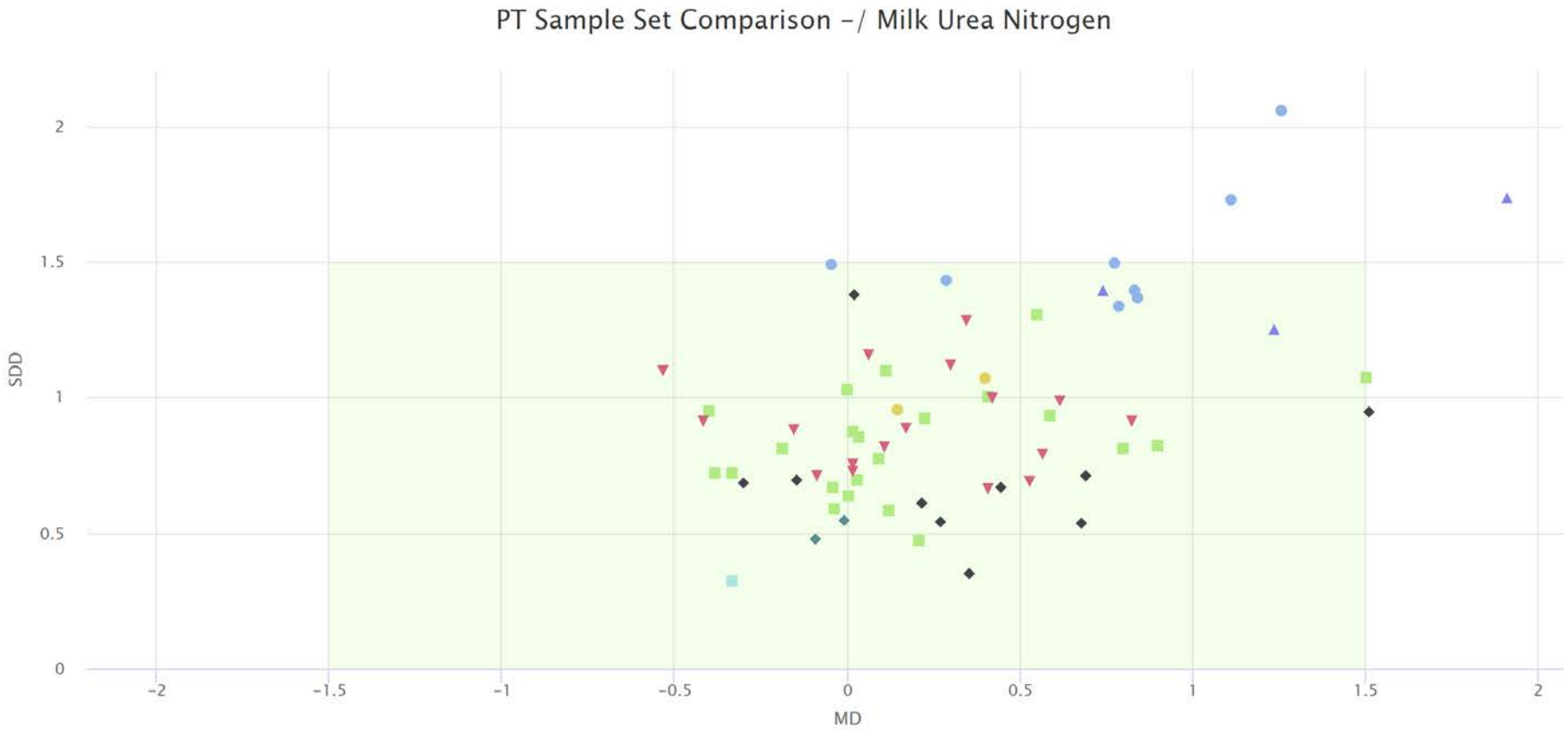


NATIONAL DHIA

Quality Certification Services Inc.

August 2019 MUN PT Results

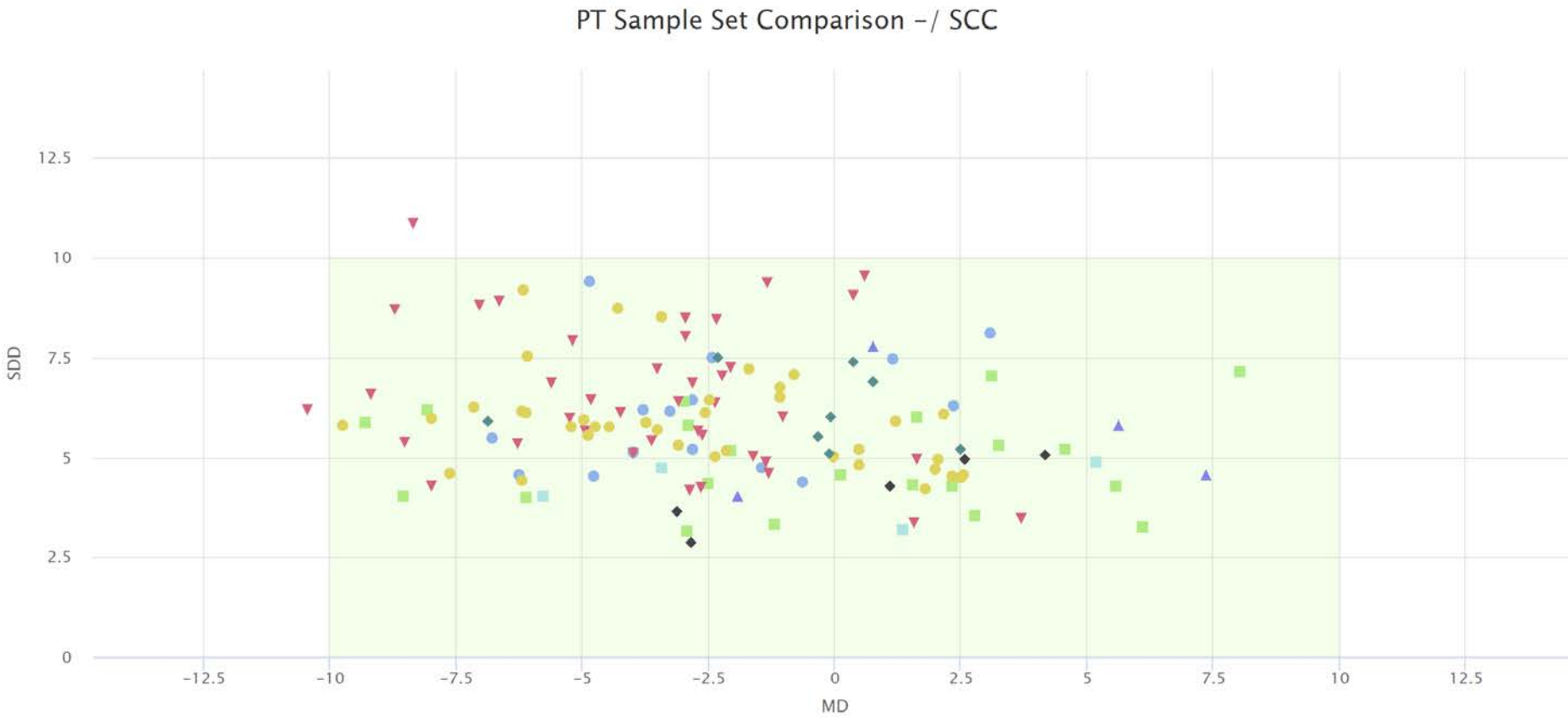
- **Significant differences in results by instrument type however the majority of instruments are within conformance standards.**
- **Opportunity to work with manufacturers if labs agree to share data.**



NATIONAL DHIA

Quality Certification Services Inc.

August 2019 SCC PT Results



NATIONAL DHIA

Quality Certification Services Inc.

Adding a New Instrument

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 adds instrument on PT platform.

Documentation Required

- **Manufacturer training is required and subsequent documentation sent to the QCS Program Manager**
- **Analyze one set of 'special' unknowns with results sent to QC Program Manager and Paul Sauvé.**
- **Perform appropriate and routine QC checks with calibration checks, hourlies and dailies for the first three weeks of operation with results sent to Steven & Paul.**

Managing Equipment at Your Lab

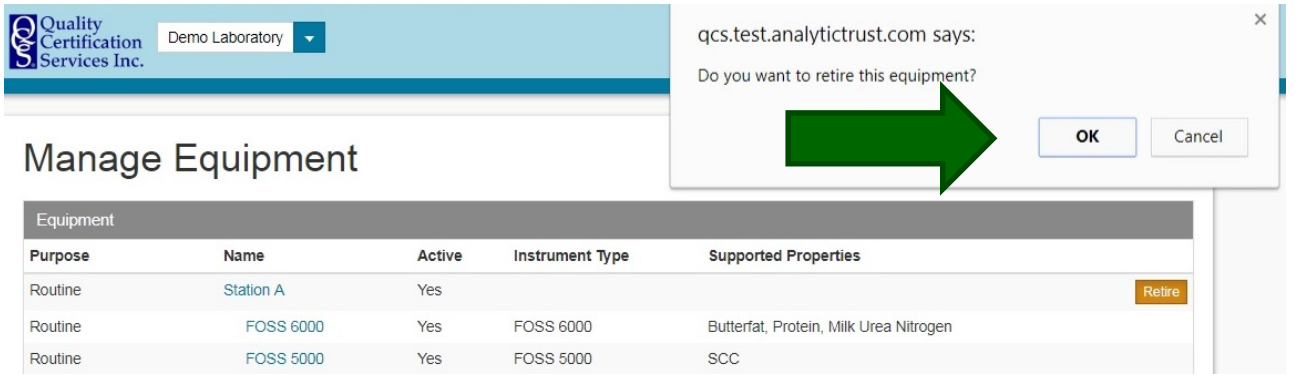
Manage Equipment

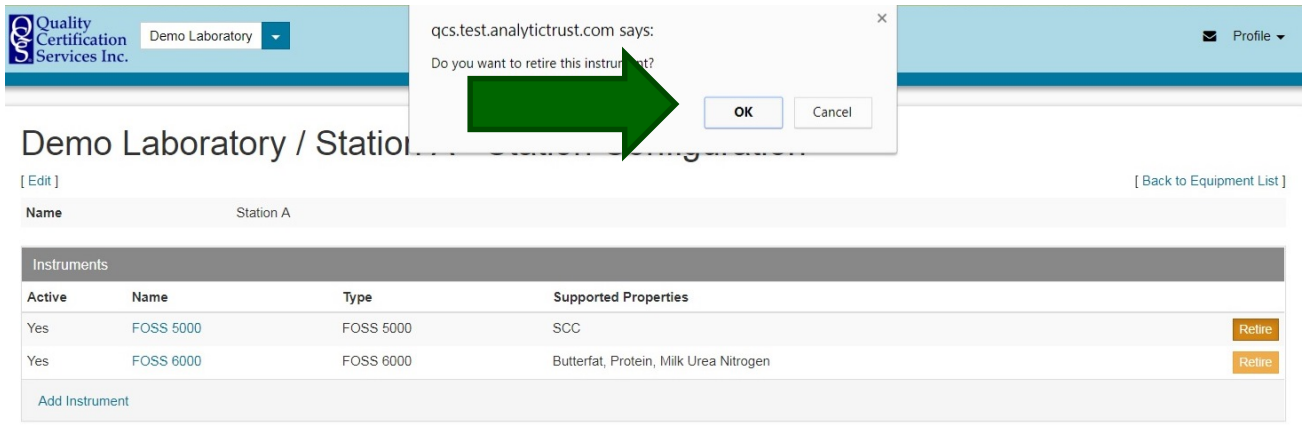
Equipment

Purpose	Name	Active	Instrument Type	Supported Properties	
Routine	Station A	Yes			Retire
Routine	FOSS 6000	Yes	FOSS 6000	Butterfat, Protein, Milk Urea Nitrogen	
Routine	FOSS 5000	Yes	FOSS 5000	SCC	
Routine	Station B	Yes			Retire
Routine	FOSS 6000	Yes	FOSS 6000	Butterfat, Protein, Milk Urea Nitrogen	
Routine	FOSS FC	Yes	FOSS FC	SCC	
Routine	Station C	Yes			Retire
Routine	FOSS FT+	Yes	FOSS FT+	Butterfat, Protein, Milk Urea Nitrogen	
Routine	FOSS 5000	Yes	FOSS 5000	SCC	
Routine	Station D	Yes			Retire
Routine	FOSS FT+	Yes	FOSS FT+	Butterfat, Protein, Milk Urea Nitrogen	
Routine	FOSS FC	Yes	FOSS FC	SCC	
Routine	Station E	Yes			Retire
Routine	FOSS FT+	Yes	FOSS FT+	Butterfat, Protein, Milk Urea Nitrogen	
Routine	FOSS FC	Yes	FOSS FC	SCC	
Reference	REF CHEM	Yes			Retire
Routine	Old Station 1	No			
Routine	FOSS 4000	No	FOSS 4000	Butterfat, Protein, Milk Urea Nitrogen	
Routine	Old Station 2	No			
Routine	FOSS 4000	No	FOSS 4000	Butterfat, Protein, Milk Urea Nitrogen	

Add Station

Retiring Stations and Instruments

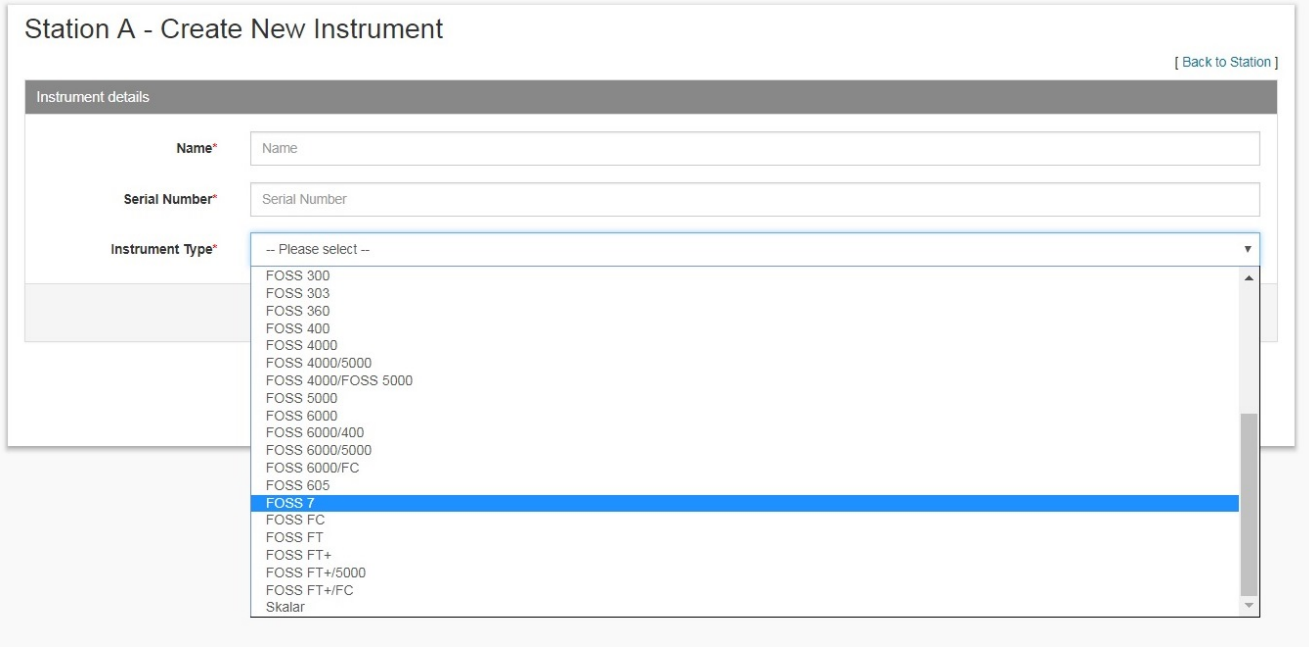




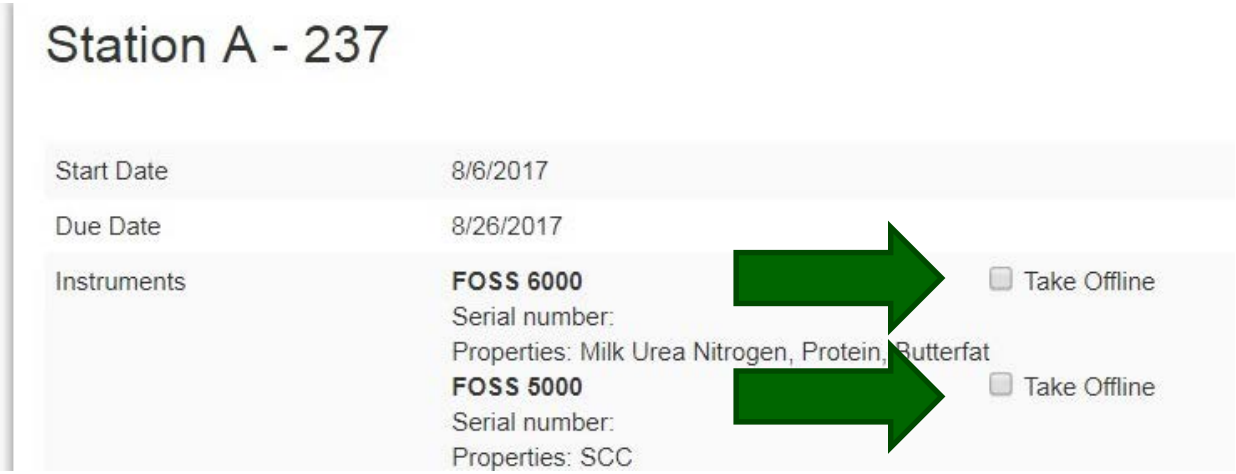
NATIONAL DHIA
Quality Certification Services Inc.

Adding a New Station

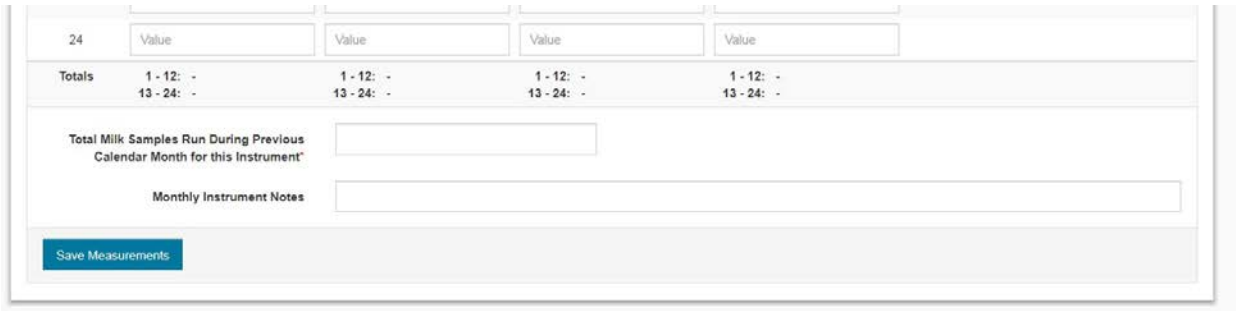
Adding a New Instrument



Marking Instruments Offline During a Monthly Trial



Must enter the number of samples run on the instrument during the previous month



NATIONAL DHIA
Quality Certification Services Inc.

Qualitative PT Programs

Milk ELISA PT for MAP & PAG

NATIONAL DHIA

Quality Certification Services Inc.

QCS Qualitative PT Platform

Designed for multiple qualitative tests

- MAP
- PAG
- Others (BLV, BVD, etc.)
- Milk or Serum based tests

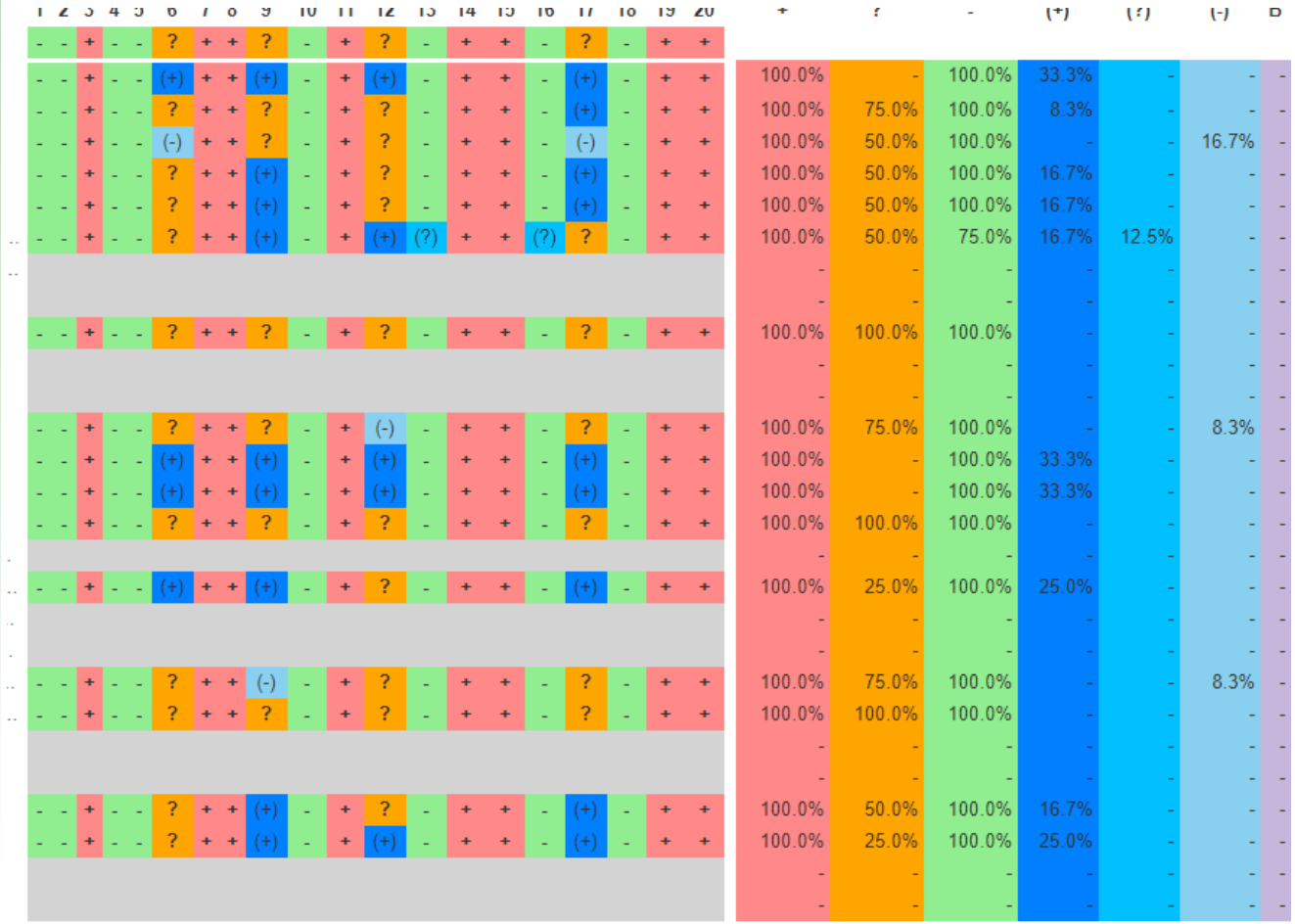
Multiple manufacturers in one PT

- Specific controls for each test kit
- Administrative overview sorted by manufacturer
- Manufacturer only sees results of those technicians using their test kit

NATIONAL DHIA
Quality Certification Services Inc.

Admin View of PT Results

- View of all results to identify trends, sample validity and identify laboratories for follow-up
- Helped gather information related to challenges in quantifying the suspect range
- Internal report only – not shared with individual labs at this time



NATIONAL DHIA

Quality Certification Services Inc.

ELISA PT Report

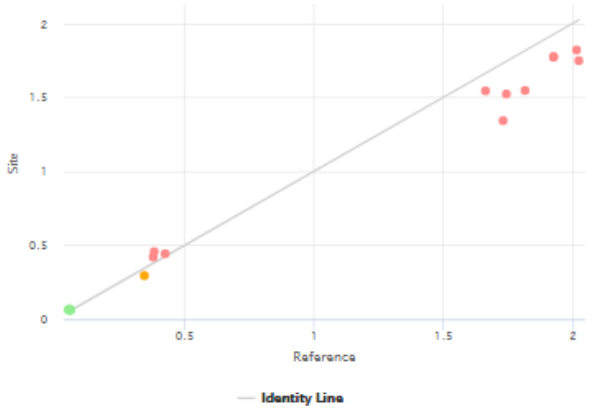
- Removed overall percentage – there is no ‘passing score’
- Shows correct & false positives, negatives, & suspects
- Incorrect suspects do NOT affect certification status
- QC is an on-going process that involves QMS in lab, PT testing & manufacturer support

	Positive	Suspect	Negative
Correct	100.0%	100.0%	100.0%
False	-	-	-

Current PT Sample Set Results

Sample	Reference	Site	Difference	Result		Conclusion
1	0.062	0.055	0.007	-	-	Correct Negative
2	1.770	1.927	-0.157	+	+	Correct Positive
3	0.443	0.427	0.016	+	+	Correct Positive
4	1.543	1.666	-0.123	+	+	Correct Positive
5	0.420	0.378	0.042	+	+	Correct Positive
6	0.063	0.060	0.003	-	-	Correct Negative
7	1.546	1.817	-0.271	+	+	Correct Positive
8	1.819	2.015	-0.196	+	+	Correct Positive
9	0.068	0.054	0.014	-	-	Correct Negative
10	0.063	0.057	0.006	-	-	Correct Negative
11	1.342	1.733	-0.391	+	+	Correct Positive
12	0.063	0.062	0.001	-	-	Correct Negative
13	0.070	0.057	0.013	-	-	Correct Negative
14	0.066	0.057	0.009	-	-	Correct Negative
15	1.522	1.746	-0.224	+	+	Correct Positive
16	1.747	2.024	-0.277	+	+	Correct Positive
17	0.295	0.347	-0.052	?	?	Correct Suspect
18	1.775	1.926	-0.151	+	+	Correct Positive
19	0.068	0.054	0.014	-	-	Correct Negative
20	0.457	0.382	0.075	+	+	Correct Positive

Regression Analysis



Historical Performance

Conclusion	Trial 200 - Johne's	Trial 199 - Johne's	Trial 198 - Johne's	Trial 197 - Johne's	Last 3 Months	Last 6 Months	Last 12 Months
Correct Positive	100.0%	100.0%	-	100.0%	100.0%	100.0%	100.0%
Correct Suspect	100.0%	100.0%	-	-	100.0%	66.7%	66.7%
Correct Negative	100.0%	100.0%	-	100.0%	100.0%	100.0%	100.0%
False Positive	-	-	-	28.6%	-	9.5%	9.5%
False Suspect	-	-	-	-	-	-	-
False Negative	-	-	-	-	-	-	-
Missing	-	-	100.0%	-	-	-	-
Bad measurement	-	-	-	-	-	-	-

Steven Sievert
Manager, Quality Certification Services

NATIONAL DHIA

Quality Certification Services Inc.

IDEXX MAP

S/P Calculation and Interpretation

Calculation of S/P Ratio

$$S/P = \frac{(\text{Sample OD} - \text{Mean NC})}{(\text{Mean PC} - \text{Mean NC})}$$

Qualitative Call	Milk	Serum/Plasma
Negative	S/P ≤ 0.20	S/P ≤ 0.45
Suspect	0.20 > S/P < 0.30	0.45 > S/P < 0.55
Positive	S/P ≥ 0.30	S/P ≥ 0.55

(Old suspect range was 0.30 to 0.40 – changed in 2015)

NATIONAL DHIA

Quality Certification Services Inc.

ELISA MAP Control Results

- Actual negative & positive controls as reported in PT program
- Positive Controls ranged from 0.490 to 1.935
- A suspect sample with OD of 0.250 will result in varying S/P ratios and qualitative calls
- What is normal variation and what is signal for action?

Test Kit	Negative 1	Negative 2	Positive 1	Positive 2	0.250 OD	Call
Ref	0.031	0.032	1.082	1.059	0.210	SUS
7067	0.037	0.038	0.882	0.833	0.259	SUS
7097	0.049	0.040	1.378	1.311	0.158	NEG
7067	0.043	0.042	0.922	0.903	0.239	SUS
7067	0.045	0.045	1.000	0.888	0.228	SUS
7067	0.038	0.039	1.181	1.196	0.184	NEG
7067	0.049	0.049	0.689	0.677	0.317	POS
7097	0.049	0.040	1.378	1.311	0.158	NEG
7097	0.045	0.041	1.687	1.634	0.128	NEG
7067	0.044	0.045	0.984	0.911	0.228	SUS
7067	0.039	0.038	1.425	1.444	0.152	NEG
7067	0.042	0.042	1.224	1.238	0.175	NEG
7067	0.037	0.039	0.832	0.845	0.265	SUS
7067	0.040	0.040	1.309	1.301	0.166	NEG
7067	0.059	0.049	1.293	1.322	0.156	NEG
7097	0.044	0.044	1.305	1.428	0.156	NEG
7097	0.051	0.050	0.583	0.591	0.372	POS
7097	0.050	0.055	0.639	0.676	0.375	POS
7067	0.022	0.024	0.841	0.855	0.275	SUS
7067	0.048	0.049	1.952	1.917	0.107	NEG
7097	0.042	0.042	1.013	1.041	0.211	SUS
7067	0.042	0.044	0.746	0.721	0.300	POS
7067	0.042	0.047	0.487	0.492	0.462	POS
7097	0.040	0.086	0.852	0.828	0.241	SUS
7097	0.040	0.042	0.948	0.857	0.243	SUS

NATIONAL DHIA Quality Certification Services Inc.

August 2019 ELISA MAP Control Results

- Initial Reference Lab Positive Controls ranged averaged 0.705
- All suspects received call of positive based on S/P calculation
- Retest by reference lab and updated reports coming
- Causes?
  - Pipettor?
  - TMB?
  - Plate Washer?
  - Control Plate for Plate Reader?
  - Procedural Drift?

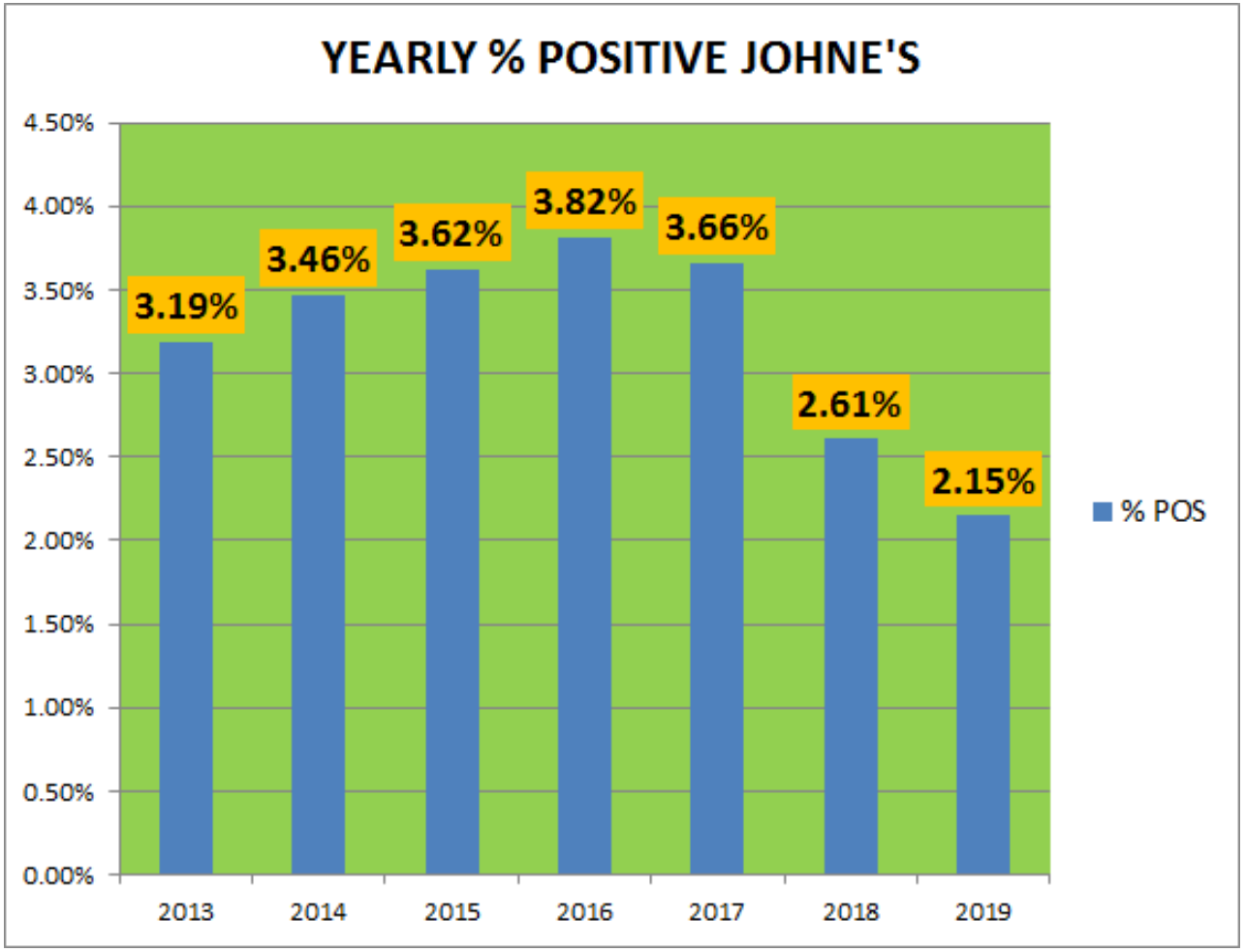
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
-	-	+	+	+	+	+	-	+	-	-	+	+	-	+	-	-	+	+	+
-	-	+	+	+	+	+	-	+	-	-	(?)	+	-	+	-	-	+	(?)	(?)
-	-	+	+	+	+	+	-	+	-	-	+	+	-	+	-	-	+	+	+
-	-	+	+	+	+	+	-	+	-	-	(?)	+	-	+	-	-	(?)	(?)	(?)
-	-	+	+	+	+	+	-	+	-	-	(?)	+	-	+	-	-	(?)	(-)	(-)
-	-	+	+	+	+	+	-	+	-	-	(?)	+	-	+	-	-	(?)	(-)	(-)
-	-	+	+	+	+	+	-	+	-	-	(?)	+	-	+	-	-	(?)	(?)	(?)
-	-	+	+	+	+	+	-	+	-	-	+	+	-	+	-	-	+	(?)	(?)
-	-	+	+	+	+	+	-	+	-	-	(?)	+	-	+	-	-	(?)	(-)	(-)
-	-	+	+	+	+	+	-	+	-	-	+	+	-	+	-	-	(?)	(?)	(?)
-	-	+	+	+	+	+	-	+	-	-	(?)	+	-	+	-	-	(?)	(?)	(?)
-	-	+	+	+	+	+	-	+	-	-	+	+	-	+	-	-	+	(?)	(?)
-	-	+	+	+	+	+	-	+	-	-	(?)	+	-	+	-	-	(?)	(?)	(?)
-	-	+	+	+	+	+	-	+	-	-	(?)	+	-	+	-	-	(?)	(?)	(-)
-	-	+	+	+	+	+	-	+	-	-	(?)	+	-	+	-	-	(?)	(-)	(-)

NATIONAL DHIA

Quality Certification Services Inc.

MAP ELISA

Drop in Percentage of Positive Calls



- Change noticed in October 2017 by Minnesota DHIA
- Thoughts and Discussion?

NATIONAL DHIA
Quality Certification Services Inc.

Milk Pregnancy PT Launch

Final details in Fall 2019

- Number of samples - 12
- Two each - pregnant, recheck, open
- Frequency – bimonthly (alternate with MAP PT test)
- All technicians performing assay participate in each test for PAG & MAP
- Multiple manufacturers supported

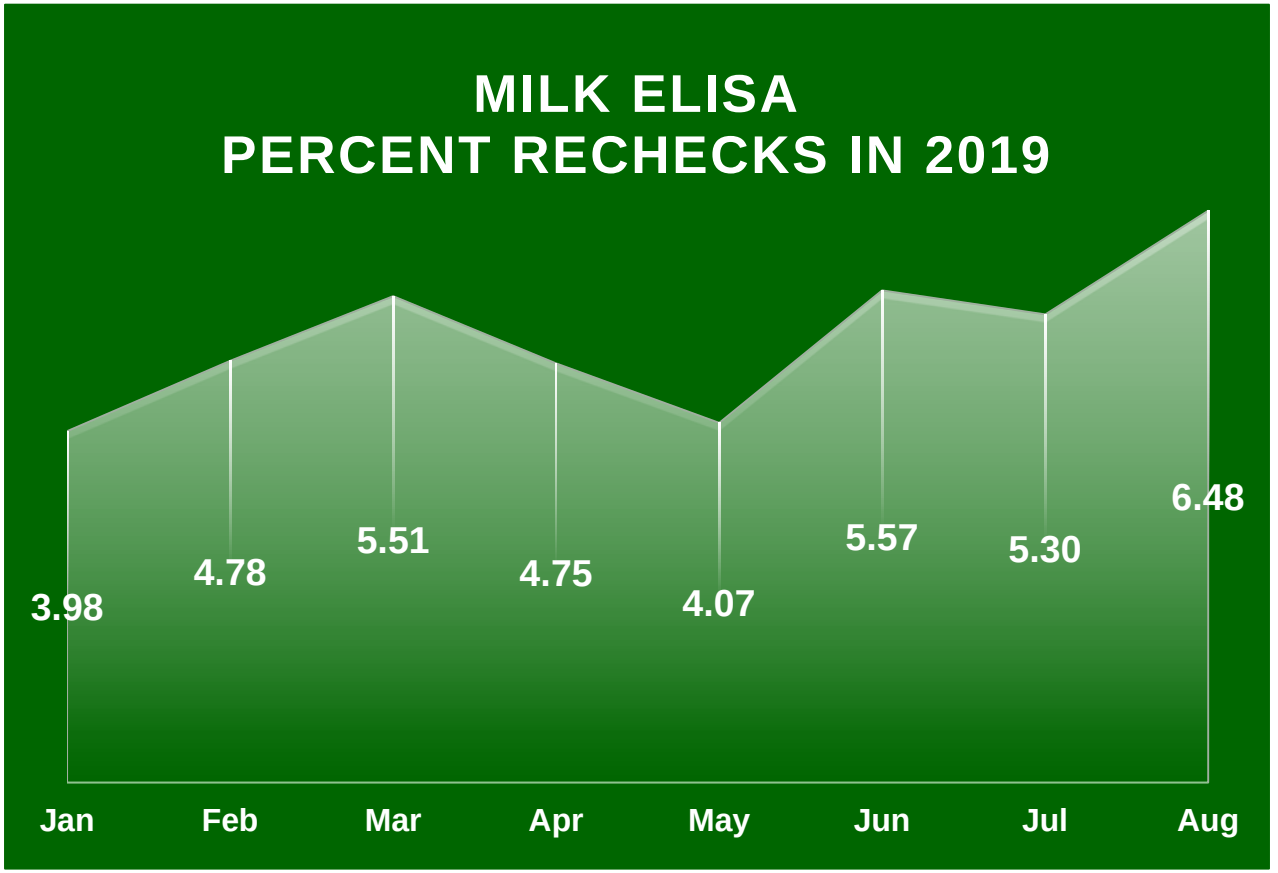
Steps to be taken

- 3-4 labs to test PT trial sensitivity – volunteers?
- Enrollment form from QCS
- Manufacturer support
- Circle of feedback and support to be finalized

NATIONAL DHIA | QCS Quality Certification Services Inc.

ELISA Milk Pregnancy

Focus on ‘Rechecks’



- Data from one lab – 19,916 ELISA PAG tests from January 2, 2019 through August 30, 2019
- Increased percent of rechecks reported by multiple labs – many over 6% recently
- Thoughts and Discussion?

NATIONAL DHIA
Quality Certification Services Inc.