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AnalyticTrust



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What's New in Version 1.2?

- Instructions for qualitative proficiency test programs such as milk ELISA PT trials (pages 34-44).
- Instructions for designating users as technicians for qualitative proficiency tests.
- Explanation of certification reports for qualitative proficiency test trials.

It is the responsibility of the program users to have the most current version of the User Guide as part of respective operating procedures for proficiency program participation.



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QCS Proficiency Testing Program Overview

What is the QCS Proficiency Testing Program?

The QCS Proficiency Testing Program is a dynamic SaaS (Software as a Solution) cloud-based platform for managing both quantitative and qualitative proficiency tests (PT) by participating laboratories. Program administration is handled by Quality Certification Services with input from reference providers, industry professionals and participating laboratories.

Key features of the QCS Proficiency Testing Program include:

- Centralized dashboard for data entry and certification reporting for various proficiency tests.
- Intuitive operation by users.
- Compatible with commonly used browsers and mobile devices.
- **Stable** platform with seamless maintenance.
- **Customizable** by participating sites to allow for managing program users, managing equipment, and designating program tasks.
- Capacity for both quantitative PT programs such as milk component results where tolerance satisfaction is the key metric and qualitative PT programs such as ELISA results where a status call determination is the key metric.
- **Expandable** to include additional PT programs as needed by the industry and/or participating laboratories including additional quantitative milk components, qualitative tests, and new streams of data from infrared analysis.

<u>Powered by the Analytic Trust Platform</u>

The QCS Proficiency Testing Program is powered by the Analytic Trust platform, developed for and by analytical instrument owners desiring flexible and customizable control over instrument procedures and routines. Analytic Trust provides program hosting and support to Quality Certification Services, Inc. for the QCS Proficiency Testing Program.

Analytic Trust does not determine the program guidelines, the conformance metrics, or the determination the certification status, all or in part, for any participating laboratory in any proficiency testing program.

Analytic Trust and Quality Certification Services provide this software and web site for the use and reporting of individual labs participating in the Quality Certification Services proficiency testing program. By entering the web site each user acknowledges and accepts the terms and conditions as presented. All warranties concerning the data and operation of the web site including all warranties of fitness for a particular purpose are limited to correction of any data or operational errors.



Common Terms Used in the QCS Proficiency Testing Program

Quality Certification Services, Inc.

Quality Certification Services, Inc. (QCS) is a wholly owned subsidiary of National DHIA and provides certification services to the various provider segments of the dairy recording industry. The services provided include periodic auditing of cooperators and periodic performance monitoring through proficiency programs.

Quality Certification Services, Inc. does not own any milk analysis or ELISA laboratory, milk recording service provider or dairy records processing center. The role of QCS is as an independent auditor of the services offered by the entity being audited. The QCS logo is a registered trademark of Quality Certification Services, Inc.

QCS does not endorse specific instruments, devices, tests, or software programs used in the DHI industry.

Quantitative Proficiency Test

A quantitative proficiency test is a periodic test that requires reporting of actual component results from routine analysis of a set of 'unknown' proficiency test samples. These results are compared with reference measurements performed on the same set of 'unknown' proficiency test samples. Guidelines for conformance with established tolerances for each component are the metric(s) for evaluation of individual site (laboratory) performance.

The QCS 'Samples Unknown' program is a quantitative proficiency test with guidelines established in the *Auditing Procedures for Laboratories* and *Policies and Procedures*. The QCS 'Samples Unknown' program currently evaluates conformance for fat, protein, MUN, and SCC in milk samples. Copies of these guidelines are available on the QCS website at www.quality-certification.com.

Additional quantitative tests may be added to the QCS Proficiency Testing Program as needed.

Qualitative Proficiency Test

A qualitative proficiency test is a periodic test that requires reporting of measured and interpretative results from a routine assay of a set of 'unknown' proficiency test samples. These results are compared to correct interpretative results from assays performed on the same set of 'unknown' proficiency test samples. Guidelines for conformance for each qualitative test are the metric(s) for evaluation of individual site (laboratory) performance.

The QCS 'ELISA Proficiency Program' is a qualitative proficiency test with guidelines established in the *Guidelines and Procedures for DHI ELISA Proficiency Testing* and *Policies and Procedures*. The QCS 'ELISA Proficiency Program' currently offers proficiency testing for milk ELISA for MAP and pregnancy. Copies of these guidelines are available on the QCS website at www.quality-certification.com.

Additional qualitative tests may be added to the QCS Proficiency Testing Program for milk and serum assays as needed.



Common Terms in the QCS Proficiency Testing Program

<u>Program Administrator</u>

The 'Program Administrator' is designated by QCS and provides the following:

- Maintenance of the QCS Proficiency Program.
- Creation of individual quantitative and qualitative proficiency tests as described in various auditing guidelines and procedures.
- Monitoring performance of participating sites in their respective proficiency tests.
- Support for participating sites using the QCS Proficiency Program.
- Maintaining the confidentiality of data submitted by participating sites.

The 'Program Administrator' may designate administrative access to certain parties for consultative review and program development as needed.

Site, Site Administrator, and User

A 'Site' refers to an individual laboratory or clinic that performs routine quantitative and/or qualitative analysis of milk or serum. A site may have differing levels of participation in various QCS proficiency testing programs.

A 'Site Administrator' refers to the person or persons with administrative control of an individual site's equipment and users. A 'Site Administrator' can add or delete users, stations, or instruments as well as reporting actual quantitative and/or qualitative results for various proficiency tests.

A 'User' within a site is limited in functionality to reporting results and viewing performance or certification reports.

Station

A 'Station' refers to a physical location at the site that comprises one or two instruments. A 'Station' may have one instrument such as a cell counter or MUN analysis instrument or may have two instruments that include a combination of an IR/FTIR instrument and a cell counter.

Site administrators can add new stations, rename existing stations, or retire stations as desired by the specific site.

Instrument

An 'Instrument' refers to a specific instrument(s) that comprise(s) a station. An instrument type is recorded in the system when a new instrument is added to a site.

Site administrators can add new instruments, rename existing instruments, or retire instruments as desired by the specific site. Both site administrators and users may enter proficiency test results for instruments as well as view instrument performance and conformance.



Program Access

QCS Samples Unknown Website Access

The QCS Samples Unknown website is found at:

www.gcs.analytictrust.com

To login into the site, use the credentials provided by the Quality Certification Services, Inc. Manager or by your Site (Laboratory) Administrator. You will have an opportunity to change your password and/or add additional users within the system.



Browser Compatibility and Settings

This website is optimized for use with the following browsers:

- Chrome
- Microsoft Edge
- Safari
- Mozilla Firefox

The website is compatible with most mobile devices for data entry, site management, and report viewing as supported by your device.

Report printing, specifically with color backgrounds, is optimized for Chrome.

A screen resolution of at least 1280x960 pixels is recommended for optimal view. The content of the website is automatically restructured according to screen size.

The website is supported in English at the present time.



Welcome to Your Dashboard

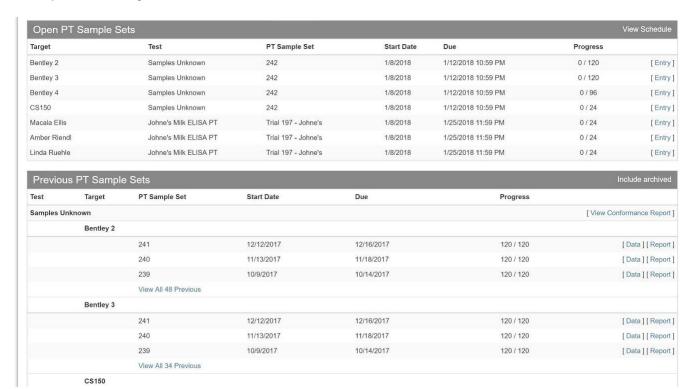
Working with Your Dashboard

After successfully logging into the QCS Proficiency Program, you will be taken to your site dashboard. The dashboard is designed to provide all core data entry and certification report functionalities in an easy to use format. The dashboard is integrated to include both quantitative and qualitative proficiency tests.

At any point while logged into the program, simply click on the QCS logo to return to your dashboard. There are also 'Back to Dashboard' links on individual pages where appropriate to guide you.

The dashboard for your site is arranged in a manner that the tasks requiring attention are positioned at the top of the dashboard with more historical data and performance reports positioned at the bottom. In addition, historical data associated with previous proficiency trials may be expanded to view the entire history for a station and its associated instruments.

For those tasks with a deadline for submission of results, the 'Due' date is prominently displayed within the top sections of your dashboard.



More details on each specific section of your dashboard may be found on the next page.



Key Sections of Your Dashboard – Open PT Sample Sets

Open PT Sample Sets

The 'Open PT Sets' section of your dashboard provides direct data entry links to provide results for any open quantitative or qualitative proficiency tests in which your site is currently a participant. Within the 'Open PT Sets' section, you will find the station (quantitative trials) or technician (qualitative trials). Included are the proficiency test name, the trial number, and the respective submission deadline for each trial. The progress count of submitted data is clearly listed.

Open PT Sample Sets View Schedul					iew Schedule	
Target	Test	PT Sample Set	Start Date	Due	Progress	
Bentley 2	Samples Unknown	242	1/8/2018	1/12/2018 10:59 PM	0 / 120	[Entry]
Bentley 3	Samples Unknown	242	1/8/2018	1/12/2018 10:59 PM	0 / 120	[Entry]
Bentley 4	Samples Unknown	242	1/8/2018	1/12/2018 10:59 PM	0 / 96	[Entry]
CS150	Samples Unknown	242	1/8/2018	1/12/2018 10:59 PM	0 / 24	[Entry]
Macala Ellis	Johne's Milk ELISA PT	Trial 197 - Johne's	1/8/2018	1/25/2018 11:59 PM	0 / 24	[Entry]
Amber Riendl	Johne's Milk ELISA PT	Trial 197 - Johne's	1/8/2018	1/25/2018 11:59 PM	0 / 24	[Entry]
Linda Ruehle	Johne's Milk ELISA PT	Trial 197 - Johne's	1/8/2018	1/25/2018 11:59 PM	0 / 24	[Entry]

To enter results for a specific station (quantitative PT) or technician (qualitative PT), select the 'Entry' option on the right side of this section. Please refer to details instructions for data entry for both quantitative and qualitative proficiency tests in this user guide.

The 'Progress' column provides a cumulative count of the values entered for each specific station with a results submission deadline. Reviewing the progress when visiting your dashboard, especially as a site administrator, provides a quick update on the submission progress for specific stations and identifies needed actions by your site. Please note that the count of values for some test also include data required for control samples such as in qualitative tests.

To view the schedule of upcoming proficiency tests, select the 'View Schedule' option in the gray 'Open PT Sets' header for this section of the dashboard.

-	•				
Test	Sample Set	Start Date	Measurement End Time	Reference Measurement End	Instruments
Samples Unknow	wn				
	237	8/6/2017	8/11/2017 8:06 AM	8/18/2017 8:06 AM	FOSS 5000, FOSS 5000, FOSS 6000, FOSS 6000 FOSS FC, FOSS FC, FOSS FT+, FOSS FT+, FOSS FT+, Station A, Station B, Station C, Station D, Station E
	238	9/11/2017	9/15/2017 11:59 PM	9/22/2017 11:59 PM	FOSS 5000, FOSS 5000, FOSS 6000, FOSS 6000 FOSS FC, FOSS FC, FOSS FC, FOSS FT+, FOSS FT+, FOSS FT+, Station A, Station B, Station C, Station D, Station E
	239	10/9/2017	10/13/2017 11:59 PM	10/20/2017 11:59 PM	FOSS 5000, FOSS 5000, FOSS 6000, FOSS 6000 FOSS FC, FOSS FC, FOSS FC, FOSS FT+, FOSS FT+, FOSS FT+, Station A, Station B, Station C, Station D, Station E
	240	11/13/2017	11/17/2017 11:59 PM	11/24/2017 11:59 PM	FOSS 5000, FOSS 5000, FOSS 6000, FOSS 6000 FOSS FC, FOSS FC, FOSS FC, FOSS FT+, FOSS FT+, FOSS FT+, Station A, Station B, Station C, Station D, Station E



Key Sections of Your Dashboard - Reference Measurement Tasks

Reference Measurement Tasks

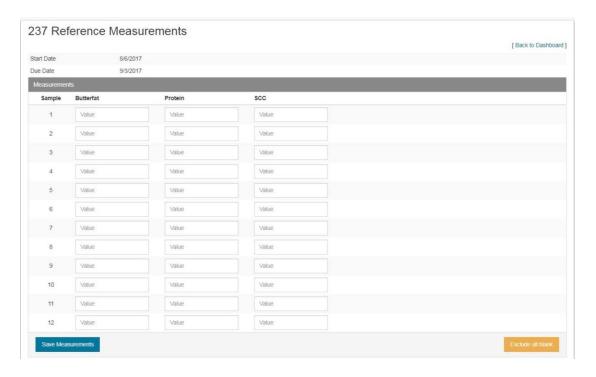
In addition to providing proficiency test results from routine analysis methods, some sites are designated as providers of reference measurements for both quantitative and/or qualitative tests. If your site is required to provide reference measurements, your dashboard will have a section called 'Reference Measurement Tasks.'



The 'Progress' column provides a cumulative count of the reference measurements entered for each proficiency trial with a results submission deadline.

To enter reference measurements for a specific quantitative or qualitative proficiency trial, select the 'Entry' option for that trial and enter the measurements. If you are not able to provide reference results for a specific component and/or sample number, you have the option to select 'Exclude All Blank' prior to saving your data. This will gray out the blank cells and record that there was no reference data provided for that sample.

Select 'Save Measurements' when completed.



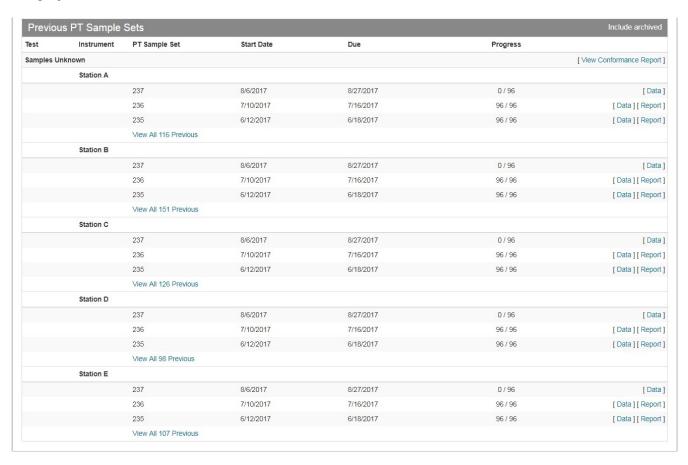


Key Sections of Your Dashboard – Previous PT Sets

Previous PT Sets - Most Recent Three Sample Sets

The 'Previous PT Sets' section of your dashboard provides direct links to both reported station data and certification reports. There is also a link to the conformance report which summarizes all stations with respect to satisfying stated component performance tolerances.

The 'Previous PT Sets' section, as a default, displays the most recent three sample sets for each active station. To include retired stations and their instruments, please select the 'Include Archived' option in the gray section header.



Specific details to viewing and printing various reports offered by the system are provided in detail in both the quantitative and qualitative test section of this user guide.



Key Sections of Your Dashboard – Previous PT Sets

<u>Previous PT Sets – Expanded Historical Sample Sets</u>

The 'Previous PT Sets' section of your dashboard, as a default, displays the most recent three sample sets for each active station. To view the historical data and certification reports for an individual station, select 'View All [Actual Number] Previous' option. When selected, a page of all sample sets that the station participated in historically will appear.



From the expanded historical list of sample sets in the 'Previous PT Sets' functionality, a site may view both data submitted and the certification report for that specific sample set.

When viewing is completed, select 'Back to Dashboard' to return to your dashboard.

Name	Start Date	Due Date	Sample Count	Sample Progress		
236	7/10/2017	7/17/2017	12	12 / 12 [View] [Report]		
235	6/12/2017	6/25/2017	12	12 / 12 [View] [Report]		
234	5/15/2017	5/20/2017	12	12 / 12 [View] [Report]		
233	4/10/2017	4/15/2017	12	12 / 12 [View] [Report]		
232	3/13/2017	3/18/2017	12	12 / 12 [View] [Report]		
231	2/13/2017	2/18/2017	12	12 / 12 [View] [Report]		
230	1/9/2017	1/14/2017	12	12 / 12 [View] [Report]		
229	12/12/2016	12/17/2016	12	12 / 12 [View] [Report]		
228	11/14/2016	11/19/2016	12	12 / 12 [View] [Report]		
227	10/10/2016	10/15/2016	12	12 / 12 [View] [Report]		
226	9/19/2016	9/24/2016	12	12 / 12 [View] [Report]		
225	8/8/2016	8/13/2016	12	12 / 12 [View] [Report]		
224	7/11/2016	7/16/2016	12	12 / 12 [View][Report]		
223	6/13/2016	6/18/2016	12	12 / 12 [View] [Report]		
222	5/9/2016	5/14/2016	12	12 / 12 [View] [Report]		
221	4/11/2016	4/16/2016	12	12 / 12 [View][Report]		
220	3/14/2016	3/19/2016	12	12 / 12 [View] [Report]		
219	2/15/2016	2/20/2016	12	12 / 12 [View] [Report]		

Specific details to viewing and printing various reports offered by the system are provided in detail in both the quantitative and qualitative test section of this user quide.



Quantitative Proficiency Tests – Entering Your Results

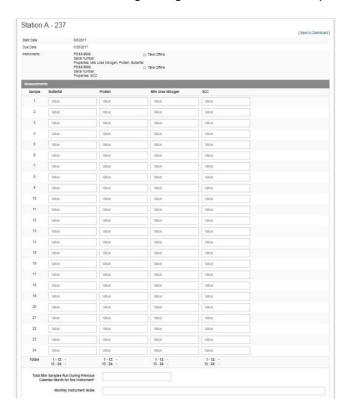
Entering Your Results

The 'Open PT Sets' section of your dashboard provides direct data entry links to provide results for any open quantitative or qualitative proficiency tests in which your site is currently a participant. To enter results for a specific station, select the 'Entry' option on the right side of this section.



Upon selection of the 'Entry' option, you will be taken to a data entry screen for that specific station. All data to be reported will be on a single page including:

- Results for individual samples for each component measured by the instruments at the station.
- Ability to mark instruments at the station offline for the current sample set.
- Reporting of the number of samples run by the station (required).
- Specific notes related to the station regarding maintenance or sample issues (optional).





Quantitative Proficiency Tests – Entering Your Results

Taking an Instrument Offline During the Current Trial

The 'Entry' functionality for each station features a 'Take Offline' option for each instrument that is associated with the station. An instrument may be reported as offline during the current test for the following reasons:

- Instrument is active but not routinely used for sample analysis.
- Instrument is not functioning properly and undergoing repairs.



When checking the 'Take Offline' box next to the specific instrument(s) for the station, the results entry cells for those properties (components) are grayed out on the screen and you will not be required to report data for the affected properties. For example, if the station's cell counter is undergoing repairs and marked offline, only results for properties (components) associated with the IR/FTIR instrument will be reported.

When remaining data entry is complete, select 'Save Measurements' to save the data for the station.

- You can enter specific comments as to the instrument marked offline in the 'Monthly Instruments Notes' box in 'Entry' functionality.
- The actual number of samples run during the previous month must be entered for instruments that are marked offline. If the instrument was offline for entire month, please enter '0' for the number of samples run.
- Station instruments marked offline remain active in the system and will be automatically included in subsequent tests on the 'Entry' functionality.
- If an instrument is permanently offline, please refer to the 'Retire Instruments' functionality described in the 'Manage Equipment' options of this user guide.



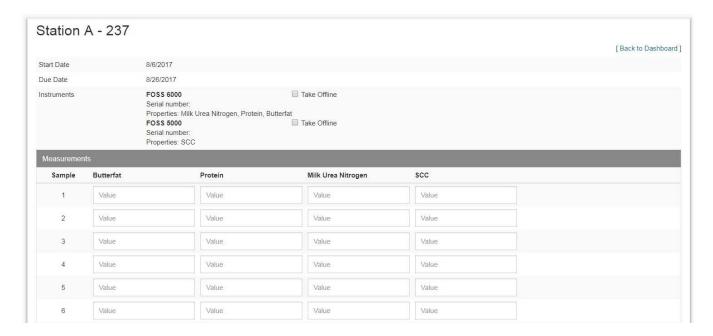
Quantitative Proficiency Tests – Entering Your Results

Manually Entering Your Data

The 'Entry' functionality for each station will populate all properties (components) for the station that are required for reporting. In the case of an instrument that requires reporting of SCC results for both the blue and red filters, columns for each of these values will appear on the 'Entry' screen for that station with those respective instruments.

Data should be entered into the appropriate cells. To navigate between cells, you have two options:

- Using the TAB and Shift-TAB keys navigate horizontally or within rows.
- Using the UP and DOWN ARROW keys navigate vertically or within columns.



- The ENTER or RETURN key cannot be used to advance between cells. The ENTER or RETURN
 key has a submit functionality in some browsing and mobile environments and cannot be used
 to advance between cells in the 'Entry' functionality.
- A site can return to 'Entry' functionality at any point prior to the submission deadline to review or correct data provided. After the submission deadline, any required data entry corrections will need to be made by the Program Administrator.



Quantitative Proficiency Tests – Entering Your Results

Subtotals, Number of Samples Run, and Instrument Notes

The bottom of 'Entry' functionality for each station has three additional features for the site administrator or user.



Subtotals for Each Component

The system will automatically provide subtotals for each component based on sample set design. This functionality allows for identification of data entry errors when reporting results. It is the responsibility of the site administrator or user to verify that the subtotals are correct compared to a site's data worksheets.

Total Number of Samples Run

The number of samples run on the station during the previous calendar month is required to be reported as part of the 'Entry' functionality. Please enter the actual number if your instrument is equipped with external or internal counters or an estimate based site volume if not equipped.

Reporting a value of '1' is not a valid count of samples run during the calendar month considering the station is reporting data for a number of samples greater than '1' in the proficiency test sample set.

Monthly Station or Instrument Notes

The site administrator or user may report specific notes associated with the station related to maintenance, performance or sample quality issues in this section of the 'Entry' functionality. This is an optional field and used by the Program Administrator when reviewing station performance.

HELPFUL HINT

 Remember to select 'Save Measurements' to save results. When you return to your dashboard, the 'Progress' functionality will automatically update to reflect successful data entry for the station.



Quantitative Proficiency Tests – Entering Your Results

Importing Your Data

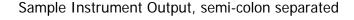
Certain laboratories may wish to use the optional 'Import' functionality for importing quantitative results instead of manually entering the data. The import functionality will import data copied from MS Excel, csv or other instrument output files. This data is pasted into the 'Configure Source Text' box in the QCS Proficiency Test Program.

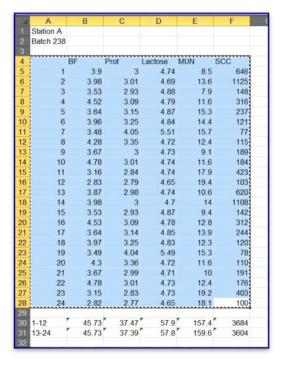
To use the import functionality, laboratories must have the source data files (Excel, csv, text, etc.) configured as follows:

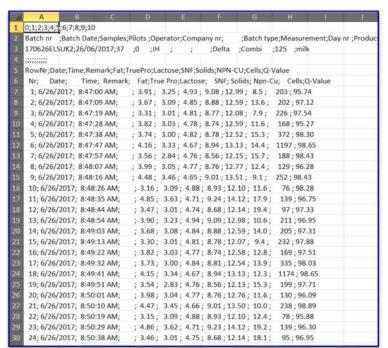
- Samples results must be in consecutive rows in numerical order.
- Calculated subtotals for replicates cannot be inserted into the sample results.
- Extra rows with instrument identification, trial information, date of analysis, and component names are acceptable.
- While the functionality will allow for additional columns of data (results), it is desirable to limit
 the columns to avoid having to scroll across the screen to view all columns for potential import
 into the program.

Example Source Data File Structures

Sample Excel Source Data









Quantitative Proficiency Tests – Entering Your Results

Importing Your Data - continued

To use the import functionality, select 'Import' under the station name. You will note that you can import your data for only one instrument at a time in the QCS Proficiency Testing Program.

Station A - 238



After selecting 'Import' a screen will open up that has two sections.

- The "Configure Source Text" box is where data from your source file is pasted.
- The 'Map Parsed Values' will display the data when pasted, allow for import of designated columns, and finalize the data import.

Configure Source Text

Field Separator
Decimal Separator
Comma Period

Map Parsed Values
Import Data
Cancel



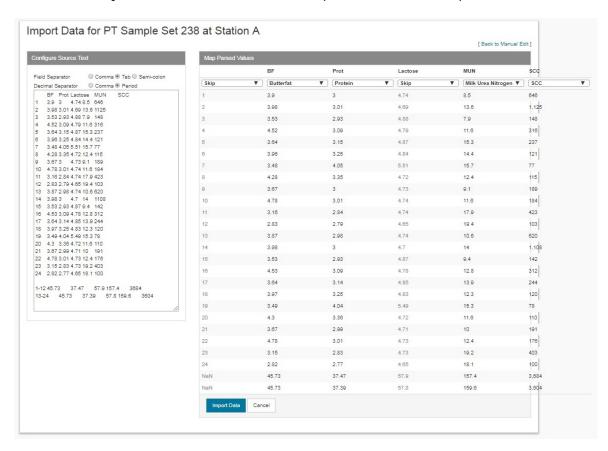
Quantitative Proficiency Tests – Entering Your Results

Importing Your Data - continued

To paste results into the 'Configure Source Text' box, simply highlight the cells in your source file, copy, and paste the data in the box as illustrated below.

To map the pasted data, you must select from the two configuration options:

- Field Separator this is the separator between data in columns
 - o Comma: CSV files
 - Tab: Excel, tab-delimited files
 - Semi-Colon: semi-colon delimited text files, some instrument output files
 - o If nothing appears in the 'Map Parsed Values' box, you can select the various options until your data appears in the appropriate structure
- Decimal Separator this is the configuration for numerical values with decimals
 - Comma: typical use of decimals in Europe (i.e. 4,44%)
 - o Period: typical use of decimals in US (i.e. 4.44%)
 - The system defaults to the use of the period for decimal separator



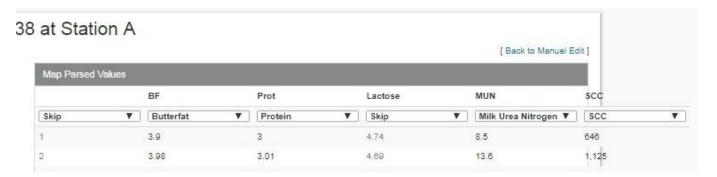


Quantitative Proficiency Tests – Entering Your Results

Importing Your Data - continued

Once your source data is properly configured with the correct field and decimal separators, the columns of data to import are selected in the 'Map Parsed Values' section of the import functionality.

All columns default to 'Skip' and the site must select appropriate component from the dropdown box of possible components for each column of data to import. You will notice that if the source data pasted in the 'Configure Source Text' box has column headers for component names, that name will be displayed above the dropdown box to aid in selecting the appropriate component to import.



After selection of the columns to import, use the 'Import Data' button to import the mapped results.



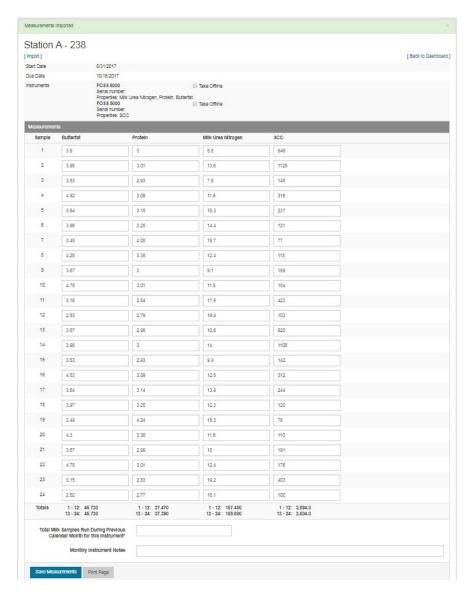


Quantitative Proficiency Tests – Entering Your Results

Importing Your Data - continued

After selecting the 'Import Data' button, your screen will return to the data entry page with the imported data for that station. To finish the import functionality:

- Verify the results were imported into the right columns for each component
- Verify the subtotals are correct
- Enter the number of samples run during the previous month (required)
- Enter any relevant instrument notes or comments
- Select 'Save Measurements' to finalize your data import





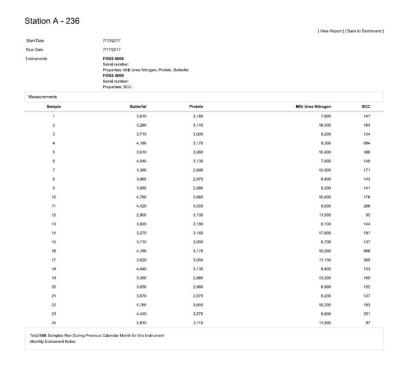
Quantitative Proficiency Tests – Data Entry Confirmation Reports

Data Entry Confirmation Report from Current Sample Sets

To print a data entry confirmation report from the current sample set, select the 'Print Page' button on the data entry screen for each instrument. You will be taken to the print dialog function in your browser.



A copy of the Data Entry Confirmation report for the station will be generated. This report may be printed or stored as a digital file (PDF).



HELPFUL HINT

The data entry confirmation report is specific to each instrument where data is provided. If you
are printing or saving entry confirmation reports, a separate report must be generated for each
active instrument.



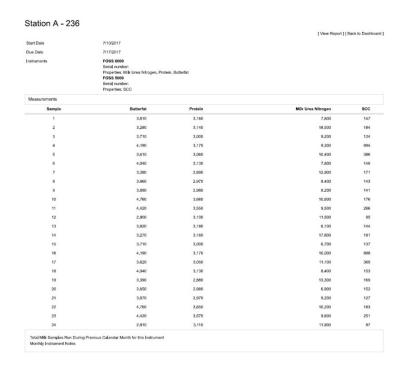
Quantitative Proficiency Tests – Data Entry Confirmation Reports

Data Entry Confirmation Report from Previous Sample Sets

To view the data reported for each station, select 'Data' in the 'Previous PT Sample Sets' functionality on your dashboard associated within the listed stations and PT Sample Sets.



A copy of the Data Entry Confirmation report for the station will be generated. This report may be printed or stored as a digital file (PDF).



HELPFUL HINT

The data display on the screen may be copied to a local file as desired. To copy the data, highlight
the data desired, right click to copy, and paste in a MS Excel workbook. Column and data
formatting will be preserved.

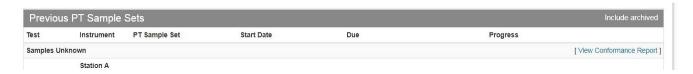


Quantitative Proficiency Tests – Conformance Reports

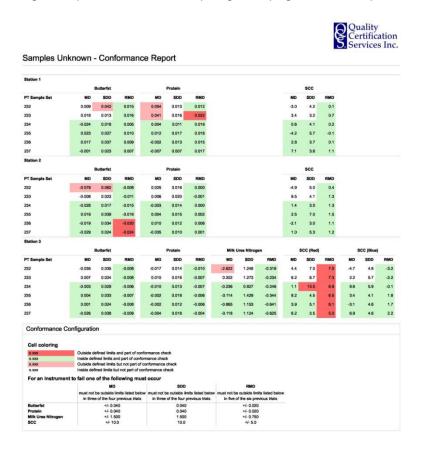
Conformance Reports

The conformance report for quantitative proficiency tests provides a summary of all stations related to performance metrics or tolerances outlined for the proficiency test. As the conformance report is a historical review, the report will always report the results of the most recently completed samples sets.

To view the report for your site, select 'View Conformance Report' in the 'Previous PT Sample Sets' functionality on your dashboard.



The bottom of the conformance report includes a legend for the color-coding of station performance and tolerances for each property (component) included in the report. The conformance report displays all active instruments at your laboratory; however, you have the option to display 'only nonconformant instruments' by selecting the option (located at top, right of page) on the report.





Quantitative Proficiency Tests – Certification Reports

Certification Reports

Certification reports for quantitative proficiency tests are specific to each station but include a comparison chart for all stations reporting results in the proficiency test sample set viewed.

To view the report for each station, select 'Report' in the 'Previous PT Sample Sets' functionality on your dashboard associated within the listed stations and PT Sample Sets.



The certification report for each station contains both summary data and charts for each property (component) measured by the instruments for the respective station. Key components of the certification report include:

- Summary statistics for each property (component) for all reporting sites and for the specific station you are viewing.
- Comparison chart of instrument performance for the property (component) for the station, other stations at your site, reference measurements (if reported by your site), and all instruments reporting results for the property as part of the PT Sample Set.
- Calculated regression and identity lines for the property (component) at the station.
- Plotted performance of the station instrument during the previous twelve trials for mean difference.
- Historical performance chart of the instrument for trial mean difference and standard deviation
 of the difference along with a calculated rolling mean difference.

- Certification reports may be printed or saved as a digital file (PDF). Printing is optimized for Chrome as a browser.
- Certification Reports are specific for the station viewing. If you have more than one station, a certification report for each station may be viewed and printed.
- The Nonconformance Report provides a summary of nonconformance issues for all stations at a specific site.

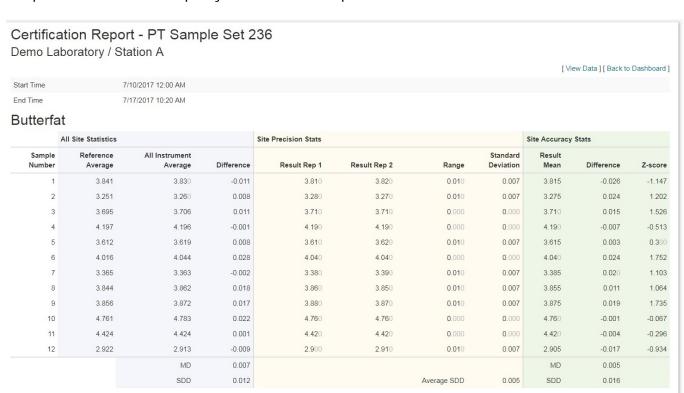


Quantitative Proficiency Tests – Certification Reports

<u>Certification Reports – Summary Statistics</u>

Certification reports for quantitative proficiency tests are specific to each station but include a comparison chart for all stations reporting results in the proficiency test sample set viewed.

The certification report is arranged by property (component) reported with summary statistics for PT sample set viewed at the top of your certification report.



Key components of the summary statistics for each property (component) in the certification report include:

- Blue section of summary statistics
 - Average of the reference measurements
 - Average results of all instruments reporting data for the property
- Yellow section of summary statistics
 - Actual results for each sample of the replicates for the station
 - Range and standard deviation for the replicate results
- Green section of the summary statistics
 - Mean result for each sample for the station
 - Standard deviation for each sample for the station
 - Z-score for each sample for the station
 - o Mean Difference (MD) and Standard Deviation of the Difference (SDD) for the station

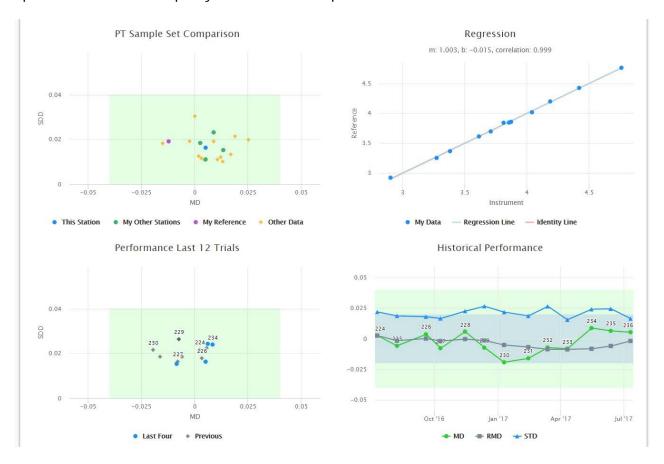


Quantitative Proficiency Tests – Certification Reports

Certification Reports - Performance Charts

Certification reports for quantitative proficiency tests are specific to each station but include a comparison chart for all stations reporting results in the proficiency test sample set viewed.

The certification report is arranged by property (component) reported with performance charts for PT sample set viewed at the top of your certification report.



There are four charts of performance for each station.

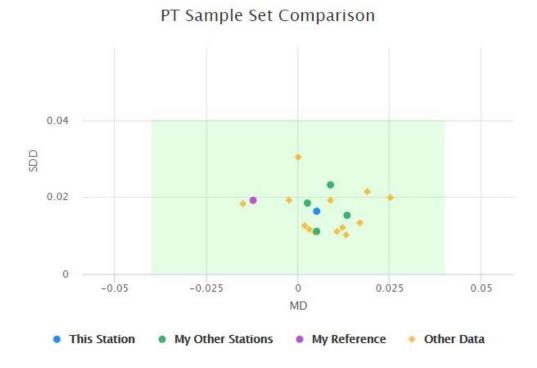
- PT sample set comparison
- Regression
- Performance of the station over the last twelve trials
- Historical performance of the station for MD, SDD, and RMD



Quantitative Proficiency Tests – Certification Reports

Certification Reports - PT Sample Set Comparison

The PT Sample Set Comparison chart combines data from all station instruments reporting results for the specific property (component) during the specific sample set.



Data is color coded and includes four types of data:

- BLUE the station being viewed
- GREEN other stations at your site that reported data for the sample set
- PURPLE reference measurement reported by your site (only for reference providers)
- ORANGE data from all stations reporting data for the sample set

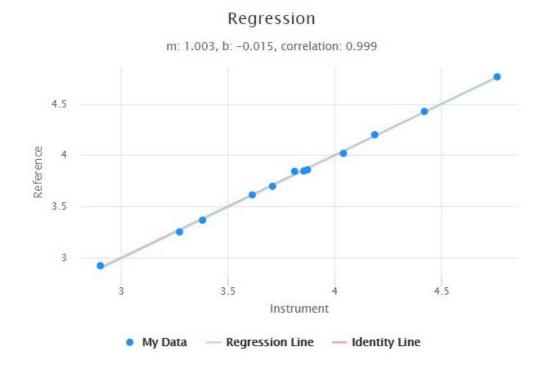
- You can toggle on or off displayed data in the chart by clicking on the legend for the chart.
- You can highlight a specific area in the chart to zoom in to view the data.
- The chart has a 'mouse-over' function that will display the actual values for MD and SDD for each point in the chart. Instrument names will only be displayed for your stations.



Quantitative Proficiency Tests – Certification Reports

Certification Reports - Regression and Identity Lines

The Regression Line chart plots all data for this station and computes a regression line with slope and intercept based on the data reported for the station.



- You can toggle on or off displayed data in the chart by clicking on the legend for the chart.
- You can highlight a specific area in the chart to zoom in to view the data.
- The chart has a 'mouse-over' function that will display the actual values for MD and SDD for each point in the chart.



Quantitative Proficiency Tests – Certification Reports

Certification Reports - Performance in Last Twelve Trials

The chart of the station performance during the previous twelve trials allows for a quick view of conformance for the station.



Data is color coded and includes three types of data:

- GREEN HIGHLIGHTED BOX the conformance area for the property (component) defined by the proficiency test guidelines
- BLUE DATA the last four trials reported by the station
- GRAY DATA data reported during the previous twelve trials by the station

- You can toggle on or off displayed data in the chart by clicking on the legend for the chart.
- You can highlight a specific area in the chart to zoom in to view the data.
- The chart has a 'mouse-over' function that will display the actual values for MD and SDD for each point in the chart.



Quantitative Proficiency Tests – Certification Reports

<u>Certification Reports - Historical Performance Chart</u>

The chart of the historical station performance during the previous twelve trials allows for a quick view of MD, SDD and RMD over time.



Data is color coded and also highlights conformance bands for MD and RMD for the property (component) in the chart.

- GREEN HIGHLIGHTED BAND the MD conformance tolerance for the property (component) defined by the proficiency test guidelines.
- BLUE HIGHLIGHTED BAND (WITHIN THE GREEN BAND) the RMD conformance tolerance for the property (component) defined by the proficiency test guidelines.

- You can toggle on or off displayed data in the chart by clicking on the legend for the chart.
- You can highlight a specific area in the chart to zoom in to view the data.
- The chart has a 'mouse-over' function that will display the actual values for MD, SDD and RMD for each point in the chart.

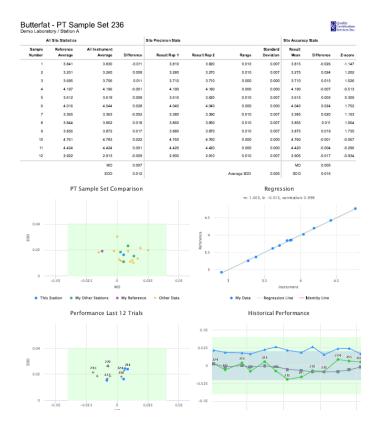


Quantitative Proficiency Tests – Certification Reports

Certification Reports - Printing Certification Reports

Certification reports for quantitative proficiency tests are specific to each station but include a comparison chart for all stations reporting results in the proficiency test sample set viewed.

Certification reports may be printed or saved as a digital file (PDF). A printed report will have a cover page and one page for each property (component) reported by the station.



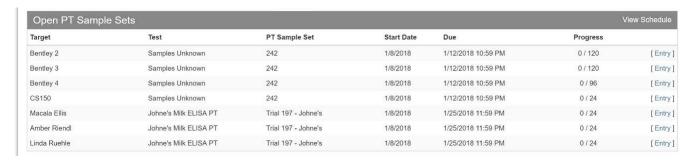
- The data displayed on the screen may be copied to a local file as desired. To copy the data, highlight the data desired, right click to copy, and paste in a MS Excel workbook. Column and data formatting will be preserved.
- Certification reports may be printed or save as a digital file (PDF). Printing is optimized for Chrome as a browser.
- Certification Reports are specific for the station viewing. If you have more than one station, a certification report for each station may be viewed and printed.



Qualitative Proficiency Tests – Entering Your Results

Entering Your Results

The 'Open PT Sets' section of your dashboard provides direct data entry links to provide results for any open quantitative or qualitative proficiency tests in which your site is currently a participant. To enter results for a specific technician, select the 'Entry' option on the right side of this section.



Upon selection of the 'Entry' option, you will be taken to a data entry screen for that specific technician. All data to be reported will be on a single page including:

- Both actual measurements and qualitative calls for individual samples for each sample measured by the technician.
- Reporting of batch information, test kit information and control samples.
- Ability to mark instruments or the technician offline for the current sample set.
- Statement of veracity of results (optional for some qualitative PT procedures).



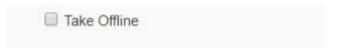


Qualitative Proficiency Tests – Entering Your Results

Taking a Technician Offline During the Current Trial

The 'Entry' functionality for each station features a 'Take Offline' option for each technician that is associated with the qualitative procedure. A technician may be reported as offline during the current test for the following reasons:

- Technician is active but not routinely performing qualitative testing.
- Technician is temporarily inactive such as maternity/paternity leave, military services, etc.



When checking the 'Take Offline' box next to the specific technician(s) for the trial, the results entry cells for those properties (components) are grayed out on the screen and you will not be required to report data for the affected properties.

When remaining data entry is complete, select 'Save Measurements' to save the data for the station.

- Technicians marked offline for a specific procedure remain active in the system and will be automatically included in subsequent tests on the 'Entry' functionality.
- If a technician performs more than one qualitative PT procedure, a technician may be marked offline for one procedure and remain active for all other procedures.
- If a technician has left the laboratory or is no longer performing the test, please refer to the 'Retire Technician' functionality described in the 'Manage Users' options of this user guide.



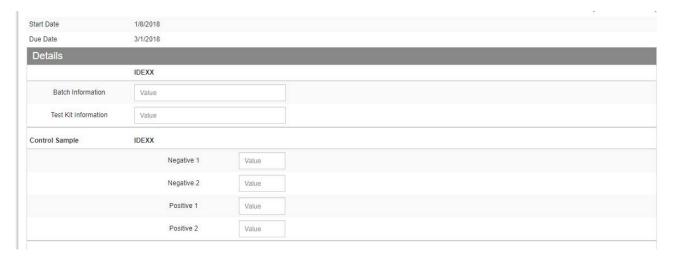
Qualitative Proficiency Tests – Entering Your Results

Entering Test Kit, Sample Lot and Control Results

Qualitative PT trials require additional information to be entered along with your actual test results. This information is used for monitoring data accuracy and trouble shooting performance issues internally at QCS and externally with the test kit manufacturer for the specific PT trial.

Data to be entered includes:

- Batch Information this is the information printed on the sample set.
- Test Kit Information this is the lot, date, etc., as printed on the manufacturer test kit.
- Control Values depending on the type of test and the manufacturer, the controls will vary
 according to test kit instructions. For example, some test kits require positive and negative
 controls to be performed in duplicate while other test kits require controls of a determined range
 of values to be performed, each as a single value.



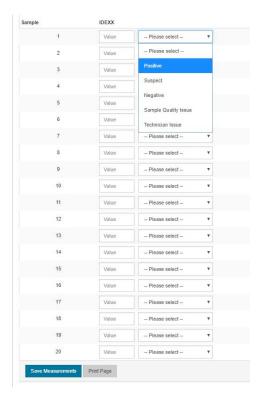
- The ENTER or RETURN key cannot be used to advance between cells. The ENTER or RETURN key has a submit functionality in some browser and mobile environments and cannot be used to advance between cells in the 'Entry' functionality.
- A site can return to 'Entry' functionality at any point prior to the submission deadline to review or correct data provided. After the submission deadline, any required data entry corrections will need to be made by the Program Administrator.



Qualitative Proficiency Tests – Entering Your Results

Entering Actual O.D. Values and Qualitative Interpretation of Results

Qualitative PT trials require two types of data to be entered for each sample. The actual optical density (OD) should be entered in the box marked 'Value' and the qualitative interpretation of the OD based on the test kit instructions should be entered using the drop-down box.



Qualitative Interpretation Options

The drop-down box will offer five (5) options for qualitative interpretation that include negative, suspect, or positive for each sample. These names may change for specific procedures such as pregnancy and will be listed as open, recheck, or pregnant in this case. In addition, two other options are available that include 'Sample Quality Issue' or 'Technician Issue' for known issues in the laboratory that could affect outcome. In all cases where a known issue with a sample is reported, the results from that sample are excluded in calculation of all performance metrics associated with the PT trial.

HELPFUL HINT

 Remember to select 'Save Measurements' to save results. When you return to your dashboard, the 'Progress' functionality will automatically update to reflect successful data entry for the station.



Qualitative Proficiency Tests – Data Entry Confirmation Reports

Data Entry Confirmation Report from Current Sample Sets

To print a data entry confirmation report from the current sample set, select the 'Print Page' button on the data entry screen for each technician. You will be taken to the print dialog function in your browser.



A copy of the Data Entry Confirmation report for the station will be generated. This report may be printed or stored as a digital file (PDF).



HELPFUL HINT

• The data entry confirmation report is specific to each technician where data is provided. If you are printing or saving entry confirmation reports, a separate report must be generated for each technician and for each procedure.



Qualitative Proficiency Tests – Certification Reports

Certification Reports

Certification reports for qualitative proficiency tests are specific to each technician for each procedure.

To view the report for each technician, select 'Report' in the 'Previous PT Sample Sets' functionality on your dashboard associated within the listed technicians and PT Sample Sets.



The certification report for each technician contains both summary data and charts for each procedure tested by the technician for the respective PT trial. Key components of the certification report include:

- Summary of qualitative interpretation and reference interpretation for each sample in the PT trial.
- Summary statistics for overall performance as well as correct and false negative, positive, and suspect samples.
- Calculated regression and identity lines for the procedure as reported by the technician.
- Summary of historical performance for each calculated metric (i.e. correct positives).

- Certification reports may be printed or saved as a digital file (PDF). Printing is optimized for Chrome as a browser.
- Certification reports are specific for the station viewing. If you have more than one station, a certification report for each station may be viewed and printed.



Qualitative Proficiency Tests – Certification Reports

<u>Certification Reports - Summary Statistics</u>

Certification reports for qualitative proficiency tests are specific to each procedure and each technician.

The certification report is arranged in key areas for view with summary statistics for PT sample set viewed at the top of your certification report.

	Positive	Suspect	Negative	Overall
Correct	62.5%	80.0%	91.7%	80.0%
False	-	15.0%	-	00.0%

Key components of the summary statistics in the certification report include:

- Overall Conformance (percentage)
- Percentage of Correct Positive Samples
- o Percentage of Correct Suspect Samples
- Percentage of Correct Negative Samples
- Percentage of False Positive Samples
- Percentage of False Suspect Samples
- o Percentage of False Negative Samples

While overall performance may be viewed as a critical measure, the qualitative PT trial is designed to measure the conformance in each class of sample. Conformance criteria may vary for each metric based on the guidelines for each qualitative procedure.

Samples reported as having a 'Sample Quality Issue' or 'Technician Issue' are excluded from all calculations of overall performance as well as individual conformance for correct/false positive, suspect, and negative samples.



Qualitative Proficiency Tests – Certification Reports

Certification Reports - Performance Charts

Certification reports for qualitative proficiency tests are specific to each technician.

The 'Current PT Sample Set Results' provides a comparison of reported technician results and reference results for each sample in the PT trial. Both actual OD results (numerical results) and qualitative interpretation of these results are included in this section of the certification report.

Current PT Sample Set Results

Sample	Reference	Site	Difference	Re	sult	Conclusion
1.	0.051	0.047	0.004		I +0	Correct Negative
2	1.663	0.914	0.749	+	?	False Suspect
3	1.187	0.978	0.209	?	?	Correct Suspect
4	1.078	0.883	0.195	?	?	Correct Suspect
5	0.107	0.051	0.056	2	-	Correct Negative
6	0.055	0.056	-0.001		1.5	Correct Negative
7	2.041	1.617	0.424	*	3.00	Correct Positive
8	0.961	0.807	0.154	?	?	Correct Suspect
9	1.053	0.893	0.160	+	?	False Suspect
10	1,650	1.391	0.259	+	3.40	Correct Positive
11	0.059	0.058	0.001	150	- 50	Correct Negative
12	0.052	0.053	-0.001	0.00	1	Correct Negative
13	0.058	0.053	0.005		В	Bad measurement
14	1.475	1.324	0.151	٠	+	Correct Positive
15	1.110	0.902	0.208	+	?	False Suspect
16	0.051	0.051	0.000	(a)	1.47	Correct Negative
17	1.920	1.618	0.302	+	+	Correct Positive
18	1.062	1.097	-0.035	?	В	Bad measurement
19	0.052	0.055	-0.003		120	Correct Negative
20	1.798	1.705	0.093	+	+	Correct Positive
21	0.058	0.054	0.004	::::		Correct Negative
22	0.878	0.741	0.137	?	?	Correct Suspect
23	0.052	0.051	0.001	3.71		Correct Negative
24	0.052	0.049	0.003	(4)	40	Correct Negative
25	0.049	0.049	0.000	•		Correct Negative

Metrics are color coded for each sample with respect to conformance metric. The colors used coordinate with colors used in the summary and historical performance sections of the certification report.

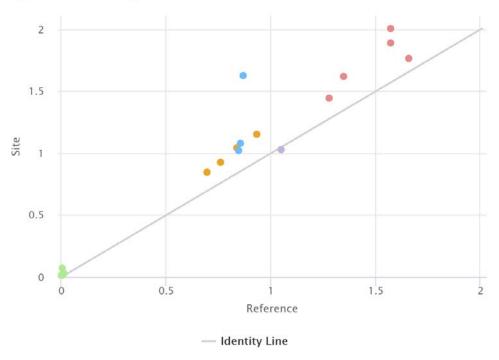


Qualitative Proficiency Tests – Certification Reports

Certification Reports - Regression and Identity Lines

The Regression Line chart plots all data for the technician and computes a regression line with slope and intercept based on the data reported by the technician.

Regression Analysis



- You can toggle on or off displayed data in the chart by clicking on the legend for the chart.
- You can highlight a specific area in the chart to zoom in to view the data.
- The chart has a 'mouse-over' function that will display the actual values for each point in the chart.



Qualitative Proficiency Tests – Certification Reports

Certification Reports - Historical Performance Summary

The chart of the historical technician performance during the previous twelve months allows for a quick view of performance metrics over various time periods.

While annual performance may be a key metric for conformance, trends over shorter periods are useful for identification of non-conformances requiring attention at the laboratory level. The conformance levels for each metric may vary by the procedure and are outlined in the guidelines for each PT trial.



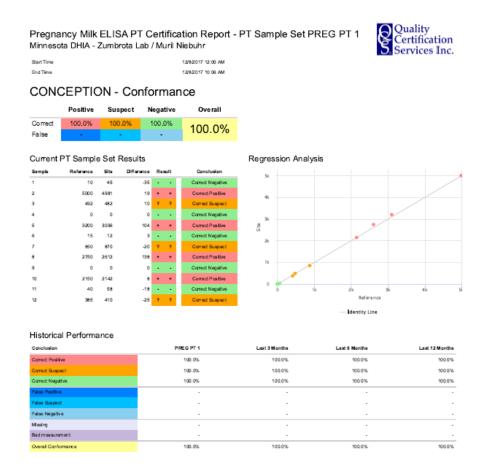
Metrics are color coded for each conformance area in the historical summary.



Qualitative Proficiency Tests – Certification Reports

Certification Reports - Printing Certification Reports

Certification reports for qualitative proficiency tests are specific to each technician. Certification reports may be printed or saved as a digital file (PDF). A printed report will have a cover page and one page for each procedure reported by the technician.



- The data displayed on the screen may be copied to a local file as desired. To copy the data, highlight the data desired, right click to copy, and paste in a MS Excel workbook. Column and data formatting will be preserved.
- Certification reports may be printed or save as a digital file (PDF). Printing is optimized for Chrome as a browser.
- Certification Reports are specific for the technician viewing. If you have more than one technician, a certification report for each station may be viewed and printed.



Managing Users – Accessing the Tools

Accessing the Manage Users Tools

To access the 'Manage Users' tools, highlight the 'Setup' dropdown on the tool bar above your dashboard. Select 'Manage Users' from the options available.



Options for 'Manage Users'

Upon selection of the 'Manage Users' functionality, the website will display a list of all users associated with your site.



There are three main options within the 'Manage Users' functionality.

- Edit Existing User
- Change Password
- Create User

To return to your dashboard at any time, select 'Back to Dashboard.'

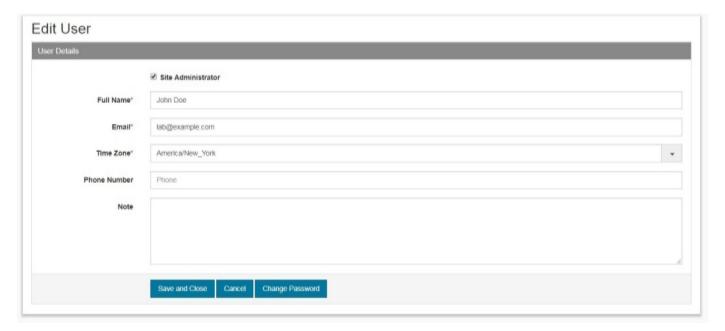


Managing Users – Edit Existing Users

Editing Existing Users

To edit an existing user, select the name of the user you wish to edit. Upon selection, edit the information as desired.

When complete, select 'Save and Close' to store the password changes.



- The fields with an asterisk are required.
- If you are the only site administrator, do not uncheck the 'site administrator' box or you will not be able to add additional users or manage equipment moving forward.
- Remember to select 'Save and Close' when your edits are complete.



Managing Users – Changing Your Password

Changing Your Password

There are two options to reach the 'Change Password' functionality.

- Select 'Change Password' for the user you wish to change on the 'Manage Users' page.
- Select 'Change Password' on the 'Edit User' page when editing a specific user.

Enter the new password in both the 'Password' and 'Password Confirmation' boxes. If the passwords entered do not match, a warning error will appear.

When complete, select 'Save and Close' to store the password changes.



- Passwords may be a combination of letters, numbers or characters. While there are no specific rules for password creation, it is advised to create a password that is strong and secure.
- Remember to select 'Save and Close' after entering and confirming your new password.



Managing Users - Create User

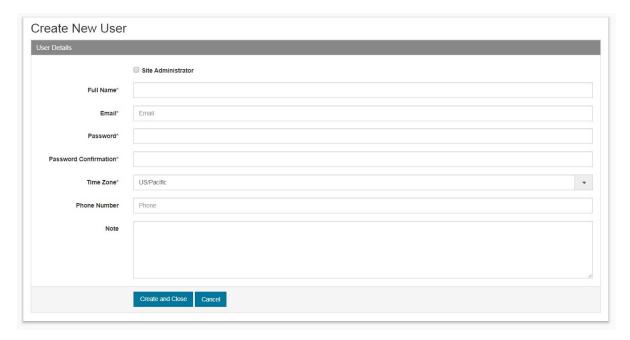
Creating a New User

To create a new user, select the 'Create User' on the 'Manage Users' page previously described. A new window will open to add the required information for the new user.

When creating a new user, you have the option to designate the user as an additional site administrator. To designate the new user as an additional administrator, mark the box adjacent to 'Site Administrator.'

- User: A user can enter test results and view reports for the various quantitative and qualitative proficiency tests that the site participates in on a routine basis.
- Administrator: In addition to all user functions, an administrator can change names of stations and instruments, retire and add instruments, and create or delete site users.

When complete, select 'Create and Close' to create the new user.



- The fields with an asterisk are required.
- Remember to select 'Create and Close' when your edits are complete.



Managing Users – Designating Users as Technicians for Qualitative Proficiency Tests

Designating Users as Technicians for Qualitative Proficiency Tests

To participate in qualitative PT trials, site users must be designated as a 'Technician' in the system. To designate a site user as a technician, select the 'Edit User' on the 'Manage Users' page previously described. A new window will open to edit an existing user.

When editing an existing user, you have the option to designate the user as a technician. To perform this function, click on 'Mark as Technician' and the system will complete the requested action.

Edit User
[Mark as Technician]
User Details

- Technicians must have a unique email and password to access the system. Site administrators can create a user at any time.
- Assignment of technicians to qualitative PT trials is completed by the Program Administrator as this step involves designation of various procedures and test kit manufacturers.



Managing Equipment – Accessing the Tools

Accessing the Manage Equipment Tools

To access the 'Manage Equipment' tools, highlight the 'Setup' dropdown on the tool bar above your dashboard. Select 'Manage Equipment' from the options available.

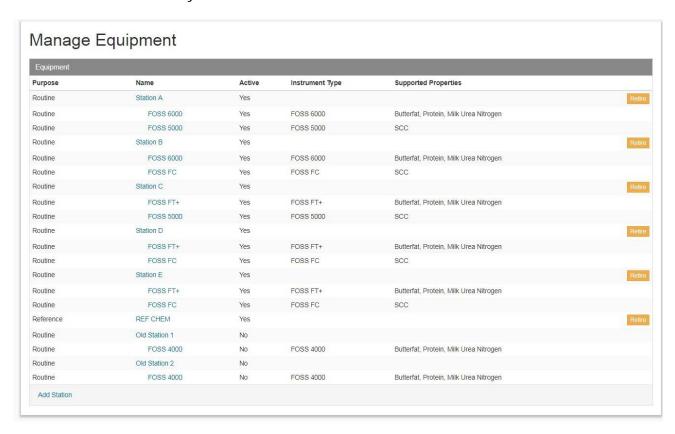




Managing Equipment - Options

Options for 'Manage Equipment'

Upon selection of the 'Manage Equipment' functionality, the website will display a list of all stations and instruments associated with your site.



There are multiple options within the 'Manage Equipment' functionality.

- Change Station Name
- Change Instrument Name and Details
- Retire Stations and/or Instruments
- Add Stations and/or Instruments
- Edit Reference Chemistry Instrument(s)

HELPFUL HINT

• The 'Manage Equipment' functionality allows for custom station configuration based on instruments. A station's instruments should not be renamed when replaced. Rather, the old instrument is 'Retired' and the new instrument is 'Added.' More details on retiring and adding instruments are detailed in this user guide.



Managing Equipment – Editing Station Names

Editing Station Names

A station is comprised of one instrument (i.e. Bentley Chemspec 150) or two instruments (i.e. FOSS FT+ and a FOSS 5000). The name of the individual stations may be changed to meet the needs of your site.

Select the station name you wish to edit. A page with the station configuration will appear.

Select 'Edit' under the laboratory/station header to edit the station name.



Enter the new station name in the field on the page and select 'Save and Close' to save the edits.



HELPFUL HINT

Remember to select 'Save and Close' after entering and confirming your new password.

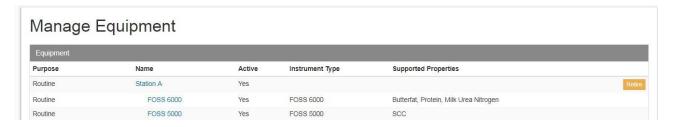


Managing Equipment – Retiring a Station

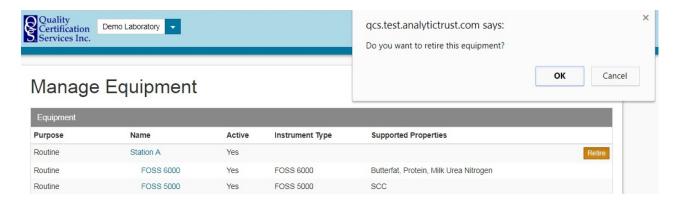
Retiring Station(s)

A station is comprised of one instrument (i.e. Bentley Chemspec 150) or two instruments (i.e. FOSS FT+ and a FOSS 5000). The instruments associated with a station may be retired when permanently placed out of service.

Select 'Retire' next to the station name to retire this station and its instruments.



The program will ask you to verify that you would like to retire this equipment permanently. Once retired, a station and its equipment are archived and marked as inactive.



IMPORTANT NOTES

- To keep the station active but replace the instruments at the station, refer to the 'Retire Instrument' and 'Add Instrument' instructions in this user guide.
- Do not use the retire function for a station or an instrument that is temporarily out of service (not being used) or down for repairs. Rather use the 'Mark Offline' function associated with quantitative data entry as described in the user guide.

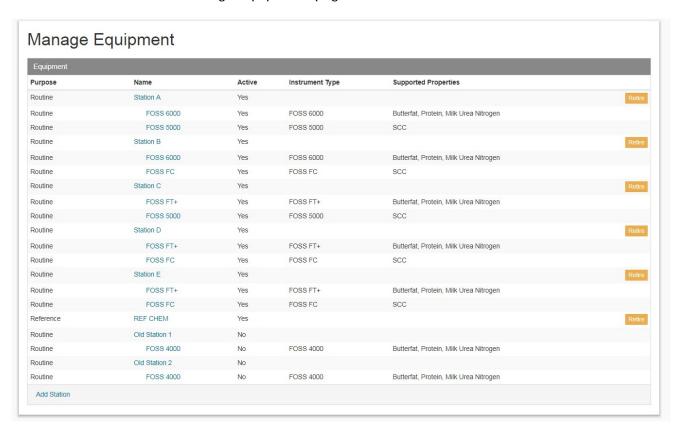


Managing Equipment – Adding a New Station

Adding a New Station

A station is comprised of one instrument (i.e. Bentley Chemspec 150) or two instruments (i.e. FOSS FT+ and a FOSS 5000). A site may add a new station as desired.

Select 'Add Station' on the 'Manage Equipment' page to add a new station.



Enter the new station name in the field on the page and select 'Save and Close' to save the edits.





Managing Equipment – Editing Instrument Details

Editing Instrument Details

A station is comprised of one instrument (i.e. Bentley Chemspec 150) or two instruments (i.e. FOSS FT+ and a FOSS 5000). The name of the individual instrument that comprises a station may be changed to meet the needs of your site.

Select the instrument name you wish to edit on the 'Station Configuration' page.



Enter the new instrument name in the field on the page on the 'Edit Instrument' page. The serial number for this instrument may be added or corrected when applicable.

Select 'Save and Close' to save the edits to the instrument name and serial number.



IMPORTANT NOTE

• The instrument type cannot be changed in the system as it was set during the 'Add Instrument' functionality in the program.

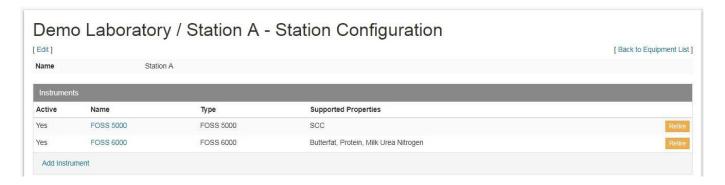


Managing Equipment – Retiring an Instrument

Retiring Instrument(s)

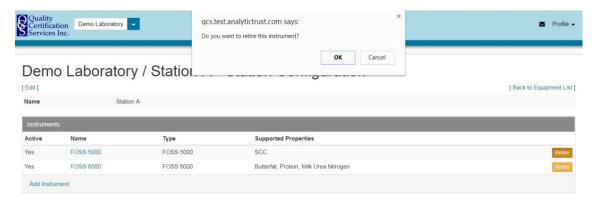
A station is comprised of one instrument (i.e. Bentley Chemspec 150) or two instruments (i.e. FOSS FT+ and a FOSS 5000). The instruments associated with a station may be retired when permanently placed out of service.

Select the station you wish to edit or configure. A page with the station configuration will appear.



Select the instrument you wish to retire. The program will ask you to verify that you would like to retire this instrument permanently. Once retired, an instrument is archived and marked as inactive.

If you are retiring both instruments that comprise a station, you will need to repeat the process for the other instrument you wish to retire for that station.



IMPORTANT NOTE

• Do not use the retire function for a station or an instrument that is temporarily out of service (not being used) or down for repairs. Rather use the 'Mark Offline' function associated with quantitative data entry as described in the user guide.



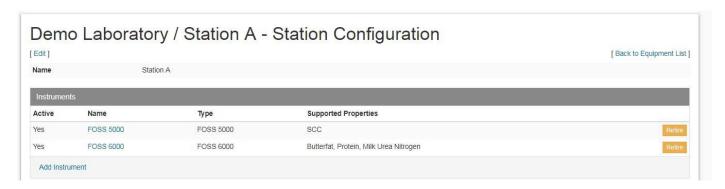
Managing Equipment – Adding an Instrument

Adding an Instrument

A station is comprised of one instrument (i.e. Bentley Chemspec 150) or two instruments (i.e. FOSS FT+ and a FOSS 5000). A site may add a new instrument to a new or to an existing station as desired.

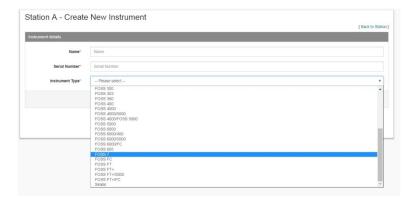
Select the station you wish to edit. A page with the station configuration will appear.

Select 'Add Instrument' on the 'Station Configuration' page to add a new instrument.



To create a new instrument, enter the instrument name and serial number. Then select the appropriate instrument type from the drop-down box. The components the instrument analyzes will be automatically included when you create the new instrument.

Select 'Create and Close' to add the new instrument.





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