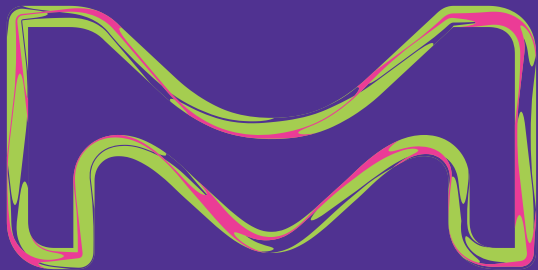


# Proficiency Testing

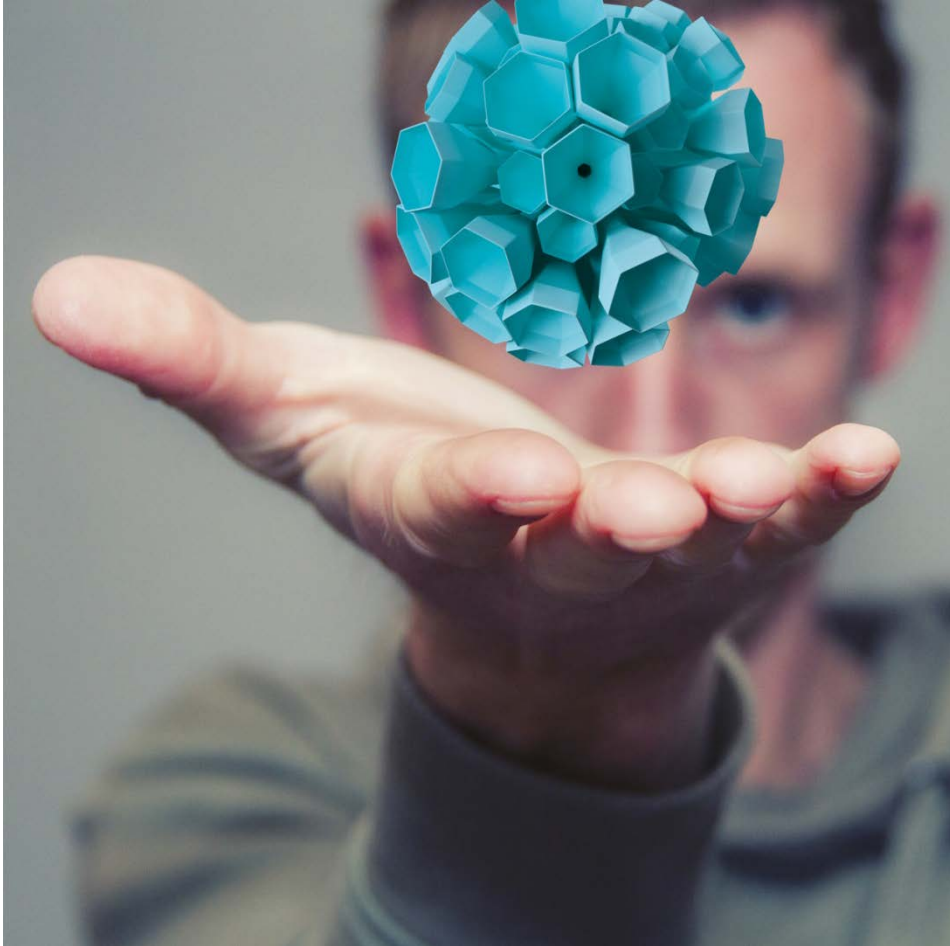
Jennifer Duhon

MilliporeSigma is a business of  
Merck KGaA, Darmstadt, Germany



**MILLIPORE**  
**SIGMA**

# Proficiency Testing Presentation Overview



**1** Who is MilliporeSigma

**2** Basic Principle of PT/Process

**3** Common Errors  
Ordering & Reporting

**4** Contacts and Resources



RTC acquired by Sigma-Aldrich in 2011

Sigma-Aldrich acquired by Merck KGaA in 2014

Merck acquires Millipore in 2010

Sigma-Aldrich and Merck Millipore combine business and we have:

## MilliporeSigma

**Merck KGaA,  
Darmstadt,  
Germany –  
the original**  
holds the global  
rights to the Merck  
name and brand.

**Exceptions are  
Canada and the  
United States,**  
where we operate  
as EMD Serono,  
MilliporeSigma and  
EMD Performance  
Materials.

Merck KGaA,  
Darmstadt,  
Germany

EMD  
SERONO

MILLIPORE  
SIGMA

EMD  
PERFORMANCE  
MATERIALS



# Where do we produce reference materials?

## 4 global production sites with highest standards

CRMS and PT since 1988

ISO 17025 + Guide 34 Accreditation

Certipure inorganic and elemental CRMs

Laramie, WY, USA

Darmstadt, Germany



Round Rock TX, USA

Buchs Switzerland

Cerilliant clinical, toxicology and pharma CRMs and RMs



Analytical standards (RMs) and CRMs

### Quality

- ISO Guide 34
- ISO 17025
- ISO 17043
- ISO 13485
- ISO 15194
- ISO 9001
- GMP

## What is Proficiency Testing (PT)

### Proficiency Testing – What for?

“The basic purpose of proficiency testing as defined by the **International Laboratory Accreditation Cooperation**, is to **assess performance** of laboratories for their conduct of specific tests, measurements or calibrations. Many laboratories operate in isolation from other laboratories and do not have ongoing opportunities to **compare** their data with others. Without such opportunities, there are risks that a laboratory’s data may have errors, biases or significant differences compared to similar laboratories.”

Many national, regional and state accreditation bodies require it (**TNI**, **USEPA**, **UKAS**)

It is a requirement for laboratories accredited to ISO 17025

It is a critical tool for quality assurance and continuous improvement

**LABS DO NOT HAVE A CHOICE!**



# What is Proficiency Testing (PT)

## Proficiency Testing – What for?

*Used over time, proficiency testing should be able to give you an accurate picture of:*

- How well your **analysts** are performing
- The performance of your **instruments**
- The **accuracy** of your methods and trending



What is the lab's role in the PT Process?

**The laboratory participating in the PT will:**

- Order samples and specify for which proficiency testing study (scheduled or quick turn)
- Order the correct samples (PT vs. QC)
- Receive, unpack and log in the samples
- Distribute the samples to the correct personnel
- Prepare and analyze the samples
- Report the results back to the provider
- Receive the evaluation and address the need for corrective action



# Environmental Analytical Standards Proficiency Testing

## Environmental PT Process



1

### Registration & Order

Prior to ordering for the first time, the lab needs to have a lab code that is obtained by registering on Sigma-Aldrich online PT reporting portal.



2

### Delivery

Blind samples are distributed accordingly to schedule. Each participant receives their samples



3

### Open Study

The study is open. Each lab analyzes the blind samples



4

### Reporting

Each lab report results through the PT Portal before the study closes



5

### Data Processing

Sigma-Aldrich process the data to issue each individual evaluation reports



6

### Evaluation Report

Report are sent as PDFs via the PT Portal. If specified when entering the result, we will send a copy to your accreditation body.





# Our PT current studies

## How to register



Sigma-Aldrich provides you with the essential performance data and premium grade testing components that help you build a valuable quality control asset. Our quality products and services allow you to work smarter, enabling a safer and healthier community and world.



### PT Search Module

Search for PT by Matrix or Analyte   [Browse All Products](#)

### Resources



<http://www.sigmaaldrich.com/PT>

### Sigma-Aldrich PT Reporting System



Quick Guides [➤ Reset Password](#) [➤ Register New Account](#) [➤ Register DMRQA](#) [➤ System Tour](#)

<https://pt.sigmainformatics.com/>

### User Login

Fields with \* are required.

Email Address \*

Password \*

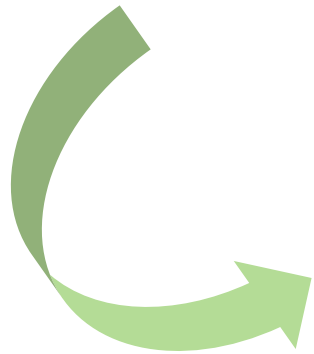
Remember me next time

Register before ordering to obtain your LAB CODE

# PT Types

## Matrices

- Drinking Water
- Waste Water
- Sea Water
- Soils
- Air
- Pharmaceutical PT



## Analytes

- Metals
- PAHs
- Pesticides
- Micro-Organisms



[www.sigma-aldrich.com/PT](http://www.sigma-aldrich.com/PT)



Ordering Mistakes

**Are you ordering the right samples?**

Drinking Water vs. Waste Water

*MIC003 SIGMA-ALDRICH*

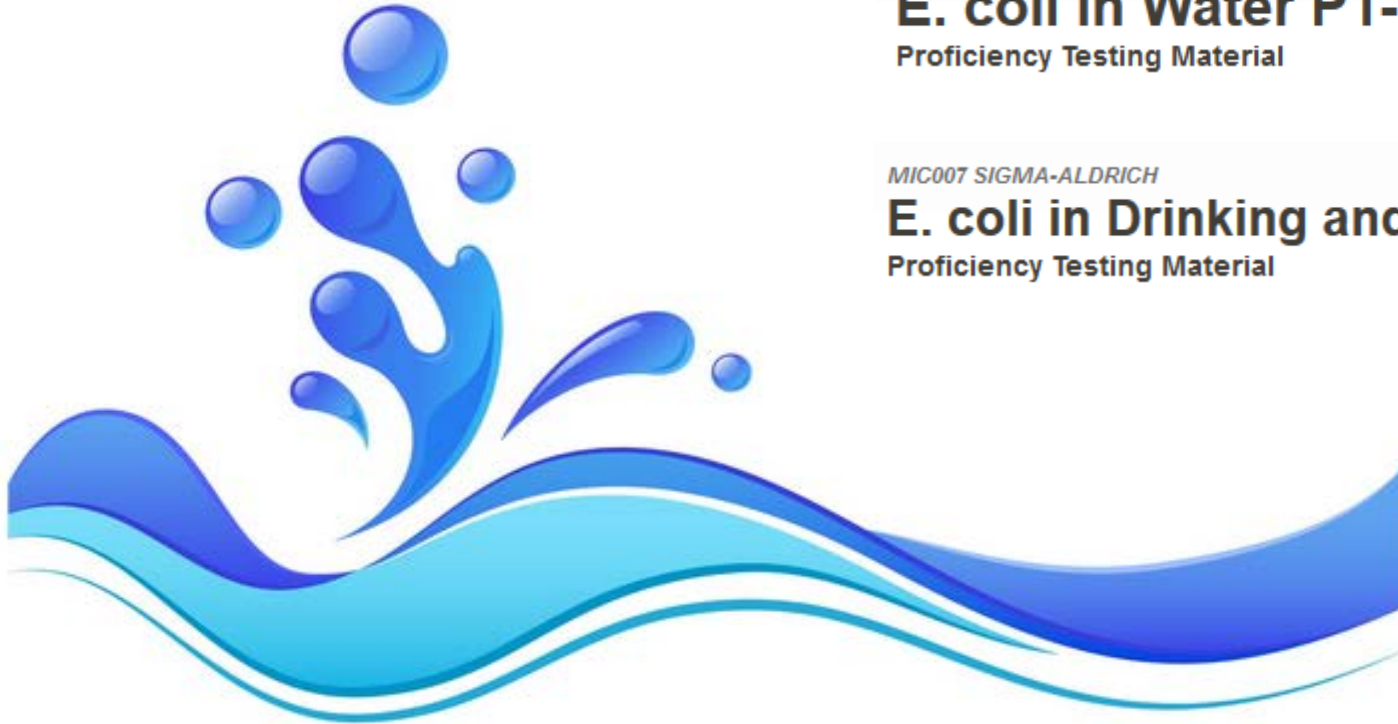
**E. coli in Water PT- Quantitative WP**

Proficiency Testing Material

*MIC007 SIGMA-ALDRICH*

**E. coli in Drinking and Surface Water PT- Quantitative - WS**

Proficiency Testing Material



Ordering Mistakes

Are you ordering the right samples?

**P**roficiency **T**esting

vs. **Q**uality **C**ontrol

PE1210 SIGMA-ALDRICH

**pH in Water- WP**

Proficiency Testing Material, Ready to use standard

QC1210 SIGMA-ALDRICH

**pH - Water**

certified reference material

**THE CERTIFICATE OF ANALYSIS IS AVAILABLE ONLINE SO  
QUALITY CONTROL SAMPLES CANNOT BE USED FOR  
PROFICIENCY TESTING!**



# Ordering Mistakes

## Are you ordering the right study?

### Scheduled Studies:

Continuing Certification (can also be used for DMRQA requirements if within right time frame)

### Quick Turns:

Corrective Action, New Certification

### DM RQA:

EPA Requirements only

Only applies to certain analytes

<http://www.sigmaaldrich.com/PT>



# Environmental Analytical Standards Proficiency Testing

## Environmental PT Process



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### Reporting

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5

### Data Processing

Sigma-Aldrich process the data to issue each individual evaluation reports



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### Evaluation Report

Report are sent as PDFs via the PT Portal. If specified when entering the result, we will send a copy to your accreditation body.



What is Proficiency Testing (PT)

## What Does a Proficiency Test Contain?


A sample that has analytes of interest, in a particular matrix, spiked in a concentration unknown to the laboratory. The sample concentration is only unknown to the participating laboratory. It has been fully tested and characterized by **M illipor eSigm a** prior to shipping to the customer.



# What is Proficiency Testing (PT)


## What does a Proficiency Test Contain?

A reporting packet that contains any necessary preparation instructions (emailed), instructions for reporting the result, the range in which each analyte is spiked and any other information critical to the analysis of the sample and how to report data online.

**REPORTING PACKET** First Choice for Quality | SIGMA-ALDRICH 

**Sample Instructions**

Item Number and Name	Mfg/LotID
FE1086-1KT COMPLETE VOLATILES KIT - WP	LRAB0210
5105 1,1,1,2-Tetrachloroethane <sup>1,2</sup>	ug/L
Analysis Method _____ (Result) _____	
Analysis Date (Optional) _____ (MM/DD/YYYY) Analyst Initials (Optional) _____	
5160 1,1,1-Trichloroethane <sup>1,2</sup>	ug/L
Analysis Method _____ (Result) _____	
Analysis Date (Optional) _____ (MM/DD/YYYY) Analyst Initials (Optional) _____	
5110 1,1,2,2-Tetrachloroethane <sup>1,2</sup>	ug/L
Analysis Method _____ (Result) _____	
Analysis Date (Optional) _____ (MM/DD/YYYY) Analyst Initials (Optional) _____	
5165 1,1,2-Trichloroethane <sup>1,2</sup>	ug/L
Analysis Method _____ (Result) _____	
Analysis Date (Optional) _____ (MM/DD/YYYY) Analyst Initials (Optional) _____	
4630 1,1-Dichloroethane <sup>1,2</sup>	ug/L
Analysis Method _____ (Result) _____	
Analysis Date (Optional) _____ (MM/DD/YYYY) Analyst Initials (Optional) _____	

**REPORTING PACKET** First Choice for Quality | SIGMA-ALDRICH 

**Quick-Turn Study**  
**QT-0004712**  
 WPCHEM\_MICRO

RTC  
 RTC Labcode

Study Date: 30-Jun-2016 through 29-Sep-2017

**Packet Instructions**

This packet consists of accrediting agency selection forms, reporting forms, and sample information for study QT-0004712. Sample preparation instructions are located in the sample information section of this packet. Once samples have been tested, results may be entered online at [pt.sigmainformatics.com](http://pt.sigmainformatics.com).

Results must be reported to RTC no later than Friday, September 29, 2017 for your results to be guaranteed for Official Evaluations.

Enter results on-line at [pt.sigmainformatics.com](http://pt.sigmainformatics.com)

If you are unable to report online you may fill out this packet and send completed originals.

Send completed originals to: \_\_\_\_\_ Or fax to: \_\_\_\_\_  
 Sigma-Aldrich 1 (855) 831-9211  
 Attn: Testing Coordinator  
 2931 Soldier Springs Road Questions/Comments:  
 Laramie, WY 82070 Phone: 1-800-576-5690  
 USA Email: PTService@sial.com

**Hard copy data must be received no later than Wednesday, September 27, 2017**

**Contact Information**

Make any necessary changes to the right of the information below. All PT reports are sent via email and will be provided as PDF attachments unless otherwise specified. Reports can also be accessed via the online reporting desktop.

RTC

Address 2931 Soldier Springs Phone (307) 742-5452  
 Laramie WY 82070 Email [crucinski@rt-corp.com](mailto:crucinski@rt-corp.com)  
 US

Check here to receive a hard copy of your PT report.

USEPA Lab Code: WY99102

Fill in your US EPA Lab Code if it is not shown. If you are unsure whether or not you have a US EPA Lab Code, email [PTService@sial.com](mailto:PTService@sial.com) for further assistance.

**Reporting Terms Agreement**

As a participant in RTC Study QT-0004712, we affirm that we have abided by the following conditions of this study. 1) We have not sent samples to any other laboratory for analysis. 2) We have not knowingly received test samples or information from another laboratory for analysis. 3) We have not shared any information for analysis of the test samples with another laboratory. 4) We have not and will not attempt to obtain or reveal any information about our results, the target values, or acceptance ranges of the test samples from RTC or any other laboratory until RTC has announced the test study has concluded. 5) We have treated these samples in the same manner as the majority of routinely tested samples in regard to analysts, methods and quality control procedures, where appropriate. 6) In addition, SSAS samples require that audit samples are to be analyzed at the same time as stationary source test samples.

APPROVED BY: \_\_\_\_\_  
 Name (Please print) Title

\_\_\_\_\_  
 Signature Date

08-2-2017 RTC QT-0004712 Completed forms must be received by 09/29/2017 Page 1 of 24



# Environmental Analytical Standards Proficiency Testing

## Environmental PT Process



1

### Registration & Order

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2

### Delivery

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3

### Open Study

The study is open. Each lab analyzes the blind samples



4

### Reporting

Each lab report results through the PT Portal before the study closes



5

### Data Processing

Sigma-Aldrich process the data to issue each individual evaluation reports



6

### Evaluation Report

Report are sent as PDFs via the PT Portal. If specified when entering the result, we will send a copy to your accreditation body.



# Data Entry

## What could go wrong?

# Read the instructions

### Description

This PT sample is designed for the quantitative analysis of total and/or fecal coliform and E. coli.

The PT sample is provided in duplicate as a stable dehydrated Vitroid™ requiring hydration. The additional sample is provided for mishaps in the lab. NELAC prohibits the practice of multiple tests on a PT sample unless it is normal laboratory practice and multiple analysis is conducted on normal day to day samples.

A 100 mL of sterile hydration fluid is supplied with the PT sample. This is a phosphate buffer. If you are following IDEXX methods for Quantitray™ do not use the buffer provided and follow the directions provided with the media (suggests using Type 1 DI water.)

When prepared according to instructions, the concentration range of the sample will be between 20-2400 CFU/100mL as per NELAC Fields of Testing, January 4, 2010.

Store the PT sample at 2 - 8°C.

The dehydrated Vitroid™ sample is stable for a time exceeding the study schedule.

### Sample Preparation

To prepare solution, partially fill a 1000mL volumetric flask with reagent-grade water (near 20°C) and add 1mL of trace-metal-grade nitric acid.

Shake ampule well prior to opening.

Open ampule 1132-20ML (be careful to avoid cuts on glass) and transfer 10.0 mL of concentrate to the volumetric flask. ★

Fill the flask to volume with reagent-grade water and mix well.



## Data Entry

### What could go wrong?

Check the units

PE1152-2ML TOTAL RESIDUAL CHLORINE (LOW LEVEL) - WP		LRAB1218
1940 Low Level TRC <sup>1,2</sup>		ug/L
Analysis Method	<input type="text"/>	Result <input type="text"/>
Analysis Date (Optional)	<input type="text"/> (MM/DD/YYYY)	Analyst initials (Optional) <input type="text"/>

Analyte	Result Units	Assigned Value	Accept. Window	Z	Evaluation
Low Level TRC <sup>1,2</sup>	0.169 ug/L	203	143 to 263	-10.14	Not Acceptable
1940 / PE1152-2ML - Lot LRAB1218 /Analyst:AM/ Analysis Date: 2017-05-10	Evaluation Criteria - 1 <input type="checkbox"/> Voluntary			Evaluation Parameter - a:1.0000, b:0.0000, c:0.0000, d:20.0000	



## Data Entry

### What could go wrong?

## Report for the correct analyte

Analyte	Result Units	Assigned Value	Accept. Window	Z	Evaluation
Coliforms, total - Sample 01 <sup>1,2</sup> 2500 / MIC001-MPN - Lot LRAB3639 /Analyst:KS/ Analysis Date: 2017-04-11	1 MPN/100mL	144	26.2 to 262	-2.43	Not Acceptable <i>Evaluation Criteria - 8</i> <input type="checkbox"/> Voluntary <i>Evaluation Parameter - a:1, b:0, c:0, d:58.9</i>
Coliforms, total - Sample 02 <sup>1,2</sup> 2500 / MIC001-MPN - Lot LRAB3639 /Analyst:KS/ Analysis Date: 2017-04-11	1 MPN/100mL	73.1	1.9 to 144	-2.03	Not Acceptable <i>Evaluation Criteria - 8</i> <input type="checkbox"/> Voluntary <i>Evaluation Parameter - a:1, b:0, c:0, d:35.6</i>



Data Entry

**What could go wrong?**

**Report for the  
correct analyte**

**Dissolved Oxygen vs. Dissolved Oxygen (winkler)**

**Calcium vs. Calcium hardness as CaCO<sub>3</sub>**

**Fecal Coliform MPN vs. Fecal Coliform CFU**

**Aluminum vs. Aluminum (total)**

**Fecal Coliform vs. E. coli**

**E. coli MPN vs. E. coli CFU**

**If you're not sure, check your scope!**

visit [www.nelac-institute.org](http://www.nelac-institute.org) for methods and analytes



## Corrective Action What went wrong?

Check your accredit or

Accreditors [\(add\)](#)

Accreditor	Position	Accrediting Labcode	Accrediting Agency	State	Division	Operation
No accreditors added						

**IMPORTANT:** If your data needs to be sent to an accreditor, you will need to assign it before the study closes. Accrediting Agencies do not normally accept a report after the laboratory has viewed their results.



# Environmental Analytical Standards Proficiency Testing

## Environmental PT Process



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### Open Study

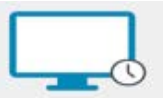
The study is open. Each lab analyzes the blind samples



4

### Reporting

Each lab report results through the PT Portal before the study closes



5

### Data Processing

MilliporeSigma process the data to issue each individual evaluation reports



6

### Evaluation Report

Report are sent as PDFs via the PT Portal. If specified when entering the result, we will send a copy to your accreditation body.



# Proficiency Testing – The Report

The report is sent in a PDF format - can be 100 pages - and contains:

- **One evaluation report** per laboratory per study – can be multiple analytes and/or analysts reported for the same sample
- **Z scores** for each reported value with our recommendation
  - +/- 3 standard deviations for wastewater and soil
  - +/- 2 standard deviations for drinking water
- **Explanations** on our statistical evaluation
- Information on our PT provider accreditation





# Evaluation Criteria

## Evaluating the Study

Iron, Fe <sup>1,2</sup>	3050 ug/L	3080	2620 to 3540	-0.19	Acceptable
1070 / PE1132-20ML - Lot LRAA9475 /Analyst:JL/ Analysis Date:	Evaluation Criteria - 1 <input type="checkbox"/> Voluntary		Evaluation Parameter - a:1, b:0, c:0.05, d:0		

**1 - Regression Equation** - Acceptance windows based on TNI adopted equation of proficiency value +/- 3 proficiency standard deviations and check limits of proficiency value +/- 2 proficiency standard deviations. Proficiency value and proficiency standard deviation are calculated from gravimetric variables a, b, c, & d as proficiency value = a \* gravimetric + b and proficiency standard deviation = c \* gravimetric + d.

**2 - Study Robust Mean and c, d regression** - Acceptance windows based on TNI adopted equation of proficiency value +/- 3 proficiency standard deviations and check limits of proficiency value +/- 2 proficiency standard deviations. Proficiency value and proficiency standard deviation calculated from robust study mean and variables c & d as proficiency value = robust mean and proficiency standard deviation = c \* proficiency value + d.

**3 - Fixed Limits** - Acceptance windows based on span of gravimetric percentage from gravimetric as gravimetric +/- gravimetric \* percentage.

**6 - Log Transform Statistics** - Acceptance windows based on lognormal distributed data. Acceptance windows = mean(lognormal) +/- span \* standard deviation(lognormal).



## Not Acceptable Results

What went wrong?

Questionable



Not Acceptable



# Corrective Action

## What went wrong?

### Common Mistakes

- Fat fingers
- Not reporting clearly in the reporting packet
  - Transcription error
- Forgetting a symbol
- Rushing to meet a deadline
- Missing a deadline
  - Accreditors will NOT accept late reports
- Not reporting enough figures
  - Example: Reported value: 0.74 mg/L but the range is 0.742 to 1mg/L



## Corrective Action FAQs

**Question:** I know what I did wrong and the study is still open. Can I fix my mistake?

**Answer:** Contact us and we will open the study for you if your data is not under review.

**Question:** I think my PT provider made a mistake on the data and/or evaluation.

**Answer:** If you notice any possible errors, contact the provider immediately.

**Question:** I received my final report and I know what I did wrong. Can you revise my report?

**Answer:** The provider cannot amend your report after it has been received. Contact your accreditor or order a quick turn study for corrective action.



## Quick-Turn (QT) Study – On-Demand PT

When a laboratory needs to perform a PT at short notice, Quick-Turn PT rounds are available for the majority of the sample portfolio

Quick-Turns are provided for the same cost as scheduled samples

In most case laboratories use these samples for:

- New Certification
- A tool for corrective action
- To train new staff



## How Quick-Turn Works

1. Find the samples required and request they are sent as a Quick-Turn
2. Samples will be dispatched as soon as possible
3. You have 45 days from time of shipment to complete the analysis
4. If the analysis is completed quicker than the 45 days, submit your results to [MilliporeSigma](#). The day the results are submitted the study will close
5. Within 48-72 hours of data submission you will receive an evaluation report



# The final report !

Coliforms, total - Sample 05 <sup>1,2</sup> 2500 / MIC001-PA - Lot LRAB3640 /Analyst:AL/ Analysis Date: 2017-04-19	1 Units <i>Evaluation Criteria - 8</i> <input type="checkbox"/> Voluntary	1	1 to 1	0	Acceptable <i>Evaluation Parameter - a:1, b:0, c:0, d:0</i>
Coliforms, total - Sample 06 <sup>1,2</sup> 2500 / MIC001-PA - Lot LRAB3640 /Analyst:AL/ Analysis Date: 2017-04-19	1 Units <i>Evaluation Criteria - 8</i> <input type="checkbox"/> Voluntary	1	1 to 1	0	Acceptable <i>Evaluation Parameter - a:1, b:0, c:0, d:0</i>
Coliforms, total - Sample 07 <sup>1,2</sup> 2500 / MIC001-PA - Lot LRAB3640 /Analyst:AL/ Analysis Date: 2017-04-19	0 Units <i>Evaluation Criteria - 8</i> <input type="checkbox"/> Voluntary	0	0 to 0	0	Acceptable <i>Evaluation Parameter - a:1, b:0, c:0, d:0</i>

**Final reports are emailed to all active emails under your account**



## Further PT Readings

What is proficiency testing? Guide for end-users of chemical data

[http://www.rsc.org/images/proficiency-testing-technical-brief-18A\\_tcm18-214885.pdf](http://www.rsc.org/images/proficiency-testing-technical-brief-18A_tcm18-214885.pdf)

Proficiency testing: assessing z-scores in the longer term

[http://www.rsc.org/images/proficiency-testing-z-scores-technical-brief-16\\_tcm18-214838.pdf](http://www.rsc.org/images/proficiency-testing-z-scores-technical-brief-16_tcm18-214838.pdf)

Understanding and acting on scores obtained in proficiency testing schemes

[http://www.rsc.org/images/proficiency-testing-technical-brief-11\\_tcm18-214875.pdf](http://www.rsc.org/images/proficiency-testing-technical-brief-11_tcm18-214875.pdf)

Robust statistics: a method of coping with outliers

[http://www.rsc.org/images/robust-statistics-technical-brief-6\\_tcm18-214850.pdf](http://www.rsc.org/images/robust-statistics-technical-brief-6_tcm18-214850.pdf)





**Proficiency Testing Home Page:**

<http://www.sigmaaldrich.com/PT>

**Technical dedicated support**

[ptservice@sial.com](mailto:ptservice@sial.com)

**Jennifer Duhon**

**Customer Service Supervisor**

