



REGULATORY TRENDS & PROFICIENCY TESTING

SEA Webinar

NOT FOR US AND CANADA AUDIENCE

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REGULATORY TRENDS & PROFICIENCY TESTING

Objectives

After completing this module, we should be able to:

- Regulatory trends (Asia)
- What is PT
- Benefits of PT
- Role of ISO 17025
- Types of RM & Institutes
- Types of Proficiency Program
- Analysis Procedures for Microbiology PT sample
- Calculate z score
- How to Troubleshoot & identify Corrective Actions
- Case Study for BSL 1 microbiologists

Global Overview

Key Regulatory Agencies



Food Samples Tested Across Globe

Surveillance Data 2018 - 2019

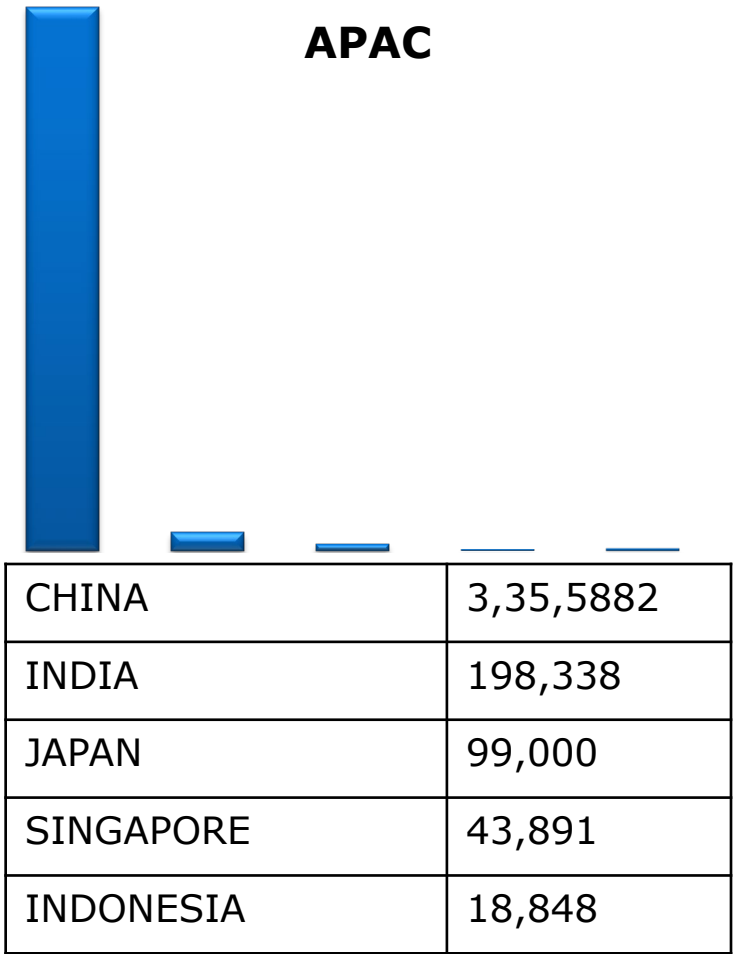
EU - EFSA

Residue Monitoring	657,818
Other Programs	295,184
Targeted	354,517
Suspected	5,095
Import	3,022

USDA - FSIS

Microbiological Surveillance Program	98,202
Chemical Residue Program	12790
Other Programs	12592

APAC



Comparison of Food Monitoring vs. Disease Surveillance

	Food Monitoring	Disease Surveillance
Prevention potential	Prevention of initial cases possible	Secondary prevention only
Speed of detection	Potentially fast	Generally slower
Testing		
Sampling Issues		
Denominator (United States)	356 billion lbs food/year (U.S.) ^a	281 million people (U.S.) ^b
Sample selection	By risk or control point	Self-selection
Agent distribution in sample	Uneven	Generally homogenous
Contamination introduction points	Many	Mouth
Testing Issues		
Pathogen load	Generally low	Generally high
Matrices	Complex, varied	Predictable
Damaged cells	Common	Less common (prior antibiotic use)
Inhibitory substances	Common	Rare
Predictive value of broad surveillance (monitoring)	Low	High
Cost of broad surveillance (monitoring)	Very high	Relatively low

^a [Kantor et al. \(1997\)](#)

^b 2000 U.S. census data.

SOURCE: [Besser \(2005\)](#).

ISO/IEC 17025:2017

General requirements for the competence of testing and calibration laboratories

3.3 interlaboratory comparison

organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions

3.5 proficiency testing

evaluation of participant performance against pre-established criteria by means of *interlaboratory comparisons* (3.3)

6.6 Externally provided products and services

NOTE Products can include, for example, measurement standards and equipment, auxiliary equipment, consumable materials and reference materials. Services can include, for example, calibration services, sampling services, testing services, facility and equipment maintenance services, proficiency testing services and assessment and auditing services.

Microbiology Proficiency Testing

Background

- As already a known fact 'Microbiology' related failures can be one of the biggest food safety risk for our business
- There is continual need to equip food microbiologist with microbiological testing capability
- **One of the best solution is:**

Participation in Proficiency Testing Program

Microbiology Proficiency Testing

ISO Standards

- ❑ **ISO 17034:2016** (previously ISO Guide 34) - General requirements for the competence of reference material producers
 - ❑ Specifies general requirements for the competence and consistent operation of reference material producers
 - ❑ Sets out the requirements in accordance with which reference materials are produced
 - ❑ It is intended to be used as part of the general quality assurance procedures of the reference material producer
 - ❑ Covers the production of all reference materials, including certified reference materials
- ❑ **ISO/IEC 17043:2010** (previously ISO Guide 43-1 & 43-2) Conformity assessment - General requirements for proficiency testing
 - ❑ General requirements for the competence of providers of proficiency testing schemes and for the development and operation of proficiency testing schemes
 - ❑ These requirements are intended to be general for all types of proficiency testing schemes, and they can be used as a basis for specific technical requirements for particular fields of application

Microbiology Proficiency Testing

What is PT?

1. PT is simply, a method that you may use to validate a particular measurement process
2. Sample's reference value is not known by the participating laboratory at the time of its measurement
3. In a well-designed proficiency test, the reference value for the sample should be principally determined by a competent laboratory with appropriate traceability to the ATCC or similar.
4. The PT samples are produced under QA/QC environment by an accredited service provider
5. The uncertainty assigned to the sample by the reference laboratory should be sufficiently smaller than the expanded uncertainty reported by the participating laboratory

Microbiology Proficiency Testing

Benefits

- ✓ Building confidence
- ✓ Reality check
- ✓ Opportunity for preventive action
- ✓ Can validate measurement method
- ✓ Technical training
- ✓ Uncertainty budgets
- ✓ Capability enhancement

Microbiology Proficiency Testing **Spreads Light on**

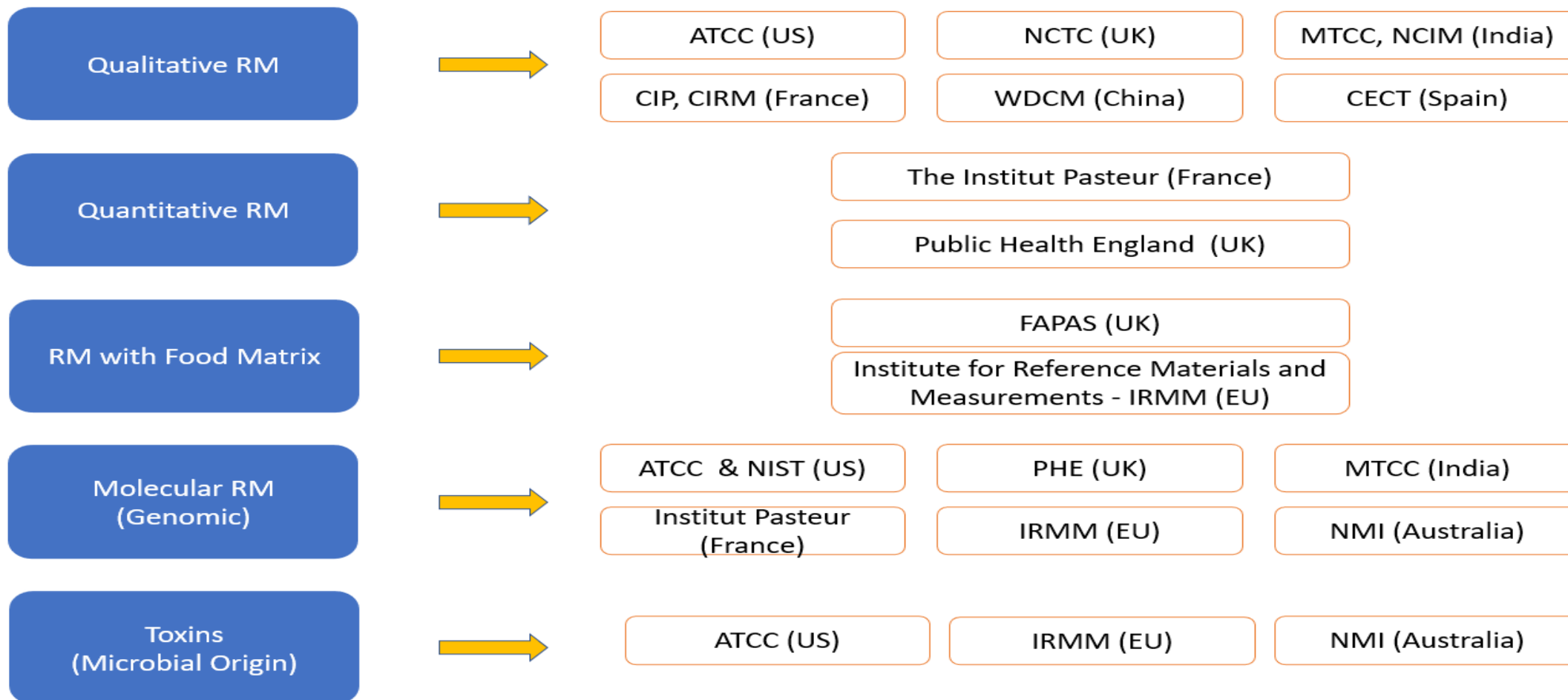
- ✓ Aseptic technique
- ✓ Analyst capability
- ✓ Matrix
- ✓ Media
- ✓ Method
- ✓ Equipment
- ✓ Environment

Does Not Spread Light on

- ✗ **Sampling Method & Technique**

Microbiology Proficiency Testing

Reference Material – Types & Key Institutes



Microbiology Proficiency Testing

Proficiency Program - Types

1. Analyte
2. Matrix
3. Water, Beverages, Chocolate, etc.
4. Customization depending of volume
5. CRM – Certified Reference Material (Lenticules & Vitroids)

[Home](#) > [Products](#) > [Analytical Chemistry](#) > [Reference Materials](#) > Proficiency Testing Standards

Proficiency Testing Standards



Proficiency testing (PT) or interlaboratory comparison testing is a critical tool not only for ISO/IEC 17025 laboratories, but also for quality assurance and continuous improvement as it allows laboratories to validate their analytical performance of specific tests, measurements, or calibrations.

- [Air PT](#)
- [DMR-QA](#)
- [Microbiology](#)
- [Pharmaceuticals](#)
- [Solids/Soil Hazardous Waste](#)
- [Water Pollution/Wastewater](#)
- [Water Supply/Drinking Water](#)

AIR PT

We offer air proficiency testing material in form of samples of ammonia, fluoride, hydrogen halides/halogens, lead, mercury, metals, NO, SO₂, H₂SO₄, and particulate matter in impinger solution as a concentrate to be diluted with reagent grade water for immediate analysis. Additionally, we also provide air PT samples such as volatiles and ketones on the sorbent, semi-volatiles on PUF, PAHs on PUF, PCBs on PUF, anions, chromium (VI), lead, mercury, metals, and particulate matter on a filter paper.

DMR-QA

Discharge Monitoring Report–Quality Assurance (DMR-QA) ensures data reliability by analyzing wastewater samples to evaluate laboratory performance.

MICROBIOLOGY

Microbiological PT samples are placed in vials containing a Vitroid™ disk, a small disk that consists of viable microorganisms with a certified number (ISO/IEC 17025), of colony forming units (CFUs). The discs contain bacteria or fungi in a solid water-soluble matrix, that rehydrates easily. The samples in the vials are dehydrated standards to provide prolonged stability.

PHARMACEUTICALS

For the chemical analysis of pharmaceutical materials, we offer PT materials for spectroscopy studies. Further, we also provide samples for conductivity, heavy metals, loss on drying, melting range, microbial enumeration test, pH, residual solvents, residue on ignition, sterility, titration, total organic carbon (TOC), and water determination.

SOLIDS/SOIL HAZARDOUS WASTE

To ensure reliable solid and soil monitoring, our dried soil/solid standards meet PT requirements. We provide organic PT material such as BNAs, BTEX/MTBE, diesel, dioxin and furans, gasoline, herbicides, nitrosamines/nitroaromatics, oil and grease, PAHs, PCBs, phenolics, total petroleum hydrocarbons (TPH) and metals in soil, dioxins and furans in tissue, free liquids in paint, PBDE/PCBs in sediment, PCB congeners in fish tissue, and toxicity characteristic leaching procedure (TCLP) semi-VOAs. In addition, our inorganics PT include anions, Cr (IV), cyanide, nutrients, solids and sulfide in the soil matrix, metals in sewage sludge, lead in powdered paint, specific gravity, the heat of combustion, flash point and corrosivity.

WATER POLLUTION/WASTEWATER

Standards with high-concentrate analytes are available for water pollution and wastewater analysis. Our water pollution/wastewater PT materials include inorganic, organic, and microbiological samples. We also offer samples, such as nutrients, minerals, oils and grease, silica, trace metals, and total suspended solids (TSS), to be tested in seawater.

WATER SUPPLY/DRINKING WATER

For quality testing of safe drinking water, our PT samples provide low-concentrate analytes to represent the levels observed in drinking water.

Proficiency Testing - Steps



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.



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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

Form Number and Name: **PT0004712 COMPLETE VOLATILES KIT - WP** info@rtc
IRAD0210

8105 1,1,1,2-Tetrachloroethane ^{1,2} **ug/L**

Analyte Method:  Result: 

Analyte Date (Optional):  (MM/DD/YYYY) Analyte Unit (Optional): 

5169 1,1,1-Trichloroethane ^{1,2} **ug/L**

Analyte Method:  Result: 

Analyte Date (Optional):  (MM/DD/YYYY) Analyte Unit (Optional): 

5119 1,1,2,2-Tetrachloroethane ^{1,2} **ug/L**

Analyte Method:  Result: 

Analyte Date (Optional):  (MM/DD/YYYY) Analyte Unit (Optional): 

8145 1,1,2-Trichloroethane ^{1,2} **ug/L**

Analyte Method:  Result: 

Analyte Date (Optional):  (MM/DD/YYYY) Analyte Unit (Optional): 

4050 1,1-Dichloroethane ^{1,2} **ug/L**

Analyte Method:  Result: 

Analyte Date (Optional):  (MM/DD/YYYY) Analyte Unit (Optional): 

REPORTING PACKET First Choice for Quality | SIGMA-ALDRICH 

Quick-Turn Study
QT-0004712
WPCHIM_MICRO

RTC
RTC Labside

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.sigmainformation.com.

Results must be reported to RTC no later than Friday, September 23, 2017 for your results to be guaranteed for Official Evaluations.

Enter results on-line at pt.sigmainformation.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) 831-0211
Attn: Testing Coordinator
2931 Soldier Springs Road
Laramie, WY 82070
USA
Questions/Comments:
Phone: 1-800-575-5800
Email: PTService@ald.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
Laramie WY 82070
US
Phone: (307) 742-5452
Email: crustad@rtc-corp.com

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

USEPA Lab Code: **WY99102**
P/E in year 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@ald.com for further assistance.

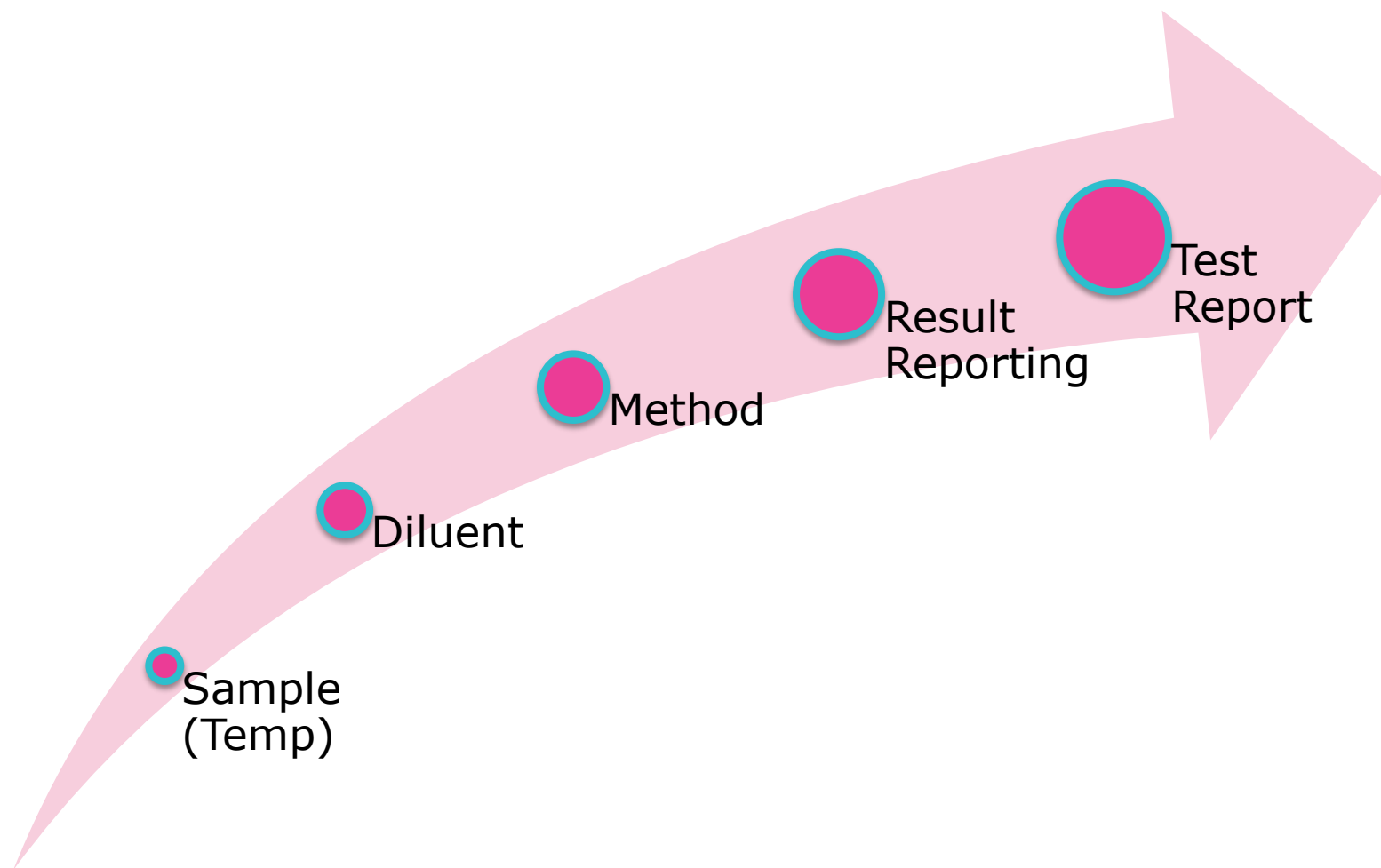
Reporting Terms Agreement

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 range 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 analysis, methods and quality control procedures, where appropriate. 6) In addition, SSAS samples require that each sample set to be analyzed at the same time as laboratory source test samples.

APPROVED BY: _____
Name (Please print) _____ Title _____
Signature _____ Date _____

88-2-2407 (R0) QT-0004712 Completed forms must be received by 09/25/2017 Page 1 of 24

Analysis Procedure



Sample Preparation

For powders and other solid samples:

- Dissolve the sample in an aseptic diluent

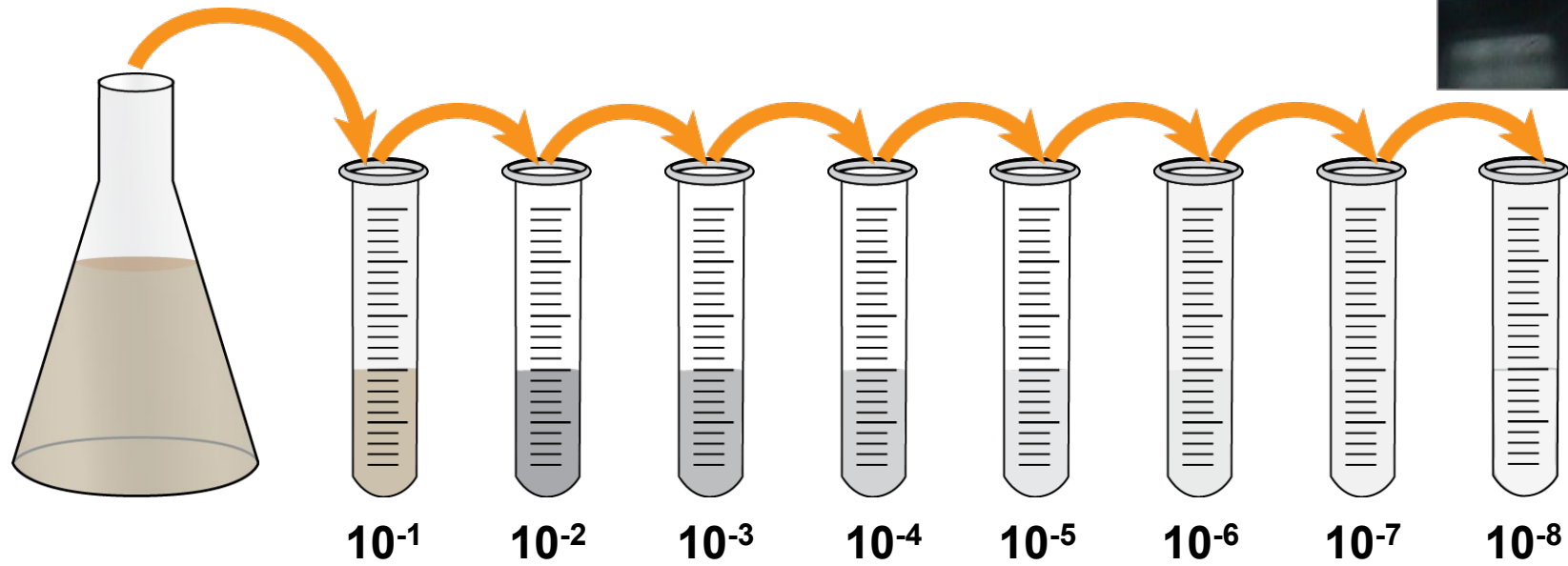
For samples that cannot be dissolved:

- Suspend the sample in a sterile diluent
- Shake it to suspend the microorganisms and ensure a representative sample
- Warm the diluent to approximately 45° C to facilitate dissolution of fatty ingredients



A mixer may also be used with samples that cannot be dissolved

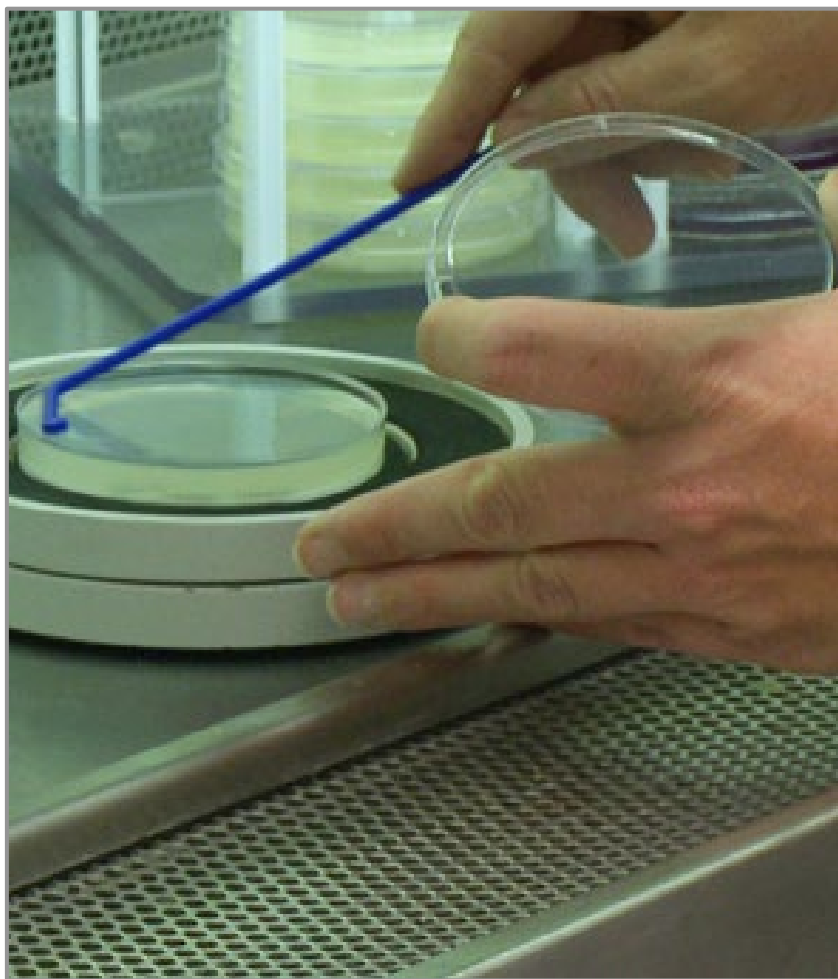
Decimal Dilution



Media Preparation



Test Methods



Controls

Why are controls needed for these tests?



- ✓ Membrane filtration
- ✓ Pour plate
- ✓ Spread Plate

Incubation

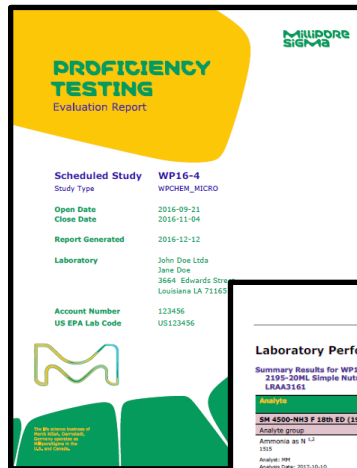


Your validated method gives you the correct incubation time and temperature

What to Count and Record

- Which plates to count ?
- How to record results ?
- How to calculate reporting value?

The final report



Laboratory Performance Evaluation Summary				
Summary Results for WP16-4 2195-20ML Simple Nutrients - Low Level LRAA3161				
Analyte	Reported Value	Assigned Value	Acceptance Window	z-score*
SM 4500-NH3 F.18th ED (1990) 2022001				
Ammonia as N ^{1,2}	13.9	14.2	11.5 - 17.0	-0.3
Units	mg/L	mg/L	mg/L	Acceptable
Analysis Date: 2016-10-10	Voluntary	Evaluation Criteria: ≤ 4	Repeatability ³ at 0.5: 1.6 or 18.0%	
Group Analysis Summary				
Acceptable: 1/1				Score: 100% - Acceptable
SM 4500-NH3 B.21st ED (1997) 2022001				
Ammonia as N ^{1,2}	13.7	14.2	11.5 - 17.0	-0.4
Units	mg/L	mg/L	mg/L	Acceptable
Analysis Date: 2016-10-10	Voluntary	Evaluation Criteria: ≤ 4	Repeatability ³ at 0.5: 1.6 or 18.0%	
Group Analysis Summary				
Acceptable: 1/1				Score: 100% - Acceptable
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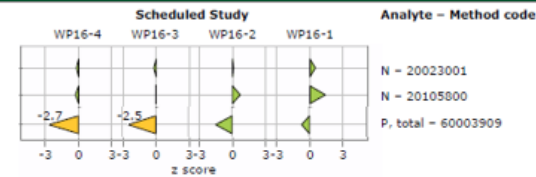
* Evaluation parameters used for the statistical analysis; explanation at the end of report; A questionable result is acceptable but to be checked.
¹ NELAP Compliant, covered by Sigma-Aldrich PTCL ABAS Proficiency Testing Provider accreditation, Cert. AP-1403
² ISO 15189 Compliant, covered by Sigma-Aldrich PTCL ABAS Proficiency Testing Provider accreditation, Cert. AP-1403

2016-12-12 123456 WP16-4 Page 4 of 15

See how well your lab has performed over several studies...

Graphical z-score Overview for WP16-4 2195-20ML Simple Nutrients - Low Level LRAA3161

z-score Overview* for WP16-4 and the previous three Scheduled Studies of this Study type



*Evaluation parameters used for the statistical analysis; explanation at the end of report

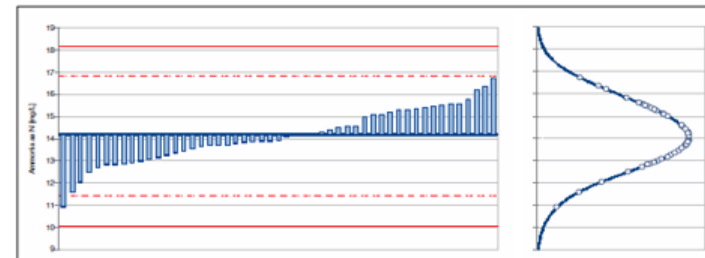
...and easily be able compare how your results measured up to other laboratories

4 Results

4.1 2195-20ML Simple Nutrients - Low Level / LRAA3161

4.1.1 Ammonia as N

Number of laboratories	40
Number of data points p	50
Assigned value x_{pt}	14.2 mg/L
Acceptance window	11.5 - 17.0 mg/L



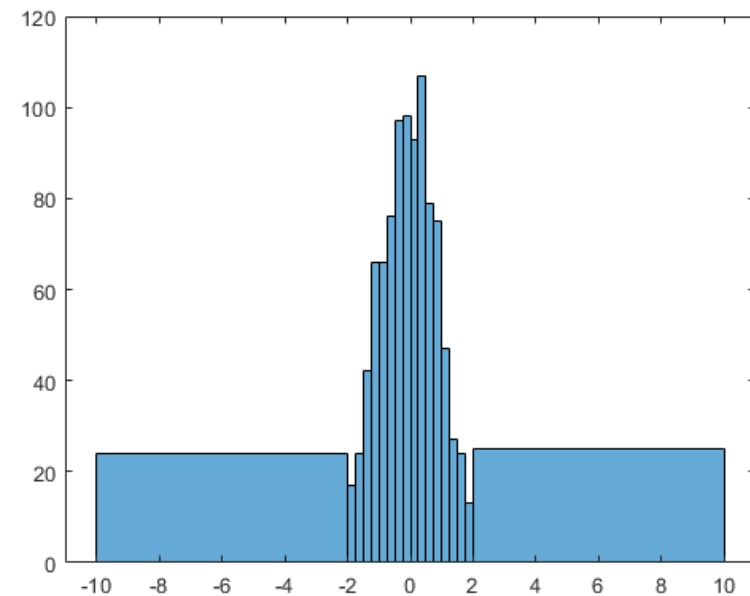
Microbiology Proficiency Testing

Z score calculation

$$z \text{ score} = \frac{(x - X)}{SD}$$

Where x – Lab value, X – Median & SD – Standard deviation

1. Quantitative
 2. Concept of log value
 3. Assigned value
- (ISO 13528: Statistical Methods for use in Proficiency Testing by Interlaboratory)
4. Standard Deviation
 5. Histogram



z Score Calculation Exercise



Proficiency Testing – z Score Calculation Worksheet

BioMonitoring: We Make World, A Safer Place

Performance Calculator (Microbiology)

Analyst	Lab Result (x)	Lab Result Log10	Assigned Value (X)	Assigned Value Log 10	SDPA	Z score

Lab Result – 70 cfu/g

Log(Lab Result) – 1.85

Assigned Value – 500 cfu/g

Log(Assigned Value) – 2.70

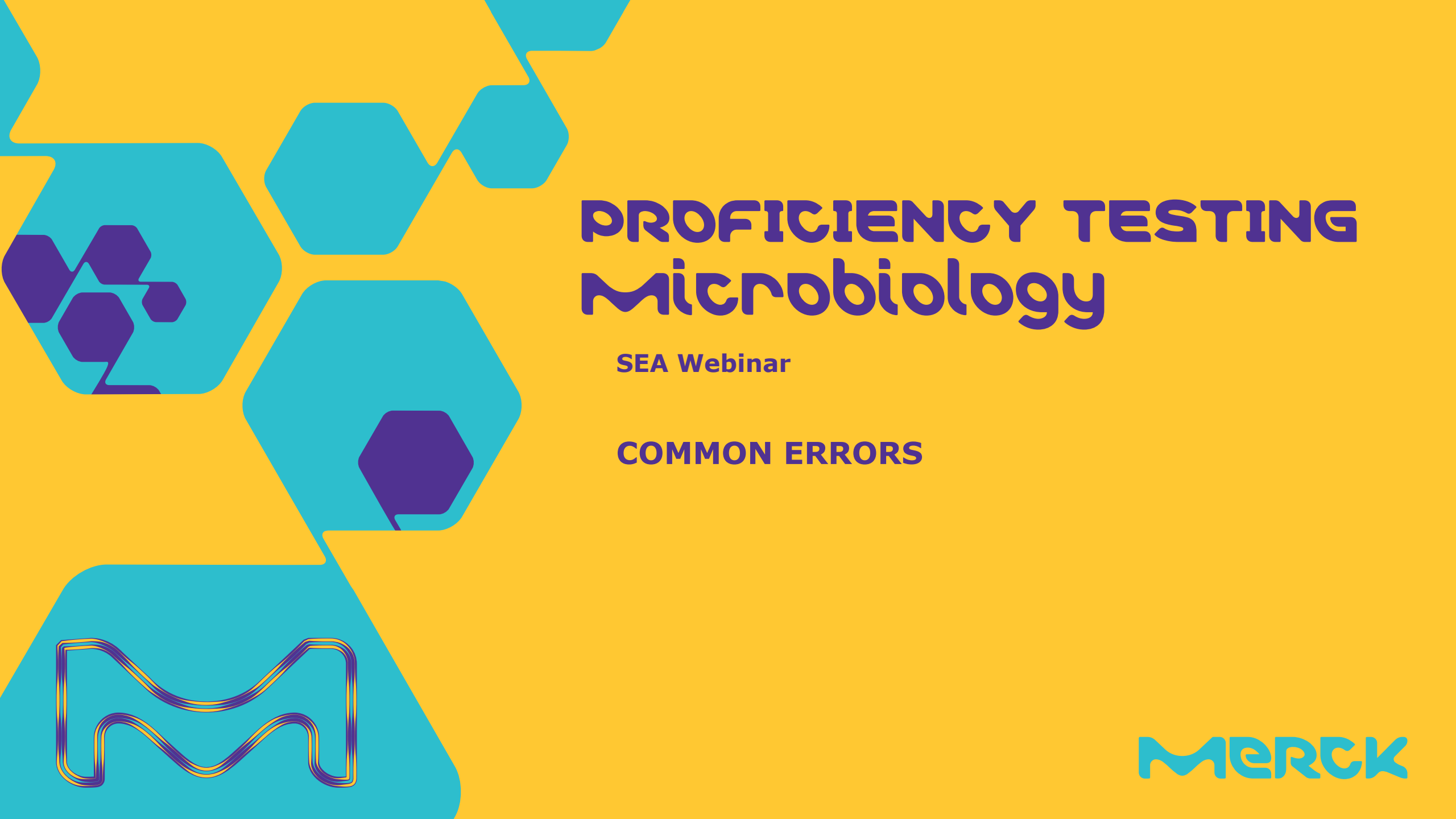
SDPA – 0.35 log10(fixed)

Z score = $(1.85 - 2.70) / 0.35 = \mathbf{-2.43}$

$|z| \leq 2.00$ Satisfactory result

$2.00 < |z| < 3.00$ Questionable result

$|z| \geq 3.00$ Unsatisfactory result



PROFICIENCY TESTING Microbiology

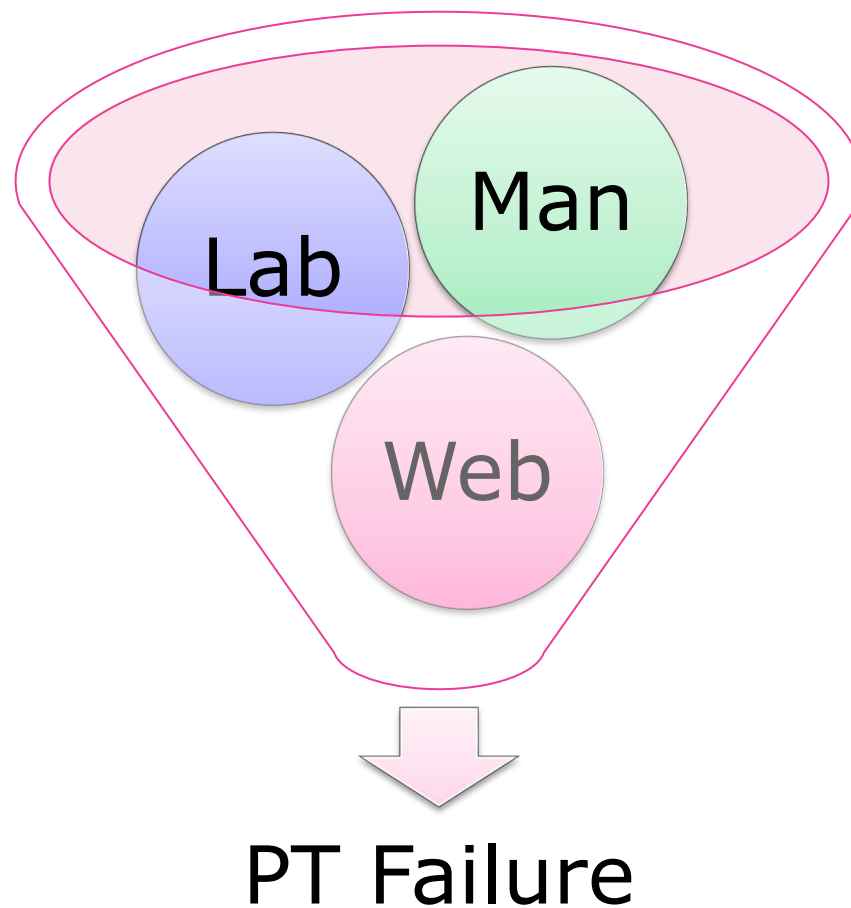
SEA Webinar

COMMON ERRORS

MERCK

Common Errors in Proficiency Test

Introduction



Microbiology Proficiency Testing

Corrective Action

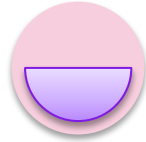
- A single poor result is not indicative of overall laboratory performance
- But neither is a single good result
- PT results should be monitored over time to detect potential bias or repeated unsatisfactory results
- There are many possible reasons for a single poor result which may include analytical and non-analytical errors
- **Analytical errors**
 - Calibration / instrument problems
 - Cross contamination
 - Interferences / matrix effects
 - Diagnostic kits / reagents
 - Analyst / method performance

Common Errors in Proficiency Test

Microbiology Media



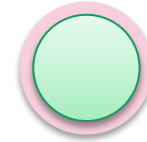
Selection
ISO 11133
QC
GPT
Usage



pH
Before
After
Calibration
Rectification



Water



Sterilization
Instruction
Autoclave

Common Errors in Proficiency Test

Diluent

Hypotonic



Hypertonic



Common Errors in Proficiency Test

Water

Quality of water used for testing should be specified and checked regularly for compliance against the specific requirements, such as conductivity, pH and microbial load etc. Only water that has been tested and found to be free from bactericidal or inhibitory compounds is to be used for the culture media, reagents and diluents.

Glassware washing procedures need to ensure that no toxic residue left from detergents, disinfectants and reagents etc

- ✓ **pH**
- ✓ **Conductivity**
- ✓ **TPC**
- ✓ **GPT**

Common Errors in Proficiency Test

Consumables

- ✓ Right Consumables
- ✓ Right Chemicals/ Reagents
- ✓ Addition in media (before or after sterilization)
- ✓ Filter sterilization



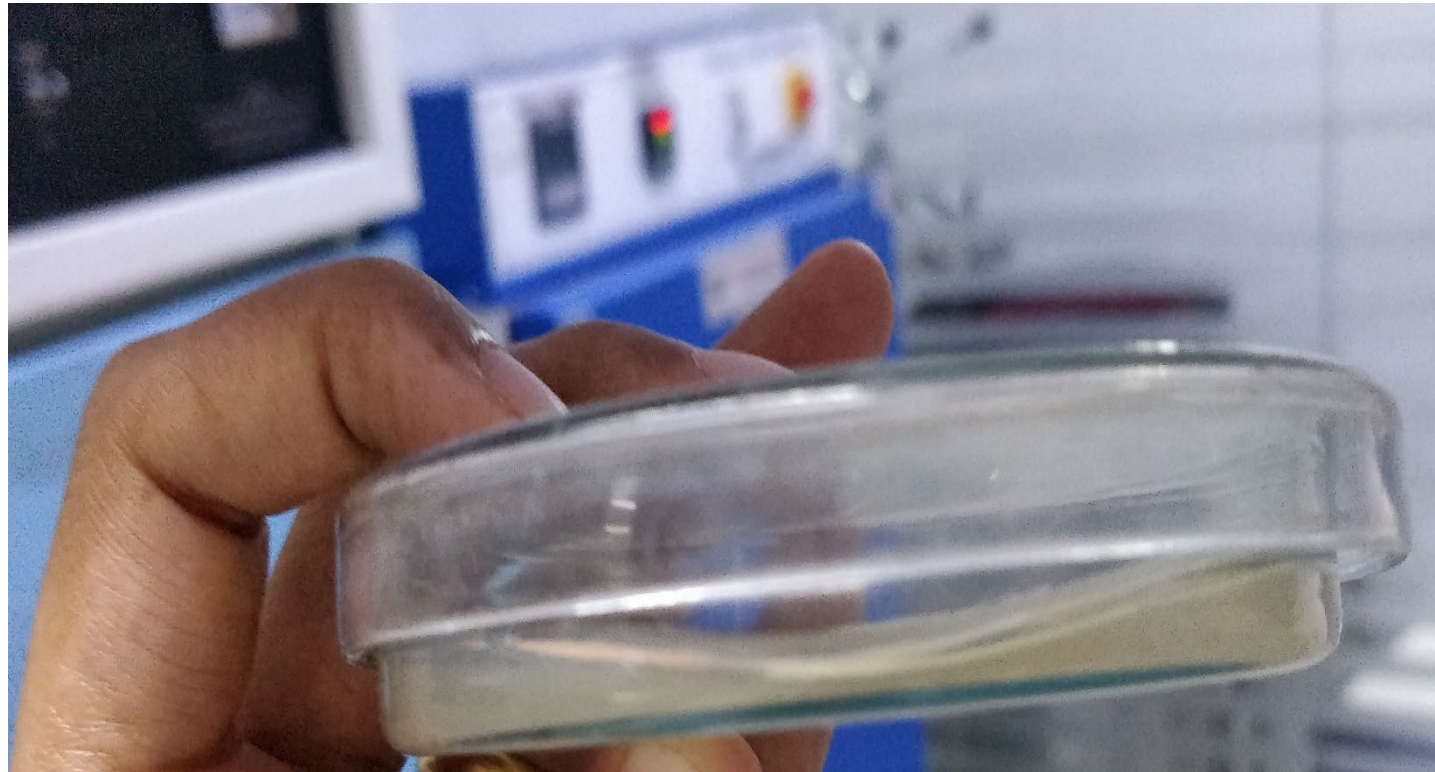
Common Errors in Proficiency Test Environment



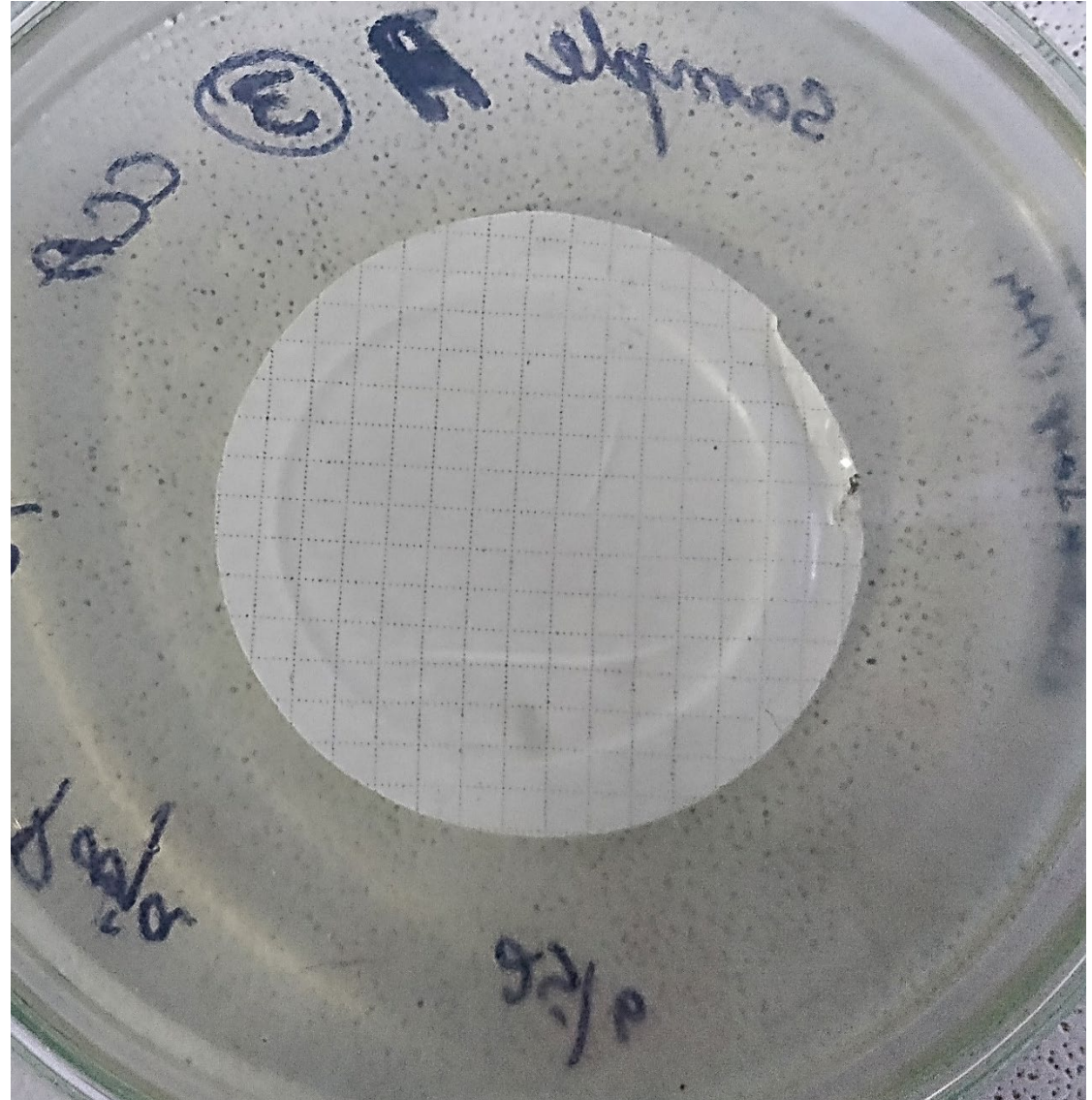
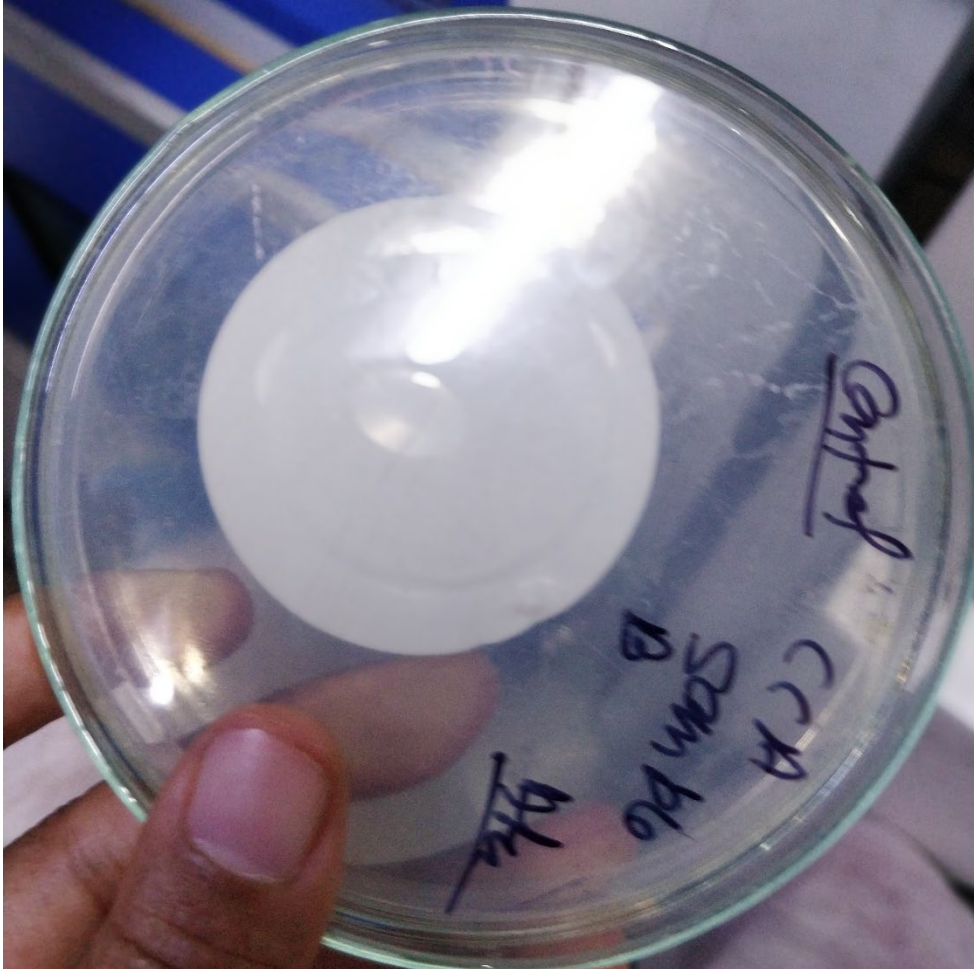
Analytical Error - Device



Analytical Error



Analytical Error - Bubble



Common Errors in Proficiency Test

Non-Analytical

- ✓ Calculation / transcription
- ✓ Reporting format / units
- ✓ Poor / incorrect storage
- ✓ Test material defects

Microbiology Proficiency Testing

Key Points

- Many service provider available
- Importance of proper disposal procedure
- Avoid cross contamination
- Proper Storage
- Do not treat PT analysis as special case

THANK YOU

