# PROFICIENCY TESTING

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### Proficiency testing presentation **Overview**







#### **Presentation of Merck range**



**Interpretation of Results** 



# What is Proficiency Testing (PT) A variety of applications

# Proficiency Testing is a **Product & Service** combination ISO 17025 accredited laboratories

- PT studies must be part of a quality management system
- Studies are at planned intervals through the year, laboratories can choose to participate in our quarterly or semi-annual PT programs, or simply purchase PT samples
- Mandatory to purchase a PT if available, if not, it is required to demonstrate that it does not exist
- Participants results are compared to produce the evaluation report
- Concept of " fit for purpose"



What is Proficiency Testing (PT)

### **Proficiency Testing – What for?**

What guarantees can you give to ensure that your results are correct?

- Validated methods
- Certified Reference Materials
- Internal QC management system
- > Accreditation ISO/IEC 17025



What is Proficiency Testing (PT)

### **Proficiency Testing – What for?**

What **guarantee** can you give to ensure that your **results are correct ?** 

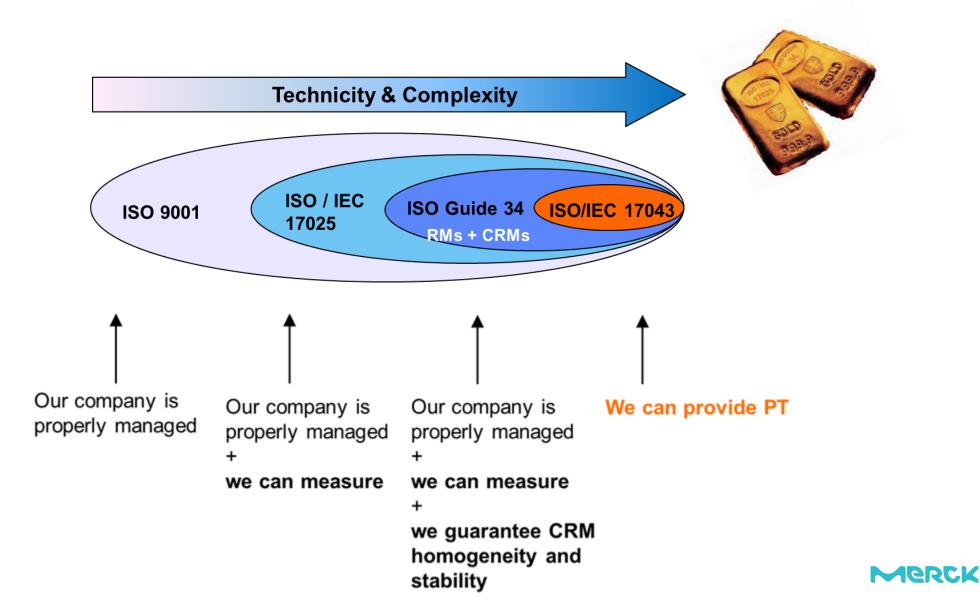
- Validated method
- Certified Reference Material
- Internal QC management system
- > Accreditation ISO/IEC 17025

# Internal controls IS there a Bias ?

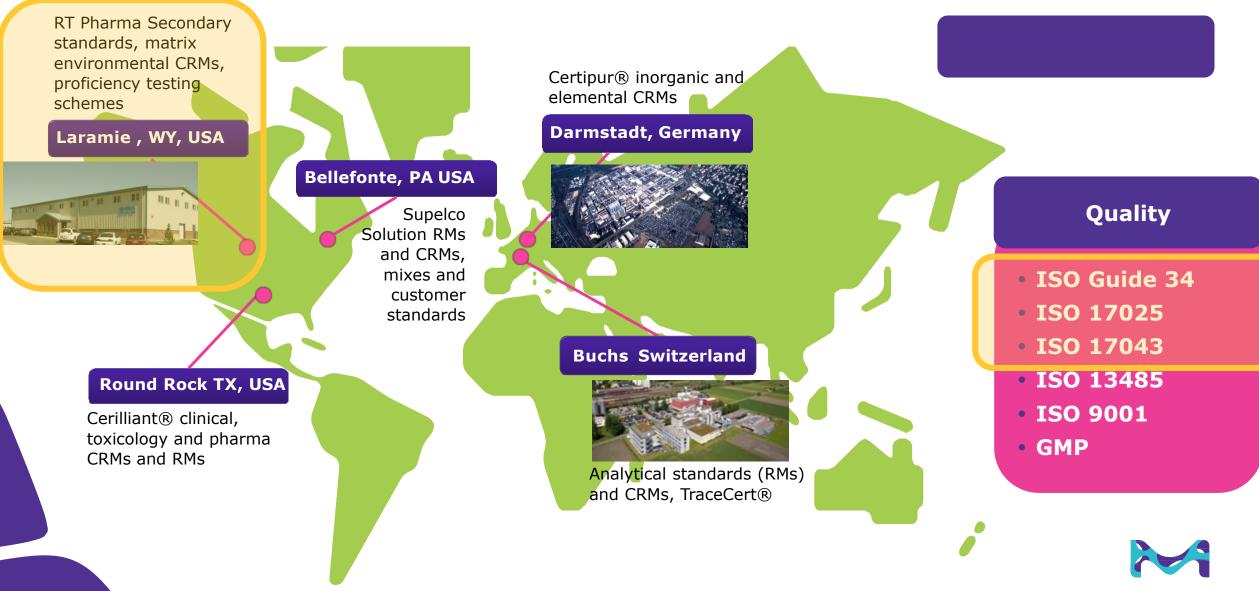
### Participating in PT = Control of the bias agains an external reference

#### Merck

# What is Proficiency Testing (PT) Who can provide PT?



# Where do we produce reference materials? **5 global production sites with the highest standards**





# We are a PT provider with over 20 years

Manufacture our **PT Samples** to **CRM** grade

More than **20'000** PT samples a year are sent to over **2'500 labs worldwide** 



www.sigma-aldrich.com/PT



# Our current offering for PT **Environmental samples**

# matrices

- Drinking Water
- Waste Water
- Sea Water
- Soils
- Air

### Range of Matrix Modifiers Products list <u>here</u>

# **Analytes**

- Metals
- PAHs
- Drugs
- Pesticides
- Micro-Organisms



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# Our current studies The MCCK offering

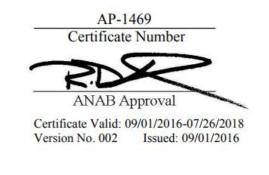


# Participate in our PT Studies and YOU can choose your samples in each scheme

Our environmental laboratory proficiency testing programs are:

- accredited by ACLASS to ISO/IEC 17043: 2010 (Certificate No AP-1469)
- recognized by all accreditation bodies worldwide







	Metals and Inorganics	Organics	Gases	Physical Properties
Drinking Water (WS)	1	1		1
WP	1	1		1
Soils and Solid Waste	1	1		
Air	1	1	1	
Micro		1		



# The Merck offering What are our advantages?



#### water:

- Matrix Modifiers Specific water matrix modifiers are available for hard, waste and sea water to simulate real water samples.
- Choice of Formats Most RTC water PT samples are available as concentrates or ready to use volumes.

### solids:

RTC Soil PT samples behave as real soils, and unless there is no alternative, they are not simply spikes added to a blank soil.

### supply:

• CRMs Match PT Samples – For every PT sample, a CRM is available.

### Reporting:

- Third Party Reports Evaluation reports can be sent to an authorized third party at no additional cost.
- Online Reporting Results can be uploaded and all PT documents can be viewed and downloaded through our secure website.
- Certificates of Excellence and Proficiency Issued to laboratories that demonstrate excellence throughout the year.



# Our current studies The MCCK offering



# Water Supply – Low Level (WS)

	Metals and Inorganics		Organics	Physical Properties
WS	<ul> <li>Anionic Surfactant (MBAS)</li> </ul>	Adipate	Phthalate	• pH
	Anions	Pesticides	<ul> <li>Dioxin, Diquat</li> </ul>	Acidity
	<ul> <li>Bromate and Bromide</li> </ul>	<ul> <li>Endothall, Glyphosate</li> </ul>	<ul> <li>Paraquat, EDB</li> </ul>	Turbidity
	Chlorate and Chlorite	DBCP	Gasoline Additives	Colour
	Chromium VI	Herbicides	<ul> <li>Organic Disinfection By-products</li> </ul>	Oxygen Demand
	Cyanide (total)     Paridual Free Chloring (REC). Siling	PCB Congeners	• VOCs	Corrosivity/Sodium
	<ul> <li>Residual Free Chlorine (RFC), Silica</li> <li>Trace Metals</li> </ul>	Total Organic Carbon (TOC)	<ul> <li>Trihalomethanes</li> </ul>	

# **116 samples** to choose from

4 distribution rounds through the year

Information an be found at : <u>http://www.sigmaaldrich.com/PT</u>



# Our current studies The MCCK offering

# Water Pollution – Mid to High Level (WP)



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	Metals and Inorganics		Organics	Physical Properties
WP	<ul> <li>Anionic Surfactant (MBAS)</li> </ul>	<ul> <li>Acid Compounds</li> </ul>	<ul> <li>Base/Neutrals Compounds (BNA)</li> </ul>	<ul> <li>pH (incl. in seawater)</li> </ul>
	Anions	<ul> <li>Diesel and Gasoline, Total</li> </ul>	<ul> <li>Organophosphorus and</li> </ul>	<ul> <li>Acidity</li> </ul>
	Chromium VI	Recoverable Petroleum	Organochlorine Pesticides	<ul> <li>Turbidity</li> </ul>
	Nutrients	Hydrocarbons		Colour
	Cyanide	• PAHs	PCB Congeners	<ul> <li>Volatile Residue / Fixed</li> </ul>
	Demand	Volatile Organic Compounds		Solids
	Minerals	· · · · · · · · · · · · · · · · · · ·		Odour
	Phenolics			<ul> <li>Tannin and Lignin</li> </ul>
	Residues			- Taninin and Eignin
	Solids			
	Residues			
	Solids			
	<ul> <li>Sulfide (Total and Soluble)</li> </ul>			
	<ul> <li>Trace Metals (Total and Soluble)</li> </ul>			

# 139 samples to choose from

6 distribution rounds through the year

Information an be found at : <u>http://www.sigmaaldrich.com/PT</u>

# Our current studies The MCK offering Soil and Solid Waste Proficiency Testing – Reliability Organics and Inorganics

	Metals and Inorganics	Organi	cs	Physical Properties
Soil and	Anions	BNAs	BTEX/MTBE	Corrosivity
Solid Waste	Chromium VI	Pesticides and Herbicides	Diesel, Gasoline	Flash Point
	• Cyanide	<ul> <li>TPH/EPH (banded and speciated)*</li> </ul>	PAHs by HPLC (Low Level)	<ul> <li>Heat of Combustion</li> </ul>
	<ul> <li>Metals (Soil and Sludge) Nutrients</li> </ul>	PCB Congeners	• PCBs	Oxidizer Screen
		VOAs		Reactivity
				<ul> <li>Solids in Soil</li> </ul>
				<ul> <li>Specific Gravity</li> </ul>

Sewage sludge also availiable
Blank soils samples CLN\*
37 samples to choose from
4 distribution rounds through the year
Information an be found at : http://www.sigmaaldrich.com/PT



# Our current studies The MCCK offering Air Proficiency Testing



	Metals and Inorganics	Organics	Gases	Physical Properties
Air	Method 29	<ul> <li>Method TO-4, TO-10A</li> </ul>	<ul> <li>Method 6</li> </ul>	Method 5
	<ul> <li>Metals in Impinger Solution</li> </ul>	– PCBs on PUF	– Sulfur Dioxide in	– Particulate Matter in Impinger
	– Metals on Filter Paper	– OCP on PUF	Impinger Solution	Solution
	– Mercury on Filter Paper	Method TO-13A	<ul> <li>Method 7</li> </ul>	<ul> <li>Particulate Matter on</li> </ul>
	<ul> <li>Mercury in Impinger Solution</li> </ul>	– PAHs on PUF	– Nitrogen Oxide	Filter Paper
	• Method 13, 14	Method 0010	– (NOx) in Impinger	
	– Anion on Filter Paper	<ul> <li>Semivolatiles on PUF or Sorbent Tube</li> </ul>	Solution	
	– Flouride in Impinger Solution	Method TO-11A		
	Method 12	<ul> <li>Aldehydes/Ketones on Sorbent</li> </ul>		
	– Lead on Filter Paper			
	<ul> <li>Lead in Impinger solution</li> </ul>			
	Method 8			
	– Sulfuric acid in Impinger solution			

- Method 26
- HCI/Halides/Halogens in Impinger solution
- Method 61/7199
- Chromium (VI) in Impinger solution

# 23 samples to choose from2 distribution rounds through the year





on for every product is very low (in some cases less than 4% standar comprehensive certificate of analysis that specifies the mean number

o assure the quality of test results (vater food, beverage, environmental etc rmance testing of media acc. ISO 11133 atom of new methods and method development

# **Microbiology Proficiency Testing**

	Water Supply	Wa	ater Pollution	Soils/Solids
Nicrobiology	<ul> <li>Pseudomonas aeruginosa</li> </ul>	<ul> <li>Total and Fecal Streptococcus</li> </ul>	<ul> <li>Enterococcus, Streptococcus</li> </ul>	• E. coli
	• Fungi and Yeast • E. coli	<ul> <li>Enterococcus, Clostridium perfringens</li> </ul>	<ul> <li>Standard Plate Count</li> </ul>	• Salmonella
	• Salmonella	• Listeria	• Legionella	CERTIFIED
	<ul> <li>Standard Plate Count</li> </ul>	• E. coli		REFERENCE MICROORGANISMS
	<ul> <li>Streptococcus/Enterococcus</li> </ul>			The Simple Way to Ensure Accurate Results, Every Time
	<ul> <li>Enterococci, Salmonella - P/A</li> </ul>			Vitroids <sup>TM</sup> and LENTICULE <sup>®</sup> Discs Defined CFU range and low standard deviation (ISO/IEC 17025) Fatt, reliable and easy to rea
2	<b>2 samples</b> to choose fro			Why use certified indicates enabled as (CENts) in Microbiology: Quide controls an assential element of a laboratory' guidey senses extern and data certained authors reference and another and an assential element of a laboratory in guidey senses extern and data certains and the need for maintains encoder grants in the text behaviory and guideather that an authoriticate on column is used in every quideat contain subale many contains the text behaviory and guideather that an authoriticate on column is used in every quideat contain subale many contains the contains and an authoriticate on column is used in every quideat contains used many contains the contains and the contains and Most are Vibraid <sup>27</sup> and LENTICULEP discost contains and any contains the contains and any contains and authoriticate and any contains and authoriticate and any contains any contains and any contains any contains any contains and any contains and any contains any contains and any contains any contains any contains any contains any contains and any contains and any contains any contains any contains any contains any contains any contains and any contains and any contains any contains and any contains any contains any contains any contains any contains any contains and any contains any contains and any contains any contains any contains any contains and any contains and any contains and contains any contains any contains any co

32 samples to choose from4 distribution rounds through the year

Information an be found at : <u>http://www.sigmaaldrich.com/PT</u>

# Our current offering for PT **Pharmaceutical samples**

# 20 PTs available

Program Areas	Analyte Groups	Specification, Standard Method, or Techniques to be Used	Analytes / Parameters Included
Pharmaceutical	Impurities	Various	Residue on Ignition Water Determination (Karl Fisher) Loss on Drying HPLC GC
Pharmaceutical	Identifi- cation	Various	Refractive Index Infrared Spectroscopy Melting Range/Point uv/vis
Pharmaceutical	Physical Properties	Various	pH Conductivity TOC
Pharmaceutical	Assay	Various	Titration
Pharmaceutical	Micro- biology	Various	Microbial Limit Sterility Microbiological – Aerobic Count



#### www.sigma-aldrich.com/PT



# Our current offering for PT Complete solution for Residual Solvent Analyses

Capillary GC Columns , Pharmaceutical Secondary CRMs, Proficiency Testing and Headspace Grade Solvents

#### Proficiency Testing samples for Residual Solvent Analyses:

Product #	Description -	
PEP019	Residual Solvents Class IIA PT Proficiency Testing Material	
PEP020	Residual Solvents Class IIB PT Proficiency Testing Material	
PEP018	Residual Solvents Class 1 PT Proficiency Testing Material	

#### complete solution for residual solvent analyses

There is a variety of solvents used in pharmaceutical processing. In the process of preparing a pharmaceutical product, you can potentially retain residual organic solvents in the final preparation. The trend has been to use less toxic solvents during the manufacture of pharmaceutical preparations. In this bulletin, we discuss the complete solution for residual solvent analyses: capillary GC columns, special solvents and standards.

Current guidelines published by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) describes a list of specific solvents, along with daily exposure limits.

tesidual Solvent - Methylene Chloride; Daceable to USP	PHR1171-3x1,2ml
Residual Solvent - Chloroform; Daceable to USP	PHR1316-3x1,2ml
tesidual Solvent - Benzene; Daceable to USP	PHR1318-3x1,2ml
tesidual Solvent - Toluene; Laceable to USP	PHR1317-3x1,2ml
Residual Solvent Class 🎞 - Trichloroethylene; Daceable to USP	PHR1319-3x1,2ml
Residual Solvent Class II - Acetonitrile; Daceable to USP	PH R132D-3 x1, 2ml
Solutions for Proficiency Testing	I
· ·	Order No. & Pack Size
Solutions for Proficiency Testing Product Residual Solvents Class IIA PT Proficiency Testing Material Residual Solvents Class IIB PT Proficiency Testing Material	Order No. & Pack Size

it solvents. No single column is capable of outlined by the United States and European or columns of different chemistries (2,3). We h the EP and USP methods for the analysis

<467>, Meinad [	D. 5 3/3 D/ 5	28 279 -U
<467>, Methada EP Methad 2.4.24 Primary calumn	D.53/3D/3	25 396
P <467≻, Methad P Methad 2.4.24 - canddiy calumn	D.53/30/1	253D1-U

nese proficiency testing samples are produced in accordance with ISO/IEC 17043:2010. All information arding the use of this material can be found in the reporting packet supplied for each sample.

#### eadspace Grade Solvents for the analysis of residual solvents acc. to Ph Eur and USP

offers application –oriented quality that helps to achieve accurate and reliable analytical results every

Nerck solvents we specify precisely the concentrations of the various residual solvents defined in ICH lines. In addition, we perform a headspace application test for every batch produced. This ensures the ration safety and reliability for daily work as well as for audit.

from Certificate of Analysis:	Certificate of A	naly sis:
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SupraSolv® Headspace solvents for the analysis of residual solvents according to Ph Eur and USP

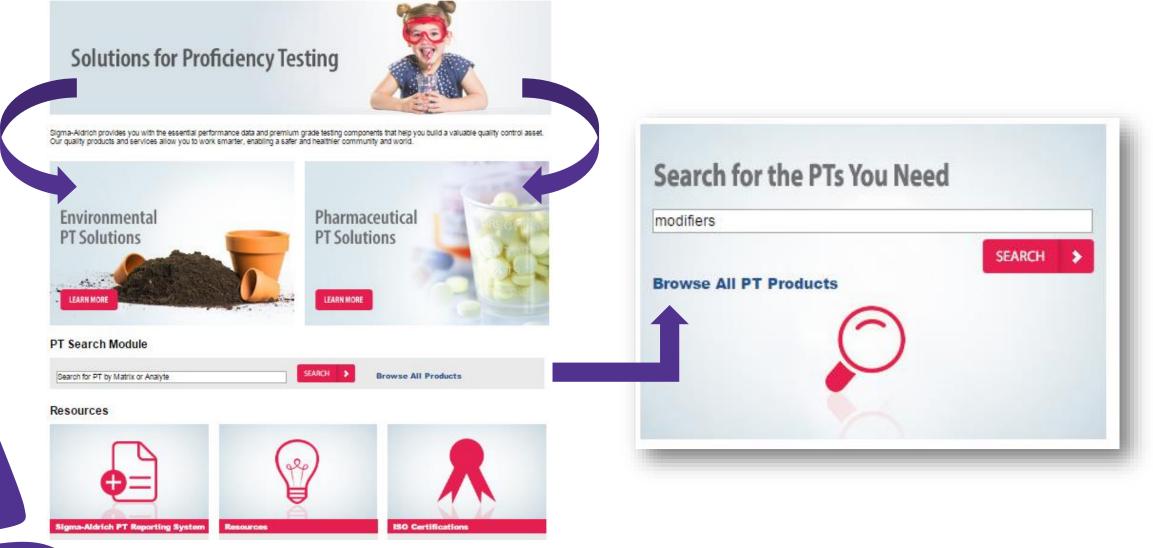
	N,N-Dimethylacetamide (DMA) SupraSolv®	SDD m I	1.DD399.DSDD
-		1000 ml	1.00399.1000
	N,N-Dimethylformemide (DMF) SupreSolv <sup>o</sup>	SDD m I	1.DD2D2.DSDD
		1000 ml	1.DD2D2.1DDD
		2500 ml	1.00202.2500
	Dimethyl sulfaxide (DMSO) SupreSalv <sup>o</sup>	SDD m I	1.D19 DD.D 5DD
		1 DDD ml	1.D19DD.1DDD
		2 SDD ml	1.019 DD.2 5DD

y direct injection of three separate mixtures, ed calibration standards specifically for this juct testing and are tested according to USP nient mix of benzene, carbon tetrachloride,

	PHR1D63-3x1,2ml
	PHR1D64-3x1,2ml
	PHR1D65-3x1,2ml
	PHR1D66-3x1,2ml
aried)	32978-2m1
	PHR117D-3×1,2ml



# Our current studies **Where to find more information**



#### www.sigmaaldrich.com/PT



# Time to participate!



## Our PT current studies How to register

#### Solutions for Proficiency Testing



Sigma-Aidrich 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 healthler community and world.



PT Search Module

Search for PT by Matrix or Analyte

SEARCH

SEARCH Browse All Products

#### Resources



### http://www.sigmaaldrich.com/PT

#### Sigma-Aldrich PT Reporting System



Quick Guides > <u>Reset Password</u> > <u>Register New Account</u>

Register DMRQA System Tour

User Login

Password<sup>\*</sup>

Login

Fields with \* are required.

Remember me next time

### https://pt.sigmainformatics.com/

**Register** before ordering to obtain your **LABCODE** 



# Environmental Analytical Standards Proficiency Testing

#### **Environmental PT Process**



#### **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.



# Environmental Analysis Proficiency Testing

#### **Environmental PT Process**



#### **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.



#### Delivery

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

#### **Open Study**

The study is open. Each lab analyzes the blind samples.

#### Sigma-Aldrich PT Reporting System



#### User Login

	are required.
Email Addı	ress *
Password	*
Rememb	er me next time
Login	



# Environmental Analysis Proficiency Testing

#### **Environmental PT Process**

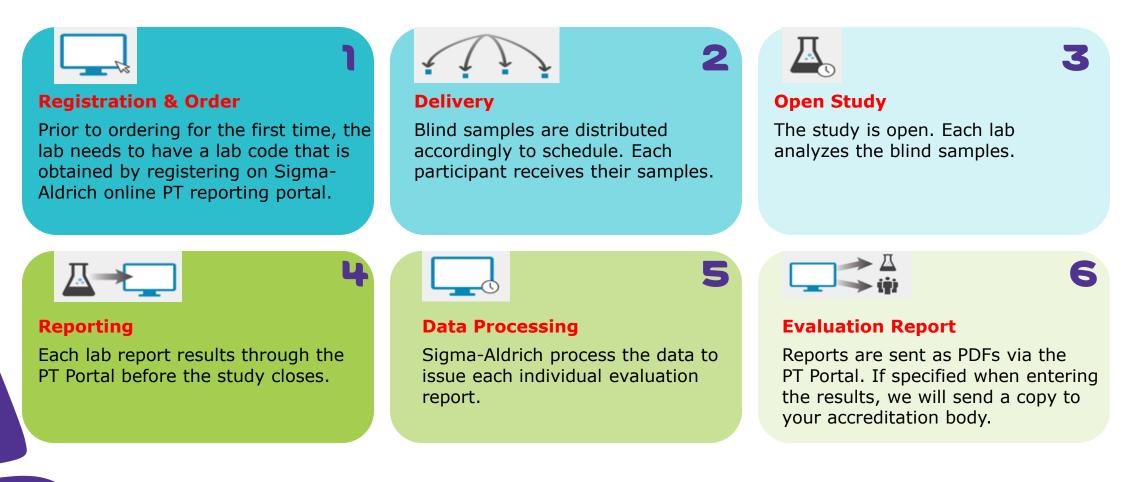






# Environmental Analysis Proficiency Testing

### **Environmental PT Process**



#### Merck

# THE REPORT HOW to Interpret



### PT Report What you can find in the report for all tested parameters

### The report is sent in a PDF format and contains:

- One evaluation report per laboratory per study
- Assigned value
- Reported value
- **Z** scores for each reported value with our recommendation
- Accepted window
- Evaluation
- At a planned PT study, participant results are compared to produce the evaluation report, therefore you can find for all tested parameters in the report also:
- Study Mean
- Study standard deviation
- Explanations on our statistical evaluation
- Information on our PT provider accreditation



#### PT Report **Interpretation of Results**

### **Important Statistical Concepts**

**Assigned Value**: most often calculated from the consensus of results using **robust** statistics - ISO/IEC 17043

**σ**<sub>**PT</sub>**: proficiency testing standard deviation</sub>

Zscore = 
$$\frac{(\text{Reported Value} - \text{Assigned Value})}{\sigma_{\text{PT}}}$$

External learning resource:

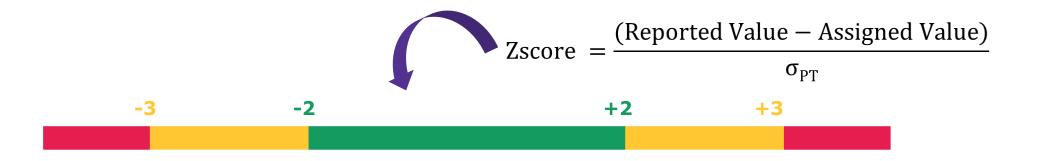
Eurachem guides and application notes:

https://www.eurachem.org/index.php/publications





Based on the Z score, we will deliver one of the following result recommendations:



# Acceptable , Questionable or Unsatisfactory

If you get a warning or a fail you will be required to initiate a planned program of corrective actions to investigate



### PT Report PT Schedule - 2017

Wastewater (view product list)		
WP16-1	January 13 – February 26, 2016	
WP16-2	March 23 – May 6, 2016	
WP16-3A	May 11 – June 24, 2016	
WP16-3B	July 6 – August 19, 2016	
WP16-4	Sept 21 – Nov 4, 2016	
WP16-5	Nov 23- Jan 6, 2017	
WP17-1	January 18 – March 3	
WP17-2	March 29 – May 12	
WP17-3A	May 17 – June 30	
WP17-3B	July 12 – August 25	
WP17-4	September 27 – November 11	
WP17-5	November 22 – January 5	
Quick-Turn Study – (non-scheduled pro	ficiency test that is available at any time)	

Drinking Water (view product list)		
WS16-1	Jan 27 – March 11, 2016	
WS16-2	April 6 – May 20, 2016	
WS16-3	July 13 – August 26, 2016	
WS16-4	Sept 28 – Nov 11, 2016	
WS17-1	January 18 – March 3	
WS17-2	March 29 – May 12	
WS17-3	July 12 – August 25	
WS17-4	September 27 – November 11	
Quick-Turn Study – (non-scheduled prof	iciency test that is available at any time)	

# Can be found at : <u>www.sigmaaldrich.com/PT</u>

https://www.sigmaaldrich.com/analytical-chromatography/proficiencytesting/study-schedule.html



# **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:

- Supporting new method validation
- A tool for corrective action
- To demonstrate analytical competence
- 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 via PT Portal. In the day the results are submitted, the study will close

5. Within 48 hours of data submission you will receive an evaluation report



# Proficiency Testing EPTIS Database

- Helps you find a Proficiency Testing Scheme for your laboratory
- Sigma-Aldich RTC is regognized by EPTIS
- Our PT scope is regularly updated (the last update 7/28/2017)



Bundesanstalt für Materialforschung und -prüfung

#### PT PROVIDER PT SCHEME LAST CHANGED ID COUNTRY **Q** Sigma-Aldrich RTC, Inc RTC Laboratory Profesency Testing Program: Waste Water 143316 United States 2017-07-28 PT provider (Sigma-Aldrich RTC, Inc) **Q** Sigma-Aldrich RTC, Inc RTC Laboratory Proficiency Testing Program: Drinking Water 143525 United States 2017-07-28 PT provider (Sigma-Aldrich RTC, Inc) **Q** Sigma-Aldrich RTC, Inc RTC Laboratory Proficiency Testing Program: Soil/Sediment 143424 United States 2017-07-28 PT provider (Sigma-Aldrich RTC, Inc) **Q** Sigma-Aldrich RTC, Inc 143481 United States RTC Laboratory Proficiency Testing Program: Air 2017-07-28 PT provider (Sigma-Aldrich RTC, Inc) **Q** Sigma-Aldrich RTC, Inc RTC Laboratory Proficiency Testing Program: Pharmaceutical 143614 United States 2017-07-28

# http://www.eptis.org/

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### **Further PT Readings**

AMC technical briefs: Royal Society of Chemistry

What is PT? Guide for end-users of chemical data.

http://www.rsc.org/images/proficiency-testing-technical-brief-18A tcm18-214885.pdf

PT: assessing z-score in the longer term.

http://www.rsc.org/images/proficiency-testing-z-scores-technical-brief-16 tcm18-214838.pdf

Understanding and action on scores obratined in PT schemes.

http://www.rsc.org/images/proficiency-testing-technical-brief-11 tcm18-214875.pdf

Robust statistic: a method of coping with outliers.

http://www.rsc.org/images/robust-statistics-technical-brief-6 tcm18-214850.pdf



# Proficiency Testing Home Page: www.sigmaaldrich.com/PT

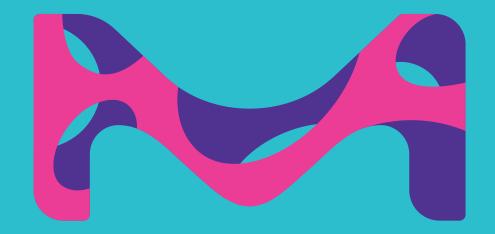
Proficiency Testing Lab Registration Form: https://pt.sigmainformatics.com/RTC/index.php

#### **Questions?**

Local sales representative or to Zuzana Antalová, FMM EE&R+

### **Technical dedicated support**

Ptservice@sial.com



# Thank you!

