



Limitations of Using AIHA Proficiency Analytical Testing (PAT) Samples for Method Verification and/or Validation

PURPOSE

The purpose of this communiqué is: a) to clarify the issues involved in using AIHA PAT samples for method verification and/or validation, and b) to explain when AIHA PAT samples can and cannot be used for this purpose.

BACKGROUND

Based on Step 2a of Section 5.6 of AIHA Guidance on Traceability adapted from Traceability of Chemical Measurements: Eurochem 2003, AIHA Laboratory Accreditation Programs (AIHA-LAP) has determined that it is, in some cases, appropriate to use AIHA PAT Programs samples as certified reference materials, since there are established values and acceptance limits based on data from a number of laboratories. Some laboratories accredited by AIHA-LAP use AIHA PAT rounds and PAT samples as a means of verifying or validating test methods, especially modified reference test methods. Some of these PAT samples are not entirely representative of actual samples because it is not always practical or technically feasible to do so. One example is Metals-in-Air, where PAT samples are prepared using liquid spikes, but actual samples usually consist of metal or metal oxide particles.

METHOD VERIFICATION AND VALIDATION

Accredited laboratories may not use PAT samples that do not represent actual samples for method validation. In such cases the laboratory must use sample matrices that are similar to those of actual samples for method validation. The following table provides information on PAT samples:

<u>PAT Analyte</u>	<u>OK to use?</u>	<u>Alternative</u>
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Organics in air	Yes	
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(on tube or badge)

Metals (inc. Pb & Be) in Air (on filter)	No	lab verification with SRM or CRM See Below*
BeO in air (on filter)	Yes	
Lead in Paint	Yes	
Lead on Dust Wipes	Yes	
Silica, crystalline in air (on filter)	Yes	
Bulk Asbestos	Yes	
Airborne Fibers (on filter)	Yes, but the PAT samples will look different than actual samples	

*A partial list of possible materials for metals:

Standard Reference Materials (SRM's) From NIST

WWW.NIST.GOV _ PHONE: (301) 975-2200 _ FAX: (301) 948-3730 _ EMAIL:
SRMINFO@NIST.GOV

2586 Trace Elements in Soil: 4 Certified elements, 18 Reference elements; 55 g; Containing Lead from Paint (Nominal 500 mg/kg Lead)

2587 Trace Elements in Soil: 4 Certified elements, 14 Reference elements; 55 g; Containing Lead from Paint (Nominal 3000 mg/kg Lead)



2709a San Joaquin Soil: 27 Certified elements, 26 Reference elements; 50 g.

2710a Montana Soil Highly Elevated Trace Elements: 22 Certified elements, 13 Reference elements; 50 g

2711a Montana Soil Moderately Elevated Trace Elements: 25 Certified Elements, 8 Reference elements; 50 g

Certified Reference Materials (CRM's)

There are also certified reference materials (CRM) from accredited suppliers

RTC is one that has both ISO/IEC 17025 and ISO Guide 34.

Validation / Verification Procedures

As part of ISO/IEC 17025 and AIHA Policy 2A5.4.1, labs should have a protocol for verifying all methods and validating laboratory developed and non-standard methods prior to use in their laboratories.

The following three are examples of the many publications that provide guidance:

How to Meet ISO 17025 Requirements for Method Verification' by AOAC International

http://www.aoac.org/alacc_guide_2008.pdf

Harmonized Guidelines for Single-Laboratory Validation of Methods Analysis' an IUPAC Technical Report

<http://www.iupac.org/publications/pac/2002/pdf/7405x0835.pdf>

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An example of a rigorous evaluation can be found in 'Ultrasonic Extraction/Anodic Stripping Voltammetry for Determining Lead in Dust: A Laboratory Evaluation' by NIST
<http://fire.nist.gov/bfrlpubs/build04/PDF/b04029.pdf>

Please direct any questions to an AIHA Laboratory Accreditation Programs staff contact as listed here <http://www.aihaaccreditedlabs.org/Pages/AccreditationStaffContacts.aspx>

Thank you!

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