

## Measurement Uncertainty in Microbiology-Notes from Day 2

1. What is required?

Labs must have:

a) a validated method with performance characteristics AND must be able to demonstrate that the analyst can meet the published performance characteristics (specifically, a standard deviation based on intra- and inter-analyst comparisons)

OR,

b) data for within analyst and between analyst standard deviations, and a calculation of the overall pooled standard deviation

The standard deviation can then be used in the calculation for measurement uncertainty.

2. If a lab has calculated a measurement uncertainty of 50%, and the 'norm' is known to be 30-40%, what is the course of action?

This is a cue for assessors to look at the PT data, the policy and application of the policy, and changes in uncertainty over time. Beyond this, assessors cannot comment on the performance. This estimation is part of the lab's overall QA program.

3. Is use of PT data only in estimation of uncertainty acceptable?

No.

4. Do counts have to be converted to logs?

No. Historically, the approach has been to analyze the data generated, assess the type of distribution, and only if needed, log transform the data.

Caution: do not use the same data for calculating the within analyst data for doing the between analyst calculations (duplicate counting).

5. Is it acceptable to run a sample and do a dilution of the same sample, and refer to this as a "duplicate"?

No. This process is a verification of the dilution process (or an alternate way of doing a calculation).

6. Does uncertainty have to be reported?

According to ISO/IEC 17025, Section 5.10.3.c, measurement uncertainty must be reported if uncertainty affects compliance to a specification.

For example:

If the compliance limit = 10 and the result is 2 +/- 5, then it is not necessary to report the uncertainty.

However, if the compliance limit = 10, and the result is 10 +/- 5, then the uncertainty needs to be reported.

There is no uncertainty associated with a value of “zero”, therefore uncertainty does not need to be reported if the test result = 0.

Therefore, for **total coliforms and E. coli or fecal coliforms**, where the specification is “zero”, there can be no uncertainty associated with the result – there is either a count there, in which case the sample is out of compliance, or there’s nothing there (and one cannot estimate uncertainty on “zero”).

**However, for HPC, where the limit = 500:**

Where the result is 250 +/- 100, it is not necessary to report uncertainty.

However, when the result is 400 +/- 100, it is necessary to report uncertainty.

Therefore, labs must be prepared to report the uncertainty associated with a test result, especially for HPC and background counts.

Note:

ISO/IEC 17025 states there if uncertainty influences compliance to a specification, labs must report it UNLESS the regulator informs labs otherwise.