

Uncertainty to Measurement

Every measurement has an element of uncertainty associated with it. When uncertainty is evaluated, it indicates the level of confidence that you have in the result of that measurement and therefore reflects the Quality of the result. Uncertainty of Measurement can be used to assess the confidence you have in a result for Qualitative and Quantitative measurements.

Uncertainty of Measurement shall be determined for every process that utilizes a measured result from a process. Sources of uncertainty of measurement exist for both quantitative and qualitative assays. These include:

- Inherent imprecision and inaccuracy of the measuring procedure.
- The incomplete definition of a test within the standard operating procedure. e.g. the volume of a reagent unstated, pH of a buffer not stated.
- Variability of reagents.
- Choice of substrates.
- The effects of environmental conditions.
- Bias in reading instruments/microscopes.
- Changes in performances since the last equipment calibration.
- Approximations or assumptions incorporated in SOPs.
- The technical competence of the analyst performing the test.
- Uncertainty of measurement in accuracy for pipettes used.
- Uncertainty of measurement in accuracy for calibrators used to standardise the test.

The relevant uncertainty components are those associated with the actual measurement process, commencing with the presentation of the sample to the measurement procedure and ending with the output of the measured value.

Measurement uncertainties may be calculated using quality values obtained by the measurement of quality control materials under intermediate precision conditions that include as many route changes as reasonably possible in the standard operation of a measurement procedure, e.g. changes of reagent by bottle and by lot and calibrator lot number, different operators, scheduled instrument maintenance & individual analyser difference.

Examples of the practical utility of uncertainty of measurement estimates might include confirmation that patients' values meet quality goals set by the laboratory and meaningful comparison of a patient value with a previous value of the same type or with a clinical decision value.

If you would like further information from Pathology First on Uncertainty of Measurement, please contact the Quality Team who will direct your query to the most appropriate Operations Manager.

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