australasian society of clinical immunology and allergy inc.

Guidelines – Uncertainty of Measurement (inter-batch/lot precision)

Parameter of Uncertainty of Measurement to be assessed = expanded uncertainty

- = Standard Deviation (SD) x 2 (rather than Coefficient of Variation [CV] x 2)
- Note: CV = (SD / Mean) x 100%

Number of measurements

- At least 60 (degrees of freedom), so at least n=61 measurements
- Across different lots/batches

What tests does this apply to?

- any test where quantitative values are used to obtain the result, including qualitative assays where a quantitative value is used to generate a test result (eg. Anti-ENA ELISA)

Reference material

- any external reference material (commercial or pooled patient samples) used for each assay
- value should be close to the cut off, clinical decision points OR mid range where curve is linear
- the kit controls should not be used instead of external reference material, as the assessment will be across different lots/batches

Reporting

- At present, we would not advise including the expanded uncertainty parameter on the report

Limitations

- We acknowledge the above expanded uncertainty parameter does not take into account bias or accuracy.

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ASCIA is the peak professional body of Clinical Immunologists and Allergists in Australia and New Zealand.