Uncertainty of Measurement:

How to Read MU Reports

NRL is a:

- **NATA-accredited proficiency testing provider, complying with ISO**
- **World Health Organization (WHO) Collaborating Centre for Diagnostics and Laboratory Support for HIV and AIDS and Other Blood-borne Infections**

NRL Science of Quality
4th Floor Healy Building
41 Victoria Parade
FITZROY VICTORIA 3065
AUSTRALIA
T: +61 3 9418 1111
F: +61 3 9418 1155
www.nrlquality.org.au
A.B.N. 52 004 705 640
SVI ST VINCENT'S INSTITUTE MEDICAL RESEARCH
NATA
World Health Organization
NRL is a WHO Collaborating Centre

1 BACKGROUND

All quantitative measurements have inherent inaccuracies (1). 1 Australian laboratories must assess this level of uncertainty of their test results by satisfying the requirements of ISO/IEC 15189 which states that The laboratory shall determine the uncertainty of results, where relevant and possible. Uncertainty components which are of importance shall be taken into account. (2). Guidance to the application of uncertainty of measurement (MU) is available from NRL, Australia (1, 2, 3, 4).

2 MU REPORTS

NRL has developed a system for estimating and reporting MU for quantitative assays based on the laboratory s test results for an external, low positive quality control (QC) sample and, on the comparison of these results with those of other laboratories using the same QC sample and assay (peer group). The MU estimation accounts for the assay s imprecision (random error) and bias (systematic error). The imprecision is measured by calculating the standard deviation (SD) of the QC sample results over a defined period of time. The bias, expressed as a SD, is calculated by comparing the mean of the QC sample results with a weighted mean of all the QC sample results of the peer group. The imprecision and bias are combined to obtain a combined standard uncertainty. This is multiplied by a factor of 2 to obtain an expanded uncertainty, which is the 95% confidence interval of the measurement.

3 HOW TO READ MU REPORTS

NRL MU report consists of three sections:

1) ASSAY DETAILS: The report provides information about the assay used, including a description of the assay, assay version, units in which results are expressed and the assay s reference range. The assay details also fully describe the measurand (the substance measured), and include a description of the analyte, the method of investigation and other factors specific to the assay.

2) FACTORS CONTRIBUTING TO MU: For each assay, the report details factors that contribute to systematic or random error within the laboratory when testing samples using the assay. The list of Interfering factors is obtained from the manufacturer s package insert. When using an assay, sources of variation can be identified. As sources of variation contributing less than 1/3 of uncertainty can be excluded from MU calculations, the list in the report is not exhaustive.

3) ESTIMATION OF MU: This section describes the QC sample, period of time QC sample results were reported and results of calculations. These results include:

- The number of QC sample results reported by your laboratory and the number reported by all laboratories in the peer group within the period of time selected;
- The mean of the peer group QC sample results, weighted for the precision and the number of QC sample results contributed by each individual laboratory in the peer group;
- The mean of the QC sample results contributed by your laboratory;
- The precision of the QC sample results reported by your laboratory expressed as a SD in the assay s units;
- The expanded uncertainty of your laboratory s test result (i.e. the mean of the QC sample results contributed by your laboratory + the expanded uncertainty, being the 95% confidence interval).

Example: If a laboratory has a mean of a low positive QC sample result of 2.65 units and an expanded uncertainty of measurement of + 0.47, then there is a 95% chance that a low positive sample with a result of 2.65 units will be between 2.18 and 3.12 units.

4 REFERENCES

1. White GH, I Farrance. 2004. Uncertainty of measurement in quantitative medical testing - a laboratory implementation guide. Clin Biochem Rev: 25:S1-S24.

2. International Standards Organization. Medical laboratories Particular requirements for quality and competence, ISO/IEC 15189.2007: ISO, Geneva.

3. Dimech W. et al. 2005. A proposed approach to estimating uncertainty of measurement in serological assays. Aust J Med Sci: 26: 58-64.

4. Dimech W. et al. 2006. Calculating uncertainty of measurement for serology assays by use of precision and bias. Clin Chem: 52: 526-529.