Biotech Laboratories
AIR FOOD WATER ENVIRONMENTAL TESTING

Every measurement is subject to some degree of uncertainty. Measurement uncertainties can come from a variety of sources and usually a combination of more than one. Such uncertainties can be estimated using statistical analysis of a set of measurements.

All NATA accredited laboratories are required to determine the measurement of uncertainty (MU) for quantitative analyses. At this time qualitative analyses such as presence/absence testing (eg Salmonella/Listeria in 25 grams and E. coli/Faecal coliforms in swabs) are not required to have MU estimates. ISO/IEC 17025, the standard to which our laboratory is NATA accredited requires procedures to estimate the uncertainty of their measurements. Furthermore, Section 5.10.3.1 c of the standard states test reports shall include information regarding MU when a customer instructs the laboratory to provide the information, when it is relevant to the validity or application of test results, or when it affects compliance to a specification limit. Measurement uncertainty reflects the range within which the true result lies at a stated level of probability (often 95%). It is different for each laboratory and within the laboratory it is a different value for each type of analysis. However, MU should not differ significantly between laboratories using the same technique for the same analysis.

Biotech Laboratories has been reporting the MU for all analyses on Legionella/Plate Counts reports from air-conditioning and potable water samples for a number of years. As stated above ISO/IEC 17025 requires accredited laboratories to report MU when the results combined with the MU may affect compliance with a specification. This requirement applies to all quantitative analysis.

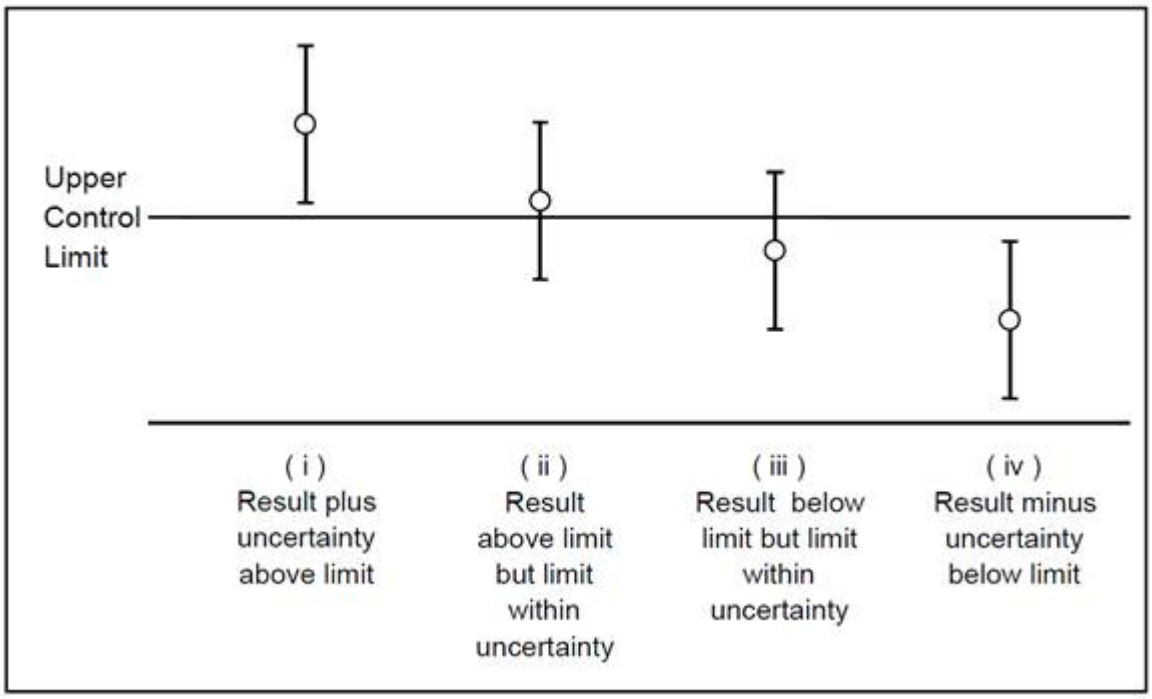
We will shortly commence the reporting the MU range on all applicable reports.

How do I interpret the measurement of uncertainty range results?

Regulatory guidelines such as AS366 Australian Drinking Water Guidelines, Food Standards Code and other documents either make no mention of MU or do not specifically state how a measurement of uncertainty result it should be interpreted.

We recommend you use the diagram from Eurochem CITAC Guide (http://eurachem2011.fc.ul.pt/pdf/QUAM2011_DIS1.pdf) description of how MU affects considerations of pass/fail.

The diagram below, from page 32 of the Eurochem CITAC Guide, describes the relationship between MU and pass/fail to a specification. It should be noted that the true value can occur anywhere in the MU range estimated is not the mid value of the range.



Case (i) is a definitely a fail as no part of the expanded MU is below the limit. Case (iv) is definitely a pass as no part is above the limit. For Case (ii) and Case (iii) it is the your decision based on risk analysis to accept the result as a pass or a fail. Case (ii) is more likely to have a true result that fails than Case (iii).

At present, Australian authorities have not stipulated how to interpret MU ranges and have indicated only they may need to be considered when interpreting results.

Until the applicable regulations and guidelines are reissued with a clear statement on how a MU range is to be interpreted, the interpretation of the report should be based on the reported analysis results, not on the MU range if it is reported. However, it is up to each company to determine how they will evaluate results where the MU is reported.

It must also be remembered that the interpretive reporting of our results, ie ticks or crosses on reports, are based on the reported result and does not include consideration of MU estimates regardless of proximity of the reported result to specifications or compliance limits.

Should you wish to discuss this further, please contact the laboratory.

Regards

Glen Pinna

General Manager