Uncertainty of Measurement in Microbiology

Every measurement or test has an error of measurement. If repeated, a test or measurement often gives a different result, even though it usually is very similar to the original result. Therefore, a test or measurement gives only an approximation of the true value of the quantity to be measured. A measurement or test is only complete if it includes the measurement uncertainty of the test. This can be thought of as a quantitative indication of the quality of the result.

The following tables show the mean of measured control values and the Standard Deviation of measured values against the measured mean. This Standard Deviation (or Standard Measurement Uncertainty) is multiplied by 2 to give the 95% confidence limit, and is expressed as the Expanded Measurement Uncertainty.[1] Units for all measurements are available upon request from Microbiology.
This data is gathered under indeterminate precision conditions, as defined in ISO 15189, and is reviewed 6 monthly.

1. Getting Practical about Measurement Uncertainty James O. Westgard JUNE 2013 http://www.westgard.com/labs-must-mu.htm

Infectious Serology

All our assays are calibrated against International Standards, and performance (precision) of the analyser monitored by using standardised controls measured against these standards. This allows the Analytical Variation of the assay system to be monitored and expressed as the Standard Deviation of these control results.

The Biological Uncertainty of measurement cannot be quantified as there is a lack of numerical data on the effects of Biological Variation. Biological factors which may affect assay performance include sample integrity (e.g. presence of haemolysis, lipaemia or icteric samples), the presence of hetrophile antibodies and the parenteral administration of Murine monoclonal antibodies for diagnostic or therapeutic purposes. The effects of these factors are controlled as much as possible by employing strict sample acceptance criteria, by confirming diagnostically significant results by alternative methods and by repeat testing of further samples.

For all assays of this type results should be interpreted taking into consideration clinical presentation. Although these assays have a high level of specificity anomalous results will be encountered hence our rigorous confirmation protocols for diagnostically significant tests.

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Measurement Uncertainty (Quantitative assays)

Analyte	Control Level	Laboratory Mean	SD (Measurement Uncertainty at this level of analyte)	95% Confidence limit (Expanded Measurement Uncertainty)
Rubella IgG	Neg	3.4	0.1	0.2
Rubella IgG	Pos	63.1	5.0	10.0
Anti HBs	Neg	2.4	0.5	1.0
Anti HBs	Pos	96.6	4.3	8.6
VZ IgG	Neg	29.7	4.1	8.2
VZ IgG	Pos	450.7	53.2	106.4
Procalcitonin	Level 1	2.3	0.25	0.5
Procalcitonin	Level 2	43.6	5.2	10.4

Measurement Uncertainty (Measurement step of Qualitative assays)

Analyte	Control Level	Laboratory Mean	SD (Measurement Uncertainty at this level of analyte)	95% Confidence limit (Expanded Measurement Uncertainty)
HIV Ag/Ab	Neg	0.21	0.02	0.04
HIV Ag/Ab	Pos	23.0	1.3	2.6
HIV Ag/Ab	Pos	65.9	5.9	11.8
Total Hep A	Neg	19.4	1.3	2.6
Total Hep A	Pos	38.4	2.2	4.4
Hep A IgM	Neg	0.37	0.04	0.08
Hep A IgM	Pos	1.88	0.12	0.24
HepB core (total)	Neg	2.3	0.07	0.14
HepB core (total)	Pos	0.48	0.08	0.16
HBsAg	Neg	0.52	0.07	0.14
HBsAg	Pos	3.8	0.4	0.8
Anti HBs	Neg	2.4	0.53	1.06
Anti HBs	Pos	94.4	4.3	8.6
Hep C antibody	Neg	0.06	0.01	0.02
Hep C antibody	Pos	3.6	0.3	0.6
CMV IgG	Neg	1.4	0.15	0.3
CMV IgG	Pos	23.0	1.9	3.8
CMV IgM	Neg	0.2	0.02	0.04
CMV IgM	Pos	2.6	0.2	0.4
Toxoplasma IgG	Neg	0.75	0.08	0.16
Toxoplasma IgG	Pos	44.0	2.4	4.8

Analyte	Control Level	Laboratory Mean	SD (Measurement Uncertainty at this level of analyte)	95 % Confidence limit (Expanded Measurement Uncertainty)
Syphilis	Neg	0.08	0.01	0.02
Syphilis	Pos	5.6	0.35	0.7
Rubella IgM	Neg	3.4	1.0	2.0
Rubella IgM	Pos	63.1	5.0	10.0
EBNA	Neg	QO(Qualitative only)	-	-
EBNA	Pos	70.3	6.7	13.4
VCAG	Neg	QO	-	-
VCAG	Pos	85.4	7.5	15.0
VCAM	Neg	QO	-	-
VCAM	Pos	74.7	13	26
Parvovirus IgG	Neg	QO	-	-
Parvovirus IgG	Pos	5.3	0.8	1.6
Parvovirus IgM	Neg	QO	-	-
Parvovirus IgM	Pos	2.4	0.3	0.6
Measles IgG	Neg	QO	-	-
Measles IgG	Pos	94.1	9.1	18.2
Mumps IgG	Neg	QO	-	-
Mumps IgG	Pos	78.9	13.3	26.6
Chlamydia IgG	Neg	QO	-	-
Chlamydia IgG	Pos	27.0	4.0	8.0
Borellia IgG	Neg	QO	-	
Borellia IgG	Pos	40.3	4.0	8.0
Borellia IgM	Neg	QO	-	-
Borellia IgM	Pos	2.3	0.3	0.6

Microbiology

Parasitology

Identification of faecal parasites depends on microscopic analysis of the parasites structure combined with comparison of the size of the parasite with published data. Measurement of size is by means of a calibrated digital display screen. Measurement uncertainty for this device is calculated by taking 20 measurements of length and width of a previously identified Giardia lamblia cyst, and using these measurements to calculate the following results.

Mean Length 13.86
Standard Measurement Uncertainty (Length) 0.47
Expanded Measurement Uncertainty (Length) 0.94

Mean Width 7.28
Standard Measurement Uncertainty (Width) 0.79
Expanded Measurement Uncertainty (Width) 1.58

Urine Microscopy

Cellular and other formed elements in Urine samples are counted using the Iris automated microscopy module, and the data from these counts is used for the semi-quantitative reporting of these components. Measurement uncertainty for the measurement phase of this process is calculated by taking 20 measurements for the commercially supplied Positive and Negative controls and using these measurements to calculate the following results.

Mean Positive control 58.8

Standard Measurement Uncertainty (Pos) 11.53

Expanded Measurement Uncertainty (Pos)23.06

Mean Negative control 7.5

Standard Measurement Uncertainty (Neg)4.86

Expanded Measurement Uncertainty (Neg)9.72