

NHS Greater Glasgow & Clyde Immunology and Neuroimmunology		
QF_4	Uncertainty of Measurement Summary Table for Immunochemistry	Version: 2
Author: Lauren Hennessy	Authoriser: Moira Thomas	Date of Issue: 01/07/19

Uncertainty of Measurement: Summary table for Immunochemistry Section

Uncertainty of measurement (UoM) is calculated using internal quality control (IQC)

The raw data and calculations can be found at the following location: <Y:\COMMON\Quality & Training\Uncertainty of Measurement>

Analyte	Anti-Hib antibodies on DS2	
	Low IQC	High IQC
Mean (x)	0.36	4.42
Number of measurements (n)	23	25
Estimated Standard Deviation (s)	0.055	0.23
Coefficient of Variance (%CV)	15.46%	5.25%
Coverage factor (k) to define a confidence level of 95%	2	2
Relative standard expanded uncertainty (U)	± 30.9%	± 10.5%
Uncertainty of measurement example (using IQC)	0.36 ±0.11 mg/L (0.25 – 0.47 mg/L)	4.42 ±0.46 mg/L (3.96 – 4.89 mg/L)

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Analyte	Anti-PCP antibodies on DS2	
	Low IQC	High IQC
Mean (x)	26.9	199.7
Number of measurements (n)	29	27
Estimated Standard Deviation (s)	1.81	31.74
Coefficient of Variance (%CV)	6.73%	15.9%
Coverage factor (k) to define a confidence level of 95%	2	2
Relative standard expanded uncertainty (U)	± 13.5%	± 31.8%
Uncertainty of measurement example (using IQC)	26.9 ± 3.62mg/L (23.3 – 30.5mg/L)	199.7 ± 63.47mg/L (136.2 – 263.2 mg/L)

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Analyte	Anti-tetanus toxoid antibodies on DS2	
	Low IQC	High IQC
Mean (x)	0.24	2.68
Number of measurements (n)	21	24
Estimated Standard Deviation (s)	0.02	0.33
Coefficient of Variance (%CV)	8.26%	12.3%
Coverage factor (k) to define a confidence level of 95%	2	2
Relative standard expanded uncertainty (U)	± 16.5%	± 24.6%
Uncertainty of measurement example (using IQC)	0.24 ± 0.04 IU/mL (0.20 – 0.28 IU/mL)	2.68 ± 0.66 IU/mL (2.02 – 3.34 IU/mL)

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Analyte	Anti-intrinsic factor antibodies on DS2	
	Negative IQC	Positive IQC
Mean (x)	3.5	95.6
Number of measurements (n)	41	38
Estimated Standard Deviation (s)	0.52	4.85
Coefficient of Variance (%CV)	14.83%	5.07%
Coverage factor (k) to define a confidence level of 95%	2	2
Relative standard expanded uncertainty (U)	± 29.7%	± 10.1%
Uncertainty of measurement example (using IQC)	3.5 ± 1.0 units (2.5 – 4.5 units)	95.6 ± 9.7 units (85.9 – 105.3 units)

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Analyte	Anti-GAD antibodies on DS2
	GAD IQC
Mean (x)	77.9
Number of measurements (n)	15
Estimated Standard Deviation (s)	5.57
Coefficient of Variance (%CV)	7.15%
Coverage factor (k) to define a confidence level of 95%	2
Relative standard expanded uncertainty (U)	± 14.3%
Uncertainty of measurement example (using IQC)	77.9 ± 11.14 U/mL (66.8 – 89.1 U/mL)

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Analyte	Serum free light chains (Kappa) on Optilite	
	Kappa low positive IQC	Kappa high positive IQC
Mean (x)	51.1	1063
Number of measurements (n)	35	16
Estimated Standard Deviation (s)	3.27	57.6
Coefficient of Variance (%CV)	6.39%	5.42%
Coverage factor (k) to define a confidence level of 95%	2	2
Relative standard expanded uncertainty (U)	± 12.8%	± 10.8%
Uncertainty of measurement example (using IQC)	51.1 ± 6.53 mg/L (44.6 – 57.7 mg/L)	1063 ± 115 mg/L (947– 1178 mg/L)

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Analyte	Serum free light chains (Lambda) on Optilite	
	Lambda low positive IQC	Lambda high positive IQC
Mean (x)	40.6	1967
Number of measurements (n)	36	30
Estimated Standard Deviation (s)	2.43	175.95
Coefficient of Variance (%CV)	5.98%	8.94%
Coverage factor (k) to define a confidence level of 95%	2	2
Relative standard expanded uncertainty (U)	± 12%	± 17.9%
Uncertainty of measurement example (using IQC)	40.6 ± 4.86 mg/L (35.8 – 45.5 mg/L)	1967 ± 352 mg/L (1615 – 2319 mg/L)

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Analyte	C1 inhibitor concentration on Optilite	
	C1 Low IQC	C1 High IQC
Mean (x)	0.160	0.366
Number of measurements (n)	6	6
Estimated Standard Deviation (s)	0.009	0.009
Coefficient of Variance (%CV)	5.34%	2.32%
Coverage factor (k) to define a confidence level of 95%	2	2
Relative standard expanded uncertainty (U)	± 10.7%	± 4.6%
Uncertainty of measurement example (using IQC)	0.160 ± 0.017 g/L (0.143 – 0.177 g/L)	0.366 ± 0.017 g/L (0.349 – 0.383 g/L)

For the details of the calculation and UoM protocol please refer to document QP_5: Uncertainty of Measurement Protocol.