Measurement Uncertainty: Summary Table for Phadia Assays

Measurement Uncertainty (MU) is calculated using internal quality control (IQC)

The raw data and calculations can be found at the following location: \\xggc-fsrv-04\GGC Biochemistry\Immunology\1IMM&NI\Quality\Uncertainty of Measurement

Analyte	**IgA anti-TTG antibodies on Phadia 2500**	
	Low IQC	High IQC
Mean (x)	16.2	67.0
Number of measurements (n)	81	162
Estimated Standard Deviation (s)	1.37	4.57
Coefficient of Variance (%CV)	8.47%	6.82%
Coverage factor (k) to define a confidence level of 95%	2	2
Relative standard expanded uncertainty (U)	**± 16.9%**	**± 13.6%**
Uncertainty of measurement **example** (using IQC**)**	16.2 ± 2.74 U/mL (13.4 – 18.9 U/mL)	67.0 ± 9.14 U/mL (57.8 – 76.1 U/mL)

Analyte	**IgG anti-TTG antibodies on Phadia 2500**
	IgG TTG IQC
Mean (x)	33.6
Number of measurements (n)	65
Estimated Standard Deviation (s)	3.22
Coefficient of Variance (%CV)	9.59%
Coverage factor (k) to define a confidence level of 95%	2
Relative standard expanded uncertainty (U)	**± 19.2%**
Uncertainty of measurement **example** (using IQC**)**	33.6 ± 6.44 U/mL (27.1 – 40.0 U/mL)

Analyte	**Anti-MPO antibodies on Phadia**	
	MPO IQC on Phadia 2500	MPO IQC on Phadia 250
Mean (x)	35.7	36.9
Number of measurements (n)	164	13
Estimated Standard Deviation (s)	2.91	2.84
Coefficient of Variance (%CV)	8.15%	7.70%
Coverage factor (k) to define a confidence level of 95%	2	2
Relative standard expanded uncertainty (U)	**± 16.3%**	**± 15.4%**
Uncertainty of measurement **example** (using IQC**)**	35.7 ± 5.8 IU/mL (29.9 – 41.5 IU/mL)	36.9 ± 5.7 IU/mL (31.2 – 42.6 IU/mL)

Analyte	**Anti-PR3 antibodies on Phadia**	
	PR3 IQC on Phadia 2500	PR3 IQC on Phadia 250
Mean (x)	29.3	23.7
Number of measurements (n)	225	18
Estimated Standard Deviation (s)	3.60	3.21
Coefficient of Variance (%CV)	12.32%	13.55%
Coverage factor (k) to define a confidence level of 95%	2	2
Relative standard expanded uncertainty (U)	**± 24.6%**	**± 27.1%**
Uncertainty of measurement **example** (using IQC**)**	29.3 ± 7.21 IU/mL (22.0 – 36.5 IU/mL)	23.7 ± 6.43 IU/mL (17.3 – 30.1 IU/mL)

Analyte	**Anti-GBM antibodies on Phadia**	
	GBM IQC on Phadia 2500	GBM IQC on Phadia 250
Mean (x)	66.3	62.8
Number of measurements (n)	78	4*
Estimated Standard Deviation (s)	6.39	2.22
Coefficient of Variance (%CV)	9.64%	3.53%
Coverage factor (k) to define a confidence level of 95%	2	2
Relative standard expanded uncertainty (U)	**± 19.3%**	**± 7.1%**
Uncertainty of measurement **example** (using IQC**)**	66.3 ± 12.78 U/mL (53.5 – 79.1 U/mL)	62.8 ± 4.43 U/mL (58.3 – 67.2 U/mL)

*Note: small number of measurements available for MU (includes monthly analyser comparison data) –250D only used as a backup analyser

Analyte	**Anti-CCP antibodies on Phadia 2500**
	CCP IQC
Mean (x)	73.8
Number of measurements (n)	301
Estimated Standard Deviation (s)	7.25
Coefficient of Variance (%CV)	9.82%
Coverage factor (k) to define a confidence level of 95%	2
Relative standard expanded uncertainty (U)	**± 19.6%**
Uncertainty of measurement **example** (using IQC**)**	73.8 ± 14.5 U/mL (59.3 – 88.3 U/mL)

Analyte	**Anti-dsDNA antibodies on Phadia 2500**	
	dsDNA Low IQC	dsDNA High IQC
Mean (x)	17.9	75.8
Number of measurements (n)	174	51
Estimated Standard Deviation (s)	1.80	8.67
Coefficient of Variance (%CV)	10.08%	11.44%
Coverage factor (k) to define a confidence level of 95%	2	2
Relative standard expanded uncertainty (U)	**± 20.2%**	**± 22.9%**
Uncertainty of measurement **example** (using IQC**)**	17.9 ± 3.6 IU/mL (14.3 – 21.5 IU/mL)	75.8 ± 17.3 IU/mL (58.5 –93.1 IU/mL)

Analyte	**Anti-ENA antibodies on Phadia 250 (ENA screen)**
	ENA screen (Symphony^{S}) IQC
Mean (x)	3.7
Number of measurements (n)	102
Estimated Standard Deviation (s)	0.39
Coefficient of Variance (%CV)	10.45%
Coverage factor (k) to define a confidence level of 95%	2
Relative standard expanded uncertainty (U)	**±20.9%**
Uncertainty of measurement **example** (using IQC**)**	3.7 ± 0.8 Ratio (2.9 – 4.5 Ratio)

Analyte	**Anti-Ro52 antibodies on Phadia 2500**
	Ro52 IQC
Mean (x)	28.8
Number of measurements (n)	40
Estimated Standard Deviation (s)	2.08
Coefficient of Variance (%CV)	7.2%
Coverage factor (k) to define a confidence level of 95%	2
Relative standard expanded uncertainty (U)	**±14.4 %**
Uncertainty of measurement **example** (using IQC**)**	28.8 ± 4.16 U/mL (24.6 – 33.0 U/mL)

Analyte	**Anti-Ro60 antibodies on Phadia 2500**
	Ro60 IQC
Mean (x)	73.1
Number of measurements (n)	159
Estimated Standard Deviation (s)	6.58
Coefficient of Variance (%CV)	8.99%
Coverage factor (k) to define a confidence level of 95%	2
Relative standard expanded uncertainty (U)	**± 18.0%**
Uncertainty of measurement **example** (using IQC**)**	73.1 ± 13.15 U/mL (60.0 – 86.3 U/mL)

Analyte	**Anti-La antibodies on Phadia 2500**
	La IQC
Mean (x)	55.0
Number of measurements (n)	41
Estimated Standard Deviation (s)	3.77
Coefficient of Variance (%CV)	6.86%
Coverage factor (k) to define a confidence level of 95%	2
Relative standard expanded uncertainty (U)	**± 13.7%**
Uncertainty of measurement **example** (using IQC**)**	55.0 ± 7.55 U/mL (47.5 – 62.6 U/mL)

Analyte	**Anti-SmD antibodies on Phadia 2500**
	SmD IQC
Mean (x)	17.7
Number of measurements (n)	25
Estimated Standard Deviation (s)	1.89
Coefficient of Variance (%CV)	10.67%
Coverage factor (k) to define a confidence level of 95%	2
Relative standard expanded uncertainty (U)	**± 21.3%**
Uncertainty of measurement **example** (using IQC**)**	17.7 ± 3.77 U/mL (13.9 – 21.5 U/mL)

Analyte	**Anti-U1RNP antibodies on Phadia 2500**
	U1-RNP IQC
Mean (x)	15.5
Number of measurements (n)	41
Estimated Standard Deviation (s)	2.46
Coefficient of Variance (%CV)	15.86%
Coverage factor (k) to define a confidence level of 95%	2
Relative standard expanded uncertainty (U)	**± 31.7%**
Uncertainty of measurement **example** (using IQC**)**	15.5 ± 4.92 U/mL (10.6 – 20.4 U/mL)

Analyte	**Anti-Jo-1 antibodies on Phadia 2500**
	Jo-1 IQC
Mean (x)	34.1
Number of measurements (n)	81
Estimated Standard Deviation (s)	3.93
Coefficient of Variance (%CV)	11.55%
Coverage factor (k) to define a confidence level of 95%	2
Relative standard expanded uncertainty (U)	**± 23.1%**
Uncertainty of measurement **example** (using IQC**)**	34.1 ± 7.87 U/mL (26.2 – 42.0 U/mL)

Analyte	**Anti-Scl-70 antibodies on Phadia 2500**
	Scl-70 IQC
Mean (x)	37.1
Number of measurements (n)	76
Estimated Standard Deviation (s)	4.26
Coefficient of Variance (%CV)	11.51%
Coverage factor (k) to define a confidence level of 95%	2
Relative standard expanded uncertainty (U)	**± 23.0%**
Uncertainty of measurement **example** (using IQC**)**	37.1 ± 8.53 U/mL (28.6 – 45.6 U/mL)

Analyte	**Anti-Ribosomal P antibodies on Phadia 2500**
	Ribosomal P IQC
Mean (x)	23.2
Number of measurements (n)	76
Estimated Standard Deviation (s)	3.26
Coefficient of Variance (%CV)	14.04%
Coverage factor (k) to define a confidence level of 95%	2
Relative standard expanded uncertainty (U)	**± 28.1%**
Uncertainty of measurement **example** (using IQC**)**	23.2 ± 6.52 U/mL (16.7 – 29.7 U/mL)

Analyte	**Anti-Centromere B antibodies on Phadia 2500**
	Centromere B IQC
Mean (x)	61.0
Number of measurements (n)	85
Estimated Standard Deviation (s)	5.10
Coefficient of Variance (%CV)	8.37%
Coverage factor (k) to define a confidence level of 95%	2
Relative standard expanded uncertainty (U)	**± 16.7%**
Uncertainty of measurement **example** (using IQC**)**	61.0 ± 10.21 U/mL (50.8 – 71.2 U/mL)

Analyte	**Total IgE on Phadia 2500**	
	Low IQC	High IQC
Mean (x)	146.0	2367.7
Number of measurements (n)	199	152
Estimated Standard Deviation (s)	10.0	167.12
Coefficient of Variance (%CV)	6.85%	7.06%
Coverage factor (k) to define a confidence level of 95%	2	2
Relative standard expanded uncertainty (U)	**± 13.7%**	**± 14.1%**
Uncertainty of measurement **example** (using IQC**)**	146.0 ± 20.0 kU/L (126– 166 kU/L)	2367.7 ± 334.2 kU/L (2033.5 – 2702.0 kU/L)

Analyte	**Allergen Specific IgE on Phadia 2500**		
	Low IQC	Medium IQC	High IQC
Mean (x)	0.47	6.2	22.0
Number of measurements (n)	160	155	182
Estimated Standard Deviation (s)	0.05	0.59	2.29
Coefficient of Variance (%CV)	9.74%	9.55%	10.38%
Coverage factor (k) to define a confidence level of 95%	2	2	2
Relative standard expanded uncertainty (U)	**± 19.5%**	**± 19.1%**	**± 20.8%**
Uncertainty of measurement **example** (using IQC**)**	0.47 ± 0.091 kAU/mL (0.37 – 0.56 kAU/mL)	6.2 ± 1.19 kAU/mL (5.0 – 7.4 kAU/mL)	22.0 ± 4.57 kAU/mL (17.4 – 26.6 kAU/mL)

Analyte	**Tryptase on Phadia 250**
	Tryptase IQC
Mean (x)	31.4
Number of measurements (n)	34
Estimated Standard Deviation (s)	1.83
Coefficient of Variance (%CV)	5.82%
Coverage factor (k) to define a confidence level of 95%	2
Relative standard expanded uncertainty (U)	**± 11.6%**
Uncertainty of measurement **example** (using IQC**)**	31.4 ± 3.66 µg/L (27.7 – 35.1 µg/L)

Analyte	**Specific IgG on Phadia 250**
	Aspergillus IgG IQC
Mean (x)	74.8
Number of measurements (n)	143
Estimated Standard Deviation (s)	8.40
Coefficient of Variance (%CV)	11.22%
Coverage factor (k) to define a confidence level of 95%	2
Relative standard expanded uncertainty (U)	**± 22.4%**
Uncertainty of measurement **example** (using IQC**)**	74.8 ± 16.79 mgA/L (58.0 – 91.6 mgA/L)

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