

NHS Greater Glasgow & Clyde Immunology and Neuroimmunology		
QF_19	Uncertainty of Measurement Summary Table for Phadia Assays	Version: 2
Author: Lauren Hennessy	Authoriser: Moira Thomas	Date of Issue: 15/06/20

Uncertainty of Measurement: Summary Table for Phadia Assays

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\1IMM&NI\Quality\Uncertainty of Measurement>

Analyte	Total IgE on Phadia 2500	
	Low IQC	High IQC
Mean (x)	99.3	2253.7
Number of measurements (n)	67	55
Estimated Standard Deviation (s)	4.87	173.85
Coefficient of Variance (%CV)	4.9%	7.71%
Coverage factor (k) to define a confidence level of 95%	2	2
Relative standard expanded uncertainty (U)	± 9.8%	± 15.4%
Uncertainty of measurement example (using IQC)	99.3 ± 9.74 kU/L (89.6 – 109.1 kU/L)	2253.7 ± 347.7 kU/L (1906 – 2601.4 kU/L)

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Analyte	Allergen Specific IgE on Phadia 2500		
	Low IQC	Medium IQC	High IQC
Mean (x)	1.5	18.6	58
Number of measurements (n)	79	79	76
Estimated Standard Deviation (s)	0.19	2.06	7.6
Coefficient of Variance (%CV)	12.06%	11.06%	7.6%
Coverage factor (k) to define a confidence level of 95%	2	2	2
Relative standard expanded uncertainty (U)	± 24.1%	± 22.1%	± 26.2%
Uncertainty of measurement example (using IQC)	1.5 ± 0.37 kAU/mL (1.2 – 1.9 kAU/mL)	18.6 ± 4.12 kAU/mL (14.5 – 22.8 kAU/mL)	58 ± 15.19 kAU/mL (42.8 – 73.2 kAU/mL)

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Analyte	IgA anti-TTG antibodies on Phadia 2500	
	Low IQC	High IQC
Mean (x)	14.4	55.2
Number of measurements (n)	104	105
Estimated Standard Deviation (s)	1.23	4.67
Coefficient of Variance (%CV)	8.57%	8.47%
Coverage factor (k) to define a confidence level of 95%	2	2
Relative standard expanded uncertainty (U)	± 17.1%	± 16.9%
Uncertainty of measurement example (using IQC)	14.4 ± 2.47 U/mL (11.9 – 16.9 U/mL)	55.2 ± 9.35 U/mL (45.9 – 64.5 U/mL)

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Analyte	IgG anti-TTG antibodies on Phadia 2500
	IgG TTG IQC
Mean (x)	31.9
Number of measurements (n)	24
Estimated Standard Deviation (s)	3.34
Coefficient of Variance (%CV)	10.48%
Coverage factor (k) to define a confidence level of 95%	2
Relative standard expanded uncertainty (U)	± 21.0%
Uncertainty of measurement example (using IQC)	31.9 ± 6.68 U/mL (25.2 – 38.6 U/mL)

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Analyte	Anti-CCP antibodies on Phadia 2500
	CCP IQC
Mean (x)	63.1
Number of measurements (n)	58
Estimated Standard Deviation (s)	5.61
Coefficient of Variance (%CV)	8.89%
Coverage factor (k) to define a confidence level of 95%	2
Relative standard expanded uncertainty (U)	± 17.8%
Uncertainty of measurement example (using IQC)	63.1 ± 11.23 U/mL (51.9 – 74.3 U/mL)

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Analyte	Anti-MPO antibodies on Phadia	
	MPO IQC on <u>Phadia 2500</u>	MPO IQC on <u>Phadia 250</u>
Mean (x)	28.6	31.8
Number of measurements (n)	52	118
Estimated Standard Deviation (s)	3.34	2.91
Coefficient of Variance (%CV)	11.69%	9.17%
Coverage factor (k) to define a confidence level of 95%	2	2
Relative standard expanded uncertainty (U)	± 23.4%	± 18.3%
Uncertainty of measurement example (using IQC)	28.6 ± 6.68 IU/mL (21.9 – 35.3 IU/mL)	31.8 ± 5.82 IU/mL (25.9 – 37.6 IU/mL)

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Analyte	Anti-PR3 antibodies on Phadia	
	<u>PR3 IQC on Phadia 2500</u>	<u>PR3 IQC on Phadia 250</u>
Mean (x)	22.7	20.9
Number of measurements (n)	47	156
Estimated Standard Deviation (s)	3.31	2.74
Coefficient of Variance (%CV)	14.57%	13.12%
Coverage factor (k) to define a confidence level of 95%	2	2
Relative standard expanded uncertainty (U)	± 29.1%	± 26.2%
Uncertainty of measurement example (using IQC)	22.7 ± 6.63 IU/mL (16.1 – 29.4 IU/mL)	20.9 ± 5.48 IU/mL (15.4 – 26.4 IU/mL)

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Analyte	Anti-GBM antibodies on Phadia	
	GBM IQC on <u>Phadia 2500</u>	GBM IQC on <u>Phadia 250</u>
Mean (x)	33.9	45.3
Number of measurements (n)	47	25
Estimated Standard Deviation (s)	4.64	7.2
Coefficient of Variance (%CV)	13.7%	15.89%
Coverage factor (k) to define a confidence level of 95%	2	2
Relative standard expanded uncertainty (U)	± 27.4%	± 31.8%
Uncertainty of measurement example (using IQC)	33.9 ± 9.28 U/mL (24.6 – 43.2 U/mL)	45.3 ± 14.39 U/mL (30.9 – 59.7 U/mL)

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Analyte	Anti-dsDNA antibodies on Phadia 2500	
	DNA Low IQC	DNA High IQC
Mean (x)	13.8	105.5
Number of measurements (n)	48	87
Estimated Standard Deviation (s)	1.39	16.06
Coefficient of Variance (%CV)	10.09%	15.23%
Coverage factor (k) to define a confidence level of 95%	2	
Relative standard expanded uncertainty (U)	± 20.2%	30.5 ± %
Uncertainty of measurement example (using IQC)	13.8 ± 2.79 IU/mL (11.0 – 16.6 IU/mL)	105.5 ± 32.12 IU/mL (73.3 – 137.6 IU/mL)

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Analyte	Anti-ENA antibodies on Phadia 250 (ENA screen)
	ENA screen (Symphony ^S) IQC
Mean (x)	3.5
Number of measurements (n)	75
Estimated Standard Deviation (s)	0.41
Coefficient of Variance (%CV)	11.71%
Coverage factor (k) to define a confidence level of 95%	2
Relative standard expanded uncertainty (U)	±23.4%
Uncertainty of measurement example (using IQC)	3.5 ± 0.83 Ratio (2.7 – 4.4 Ratio)

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Analyte	Anti-Ro52 antibodies on Phadia 2500
	Ro52 IQC
Mean (x)	131.8
Number of measurements (n)	32
Estimated Standard Deviation (s)	10.58
Coefficient of Variance (%CV)	8.03%
Coverage factor (k) to define a confidence level of 95%	2
Relative standard expanded uncertainty (U)	± 16.1%
Uncertainty of measurement example (using IQC)	131.8 ± 21.16 U/mL (110.6– 152.9 U/mL)

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Analyte	Anti-Ro60 antibodies on Phadia 2500
	Ro60 IQC
Mean (x)	52.5
Number of measurements (n)	63
Estimated Standard Deviation (s)	4.76
Coefficient of Variance (%CV)	9.06%
Coverage factor (k) to define a confidence level of 95%	2
Relative standard expanded uncertainty (U)	± 18.1%
Uncertainty of measurement example (using IQC)	52.5 ± 9.52 U/mL (43.0 – 62.0 U/mL)

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Analyte	Anti-La antibodies on Phadia 2500
	La IQC
Mean (x)	73.8
Number of measurements (n)	35
Estimated Standard Deviation (s)	6.27
Coefficient of Variance (%CV)	8.49%
Coverage factor (k) to define a confidence level of 95%	2
Relative standard expanded uncertainty (U)	± 17.0%
Uncertainty of measurement example (using IQC)	73.8 ± 12.53 U/mL (61.3 – 86.4 U/mL)

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Analyte	Anti-SmD antibodies on Phadia 2500
	SmD IQC
Mean (x)	23.8
Number of measurements (n)	28
Estimated Standard Deviation (s)	2.48
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)	23.8 ± 4.97 U/mL (18.8 – 28.8 U/mL)

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Analyte	Anti-U1RNP antibodies on Phadia 2500
	U1-RNP IQC
Mean (x)	8.6
Number of measurements (n)	35
Estimated Standard Deviation (s)	1.05
Coefficient of Variance (%CV)	12.24%
Coverage factor (k) to define a confidence level of 95%	2
Relative standard expanded uncertainty (U)	± 24.5%
Uncertainty of measurement example (using IQC)	8.6 ± 2.1 U/mL (6.5 – 10.7 U/mL)

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Analyte	Anti-Jo-1 antibodies on Phadia 2500
	Jo-1 IQC
Mean (x)	33.8
Number of measurements (n)	27
Estimated Standard Deviation (s)	3.06
Coefficient of Variance (%CV)	9.06%
Coverage factor (k) to define a confidence level of 95%	2
Relative standard expanded uncertainty (U)	± 18.1%
Uncertainty of measurement example (using IQC)	33.8 ± 6.13 U/mL (27.2 – 39.9 U/mL)

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Analyte	Anti-Scl-70 antibodies on Phadia 2500
	Scl-70 IQC
Mean (x)	43.9
Number of measurements (n)	64
Estimated Standard Deviation (s)	3.46
Coefficient of Variance (%CV)	7.90%
Coverage factor (k) to define a confidence level of 95%	2
Relative standard expanded uncertainty (U)	± 15.8%
Uncertainty of measurement example (using IQC)	43.9 ± 6.93 U/mL (36.9 – 50.8 U/mL)

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Analyte	Anti-Ribosomal P antibodies on Phadia 2500
	RiboP IQC
Mean (x)	18.2
Number of measurements (n)	28
Estimated Standard Deviation (s)	1.74
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)	18.2 ± 3.49 U/mL (14.7 – 21.7 U/mL)

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Analyte	Anti-Centromere B antibodies on Phadia 2500
	CENTB IQC
Mean (x)	76.0
Number of measurements (n)	25
Estimated Standard Deviation (s)	5.51
Coefficient of Variance (%CV)	7.26%
Coverage factor (k) to define a confidence level of 95%	2
Relative standard expanded uncertainty (U)	± 14.5%
Uncertainty of measurement example (using IQC)	76.0 ± 11.02 U/mL (64.9 – 87.0 U/mL)

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Analyte	Specific IgG on Phadia 250
	ASP IQC
Mean (x)	62.7
Number of measurements (n)	53
Estimated Standard Deviation (s)	5.64
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)	62.7 ± 11.27 mgA/L (51.4 – 74.0 mgA/L)

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Analyte	Tryptase on Phadia 250
	TRYP IQC
Mean (x)	26.8
Number of measurements (n)	52
Estimated Standard Deviation (s)	1.78
Coefficient of Variance (%CV)	6.65%
Coverage factor (k) to define a confidence level of 95%	2
Relative standard expanded uncertainty (U)	± 13.3%
Uncertainty of measurement example (using IQC)	13.3 ± 3.57 µg/L (23.2 – 30.4 µg/L)

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