

NHS Greater Glasgow & Clyde Immunology and Neuroimmunology		
LI_ICHEM_3	Measurement Uncertainty Summary Table for Optilite assays	Version: 5
Author: Lauren Hennessy	Authoriser: Sylvia Arthur	Date of Issue: 01/07/2026

Measurement Uncertainty: Summary table for Optilite 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\QUALITY\Quality Control\Uncertainty of Measurement>

Analyte	C1 inhibitor concentration on Optilite	
	C1 Inhibitor Low IQC	C1 Inhibitor High IQC
Mean (x)	0.12	0.329
Number of measurements (n)	70	73
Estimated Standard Deviation (s)	0.01	0.02
Coefficient of Variance (%CV)	7.84%	5.17%
Coverage factor (k) to define a confidence level of 95%	2	2
Relative standard expanded uncertainty (U)	± 15.7%	± 10.3%
Uncertainty of measurement example (using IQC)	0.12 ± 0.019 g/L	0.33 ± 0.034 g/L
	(0.10 – 0.14 g/L)	(0.30 – 0.36 g/L)

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Analyte	Serum free light chains (Kappa) on Optilite	
	Kappa low positive IQC	Kappa high positive IQC
Mean (x)	39.6	393.5
Number of measurements (n)	191	383
Estimated Standard Deviation (s)	1.33	18.51
Coefficient of Variance (%CV)	3.35%	4.70%
Coverage factor (k) to define a confidence level of 95%	2	2
Relative standard expanded uncertainty (U)	± 6.7%	± 9.4%
Uncertainty of measurement example (using IQC)	39.6 ± 2.7 mg/L (36.9 – 42.3 mg/L)	393.5 ± 37.0 mg/L (356.5– 430.5 mg/L)

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Analyte	Serum free light chains (Lambda) on Optilite	
	Lambda low positive IQC	Lambda high positive IQC
Mean (x)	33.1	311.5
Number of measurements (n)	406	152
Estimated Standard Deviation (s)	1.20	12.52
Coefficient of Variance (%CV)	3.64%	4.02%
Coverage factor (k) to define a confidence level of 95%	2	2
Relative standard expanded uncertainty (U)	± 7.3%	± 8.0%
Uncertainty of measurement example (using IQC)	33.1 ± 2.4 mg/L (30.7 – 35.5 mg/L)	311.5 ± 25.0 mg/L (286.5 – 336.6 mg/L)

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