| NHS Greater Glasgow & Clyde Immunology and Neuroimmunology | | |
|---|---|---|
| QF_4 | Uncertainty of Measurement Summary Table for Optilite assays | Version: 4 |
| Author: Lauren Hennessy | Authoriser: Moira Thomas | Date of Issue:  20/03/24 |

## Uncertainty of Measurement: Summary table for Optilite assays

Uncertainty of measurement (UoM) 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 | C1 inhibitor concentration on Optilite | |
|---|---|---|
| | C1 Inhibitor Low IQC | C1 Inhibitor High IQC |
| Mean (x) | 0.181 | 0.339 |
| Number of measurements (n) | 35 | 28 |
| Estimated Standard Deviation (s) | 0.008 | 0.014 |
| Coefficient of Variance (%CV) | 4.21% | 4.26% |
| Coverage factor (k) to define a confidence level of 95% | 2 | 2 |
| | | |
| **Relative standard expanded uncertainty (U)** | **± 8.4%** | **± 8.5%** |
| | | |
| Uncertainty of measurement **example** (using IQC**)** | 0.181 ± 0.015 g/L<br><br>(0.166 –  0.196 g/L) | 0.339  ± 0.029 g/L<br><br>(0.310 –  0.368 g/L) |
| | | |

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| Analyte | Serum free light chains (Kappa) on Optilite | |
|---|---|---|
| | Kappa low positive IQC | Kappa high positive IQC |
| Mean (x) | 44.0 | 384.7 |
| Number of measurements (n) | 228 | 161 |
| Estimated Standard Deviation (s) | 2.39 | 21.83 |
| Coefficient of Variance (%CV) | 5.43% | 5.67% |
| Coverage factor (k) to define a confidence level of 95% | 2 | 2 |
| | | |
| **Relative standard expanded uncertainty (U)** | **± 10.9%** | **± 11.3%** |
| | | |
| Uncertainty of measurement **example** (using IQC**)** | 44.0 ± 4.78 mg/L<br><br>(39.2 – 48.8 mg/L) | 384.7 ± 43.7 mg/L<br><br>(341– 428 mg/L) |
| | | |

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| Analyte | Serum free light chains (Lambda) on Optilite | |
|---|---|---|
| | Lambda low positive IQC | Lambda high positive IQC |
| Mean (x) | 43.4 | 434.4 |
| Number of measurements (n) | 100 | 100 |
| Estimated Standard Deviation (s) | 2.05 | 21.6 |
| Coefficient of Variance (%CV) | 4.73% | 4.97% |
| Coverage factor (k) to define a confidence level of 95% | 2 | 2 |
| | | |
| **Relative standard expanded uncertainty (U)** | **± 9.5%** | **± 9.9%** |
| | | |
| Uncertainty of measurement **example** (using IQC**)** | 43.4  ±  4.10 mg/L<br><br>(39.3 – 47.5  mg/L) | 434.4 ±  43.2 mg/L<br><br>(391 – 478 mg/L) |
| | | |

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