**Supplementary Material****s**

**Tables**

Table s1. pTau217 validation summary table (Matrix: Human Plasma).

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Minimum Sample Volume | 33.3 µL for Human Plasma | | | | | |
| Standard Curve Fit | 5PL with weighting factor of 1/Y2 | | | | | |
| Lower Limit of Quantification (LLOQ) (ng/mL) | 0.00977 pg/mL | | | | | |
| Upper Limit of Quantification (ULOQ) (ng/mL) | 10.0 pg/mL | | | | | |
| Standard Curve Range | 0.00977 pg/mL to 10.0 pg/mL define the standard curve limits of quantification. | | | | | |
| Minimum Required Dilution (MRD) | 1:3 | | | | | |
| Accuracy and Precision | Parameters | LLOQ (0.00977 pg/mL) | pLQC (0.146 pg/mL) | pMQC (0.503 pg/mL) | HQC (2.50 pg/mL) | ULOQ (10.0 pg/mL) |
| Intra-assay | 2.4 | -3.8 | -3.5 | -1.6 | -1.8 |
| Relative Error (%RE) |
| Intra-assay | 6.0 | 7.7 | 3.9 | 4.1 | 2.5 |
| Precision (%CV) |
| Inter-assay | 1.2 | 0.1 | 0.1 | 2.0 | 1.5 |
| Relative Error (%RE) |
| Inter-assay | 0.0 | 6.9 | 6.0 | 5.1 | 4.9 |
| Precision (%CV) |
| %Total Error (%TE) | 1.2 | 7.0 | 6.1 | 7.1 | 6.4 |
| Linearity of Dilution | Human plasma samples were diluted in Sample Diluent starting at the MRD (1:3) to a maximum dilution of 1:48. Dilution linearity was observed between the dilution series from 1:3 (MRD) to 1:48. | | | | | |
| Freeze Thaw Stability | pTau217 in human plasma is stable for up to 5 freeze-thaw cycles from -70°C (nominal) to ambient temperature. | | | | | |
| Bench-top Stability | pTau217 in human plasma is stable for up to 6 hours on bench-top at ambient temperature. | | | | | |
| Refrigerator Stability | pTau217 in human plasma is stable for up to 24 hours at 4°C. | | | | | |

Table s2. pTau217 validation summary table (Matrix: Human Serum).

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Minimum Sample Volume | 33.3 µL for Human Serum | | | | | |
| Standard Curve Fit | 5PL with weighting factor of 1/Y2 | | | | | |
| Lower Limit of Quantification (LLOQ) (ng/mL) | 0.00977 pg/mL | | | | | |
| Upper Limit of Quantification (ULOQ) (ng/mL) | 10.0 pg/mL | | | | | |
| Standard Curve Range | 0.00977 pg/mL to 10.0 pg/mL define the standard curve limits of quantification. | | | | | |
| Minimum Required Dilution (MRD) | 1:3 | | | | | |
| Accuracy and Precision | Parameters | LLOQ (0.00977 pg/mL) | sLQC (0.130 pg/mL) | sMQC (0.340 pg/mL) | HQC (2.50 pg/mL) | ULOQ (10.0 pg/mL) |
| Intra-assay | 2.4 | -2.2 | 3.0 | -1.6 | -1.8 |
| Relative Error (%RE) |
| Intra-assay | 6.0 | 2.8 | 3.4 | 4.1 | 2.5 |
| Precision (%CV) |
| Inter-assay | 1.2 | 0.1 | 0.1 | 2.0 | 1.5 |
| Relative Error (%RE) |
| Inter-assay | 0.0 | 7.7 | 5.9 | 5.1 | 4.9 |
| Precision (%CV) |
| %Total Error (%TE) | 1.2 | 7.0 | 6.1 | 7.1 | 6.4 |
| Linearity of Dilution | Human serum samples were diluted in Sample Diluent starting at the MRD (1:3) to a maximum dilution of 1:48. Dilution linearity was observed between the dilution series from 1:3 (MRD) to 1:12. | | | | | |
| Freeze Thaw Stability | pTau217 in human serum is stable for up to 5 freeze-thaw cycles from -70°C (nominal) to ambient temperature. | | | | | |
| Bench-top Stability | pTau217 in human serum is stable for up to 6 hours on bench-top at ambient temperature. | | | | | |
| Refrigerator Stability | pTau217 in human serum is stable for up to 24 hours at 4°C. | | | | | |

Table s3. pTau217 validation summary table (Matrix: Human CSF).

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Minimum Sample Volume | 5 µL for Human CSF | | | | | |
| Standard Curve Fit | 5PL with weighting factor of 1/Y2 | | | | | |
| Lower Limit of Quantification (LLOQ) (ng/mL) | 0.00977 pg/mL | | | | | |
| Upper Limit of Quantification (ULOQ) (ng/mL) | 10.0 pg/mL | | | | | |
| Standard Curve Range | 0.00977 pg/mL to 10.0 pg/mL define the standard curve limits of quantification. | | | | | |
| Minimum Required Dilution (MRD) | 1:20 | | | | | |
| Accuracy and Precision | Parameters | LLOQ (0.00977 pg/mL) | cLQC (3.32 pg/mL) | cMQC (9.61 pg/mL) | HQC (2.50 pg/mL) | ULOQ (10.0 pg/mL) |
| Intra-assay | 2.4 | 2.2 | 1.6 | -1.6 | -1.8 |
| Relative Error (%RE) |
| Intra-assay | 6.0 | 2.4 | 3.4 | 4.1 | 2.5 |
| Precision (%CV) |
| Inter-assay | 1.2 | 0.1 | 0.1 | 2.0 | 1.5 |
| Relative Error (%RE) |
| Inter-assay | 0.0 | 8.7 | 9.8 | 5.1 | 4.9 |
| Precision (%CV) |
| %Total Error (%TE) | 1.2 | 7.0 | 6.1 | 7.1 | 6.4 |
| Linearity of Dilution | Human CSF samples were diluted in Sample Diluent starting at the MRD (1:20) to a maximum dilution of 1:320. Dilution linearity was observed between the dilution series from 1:20 (MRD) to 1:320. | | | | | |
| Freeze Thaw Stability | pTau217 in human CSF is stable for up to 5 freeze-thaw cycles from -70°C (nominal) to ambient temperature. | | | | | |
| Bench-top Stability | pTau217 in human CSF is stable for up to 6 hours on bench-top at ambient temperature. | | | | | |
| Refrigerator Stability | pTau217 in human CSF is stable for up to 24 hours at 4°C. | | | | | |

Table s4. pTau217 Standards

|  |  |
| --- | --- |
| **Calibration Standard** | **pTau217 (pg/mL)** |
| STD1 (ULOQ) | 10.0 |
| STD2 | 5.00 |
| STD3 | 2.50 |
| STD4 | 0.625 |
| STD5 | 0.156 |
| STD6 | 0.0391 |
| STD7 | 0.0195 |
| STD8 (LLOQ) | 0.00977 |
| Blank | 0.00 |

Table s5. QCs

|  |  |
| --- | --- |
| **Quality Control** | **pTau217 (pg/mL)** |
| ULOQ (Buffer) | 10.0 |
| HQC (Buffer) | 2.50 |
| MQC (Plasma) | 0.503 |
| LQC (Plasma) | 0.146 |
| MQC (Serum) | 0.340 |
| LQC (Serum) | 0.130 |
| MQC (CSF) | 9.61 |
| LQC (CSF) | 3.32 |
| LLOQ (Buffer) | 0.00977 |

Note: MRD 1:3 only applies to matrix plasma and serum MQC and LQC.

MRD 1:20 only applies to matrix CSF MQC and LQC.

Table s6. Accuracy and Precision from All QCs (pTau217 in Human Plasma)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **P&A Summary Data** | | Nominal Concentration (pg/mL) | | | | |
| LLOQ | pLQC | pMQC | HQC | ULOQ |
| **Characteristic** | **Statistic** | 0.00977 | 0.146 | 0.503 | 2.50 | 10.0 |
| # Results | N | 24 | 21 | 21 | 21 | 21 |
| Accuracy | Mean Bias (%RE) | 1.2 | 0.1 | 0.1 | 2.0 | 1.5 |
| Inter-assay (%CV) | 0.0 | 6.9 | 6.0 | 5.1 | 4.9 |
| Total Error | ABS(%RE) + Inter-assay (%CV) | 1.2 | 7.0 | 6.1 | 7.1 | 6.4 |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| QC (pg/mL) | Run | Replicate Results | | | | | | Intrabatch (within-run) | | | | | % TE |
| 1 | 2 | 3 | 4 | 5 | 6 | n | Mean | SD | %CV | %RE |  |
| 10.0 | 1 | 10.7 | 10.7 | 9.60 |  |  |  | 3 | 10.3 | 0.640 | 6.2 | 3.3 |  |
| 3 | 10.1 | 10.1 | 9.83 |  |  |  | 3 | 10.0 | 0.160 | 1.6 | 0.1 |  |
| 4 | 11.0 | 10.9 | 11.0 |  |  |  | 3 | 11.0 | 0.060 | 0.5 | 9.7 |  |
| 5 | 9.88 | 9.98 | 10.5 |  |  |  | 3 | 10.1 | 0.330 | 3.3 | 1.2 |  |
| (ULOQ) | 6 | 10.7 | 10.1 | 10.1 |  |  |  | 3 | 10.3 | 0.350 | 3.4 | 3.0 |  |
| 13 | 9.88 | 9.57 | 10.0 | 9.39 | 9.64 | 9.39 | 6 | 9.65 | 0.250 | 2.6 | -3.5 |  |
| Interbatch (between-run) | | | | | | | 21 | 10.1 | 0.500 | 4.9 | 1.5 | 6.4 |
| 2.50 | 1 | 2.56 | 2.61 | 2.62 |  |  |  | 3 | 2.60 | 0.00 | 0.0 | 3.9 |  |
| 3 | 2.40 | 2.42 | 2.43 |  |  |  | 3 | 2.42 | 0.00 | 0.0 | -3.3 |  |
| 4 | 2.74 | 2.85 | 2.71 |  |  |  | 3 | 2.77 | 0.100 | 3.6 | 10.7 |  |
| 5 | 2.44 | 2.51 | 2.53 |  |  |  | 3 | 2.49 | 0.00 | 0.0 | -0.3 |  |
| (HQC) | 6 | 2.59 | 2.65 | 2.71 |  |  |  | 3 | 2.65 | 0.100 | 3.8 | 6.0 |  |
| 13 | 2.48 | 2.49 | 2.56 | 2.35 | 2.45 | 2.43 | 6 | 2.46 | 0.100 | 4.1 | -1.6 |  |
| Interbatch (between-run) | | | | | | | 21 | 2.55 | 0.130 | 5.1 | 2.0 | 7.1 |
| 0.503 | 1 | 0.543 | 0.532 | 0.521 |  |  |  | 3 | 0.532 | 0.0110 | 2.1 | 5.8 |  |
| 3 | 0.540 | 0.527 | 0.548 |  |  |  | 3 | 0.538 | 0.0110 | 2.0 | 7.1 |  |
| 4 | 0.457 | 0.489 | 0.477 |  |  |  | 3 | 0.474 | 0.0160 | 3.4 | -5.6 |  |
| 5 | 0.498 | 0.463 | 0.486 |  |  |  | 3 | 0.482 | 0.0180 | 3.7 | -4.0 |  |
| (pMQC) | 6 | 0.505 | 0.525 | 0.535 |  |  |  | 3 | 0.522 | 0.0150 | 2.9 | 3.8 |  |
| 13 | 0.499 | 0.502 | 0.501 | 0.482 | 0.468 | 0.460 | 6 | 0.485 | 0.0180 | 3.7 | -3.4 |  |
| Interbatch (between-run) | | | | | | | 21 | 0.503 | 0.0300 | 6.0 | 0.1 | 6.1 |
| 0.146 | 1 | 0.149 | 0.147 | 0.166 |  |  |  | 3 | 0.150 | 0.0104 | 6.9 | 3.0 |  |
| 3 | 0.165 | 0.153 | 0.165 |  |  |  | 3 | 0.160 | 0.00690 | 4.3 | 9.9 |  |
| 4 | 0.140 | 0.133 | 0.130 |  |  |  | 3 | 0.130 | 0.00510 | 3.9 | -10.7 |  |
| 5 | 0.137 | 0.122 | 0.137 |  |  |  | 3 | 0.130 | 0.00870 | 6.7 | -10.7 |  |
| (pLQC) | 6 | 0.159 | 0.145 | 0.153 |  |  |  | 3 | 0.150 | 0.00700 | 4.7 | 3.0 |  |
| 13 | 0.130 | 0.146 | 0.145 | 0.151 | 0.155 | 0.129 | 6 | 0.140 | 0.0108 | 7.7 | -3.8 |  |
| Interbatch (between-run) | | | | | | | 21 | 0.146 | 0.0100 | 6.9 | 0.1 | 7.0 |
| 0.00977 | 1 | 0.0443\* | 0.0434\* | 0.0474\* |  |  |  | 0 | NA | NA | NA | NA |  |
| 3 | 0.00904 | 0.00951 | 0.00932 |  |  |  | 3 | 0.0090 | 0.000200 | 2.2 | -7.9 |  |
| 4 | 0.00988 | 0.0102 | 0.0104 | 0.00986 | 0.00949 | 0.0104 | 6 | 0.0100 | 0.000400 | 4.0 | 2.4 |  |
| 5 | 0.0103 | 0.00960 | 0.0110 |  |  |  | 3 | 0.0100 | 0.000700 | 7.0 | 2.4 |  |
| (LLOQ) | 6 | 0.0110 | 0.0101 | 0.0105 |  |  |  | 3 | 0.0110 | 0.000450 | 4.1 | 12.6 |  |
| 11 | 0.00966 | 0.0102 | 0.00930 |  |  |  | 3 | 0.0100 | 0.000500 | 5.0 | 2.4 |  |
| 13 | 0.00965 | 0.0107 | 0.00948 | 0.00915 | 0.00956 | 0.00901 | 6 | 0.0100 | 0.000600 | 6.0 | 2.4 |  |
| Interbatch (between-run) | | | | | | | 24 | 0.00989 | 0.00 | 0.0 | 1.2 | 1.2 |

\*: LLOQ preparation error.

Table s7. Accuracy and Precision from All QCs (pTau217 in Human Serum)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **P&A Summary Data** | | Nominal Concentration (pg/mL) | | | | |
| LLOQ | cLQC | cMQC | HQC | ULOQ |
| **Characteristic** | **Statistic** | 0.00977 | 0.130 | 0.340 | 2.50 | 10.0 |
| # Results | N | 24 | 21 | 20 | 21 | 21 |
| Accuracy | Mean Bias (%RE) | 1.2 | 0.1 | 0.1 | 2.0 | 1.5 |
| Inter-assay (%CV) | 0.0 | 7.7 | 5.9 | 5.1 | 4.9 |
| Total Error | ABS(%RE) + Inter-assay (%CV) | 1.2 | 7.8 | 6.0 | 7.1 | 6.4 |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| QC (pg/mL) | Run | Replicate Results | | | | | | Intrabatch (within-run) | | | | | % TE |
| 1 | 2 | 3 | 4 | 5 | 6 | n | Mean | SD | %CV | %RE |  |
| 10.0 | 1 | 10.7 | 10.7 | 9.60 |  |  |  | 3 | 10.3 | 0.640 | 6.2 | 3.3 |  |
| 2 | 9.88 | 9.57 | 10.0 | 9.39 | 9.64 | 9.39 | 6 | 9.65 | 0.250 | 2.6 | -3.5 |  |
| 3 | 10.1 | 10.1 | 9.83 |  |  |  | 3 | 10.0 | 0.160 | 1.6 | 0.1 |  |
| 4 | 11.0 | 10.9 | 11.0 |  |  |  | 3 | 11.0 | 0.0600 | 0.5 | 9.7 |  |
| (ULOQ) | 5 | 9.88 | 9.98 | 10.5 |  |  |  | 3 | 10.1 | 0.330 | 3.3 | 1.2 |  |
| 6 | 10.7 | 10.1 | 10.1 |  |  |  | 3 | 10.3 | 0.350 | 3.4 | 3.0 |  |
| Interbatch (between-run) | | | | | | | 21 | 10.1 | 0.500 | 4.9 | 1.5 | 6.4 |
| 2.50 | 1 | 2.56 | 2.61 | 2.62 |  |  |  | 3 | 2.60 | 0.00 | 0.0 | 3.9 |  |
| 2 | 2.48 | 2.49 | 2.56 | 2.35 | 2.45 | 2.43 | 6 | 2.46 | 0.100 | 4.1 | -1.6 |  |
| 3 | 2.40 | 2.42 | 2.43 |  |  |  | 3 | 2.42 | 0.000 | 0.0 | -3.3 |  |
| 4 | 2.74 | 2.85 | 2.71 |  |  |  | 3 | 2.77 | 0.100 | 3.6 | 10.7 |  |
| (HQC) | 5 | 2.44 | 2.51 | 2.53 |  |  |  | 3 | 2.49 | 0.00 | 0.0 | -0.3 |  |
| 6 | 2.59 | 2.65 | 2.71 |  |  |  | 3 | 2.65 | 0.100 | 3.8 | 6.0 |  |
| Interbatch (between-run) | | | | | | | 21 | 2.55 | 0.130 | 5.1 | 2.0 | 7.1 |
| 0.340 | 1 | 0.339 | 0.350 | 0.352\* |  |  |  | 2.000 | 0.345 | 0.008 | 2.3 | 1.2 |  |
| 2 | 0.342 | 0.334 | 0.345 | 0.361 | 0.367 | 0.354 | 6 | 0.351 | 0.0120 | 3.4 | 3.0 |  |
| 3 | 0.369 | 0.364 | 0.355 |  |  |  | 3 | 0.363 | 0.00700 | 1.9 | 6.5 |  |
| 4 | 0.321 | 0.320 | 0.302 |  |  |  | 3 | 0.314 | 0.0110 | 3.5 | -7.7 |  |
| (sMQC) | 5 | 0.326 | 0.320 | 0.315 |  |  |  | 3 | 0.320 | 0.00600 | 1.9 | -5.9 |  |
| 6 | 0.330 | 0.350 | 0.344 |  |  |  | 3 | 0.341 | 0.0100 | 2.9 | 0.3 |  |
| Interbatch (between-run) | | | | | | | 20 | 0.340 | 0.0200 | 5.9 | 0.1 | 6.0 |
| 0.130 | 1 | 0.141 | 0.135 | 0.140 |  |  |  | 3 | 0.139 | 0.00320 | 2.3 | 6.9 |  |
| 2 | 0.126 | 0.124 | 0.122 | 0.129 | 0.128 | 0.132 | 6 | 0.127 | 0.00360 | 2.8 | -2.2 |  |
| 3 | 0.135 | 0.145 | 0.139 |  |  |  | 3 | 0.140 | 0.00500 | 3.6 | 7.7 |  |
| 4 | 0.114 | 0.135 | 0.126 |  |  |  | 3 | 0.125 | 0.0105 | 8.4 | -3.6 |  |
| (sLQC) | 5 | 0.124 | 0.124 | 0.115 |  |  |  | 3 | 0.121 | 0.00520 | 4.3 | -6.7 |  |
| 6 | 0.137 | 0.134 | 0.119 |  |  |  | 3 | 0.130 | 0.00960 | 7.4 | 0.2 |  |
| Interbatch (between-run) | | | | | | | 21 | 0.130 | 0.0100 | 7.7 | 0.1 | 7.8 |
| 0.00977 | 1 | 0.0443\* | 0.0434\* | 0.0474\* |  |  |  | 0 | NA | NA | NA | NA |  |
| 2 | 0.00965 | 0.0107 | 0.00948 | 0.00915 | 0.00956 | 0.00901 | 6 | 0.0100 | 0.000600 | 6.0 | 2.4 |  |
| 3 | 0.00904 | 0.00951 | 0.00932 |  |  |  | 3 | 0.00900 | 0.000200 | 2.2 | -7.9 |  |
| 4 | 0.00988 | 0.0102 | 0.0104 | 0.00986 | 0.00949 | 0.0104 | 6 | 0.0100 | 0.000400 | 4.0 | 2.4 |  |
| (LLOQ) | 5 | 0.0103 | 0.00960 | 0.0110 |  |  |  | 3 | 0.0100 | 0.000700 | 7.0 | 2.4 |  |
| 6 | 0.0110 | 0.0101 | 0.0105 |  |  |  | 3 | 0.0110 | 0.000500 | 4.5 | 12.6 |  |
| 11 | 0.00966 | 0.0102 | 0.00930 |  |  |  | 3 | 0.0100 | 0.000500 | 5.0 | 2.4 |  |
| Interbatch (between-run) | | | | | | | 24 | 0.00989 | 0.00 | 0.0 | 1.2 | 1.2 |

\*: LLOQ preparation error.

Table s8. Accuracy and Precision from All QCs (pTau217 in Human CSF)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **P&A Summary Data** | | Nominal Concentration (pg/mL) | | | | |
| LLOQ | cLQC | cMQC | HQC | ULOQ |
| **Characteristic** | **Statistic** | 0.00977 | 3.32 | 9.61 | 2.50 | 10.0 |
| # Results | N | 24 | 21 | 21 | 21 | 21 |
| Accuracy | Mean Bias (%RE) | 1.2 | 0.1 | 0.1 | 2.0 | 1.5 |
| Inter-assay (%CV) | 0.0 | 8.7 | 9.8 | 5.1 | 4.9 |
| Total Error | ABS(%RE) + Inter-assay (%CV) | 1.2 | 8.8 | 9.9 | 7.1 | 6.4 |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| QC (pg/mL) | Run | Replicate Results | | | | | | Intrabatch (within-run) | | | | | % TE |
| 1 | 2 | 3 | 4 | 5 | 6 | n | Mean | SD | %CV | %RE |
| 10.0 | 1 | 10.7 | 10.7 | 9.60 |  |  |  | 3 | 10.3 | 0.640 | 6.2 | 3.3 |  |
| 2 | 9.88 | 9.57 | 10.0 | 9.39 | 9.64 | 9.39 | 6 | 9.65 | 0.250 | 2.6 | -3.5 |  |
| 3 | 10.1 | 10.1 | 9.83 |  |  |  | 3 | 10.01 | 0.160 | 1.6 | 0.1 |  |
| 4 | 11.0 | 10.9 | 11.0 |  |  |  | 3 | 11.0 | 0.0600 | 0.5 | 9.7 |  |
| (ULOQ) | 5 | 9.88 | 9.98 | 10.5 |  |  |  | 3 | 10.1 | 0.330 | 3.3 | 1.2 |  |
| 6 | 10.7 | 10.1 | 10.1 |  |  |  | 3 | 10.3 | 0.350 | 3.4 | 3.0 |  |
| Interbatch (between-run) | | | | | | | 21 | 10.1 | 0.500 | 4.9 | 1.5 | 6.4 |
| 2.50 | 1 | 2.56 | 2.61 | 2.62 |  |  |  | 3 | 2.60 | 0.000 | 0.0 | 3.9 |  |
| 2 | 2.48 | 2.49 | 2.56 | 2.35 | 2.45 | 2.43 | 6 | 2.46 | 0.100 | 4.1 | -1.6 |  |
| 3 | 2.40 | 2.42 | 2.43 |  |  |  | 3 | 2.42 | 0.000 | 0.0 | -3.3 |  |
| 4 | 2.74 | 2.85 | 2.71 |  |  |  | 3 | 2.77 | 0.100 | 3.6 | 10.7 |  |
| (HQC) | 5 | 2.44 | 2.51 | 2.53 |  |  |  | 3 | 2.49 | 0.000 | 0.0 | -0.3 |  |
| 6 | 2.59 | 2.65 | 2.71 |  |  |  | 3 | 2.65 | 0.100 | 3.8 | 6.0 |  |
| Interbatch (between-run) | | | | | | | 21 | 2.55 | 0.130 | 5.1 | 2.0 | 7.1 |
| 9.61 | 1 | 10.9 | 11.7 | 11.3 |  |  |  | 3 | 11.3 | 0.400 | 3.5 | 17.6 |  |
| 2 | 9.26 | 9.70 | 9.79 | 9.84 | 9.69 | 10.3 | 6 | 9.76 | 0.334 | 3.4 | 1.6 |  |
| 3 | 10.5 | 9.75 | 9.58 |  |  |  | 3 | 9.94 | 0.490 | 4.9 | 3.5 |  |
| 4 | 8.94 | 8.73 | 8.95 |  |  |  | 3 | 8.87 | 0.124 | 1.4 | -7.6 |  |
| (cMQC) | 5 | 8.41 | 8.21 | 8.34 |  |  |  | 3 | 8.32 | 0.101 | 1.2 | -13.4 |  |
| 6 | 9.76 | 9.14 | 8.95 |  |  |  | 3 | 9.28 | 0.424 | 4.6 | -3.4 |  |
| Interbatch (between-run) | | | | | | | 21 | 9.61 | 0.940 | 9.8 | 0.1 | 9.9 |
| 3.32 | 1 | 3.64 | 3.70 | 3.75 |  |  |  | 3 | 3.70 | 0.0551 | 1.5 | 11.6 |  |
| 2 | 3.41 | 3.28 | 3.50 | 3.45 | 3.33 | 3.38 | 6 | 3.39 | 0.0799 | 2.4 | 2.2 |  |
| 3 | 3.49 | 3.63 | 3.65 |  |  |  | 3 | 3.59 | 0.0872 | 2.4 | 8.3 |  |
| 4 | 2.85 | 2.93 | 2.93 |  |  |  | 3 | 2.90 | 0.0462 | 1.6 | -12.5 |  |
| (cLQC) | 5 | 3.09 | 2.85 | 2.99 |  |  |  | 3 | 2.98 | 0.121 | 4.0 | -10.1 |  |
| 6 | 3.28 | 3.20 | 3.30 |  |  |  | 3 | 3.26 | 0.0529 | 1.6 | -1.7 |  |
| Interbatch (between-run) | | | | | | | 21 | 3.32 | 0.290 | 8.7 | 0.1 | 8.8 |
| 0.00977 | 1 | 0.0443\* | 0.0434\* | 0.0474\* |  |  |  | 0 | NA | NA | NA | NA |  |
| 2 | 0.00965 | 0.0107 | 0.00948 | 0.00915 | 0.00956 | 0.00901 | 6 | 0.0100 | 0.000600 | 6.0 | 2.4 |  |
| 3 | 0.00904 | 0.00951 | 0.00932 |  |  |  | 3 | 0.0100 | 0.000200 | 2.0 | 2.4 |  |
| 4 | 0.00988 | 0.0102 | 0.0104 | 0.00986 | 0.00949 | 0.0104 | 6 | 0.0100 | 0.000400 | 4.0 | 2.4 |  |
| (LLOQ) | 5 | 0.0103 | 0.00960 | 0.0110 |  |  |  | 3 | 0.0100 | 0.000700 | 7.0 | 2.4 |  |
| 6 | 0.0110 | 0.0101 | 0.0105 |  |  |  | 3 | 0.0100 | 0.000500 | 5.0 | 2.4 |  |
| 9 | 0.00965 | 0.0102 | 0.00928 |  |  |  | 3 | 0.00991 | 0.000000 | 0.0 | 1.5 |  |
| Interbatch (between-run) | | | | | | | 24 | 0.00989 | 0.000000 | 0.0 | 1.2 | 1.2 |

\*: LLOQ preparation error.

Table s9. Dilution Linearity Test for pTau217 in Human Plasma

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Sample Lot** | **Dilution factor** | **Measured Conc. (after Dilution Factor, ng/mL)** | **%CV** | **%Recovery** | **%CV (Inter)** |
| HMN1127720 | 3 | 2.51 | 3.1 | NA | 3.9 |
| 6 | 2.65 | 2.9 | 105.6 |
| 12 | 2.73 | 1.6 | 108.8 |
| 24 | 2.73 | 9.3 | 108.8 |
| 48 | 2.78 | 5.3 | 110.8 |
| HMN1127721 | 3 | 2.12 | 5.7 | NA | 8.6 |
| 6 | 2.39 | 3.6 | 112.7 |
| 12 | 2.44 | 0.3 | 115.1 |
| 24 | 2.62 | 5.6 | 123.6 |
| 48 | 2.69 | 3.4 | **126.9** |
| HMN1127724 | 3 | 2.48 | 2.6 | NA | 6.5 |
| 6 | 2.83 | 6.3 | 114.1 |
| 12 | 2.67 | 1.3 | 107.7 |
| 24 | 2.92 | 0.7 | 117.7 |
| 48 | 2.87 | 3.2 | 115.7 |
| HMN1127725 | 3 | 2.89 | 0.5 | NA | 3.5 |
| 6 | 2.89 | 1.2 | 100 |
| 12 | 3.14 | 2.5 | 108.7 |
| 24 | 3.02 | 2.8 | 104.5 |
| 48 | 2.99 | 0.2 | 103.5 |
| HMN1127727 | 3 | 2.35 | 0.3 | NA | 7.5 |
| 6 | 2.49 | 0.0 | 106.0 |
| 12 | 2.51 | 2.8 | 106.8 |
| 24 | 2.86 | 7.4 | 121.7 |
| 48 | 2.64 | 4.3 | 112.3 |
| HMN1127728 | 3 | 2.55 | 6.4 | NA | 4.6 |
| 6 | 2.47 | 5.4 | 96.9 |
| 12 | 2.73 | 3.6 | 107.1 |
| 24 | 2.47 | 5.1 | 96.9 |
| 48 | 2.67 | 5.3 | 104.7 |

Pass criteria: %CV ≤ 20%, %Recovery within 100±25%.

Table s10. Dilution Linearity Test for pTau217 in Human Serum

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Sample Lot** | **Dilution factor** | **Measured Conc. (after Dilution Factor, ng/mL)** | **%CV** | **%Recovery** | **%CV (Inter)** |
| HMN1127733 | 3 | 2.31 | 7.7 | NA | 14.6 |
| 6 | 2.66 | 3.2 | 115.2 |
| 12 | 2.52 | 1.7 | 109.1 |
| 24 | 3.15 | 4.0 | **136.4** |
| 48 | 3.25 | 5.9 | **140.7** |
| HMN1127734 | 3 | 2.57 | 1.6 | NA | 5.9 |
| 6 | 2.94 | 2.9 | 114.4 |
| 12 | 2.87 | 1.5 | 111.7 |
| 24 | 2.87 | 1.7 | 111.7 |
| 48 | NA | NA | **NA** |
| HMN1127735 | 3 | 2.28 | 4.0 | NA | 8.5 |
| 6 | 2.53 | 0.3 | 111.0 |
| 12 | 2.68 | 4.5 | 117.5 |
| 24 | 2.73 | 1.6 | 119.7 |
| 48 | 2.86 | 0.0 | **125.4** |
| HMN1127736 | 3 | 1.85 | 3.8 | NA | 17.2 |
| 6 | 2.34 | 4.5 | **126.5** |
| 12 | 2.87 | 6.9 | **155.1** |
| 24 | 2.76 | 4.9 | **149.2** |
| 48 | 2.83 | 2.5 | **153.0** |
| HMN1127737 | 3 | 1.18 | 0.6 | NA | 24.2 |
| 6 | 1.84 | 4.6 | **155.9** |
| 12 | 2.10 | 1.3 | **178.0** |
| 24 | 2.24 | 3.2 | **189.8** |
| 48 | 2.37 | 3.6 | **200.8** |
| HMN1127738 | 3 | 2.26 | 9.7 | NA | 3.6 |
| 6 | 2.34 | 4.8 | 103.5 |
| 12 | 2.36 | 7.8 | 104.4 |
| 24 | 2.48 | 6.6 | 109.7 |
| 48 | 2.43 | 2.0 | 107.5 |

Pass criteria: %CV ≤ 20%, %Recovery within 100±25%.

Table s11. Dilution Linearity Test for pTau217 in Human CSF

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Sample Lot** | **Dilution factor** | **Measured Conc. (after Dilution Factor, ng/mL)** | **%CV** | **%Recovery** | **%CV (Inter)** |
| HMN757483 | 20 | 84.5 | 2.9 | NA | 3.3 |
| 40 | 86.6 | 2.6 | 102.5 |
| 80 | 81.6 | 2.8 | 96.6 |
| 160 | 79.5 | 2.8 | 94.1 |
| 320 | 81.8 | 0.4 | 96.8 |
| HMN757484 | 20 | 88.8 | 1.2 | NA | 0.9 |
| 40 | 87.6 | 3.6 | 98.6 |
| 80 | 87.5 | 2.9 | 98.5 |
| 160 | 89.0 | 6.4 | 100.2 |
| 320 | 92.7 | 3.2 | 104.4 |
| HMN757500 | 20 | 84.3 | 1.4 | NA | 2.5 |
| 40 | 83.6 | 1.0 | 99.2 |
| 80 | 87.2 | 0.2 | 103.4 |
| 160 | 88.7 | 3.3 | 105.2 |
| 320 | 85.0 | 2.6 | 100.8 |
| HMN757501 | 20 | 88.3 | 2.2 | NA | 1.2 |
| 40 | 88.3 | 0.1 | 100.0 |
| 80 | 86.6 | 4.7 | 98.1 |
| 160 | 88.5 | 3.9 | 100.2 |
| 320 | 86.4 | 3.4 | 97.8 |
| HMN757502 | 20 | 87.4 | 6.0 | NA | 2.6 |
| 40 | 82.5 | 3.0 | 94.4 |
| 80 | 82.4 | 1.3 | 94.3 |
| 160 | 83.1 | 0.9 | 95.1 |
| 320 | 85.2 | 0.7 | 97.5 |
| HMN757503 | 20 | 76.0 | 1.9 | NA | 6.8 |
| 40 | 88.1 | 2.5 | 115.9 |
| 80 | 90.0 | 2.5 | 118.4 |
| 160 | 90.3 | 1.1 | 118.8 |
| 320 | 86.1 | 1.0 | 113.3 |

Pass criteria: %CV ≤ 20%, %Recovery within 100±25%.

Table s12. Short-Term Stability Test for pTau217 in Human Plasma

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Condition** | **Reps** | **LQC (0.146 pg/mL)** | | | **MQC (0.503 pg/mL)** | | |
| **Concentration (pg/mL)** | **% CV** | **% RE** | **Concentration (pg/mL)** | **% CV** | **% RE** |
| **Refrigerator (24 hrs)** | 1 | 0.148 | 0.5 | 1.4 | 0.505 | 1.4 | 0.4 |
| 2 | 0.144 | 1.5 | -1.4 | 0.537 | 7.6 | 6.8 |
| 3 | 0.154 | 2.8 | 5.5 | 0.509 | 6.2 | 1.2 |
| **Benchtop (6 hrs)** | 1 | 0.139 | 5.1 | -4.8 | 0.481 | 5.6 | -4.4 |
| 2 | 0.139 | 1.0 | -4.8 | 0.474 | 11.6 | -5.8 |
| 3 | 0.149 | 1.4 | 2.1 | 0.546 | 3.8 | 8.5 |
| **Freeze/Thaw (5 cycles)** | 1 | 0.144 | 5.4 | -1.4 | 0.490 | 1.4 | -2.6 |
| 2 | 0.129 | 0.5 | -11.6 | 0.443 | 3.2 | -11.9 |
| 3 | 0.148 | 4.3 | 1.4 | 0.501 | 9.7 | -0.4 |

Pass criteria: %CV ≤ 20%, %RE within ±20%.

Table s13. Short-Term Stability Test for pTau217 in Human Serum

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Condition** | **Repeats** | **LQC (0.130 pg/mL)** | | | **MQC (0.340 pg/mL)** | | |
| **Concentration (pg/mL)** | **% CV** | **% RE** | **Concentration (pg/mL)** | **% CV** | **% RE** |
| **Refrigerator (24 hrs)** | 1 | 0.130 | 7.6 | 0.0 | 0.330 | 1.1 | -2.9 |
| 2 | 0.147 | 5.8 | 13.1 | 0.329 | 7.8 | -3.2 |
| 3 | 0.126 | 3.4 | -3.1 | 0.340 | 0.0 | 0.0 |
| **Benchtop (6 hrs)** | 1 | 0.127 | 0.0 | -2.3 | 0.351 | 3.2 | 3.2 |
| 2 | 0.133 | 11.1 | 2.3 | 0.347 | 5.7 | 2.1 |
| 3 | 0.146 |  | 12.3 | 0.354 | 1.8 | 4.1 |
| **Freeze Thaw (5X)** | 1 | 0.124 | 3.4 | -4.6 | 0.335 | 5.1 | -1.5 |
| 2 | 0.128 | 4.4 | -1.5 | 0.338 | 1.5 | -0.6 |
| 3 | 0.131 | 3.2 | 0.8 | 0.354 | 1.4 | 4.1 |

Pass criteria: %CV ≤ 20%, %RE within ±20%.

Table s14. Short-Term Stability Test for pTau217 in Human CSF

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Condition** | **Repeats** | **cLQC (3.32 pg/mL)** | | | **cMQC (9.61 pg/mL)** | | |
| **Concentration (pg/mL)** | **% CV** | **% RE** | **Concentration (pg/mL)** | **% CV** | **% RE** |
| **Refrigerator (24 hrs)** | 1 | 3.34 | 2.8 | 0.6 | 10.0 | 2.9 | 0.4 |
| 2 | 3.43 | 8.5 | 3.3 | 10.2 | 2.1 | 2.4 |
| 3 | 3.42 | 5.0 | 3.0 | NA | NA | NA |
| **Benchtop (6 hrs)** | 1 | 3.34 | 0.4 | 0.6 | 9.51 | 4.5 | -4.5 |
| 2 | 3.40 | 10.4 | 2.4 | 10.2 | 8.7 | 2.4 |
| 3 | 3.21 | 4.0 | -3.3 | 9.69 | 11.9 | -2.7 |
| **Freeze Thaw (5X)** | 1 | 3.41 | 4.1 | 2.7 | 10.0 | 0.9 | 0.4 |
| 2 | 3.35 | 2.5 | 0.9 | 10.4 | 2.7 | 4.4 |
| 3 | 3.34 | 2.3 | 0.6 | 9.84 | 2.0 | -1.2 |

Pass criteria: %CV ≤ 20%, %RE within ±20%.

NA: one of the duplicates of this sample was BQL, thus the data from this sample is not valid.

Table s15. Long-term stability test for pTau217 in human plasma at one-month time point

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Condition** | **Repeats** | **LQC (0.146 pg/mL)** | | | **MQC (0.503 pg/mL)** | | |
| **Concentration (pg/mL)** | **% CV** | **% RE** | **Concentration (pg/mL)** | **% CV** | **% RE** |
| **-70°C (1-month)** | 1 | 0.158 | 6.7 | 8.2 | 0.549 | 8.4 | 9.1 |
| 2 | 0.161 | 5.7 | 10.3 | 0.518 | 6.1 | 3.0 |
| 3 | 0.142 | 2.5 | -2.7 | 0.593 | 6.8 | 17.9 |

Pass criteria: %CV ≤ 20%, %RE within ±20%.

Table s16. Long-term stability test for pTau217 in human serum at one-month time point

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Condition** | **Repeats** | **LQC (0.130 pg/mL)** | | | **MQC (0.340 pg/mL)** | | |
| **Concentration (pg/mL)** | **% CV** | **% RE** | **Concentration (pg/mL)** | **% CV** | **% RE** |
| **-70°C (1-month)** | 1 | 0.162 | 0.4 | **24.6** | 0.325 | 14.8 | -4.4 |
| 2 | 0.141 | 11.6 | 8.5 | 0.338 | 4.6 | -0.6 |
| 3 | 0.148 | 3.3 | 13.8 | 0.333 | 5.7 | -2.1 |

Pass criteria: %CV ≤ 20%, %RE within ±20%.

**Bold**: %RE not pass acceptance criteria.

Table s17. Long-term stability test for pTau217 in human CSF at one-month time point

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Condition** | **Repeats** | **LQC (3.32 pg/mL)** | | | **MQC (9.61 pg/mL)** | | |
| **Concentration (pg/mL)** | **% CV** | **% RE** | **Concentration (pg/mL)** | **% CV** | **% RE** |
| **-70°C (1-month)** | 1 | 3.36 | 4.6 | 1.2 | NA | NA | NA |
| 2 | 3.23 | 5.7 | -2.7 | 9.67 | 1.9 | 0.5 |
| 3 | 3.85 | 5.5 | 16.0 | 9.32 | 0.7 | -3.1 |

Pass criteria: %CV ≤ 20%, %RE within ±20%.

NA: one of the duplicates of this sample was BQL, thus the data from this sample is not valid.

Table s18. Interference for pTau217 in Human Plasma

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Interferent** | **Interferent level** | **Matrix level** | **Mean Conc. (pg/mL)** | **Normalized Conc. (pg/mL)** | **%CV** | **%Recovery** |
|  |  | LQC | 0.112 | 0.118 | 6.9 | NA |
| 0.121 | 2.9 |
| 0.122 | 4.6 |
| MQC | 0.528 | 0.528 | 2.5 | NA |
| 0.534 | 4.0 |
| 0.522 | 8.0 |
| Hemolyzed blood | 1.00% | LQC | 0.111 |  | 12.7 | 94.1 |
| 0.123 | 6.9 | 104.2 |
| 0.115 | 8.0 | 97.5 |
| MQC | 0.471 |  | 12.6 | 89.2 |
| 0.495 | 3.0 | 93.8 |
| 0.501 | 0.6 | 94.9 |
| 3.00% | LQC | 0.125 |  | 11.3 | 105.9 |
| 0.117 | 3.0 | 99.2 |
| 0.126 | 8.4 | 106.8 |
| MQC | 0.493 |  | 9.3 | 93.4 |
| 0.512 | 4.4 | 97.0 |
| 0.529 | 4.5 | 100.2 |
| Lipid | 150 mg/DL | LQC | 0.128 |  | 6.1 | 108.5 |
| 0.124 | 6.8 | 105.1 |
| 0.132 | 12.3 | 111.9 |
| MQC | 0.576 |  | 1.2 | 109.1 |
| 0.548 | 5.9 | 103.8 |
| 0.518 | 6.1 | 98.1 |
| 300 mg/DL | LQC | 0.116 |  | 1.2 | 98.3 |
| 0.120 | 3.0 | 101.7 |
| 0.114 | 0.6 | 96.6 |
| MQC | 0.582 |  | 3.5 | 110.2 |
| 0.538 | 6.7 | 101.9 |
| 0.577 | 6.6 | 109.3 |

Pass criteria: %CV ≤ 20%, %Recovery within 100±20%.

Table s19. Interference for pTau217 in Human Serum

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Interferent** | **Inteferent level** | **Matrix level** | **Mean Conc. (pg/mL)** | **Normalized Conc. (pg/mL)** | **%CV** | **%Recovery** |
|  |  | LQC | 0.143 | 0.142 | 4.9 | NA |
| 0.137 | 9.8 |
| 0.146 | 8.7 |
| MQC | 0.370 | 0.390 | 0.0 | NA |
| 0.403\* | NA |
| 0.409 | 3.1 |
| Hemolyzed blood | 1.00% | LQC | 0.153 |  | 11.6 | 107.7 |
| 0.160 | 0.9 | 112.7 |
| 0.143 | 2.0 | 100.7 |
| MQC | 0.371 |  | 1.3 | 95.1 |
| 0.401 | 0.5 | 102.8 |
| 0.379 | 5.2 | 97.2 |
| 3.00% | LQC | 0.167 |  | 10.6 | 117.6 |
| 0.155 | 4.1 | 109.2 |
| 0.164 | 6.0 | 115.5 |
| MQC | 0.363 |  | 0.2 | 93.1 |
| 0.397 | 9.8 | 101.8 |
| 0.403 | 6.3 | 103.3 |
| Lipid | 150 mg/DL | LQC | 0.151 |  | 2.8 | 106.3 |
| 0.154 | 2.3 | 108.5 |
| 0.150 | 0.0 | 105.6 |
| MQC | 0.362 |  | 1.4 | 92.8 |
| 0.362 | 5.7 | 92.8 |
| 0.345 | 0.8 | 88.5 |
| 300 mg/DL | LQC | 0.150 |  | 3.8 | 105.6 |
| 0.151 | 0.5 | 106.3 |
| 0.146 | 3.4 | 102.8 |
| MQC | 0.366 |  | 0.4 | 93.8 |
| 0.347 | 4.3 | 89.0 |
| 0.380 | 1.3 | 97.4 |

Pass criteria: %CV ≤ 20%, %Recovery within 100±20%.

\*: %CV did not pass acceptance criteria.

Table s20. Back-calculated pTau217 Concentrations (pg/mL) of A&P Standards

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **pTau217** | | | | | | | | | |
| **Run Date** | **Curve  Number** | **0.00977  (pg/mL)** | **0.0195  (pg/mL)** | **0.0391  (pg/mL)** | **0.156  (pg/mL)** | **0.625  (pg/mL)** | **2.50  (pg/mL)** | **5.00  (pg/mL)** | **10.0  (pg/mL)** |
| 12-Jun-2023 | 1 | 0.00998 | 0.0177 | 0.0415 | 0.159 | 0.629 | 2.44 | 4.98 | 10.1 |
|  |  | 0.0102 | 0.0190 | 0.0401 | 0.151 | 0.637 | 2.50 | 5.03 | 9.90 |
| Intrarun Mean |  | 0.0101 | 0.0184 | 0.0408 | 0.155 | 0.633 | 2.47 | 5.01 | 10.0 |
| Intrarun SD |  | 0.000156 | 0.000919 | 0.000990 | 0.00566 | 0.00566 | 0.0424 | 0.0354 | 0.141 |
| Intrarun %CV |  | 1.5 | 5.0 | 2.4 | 3.7 | 0.9 | 1.7 | 0.7 | 1.4 |
| Intrarun %Bias |  | 3.4 | -5.6 | 4.3 | -0.6 | 1.3 | -1.2 | 0.2 | 0.0 |
| n |  | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| 13-Jun-2023 | 2 | 0.0105 | 0.0220 | 0.0405 | 0.161 | 0.643 | 2.48 | 4.95 | 10.2 |
|  |  | 0.00919 | 0.0175 | 0.0386 | 0.152 | 0.611 | 2.41 | 5.16 | 9.96 |
| Intrarun Mean |  | 0.00985 | 0.0198 | 0.0396 | 0.157 | 0.627 | 2.45 | 5.06 | 10.1 |
| Intrarun SD |  | 0.000926 | 0.00318 | 0.00134 | 0.00636 | 0.0226 | 0.0495 | 0.148 | 0.170 |
| Intrarun %CV |  | 9.4 | 16.1 | 3.4 | 4.1 | 3.6 | 2.0 | 2.9 | 1.7 |
| Intrarun %Bias |  | 0.8 | 1.5 | 1.3 | 0.6 | 0.3 | -2.0 | 1.2 | 1.0 |
| n |  | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| 14-Jun-2023 | 3 | 0.0101 | 0.0187 | 0.0424 | 0.158 | 0.631 | 2.54 | 4.87 | 10.2 |
|  |  | 0.00992 | 0.0193 | 0.0361 | 0.161 | 0.615 | 2.53 | 4.86 | 10.0 |
| Intrarun Mean |  | 0.0100 | 0.0190 | 0.0393 | 0.160 | 0.623 | 2.54 | 4.87 | 10.1 |
| Intrarun SD |  | 0.000127 | 0.000424 | 0.00445 | 0.00212 | 0.0113 | 0.00707 | 0.00707 | 0.141 |
| Intrarun %CV |  | 1.3 | 2.2 | 11.3 | 1.3 | 1.8 | 0.3 | 0.1 | 1.4 |
| Intrarun %Bias |  | 2.4 | -2.6 | 0.5 | 2.6 | -0.3 | 1.6 | -2.6 | 1.0 |
| n |  | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| 15-Jun-2023 | 4 | 0.0108 | \*0.0173 | 0.0376 | 0.163 | 0.646 | 2.36 | 4.86 | 9.99 |
|  |  | 0.00908 | \*0.0264 | 0.0392 | 0.158 | 0.622 | 2.41 | 5.06 | 10.8 |
| Intrarun Mean |  | 0.00994 |  | 0.0384 | 0.161 | 0.634 | 2.39 | 4.96 | 10.4 |
| Intrarun SD |  | 0.00122 |  | 0.00113 | 0.00354 | 0.0170 | 0.0354 | 0.141 | 0.573 |
| Intrarun %CV |  | 12.3 |  | 2.9 | 2.2 | 2.7 | 1.5 | 2.8 | 5.5 |
| Intrarun %Bias |  | 1.7 |  | -1.8 | 3.2 | 1.4 | -4.4 | -0.8 | 4.0 |
| n |  | 2 |  | 2 | 2 | 2 | 2 | 2 | 2 |
| 16-Jun-2023 | 5 | 0.00897 | 0.0199 | 0.0410 | 0.154 | 0.649 | 2.57 | 4.97 | 9.98 |
|  |  | 0.0106 | 0.0195 | 0.0384 | 0.150 | 0.628 | 2.39 | 5.12 | 9.96 |
| Intrarun Mean |  | 0.00979 | 0.0197 | 0.0397 | 0.152 | 0.639 | 2.48 | 5.05 | 9.97 |
| Intrarun SD |  | 0.00115 | 0.000283 | 0.00184 | 0.00283 | 0.0148 | 0.127 | 0.106 | 0.0141 |
| Intrarun %CV |  | 11.7 | 1.4 | 4.6 | 1.9 | 2.3 | 5.1 | 2.1 | 0.1 |
| Intrarun %Bias |  | 0.2 | 1.0 | 1.5 | -2.6 | 2.2 | -0.8 | 1.0 | -0.3 |
| n |  | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| 19-Jun-2023 | 6 | 0.0101 | 0.0210 | 0.0373 | 0.163 | 0.654 | 2.52 | 4.88 | 10.4 |
|  |  | 0.00929 | 0.0203 | 0.0361 | 0.162 | 0.601 | 2.47 | 4.89 | 9.98 |
| Intrarun Mean |  | 0.00970 | 0.0207 | 0.0367 | 0.163 | 0.628 | 2.50 | 4.89 | 10.2 |
| Intrarun SD |  | 0.000573 | 0.000495 | 0.000849 | 0.000707 | 0.0375 | 0.0354 | 0.00707 | 0.297 |
| Intrarun %CV |  | 5.9 | 2.4 | 2.3 | 0.4 | 6.0 | 1.4 | 0.1 | 2.9 |
| Intrarun %Bias |  | -0.7 | 6.2 | -6.1 | 4.5 | 0.5 | 0.0 | -2.2 | 2.0 |
| n |  | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| 01-Aug-2023 | 9 | 0.00992 | 0.0206 | 0.0395 | 0.160 | 0.635 | 2.43 | 5.07 | 10.3 |
|  |  | 0.00985 | 0.0178 | 0.0394 | 0.162 | 0.587 | 2.49 | 5.00 | 9.96 |
| Intrarun Mean |  | 0.00989 | 0.0192 | 0.0395 | 0.161 | 0.611 | 2.46 | 5.04 | 10.1 |
| Intrarun SD |  | 0.0000495 | 0.00198 | 0.0000707 | 0.00141 | 0.0339 | 0.0424 | 0.0495 | 0.240 |
| Intrarun %CV |  | 0.5 | 10.3 | 0.2 | 0.9 | 5.5 | 1.7 | 1.0 | 2.4 |
| Intrarun %Bias |  | 1.2 | -1.5 | 1.0 | 3.2 | -2.2 | -1.6 | 0.8 | 1.0 |
| n |  | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| Mean Concentration Found (pg/mL) |  | 0.00989 | 0.0194 | 0.0391 | 0.158 | 0.628 | 2.47 | 4.98 | 10.1 |
| Inter-run SD |  | 0.000572 | 0.00140 | 0.00192 | 0.00455 | 0.0190 | 0.0623 | 0.0998 | 0.245 |
| Inter-run %CV |  | 5.8 | 7.2 | 4.9 | 2.9 | 3.0 | 2.5 | 2.0 | 2.4 |
| Inter-run %Bias |  | 1.2 | -0.5 | 0.0 | 1.3 | 0.5 | -1.2 | -0.4 | 1.0 |
| n |  | 14 | 12 | 14 | 14 | 14 | 14 | 14 | 14 |