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| --- | --- |
| Qualification Test | Result |
| Screening Assay Cut-Point | 1.08 S/N |
| Specificity / Confirmatory Assay Cut-Point | % Signal Inhibition = 20.06% |
| Sensitivity | Screening Assay – 4.21 ng/mLConfirmatory Assay – 4.20 ng/mL |
| Intra-Assay Statistics (%)-Screening Assay | Level | Concentration(ng/mL) | RLU Precision (%) |
| NC | N/A | 1.6 |
| LPC | 10 | 1.1 |
| MPC | 100 | 13.6 |
| HPC | 4000 | 13.2 |
| Intra-Assay Statistics (%)-Confirmatory Assay | Level | Concentration(ng/mL) | % Inhibition Precision |
| NC | N/A | <0.0 |
| LPC | 10 | 1.8 |
| MPC | 100 | 1.2 |
| HPC | 4000 | 0.0 |
| Inter-Assay Statistics (%)-Screening Assay | Level | Concentration(ng/mL) | RLU Precision (%) |
| NC | N/A | 9.3 |
| LPC | 10 | 8.4 |
| MPC | 100 | 14.3 |
| HPC | 4000 | 15.0 |
| Inter-Assay Statistics (%)-Confirmatory Assay | Level | Concentration (ng/mL) | % Inhibition Precision |
| NC | N/A | >20.0 |
| LPC | 10 | 8.9 |
| MPC | 100 | 1.8 |
| HPC | 4000 | 0.1 |