

| | |
|------------------------|-------------|
| Product Number: | 103769 |
| Lot Number: | 503179 |
| Expiration: | 12-Jul-2022 |
| Platform(s): | HD-X |
| Product Number (Bulk): | 103845 |
| Lot Number (Bulk): | N/A |

| Component | Part Number | Lot Number |
|------------------|-------------|------------------|
| Bead Reagent | 103758 | 128403 |
| Detector Reagent | 103760 | 128404 |
| SBG Reagent | 103762 | 128506 |
| Sample Diluent | 103763 | 128505 |
| Calibrators | 103766 | 130804 |
| Control 1 | 103767 | 130805 |
| Control 2 | 103768 | 130805 |
| Control 3 | 103773 | 130805 |
| RGP Reagent | 103159 | N/A ¹ |

¹ RGP is not Kit Lot Specific



Data below represents results generated on the Simoa™ HD-X Analyzer.

| Release Materials* | | | | |
|--------------------|--------|----------------|------------------------|-------------------------|
| Sample | Lot | Result (ng/mL) | Mean Low limit (ng/mL) | Mean High Limit (ng/mL) |
| Control 1 | 130805 | 439 | 307 | 516 |
| Control 2 | 130805 | 4008 | 3037 | 4854 |
| Control 3 | 130805 | 17156 | 15664 | 23496 |

* Ranges shown are generated internally for new lot release only. Customer should generate their own control ranges.

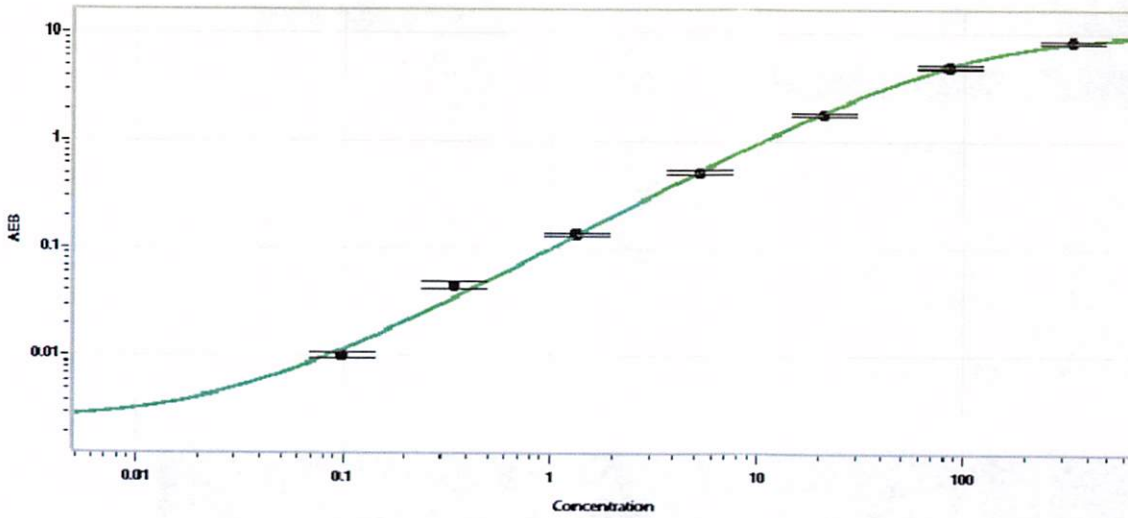
| Sample | Lot | Result (ng/mL) | Mean Low limit (ng/mL) | Mean High Limit (ng/mL) |
|----------|--------|----------------|------------------------|-------------------------|
| Panel 1 | 121601 | 1.05 | 0.846 | 1.28 |
| Panel 2 | 121601 | 2.12 | 1.60 | 2.40 |
| Panel 3 | 121601 | 4.06 | 2.91 | 4.85 |
| Panel 4 | 121601 | 7.57 | 5.63 | 8.80 |
| Panel 5 | 121601 | 14.0 | 10.3 | 19.9 |
| Panel 6 | 121601 | 25.4 | 20.6 | 32.8 |
| Panel 7 | 121601 | 1.62 | 1.28 | 1.92 |
| Panel 8 | 121601 | 6.33 | 3.84 | 7.36 |
| Panel 9 | 121601 | 7.66 | 5.77 | 8.80 |
| Panel 10 | 121601 | 16.5 | 12.9 | 19.8 |
| Panel 11 | 121601 | 0.024 | Reported Result | |
| Panel 12 | 121601 | 0.024 | Reported Result | |
| Panel 13 | 121601 | 0.013 | Reported Result | |
| Panel 14 | 121601 | 0.010 | Reported Result | |
| Panel 15 | 121601 | 0.187 | Reported Result | |
| Panel 16 | 121601 | 0.019 | Reported Result | |
| Panel 17 | 121601 | 0.017 | Reported Result | |
| Panel 18 | 121601 | 0.030 | Reported Result | |
| Panel 19 | 121601 | 0.033 | Reported Result | |
| Panel 20 | 121601 | 0.576 | Reported Result | |

Review/Approval

Wenkai Tsai QC Supervisor
Name Title

 01 Dec 2021
Signature/Date

503179



Calibrator Levels
(ng/mL)

| | |
|----------|-------|
| A | 0.000 |
| B | 0.098 |
| C | 0.345 |
| D | 1.34 |
| E | 5.30 |
| F | 21.1 |
| G | 84.4 |
| H | 338 |