

|                        |             |
|------------------------|-------------|
| Product Number:        | 103769      |
| Lot Number:            | 502822      |
| Expiration:            | 12-Mar-2022 |
| Platform(s):           | HD-X        |
| Product Number (Bulk): | 103845      |
| Lot Number (Bulk):     | N/A         |



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

| Component        | Part Number | Lot Number       |
|------------------|-------------|------------------|
| Bead Reagent     | 103758      | 107101           |
| Detector Reagent | 103760      | 107303           |
| SBG Reagent      | 103762      | 107901           |
| Sample Diluent   | 103763      | 107409           |
| Calibrators      | 103766      | 107607           |
| Control 1        | 103767      | 107804           |
| Control 2        | 103768      | 107804           |
| Control 3        | 103773      | 107804           |
| RGP Reagent      | 103159      | N/A <sup>1</sup> |

<sup>1</sup> RGP is not Kit Lot Specific

| Release Materials* |        |                |                        |                         |
|--------------------|--------|----------------|------------------------|-------------------------|
| Sample             | Lot    | Result (ng/mL) | Mean Low limit (ng/mL) | Mean High Limit (ng/mL) |
| Control 1          | 107804 | 456            | 234                    | 609                     |
| Control 2          | 107804 | 3436           | 2937                   | 4406                    |
| Control 3          | 107804 | 17759          | 11941                  | 20550                   |

\* 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  | 020901 | 25.3           | 12.6                   | 26.8                    |
| Panel 2  | 020901 | 6.31           | 4.11                   | 6.48                    |
| Panel 3  | 020901 | 20.9           | 13.3                   | 25.1                    |
| Panel 4  | 020901 | 23.5           | 13.4                   | 24.8                    |
| Panel 5  | 020901 | 34.8           | 15.9                   | 39.0                    |
| Panel 6  | 020901 | 24.5           | 12.8                   | 26.9                    |
| Panel 7  | 020901 | 5.99           | 2.40                   | 6.50                    |
| Panel 8  | 020901 | 2.14           | 0.758                  | 2.52                    |
| Panel 9  | 020901 | 6.41           | 2.47                   | 6.96                    |
| Panel 10 | 020901 | 126            | 41.9                   | 135                     |
| Panel 11 | 020901 | 0.532          | Reported Result        |                         |
| Panel 12 | 020901 | 0.059          | Reported Result        |                         |
| Panel 13 | 020901 | 0.115          | Reported Result        |                         |
| Panel 14 | 020901 | 0.030          | Reported Result        |                         |
| Panel 15 | 020901 | 0.068          | Reported Result        |                         |
| Panel 16 | 020901 | 0.099          | Reported Result        |                         |
| Panel 17 | 031107 | 0.078          | Reported Result        |                         |
| Panel 18 | 031109 | 0.027          | Reported Result        |                         |
| Panel 19 | 106401 | 0.042          | Reported Result        |                         |
| Panel 20 | 106402 | 0.049          | Reported Result        |                         |

Review/Approval

Junpil Park QC Supervisor

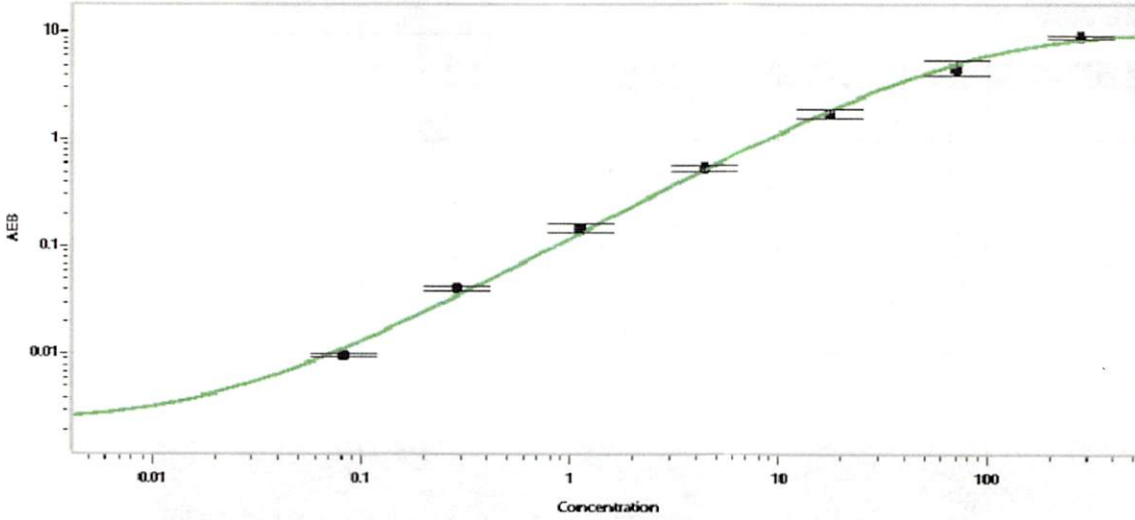
 28 Mar 2021

Name

Title

Signature/Date

Calibration Curve



**Calibrator Levels  
(ng/mL)**

|          |       |
|----------|-------|
| <b>A</b> | 0.000 |
| <b>B</b> | 0.082 |
| <b>C</b> | 0.287 |
| <b>D</b> | 1.11  |
| <b>E</b> | 4.39  |
| <b>F</b> | 17.5  |
| <b>G</b> | 69.9  |
| <b>H</b> | 280   |