

| | |
|-----------------|-------------|
| Product Number: | 103670 |
| Lot Number: | 502542 |
| Expiration: | 14-Jul-2021 |
| Platform(s): | HD-X |



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

| Component | Part Number | Lot Number |
|-----------------------|-------------|------------------|
| Bead Reagent | 103653 | 026603 |
| Detector Reagent | 103655 | 026807 |
| SBG Reagent | 103657 | 026711 |
| Plasma Sample Diluent | 103659 | 026708 |
| CSF Sample Diluent | 103727 | 026802 |
| Calibrators | 103667 | 028102 |
| Control 1 | 103668 | 028103 |
| Control 2 | 103669 | 028103 |
| RGP Reagent | 103159 | N/A ¹ |

¹ RGP is not Kit Lot Specific

| Release Materials | | | |
|-------------------|--------|----------------|--------------------|
| Abeta 40 | | | |
| | Lot | Result (pg/mL) | Mean Range (pg/mL) |
| Control 1 | 028103 | 15.5 | 12.6-18.9 |
| Control 2 | 028103 | 118 | 92.5-139 |
| Panel 1 | 027301 | 26.5 | 23.3-35.0 |
| Panel 2 | 018109 | 53.0 | 43.6-65.4 |
| Panel 3 | 018109 | 137 | 109-164 |
| Abeta 42 | | | |
| | Lot | Result (pg/mL) | Mean Range (pg/mL) |
| Control 1 | 028103 | 5.82 | 4.66-7.00 |
| Control 2 | 028103 | 32.3 | 25.6-38.3 |
| Panel 1 | 027301 | 2.30 | 2.01-3.03 |
| Panel 2 | 018109 | 20.2 | 16.8-25.2 |
| Panel 3 | 018109 | 45.9 | 36.2-54.3 |
| GFAP® | | | |
| | Lot | Result (pg/mL) | Mean Range (pg/mL) |
| Control 1 | 028103 | 235 | 183-275 |
| Control 2 | 028103 | 5055 | 3761-5641 |
| Panel 1 | 027301 | 44.9 | 37.8-56.7 |
| Panel 2 | 018109 | 547 | 446-669 |
| Panel 3 | 018109 | 2459 | 1892-2940 |
| NF-light® | | | |
| | Lot | Result (pg/mL) | Mean Range (pg/mL) |
| Control 1 | 028103 | 33.1 | 20.6-37.0 |
| Control 2 | 028103 | 669 | 393-774 |
| Panel 1 | 027301 | 10.82 | 8.37-12.6 |
| Panel 2 | 018109 | 77.4 | 59.7-89.5 |
| Panel 3 | 018109 | 415 | 305-473 |

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

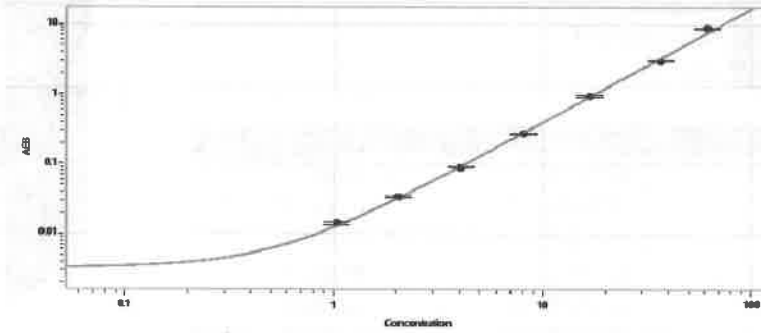
Review/Approval

Shivani Goel
Name

QC Manager
Title

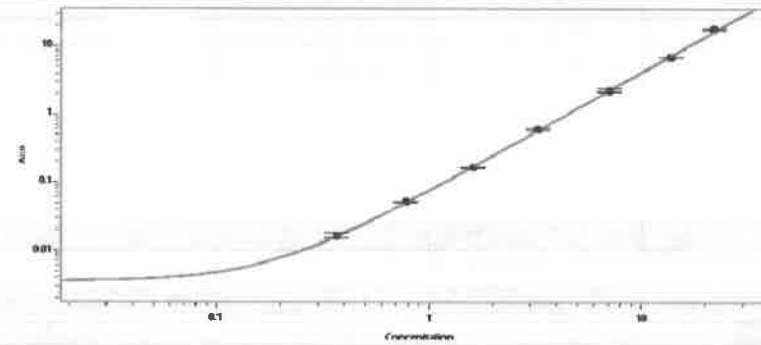
Shivani Goel 15Oct2020
Signature/Date

Abeta 40 Calibration Curve



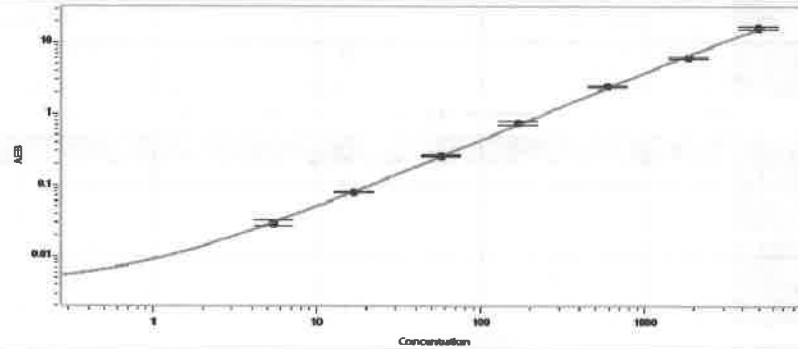
| Calibrator Levels (pg/mL) | |
|---------------------------|-------|
| A | 0.000 |
| B | 1.04 |
| C | 2.05 |
| D | 4.09 |
| E | 8.14 |
| F | 16.8 |
| G | 36.6 |
| H | 61.4 |

Abeta 42 Calibration Curve



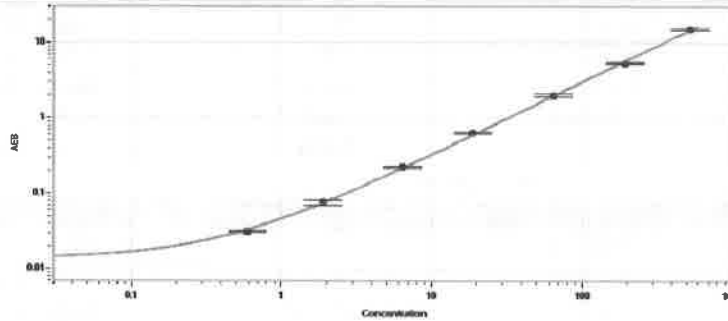
| Calibrator Levels (pg/mL) | |
|---------------------------|-------|
| A | 0.000 |
| B | 0.367 |
| C | 0.782 |
| D | 1.62 |
| E | 3.25 |
| F | 7.07 |
| G | 13.8 |
| H | 22.0 |

GFAP® Calibration Curve



| Calibrator Levels (pg/mL) | |
|---------------------------|-------|
| A | 0.000 |
| B | 5.41 |
| C | 16.7 |
| D | 56.9 |
| E | 166 |
| F | 589 |
| G | 1827 |
| H | 4920 |

NF-light® Calibration Curve



| Calibrator Levels (pg/mL) | |
|---------------------------|-------|
| A | 0.000 |
| B | 0.597 |
| C | 1.88 |
| D | 6.42 |
| E | 18.7 |
| F | 64.4 |
| G | 195 |
| H | 528 |