

Product Number: 103670  
Lot Number: 502535  
Expiration: 24-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      | 023705           |
| Detector Reagent      | 103655      | 025209           |
| SBG Reagent           | 103657      | 020602           |
| Plasma Sample Diluent | 103659      | 020904           |
| CSF Sample Diluent    | 103727      | 020603           |
| Calibrators           | 103667      | 021801           |
| Control 1             | 103668      | 021802           |
| Control 2             | 103669      | 021802           |
| RGP Reagent           | 103159      | N/A <sup>1</sup> |

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

**Release Materials**

**Abeta 40**

|           | Lot    | Result (pg/mL) | Mean Range (pg/mL) |
|-----------|--------|----------------|--------------------|
| Control 1 | 021802 | 14.3           | 12.4-18.5          |
| Control 2 | 021802 | 106            | 90.1-135           |
| Panel 1   | 016412 | 14.3           | 11.4-21.3          |
| Panel 2   | 018109 | 47.9           | 43.9-65.9          |
| Panel 3   | 018109 | 130            | 109 - 164          |

**Abeta 42**

|           | Lot    | Result (pg/mL) | Mean Range (pg/mL) |
|-----------|--------|----------------|--------------------|
| Control 1 | 021802 | 5.24           | 4.36-6.54          |
| Control 2 | 021802 | 28.3           | 22.9-34.3          |
| Panel 1   | 016412 | 1.35           | 0.591-2.84         |
| Panel 2   | 018109 | 18.9           | 17.0-25.5          |
| Panel 3   | 018109 | 44.5           | 36.0-54.1          |

**GFAP®**

|           | Lot    | Result (pg/mL) | Mean Range (pg/mL) |
|-----------|--------|----------------|--------------------|
| Control 1 | 021802 | 228            | 190-285            |
| Control 2 | 021802 | 4663           | 3800-5700          |
| Panel 1   | 016412 | 29.9           | 22.5-45.0          |
| Panel 2   | 018109 | 547            | 448-672            |
| Panel 3   | 018109 | 2668           | 1861-2950          |

**NF-light®**

|           | Lot    | Result (pg/mL) | Mean Range (pg/mL) |
|-----------|--------|----------------|--------------------|
| Control 1 | 021802 | 21.8           | 15.6-24.3          |
| Control 2 | 021802 | 407            | 327-491            |
| Panel 1   | 016412 | 6.75           | 5.55-8.32          |
| Panel 2   | 018109 | 75.0           | 59.1-88.6          |
| Panel 3   | 018109 | 413            | 306-459            |

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

Review/Approval

Shivani Goel

QC Manager

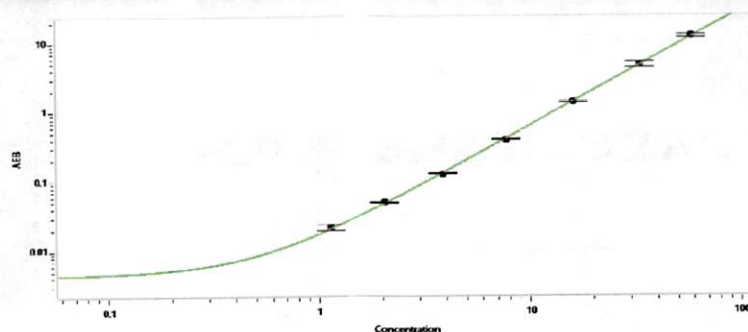
Name

Title

Signature/Date

Shivani Goel 08 Jun 2021

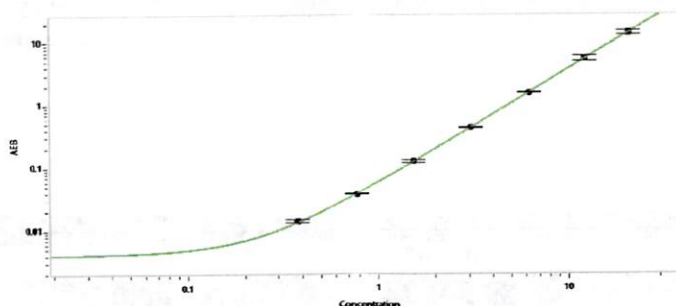
**Abeta 40 Calibration Curve**



**Calibrator Levels  
(pg/mL)**

|   |       |
|---|-------|
| A | 0.000 |
| B | 1.13  |
| C | 2.03  |
| D | 3.86  |
| E | 7.75  |
| F | 16.1  |
| G | 33.3  |
| H | 58.5  |

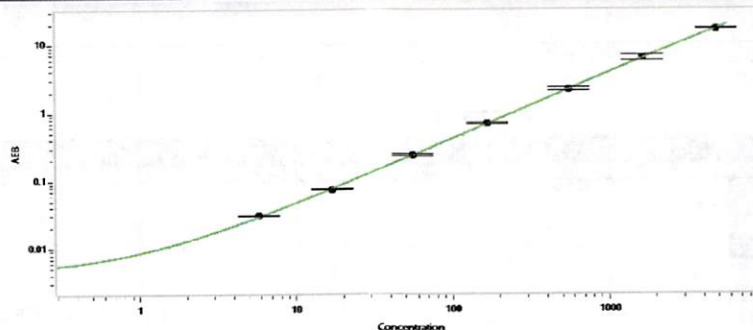
**Abeta 42 Calibration Curve**



**Calibrator Levels  
(pg/mL)**

|   |       |
|---|-------|
| A | 0.000 |
| B | 0.378 |
| C | 0.780 |
| D | 1.54  |
| E | 3.09  |
| F | 6.25  |
| G | 12.2  |
| H | 20.7  |

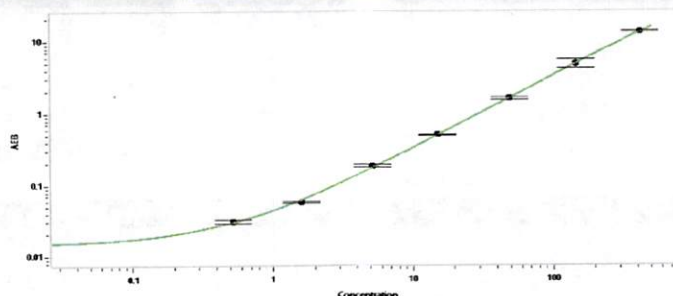
**GFAP® Calibration Curve**



**Calibrator Levels  
(pg/mL)**

|   |       |
|---|-------|
| A | 0.000 |
| B | 5.78  |
| C | 17.2  |
| D | 55.8  |
| E | 167   |
| F | 550   |
| G | 1642  |
| H | 4860  |

**NF-light® Calibration Curve**



**Calibrator Levels  
(pg/mL)**

|   |       |
|---|-------|
| A | 0.000 |
| B | 0.519 |
| C | 1.60  |
| D | 5.10  |
| E | 15.1  |
| F | 49.3  |
| G | 148   |
| H | 420   |