

### **CERTIFICATE OF ANALYSIS**

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**Product Description:** Aβ Peptide Panel 1 (6E10) V-PLEX<sup>TM</sup> and V-PLEX Plus **Kit Catalog Numbers:** K15200E-1, K15200E-2, K15200E-4, K15200G-1, K15200G-2, K15200G-4 **Kit Lot Number:** K0040254 **Expiration Date:** 31 MAY 2016

#### Acceptance Data:

|                             |             |                |      | Assay |      |
|-----------------------------|-------------|----------------|------|-------|------|
| Metric                      |             | Specifications | Αβ40 | Αβ38  | Αβ42 |
| % Recovery<br>Concentration | Calibrators | 80% - 120%     | Pass | Pass  | Pass |
|                             | Controls    | 75% - 125%     | Pass | Pass  | Pass |
|                             | ULOQ        | 80% - 120%     | Pass | Pass  | Pass |
|                             | LLOQ        | 80% - 120%     | Pass | Pass  | Pass |
| % Recovery<br>CV            | Calibrators | <20%           | Pass | Pass  | Pass |
|                             | Controls    | <20%           | Pass | Pass  | Pass |
|                             | ULOQ        | <20%           | Pass | Pass  | Pass |
|                             | LLOQ        | <20%           | Pass | Pass  | Pass |
| Non-specific binding        |             | <1.0%          | Pass | Pass  | Pass |

#### **Concentration of Materials Tested:**

| Units = pg/mL                             | Assay   |         |        |
|---|---------|---------|--------|
|   | Αβ40    | Αβ38    | Αβ42   |
| 40X Calibrator <sup>a</sup>               | 599 000 | 427 000 | 53 300 |
| Neurodegeneration Control 1<br>(A00C0216) | 8886    | 4442    | 1496   |
| Neurodegeneration Control 2<br>(A00C0217) | 2988    | 1097    | 489    |
| Neurodegeneration Control 3<br>(A00C0218) | 521     | 234     | 186    |
| CSF Control 1 <sup>b</sup>                | 6913    | 4540    | 1687   |
| CSF Control 2 <sup>b</sup>                | 3671    | 5183    | 568    |
| CSF Control 3 <sup>b</sup>                | 1897    | 645     | 256    |
| ULOQ                                      | 7000    | 8475    | 1271   |
| LLOQ                                      | 25.0    | 60.0    | 3.13   |

<sup>&</sup>lt;sup>a</sup> Concentrations provided in this table refer to the stock concentration of the calibrators. For top of the standard curve concentration, please refer to the Standard Curve Data on page 2.

<sup>&</sup>lt;sup>b</sup> CSF Controls are multi-analyte controls used to verify assay performance and precision in Human CSF test matrices. Please see Product Insert for experimental data.



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### Standard Curve Data from Kit QC:

| Αβ40              |                   |     |  |
|-------------------|-------------------|-----|--|
| Conc.,<br>(pg/mL) | Average<br>Signal | %CV |  |
| 14 975            | 661 110           | 5.3 |  |
| 3744              | 205 799           | 3.8 |  |
| 936               | 36 446            | 4.2 |  |
| 234               | 3830              | 5.1 |  |
| 58.5              | 474               | 5.8 |  |
| 14.6              | 139               | 4.3 |  |
| 3.66              | 92                | 5.8 |  |
| 0                 | 81                | 7.3 |  |

| Αβ38              |                   |     |  |  |
|-------------------|-------------------|-----|--|--|
| Conc.,<br>(pg/mL) | Average<br>Signal | %CV |  |  |
| 10 675            | 796 351           | 5.0 |  |  |
| 2669              | 122 100           | 5.2 |  |  |
| 667               | 12 213            | 3.7 |  |  |
| 167               | 1334              | 4.8 |  |  |
| 41.7              | 282               | 5.6 |  |  |
| 10.4              | 143               | 6.6 |  |  |
| 2.61              | 113               | 7.1 |  |  |
| 0                 | 106               | 8.4 |  |  |

| Αβ42              |                   |     |  |
|-------------------|-------------------|-----|--|
| Conc.,<br>(pg/mL) | Average<br>Signal | %CV |  |
| 1333              | 835 817           | 3.8 |  |
| 333               | 195 777           | 3.6 |  |
| 83.3              | 31 410            | 4.2 |  |
| 20.8              | 3967              | 5.1 |  |
| 5.21              | 735               | 5.2 |  |
| 1.30              | 201               | 5.1 |  |
| 0.325             | 99                | 6.3 |  |
| 0                 | 70                | 8.0 |  |

| Aβ Peptide Panel 1 (6E10) V-PLEX Components   |   |                     |                        |  |
|---|---|---------------------|------------------------|--|
| Description                                   | Lot Number                                      | Storage Temperature | <b>Expiration Date</b> |  |
| Aβ Peptide Panel 1 Plate                      | Z0055037  | 2-8°C               | 30 NOV 2016            |  |
| Anti-Aβ 6E10 Antibody                         | D0040447  | 2-8°C               | 31 OCT 2016            |  |
| Aβ1-38 Peptide                                | A0040085  | $\leq$ -70°C        | 31 MAY 2016            |  |
| Aβ1-40 Peptide                                | A0040100  | $\leq$ -70°C        | 31 OCT 2016            |  |
| Aβ1-42 Peptide                                | A0040101  | $\leq$ -70°C        | 31 OCT 2016            |  |
| Diluent 35                                    | M0350019  | 2-8°C               | 31 OCT 2016            |  |
| Diluent 100                                   | Y0270200  | 2-8°C               | 30 NOV 2016            |  |
| Aβ40 Blocker                                  | R0110006  | 2-8°C               | 30 NOV 2016            |  |
| MSD Read Buffer T (4X)                        | Not Kit Specific                                | Room Temperature    | N/A                    |  |
| Additional Components Included in V-PLEX Plus |   |                     |                        |  |
| Wash Buffer (20X), 100 mL                     | Not Kit Specific                                | Room Temperature    | N/A                    |  |
| Plate Seals                                   | Not Kit Specific                                | Room Temperature    | N/A                    |  |
| Neurodegeneration Control 1                   |   | ·                   |                        |  |
| Neurodegeneration Control 2                   | Not Kit Specific; See Separate Control Pack CoA |                     |                        |  |
| Neurodegeneration Control 3                   |   |                     |                        |  |



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**Statement:** The above kit lot was tested using MSD procedures and it conforms to MSD's specifications. The above product is intended for Research Use Only. Not for use in Diagnostic Procedures.

|                 | Name       | Function        | Signature | Date        |
|-----------------|------------|-----------------|-----------|-------------|
| Review/Approval | Dana Short | Quality Control | DSRQ      | 22 SEP 2014 |

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