

RFE MEMO

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Product Description(s): V-PLEX® and V-PLEX Plus Aβ 42 Peptide (4G8) Kit

Catalog Number(s) / Size(s): K150SL-Series

Lot Number: K0040347

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0040347 has been extended to 31 Jan 2019.

The expiration dates for the following kit components have also been extended:

| Description | Lot Number | Original Expiration Date | New Expiration Date |
|----------------------|------------|--------------------------|------------------------|
| Aβ42 Peptide Plate | Z0055569 | 30 Nov 2018 | 31 JAN 2019 |
| Anti-Aβ 4G8 Antibody | D0040613 | 30 Sep 2018 | 31 JAN 2019 |
| Aβ1- 42 Peptide | A0040134 | 31 Jan 2018 | 31 JAN 2019 |
| Diluent 35 | M0350024 | 30 Sep 2018 | 31 JAN 2019 |
| Diluent 100 | Y0270232 | 31 May 2018 | 31 JAN 2019 |

| Function | Name | Signature | Date |
|--------------------------|--------------|--------------|-------------|
| Quality Assurance | Dawn Stollar | Dawn Stollar | 12 JAN 2018 |

This memo supersedes all other statements regarding date of expiration for this product.

Memo Rev. A CM-00289-B

CERTIFICATE OF ANALYSIS

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Product Description: V-PLEX® and V-PLEX Plus Aβ 42 Peptide (4G8) Kit

Kit Catalog Numbers: K150SLE-1, K150SLE-2, K150SLE-4, K150SLG-1, K150SLG-2, K150SLG-4

Kit Lot Number: K0040347

Expiration Date: 31 Jan 2018

Acceptance Data/ Percent Recovery Specifications:

| | | Calibrator | | Neurodegeneration Control 1 | | Neurodegeneration Control 2 | | Neurodegeneration Control 3 | |
|------|------|------------|-------|-----------------------------|-------|-----------------------------|-------|-----------------------------|-------|
| Spot | Name | Recovery | CV | Recovery | CV | Recovery | CV | Recovery | CV |
| 1 | Αβ42 | 80% - 120% | < 20% | 75% - 125% | < 20% | 75% - 125% | < 20% | 75% - 125% | < 20% |

| | | LLOQ | | | .OQ ULOQ | | |
|------|------|-------|------------|-------|----------|------------|-------|
| Spot | Name | Value | Recovery | CV | Value | Recovery | CV |
| 1 | Αβ42 | 2.50 | 80% - 120% | < 20% | 1270 | 80% - 120% | < 20% |

Stock Concentration of Material Tested:

| Spot | Name | Item | Conc | Units |
|------|----------------|-----------------------------|-------|-------|
| | 40X Calibrator | 55200 | pg/mL | |
| 1 | 1 Αβ42 | Neurodegeneration Control 1 | 1680 | pg/mL |
| 1 | | Neurodegeneration Control 2 | 545 | pg/mL |
| | | Neurodegeneration Control 3 | 230 | pg/mL |

Controls tested may not be the same lot as shipped.

Concentrations provided in this table refer to the stock concentration of the calibrators. For top of the standard curve concentrations, please refer to the Standard Curve Data

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Standard Curve Data:

| Aβ42 - Spot 1 | | | | | |
|----------------|---------------|-----|--|--|--|
| Conc. pg/mL | ECL Signal | %CV | | | |
| 1380 | 1,160,000 | 1.6 | | | |
| 345 | 287,000 | 1.7 | | | |
| 86.3 | 54,800 | 2.2 | | | |
| 21.6 | 8,900 | 1.3 | | | |
| 5.39 | 1,650 | 2.5 | | | |
| 1.35 | 500 | 2.5 | | | |
| 0.337 | 269 | 3.1 | | | |
| 0.00 | 194 | 3.3 | | | |

Components:

| Description | Lot Number | Storage Temperature | Expiration Date |
|------------------------|------------------|---------------------|-----------------|
| Aβ42 Peptide Plate | Z0055569 | 2-8°C | 30 Nov 2018 |
| Anti-Aβ 4G8 Antibody | D0040613 | 2-8°C | 30 Sep 2018 |
| Aβ1- 42 Peptide | A0040134 | ≤ -70°C | 31 Jan 2018 |
| Diluent 35 | M0350024 | 2-8°C | 30 Sep 2018 |
| Diluent 100 | Y0270232 | 2-8°C | 31 May 2018 |
| MSD Read Buffer T (4X) | Not Kit Specific | Not Kit Specific | N/A |

| Additional Components Included in V-PLEX Plus | | | |
|---|------------------|--|--|
| Plate Seals | Not Kit Specific | | |
| Wash Buffer (20X), 100mL | Not Kit Specific | | |
| Neurodegeneration Control 1 | Not Kit Specific | | |
| Neurodegeneration Control 2 | Not Kit Specific | | |
| Neurodegeneration Control 3 | Not Kit Specific | | |

Statement:

The above kit 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 | Dawn Stollar | Quality Assurance | Dawn Stollar | 02 AUG 2016 |