



February 2024

Re: Neurodegeneration Control Pack 1 (4G8) (Catalog No. C40RQ-1), Lot No. CP000089, Revised Concentrations

Dear Valued Customer,

As part of our process for continuous product improvement, we periodically review the performance specifications of V-PLEX[®] products. As we accumulate data from additional lots, if the larger data set indicates a change to a more accurate value, we update the product accordingly.

We recently reviewed the data for the controls in our Neurodegeneration Control Pack 1 (4G8) Lot No. CP000089. Based on the larger data set, we decided to reassign the values of the controls for all of the analytes in this panel. We do not believe that the controls have changed. Rather, we believe that the larger data set provides more accurate values for the controls. The revised (Table 1) and original (Table 2) values for the controls are listed below. Tau assignments were not analyzed for reassignment because the V-PLEX Human Total Tau has been discontinued; future lots of Neurodegeneration Control Pack 1 (4G8) will be manufactured without Tau.

| Units = pg/mL | Assay | | | |
|-------------------------|--------------|--------------|--------------|------|
| | A β 40 | A β 38 | A β 42 | Tau |
| Control 1 (A00C0643) | 7790 | 3840 | 1490 | 1330 |
| Control 2 (A00C0644) | 2650 | 961 | 516 | 415 |
| Control 3 (A00C0645) | 417 | 223 | 205 | 161 |

Table 1. Revised concentrations

| Units = pg/mL | Assay | | | |
|-------------------------|--------------|--------------|--------------|------|
| | A β 40 | A β 38 | A β 42 | Tau |
| Control 1 (A00C0643) | 8040 | 4020 | 1410 | 1330 |
| Control 2 (A00C0644) | 2700 | 1050 | 515 | 415 |
| Control 3 (A00C0645) | 445 | 256 | 211 | 161 |

Table 2. Original concentrations

If you have any questions or concerns, please contact MSD Scientific Support at +1 240-314-2798 or scientificsupport@mesoscale.com.

Sincerely,

MSD Quality Assurance



RFE MEMO

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Product Description(s): Neurodegeneration Control Pack 1 (4G8)

Catalog Number(s) / Size(s): C40RQ-1

Lot Number: CP000089

Based on additional testing, the original date of expiration for this Control Pack has been extended by 36 months. The expiration date of CP000089 has been extended to 31 MAR 2025.

The expiration dates for the following controls have been extended:

| Description | Lot Number | Original Expiration Date | New Expiration Date |
|-----------------------------------|------------|--------------------------|---------------------|
| Neurodegeneration Control 1 (4G8) | A00C0643 | 31 MAR 2022 | 31 MAR 2025 |
| Neurodegeneration Control 2 (4G8) | A00C0644 | 31 MAR 2022 | 31 MAR 2025 |
| Neurodegeneration Control 3 (4G8) | A00C0645 | 31 MAR 2022 | 31 MAR 2025 |

| Function | Name | Signature | Date |
|----------|---------------|-----------|-------------|
| Quality | Karen Hamilla | | 05 MAR 2024 |

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



CERTIFICATE OF ANALYSIS

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Control Pack Description: Neurodegeneration Control Pack 1 (4G8)

Catalog Number: C40RQ-1

Lot Number: CP000089

Expiration Date: 31 MAR 2022

Concentration Assignment: The following concentrations were measured using the A β Peptide Panel 1 (4G8) V-PLEX® kit:

| Analyte | Control 1 | Control 2 | Control 3 | Unit of Measure |
|--------------|-----------|-----------|-----------|-----------------|
| A β 40 | 7790 | 2650 | 417 | pg/mL |
| A β 38 | 3840 | 961 | 223 | pg/mL |
| A β 42 | 1490 | 516 | 205 | pg/mL |

The following concentrations were measured using the Human Total Tau V-PLEX® kit:

| Analyte | Control 1 | Control 2 | Control 3 | Unit of Measure |
|---------|-----------|-----------|-----------|-----------------|
| Tau | 1330 | 415 | 161 | pg/mL |

Components:

| Description | Lot Number | Storage Temperature | Expiration Date |
|-----------------------------------|------------|----------------------------|-----------------|
| Neurodegeneration Control 1 (4G8) | A00C0643 | $\leq -70^{\circ}\text{C}$ | 31 MAR 2022 |
| Neurodegeneration Control 2 (4G8) | A00C0644 | $\leq -70^{\circ}\text{C}$ | 31 MAR 2022 |
| Neurodegeneration Control 3 (4G8) | A00C0645 | $\leq -70^{\circ}\text{C}$ | 31 MAR 2022 |

This product is intended for Research Use Only. Not for use in Diagnostic Procedures.

| | Name | Function | Signature | Date |
|-----------------|---------------|----------|-----------|-------------|
| Review/Approval | Karen Hamilla | Quality | | 05 MAR 2024 |