



RFE MEMO

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Product Description(s): V-PLEX® and V-PLEX Plus Aβ Peptide Panel 1 (4G8) Kit

Catalog Number(s) / Size(s): K15199-Series; K150SH-Series

Lot Number: K0081678

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0081678 has been extended to 30 SEP 2022.

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

Description	Lot Number	Original Expiration Date	New Expiration Date
Aβ Peptide Panel 1 (4G8) Plate	Z0056580	28 FEB 2022	30 SEP 2022
Aβ1-38 Peptide (4G8)	A0080189	30 SEP 2021	30 SEP 2022
Aβ1-40 Peptide (4G8)	A0080202	30 SEP 2021	30 SEP 2022
Aβ1-42 Peptide (4G8)	A0080201	31 MAY 2022	30 SEP 2022
Diluent 35	M0350031	31 MAR 2022	30 SEP 2022
Diluent 100	Y0270266	28 FEB 2022	30 SEP 2022

Function	Name	Signature	Date
Quality	Karen Hamilla		01 DEC 2021

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



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Product Description(s): A β 1-42 Peptide (4G8)

Catalog Number(s) / Size(s): C003A-2

Lot Number: A0080201

Based on additional testing, the original date of expiration for this calibrator has been extended by 10 months. The expiration date of A0080201 has been extended to 31 MAY 2022.

Function	Name	Signature	Date
Quality	Karen Hamilla		08 APR 2021

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



CERTIFICATE OF ANALYSIS

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Product Description: A β 1-42 Peptide (4G8)

Catalog Number: C003A-2

Lot Number: A0080201

Expiration Date: 31 JUL 2021


Storage Temperature: $\leq -70^{\circ}\text{C}$

Concentration of Materials Tested:

	Assay
	A β 1-42 Peptide (4G8)
Calibrator (pg/mL)	99 200

Concentration: 40X

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

	Name	Function	Signature	Date
Review/Approval	Dawn Stollar	Quality Assurance		15 APR 2019

CERTIFICATE OF ANALYSIS

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Product Description: V-PLEX® and V-PLEX Plus A β Peptide Panel 1 (4G8) Kit
Kit Lot Number: K0081678
Expiration Date: 30 Sep 2021
Kit Catalog Numbers: K15199-Series; K150SH-Series

Precision and Accuracy Specifications:

Spot	Name	Calibrator		Neurodegeneration Control 1		Neurodegeneration Control 2		Neurodegeneration Control 3	
		Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	A β 40	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%
2	A β 38	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%
4	A β 42	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%

Spot	Name	LLOQ			ULOQ		
		Value	Recovery	CV	Value	Recovery	CV
1	A β 40	20.0	80% - 120%	< 20%	6000	80% - 120%	< 20%
2	A β 38	60.0	80% - 120%	< 20%	7500	80% - 120%	< 20%
4	A β 42	2.50	80% - 120%	< 20%	1270	80% - 120%	< 20%

Non-Specific Binding Specifications:

Spot	Name	NSB Spec
1	A β 40	< 1.0%
2	A β 38	< 1.0%
4	A β 42	< 1.0%

Stock Concentration of Calibrator:

Spot	Name	Conc.	Units
1	A β 40	584000	pg/mL
2	A β 38	480000	pg/mL
4	A β 42	99200	pg/mL


CERTIFICATE OF ANALYSIS

Lot-Specific Components:

Description	Lot Number	Storage Temperature	Expiration Date
A β Peptide Panel 1 (4G8) Plate	Z0056580	2-8°C	28 Feb 2022
Anti-A β 4G8 Antibody	D0081341	2-8°C	30 Jun 2023
A β 1-38 Peptide (4G8)	A0080189	\leq -70°C	30 Sep 2021
A β 1-40 Peptide (4G8)	A0080202	\leq -70°C	30 Sep 2021
A β 1-42 Peptide (4G8)	A0080201	\leq -70°C	31 May 2022
A β 40 Blocker	R0010692	2-8°C	30 Sep 2022
Diluent 35	M0350031	2-8°C	31 Mar 2022
Diluent 100	Y0270266	2-8°C	28 Feb 2022

Additional components may be provided to execute the assay. Additional components are not lot-specific.

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

	Name	Function	Signature	Date
Review/Approval	Karen Hamilla	Quality		09 APR 2021