



RFE MEMO

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Product Description(s): V-PLEX® and V-PLEX Plus A β Peptide Panel 1 (6E10) Kit

Catalog Number(s) / Size(s): K15200-Series, K150SI-Series

Lot Number: K0081654

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0081654 has been extended to 31 JUL 2023.

The expiration date for the following kit component has been extended:

Description	Lot Number	Original Expiration Date	New Expiration Date
A β 1-38 Peptide (6E10)	A0080243	31 JUL 2022	31 JUL 2023
A β 1-42 Peptide (6E10)	A0080245	31 JUL 2022	31 JUL 2023
Diluent 35	M0350032	31 MAR 2023	31 JUL 2023

Function	Name	Signature	Date
Quality	Karen Hamilla		20 APR 2022

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

CERTIFICATE OF ANALYSIS

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Product Description: V-PLEX® and V-PLEX Plus A β Peptide Panel 1 (6E10) Kit
Kit Lot Number: K0081654
Expiration Date: 31 Jul 2022
Kit Catalog Numbers: K15200-Series, K150SI-Series

Precision and Accuracy Specifications:

		Calibrator		Neurodegeneration Control 1		Neurodegeneration Control 2		Neurodegeneration Control 3	
Spot	Name	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%

		LLOQ			ULOQ		
Spot	Name	Value	Recovery	CV	Value	Recovery	CV
1	A β 40	50.0	80% - 120%	< 20%	7000	80% - 120%	< 20%
2	A β 38	60.0	80% - 120%	< 20%	8480	80% - 120%	< 20%
4	A β 42	3.13	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	612000	pg/mL
2	A β 38	508000	pg/mL
4	A β 42	73600	pg/mL


CERTIFICATE OF ANALYSIS

Lot-Specific Components:

Description	Lot Number	Storage Temperature	Expiration Date
A β Peptide Panel 1 (6E10) Plate	Z0056874	2-8°C	31 Jul 2023
Anti-A β 6E10 Antibody	D0081630	2-8°C	31 Jul 2024
A β 1-38 Peptide (6E10)	A0080243	\leq -70°C	31 Jul 2022
A β 1-40 Peptide (6E10)	A0080277	\leq -70°C	30 Sep 2023
A β 1-42 Peptide (6E10)	A0080245	\leq -70°C	31 Jul 2022
Diluent 35	M0350032	2-8°C	31 Mar 2023
Diluent 100	Y0270290	2-8°C	31 Jul 2023
A β 40 Blocker	R0010728	2-8°C	31 Aug 2023

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		10 MAY 2021