

RFE MEMO

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Product Description(s): V-PLEX® and V-Plex Plus Aβ42 Peptide (4G8) Kit

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

Lot Number: K0081410

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0081410 has been extended to 31 May 2022.

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

Description	Lot Number	Original Expiration Date	New Expiration Date
Aβ1-42 Peptide (4G8)	A0080201	31 Jul 2021	31 May 2022
Diluent 35	M0350030	31 May 2021	31 May 2022

Function	Name	Name Signature	
Quality	Karen Hamilla	Haven Hamille	25 JAN 2021

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 Aβ42 Peptide (4G8) Kit

Kit Catalog Numbers: K150SL-Series

Kit Lot Number: K0081410 **Expiration Date**: 31 May 2021

Acceptance Data/ Percent Recovery Specifications:

		Calibrator		Neurodegeneration Control 1 (4G8)		Neurodegeneration Control 2 (4G8)		Neurodegeneration Control 3 (4G8)	
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				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
1 Αβ42	40X Calibrator	99200	0	
	A D 4 2	Neurodegeneration Control 1 (4G8)	1410	0
	Ар42	Neurodegeneration Control 2 (4G8)	515	0
		Neurodegeneration Control 3 (4G8)	211	0

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

Standard Curve Data:

Aβ42 - Spot 1				
Conc. 0				
2480	1,250,000	1.1		
620	395,000	5.4		
155	66,100	3.2		
38.8	7,910	5.0		
9.69	1,010	4.3		
2.42	293	2.1		
0.605	196	3.7		
0.00	168	3.2		

Components:

Description	Lot Number	Storage Temperature	Expiration Date
Aß42 Peptide Plate	Z0056655	2-8°C	31 Aug 2022
Anti-Aβ 4G8 Antibody	D0081432	2-8°C	31 Aug 2023
Aβ1-42 Peptide (4G8)	A0080201	≤ -70°C	31 Jul 2021
Diluent 35	M0350030	2-8°C	31 May 2021
Diluent 100	Not Kit Specific	Not Kit Specific	N/A
MSD Read Buffer T	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 (4G8)	Not Kit Specific			
Neurodegeneration Control 2 (4G8)	Not Kit Specific			
Neurodegeneration Control 3 (4G8)	Not Kit Specific			

Statement:

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

	Name	Function	Signature	Date
Review/Approval	Karen Hamilla	Quality	Haver Hamille	14 APR 2020