

RFE MEMO

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Product Description(s): V-PLEX® and V-PLEX Plus Human Aβ42 Kit

Catalog Number(s) / Size(s): K151LB - Series

Lot Number: K0081362

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0081362 has been extended to 30 JUN 2022.

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

Description	Lot Number	Original Expiration Date	New Expiration Date
Aβ42 Peptide Plate	Z0056622	30 APR 2022	30 JUN 2022
Aβ1-42 Peptide (6E10)	A0080200	30 JUN 2021	30 JUN 2022
Diluent 35	M0350031	31 MAR 2022	30 JUN 2022

Function	Name	Signature	Date
Quality	Karen Hamilla	Haven Hamille	05 MAY 2021

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

Memo Rev. A CM-00289-B

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Product Description: V-PLEX® and V-PLEX Plus Human Aβ42 Kit

Kit Catalog Numbers: K151LB-Series

Kit Lot Number: K0081362 **Expiration Date**: 30 Jun 2021

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				ULOQ	
Spot	Name	Value	Recovery	cv	Value	Recovery	CV
1	Αβ42	3.00	80% - 120%	< 20%	2000	80% - 120%	< 20%

Stock Concentration of Material Tested:

Spot	Name	Item	Conc	Units
	20X Calibrator	70000	pg/mL	
1	1 Αβ42	Neurodegeneration Control 1	1440	pg/mL
1		Neurodegeneration Control 2	506	pg/mL
		Neurodegeneration Control 3	203	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

Standard Curve Data:

Aβ42 - Spot 1					
Conc. pg/mL	ECL Signal	%CV			
3500	1,010,000	5.4			
875	394,000	5.0			
219	93,000	7.0			
54.7	17,200	6.1			
13.7	3,170	6.9			
3.42	739	5.8			
0.854	248	5.3			
0.00	127	5.2			

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Components:

Description	Lot Number	Storage Temperature	Expiration Date
Aβ42 Peptide Plate	Z0056622	2-8°C	30 Apr 2022
Anti-Aβ 6E10 Antibody	D0081268	2-8°C	31 Aug 2022
Aβ1-42 Peptide	A0080200	≤ -70°C	30 Jun 2021
Diluent 35	M0350031	2-8°C	31 Mar 2022
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	Not Kit Specific			
Neurodegeneration Control 2	Not Kit Specific			
Neurodegeneration Control 3	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	Haven Hamille	20 DEC 2019