

RFE MEMO

Page 1 of 1

Product Description(s): V-PLEX® and V-PLEX Plus Human Aβ42 Kit **Catalog Number(s) / Size(s):** K151LB-Series **Lot Number:** K0080679

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0080679 has been extended to 30 Nov 2019.

Description	Lot Number	Original Expiration Date	New Expiration Date	
Aβ42 Peptide Plate	Z0055864	31 AUG 2019	30 NOV 2019	
Anti-Aβ 6E10 Antibody	D0080970	31 AUG 2019	30 NOV 2019	
Aβ1-42 Peptide	A0040169	30 NOV 2018	30 NOV 2019	
Diluent 35	M0350026	31 JUL 2019	30 NOV 2019	

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

Function	Name	Signature	Date	
Quality Assurance	Dawn Stollar	Dawn Stollar	01 OCT 2018	

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



Page 1 of 2

Product Description:V-PLEX® and V-PLEX Plus Human Aβ42 KitKit Catalog Numbers:K151LB-seriesKit Lot Number:K0080679Expiration Date:30 Nov 2018

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	hu Aβ42	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%

		LLOQ			ULOQ		
Spot	Name	Value	Recovery	CV	Value	Recovery	CV
1	hu Aβ42	3.00	80% - 120%	< 20%	2000	80% - 120%	< 20%

Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1 1 40/0	20X Calibrator	69200	pg/mL	
	Neurodegeneration Control 1	1470	pg/mL	
1	1 hu Aβ42	Neurodegeneration Control 2	494	pg/mL
		Neurodegeneration Control 3	207	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

Meso Scale Diagnostics, LLC. CERTIFICATE OF ANALYSIS

Page 2 of 2

Standard Curve Data:

hu Aβ42 - Spot 1				
Conc. pg/mL	ECL Signal	%CV		
3460	714,000	10.0		
865	268,000	7.2		
216	63,400	11.0		
54.1	10,700	11.0		
13.5	1,890	16.0		
3.38	467	7.9		
0.845	167	5.5		
0.211	104	4.5		
0.00	83	6.8		

Components:

Description	Lot Number	Storage Temperature	Expiration Date
Aβ42 Peptide Plate	Z0055864	2-8°C	31 Aug 2019
Anti-Aβ 6E10 Antibody	D0080970	2-8°C	31 Aug 2019
Aβ1-42 Peptide	A0040169	\leq -70°C	30 Nov 2018
Diluent 35	M0350026	2-8°C	31 Jul 2019
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)	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	Dawn Stollar	Quality Assurance	Dawn Stollar	28 JUN 2017