



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: K0081205

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0081205 has been extended to 31 JAN 2022.

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

Description	Lot Number	Original Expiration Date	New Expiration Date
A β Peptide Panel 1 (6E10) Plate	Z0056478	31 AUG 2021	31 JAN 2022
A β 1-38 Peptide	A0080181	28 FEB 2021	31 JAN 2022
A β 1-40 Peptide	A0080190	30 APR 2021	31 JAN 2022
A β 1-42 Peptide (6E10)	A0080200	30 JUN 2021	31 JAN 2022
A β 40 Blocker	R0010642	31 JAN 2021	31 JAN 2022
Diluent 35	M0350030	31 MAY 2021	31 JAN 2022
Diluent 100	Y0270260	30 JUN 2021	31 JAN 2022

Function	Name	Signature	Date
Quality	Karen Hamilla		07 JUN 2021

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 Aβ Peptide Panel 1 (6E10) Kit

Kit Catalog Numbers: K15200-Series, K150SI-Series

Kit Lot Number: K0081205

Expiration Date: 31 Jan 2021

Acceptance Data/ Percent Recovery Specifications:

Spot	Name	Calibrator		Neurodegeneration Control 1		Neurodegeneration Control 2		Neurodegeneration Control 3	
		Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	Aβ1-40	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%
2	Aβ1-38	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%
4	Aβ1-42	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%

Spot	Name	LLOQ			ULOQ		
		Value	Recovery	CV	Value	Recovery	CV
1	Aβ1-40	50.0	80% - 120%	< 20%	7000	80% - 120%	< 20%
2	Aβ1-38	60.0	80% - 120%	< 20%	8480	80% - 120%	< 20%
4	Aβ1-42	3.13	80% - 120%	< 20%	1270	80% - 120%	< 20%

Acceptance Data/ Non Specific Binding Specifications:

Spot	Name	NSB Spec
1	Aβ1-40	< 1.0%
2	Aβ1-38	< 1.0%
4	Aβ1-42	< 1.0%

Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	Aβ1-40	40X Calibrator	604000	pg/mL
		Neurodegeneration Control 1	10100	pg/mL
		Neurodegeneration Control 2	3290	pg/mL
		Neurodegeneration Control 3	571	pg/mL
2	Aβ1-38	40X Calibrator	516000	pg/mL
		Neurodegeneration Control 1	4160	pg/mL
		Neurodegeneration Control 2	1060	pg/mL
		Neurodegeneration Control 3	236	pg/mL
4	Aβ1-42	40X Calibrator	70000	pg/mL
		Neurodegeneration Control 1	1360	pg/mL
		Neurodegeneration Control 2	476	pg/mL
		Neurodegeneration Control 3	193	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

CERTIFICATE OF ANALYSIS

Standard Curve Data:

Aβ1-40 - Spot 1			Aβ1-38 - Spot 2			Aβ1-42 - Spot 4		
Conc. pg/mL	ECL Signal	%CV	Conc. pg/mL	ECL Signal	%CV	Conc. pg/mL	ECL Signal	%CV
15100	897,000	1.8	12900	812,000	3.2	1750	856,000	1.9
3780	311,000	2.6	3230	149,000	3.2	438	222,000	6.0
944	55,900	3.8	806	15,800	2.7	109	35,900	3.6
236	6,570	4.6	202	1,690	3.2	27.3	4,580	5.1
59.0	847	4.2	50.4	362	3.5	6.84	816	2.7
14.7	201	4.6	12.6	159	6.4	1.71	229	3.7
3.69	105	3.8	3.15	117	5.7	0.427	118	4.3
0.00	80	4.8	0.00	108	4.7	0.00	89	16.0

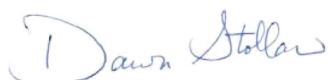
Components:

Description	Lot Number	Storage Temperature	Expiration Date
Aβ Peptide Panel 1 (6E10) Plate	Z0056478	2-8°C	31 Aug 2021
Anti-Aβ 6E10 Antibody	D0081268	2-8°C	31 Aug 2022
Aβ1-38 Peptide	A0080181	≤ -70°C	28 Feb 2021
Aβ1-40 Peptide	A0080190	≤ -70°C	30 Apr 2021
Aβ1-42 Peptide (6E10)	A0080200	≤ -70°C	30 Jun 2021
Aβ40 Blocker	R0010642	2-8°C	31 Jan 2021
Diluent 35	M0350030	2-8°C	31 May 2021
Diluent 100	Y0270260	2-8°C	30 Jun 2021
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	Dawn Stollar	Quality		11 JUN 2019