



RFE MEMO

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Product Description(s): V-PLEX® and V-PLEX Plus GLP-1 Active Kit

Catalog Number(s) / Size(s): K1503O-Series

Lot Number: K0080908

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0080908 has been extended to 31 Mar 2021.

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

Description	Lot Number	Original Expiration Date	New Expiration Date
GLP-1 (active) Plate	Z0056101	30 Apr 2020	31 Mar 2021
Diluent 13	M0130042	31 Mar 2020	31 Mar 2021
Diluent 12	M0120061	31 Mar 2020	31 Mar 2021

Function	Name	Signature	Date
Quality	Karen Hamilla		28 JAN 2020

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 GLP-1 Active Kit
Kit Catalog Numbers: K1503O-Series
Kit Lot Number: K0080908
Expiration Date: 31 Mar 2020

Acceptance Data/ Percent Recovery Specifications:

Spot	Name	Calibrator		GLP-1 (active) Control 1		GLP-1 (active) Control 2		GLP-1 (active) Control 3	
		Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	GLP-1 (active)	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%

Spot	Name	LLOQ			ULOQ		
		Value	Recovery	CV	Value	Recovery	CV
1	GLP-1 (active)	0.300	80% - 120%	< 20%	120	80% - 120%	< 20%

Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	GLP-1 (active)	Calibrator	276	pM
		GLP-1 (active) Control 1	122	pM
		GLP-1 (active) Control 2	44.3	pM
		GLP-1 (active) Control 3	14.6	pM

Controls tested may not be the same lot as shipped.

Standard Curve Data:

GLP-1 (active) - Spot 1		
Conc. pM	ECL Signal	%CV
276	1,100,000	1.5
69.0	209,000	3.3
17.3	41,900	3.2
4.31	9,610	2.3
1.08	2,500	4.1
0.270	795	2.4
0.0674	372	3.5
0.00	244	4.4

CERTIFICATE OF ANALYSIS

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Components:

Description	Lot Number	Storage Temperature	Expiration Date
GLP-1 (active) Plate	Z0056101	2-8°C	30 Apr 2020
GLP-1 (active) Antibody	D0081039	2-8°C	31 Mar 2021
GLP-1 (active) Calibrator Blend	A0080155	2-8°C	30 Nov 2022
Diluent 13	M0130042	≤ -10°C	31 Mar 2020
Diluent 12	M0120061	≤ -10°C	31 Mar 2020
Aprotinin	Not Kit Specific	Not Kit Specific	N/A
MSD GOLD™ Read Buffer	Not Kit Specific	Not Kit Specific	N/A

Additional Components Included in V-PLEX Plus	
Plate Seals	Not Kit Specific
Wash Buffer (20x), 100 mL	Not Kit Specific
GLP-1 (active) Control 1	Not Kit Specific
GLP-1 (active) Control 2	Not Kit Specific
GLP-1 (active) 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	<i>Dawn Stollar</i>	04 JAN 2018