

RFE MEMO

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Product Description(s): V-PLEX® and V-PLEX Plus Human MCP-1 Kit

Catalog Number(s) / Size(s): K151NN-Series

Lot Number: K0080876

Based on additional testing, the original date of expiration for this kit has been extended by 6 months. The expiration date of K0080876 has been extended to 31 Dec 2019.

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

Description	Lot Number	Original Expiration Date	New Expiration Date
Anti-hu MCP-1 Antibody	D0080865	30 JUN 2019	31 DEC 2019

Function	Function Name Signatur		Date
Quality Assurance	Dawn Stollar	Dawn Stollar	12 FEB 2018

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 Human MCP-1 Kit

Kit Catalog Numbers: K151NN-Series

Kit Lot Number: K0080876 **Expiration Date**: 30 Jun 2019

Acceptance Data/ Percent Recovery Specifications:

		Calibrator		Chemokine Panel 1(Human) Control 1		Chemokine Panel 1(Human) Control 2		Chemokine Panel 1(Human) Control 3	
Spot	Name	Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	hu MCP-1	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%

		LLOQ				ULOQ	
Spot	Name	Value	Recovery	CV	Value	Recovery	CV
1	hu MCP-1	1.09	80% - 120%	< 20%	375	80% - 120%	< 20%

Stock Concentration of Material Tested:

Spot	Name	Item	Conc	Units
1 hu MCP-1	Calibrator	686	pg/mL	
	Chemokine Panel 1(Human) Control 1	420	pg/mL	
	Chemokine Panel 1(Human) Control 2	66.6	pg/mL	
		Chemokine Panel 1(Human) Control 3	11.1	pg/mL

Controls tested may not be the same lot as shipped.

Standard Curve Data:

hu MCP-1 - Spot 1				
Conc. pg/mL	ECL Signal	%CV		
686	212,000	3.6		
172	53,300	3.3		
42.9	13,500	2.0		
10.7	3,490	2.8		
2.68	943	3.4		
0.670	277	2.5		
0.167	110	2.1		
0.00	56	5.6		

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Components:

Description	Lot Number	Storage Temperature	Expiration Date
Human MCP-1 Plate	Z0046607	2-8°C	31 Jan 2020
Anti-hu MCP-1 Antibody	D0080865	2-8°C	30 Jun 2019
Chemokine Panel 1 (Human) Calibrator Blend	A0080131	2-8°C	31 Jul 2022
Diluent 43	M0430023	≤ -10°C	31 Dec 2019
Diluent 3	M0030078	≤ -10°C	31 Jan 2020
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			
Chemokine Panel 1(Human) Control 1	Not Kit Specific			
Chemokine Panel 1(Human) Control 2	Not Kit Specific			
Chemokine Panel 1(Human) 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	10 OCT 2017