



RFE MEMO

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


Catalog Number(s) / Size(s): K156NN-Series

Lot Number: K0081057

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0081057 has been extended to 31 JUL 2020.

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	D0080904	31 JUL 2019	31 JUL 2020

Function	Name	Signature	Date
Quality Assurance	Dawn Stollar		29 MAR 2019

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 NHP MCP-1 Kit
Kit Catalog Numbers: K156NN-Series
Kit Lot Number: K0081057
Expiration Date: 31 Jul 2019

Acceptance Data/ Percent Recovery Specifications:

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

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

Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	NHP MCP-1	Calibrator	540	pg/mL
		Chemokine Panel 1 (human) Control 1	478	pg/mL
		Chemokine Panel 1 (human) Control 2	73.3	pg/mL
		Chemokine Panel 1 (human) Control 3	12.8	pg/mL

Controls tested may not be the same lot as shipped.

The calibrator and controls for this assay contain a human recombinant cytokine calibrator sequence that is highly homologous to the non-human primate cytokine. This assay has been verified to cross-react with homologs of rhesus and cynomolgus monkeys. See Product Insert for experimental data.

Standard Curve Data:

NHP MCP-1 - Spot 1		
Conc. pg/mL	ECL Signal	%CV
540	167,000	2.8
135	43,000	4.1
33.8	11,400	2.7
8.44	2,920	3.3
2.11	787	3.6
0.527	239	3.1
0.132	107	4.2
0.00	63	4.8

CERTIFICATE OF ANALYSIS

Components:

Description	Lot Number	Storage Temperature	Expiration Date
Human MCP-1	Z0046877	2-8°C	31 Dec 2020
Anti-hu MCP-1 Antibody	D0080904	2-8°C	31 Jul 2019
Chemokine Panel 1 (human) Calibrator Blend	A0080171	2-8°C	30 Jun 2023
Diluent 43	M0430027	≤ -10°C	31 Dec 2020
Diluent 3	M0030084	≤ -10°C	31 Jan 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), 100 mL	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	<i>Dawn Stollar</i>	25 SEP 2018