

RFE MEMO

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Product Description(s): V-PLEX® and V-Plex Plus NHP MIP-1ß Kit

Catalog Number(s) / Size(s): K156NR-Series

Lot Number: K0080913

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0080913 has been extended to 31 JUL 2019.

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

Description	Lot Number	Original Expiration Date	New Expiration Date
Human MIP-1β Plate	Z0046178	31 Jan 2019	31 JUL 2019
Anti-hu MIP-1β Antibody	D0080685	30 Nov 2018	31 JUL 2019
Diluent 43	M0430017	31 Dec 2018	31 JUL 2019
Diluent 3	M0030070	31 Jul 2018	31 JUL 2019

Function	Name	Signature	Date
Quality Assurance	Dawn Stollar	Dawn Stollar	09 APR 2019

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 NHP MIP-1ß Kit

Kit Catalog Numbers: K156NR-Series

Kit Lot Number: K0080913 Expiration Date: 31 Jul 2018

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	NHP MIP-1β	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%

		LLOQ				ULOQ	
Spot	Name	Value	Recovery	CV	Value	Recovery	CV
1	NHP MIP-1β	2.27	80% - 120%	< 20%	750	80% - 120%	< 20%

Stock Concentration of Material Tested:

Spot	Name	Item	Conc	Units
1 NHP MIP-		Calibrator	1050	pg/mL
	NIIID MID 10	Chemokine Panel 1 (human) Control 1	797	pg/mL
	NHP MIP-1p	Chemokine Panel 1 (human) Control 2	130	pg/mL
		Chemokine Panel 1 (human) Control 3	22.4	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 MIP-1β - Spot 1					
Conc. pg/mL	ECL Signal	%CV			
1050	521,000	3.0			
263	114,000	3.8			
65.6	20,500	3.1			
16.4	3,990	4.2			
4.10	987	4.8			
1.03	285	4.2			
0.256	120	3.8			
0.00	73	7.4			

CERTIFICATE OF ANALYSIS

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Components:

Description	Lot Number	Storage Temperature	Expiration Date
Human MIP-1β Plate	Z0046178	2-8°C	31 Jan 2019
Anti-hu MIP-1β Antibody	D0080685	2-8°C	30 Nov 2018
Chemokine Panel 1 (human) Calibrator Blend	A0080131	2-8°C	31 Jul 2022
Diluent 43	M0430017	≤-10°C	31 Dec 2018
Diluent 3	M0030070	≤-10°C	31 Jul 2018
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	09 APR 2019