



RFE MEMO

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Product Description(s): V-PLEX® and V-PLEX Plus NHP IL-12/IL-23 p40 Kit

Catalog Number(s) / Size(s): K156RJ-Series

Lot Number: K0080617

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0080617 has been extended to 30 Apr 2019.

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

Description	Lot Number	Original Expiration Date	New Expiration Date
Human IL-12/IL-23 p40 Plate	Z0046206	28 FEB 2019	30 APR 2019
Anti-hu IL-12/23p40	D0080656	30 APR 2018	30 APR 2019
Diluent 43	M0430017	31 DEC 2018	30 APR 2019
Diluent 3	M0030070	31 JUL 2018	30 APR 2019

Function	Name	Signature	Date
Quality Assurance	Dawn Stollar	<i>Dawn Stollar</i>	29 AUG 2018

This memo supersedes all other statements regarding date of expiration for this product.

CERTIFICATE OF ANALYSIS

COA-07767

Product Description: V-PLEX® and V-PLEX Plus NHP IL-12/IL-23 p40 Kit
Kit Catalog Numbers: K156RJD-1, K156RJD-2, K156RJD-4, K156RJD-1, K156RJD-2, K156RJD-4
Kit Lot Number: K0080617
Expiration Date: 30 Apr 2018

Acceptance Data/ Percent Recovery Specifications:

Spot	Name	Calibrator		Cytokine Panel 1 (human) Control 1		Cytokine Panel 1 (human) Control 2		Cytokine Panel 1 (human) Control 3	
		Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	NHP IL-12/23p40	80% - 120%	< 20%	90% - 130%	< 20%	90% - 130%	< 20%	90% - 130%	< 20%

Spot	Name	LLOQ			ULOQ		
		Value	Recovery	CV	Value	Recovery	CV
1	NHP IL-12/23p40	5.68	80% - 120%	< 20%	2250	80% - 120%	< 20%

Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	NHP IL-12/23p40	Calibrator	3180	pg/mL
		Cytokine Panel 1 (human) Control 1	1290	pg/mL
		Cytokine Panel 1 (human) Control 2	208	pg/mL
		Cytokine Panel 1 (human) Control 3	37.6	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.

CERTIFICATE OF ANALYSIS

COA-07767

Standard Curve Data:

NHP IL-12/23p40 - Spot 1		
Conc. pg/mL	ECL Signal	%CV
3180	249,000	2.0
795	65,700	2.1
199	16,600	1.6
49.7	4,090	3.0
12.4	1,070	3.4
3.11	321	3.9
0.776	127	4.6
0.00	67	5.4


Components:

Description	Lot Number	Storage Temperature	Expiration Date
Human IL-12/IL-23 p40 Plate	Z0046206	2-8°C	28 Feb 2019
Anti-hu IL-12/23p40	D0080656	2-8°C	30 Apr 2018
Cytokine Panel 1 (human) Calibrator Blend	A0080063	2-8°C	31 Jul 2020
Diluent 43	M0430017	≤ -10°C	31 Dec 2018
Diluent 3	M0030070	≤ -10°C	31 Jul 2018
MSD Read Buffer T (4x)	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
Cytokine Panel 1 (human) Control 1	Not Kit Specific
Cytokine Panel 1 (human) Control 2	Not Kit Specific
Cytokine Panel 1 (human) Control 3	Not Kit Specific

Statement:

The above kit was tested using MSD procedures and it conforms to MSD's specifications. 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		16 JAN 2017