



RFE MEMO

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Product Description(s): V-PLEX® and V-PLEX Plus NHP IL-16 Kit
Catalog Number(s) / Size(s): K156RE-Series
Lot Number: K0080885

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0080885 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
Human IL-16 Plate	Z0046635	28 Feb 2020	31 Jul 2020
Anti-hu IL-16 Antibody	D0080891	31 Jul 2019	31 Jul 2020
Diluent 43	M0430021	30 Sep 2019	31 Jul 2020
Diluent 3	M0030077	30 Nov 2019	31 Jul 2020

Function	Name	Signature	Date
Quality	Karen Hamilla		06 JUN 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 IL-16 Kit
Kit Catalog Numbers: K156QX-Series
Kit Lot Number: K0080885
Expiration Date: 31 Jul 2019

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-16	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%

Spot	Name	LLOQ			ULOQ		
		Value	Recovery	CV	Value	Recovery	CV
1	NHP IL-16	19.1	80% - 120%	< 20%	1870	80% - 120%	< 20%

Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	NHP IL-16	Calibrator	2450	pg/ml
		Cytokine Panel 1 (Human) Control 1	1160	pg/ml
		Cytokine Panel 1 (Human) Control 2	328	pg/ml
		Cytokine Panel 1 (Human) Control 3	126	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 IL-16 - Spot 1		
Conc. pg/ml	ECL Signal	%CV
2450	405,000	2.6
613	86,600	3.8
153	17,300	4.4
38.3	3,890	4.7
9.57	1,090	4.4
2.39	322	2.2
0.598	135	3.5
0.00	73	5.1

CERTIFICATE OF ANALYSIS

Components:


Description	Lot Number	Storage Temperature	Expiration Date
Human IL-16 Plate	Z0046635	2-8°C	28 Feb 2020
Anti-hu IL-16 Antibody	D0080891	2-8°C	31 Jul 2019
Cytokine Panel 1 (human) Calibrator Blend	A0080063	2-8°C	31 Jul 2020
Diluent 43	M0430021	≤ -10°C	30 Sep 2019
Diluent 3	M0030077	≤ -10°C	30 Nov 2019
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
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 product is intended for Research Use Only. Not for use in Diagnostic Procedures.

	Name	Function	Signature	Date
Review/Approval	Dawn Stollar	Quality Assurance		09 OCT 2017