



RFE MEMO

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Product Description(s): V-PLEX® and V-PLEX Plus NHP IP-10 Kit

Catalog Number(s) / Size(s): K156NV-Series

Lot Number: K0081018

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0081018 has been extended to 31 Dec 2020.

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

Description	Lot Number	Original Expiration Date	New Expiration Date
Human IP-10 Plate	Z0046839	30 NOV 2020	31 DEC 2020
Anti-hu IP-10 Antibody	D0080994	31 DEC 2019	31 DEC 2020
Diluent 43	M0430026	31 AUG 2020	31 DEC 2020
Diluent 3	M0030082	31 OCT 2020	31 DEC 2020

Function	Name	Signature	Date
Quality	Karen Hamilla		18 OCT 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 IP-10 Kit
Kit Catalog Numbers: K156NV-Series
Kit Lot Number: K0081018
Expiration Date: 31 Dec 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 IP-10	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%

Spot	Name	LLOQ			ULOQ		
		Value	Recovery	CV	Value	Recovery	CV
1	NHP IP-10	1.37	80% - 120%	< 20%	500	80% - 120%	< 20%

Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	NHP IP-10	Calibrator	2090	pg/mL
		Chemokine Panel 1 (human) Control 1	601	pg/mL
		Chemokine Panel 1 (human) Control 2	92.1	pg/mL
		Chemokine Panel 1 (human) Control 3	15.5	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 IP-10 - Spot 1		
Conc. pg/mL	ECL Signal	%CV
2090	418,000	2.2
523	126,000	1.9
131	32,400	3.6
32.7	8,360	2.8
8.16	2,130	3.4
2.04	600	2.4
0.510	189	2.1
0.00	66	5.4

CERTIFICATE OF ANALYSIS


Components:

Description	Lot Number	Storage Temperature	Expiration Date
Human IP-10 Plate	Z0046839	2-8°C	30 Nov 2020
Anti-hu IP-10 Antibody	D0080994	2-8°C	31 Dec 2019
Chemokine Panel 1 (human) Calibrator Blend	A0080171	2-8°C	30 Jun 2023
Diluent 43	M0430026	≤ -10°C	31 Aug 2020
Diluent 3	M0030082	≤ -10°C	31 Oct 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), 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		10 SEP 2018