



RFE MEMO

Page 1 of 1

Product Description(s): V-PLEX[®] and V-PLEX Plus Human MDC Kit

Catalog Number(s) / Size(s): K151NP-Series

Lot Number: K0080996

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0080996 has been extended to 30 JUN 2020.

The expiration date for the following kit component has been extended:

Description	Lot Number	Original Expiration Date	New Expiration Date
Anti-hu MDC Antibody	D0080866	30 JUN 2019	30 JUN 2020
Diluent 43	M0430024	31 JAN 2020	30 JUN 2020

Function	Name	Signature	Date
Quality	Karen Hamilla		03 SEP 2019

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

CERTIFICATE OF ANALYSIS

Page 1 of 2

Product Description: V-PLEX® and V-PLEX Plus Human MDC Kit
Kit Catalog Numbers: K151NP-Series
Kit Lot Number: K0080996
Expiration Date: 30 Jun 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	hu MDC	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%

Spot	Name	LLOQ			ULOQ		
		Value	Recovery	CV	Value	Recovery	CV
1	hu MDC	88.3	80% - 120%	< 20%	7500	80% - 120%	< 20%

Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	hu MDC	Calibrator	11600	pg/mL
		Chemokine Panel 1 (human) Control 1	9420	pg/mL
		Chemokine Panel 1 (human) Control 2	2770	pg/mL
		Chemokine Panel 1 (human) Control 3	878	pg/mL

Controls tested may not be the same lot as shipped.

Standard Curve Data:

hu MDC - Spot 1		
Conc. pg/mL	ECL Signal	%CV
11600	740,000	3.8
2900	103,000	3.3
725	16,200	3.5
181	3,320	2.5
45.3	863	2.1
11.3	257	3.5
2.83	116	3.2
0.00	64	3.8

CERTIFICATE OF ANALYSIS

Page 2 of 2

Components:

Description	Lot Number	Storage Temperature	Expiration Date
Human MDC Plate	Z0046803	2-8°C	30 Sep 2020
Anti-hu MDC Antibody	D0080866	2-8°C	30 Jun 2019
Chemokine Panel 1 (human) Calibrator Blend	A0080159	2-8°C	31 Dec 2022
Diluent 43	M0430024	≤ -10°C	31 Jan 2020
Diluent 3	M0030081	≤ -10°C	30 Sep 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	<i>Dawn Stollar</i>	23 MAY 2018