



**RFE MEMO**

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**Product Description(s):** V-PLEX® and V-PLEX Plus Human GM-CSF Kit

**Catalog Number(s) / Size(s):** K151RI-Series; K156RI-Series

**Lot Number:** K0081118

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0081118 has been extended to 31 JAN 2021.

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

Description	Lot Number	Original Expiration Date	New Expiration Date
Human GM-CSF Plate	Z0046679	30 APR 2020	31 JAN 2021
Anti-hu GM-CSF Antibody	D0081052	30 APR 2020	31 JAN 2021
Diluent 43	M0430024	31 JAN 2020	31 JAN 2021
Diluent 3	M0030078	31 JAN 2020	31 JAN 2021

Function	Name	Signature	Date
Quality	Karen Hamilla		13 DEC 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 Human GM-CSF Kit  
**Kit Catalog Numbers:** K151RI-Series; K156RI-Series  
**Kit Lot Number:** K0081118  
**Expiration Date:** 31 Jan 2020

**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	GM-CSF	80% - 120%	< 20%	90% - 130%	< 20%	90% - 130%	< 20%	90% - 130%	< 20%

Spot	Name	LLOQ			ULOQ		
		Value	Recovery	CV	Value	Recovery	CV
1	GM-CSF	0.842	80% - 120%	< 20%	750	80% - 120%	< 20%

**Stock Concentration of Material Tested :**

Spot	Name	Item	Conc	Units
1	GM-CSF	Calibrator	1100	pg/mL
		Cytokine Panel 1 (human) Control 1	394	pg/mL
		Cytokine Panel 1 (human) Control 2	61.7	pg/mL
		Cytokine Panel 1 (human) Control 3	8.11	pg/mL

Controls tested may not be the same lot as shipped.

**Standard Curve Data:**

GM-CSF - Spot 1		
Conc. pg/mL	ECL Signal	%CV
1100	215,000	1.4
275	57,400	1.6
68.8	14,900	1.9
17.2	3,770	2.3
4.30	1,000	1.7
1.07	288	2.0
0.269	108	3.3
0.00	49	5.2

**CERTIFICATE OF ANALYSIS**

**Components:**


Description	Lot Number	Storage Temperature	Expiration Date
Human GM-CSF Plate	Z0046679	2-8°C	30 Apr 2020
Anti-hu GM-CSF Antibody	D0081052	2-8°C	30 Apr 2020
Cytokine Panel 1 (human) Calibrator Blend	A0080121	2-8°C	28 Feb 2022
Diluent 43	M0430024	≤ -10°C	31 Jan 2020
Diluent 3	M0030078	≤ -10°C	31 Jan 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 (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
<b>Review/Approval</b>	Karen Hamilla	Quality		13 DEC 2019