



RFE MEMO

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

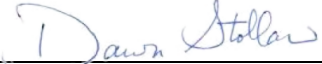
Catalog Number(s) / Size(s): K151QW-Series

Lot Number: K0080956

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0080956 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
Anti-hu TNF- α Antibody	D0080923	31 JUL 2019	31 JUL 2020
Diluent 2	M0020098	28 FEB 2020	31 JUL 2020
Diluent 3	M0030076	30 SEP 2019	31 JUL 2020

Function	Name	Signature	Date
Quality	Dawn Stollar		23 APR 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 TNF- α Kit
Kit Catalog Numbers: K151QW-Series
Kit Lot Number: K0080956
Expiration Date: 31 Jul 2019

Acceptance Data/ Percent Recovery Specifications:

Spot	Name	Calibrator		Proinflammatory Panel 1(human) Control 1		Proinflammatory Panel 1(human) Control 2		Proinflammatory Panel 1(human) Control 3	
		Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	hu TNF- α	80% - 120%	< 20%	90% - 130%	< 20%	90% - 130%	< 20%	90% - 130%	< 20%

Spot	Name	LLOQ			ULOQ		
		Value	Recovery	CV	Value	Recovery	CV
1	hu TNF- α	0.690	80% - 120%	< 20%	248	80% - 120%	< 20%

Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	hu TNF- α	Calibrator	378	pg/mL
		Proinflammatory Panel 1(human) Control 1	86.7	pg/mL
		Proinflammatory Panel 1(human) Control 2	16	pg/mL
		Proinflammatory Panel 1(human) Control 3	2.06	pg/mL

Controls tested may not be the same lot as shipped.

Standard Curve Data:

hu TNF- α - Spot 1		
Conc. pg/mL	ECL Signal	%CV
378	183,000	1.6
94.5	44,000	3.6
23.6	11,100	2.1
5.91	2,780	1.3
1.48	763	2.1
0.369	241	2.7
0.0923	110	3.7
0.00	70	5.1

CERTIFICATE OF ANALYSIS

Components:

Description	Lot Number	Storage Temperature	Expiration Date
Human TNF- α Plate	Z0046758	2-8°C	31 Jul 2020
Anti-hu TNF- α Antibody	D0080923	2-8°C	31 Jul 2019
ProInflammatory Panel 1 (human) Calibrator Blend	A0080153	2-8°C	31 Oct 2022
Diluent 2	M0020098	\leq -10°C	28 Feb 2020
Diluent 3	M0030076	\leq -10°C	30 Sep 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
Proinflammatory Panel 1(human) Control 1	Not Kit Specific
Proinflammatory Panel 1(human) Control 2	Not Kit Specific
Proinflammatory 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>	24 MAY 2018