



RFE MEMO

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

Catalog Number(s) / Size(s): K153QW-Series

Lot Number: K0081069

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0081069 has been extended to 30 SEP 2020.

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

Description	Lot Number	Original Expiration Date	New Expiration Date
Anti-rat TNF- α Antibody	D0081033	29 FEB 2020	30 SEP 2020
Blocker H	R0100015	30 SEP 2019	30 SEP 2020
Diluent 40	M0400011	31 AUG 2020	30 SEP 2020
Diluent 42	M0420010	31 JUL 2020	30 SEP 2020

Function	Name	Signature	Date
Quality	Karen Hamilla		05 AUG 2019

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

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Product Description: V-PLEX® and V-PLEX Plus Rat TNF- α Kit
Kit Catalog Numbers: K153QW-Series
Kit Lot Number: K0081069
Expiration Date: 30 Sep 2019

Acceptance Data/ Percent Recovery Specifications:

Spot	Name	Calibrator		Proinflammatory Panel 1 (rat) Control 1		Proinflammatory Panel 1 (rat) Control 2		Proinflammatory Panel 1 (rat) Control 3	
		Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	rt TNF- α	80% - 120%	< 20%	75% - 125%	< 25%	75% - 125%	< 25%	75% - 125%	< 25%

Spot	Name	LLOQ			ULOQ		
		Value	Recovery	CV	Value	Recovery	CV
1	rt TNF- α	9.10	75% - 125%	< 25%	793	75% - 125%	< 25%

Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	rt TNF- α	Calibrator	1360	pg/mL
		Proinflammatory Panel 1 (rat) Control 1	868	pg/mL
		Proinflammatory Panel 1 (rat) Control 2	266	pg/mL
		Proinflammatory Panel 1 (rat) Control 3	87.7	pg/mL

Controls tested may not be the same lot as shipped.

Standard Curve Data:

rt TNF- α - Spot 1		
Conc. pg/mL	ECL Signal	%CV
1360	338,000	1.6
340	66,200	2.4
85.0	14,900	2.4
21.3	3,590	2.5
5.31	1,020	1.7
1.33	329	2.8
0.332	160	3.6
0.00	101	4.8

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Components:

Description	Lot Number	Storage Temperature	Expiration Date
Rat TNF- α Plate	Z0046890	2-8°C	31 Jan 2021
Anti-rat TNF- α Antibody	D0081033	2-8°C	29 Feb 2020
Proinflammatory Panel 1 (rat) Calibrator Blend	A0080124	2-8°C	31 Mar 2022
Blocker H	R0100015	Room Temperature	30 Sep 2019
Diluent 42	M0420010	$\leq -10^{\circ}\text{C}$	31 Jul 2020
Diluent 40	M0400011	$\leq -10^{\circ}\text{C}$	31 Aug 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
Proinflammatory Panel 1 (rat) Control 1	Not Kit Specific
Proinflammatory Panel 1 (rat) Control 2	Not Kit Specific
Proinflammatory Panel 1 (rat) 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		02 NOV 2018