



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: K0081399

Based on additional testing, the original date of expiration for this kit has been extended by 24 months. The expiration date of K0081399 has been extended to 31 JAN 2023.

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

Description	Lot Number	Original Expiration Date	New Expiration Date
Human TNF- α Plate	Z0046930	31 MAR 2021	31 JAN 2023
Anti-hu TNF- α Antibody	D0081228	31 MAY 2022	31 JAN 2023
Diluent 2	M0020102	28 FEB 2021	31 JAN 2023
Diluent 3	M0030084	31 JAN 2021	31 JAN 2023

Function	Name	Signature	Date
Quality	Karen Hamilla		04 APR 2022

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: K0081399

Expiration Date: 31 Jan 2021

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	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	TNF- α	0.690	80% - 120%	< 20%	248	80% - 120%	< 20%

Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	TNF- α	Calibrator	369	pg/mL
		Proinflammatory Panel 1 (human) Control 1	113	pg/mL
		Proinflammatory Panel 1 (human) Control 2	17.3	pg/mL
		Proinflammatory Panel 1 (human) Control 3	2.61	pg/mL

Controls tested may not be the same lot as shipped.

Standard Curve Data:

TNF- α - Spot 1		
Conc. pg/mL	ECL Signal	%CV
369	159,000	1.7
92.3	40,600	2.8
23.1	10,100	2.2
5.77	2,600	2.6
1.44	690	2.4
0.360	221	2.7
0.0901	100	4.7
0.00	63	6.6

CERTIFICATE OF ANALYSIS

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Components:

Description	Lot Number	Storage Temperature	Expiration Date
Human TNF- α Plate	Z0046930	2-8°C	31 Mar 2021
Anti-hu TNF- α Antibody	D0081228	2-8°C	31 May 2022
Proinflammatory Panel 1 (human) Calibrator Blend	A0080178	2-8°C	31 Aug 2023
Diluent 2	M0020102	\leq -10°C	28 Feb 2021
Diluent 3	M0030084	\leq -10°C	31 Jan 2021
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	Karen Hamilla	Quality		02 MAR 2020