

RFE MEMO

Page 1 of 1

Product Description(s): V-PLEX® and V-PLEX Plus Human IL-17A Kit **Catalog Number(s) / Size(s):** K151RF-Series **Lot Number:** K0081109

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0081109 has been extended to 31 Oct 2020.

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

Description	Lot Number	Original Expiration Date	New Expiration Date
Anti-hu IL-17A Antibody	D0080984	31 Oct 2019	31 OCT 2020

Function	Name	Signature	Date
Quality	Karen Hamilla	Haven Hamille	30 JUL 2019

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

Meso Scale Diagnostics, LLC. CERTIFICATE OF ANALYSIS

Page 1 of 2

Product Description:	V-PLEX® and V-PLEX Plus Human IL-17A Kit
Kit Catalog Numbers:	K151RF-Series
Kit Lot Number:	K0081109
Expiration Date:	31 Oct 2019

Acceptance Data/ Percent Recovery Specifications:

		Calibrator		Cytokine Panel 1 (human) Control 1				Cytokine Panel 1 (human) Control 3	
Spot	Name	Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	hu IL-17A	80% - 120%	< 20%	90% - 130%	< 20%	90% - 130%	< 20%	90% - 130%	< 20%

		LLOQ				ULOQ	
Spot	Name	Value	Recovery	CV	Value	Recovery	CV
1	hu IL-17A	3.19	80% - 120%	< 20%	3650	80% - 120%	< 20%

Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
	1 hu IL-17A	Calibrator	6240	pg/mL
1		Cytokine Panel 1 (human) Control 1	2020	pg/mL
1		Cytokine Panel 1 (human) Control 2	277	pg/mL
		Cytokine Panel 1 (human) Control 3	42.9	pg/mL

Controls tested may not be the same lot as shipped.

Standard Curve Data:

hu IL-17A - Spot 1				
Conc. pg/mL	ECL Signal	%CV		
6240	687,000	2.7		
1560	178,000	4.2		
390	43,400	4.0		
97.5	10,800	4.5		
24.4	2,780	2.9		
6.09	755	6.1		
1.52	230	4.4		
0.00	67	6.8		

Meso Scale Diagnostics, LLC.

CERTIFICATE OF ANALYSIS

Page 2 of 2

Components:

Description	Lot Number	Storage Temperature	Expiration Date
Human IL-17A Plate	Z0046940	2-8°C	31 Mar 2021
Anti-hu IL-17A Antibody	D0080984	2-8°C	31 Oct 2019
Cytokine Panel 1 (human) Calibrator Blend	A0080170	2-8°C	30 Jun 2023
Diluent 43	M0430028	\leq -10°C	31 Jan 2021
Diluent 3	M0030085	\leq -10°C	28 Feb 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
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
Review/Approval	Dawn Stollar	Quality Assurance	Dawn Stollar	19 MAR 2019