



RFE MEMO

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Product Description(s): V-PLEX® and V-PLEX Plus Human IL-17A Gen. B Kit

Catalog Number(s) / Size(s): K151WM-Series

Lot Number: K0081112

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0081112 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
Human IL-17A Gen. B Plate	Z0046395	31 JUL 2019	31 JUL 2020

Function	Name	Signature	Date
Quality	Dawn Stollar		08 JUN 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 IL-17A Gen. B Kit
Kit Catalog Numbers: K151WM-Series
Kit Lot Number: K0081112
Expiration Date: 31 Jul 2019

Acceptance Data/ Percent Recovery Specifications:

Spot	Name	Calibrator		TH17 Panel 1 (human) Control 1		TH17 Panel 1 (human) Control 2		TH17 Panel 1 (human) Control 3	
		Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	hu IL-17A	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%

Spot	Name	LLOQ			ULOQ		
		Value	Recovery	CV	Value	Recovery	CV
1	hu IL-17A	5.86	80% - 120%	< 20%	1950	80% - 120%	< 20%

Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	hu IL-17A	Calibrator	2730	pg/mL
		TH17 Panel 1 (human) Control 1	2690	pg/mL
		TH17 Panel 1 (human) Control 2	429	pg/mL
		TH17 Panel 1 (human) Control 3	61.4	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
2730	161,000	4.9
683	37,200	2.4
171	8,990	2.9
42.7	2,340	2.7
10.7	618	3.2
2.67	217	2.1
0.667	113	4.7
0.00	83	4.8

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Components:

Description	Lot Number	Storage Temperature	Expiration Date
Human IL-17A Gen. B Plate	Z0046395	2-8°C	31 Jul 2019
Anti-hu IL-17A Antibody	D0081135	2-8°C	30 Apr 2022
TH17 Panel 1 (human) Calibrator Blend	A0080101	2-8°C	30 Sep 2021
Diluent 43	M0430028	≤ -10°C	31 Jan 2021
Diluent 3	M0030085	≤ -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
TH17 Panel 1 (human) Control 1	Not Kit Specific
TH17 Panel 1 (human) Control 2	Not Kit Specific
TH17 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>	05 DEC 2018