



RFE MEMO

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Product Description(s): V-PLEX® and V-PLEX Plus Human IL-27 Kit

Catalog Number(s) / Size(s): K151WX-Series

Lot Number: K0081052

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0081052 has been extended to 28 Feb 2020.

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

Description	Lot Number	Original Expiration Date	New Expiration Date
Human IL-27 Plate	Z0046180	28 Feb 2019	28 Feb 2020
Anti-hu IL-27 Antibody	D0080896	31 Jul 2019	28 Feb 2020
Diluent 43	M0430021	30 Sep 2019	28 Feb 2020
Diluent 3	M0030076	30 Sep 2019	28 Feb 2020

Function	Name	Signature	Date
Quality Assurance	Dawn Stollar	<i>Dawn Stollar</i>	14 DEC 2018

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-27 Kit
Kit Catalog Numbers: K151WX-Series
Kit Lot Number: K0081052
Expiration Date: 28 Feb 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-27	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-27	38.7	80% - 120%	< 20%	13000	80% - 120%	< 20%

Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	hu IL-27	Calibrator	17100	pg/mL
		TH17 Panel 1 (human) Control 1	21400	pg/mL
		TH17 Panel 1 (human) Control 2	4190	pg/mL
		TH17 Panel 1 (human) Control 3	952	pg/mL

Controls tested may not be the same lot as shipped.

Standard Curve Data:

hu IL-27 - Spot 1		
Conc. pg/mL	ECL Signal	%CV
17100	126,000	5.7
4280	26,600	3.4
1070	6,320	3.7
267	1,600	4.0
66.8	481	2.5
16.7	181	2.7
4.17	104	2.8
0.00	81	3.8

CERTIFICATE OF ANALYSIS

Components:

Description	Lot Number	Storage Temperature	Expiration Date
Human IL-27 Plate	Z0046180	2-8°C	28 Feb 2019
Anti-hu IL-27 Antibody	D0080896	2-8°C	31 Jul 2019
TH17 Panel 1 (human) Calibrator Blend	A0080101	2-8°C	30 Sep 2021
Diluent 43	M0430021	≤ -10°C	30 Sep 2019
Diluent 3	M0030076	≤ -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
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>	15 AUG 2018