

RFE MEMO

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Product Description(s): V-PLEX® AND V-PLEX Plus Human IL-1RA Kit

Catalog Number(s) / Size(s): K151WT-Series

Lot Number: K0081012

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0081012 has been extended to 30 APR 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-1RA	D0080771	30 APR 2019	30 APR 2020
Diluent 43	M0430021	30 SEP 2019	30 APR 2020
Diluent 3	M0030077	30 NOV 2019	30 APR 2020

Function	Name	Signature	Date	
Quality Assurance	Dawn Stollar	Dawn Stollar	12 FEB 2019	

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

Memo Rev. A CM-00289-B

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Product Description: V-PLEX® and V-PLEX Plus Human IL-1RA Kit

Kit Catalog Numbers: K151WT- Series

Kit Lot Number: K0081012 **Expiration Date**: 30 Apr 2019

Acceptance Data/ Percent Recovery Specifications:

		Calibrator		Cytokine Panel 2 (human) Control 1		Cytokine Panel 2 (human) Control 2		Cytokine Panel 2 (human) Control 3	
Spot	Name	Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	Human IL-1RA	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%

	LLOQ			LLOQ			
Spot	Name	Value	Recovery	CV	Value	Recovery	CV
1	Human IL-1RA	9.19	75% - 125%	< 25%	650	80% - 120%	< 20%

Stock Concentration of Material Tested:

Spot	Name	Item	Conc	Units
1 Human IL-1RA	Calibrator	732	pg/mL	
	Cytokine Panel 2 (human) Control 1	670	pg/mL	
	Hullian IL-1KA	Cytokine Panel 2 (human) Control 2	143	pg/mL
		Cytokine Panel 2 (human) Control 3	50	pg/mL

Controls tested may not be the same lot as shipped.

Standard Curve Data:

Human IL-1RA - Spot 1				
Conc. pg/mL	ECL Signal	%CV		
732	226,000	4.3		
183	41,000	2.0		
45.8	8,050	3.1		
11.4	1,900	3.1		
2.86	653	5.0		
0.715	330	11.0		
0.179	290	20.0		
0.00	302	51.0		



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Components:

Description	Lot Number	Storage Temperature	Expiration Date
Human IL-1RA Plate	Z0046826	2-8°C	31 Oct 2020
Anti-hu IL-1RA	D0080771	2-8°C	30 Apr 2019
Cytokine Panel 2 (human) Calibrator Blend	A0080126	2-8°C	31 Mar 2022
Diluent 43	M0430021	≤ -10°C	30 Sep 2019
Diluent 3	M0030077	≤ -10°C	30 Nov 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), 100 mL	Not Kit Specific			
Cytokine Panel 2 (human) Control 1	Not Kit Specific			
Cytokine Panel 2 (human) Control 2	Not Kit Specific			
Cytokine Panel 2 (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	21 JUN 2018