

RFE MEMO

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Product Description(s): V-PLEX® and V-Plex Plus Human IL-23 Kit

Catalog Number(s) / Size(s): K151WW- Series

Lot Number: K0081139

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0081139 has been extended to 28 FEB 2022.

The expiration date for the following kit component has been extended:

Description	Lot Number	Original Expiration Date	New Expiration Date
Human IL-23 Plate	Z0046966	30 APR 2021	28 FEB 2022
TH17 Panel 1 (human) Calibrator Blend	A0080119	31 JAN 2022	28 FEB 2022
Diluent 3	M0030085	28 FEB 2021	28 FEB 2022
Diluent 43	M0430029	30 APR 2021	28 FEB 2022

Function	Name	Signature	Date
Quality	Karen Hamilla	Laur Hamille	03 JUN 2021

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

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Product Description: V-PLEX® and V-Plex Plus Human IL-23 Kit

Kit Catalog Numbers: K151WW-Series

Kit Lot Number: K0081139 **Expiration Date**: 28 Feb 2021

Acceptance Data/ Percent Recovery Specifications:

		Calibrator		TH17 Panel 1 (human) Control 1		TH17 Panel 1 (human) Control 2		TH17 Panel 1 (human) Control 3	
Spot	Name	Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	hu IL-23	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%

		LLOQ			ULOQ		
Spot	Name	Value	Recovery	CV	Value	Recovery	CV
1	hu IL-23	4.60	80% - 120%	< 20%	3250	80% - 120%	< 20%

Stock Concentration of Material Tested:

Spot	Name	Item	Conc	Units
1 hu IL-23	Calibrator	4600	pg/mL	
	TH17 Panel 1 (human) Control 1	4190	pg/mL	
	TH17 Panel 1 (human) Control 2	487	pg/mL	
		TH17 Panel 1 (human) Control 3	58.2	pg/mL

Controls tested may not be the same lot as shipped.

Standard Curve Data:

hu IL-23 - Spot 1				
Conc. pg/mL	ECL Signal	%CV		
4600	206,000	2.5		
1150	56,900	2.8		
288	15,000	2.8		
71.9	3,650	3.4		
18.0	990	2.0		
4.49	296	2.2		
1.12	131	3.9		
0.00	77	4.6		

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Components:

Description	Lot Number	Storage Temperature	Expiration Date
Human IL-23 Plate	Z0046966	2-8°C	30 Apr 2021
Anti-hu IL-23 Antibody	D0081138	2-8°C	31 Mar 2022
TH17 Panel 1 (human) Calibrator Blend	A0080119	2-8°C	31 Jan 2022
Diluent 43	M0430029	≤ -10°C	30 Apr 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), 100 mL	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	Dawn Stollar	09 JAN 2019