



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: K0081352

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0081352 has been extended to 28 FEB 2022.

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

Description	Lot Number	Original Expiration Date	New Expiration Date
Diluent 43	M0430029	30 APR 2021	28 FEB 2022
Diluent 3	M0030085	28 FEB 2021	28 FEB 2022

Function	Name	Signature	Date
Quality	Karen Hamilla		01 FEB 2021

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-23 Kit

Kit Catalog Numbers: K151WW-Series

Kit Lot Number: K0081352

Expiration Date: 28 Feb 2021

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	IL-23	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%

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

Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	IL-23	Calibrator	5730	pg/mL
		TH17 Panel 1 (human) Control 1	5730	pg/mL
		TH17 Panel 1 (human) Control 2	632	pg/mL
		TH17 Panel 1 (human) Control 3	71	pg/mL

Controls tested may not be the same lot as shipped.

Standard Curve Data:

IL-23 - Spot 1		
Conc. pg/mL	ECL Signal	%CV
5730	200,000	5.3
1430	52,600	3.3
358	12,500	5.0
89.5	3,230	4.9
22.4	841	3.9
5.60	277	3.6
1.40	137	5.5
0.00	93	3.6

CERTIFICATE OF ANALYSIS

Components:


Description	Lot Number	Storage Temperature	Expiration Date
Human IL-23 Plate	Z0047205	2-8°C	31 Mar 2022
Anti-hu IL-23 Antibody	D0081138	2-8°C	31 Mar 2022
TH17 Panel 1 (human) Calibrator Blend	A0080232	2-8°C	31 Oct 2024
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), 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	Karen Hamilla	Quality		20 FEB 2020