



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: K0081612

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0081612 has been extended to 30 APR 2023.

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

Description	Lot Number	Original Expiration Date	New Expiration Date
Anti-hu IL-17A Antibody	D0081135	30 APR 2022	30 APR 2023
Diluent 3	M0030101	31 DEC 2022	30 APR 2023

Function	Name	Signature	Date
Quality	Karen Hamilla		03 JUN 2022

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 Lot Number: K0081612
Expiration Date: 30 Apr 2022
Kit Catalog Numbers: K151WM-Series

Precision and Accuracy 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-17A Gen.B	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%

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

Stock Concentration of Calibrator:


Spot	Name	Conc.	Units
1	IL-17A Gen.B	2640	pg/mL

Lot-Specific Components:

Description	Lot Number	Storage Temperature	Expiration Date
Human IL-17 A Gen B Sector Plate	Z0047437	2-8°C	31 May 2023
Anti-hu IL-17A Antibody	D0081135	2-8°C	30 Apr 2022
TH17 Panel 1 (Human) Calibrator Blend	A0080219	2-8°C	30 Apr 2024
Diluent 43	M0430042	≤ -10°C	30 Apr 2023
Diluent 3	M0030101	≤ -10°C	31 Dec 2022

Additional components may be provided to execute the assay. Additional components are not lot-specific.

The above product is intended for Research Use Only. Not for use in Diagnostic Procedures.

	Name	Function	Signature	Date
Review/Approval	Karen Hamilla	Quality		06 JAN 2021