

RFE MEMO

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Product Description(s): V-Plex® and V-Plex Plus Human IL-9 Kit

Catalog Number(s) / Size(s): K151XC-Series

Lot Number: K0080684

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0080684 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
Human IL-9 Plate	Z0046331	30 JUN 2019	30 APR 2020
Anti-hu IL-9 Antibody	D0080773	30 APR 2019	30 APR 2020
Diluent 43	M0430020	30 JUN 2019	30 APR 2020
Diluent 3	M0030074	30 JUN 2019	30 APR 2020

Function	Name	Signature	Date
Quality	Karen Hamilla	Harr Hamille	03 JUN 2019

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

Memo Rev. A CM-00289-B

CERTIFICATE OF ANALYSIS

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Product Description: V-PLEX® and V-PLEX Plus Human IL-9 Kit

Kit Catalog Numbers: K151XC-Series

Kit Lot Number: K0080684

Expiration Date: 30 Apr 2019

Acceptance Data/ Percent Recovery Specifications:

		Calibrator		V-Plex Cytokine Panel 2 (hu) Control 1		V-Plex Cytokine Panel 2 (hu) Control 2		V-Plex Cytokine Panel 2 (hu) Control 3	
Spot	Name	Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	hu IL-9	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-9	2.23	80% - 120%	< 25%	975	80% - 120%	< 20%

Stock Concentration of Material Tested:

Spot	Name	Item	Conc	Units
	Calibrator	1440	pg/ml	
1	1 1 1 1 1	Cytokine Panel 2 (human) Control 1	665	pg/ml
1 hu IL-9	Cytokine Panel 2 (human) Control 2	170	pg/ml	
		Cytokine Panel 2 (human) Control 3	39.1	pg/ml

Controls tested may not be the same lot as shipped.

Standard Curve Data:

hu IL-9 - Spot 1				
Conc. pg/ml	ECL Signal	%CV		
1440	368,000	3.9		
360	90,800	2.7		
90.0	22,100	2.3		
22.5	5,490	4.9		
5.63	1,370	3.2		
1.41	397	2.2		
0.352	151	3.3		
0.00	73	4.4		

CERTIFICATE OF ANALYSIS

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Components:

Description	Lot Number	Storage Temperature	Expiration Date
Human IL-9 Plate	Z0046331	2-8°C	30 Jun 2019
Anti-hu IL-9 Antibody	D0080773	2-8°C	30 Apr 2019
Cytokine Panel 2 (human) Calibrator Blend	A0080116	2-8°C	31 Jan 2022
Diluent 43	M0430020	≤ -10°C	30 Jun 2019
Diluent 3	M0030074	≤ -10°C	30 Jun 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/Approva	Dawn Stollar	Quality Assurance	Dawn Stollar	21 JUL 2017