

RFE MEMO

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Product Description(s): V-PLEX® and V-PLEX Plus Human TSLP Kit

Catalog Number(s) / Size(s): K151XE-Series

Lot Number: K0080690

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0080690 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 TSLP Plate	Z0046344	30 JUN 2019	30 APR 2020
Anti-hu TSLP Antibody	D0080775	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 Assurance	Dawn Stollar	Dawn Stollar	28 MAR 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 TSLP Kit

Kit Catalog Numbers: K151XE-Series

Kit Lot Number: K0080690

Expiration Date: 30 Apr 2019

Acceptance Data/ Percent Recovery Specifications:

		Calibrator		V-Plex Cytokine Panel 2 (hu) Control 1		hu) 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 TSLP	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%

		LLOQ				ULOQ	
Spot	Name	Value	Recovery	CV	Value	Recovery	CV
1	hu TSLP	0.460	75% - 125%	< 20%	325	75% - 125%	< 20%

Stock Concentration of Material Tested:

Spot	Name	Item	Conc	Units
1 hu TSLP	Calibrator	515	pg/ml	
	Cytokine Panel 2 (human) Control 1	229	pg/ml	
	Cytokine Panel 2 (human) Control 2	32.8	pg/ml	
	Cytokine Panel 2 (human) Control 3	5.01	pg/ml	

Controls tested may not be the same lot as shipped.

Standard Curve Data:

hu TSLP - Spot 1				
Conc. pg/ml	ECL Signal	%CV		
515	255,000	1.7		
129	65,200	1.8		
32.2	16,100	2.4		
8.05	3,850	2.2		
2.01	1,020	1.6		
0.503	313	2.8		
0.126	129	3.2		
0.00	64	4.4		

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Components:

Description	Lot Number	Storage Temperature	Expiration Date
Human TSLP Plate	Z0046344	2-8°C	30 Jun 2019
Anti-hu TSLP Antibody	D0080775	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)	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 JUL 2017