

RFE MEMO

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Product Description(s): V-PLEX® and V-PLEX Plus Mouse IL-17F

Catalog Number(s) / Size(s): K152WS-Series

Lot Number: K0081252

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0081252 has been extended to 30 SEP 2020.

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

Description	Lot Number	Original Expiration Date	New Expiration Date
Mouse IL-17F Plate	Z0046472	30 SEP 2019	30 SEP 2020
Diluent 41	M0410018	30 NOV 2019	30 SEP 2020
Diluent 45	M0450019	31 DEC 2019	30 SEP 2020
Anti-ms IL-17F Antibody	D0080955	31 OCT 2019	30 SEP 2020

Function	Name	Signature	Date
Quality	Karen Hamilla	Haur Hamille	07 AUG 2019

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 Mouse IL-17F Kit

Kit Catalog Numbers: K152WS-Series

Kit Lot Number: K0081252

Expiration Date: 30 Sep 2019

Acceptance Data/ Percent Recovery Specifications:

		Calibrator		TH17 Panel 1 (mouse) Control 1		TH17 Panel 1 (mouse) Control 2		TH17 Panel 1 (mouse) Control 3	
Spot	Name	Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	IL-17F	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%

		LLOQ				ULOQ	
Spot	Name	Value	Recovery	CV	Value	Recovery	CV
1	IL-17F	320	75% - 125%	< 20%	52000	75% - 125%	< 20%

Stock Concentration of Material Tested:

Spot	Name	Item	Conc	Units
H 17F	Calibrator	91800	pg/mL	
	TH17 Panel 1 (mouse) Control 1	59000	pg/mL	
1	1 IL-17F	TH17 Panel 1 (mouse) Control 2	10500	pg/mL
		TH17 Panel 1 (mouse) Control 3	2360	pg/mL

Controls tested may not be the same lot as shipped.

Standard Curve Data:

IL-17F - Spot 1				
Conc. pg/mL	ECL Signal	%CV		
91800	266,000	2.6		
23000	78,200	3.9		
5740	19,800	4.5		
1430	5,020	2.1		
359	1,280	2.6		
89.6	365	4.7		
22.4	138	2.7		
0.00	67	10.0		

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Components:

Description	Lot Number	Storage Temperature	Expiration Date
Mouse IL-17F Plate	Z0046472	2-8°C	30 Sep 2019
Anti-ms IL-17F Antibody	D0080955	2-8°C	31 Oct 2019
TH17 Panel 1 (mouse) Calibrator Blend	A0080157	2-8°C	31 Oct 2022
Diluent 41	M0410018	≤ -10°C	30 Nov 2019
Diluent 45	M0450019	≤ -10°C	31 Dec 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), 100mL	Not Kit Specific			
TH17 Panel 1 (mouse) Control 1	Not Kit Specific			
TH17 Panel 1 (mouse) Control 2	Not Kit Specific			
TH17 Panel 1 (mouse) 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	Dawn Stollar	17 MAY 2019