

RFE MEMO

Page 1 of 1

Product Description(s): V-PLEX[®] and V-PLEX Plus Mouse IL-15 Kit **Catalog Number(s) / Size(s):** K152RD-Series **Lot Number:** K0080729

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0080729 has been extended to 31 AUG 2020.

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

Description	Lot Number	Original Expiration Date	New Expiration Date
Mouse IL-15 Plate	Z0046393	30 SEP 2019	31 AUG 2020
Anti-ms IL-15 Antibody	D0080935	31 AUG 2019	31 AUG 2020
Diluent 41	M0410016	31 AUG 2019	31 AUG 2020
Diluent 45	M0450016	30 SEP 2019	31 AUG 2020

Function	Name	Signature	Date
Quality	Karen Hamilla	Haven Hamille	03 SEP 2019

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

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Page 1 of 2

Product Description:	V-PLEX® and V-PLEX Plus Mouse IL-15 Kit
Kit Catalog Numbers:	K152RD-Series
Kit Lot Number:	K0080729
Expiration Date:	31 Aug 2019

Acceptance Data/ Percent Recovery Specifications:

		Calibrator		Cytokine Panel (mouse) Control 1		Cytokine Panel (mouse) Control 2		Cytokine Panel (mouse) Control 3	
Spot	Name	Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	ms IL-15	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%

		LLOQ			ULOQ		
Spot	Name	Value	Recovery	CV	Value	Recovery	CV
1	ms IL-15	43.2	75% - 125%	< 20%	26000	75% - 125%	< 20%

Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1 ms IL-15	Calibrator	37600	pg/mL	
	Cytokine Panel (mouse) Control 1	28300	pg/mL	
	Cytokine Panel (mouse) Control 2	4180	pg/mL	
		Cytokine Panel (mouse) Control 3	705	pg/mL

Controls tested may not be the same lot as shipped.

Standard Curve Data:

ms IL-15 - Spot 1				
Conc. pg/mL	ECL Signal	%CV		
37600	250,000	1.9		
9400	96,500	2.0		
2350	26,100	1.8		
588	6,060	1.8		
147	1,570	3.0		
36.7	501	2.7		
9.18	230	2.1		
0.00	137	2.1		

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Page 2 of 2

Components:

Description	Lot Number	Storage Temperature	Expiration Date
Mouse IL-15 Plate	Z0046393	2-8°C	30 Sep 2019
Anti-ms IL-15 Antibody	D0080935	2-8°C	31 Aug 2019
Cytokine Panel 1 (mouse) Calibrator Blend	A0080125	2-8°C	31 Mar 2022
Diluent 41	M0410016	\leq -10°C	31 Aug 2019
Diluent 45	M0450016	\leq -10°C	30 Sep 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			
Cytokine Panel (mouse) Control 1	Not Kit Specific			
Cytokine Panel (mouse) Control 2	Not Kit Specific			
Cytokine Panel (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 Assurance	Dawn Stollar	23 JUN 2017