

RFE MEMO

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Product Description(s): V-PLEX® and V-PLEX Plus Mouse IL-10 Kit

Catalog Number(s) / Size(s): K152QU- Series

Lot Number: K0080599

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0080599 has been extended to 31 Mar 2019.

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

Description	Lot Number	Original Expiration Date	New Expiration Date
Anti-ms IL-10 Antibody	D0080640	31 MAR 2018	31 MAR 2019
Mouse IL-10 Plate	Z0046188	31 JAN 2019	31 MAR 2019
Diluent 41	M0410014	31 DEC 2018	31 MAR 2019
Diluent 45	M0450010	30 JUN 2018	31 MAR 2019

Function Name		Signature	Date
Quality Assurance	Dawn Stollar	Dawn Stollar	01 FEB 2018

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 Mouse IL-10 Kit

Kit Catalog Numbers: K152QUD-1, K152QUD-2, K152QUD-4, K152QUG-1, K152QUG-2, K152QUG-4

Kit Lot Number: K0080599

Expiration Date: 31 Mar 2018

Acceptance Data/ Percent Recovery Specifications:

		Calibrator		Proinflammatory Panel 1 (mouse) Control 1		Proinflammatory Panel 1 (mouse) Control 2		Proinflammatory Panel 1 (mouse) Control 3	
Spot	Name	Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	ms IL-10	80% - 120%	< 20%	80% - 130%	< 25%	80% - 130%	< 25%	80% - 130%	< 25%

		LLOQ				ULOQ	
Spot	Name	Value	Recovery	CV	Value	Recovery	CV
1	ms IL-10	19.8	75% - 125%	< 25%	2030	75% - 125%	< 25%

Stock Concentration of Material Tested:

Spot	Name	Item	Conc	Units
	Calibrator	2630	pg/mL	
1	1 ms IL-10	Proinflammatory Panel 1 (mouse) Control 1	1140	pg/mL
1		Proinflammatory Panel 1 (mouse) Control 2	289	pg/mL
		Proinflammatory Panel 1 (mouse) Control 3	113	pg/mL

Controls tested may not be the same lot as shipped.

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Standard Curve Data:

ms IL-10 - Spot 1				
Conc. pg/mL	ECL Signal	%CV		
2630	343,000	3.8		
658	78,600	2.9		
164	18,400	4.1		
41.1	4,600	4.9		
10.3	1,390	3.6		
2.57	522	2.7		
0.642	318	2.9		
0.00	251	4.9		

Components:

Description	Lot Number	Storage Temperature	Expiration Date
Mouse IL-10 Plate	Z0046188	2-8°C	31 Jan 2019
Anti-ms IL-10 Antibody	D0080640	2-8°C	31 Mar 2018
Proinflammatory Panel 1 (mouse) Calibrator Blend	A0080060	2-8°C	31 Jul 2020
Diluent 41	M0410014	≤ -10°C	31 Dec 2018
Diluent 45	M0450010	≤ -10°C	30 Jun 2018
MSD Read Buffer T(4X)	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			
Proinflammatory Panel 1 (mouse) Control 1	Not Kit Specific			
Proinflammatory Panel 1 (mouse) Control 2	Not Kit Specific			
Proinflammatory Panel 1 (mouse) Control 3	Not Kit Specific			

Statement:

The above kit was tested using MSD procedures and it conforms to MSD's specifications. 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	14 SEP 2016