



RFE MEMO

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Product Description(s): V-PLEX® and V-PLEX Plus Mouse TNF- α Kit

Catalog Number(s) / Size(s): K152QW-Series

Lot Number: K0080863

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0080863 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
Mouse TNF- α Plate	Z0045988	30 JUN 2018	31 MAR 2019
Anti-ms TNF- α Antibody	D0080642	31 MAR 2018	31 MAR 2019

Function	Name	Signature	Date
Quality Assurance	Dawn Stollar	<i>Dawn Stollar</i>	15 MAR 2018

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

CERTIFICATE OF ANALYSIS

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Product Description: V-PLEX® and V-PLEX Plus Mouse TNF- α Kit
Kit Catalog Numbers: K152QW-series
Kit Lot Number: K0080863
Expiration Date: 31 Mar 2018

Acceptance Data/ Percent Recovery Specifications:

Spot	Name	Calibrator		Proinflammatory Panel 1 (mouse) Control 1		Proinflammatory Panel 1 (mouse) Control 2		Proinflammatory Panel 1 (mouse) Control 3	
		Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	ms TNF- α	80% - 120%	< 20%	125% - 150%	< 25%	125% - 150%	< 25%	75% - 125%	< 25%

Spot	Name	LLOQ			ULOQ		
		Value	Recovery	CV	Value	Recovery	CV
1	ms TNF- α	0.980	75% - 125%	< 25%	403	75% - 125%	< 25%

Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	ms TNF- α	Calibrator	628	pg/mL
		Proinflammatory Panel 1 (mouse) Control 1	140	pg/mL
		Proinflammatory Panel 1 (mouse) Control 2	27.8	pg/mL
		Proinflammatory Panel 1 (mouse) Control 3	5.12	pg/mL

Controls tested may not be the same lot as shipped.

Standard Curve Data:

ms TNF- α - Spot 1		
Conc. pg/mL	ECL Signal	%CV
628	204,000	2.1
157	47,700	2.8
39.3	11,200	2.8
9.81	2,800	2.6
2.45	777	3.0
0.613	284	1.8
0.153	163	3.3
0.00	125	4.2

CERTIFICATE OF ANALYSIS


Components:

Description	Lot Number	Storage Temperature	Expiration Date
Mouse TNF- α Plate	Z0045988	2-8°C	30 Jun 2018
Anti-ms TNF- α Antibody	D0080642	2-8°C	31 Mar 2018
Proinflammatory Panel 1 (mouse) Calibrator Blend	A0080071	2-8°C	30 Nov 2020
Diluent 41	M0410017	\leq -10°C	31 Oct 2019
Diluent 45	M0450018	\leq -10°C	30 Nov 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
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 product is intended for Research Use Only. Not for use in Diagnostic Procedures.

	Name	Function	Signature	Date
Review/Approval	Dawn Stollar	Quality Assurance		09 OCT 2017