



RFE MEMO

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Product Description(s): V-PLEX® and V-PLEX Plus Human MIP-3 α Kit

Catalog Number(s) / Size(s): K151XD-Series

Lot Number: K0080703

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0080703 has been extended to 31 Jan 2020.

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

Description	Lot Number	Original Expiration Date	New Expiration Date
Human MIP-3 α Plate	Z0046332	31 May 2019	31 Jan 2020
Anti-hu MIP-3 α Antibody	D0080763	31 Jan 2019	31 Jan 2020
Diluent 43	M0430018	31 Jan 2019	31 Jan 2020
Diluent 3	M0030073	31 Mar 2019	31 Jan 2020

Function	Name	Signature	Date
Quality Assurance	Dawn Stollar		15 MAR 2019

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 Human MIP-3 α Kit
Kit Catalog Numbers: K151XD-Series
Kit Lot Number: K0080703
Expiration Date: 31 Jan 2019

Acceptance Data/ Percent Recovery Specifications:

Spot	Name	Calibrator		TH17 Panel 1 (hu) Control 1		TH17 Panel 1 (hu) Control 3		TH17 Panel 1 (hu) Control 2	
		Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	MIP-3 α	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%

Spot	Name	LLOQ			ULOQ		
		Value	Recovery	CV	Value	Recovery	CV
1	MIP-3 α	0.590	80% - 120%	< 20%	325	80% - 120%	< 20%

Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	MIP-3 α	Calibrator	443	pg/mL
		TH17 Panel 1 (hu) Control 1	592	pg/mL
		TH17 Panel 1 (hu) Control 2	235	pg/mL
		TH17 Panel 1 (hu) Control 3	83	pg/mL

Controls tested may not be the same lot as shipped.

Standard Curve Data:

MIP-3 α - Spot 1		
Conc. pg/mL	ECL Signal	%CV
443	164,000	1.8
111	34,600	2.1
27.7	7,070	4.1
6.92	1,660	2.9
1.73	518	5.2
0.433	231	2.4
0.108	156	3.6
0.00	130	3.3

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Components:

Description	Lot Number	Storage Temperature	Expiration Date
Human MIP-3 α Plate	Z0046332	2-8°C	31 May 2019
Anti-hu MIP-3 α Antibody	D0080763	2-8°C	31 Jan 2019
TH17 Panel 1 (human) Calibrator Blend	A0080111	2-8°C	30 Nov 2021
Diluent 43	M0430018	\leq -10°C	31 Jan 2019
Diluent 3	M0030073	\leq -10°C	31 Mar 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
TH17 Panel 1 (human) Control 1	Not Kit Specific
TH17 Panel 1 (human) Control 2	Not Kit Specific
TH17 Panel 1 (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	<i>Dawn Stollar</i>	03 MAR 2017