

RFE MEMO

Page 1 of 1

Product Description(s): V-PLEX® and V-PLEX Plus Human Flt-1 Kit

Catalog Number(s) / Size(s): K151RZ - Series

Lot Number: K0080657

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0080657 has been extended to 31 May 2019.

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

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Description	Lot Number	Original Expiration Date	New Expiration Date
Human Flt-1 Plate	Z0055782	30 Apr 2019	31 May 2019
Anti-hu Flt-1 Antibody	D0080779	31 Mar 2019	31 May 2019
Angiogenesis Panel 1 (human) Calibrator Blend	A0040144	31 May 2018	31 May 2019
Diluent 7	M0070050	31 Oct 2018	31 May 2019
Diluent 11	M0110029	31 Dec 2018	31 May 2019

Function	Name	Signature	Date
Quality Assurance	Dawn Stollar	Dawn Stollar	12 JUN 2018

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

Memo Rev. A CM-00289-B

CERTIFICATE OF ANALYSIS

Page 1 of 2

Product Description: V-PLEX® and V-PLEX Plus Human Flt-1 Kit

Kit Catalog Numbers: K151RZ - Series

Kit Lot Number: K0080657

Expiration Date: 31 May 2018

Acceptance Data/ Percent Recovery Specifications:

		Calibrator		Angiogenesis Control 1		Angiogenesis Control 2		Angiogenesis Control 3	
Spot	Name	Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	hu Flt-1	80% - 120%	< 20%	75% - 125%	< 25%	75% - 125%	< 25%	75% - 125%	< 25%

		LLOQ				ULOQ	
Spot	Name	Value	Recovery	CV	Value	Recovery	CV
1	hu Flt-1	10.0	80% - 120%	< 20%	6410	80% - 120%	< 20%

Stock Concentration of Material Tested:

Spot	Name	Item	Conc	Units
1 hu Flt-1	20X Calibrator	180200	pg/mL	
	Angiogenesis Control 1	6510	pg/mL	
	Angiogenesis Control 2	549	pg/mL	
		Angiogenesis Control 3	67.4	pg/mL

Controls tested may not be the same lot as shipped.

Concentrations provided in this table refer to the stock concentration of the calibrators. For top of the standard curve concentrations, please refer to the Standard Curve Data

Standard Curve Data:

hu Flt-1 - Spot 1				
Conc. pg/mL	ECL Signal	%CV		
9010	168,000	2.1		
2250	43,700	2.5		
563	11,100	1.5		
141	2,790	0.8		
35.2	741	3.2		
8.80	241	3.0		
2.20	119	4.2		
0.00	78	6.5		

CERTIFICATE OF ANALYSIS

Page 2 of 2

Components:

Description	Lot Number	Storage Temperature	Expiration Date
Human Flt-1 Plate	Z0055782	2-8°C	30 Apr 2019
Anti-hu Flt-1 Antibody	D0080779	2-8°C	31 Mar 2019
Angiogenesis Panel 1 (human) Calibrator Blend	A0040144	≤ -70°C	31 May 2018
MSD Blocker A	Not Kit Specific	Not Kit Specific	N/A
Diluent 7	M0070050	≤ -10°C	31 Oct 2018
Diluent 11	M0110029	≤ -10°C	31 Dec 2018
MSD Phosphate Buffer (5X)	Not Kit Specific	Not Kit Specific	N/A
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		
Angiogenesis Control 1	Not Kit Specific		
Angiogenesis Control 2	Not Kit Specific		
Angiogenesis 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	12 JAN 2017