



RFE MEMO

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

Catalog Number(s) / Size(s): K151ME-Series

Lot Number: K0080733

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0080733 has been extended to 31 DEC 2019.

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

Description	Lot Number	Original Expiration Date	New Expiration Date
Human PIGF Plate	Z0055850	31 AUG 2019	31 DEC 2019
Anti-hu PIGF Antibody	D0080948	31 AUG 2019	31 DEC 2019
Angiogenesis Panel 1 (human) Calibrator Blend	A0080078	31 DEC 2018	31 DEC 2019
Diluent 7	M0070051	31 MAR 2019	31 DEC 2019
Diluent 11	M0110029	31 DEC 2018	31 DEC 2019

Function	Name	Signature	Date
Quality Assurance	Dawn Stollar	<i>Dawn Stollar</i>	03 JAN 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 PIGF Kit
Kit Catalog Numbers: K151ME-Series
Kit Lot Number: K0080733
Expiration Date: 31 Dec 2018

Acceptance Data/ Percent Recovery Specifications:

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

Spot	Name	LLOQ			ULOQ		
		Value	Recovery	CV	Value	Recovery	CV
1	hu PIGF	1.50	80% - 120%	< 20%	800	80% - 120%	< 20%

Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	hu PIGF	20X Calibrator	24400	pg/mL
		Angiogenesis Control 1	239	pg/mL
		Angiogenesis Control 2	48.6	pg/mL
		Angiogenesis Control 3	15.8	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 PIGF - Spot 1		
Conc. pg/mL	ECL Signal	%CV
1220	285,000	1.8
305	65,100	2.3
76.3	15,400	1.2
19.1	3,780	2.5
4.77	1,040	2.3
1.19	333	3.0
0.298	156	3.8
0.00	100	4.8

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Components:

Description	Lot Number	Storage Temperature	Expiration Date
Human PIGF Plate	Z0055850	2-8°C	31 Aug 2019
Anti-hu PIGF Antibody	D0080948	2-8°C	31 Aug 2019
Angiogenesis Panel 1 (human) Calibrator Blend	A0080078	≤ -70°C	31 Dec 2018
MSD Blocker A	Not Kit Specific	Not Kit Specific	N/A
Diluent 7	M0070051	≤ -10°C	31 Mar 2019
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	Vanessa Castleberry	Quality Assurance	<i>Vanessa Castleberry</i>	19APR2017