



RFE MEMO

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Product Description(s): Human TIMP-1 Kit
Catalog Number(s) / Size(s): K151JFC-Series
Lot Number: K0040342

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0040342 has been extended to 30 APR 2019.

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

Description	Lot Number	Original Expiration Date	New Expiration Date
Human TIMP-1 Plate	Z0055584	30 SEP 2018	30 APR 2019
Human TIMP-1 Antibody	D0040611	31 AUG 2018	30 APR 2019
Human TIMP-1 Calibrator	A0040167	30 SEP 2018	30 APR 2019
Diluent 2	M0020090	30 NOV 2018	30 APR 2019
Diluent 3	M0030071	30 SEP 2018	30 APR 2019

Function	Name	Signature	Date
Quality Assurance	Dawn Stollar		16 APR 2019

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

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COA-07236

Product Description: Human TIMP-1 Kit
Kit Catalog Numbers: K151JFC-1, K151JFC-2, K151JFC-4
Kit Lot Number: K0040342
Expiration Date: 30 Apr 2018

Acceptance Data/ Percent Recovery Specifications:

Spot	Name	Calibrator		Control 1		Control 2		Control 3	
		Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	TIMP-1	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%

Spot	Name	Value	LLOQ		Value	ULOQ	
			Recovery	CV		Recovery	CV
1	TIMP-1	494	80% - 120%	< 20%	32000	80% - 120%	< 20%

Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	TIMP-1	10X Calibrator	413000	pg/mL
		Control 1	715000	pg/mL
		Control 2	211500	pg/mL
		Control 3	70500	pg/mL

Control data was generated utilizing internal reference controls.

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

CERTIFICATE OF ANALYSIS
Standard Curve Data:


TIMP-1 - Spot 1		
Conc. pg/mL	ECL Signal	%CV
41300	1,110,000	2.0
13800	354,000	2.8
4590	72,400	2.8
1530	12,000	2.6
510	1,940	3.8
170	438	3.6
56.7	162	2.9
0.00	78	4.6

Components:

Description	Lot Number	Storage Temperature	Expiration Date
Human TIMP-1 Plate	Z0055584	2-8°C	30 Sep 2018
Anti-hu TIMP-1 Antibody	D0040611	2-8°C	31 Aug 2018
Human TIMP-1 Calibrator	A0040167	≤ -70°C	30 Sep 2018
Diluent 2	M0020090	≤ -10°C	30 Apr 2018
Diluent 3	M0030071	≤ -10°C	30 Sep 2018
Read Buffer T (4X)	Not Kit Specific	Room Temperature	N/A

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		16 APR 2019