



RFE MEMO

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Product Description(s): Inflammation Panel 1 (rat) Kit

Catalog Number(s) / Size(s): K15179C- Series

Lot Number: K0040485

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0040485 has been extended to 31 MAR 2022.

The expiration date for the following kit component has been extended:

Description	Lot Number	Original Expiration Date	New Expiration Date
Inflammation Panel 1 (rat) Calibrator Blend	A0040220	31 MAR 2021	31 MAR 2022

Function	Name	Signature	Date
Quality	Karen Hamilla		26 MAR 2021

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

CERTIFICATE OF ANALYSIS

Product Description: Inflammation Panel 1 (rat) Kit
Kit Catalog Numbers: K15179C-Series
Kit Lot Number: K0040485
Expiration Date: 31 Mar 2021

Acceptance Data/ Percent Recovery Specifications:

Spot	Name	Calibrator		Inflammation Panel 1 (rat) Control 1		Inflammation Panel 1 (rat) Control 2		Inflammation Panel 1 (rat) Control 3	
		Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	Lipocalin-2	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%
2	TSP-1	80% - 120%	< 20%	75% - 125%	< 25%	75% - 125%	< 25%	75% - 125%	< 25%
3	TIMP-1	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%
4	MCP-1	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%

Spot	Name	LLOQ			ULOQ		
		Value	Recovery	CV	Value	Recovery	CV
1	Lipocalin-2	0.0330	80% - 120%	< 20%	27.6	75% - 125%	< 25%
2	TSP-1	29.7	80% - 120%	< 20%	766	75% - 125%	< 25%
3	TIMP-1	0.0567	80% - 120%	< 20%	6.71	75% - 125%	< 25%
4	MCP-1	0.0447	80% - 120%	< 20%	11.0	75% - 125%	< 25%

Acceptance Data/ Non Specific Binding Specifications:

Spot	Name	NSB Spec
1	Lipocalin-2	< 1.0%
2	TSP-1	< 3.0%
3	TIMP-1	< 1.0%
4	MCP-1	< 1.0%

CERTIFICATE OF ANALYSIS

Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	Lipocalin-2	20X Calibrator	1072	ng/mL
		Inflammation Panel 1 (rat) Control 1	225	ng/mL
		Inflammation Panel 1 (rat) Control 2	20.4	ng/mL
		Inflammation Panel 1 (rat) Control 3	2.12	ng/mL
2	TSP-1	20X Calibrator	43600	ng/mL
		Inflammation Panel 1 (rat) Control 1	9150	ng/mL
		Inflammation Panel 1 (rat) Control 2	5500	ng/mL
		Inflammation Panel 1 (rat) Control 3	3290	ng/mL
3	TIMP-1	20X Calibrator	186	ng/mL
		Inflammation Panel 1 (rat) Control 1	66.9	ng/mL
		Inflammation Panel 1 (rat) Control 2	17.6	ng/mL
		Inflammation Panel 1 (rat) Control 3	3.65	ng/mL
4	MCP-1	20X Calibrator	266	ng/mL
		Inflammation Panel 1 (rat) Control 1	88.1	ng/mL
		Inflammation Panel 1 (rat) Control 2	18.5	ng/mL
		Inflammation Panel 1 (rat) Control 3	3.63	ng/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

Standard Curve Data:

Lipocalin-2 - Spot 1			TSP-1 - Spot 2			TIMP-1 - Spot 3		
Conc. ng/mL	ECL Signal	%CV	Conc. ng/mL	ECL Signal	%CV	Conc. ng/mL	ECL Signal	%CV
53.6	562,000	3.7	2180	44,000	4.6	9.32	341,000	5.2
17.9	366,000	4.4	727	20,800	6.4	3.11	80,200	6.9
5.96	146,000	5.1	242	7,010	8.2	1.04	13,500	7.5
1.99	51,400	5.8	80.7	2,440	10.0	0.345	2,570	4.4
0.662	17,200	3.8	26.9	991	11.0	0.115	665	3.9
0.221	5,940	4.9	8.97	561	14.0	0.0384	248	4.8
0.0735	2,090	4.9	2.99	404	18.0	0.0128	127	5.0
0.00	82	33.0	0.00	271	50.0	0.00	73	9.3

CERTIFICATE OF ANALYSIS

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MCP-1 - Spot 4		
Conc. ng/mL	ECL Signal	%CV
13.3	492,000	2.9
4.43	217,000	4.9
1.48	62,200	4.7
0.493	18,700	6.6
0.164	6,090	4.6
0.0547	2,320	3.0
0.0182	1,010	3.1
0.00	392	3.3

Components:

Description	Lot Number	Storage Temperature	Expiration Date
Inflammation Panel 1 (rat) Plate	Z0056615	2-8°C	31 Mar 2022
Anti-rat Lipocalin-2 Antibody	D0040889	2-8°C	31 Jul 2023
Anti-rat TSP-1 Antibody	D0040890	2-8°C	30 Nov 2023
Anti-rat TIMP-1 Antibody	D0040892	2-8°C	31 Jul 2023
Anti-rat MCP-1 Antibody	D0040891	2-8°C	31 May 2023
Inflammation Panel 1 (rat) Calibrator Blend	A0040220	≤ -70°C	31 Mar 2021
Diluent 7	M0070062	≤ -10°C	31 May 2022
Diluent 100	Not Kit Specific	Not Kit Specific	N/A
MSD Read Buffer T	Not Kit Specific	Not Kit Specific	N/A

Statement:

The above product is intended for Research Use Only. Not for use in Diagnostic Procedures.

	Name	Function	Signature	Date
Review/Approval	Karen Hamilla	Quality		02 JUL 2020