



RFE MEMO


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Product Description(s): Diluent 101

Catalog Number(s) / Size(s): R51AD-Series

Lot Number: M1010030

Based on additional testing, the original date of expiration for this diluent has been extended by 12 months. The expiration date of M1010030 has been extended to 31 JUL 2021.

Function	Name	Signature	Date
Quality	Karen Hamilla		11 JUN 2020

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 CRP Kit

Kit Catalog Numbers: K151ST-Series

Kit Lot Number: K0081479

Expiration Date: 31 Jul 2021

Acceptance Data/ Percent Recovery Specifications:

Spot	Name	Calibrator		Vascular Injury Control 1		Vascular Injury Control 2		Vascular Injury Control 3	
		Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	CRP	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%

Spot	Name	LLOQ			ULOQ		
		Value	Recovery	CV	Value	Recovery	CV
1	CRP	27.6	80% - 120%	< 20%	49600	80% - 120%	< 20%

Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	CRP	20X Calibrator	3920000	pg/mL
		Vascular Injury Control 1	23700	pg/mL
		Vascular Injury Control 2	4620	pg/mL
		Vascular Injury Control 3	613	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:

CRP - Spot 1		
Conc. pg/mL	ECL Signal	%CV
196000	1,060,000	2.2
39200	400,000	1.9
7840	89,700	2.8
1570	18,400	2.2
314	3,600	1.3
62.7	745	2.1
12.5	170	2.9
0.00	29	17.0

CERTIFICATE OF ANALYSIS


Components:

Description	Lot Number	Storage Temperature	Expiration Date
Human CRP Plate	Z0056562	2-8°C	31 Jan 2022
Anti-hu CRP Antibody	D0081257	2-8°C	31 Oct 2022
Vascular Panel 2 (human) Calibrator Blend	A0080212	≤ -70°C	30 Nov 2021
Diluent 101	M1010030	≤ -10°C	31 Jul 2021
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
Vascular Injury Control 1	Not Kit Specific
Vascular Injury Control 2	Not Kit Specific
Vascular Injury 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	Karen Hamilla	Quality		25 JUN 2020