



RFE MEMO

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

Catalog Number(s) / Size(s): K151V5-Series;

Lot Number: K0081323

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0081323 has been extended to 28 FEB 2023.

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

Description	Lot Number	Original Expiration Date	New Expiration Date
Human Leptin Plate	Z0047172	28 FEB 2022	28 FEB 2023
Diluent 56	M0560001	30 APR 2022	28 FEB 2023
Diluent 11	M0110042	28 FEB 2022	28 FEB 2023

Function	Name	Signature	Date
Quality	Karen Hamilla		14 MAR 2022

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 Leptin Kit

Kit Catalog Numbers: K151V5-Series

Kit Lot Number: K0081323

Expiration Date: 28 Feb 2022

Acceptance Data/ Percent Recovery Specifications:

Spot	Name	Calibrator		Metabolic Panel 1 Control 1		Metabolic Panel 1 Control 2		Metabolic Panel 1 Control 3	
		Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	Leptin	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%

Spot	Name	LLOQ			ULOQ		
		Value	Recovery	CV	Value	Recovery	CV
1	Leptin	37.7	80% - 120%	< 20%	7150	80% - 120%	< 20%

Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	Leptin	Calibrator	9930	pg/mL
		Metabolic Panel 1 Control 1	3290	pg/mL
		Metabolic Panel 1 Control 2	458	pg/mL
		Metabolic Panel 1 Control 3	104	pg/mL

Controls tested may not be the same lot as shipped.

Standard Curve Data:

Leptin - Spot 1		
Conc. pg/mL	ECL Signal	%CV
9930	391,000	2.8
2480	84,500	4.3
621	15,000	5.1
155	2,680	4.0
38.8	691	4.8
9.70	232	5.0
2.42	125	4.4
0.00	89	2.9

CERTIFICATE OF ANALYSIS


Components:

Description	Lot Number	Storage Temperature	Expiration Date
Human Leptin Plate	Z0047172	2-8°C	28 Feb 2022
Human Leptin Antibody	D0081377	2-8°C	31 Mar 2023
Metabolic Panel 1 Calibrator Blend	A0080230	2-8°C	30 Sep 2024
Diluent 56	M0560001	≤ -10°C	30 Apr 2022
Diluent 11	M0110042	≤ -10°C	28 Feb 2022
MSD Gold Read Buffer B	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
Metabolic Panel 1 Control 1	Not Kit Specific
Metabolic Panel 1 Control 2	Not Kit Specific
Metabolic Panel 1 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		20 FEB 2020