



**RFE MEMO**

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**Product Description(s):** V-PLEX® and V-PLEX Plus Glucagon Kit

**Catalog Number(s) / Size(s):** K150U5-Series

**Lot Number:** K0081322

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0081322 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
Glucagon Plate	Z0047171	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		25 JAN 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 Glucagon Kit  
**Kit Catalog Numbers:** K150U5-Series  
**Kit Lot Number:** K0081322  
**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	Glucagon	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%

Spot	Name	LLOQ			ULOQ		
		Value	Recovery	CV	Value	Recovery	CV
1	Glucagon	0.329	80% - 120%	< 20%	52.0	80% - 120%	< 20%

**Stock Concentration of Material Tested :**

Spot	Name	Item	Conc	Units
1	Glucagon	Calibrator	77.4	pM
		Metabolic Panel 1 Control 1	28.2	pM
		Metabolic Panel 1 Control 2	3.76	pM
		Metabolic Panel 1 Control 3	1.11	pM

Controls tested may not be the same lot as shipped.

**Standard Curve Data:**

Glucagon - Spot 1		
Conc. pM	ECL Signal	%CV
77.4	181,000	3.4
19.4	45,000	3.5
4.84	10,900	3.2
1.21	3,000	1.9
0.302	964	3.8
0.0756	487	3.2
0.0189	348	3.1
0.00	315	3.4

## CERTIFICATE OF ANALYSIS

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**Components:**

Description	Lot Number	Storage Temperature	Expiration Date
Glucagon Plate	Z0047171	2-8°C	28 Feb 2022
Glucagon Antibody	D0081375	2-8°C	30 Apr 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), 100 mL	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
<b>Review/Approval</b>	Karen Hamilla	Quality		28 JAN 2020