



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: K0082080

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0082080 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

Function	Name	Signature	Date
Quality	Xiomara Talavera		02 AUG 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 Lot Number: K0082080
Expiration Date: 28 Feb 2022
Kit Catalog Numbers: K150U5-Series

Precision and Accuracy Specifications:

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

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

Stock Concentration of Calibrator:


Spot	Name	Conc.	Units
1	Glucagon	77.4	pM

Lot-Specific 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 11	M0110056	≤ -10°C	31 Oct 2024
Diluent 56	M0560003	≤ -10°C	31 Oct 2024

Additional components may be provided to execute the assay. Additional components are not lot-specific.

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

	Name	Function	Signature	Date
Review/Approval	Xiomara Talavera	Quality		02 AUG 2022