



RFE MEMO

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Product Description(s): S-PLEX® Human IFN- γ Kit
Catalog Number(s) / Size(s): K151X9S - Series
Lot Number: K00S0082

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K00S0082 has been extended to 29 FEB 2024.

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

Description	Lot Number	Original Expiration Date	New Expiration Date
Diluent 58	M0580001	28 FEB 2023	29 FEB 2024
Blocker S1	R0010757	31 JAN 2024	29 FEB 2024

Function	Name	Signature	Date
Quality	Karen Hamilla		24 FEB 2023

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



CERTIFICATE OF ANALYSIS

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Product Description: S-PLEX[®] Human IFN- γ Kit

Catalog Number: K151X9S - Series

Lot Number: K00S0082

Expiration Date: 28 FEB 2023

Lot-Specific Components:

Description	Lot Number	Storage Temperature	Expiration Date
TURBO-BOOST [™] Human IFN- γ Antibody	D00T0085	2-8°C	31 DEC 2025
Biotin Human IFN- γ Antibody	B00T0085	2-8°C	30 SEP 2025
Human IFN- γ Calibrator	A00S0026	2-8°C	30 SEP 2025
Diluent 58	M0580001	$\leq -10^{\circ}\text{C}$	28 FEB 2023
S-PLEX Coating Reagent C1	351987	$\leq -70^{\circ}\text{C}$	30 APR 2024
Blocker S1	R0010757	$\leq -10^{\circ}\text{C}$	31 JAN 2024
S-PLEX Enhance E1	Y0550008	$\leq -10^{\circ}\text{C}$	30 NOV 2024
S-PLEX Enhance E2	Y0560010	$\leq -10^{\circ}\text{C}$	31 JAN 2025
S-PLEX Enhance E3	Y0570009	$\leq -70^{\circ}\text{C}$	30 SEP 2024
S-PLEX Detect D1 with TURBO-TAG [™] reagent	Y0580013	$\leq -70^{\circ}\text{C}$	31 DEC 2024
S-PLEX Detect D2	Y0590009	$\leq -70^{\circ}\text{C}$	30 NOV 2024

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

Precision, Accuracy, and Sensitivity Specifications:

Name	Calibrator	
	Recovery	CV
IFN- γ	80% - 120%	< 20%

Name	LLOQ				LLOD		
	Range Tested	Observed	Units	Recovery	CV	Observed	Units
IFN- γ	3.96 - 63.4	31.7	fg/mL	80% - 120%	< 20%	4.53	fg/mL

Stock Concentration of Calibrator:

Name	Item	Concentration	Units
IFN- γ	1X Calibrator	25400	fg/mL

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

	Name	Function	Signature	Date
Review/Approval	Karen Hamilla	Quality		30 AUG 2022