



RFE MEMO

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Product Description(s): S-PLEX[®] Human GM-CSF Kit
Catalog Number(s) / Size(s): K151F3S-Series; K156F3S-Series
Lot Number: K00S0042

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K00S0042 has been extended to 31 JAN 2023.

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

Description	Lot Number	Original Expiration Date	New Expiration Date
Diluent 43	M0430033	31 JAN 2022	31 JAN 2023

Function	Name	Signature	Date
Quality	Karen Hamilla		08 FEB 2022

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 GM-CSF Kit

Catalog Number: K151F3S-Series

Lot Number: K00S0042

Expiration Date: 31 Jan 2022

Precision, Accuracy, and Sensitivity Specifications:

Calibrator		
Name	Recovery	CV
GM-CSF	80% - 120%	< 20%

LLOQ					
Name	Range Tested	Observed	Units	Recovery	CV
GM-CSF	8.79 – 35.2	35.2	fg/mL	80% - 120%	< 20%

LLOD		
Name	Observed	Units
GM-CSF	2.19	fg/mL

Stock Concentration of Calibrator:

Name	Item	Concentration	Units
GM-CSF	50X Calibrator	1350000	fg/mL

Lot-Specific Components:

Description	Lot Number	Storage Temperature	Expiration Date
TURBO-BOOST™ Human GM-CSF Antibody	D00T0021A	2-8°C	30 Sep 2023
Biotin Human GM-CSF Antibody	B00T0021A	2-8°C	31 May 2024
Human GM-CSF Calibrator	A00S0043	2-8°C	31 Dec 2025
Diluent 43	M0430033	≤ -10°C	31 Jan 2022
Diluent 3	M0030104	≤ -10°C	30 Jun 2023
S-PLEX Coating Reagent C1	329998	≤ -70°C	31 Aug 2023
Blocker S1	R0140004	≤ -10°C	30 Apr 2023
S-PLEX Enhance E1	Y0550004	≤ -10°C	28 Feb 2023
S-PLEX Enhance E2	Y0560006	≤ -10°C	31 May 2023
S-PLEX Enhance E3	Y0570004	≤ -70°C	31 Jan 2023
S-PLEX Detect D1	Y0580006	≤ -70°C	31 Mar 2023
S-PLEX Detect D2	Y0590004	≤ -70°C	31 Jan 2023

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	Karen Hamilla	Quality		02 MAR 2021