



RFE MEMO

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Product Description(s): S-PLEX[®] Human G-CSF Kit
Catalog Number(s) / Size(s): K151K3S-Series; K156K3S-Series
Lot Number: K00S0061

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K00S0061 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
TURBO-BOOST [™] Human G-CSF Antibody	D00T0012A	31 OCT 2022	31 JAN 2023
Biotin Human G-CSF Antibody	B00T0012A	31 OCT 2022	31 JAN 2023
Diluent 43	M0430033	31 JAN 2022	31 JAN 2023
Diluent 3	M0030091	31 JAN 2022	31 JAN 2023

Function	Name	Signature	Date
Quality	Karen Hamilla		07 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 G-CSF Kit
Catalog Number: K151K3S-Series; K156K3S-Series
Lot Number: K00S0061
Expiration Date: 31 Jan 2022

Precision, Accuracy, and Sensitivity Specifications:

Calibrator		
Name	Recovery	CV
G-CSF	75% - 125%	< 25%

LLOQ					
Name	Range Tested	Observed	Units	Recovery	CV
G-CSF	27.5-440	110.0	fg/mL	75% - 125%	< 25%

LLOD		
Name	Observed	Units
G-CSF	40.7	fg/mL

Stock Concentration of Calibrator:

Name	Item	Concentration	Units
G-CSF	50X	27000000	fg/mL

Lot-Specific Components:

Description	Lot Number	Storage Temperature	Expiration Date
TURBO-BOOST™ Human G-CSF Antibody	D00T0012A	2-8°C	31 Oct 2022
Biotin Human G-CSF Antibody	B00T0012A	2-8°C	31 Oct 2022
Human G-CSF Calibrator	A00S0015	2-8°C	31 Jul 2024
Diluent 43	M0430033	≤ -10°C	31 Jan 2022
Diluent 3	M0030091	≤ -10°C	31 Jan 2022
S-PLEX Coating Reagent C1	314374	≤ -70°C	28 Feb 2023
Blocker S1	R0140004	≤ -10°C	30 Apr 2023
S-PLEX Enhance E1	Y0550005	≤ -10°C	31 May 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	Y0580007	≤ -70°C	31 May 2023
S-PLEX Detect D2	Y0590005	≤ -70°C	28 Feb 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		27 AUG 2021