



RFE MEMO

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Product Description(s): S-PLEX[®] Human IL-4 Kit

Catalog Number(s) / Size(s): K151A3S-Series

Lot Number: K00S0052

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K00S0052 has been extended to 31 JUL 2023.

The expiration date for the following kit component has been extended:

Description	Lot Number	Original Expiration Date	New Expiration Date
Diluent 2	M0020112	31 JUL 2022	31 JUL 2023
Blocker S1	R0140004	30 APR 2023	31 JUL 2023
S-PLEX Enhance E1	Y0550005	31 MAY 2023	31 JUL 2023
S-PLEX Enhance E2	Y0560006	31 MAY 2023	31 JUL 2023
S-PLEX Enhance E3	Y0570005	28 FEB 2023	31 JUL 2023
S-PLEX Detect D1	Y0580007	31 MAY 2023	31 JUL 2023
S-PLEX Detect D2	Y0590005	28 FEB 2023	31 JUL 2023

Function	Name	Signature	Date
Quality	Karen Hamilla		17 AUG 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 IL-4 Kit

Catalog Number: K151A3S-Series

Lot Number: K00S0052

Expiration Date: 31 JUL 2022

Precision, Accuracy, and Sensitivity Specifications:

Calibrator		
Name	Recovery	CV
IL-4	80% - 120%	< 20%

LLOQ					
Name	Range Tested	Observed	Units	Recovery	CV
IL-4	0.306 - 9.80	9.80	fg/mL	80% - 120%	< 20%

LLOD		
Name	Observed	Units
IL-4	0.578	fg/mL

Stock Concentration of Calibrator:

Name	Item	Concentration	Units
IL-4	20X Calibrator	114000	fg/mL

Lot-Specific Components:

Description	Lot Number	Storage Temperature	Expiration Date
TURBO-BOOST [™] Human IL-4 Antibody	D00T0061A	2-8°C	30 Sep 2024
Biotin Human IL-4 Antibody	B00T0061A	2-8°C	31 Jul 2024
Human IL-4 Calibrator	A00S0041	2-8°C	30 Nov 2025
Diluent 2	M0020112	≤ -10°C	31 Jul 2022
Diluent 3	M0030106	≤ -10°C	31 Aug 2023
S-PLEX Coating Reagent C1	329998	≤ -70°C	31 Aug 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	Y0570005	≤ -70°C	28 Feb 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		04 JUN 2021