



RFE MEMO

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Product Description(s): S-PLEX® SARS-CoV-2 Spike Kit

Catalog Number(s) / Size(s): K150ADJS - Series

Lot Number: K00S0046

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K00S0046 has been extended to 31 JAN 2024.

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

Description	Lot Number	Original Expiration Date	New Expiration Date
SARS-CoV-2 Spike Calibrator	A00S0046	31 AUG 2023	31 JAN 2024
S-PLEX Coating Reagent C1	329998	31 AUG 2023	31 JAN 2024
Diluent 61	M0610001	31 MAR 2023	31 JAN 2024
Blocker S1	R0140004	30 APR 2023	31 JAN 2024
S-PLEX Enhance E1	Y0550005	31 MAY 2023	31 JAN 2024
S-PLEX Enhance E2	Y0560006	31 MAY 2023	31 JAN 2024
S-PLEX Enhance E3	Y0570005	28 FEB 2023	31 JAN 2024
S-PLEX Detect D1	Y0580007	31 MAY 2023	31 JAN 2024
S-PLEX Detect D2	Y0590004	31 JAN 2023	31 JAN 2024

Function	Name	Signature	Date
Quality	Karen Hamilla		30 NOV 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® SARS-CoV-2 Spike Kit

Catalog Number: K150ADJS - Series

Lot Number: K00S0046

Expiration Date: 31 JAN 2023

Precision, Accuracy, and Sensitivity Specifications:

Name	Calibrator	
	Recovery	CV
SARS-CoV-2 Spike	75% - 125%	< 25%

Name	Range Tested	Observed	Units	LLOQ	
				Recovery	CV
SARS-CoV-2 Spike	175-2800	350	fg/mL	75% - 125%	< 25%

Name	LLOD	
	Observed	Units
SARS-CoV-2 Spike	95	fg/mL

Stock Concentration of Calibrator:

Name	Item	Concentration	Units
SARS-CoV-2 Spike	20X Calibrator	7520000	fg/mL

Lot-Specific Components:

Description	Lot Number	Storage Temperature	Expiration Date
TURBO-BOOST™ SARS-CoV-2 Spike Antibody	D00T0064A	2-8°C	31 AUG 2024
Biotin SARS-CoV-2 Spike Antibody	B00T0064A	2-8°C	31 JUL 2024
SARS-CoV-2 Spike Calibrator	A00S0046	≤ -70°C	31 AUG 2023
S-PLEX Coating Reagent C1	329998	≤ -70°C	31 AUG 2023
Diluent 61	M0610001	≤ -10°C	31 MAR 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	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		19 MAR 2021