



RFE MEMO

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

Catalog Number(s) / Size(s): K150ADHS-Series

Lot Number: K00S0069

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K00S0069 has been extended to 31 DEC 2023.

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

Description	Lot Number	Original Expiration Date	New Expiration Date
S-PLEX Coating Reagent C1	329998	31 Aug 2023	31 Dec 2023
SARS-CoV-2 N Calibrator	A00S0034	31 Mar 2023	31 Dec 2023
Diluent 61	M0610001	31 Mar 2023	31 Dec 2023
Blocker D-R	R0060025	28 Feb 2023	31 Dec 2023
Blocker S1	R0140005	31 Aug 2023	31 Dec 2023
S-PLEX Enhance E1	Y0550004	28 Feb 2023	31 Dec 2023
S-PLEX Enhance E2	Y0560004	31 Jan 2023	31 Dec 2023
S-PLEX Enhance E3	Y0570003	31 Dec 2022	31 Dec 2023
S-PLEX Detect D1	Y0580005	31 Mar 2023	31 Dec 2023
S-PLEX Detect D2	Y0590003	31 Dec 2022	31 Dec 2023

Function	Name	Signature	Date
Quality	Karen Hamilla		03 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 N Kit

Catalog Number: K150ADHS-Series

Lot Number: K00S0069

Expiration Date: 31 DEC 2022

Lot-Specific Components:

Description	Lot Number	Storage Temperature	Expiration Date
TURBO-BOOST™ SARS-CoV-2 N Antibody	D00T0045A	2-8°C	31 MAR 2024
Biotin SARS-CoV-2 N Antibody	B00T0045A	2-8°C	31 MAR 2024
S-PLEX Coating Reagent C1	329998	≤ -70°C	31 AUG 2023
SARS-CoV-2 N Calibrator	A00S0034	≤ -70°C	31 MAR 2023
Diluent 61	M0610001	≤ -10°C	31 MAR 2023
Blocker D-R	R0060025	≤ -10°C	28 FEB 2023
Blocker S1	R0140005	≤ -10°C	31 AUG 2023
S-PLEX Enhance E1	Y0550004	≤ -10°C	28 FEB 2023
S-PLEX Enhance E2	Y0560004	≤ -10°C	31 JAN 2023
S-PLEX Enhance E3	Y0570003	≤ -70°C	31 DEC 2022
S-PLEX Detect D1	Y0580005	≤ -70°C	31 MAR 2023
S-PLEX Detect D2	Y0590003	≤ -70°C	31 DEC 2022

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

Precision, Accuracy, and Sensitivity Specifications:

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

Name	LLOQ				LLOD		
	Range Tested	Observed	Units	Recovery	CV	Observed	Units
SARS-CoV-2 N	86.3 - 1380	173	fg/mL	75% - 125%	< 25%	41.1	fg/mL

Stock Concentration of Calibrator:

Name	Item	Concentration	Units
SARS-CoV-2 N	20X Calibrator	21800000	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		23 FEB 2022