



RFE MEMO

Page 1 of 1

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


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

Lot Number: K00S0143

Based on additional testing, the original date of expiration for this kit has been extended by 10 months. The expiration date of K00S0143 has been extended to 31 DEC 2023.

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

Description	Lot Number	Original Expiration Date	New Expiration Date
SARS-CoV-2 N Calibrator	A00S0034	31 MAR 2023	31 DEC 2023
Blocker D-R	R0060025	28 FEB 2023	31 DEC 2023

Function	Name	Signature	Date
Quality	Karen Hamilla		01 JUN 2023

This memo supersedes all other statements regarding date of expiration for this product.



CERTIFICATE OF ANALYSIS

Page 1 of 1

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

Catalog Number: K150ADHS-Series

Lot Number: K00S0143

Expiration Date: 28 FEB 2023

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	417723	≤ -70°C	31 AUG 2025
SARS-CoV-2 N Calibrator	A00S0034	≤ -70°C	31 MAR 2023
Diluent 61	M0610004	≤ -10°C	31 AUG 2025
Blocker D-R	R0060025	≤ -10°C	28 FEB 2023
Blocker S1	R0010831	≤ -10°C	31 JUL 2025
S-PLEX Enhance E1	Y0550012	≤ -10°C	31 AUG 2025
S-PLEX Enhance E2	Y0560013	≤ -10°C	31 AUG 2025
S-PLEX Enhance E3	Y0570013	≤ -70°C	31 JUL 2025
S-PLEX Detect D1 with TURBO-TAG™ reagent	Y0580017	≤ -70°C	31 AUG 2025
S-PLEX Detect D2	Y0590013	≤ -70°C	31 JUL 2025

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	86.3	fg/mL	75% - 125%	< 25%	46.2	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		01 JUN 2023