



RFE MEMO

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Product Description: S-PLEX[®] Human Tau (pT231) Kit
Catalog Number: K151AGNS-Series; K156AGNS-Series
Lot Number: K00S0057

Based on additional testing, the original date of expiration for this kit has been extended by 6 months. The expiration date of K00S0057 has been extended to 31 OCT 2023.

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

Description	Lot Number	Original Expiration Date	New Expiration Date
Diluent 2	M0020115	31 MAY 2023	31 OCT 2023
S-PLEX Coating Reagent C1	329998	31 AUG 2023	31 OCT 2023
Blocker S1	R0140004	30 APR 2023	31 OCT 2023

Function	Name	Signature	Date
Quality	Karen Hamilla		17 APR 2023

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 Tau (pT231) Kit

Catalog Number: K151AGNS-Series; K156AGNS-Series

Lot Number: K00S0057

Expiration Date: 30 Apr 2023

Lot-Specific Components:

Description	Lot Number	Storage Temperature	Expiration Date
TURBO-BOOST [™] Human Tau Antibody	D00T0067	2-8°C	31 Dec 2024
Biotin Human Tau (pT231) Antibody	B00T0067	2-8°C	30 Nov 2024
Human Tau (pT231) Calibrator	A00S0052	2-8°C	30 Jun 2026
Diluent 2	M0020115	≤ -10°C	31 May 2023
S-PLEX Coating Reagent C1	329998	≤ -70°C	31 Aug 2023
Blocker S1	R0140004	≤ -10°C	30 Apr 2023
S-PLEX Enhance E1	Y0550006	≤ -10°C	31 Oct 2023
S-PLEX Enhance E2	Y0560007	≤ -10°C	31 Oct 2023
S-PLEX Enhance E3	Y0570006	≤ -70°C	31 Oct 2023
S-PLEX Detect D1	Y0580008	≤ -70°C	30 Nov 2023
S-PLEX Detect D2	Y0590006	≤ -70°C	31 Oct 2023

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

Precision, Accuracy, and Sensitivity Specifications:

Name	Calibrator	
	Recovery	CV
Tau (pT231)	80% - 120%	< 20%

Name	Range Tested	Observed	LLOQ			LLOD	
			Units	Recovery	CV	Observed	Units
Tau (pT231)	3680 - 58800	14700	fg/mL	80% - 120%	< 20%	3070	fg/mL

Stock Concentration of Calibrator:

Name	Item	Concentration	Units
Tau (pT231)	1X Calibrator	40000000	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 NOV 2021