AMPRION®

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Patient Report: FINAL

Amprion Accession ID	Collection Date	Received Date	Report Date
26-001234	1/1/2026	1/2/2026	1/5/2026

Patient:	Doe, John	**Ordering Physician:**	Dr. Physician
DOB:	1/1/1900	**Client Account:**	C9999
Sex:	Male	**Client Name:**	Main Hospital
MRN:	123456789		
Specimen Type:	Cerebrospinal Fluid	**Client Address:**	12345 1st Street
Specimen ID:	S123456789		Anytown, US 00001

SAAmplify®-αSYN Plus (CSF)

Result:

Detected-1: Misfolded α-Synuclein protein aggregates detected.

Interpretation:

Amplification profile consistent with that found predominantly in patients with primary or secondary neuronal synuclein disease (e.g., Parkinson’s disease, dementia with Lewy bodies, Alzheimer's disease with Lewy body pathology (AD-LB)).

Comments:
N/A

Report Reviewed By:	Technical Signature	**Date:**	1/5/2026

This test was developed and its performance characteristics determined by Amprion Inc. This test is used for clinical purposes.
It should not be regarded as investigational or for research. It has not been cleared or approved by the FDA.
The laboratory is regulated under CLIA as qualified to perform high-complexity testing.

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Intended Use:

SAAmplify–αSYN Plus (CSF) is an in vitro diagnostic test for qualitative detection of aggregates of misfolded α-synuclein (αSyn) in cerebrospinal fluid (CSF) intended for use in adult patients with clinically uncertain cognitive decline or clinically uncertain Parkinsonian syndromes. Results are used to aid diagnosis of synucleinopathies such as Parkinson's disease (PD), dementia with Lewy bodies (DLB), Alzheimer's disease with Lewy body pathology (AD-LB), and multiple system atrophy (MSA). The results must be interpreted in conjunction with other patient clinical information. The test is for professional use only.

Test and Methodology:

SAAmplify–αSYN Plus (CSF) is a seed amplification assay (SAA). The novel SAA strategy essentially mimics the biological process in which in vivo protein misfolding and aggregation follow a seeding/nucleation mechanism. Briefly, CSF samples are incubated with an excess of monomeric human recombinant (rec) αSyn and subjected to intermittent shaking/incubation cycles. If soluble misfolded αSyn aggregates are present in the sample, these aggregates are amplified using rec-αSyn as substrate. αSyn aggregates formed in the reaction are detected as an increase in fluorescence due to the presence of the amyloid-specific binding dye, Thioflavin T (ThT). In the absence of αSyn aggregates, fluorescence remains below the validated assay cutoff.

Limitations:

SAAmplify–αSYN Plus (CSF) utilizes fluorescence to detect increases in αSyn aggregate formation. Validation studies have determined that certain substances such as blood, hemoglobin, and conjugated bilirubin may affect results at concentrations where visible discoloration is evident. The laboratory will evaluate all specimens submitted for suitability for testing. Results should be interpreted in conjunction with patient clinical and other ancillary information.

References:

1. Plastini, M.J., et al. (2024). "Multiple biomarkers improve diagnostic accuracy across Lewy body and Alzheimer's disease spectra." Ann Clin Transl Neurol 11(5): 1197–1210.
2. Rizzo, G., et al. (2016). "Accuracy of clinical diagnosis of Parkinson disease: A systematic review and meta-analysis." Neurology 86(6): 566-576.
3. Rizzo, G., et al. (2018). "Accuracy of clinical diagnosis of dementia with Lewy bodies: a systematic review and meta-analysis." J Neurol Neurosurg Psychiatry 89(4): 358-366.
4. Tosun, D., et al. (2024). "A cross-sectional study of α-synuclein seed amplification assay in Alzheimer's Disease Neuroimaging Initiative: Prevalence and associations with Alzheimer's disease biomarkers and cognitive function." Alzheimers Dement 20(8): 5114–5131.
5. Wenning G.K., et al. (2022). "The Movement Disorder Society Criteria for the Diagnosis of Multiple System Atrophy." Movement Disorders 37(6): 1131-1148.