AMPRION
Navigate Your Brain Health

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PATIENT INFORMATION	ORDERING PHYSICIAN	SPECIMEN INFORMATION
Name: **Patient, Negative**	Name: **Sample Physician, MD**	Specimen ID: **ND0000002**
DOB: **02/02/2002**	Practice: **Sample Hospital**	Accession #: **20-000002**
Gender: **F**	Address: **111 1st Street**	Sample Type: **CSF**
MRN: **0000**	City, State, Zip: **San Diego, CA 92121**	Date Collected: **02/04/2021**
Other ID:	Account #: **1234567**	Date Received: **02/05/2021**

SYNTap™ Biomarker Test - CSF

Test Result:	Interpretation:
Not Detected	A "Not Detected" result indicates misfolded α-synuclein protein aggregates are not present in the CSF sample or are at levels too low to be detected by the assay.

Clinical Significance/Intended Use:

The SYNTap Biomarker Test is used to detect misfolded alpha-synuclein protein aggregates in cerebrospinal fluid (CSF) as an aid in the diagnosis of synucleinopathies associated with several neurodegenerative diseases, including primary synucleinopathies, e.g., Parkinson's Disease (PD), Dementia with Lewy Bodies (DLB), and Multiple System Atrophy (MSA), and secondary synucleinopathies, e.g., co-pathology of synucleinopathy and Alzheimer's Disease (AD).
SYNTap Test results are intended for use alongside other clinical and diagnostic findings for patient case management. Although this test highly correlates with the presence of synucleinopathies, the findings of this test cannot definitively rule-in or rule-out synucleinopathies.

Test Description:

CSF is tested by seed amplification assay (SAA). The test is based on the ability of misfolded α-synuclein (α-syn) protein aggregates present in a sample to act as seeds and induce misfolding and aggregation of monomeric, recombinant α-syn added to the sample, thereby amplifying the amount of misfolded protein aggregates to a level where they can be detected. Seeded aggregation occurs when misfolded aggregates are present in a patient sample but does not occur when there are no misfolded aggregates in a patient sample, providing a qualitative determination of the presence or absence of misfolded α-syn protein aggregates in the sample.

References:

1. Kang UJ, Boehme AK, Fairfoul G, Shahnawaz M, Ma TC, Hutten SJ, Green A, Soto C. Comparative study of cerebrospinal fluid α-synuclein seeding aggregation assays for diagnosis of Parkinson's disease. Mov Disord. 2019 Apr;34(4):536-544. doi: 10.1002/mds.27646. Epub 2019 Mar 6. PMID: 30840785; PMCID: PMC6519150.
2. Shahnawaz M, Tokuda T, Waragai M, et al. Development of a Biochemical Diagnosis of Parkinson Disease by Detection of α-Synuclein Misfolded Aggregates in Cerebrospinal Fluid. JAMA Neurol. 2017;74(2):163–172. doi:10.1001/jamaneurol.2016.4547

Report Approval	Report Date
Kendal J. Jensen, MD, PhD *This test was performed under the direction of Kendal J. Jensen, MD, PhD.*	02/12/2021

COMMENTS:

DISCLAIMER

This test was developed, and its performance characteristics determined by, Amprion Inc. It has not been cleared or approved by the US Food and Drug Administration (FDA). This test is used for clinical purposes. It should not be regarded as investigational or for research. The laboratory is regulated under CLIA as qualified to perform high-complexity testing. Performance characteristics are available upon request at Customer.Service@AmprionMe.com.