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10355 Science Center Drive, Suite 240
San Diego, CA 92121
Laboratory Director: Miriam Bloch, MD
CLIA ID # 05D2209417

Patient Report: **FINAL**

Amprion Accession #	Collection Date	Received Date	Report Date
20-50301	12/11/2020	12/15/2020	12/19/2020

Patient: **Patient, Isaac**
DOB: 02/29/1957
Sex: M
MRN: 99999999
Specimen Type: Cerebrospinal Fluid
Specimen ID: S999521

Ordering Physician: Dr. Registered Physician
Client Account: 111111
Client Name: Main Hospital
Client Address: 12345 1st Street Anytown, US, 00001
Client Telephone #: 999-258-6523

SAAmplify™-αSYN (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:** 12/19/2020

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 (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 (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 seeds, fluorescence remains below the validated assay cutoff.

Limitations:

SAAmplify–αSYN (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. Sensitivity for detection of αSyn aggregates with a Detected-2 profile is low; therefore results should be interpreted with caution for the purposes of rule in/rule out MSA.

References:

1. Rizzo, G., et al. (2016). "Accuracy of clinical diagnosis of Parkinson disease: A systematic review and meta-analysis." Neurology 86(6): 566-576.

2. 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.

3. Wenning G.K., et al. (2022). "The Movement Disorder Society Criteria for the Diagnosis of Multiple System Atrophy." Movement Disorders 37(6): 1131-1148.