AMPRION®

The SYNTap® Biomarker CSF Test is the essential piece in solving the diagnostic puzzle.

The only validated SAA for the detection of misfolded α-synuclein.

Visit AmprionDx.com

The SYNTap Biomarker CSF Test can help shorten a patient's diagnostic journey and optimize personalized treatment strategies for synuclein pathologies such as:

- Parkinson's disease
- Lewy body dementia
- AD with Lewy body dementia (AD/DLB)
- Mild cognitive impairment
- Multiple system atrophy

Parkinsonisms

Research shows up to 40% of patients clinically diagnosed with early PD do not have PD*

Neurodegenerative diseases **with Parkinsonism symptoms** but **without synuclein pathology** require different treatment/management strategies, so early differential diagnosis is **imperative**.

The SYNTap Biomarker CSF Test can help

- Distinguish PD from MSA at early stages
- Rule in/out other Parkinsonism (PSP, CBD, and vascular)

Alzheimer's

30%-50% of AD patients have Lewy body co-pathology associated with α-Syn in their brains at autopsy

α-Synuclein co-pathology is associated with **faster decline** in **cognitive function and disease progression** compared with classic AD†. And because AD/DLB isn't usually identified at the time of AD diagnosis, patients can be mismanaged when Lewy body symptoms develop.

The SYNTap Biomarker CSF Test can help

- Distinguish AD/DLB vs. classic AD at early stages
- Detect synuclein pathology at MCI stage

*Beach, T. G., & Adler, C. H. (2018). Importance of low diagnostic Accuracy for early Parkinson's disease. Movement Disorders, 33(10), 1551-1554.
†Twohig, D., & Nielsen, H. M. (2019). α-synuclein in the pathophysiology of Alzheimer's disease. Molecular neurodegeneration, 14(1), 23.

SYNTap® Biomarker CSF Test Performance Overview

Intended Use and Result Interpretation

The SYNTap Biomarker CSF Test is a first-in-class Laboratory Developed Test (LDT) for accurate and reliable detection of misfolded **aggregates of α-Synuclein** in cerebrospinal fluid (CSF). Test results are intended to aid the diagnosis of synucleinopathies such as **Parkinson's disease (PD)** and **Lewy body dementia (LBD)**. Test results may also be used at the discretion of the clinician to aid the diagnosis of **multiple system atrophy (MSA)** and **Alzheimer's disease with Lewy body dementia (AD/DLB)**. SYNTap Biomarker CSF Test results are used alongside other clinical and diagnostic findings for patient case management. A **"Detected"** result indicates the presence of misfolded **α-Synuclein protein aggregates** in the patient sample and is consistent with diagnosis of α-synucleinopathy. A **"Not Detected"** result is inconsistent with a neuropathological diagnosis of a synucleinopathy at the time of the test. MSA follows a distinct profile that is recognized and reported by the director as a comment supported by limited publication data.

Clinical and Analytical Performance

To evaluate clinical accuracy for detection of **α-Synuclein aggregates** associated with **PD**, a study was performed using 164 biospecimens (55 PD and 109 healthy controls) obtained from the Michael J. Fox Foundation, Parkinson's Progression Markers Initiative (PPMI) repository. PPMI cohort assignments are based on clinical symptoms plus dopamine transporter (DAT) SPECT imaging results. Results are summarized below.

For additional performance characteristics and research acknowledgments, refer to the complete Performance Characteristics document available for download from our website, AmprionDx.com.

Clinical Accuracy Parameter	SYNTap Test Performance	
Overall Accuracy:	93.9%	(95% CI: 0.891 – 0.970)
Sensitivity:	87.3%	(95% CI: 0.755 – 0.947)
Specificity:	97.2%	(95% CI: 0.922 – 0.994)
Positive Predictive Value:	94.1%	(95% CI: 0.838 – 0.988)
Negative Predictive Value:	93.8%	(95% CI: 0.877 – 0.975)

In other analytical performance studies, **SYNTap Biomarker CSF Test reproducibility was 95% and repeatability was 100%**. Using known quantities of commercially available recombinant human **α-Synuclein protein aggregate**, the limit of detection was estimated to be ~44 fg/mL. Interference was generally not observed when protein, bilirubin, whole blood, and hemoglobin were spiked into CSF samples at supraphysiologic concentrations.

Test Ordering & Results

- **Visit** our website to place an online order for test kits 24/7.
- **Download** the Test Requisition Form, Patient Consent Form, and ABN (when needed).
- **Send** the completed forms, along with the collected sample to Amprion's Clinical Laboratory.
- **TAT** within 15 business days.

Sample Requirements

- **Submit** a minimum of 0.5 mL CSF, collected following standard institutional practice.
- **Ship** samples either refrigerated or frozen.

Billing and Coding

To improve patient access to the SYNTap Biomarker CSF Test, Amprion offers the following billing options:

- **Affordable self-pay** price of $995.00 (financial assistance and/or interest-free payment options for qualifying patients)
- **Courtesy billing** for both Medicare and private insurance

Please note: The SYNTap Biomarker CSF Test does not currently have Medicare coverage determination and is not yet in network with most insurers.

The SYNTap Biomarker CSF Test CPT® PLA code is 0393U

For questions, please contact us at (858) 461-6338 (M - F 9 am - 5 pm PST) or Customer.Service@AmprionDx.com