

MLM Medical Labs and Amprion Announce Strategic Collaboration to Expand Access to α -Synuclein Testing in Europe

MLM and Amprion partner to expand access to breakthrough α -synuclein biomarker testing for European neurodegenerative clinical trials.

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Scott Houlton, CEO

/EINPresswire.com/ -- [MLM Medical Labs](#) (MLM), a leading global central and specialty laboratory, today announced a strategic licensing collaboration with [Amprion](#).

The collaboration focuses on expanding access to advanced α -synuclein biomarker testing for clinical trials in Europe, supporting research into neurodegenerative diseases, including Parkinson’s disease and Lewy body disease (LBD), and enabling improved characterization of patient populations in adjacent indications such as Alzheimer’s disease.

Through the agreement, Amprion will license its

proprietary seed amplification assay (SAA) methodology, the technology that powers its [SAAmplify- \$\alpha\$ SYN™](#) test, to MLM. SAAmplify- α SYN is the only commercially available CSF test that detects α -synuclein, a key biomarker in synucleinopathies such as Parkinson's disease, Lewy body dementia, multiple system atrophy (MSA), and Alzheimer's disease with Lewy body co-pathology.

Amprion operates the world’s first and only U.S.-based CAP-accredited, CLIA-certified laboratory offering the clinically validated SAAmplify- α SYN test as a Laboratory Developed Test (LDT) for clinical and research use. The assay detects misfolded α -synuclein with high sensitivity and specificity and has received Breakthrough Device Designation from the U.S. Food and Drug Administration (FDA). The FDA has also issued a Letter of Support encouraging the use of α -synuclein seed amplification assays in clinical research, underscoring its growing importance in neurodegenerative drug development.

Through this collaboration, MLM Medical Labs will serve as the dedicated European laboratory partner, validating and performing seed amplification testing to detect misfolded α -synuclein as

an IVDR-compliant LDT. As a health institution under European regulations, MLM will enable the implementation of this testing capability within an IVDR-compliant framework, making the assay accessible to sponsors conducting clinical trials in Europe.

For sponsors, this provides first-time access to α -synuclein SAA testing within Europe while enabling a single, harmonized biomarker strategy across global studies—eliminating the need for region-specific assay approaches, reducing operational complexity, accelerating study start-up, and minimizing regulatory risk.

“Expanding access to innovative biomarker technologies is critical to advancing research in neurodegenerative diseases,” said Scott Houlton, CEO of MLM Medical Labs. “This collaboration with Amprion allows us to bring a highly differentiated and scientifically validated assay to sponsors conducting clinical trials in Europe, while supporting globally harmonized study designs.”

“Neurodegenerative research is global, and access to pathology-based testing should be too,” said Russ Lebovitz, MD, PhD, CEO and co-founder of Amprion. “The demand for seed amplification testing from European researchers and biopharma sponsors is already strong. This collaboration will help identify the right patients for trials and produce richer data as we all work to better understand and treat neurodegenerative disease.”

By combining Amprion’s proprietary assay technology with MLM’s European laboratory capabilities, the collaboration addresses a key gap for sponsors seeking to incorporate α -synuclein biomarkers into multinational studies while maintaining regulatory alignment across regions. This collaboration further strengthens MLM’s capabilities in neurology and biomarker-driven clinical trials, reinforcing its position as a global partner for complex, international drug development programs.

About MLM Medical Labs

MLM Medical Labs is a global provider of end-to-end central and specialty laboratory solutions for complex clinical trials with a significant biomarker workload. With wholly owned and fully integrated laboratories in Europe, the United States, and South Africa, MLM delivers comprehensive scientific support, customized testing solutions, and seamless global logistics across all phases of drug development to biopharma sponsors worldwide.

About SAAmplify- α SYN (formerly SYNTap®)

Amprion's SAAmplify- α SYN test is a first-in-class qualitative Laboratory Developed Test and the only seed amplification assay available to aid the diagnosis of synucleinopathies such as Parkinson's disease, Lewy body dementia and Alzheimer's disease with Lewy body co-pathology. The U.S. Food and Drug Administration granted Amprion Breakthrough Device Designation in 2019 for use of the test as an aid in the diagnosis of Parkinson's disease. The test became commercially available in the United States in 2021.

About Amprion

Amprion is the global leader advancing diagnosis of neurodegenerative disorders through seed amplification testing. Amprion's intellectual property surrounding seed amplification assay methodology extends to research, drug development and commercialization. SAAmplify- α SYN is the only seed amplification assay available to aid the diagnosis of synucleinopathies such as Parkinson's disease, Lewy body dementia and Alzheimer's disease with Lewy body co-pathology. Amprion is also accelerating precision medicine for neurodegenerative disorders by helping biopharma partners identify new drug candidates and underlying pathologies.

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