

New Standard for Parkinson's Diagnostics – German Biotech Company MODAG Unveils World's First CE-Certified Test Kit

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- The PD DETECT® test kit marks the end of an era in which Parkinson's diagnostics relied primarily on observation of clinical symptoms.
- This advanced molecular analysis, previously limited to a few research centers, can now be performed directly on-site in laboratories and clinics.
- Reliable early detection and precise differentiation from similar conditions provide the crucial foundation for a new era of precision diagnostics and the development of targeted therapies.

MODAG GmbH today announced the market launch of PD DETECT®. With the world's first CE-certified test kit for Parkinson's disease, the German company is making innovative Seed Amplification Assay (SAA) technology broadly accessible as a standardized procedure for specialized diagnostic laboratories and hospitals for the first time.

Until now, the diagnosis of Parkinson's disease was primarily based on the observation of clinical symptoms, which often only become clear in advanced stages of the disease. The highly sensitive biochemical detection of pathological alpha-synuclein aggregates in cerebrospinal fluid (CSF) was restricted to a few specialized research centers. With PD DETECT®, MODAG now provides a validated system that enables medical institutions to integrate this complex analysis directly into their clinical routine on-site.

Developed in cooperation with the AESKU.GROUP, the kit contains all necessary components to precisely identify Parkinson's patients at the molecular level – with a sensitivity of 97.8% and a specificity of 100%. By providing this as a test kit, MODAG aims to decentralize cutting-edge diagnostics, making them broadly available and establishing biological certainty rather than clinical probability as the new standard in patient care.

The test addresses the urgent medical need for objective biomarkers in neurology. By specifically detecting the disease-associated "Lewy fold" conformation of α -synuclein, PD DETECT® can not only confirm Parkinson's disease but also help distinguish it from other neurodegenerative disorders.

Dr. Torsten Matthias, CEO of MODAG GmbH, commented: "The launch of PD DETECT® is a significant milestone for our company and for patient care. From the beginning, our approach has been to view diagnostics and therapy as a single unit. With this test, we are providing physicians with a tool that decisively improves diagnostic certainty. This is a fundamental requirement for identifying patients earlier and, prospectively, treating them earlier."

Prof. Dr. Johannes Levin, Chief Medical Officer at MODAG, added on the clinical relevance: "The ability to detect Parkinson's disease on a biological basis, rather than relying solely on clinical phenotypes, is a true game-changer for neurology. PD DETECT® allows us to detect the underlying pathology even before classic motor symptoms are fully developed. This is of invaluable importance for the development of new, disease-modifying therapies."

The PD DETECT® test kit is available immediately for specialized diagnostic laboratories, university clinics, and research institutions. It includes all reagents and protocols required to perform the Seed Amplification Assay (SAA). In this process, tiny, pathological protein aggregates from a patient sample are artificially amplified to make them visible and measurable using fluorescence.

About MODAG

MODAG GmbH is a privately held German biotechnology company focused on the development of disease-modifying therapeutics and diagnostics for neurodegenerative diseases. Based on a broad portfolio of patented compounds, MODAG develops innovative oligomer modulators and diagnostic tools to specifically target the causes of synucleinopathies such as Parkinson's, MSA, as well as other neurodegenerative diseases such as Alzheimer's. For more information, visit www.modag.net.

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