In vitro method for the diagnosis and stratification of MS patients

Novel protein biomarkers, measurable by ELISA for the diagnosis and stratification of MS patients

Medical Need

Multiple sclerosis (MS) is a chronic autoimmune disease of the central nervous system that causes demyelination, neurodegeneration, and inflammation. It is the leading cause of non-traumatic neurological disability in young adults. Current diagnosis is complex and error-prone, and although treatments are available, many patients continue to suffer relapses and progression. Therefore, there is a need for reliable biomarkers for early diagnosis, stratification, and prognosis.

Technology

The invention proposes an *in vitro* method and a diagnostic kit based on the quantification of protein biomarkers in biological samples (preferably serum). Six biomarkers have been identified. Techniques such as ELISA, mass spectrometry, aptamers and proximity assays are used to measure its expression. The method makes it possible to differentiate between clinical forms of MS and establish severity prognoses by correlating them with clinical scales.

Opportunity

Prevalence

It affects about 2.8 million people worldwide.

Spain: 26.6 new cases per 100,000 inhabitants each year.

Market

Global market: $33,980 million in 2029.

CAGR 3.75%.

Other solutions

There are currently no validated biomarkers, the diagnosis is made based on the McDonald criteria (updated in 2025)

Results

Discovery phase:

393 dysregulated proteins identified in MS.
Two biomarkers showed overexpression in MS.
Two biomarkers showed differential patterns between clinical subtypes.

Validation phase (ELISA):

Differential expression of 6 proteins confirmed
Cut-off values were established for diagnosis and clinical stratification.

Roadmap

IBIMA BIONAND platform is looking for a partner to further develop the technology through a co-development or licensing agreement.

Patent:
National patent application
Priority: 08/08/2025

Team:
Neuroimmunology and Neuroinflammation research group at IBIMA BIONAND Platform

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