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Field

- Multiple Sclerosis
- Diagnosis
- Prognosis

Technology

Technology Key Words

Advantages

- Early Diagnosis
- Precise Prognosis
- Treatment Response Prediction

Status

Available for licensing

Patent Status

U.S. Patent 10,487,360 (issued) U.S. Patent 10,280,465 (issued)

UMB Docket Reference

HR-2010-081

External Reference

- Multiple Sclerosis Therapeutics Market Analysis Report, 2024.
- Alvaro Martin et al. "Role of SIRT1 in autoimmune demyelination and neurodegeneration." Link
- Cosmin A. Tegla et al. "Dual role of Response gene to complement-32 in multiple sclerosis." Link
- S. Vlaicu et al. "Role of C5b-9 complement complex and response gene to complement-32 (RGC-32) in cancer." Link

DIAGNOSIS AND PROGNOSIS OF MULTIPLE **SCLEROSIS**

Summary

The patent introduces a novel method for determining whether an individual with relapsing-remitting multiple sclerosis (RRMS) will experience a relapse or respond positively to treatments. By analyzing the ratio of mRNA levels of Response Gene to Complement-32, FasL, or IL-21 to L13, the method offers a precise diagnosis and prognosis of MS. This innovation offers an early diagnosis and prediction of disease activity, filling a significant gap in the current landscape.

Market

The global multiple sclerosis (MS) therapeutics market has seen significant growth. As of 2021, the market is estimated to be worth over USD 25 billion, reflecting the increasing prevalence and awareness of the disease. MS affects millions worldwide, with the U.S. alone reporting over 500,000 cases.

The diagnosis of MS primarily relies on clinical evaluations, magnetic resonance imaging (MRI), and cerebrospinal fluid (CSF) analysis. While MRIs can show areas of inflammation and damage in the brain, they cannot specifically pinpoint MS. CSF analysis, on the other hand, looks for specific markers associated with MS but requires an invasive lumbar puncture. These methods have limitations in terms of invasiveness, specificity, and the potential for false positives or negatives.

The patented technology offers a novel approach to MS diagnosis. By analyzing the mRNA levels of specific genes, it provides a non-invasive, highly specific, and accurate method to determine the likelihood of an RRMS patient experiencing a relapse or responding positively to treatments. This method can reduce the need for more invasive tests, provide quicker results, and offer a more definitive diagnosis.

Technology

Multiple Sclerosis (MS) is a chronic neurological disorder characterized by inflammation and demyelination within the central nervous system. The clinical presentation of MS is diverse, with patients exhibiting a range of symptoms from benign to more severe forms such as relapsing-remitting, chronic progressive, or the rare fulminant course. Given this variability, there is a pressing need for precise diagnostic tools that can not only detect the disease early but also predict its potential course. The described invention offers a significant advancement in the diagnostic and therapeutic domain of neurology, specifically targeting MS.

The progression of cells through their cycle is regulated by specific cyclin-dependent kinases (CDK), their interplay with cyclins, and the modulation by CDK inhibitors (CKI). Cyclins undergo periodic fluctuations in their expression throughout the cell cycle, whereas CKIs are typically down-regulated in response to mitogenic signals. Any perturbation in these regulatory mechanisms can lead to pathological conditions, including MS.

The invention relies on the critical role of specific genes in the context of MS, notably the Response Gene to Complement-32, FasL, and IL-21. The proposed method involves

collecting a peripheral blood sample from an individual diagnosed with relapsing-remitting MS, isolating peripheral blood mononuclear cells, and quantifying specific mRNA levels within these cellsBy analyzing these molecular markers, the method can prognosticate an individual's response to standard treatments, such as glatiramer acetate or interferon-β. Such predictive capabilities are paramount in devising effective therapeutic strategies, ensuring timely and appropriate interventions.