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# Gene Expression Diagnostic For Schizophrenia And **Bipolar Disorder**

Tech ID: 28891 / UC Case 2014-924-0

#### BRIEF DESCRIPTION

Schizophrenia and Bipolar Disorder are two highly prevalent disorders in the US. Diagnosis is limited to observation of clinical symptoms, often leading to under-diagnosis or misdiagnosis. It can therefore take months to years to accurately diagnose an individual and implement an effective treatment. To address this issue, researchers at UCI have identified blood based biomarkers for schizophrenia and bipolar disorder. By determining methods for evaluating expression levels of these biomarkers, they have developed a commercial test to discriminate between normal bipolar disorder and schizophrenia patients, which will allow for more efficient diagnoses.

#### FULL DESCRIPTION

Over 2,000,000 individuals in the US are clinically diagnosed as living with schizophrenia. Over 100,000 adolescent Americans suffer from an initial episode of psychosis, such as bipolar disorder per year. Diagnosis is limited to clinical observation of symptoms by physicians or patients' reporting, causing under diagnosis and misdiagnosis that significantly delays effective treatment by months to even years. Consequently, the rate of suicides from schizophrenia and bipolar disorder is high. There are currently no FDA approved biomarkers for schizophrenia or bipolar disorder that would allow for more accurate, timely diagnoses.

The disclosed invention is a diagnostic test that can differentiate between schizophrenia, bipolar disorder, major depressive disorder, and healthy individuals. Specifically, the inventors have identified a set of blood based biomarkers that can differentiate schizophrenia, bipolar disorder, major depressive disorder and healthy individuals. These biomarkers can be used to screen, assess risk, diagnose and monitor the onset or progression of psychotic and mood disorders. The inventors have developed an algorithm to evaluate expression levels of these biomarkers in blood samples, and accurately diagnose an individual with either schizophrenia or bipolar disorder.

#### PATENT STATUS

Country	Туре	Number	Dated	Case
United States Of America	Issued Patent	11,713,486	08/01/2023	2014-924

Additional Patent Pending

## STATE OF DEVELOPMENT

A biomarker panel of between 17-30 diagnostic genes has been identified. A reliable gene expression platform, Affymetrix Exon Array, has been used to show temporal stability of the biomarker panel by comparing two different visits per each subject, showing significant correlations between each visit for gene markers in the panel.

#### CONTACT

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### OTHER INFORMATION

#### CATEGORIZED AS

- >> Medical
  - » Diagnostics

» Disease: Central **Nervous System** 

- >> Other
- » Screening
- >> Research Tools

» Nucleic Acids/DNA/RNA

Screening Assays

#### **RELATED CASES**

2014-924-0

### ADVANTAGES

§ Biomarkers consist of gene expression signatures, including specific mRNA, tRNA, rRNA and proteins that can be found in blood samples

§ Inventors have detailed methods (algorithm) for detecting and evaluating expression levels of biomarkers, allowing the diagnosis of SZ or BD

§ Effective at diagnosis specifically in younger subjects, thus earlier in the course of illness

#### **RELATED MATERIALS**

» Morgan et al (2016). Quantitative Trait Locus and Brain Expression of HLA-DPA1 Offers Evidence of Shared Immune Alterations in Psychiatric Disorders. Microarrays 5(1): 6. - 03/07/2016

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