Laguna Diagnostics Announces Publication of Peer-Reviewed Study in *Molecular Neuropsychiatry*

Study developed potential blood-based biomarkers for differential diagnosis of schizophrenia and bipolar disorder

Irvine, CA — MAY 15, 2018 -- Laguna Diagnostics, LLC, focused on development of proprietary blood-based, molecular biomarker tests for diagnosis of mental disorders and neurodegenerative diseases, announces the recent publication of a peer-reviewed study, "Exon Array Biomarkers for the Differential Diagnosis of Schizophrenia and Bipolar Disorder" in *Molecular Neuropsychiatry*. The publication is available online: www.karger.com/Article/Abstract/485800.

The Small Business Innovation Research (SBIR) program provided funding and was awarded by the National Institute of Mental Health. Ninety subjects, ranging in age from 18-45 years, enrolled in the Institutional Review Board-approved study at the University of Iowa.

The study developed potential blood-based biomarker tests for diagnosing and differentiating schizophrenia (SZ), bipolar I disorder (BD), and psychiatric control subjects (30 per group) using mRNA gene expression signatures. Subjects provided blood samples at two visits. Affymetrix exon microarray was used to profile messenger RNA expression. The patent-pending 18-gene biomarker panels, using logistic regression modeling, correctly differentiated the three groups with high accuracy (83-88%) across two clinical visits.

"We found stable trait gene panel markers for lifelong psychiatric disorders that may have diagnostic utility in younger undiagnosed patients where there is critical unmet need", stated Marquis Vawter, MA, MS, PhD, lead author and Director of the Functional Genomics Laboratory and Research Professor of Psychiatry, University of California - Irvine, School of Medicine. "Currently, there are no FDA-approved clinical diagnostic tests for psychiatric disorders. Biomarker signatures could lead to faster, more accurate diagnoses, reducing the duration of untreated psychosis, suicidality, and cognitive decline, as well as advancing understanding of shared and unique pathophysiologies of each disorder."

A validation study with replication is required for ultimate proof of utility of the differential diagnosis. Blood test results described in the study may offer molecular diagnostic support for psychiatrists' clinical evaluation with rapid, overnight laboratory test results.

Schizophrenia and Bipolar Disorder

SZ and BD are chronic, severe, and disabling brain disorders affecting approximately 1 and 2%, respectively, of the US population 18 years and older. One estimate of the direct and indirect annual costs in the US for SZ is $174 billion, and an additional $151 billion for BD. Today, diagnosis and treatment are based on patients reporting symptoms and clinical observations over months or years. Patients often do not receive timely treatment because the disorder is not correctly recognized. As a result, patients experience multiple hospitalizations and incur socioeconomic disadvantages that can last for decades. Objective biomarkers are important to help implement treatment at an early stage.[1]

[1]Cloutier M, et al: J Clin Psychiatry 2016; 77:764–771. Dilsaver SC: J Affect Disord 2011:129:79–83.

Laguna Diagnostics, LLC

Laguna Diagnostics, LLC, develops proprietary blood-based, molecular biomarker diagnostic tests for accurate diagnosis of mental disorders and neurodegenerative diseases. First products are gene expression tests to diagnose and differentiate schizophrenia and bipolar disorder from control subjects. Visit website: www.lagunadiagnostics.com.

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