Laguna Diagnostics Awarded Second U.S. Patent for Rapid Blood Tests to Differentiate Schizophrenia and Bipolar Disorder, Expanding IP Portfolio in $3B Market

Irvine, CA — [October 1, 2025] — Laguna Diagnostics, LLC, a pioneer in blood-based diagnostics for mental health, today announced it has been awarded its second U.S. patent: *"Biomarkers for Bipolar Disorder and Schizophrenia"* (U.S. Patent No. 12,404,553 B2). This patent expands the company's intellectual property portfolio with breakthrough rapid blood tests that accurately diagnose and differentiate schizophrenia and bipolar disorder—addressing a $3 billion market opportunity.

Schizophrenia and bipolar disorder affect millions of Americans but are often misdiagnosed due to overlapping symptoms and reliance on subjective assessments. Laguna's patented blood tests deliver objective results with over 90% accuracy in **Days rather than Years, ™** enabling earlier interventions, improving patient outcomes, and reducing the significant costs associated with delayed or inaccurate diagnoses.

This milestone patent strengthens Laguna's intellectual property portfolio and validates its proprietary approach to transforming the diagnosis of mental health disorders—shifting from years of subjective assessments to objective blood tests delivered in days.

Addressing a Critical Unmet Need

Currently, it takes too long for patients to receive a correct diagnosis of mental disorders. Schizophrenia and bipolar disorder affect millions of Americans and are notoriously difficult to distinguish clinically due to overlapping symptoms. Current methods, based mainly on patient self-reporting and long-term observation, often require 1–3+ years to reach a conclusion, and result in **50% misdiagnosis of schizophrenia and 70% misdiagnosis of bipolar disorder.**

Laguna's breakthrough tests differentiate these disorders with over 90% accuracy, offering results in *'Days, NOT Years™'*, and enabling earlier interventions and improved patient outcomes.

> Patient's mother's comment: "How different life would have been for my 12-year-old daughter and our family if there had been a blood test that diagnosed her with bipolar disorder. We faced nearly 30 years of uncertainty, enduring repeated misdiagnoses and experimenting with various medications that frequently worsened her symptoms. She suffered, and so did our family. These tests will be life-changing for patients and their families!"

About the Invention

The patented method represents the **only rapid blood tests** capable of diagnosing SZ or BD from psychiatrically normal individuals (NC). The method comprises:

a) Precision Biomarker Signatures determining the mRNA* gene expression level of 18 genes;
b) proceeds in a four-step process;
c) calculating the probability that a sample comes from a subject with or without SZ or BD; and
d) diagnosing the patient as SZ, BD, or NC based on results from the blood sample compared to a pre-determined cut-off.

The primary endpoint is the **area under the curve (AUC)** of the receiver operating characteristic (ROC), giving the sensitivity and specificity derived from transcript abundance. Diagnostic performance was exceptionally strong, with AUCs of 0.995 (NC vs. BD+SZ), 0.967 (NC vs. SZ), 0.987 (NC vs. BD), and 0.996 (SZ vs. BD).

Ribonucleic acid (RNA) is a polymeric molecule essential for most biological functions, either performing roles directly (non-coding RNA) or serving as the template for protein production (messenger RNA).

A Proven Track Record

This second patent builds on Laguna's first patent in 2023 (**U.S. Patent No. 11,713,486 B2**) and the **2018 peer-reviewed publication in *Molecular Neuropsychiatry*,** which first reported the discovery of 18-gene biomarker panels capable of differentiating schizophrenia, bipolar disorder, and healthy controls with 88–96% accuracy.

The company's pioneering work has been supported by two earlier **SBIR grants from the National Institute of Mental Health**, with ongoing collaborations with the University of California–Irvine, University of Iowa, and Innovative Analytics.

Executive Commentary

"This second patent further establishes Laguna Diagnostics as the leader in objective, blood-based diagnostics for mental health," said Terry W. Osborn, PhD, MBA, Co-Founder, Chief Executive Officer. "Our technology not only differentiates between bipolar disorder and schizophrenia affecting ~2 million patients annually and representing a ~$3 billion SAM but also has broad potential to diagnose and differentiate other mental illnesses, truly revolutionizing the field of psychiatry and giving physicians tools they have never had before."

About the Inventors

- Marquis (Mark) P. Vawter, MA, MS, PhD —Co-Founder, Chief Scientific Officer, Laguna Diagnostics, LLC, and Research Professor of Psychiatry and Director of the Functional Genomics Laboratory, University of California–Irvine. Dr. Vawter is an internationally recognized expert in psychiatric genomics, transcriptomics, and neurobiology of severe mental illness.
- Terry W. Osborn, PhD, MBA — Co-Founder, Chief Executive Officer, Laguna Diagnostics, LLC. Dr. Osborn earned his doctorate in Biochemistry (University of California–Riverside) and holds an MBA (Pepperdine University). Dr. Osborn is a seasoned executive with over 40 years of leadership experience in the life sciences industry, specializing in startups, corporate turnarounds, and innovation-driven growth. He is a veteran of the U.S. Army's 101st Airborne Division.

About Laguna Diagnostics

Laguna Diagnostics, LLC develops proprietary blood-based RNA gene biomarker tests for diagnosing and differentiating psychiatric disorders. Its tests, protected under two issued U.S. patents, address *one of the greatest unmet needs in healthcare: the accurate and timely diagnosis of severe mental illnesses.* By reducing the time to diagnosis from years to days, Laguna is poised to transform clinical psychiatry, patient care, and healthcare economics.

Laguna Diagnostics is raising seed funding to support the validation of CAP/CLIA Laboratory Developed Tests (in collaboration with our lab partner), strategic hires, and initiate our FDA clinical validation trial for FDA approval.

For more information, visit: www.lagunadiagnostics.com

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