FOR IMMEDIATE RELEASE

U.S. FDA Grants Breakthrough Device Designation to Laguna Diagnostics' mRNA Gene Biomarker Test to Aid in Differentiation of Schizophrenia and Bipolar I Disorder

Irvine, CA — [April 28, 2026] — Laguna Diagnostics, LLC today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device Designation to the company's mRNA Gene Biomarker Test, a novel blood-based test designed to aid in the differentiation of schizophrenia and bipolar I disorder in symptomatic patients.

Schizophrenia and bipolar disorder affect millions of Americans, yet current diagnostic methods rely heavily on subjective assessments, long-term observation, and patient self-reporting. Research suggests misdiagnosis rates may exceed 50%[1], and current methods often require 1–3+ years to reach a conclusion.

The designation highlights the potential of Laguna's approach to address a longstanding challenge in psychiatry, where diagnosis often relies on subjective assessment, extended observation, and patient-reported symptoms—frequently resulting in delayed or uncertain diagnoses.

Laguna's test uses mRNA biomarker signatures derived from a simple venous blood sample to generate an objective probability score that may help distinguish between schizophrenia and bipolar I disorder. The test is intended for use in conjunction with clinical assessment and other patient information and is not a standalone diagnostic.

As part of the FDA Breakthrough Device process, Laguna was asked to reanalyze its pivotal study data with suggested modifications and a locked diagnostic algorithm. The results demonstrated 96.7% sensitivity for schizophrenia, 100% specificity for bipolar I disorder, and 98.3% overall accuracy. These findings indicate a highly discriminative biological signal and support the test's potential to provide clinically meaningful insights in cases where the differential diagnosis includes both conditions. With the test demonstrating high levels of sensitivity and specificity, it further supporting its potential clinical utility.

Addressing an Urgent Clinical Need

Schizophrenia and bipolar I disorder are serious and often debilitating psychiatric conditions that affect millions of individuals in the United States. Differentiating between the two can be complex, with diagnostic timelines frequently extending months or years. Earlier and more objective tools could help clinicians make more informed decisions and reduce the burden on patients and families.

Breakthrough Device Designation

The FDA Breakthrough Devices Program is designed to accelerate the development and review of technologies that may offer more effective diagnosis or treatment of life-threatening or irreversibly debilitating conditions. The designation provides enhanced interaction with the FDA and prioritized review as the technology advances through the regulatory process.

Importantly, Breakthrough Device Designation does not change the FDA's standards for safety and effectiveness, nor does it guarantee marketing approval. Laguna is currently advancing its technology through further clinical validation studies, with continued engagement with the FDA under the Breakthrough Device program.

Leadership Commentary

"This designation is an important milestone in our mission to bring objective, biology-based, blood-based mRNA biomarker tools with a strong biological rationale into psychiatric care," said Terry W. Osborn, PhD, MBA, Co-Founder and Chief Executive Officer of Laguna Diagnostics. "We believe our approach has the potential to support clinicians in making more informed diagnostic decisions and, ultimately, improve outcomes for patients."

About Laguna Diagnostics

Laguna Diagnostics, LLC is focused on developing rapid, objective, blood-based mRNA biomarker tests to improve the diagnosis and differentiation of psychiatric disorders. This breakthrough in vitro diagnostic represents a novel blood-based mRNA biomarker approach supported by a clearly articulated biological rationale for the objective assessment of mental illnesses.

The company's precision psychiatry platform is designed to deliver objective, data-driven insights that support clinical decision-making and improve patient care. 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 is currently raising funding to support CAP/CLIA validation, strategic hires, and initiation of its clinical validation trial with FDA study design support.

For more information, visit: www.lagunadiagnostics.com

Media Contact:
Terry W. Osborn, PhD, MBA
Co-Founder & CEO
osbornt@lagunadiagnostics.com | 847-778-0522

References

[1] Ayano, G. (2021). *Schizophrenia: A concise overview of etiology, epidemiology, diagnosis, and management.*
Hirschfeld, R.M.A., et al. (2003). *Perceptions and impact of bipolar disorder: How far have we really come? Results of the National Depressive and Manic-Depressive Association 2000 survey of individuals with bipolar disorder.*