



Positive Clinical Results for Bluejay's Symphony IL-6 Test Presented at AACC 2022

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Demonstrated 98% NPV¹ to Identify COVID-19 Patients at Risk for Severe Illness

Study Data Indicate Symphony IL-6 Test Could be a Rapid and Precise Diagnostic Platform for Near-Patient Management of Critical Care

ACTON, Mass., July 27, 2022 (GLOBE NEWSWIRE) -- Bluejay Diagnostics, Inc. (NASDAQ: BJDJX) ("Bluejay" or the "Company"), a medical diagnostics company focused on developing cost-effective, rapid, near-patient tests for triage and monitoring of disease progression, today announced that **positive results of analytical and clinical studies of Bluejay's Symphony IL-6 Test were presented at AACC 2022, the leading industry conference for clinical laboratory medicine.**

The presentation, **Evaluation of a new, Near-Patient Testing (NPT) IL-6 Assay on Symphony Immunoanalyzer** (K. Jaleta, et al, [AACC Poster B-204](#)), presented by investigators from the University of Texas Southwestern (UTSW) Medical Center in Dallas Texas, found the analytical and clinical performance of the Symphony IL-6 Test ("the Symphony IL-6 NPT") is comparable to the Emergency Use Authorization (EUA)-approved Roche Elecsys® IL-6 assay² ("the Roche Test"). It is mentioned in the presentation that "Dysregulated interleukin-6 (IL-6) levels underlie several pathological conditions, such as sepsis, progression of cancer, rheumatoid arthritis, and many other conditions. Prior studies indicate that high levels of IL-6 serve as an early indication of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)-induced hyperinflammation, disease severity, and multiorgan failure."

Results from the analytical and clinical studies conclude that the Symphony IL-6 Test is an innovative technology for use in Emergency Department and Intensive Care Unit settings to identify COVID-19 patients at higher risk for severe disease, including the requirement for Invasive Mechanical Ventilation (IMV). This conclusion is based on the study results and the unique characteristics of the Symphony IL-6 NPT, relative to much larger, more expensive lab analyzers. Key differentiators noted by the authors include faster turn-around time (< 20 minutes), ease of use (tested directly from whole blood, without need for significant laboratory infrastructure) and analytical precision, as noted below.

Key Study Highlights:

- **Clinical Performance (NPV)³: The Symphony IL-6 NPT demonstrated a 98% Negative Predictive Value (NPV)**, notably better than devices currently granted EUA by the Food and Drug Administration (FDA) for "clinical use" whose NPVs were recorded as 78.6%, 86%, and 92.9%. The 98% NPV indicates the usefulness of the test in ruling out the risk of severe disease, including the risk of IMV, in patients with COVID-19.
- **Clinical Performance (Sensitivity and Specificity)⁴**: An evaluation of 147 COVID-19 patient samples, including 18 IMV patients, found the Clinical Sensitivity and Specificity of the Symphony IL-6 Test were slightly better but comparable, based on **Sensitivity and Specificity for the Symphony IL-6 NPT of 89% and 64%, respectively**, to other devices currently permitted to be used clinically (granted EUA by the FDA).
- **Analytical Performance**: Results of an evaluation of 152 COVID-19 patient samples tested with the Symphony IL-6 NPT (using whole blood) and the Roche Test (using plasma) showed **an excellent correlation between two test methods (r=0.9490)^{5,6}**. The authors also report that the analytical precision of the Symphony IL-6 NPT was acceptable, with less than 15% imprecision.

Neil Dey, Chief Executive Officer, said, "Bluejay is very pleased that the results of the Symphony IL-6 testing program are being presented at AACC 2022 by our collaborators from the UTSW Medical Center. The result of the independent study establishes the credibility of the Symphony IL-6 NPT in the critical care community."

Mr. Dey concluded, "Bluejay is excited to be developing a potential solution to meet the market need for a rapid, reliable, cost-effective, near-patient tool to measure IL-6 levels using whole blood. We believe the Symphony technology will provide medical professionals the ability to make more timely decisions in determining the most effective treatment regimen in critical care."

Bluejay plans to host a Key Opinion Leader (KOL) event during Summer 2022 to provide a detailed review of the Symphony IL-6 Test data presented at AACC and to discuss the importance of rapidly measuring IL-6 levels in near-patient, critical care settings.

Notes:

1. *Negative Predictive Value: <https://geekymedics.com/sensitivity-specificity-ppv-and-npv/>*
2. *The words "assay" and "test" are used interchangeably in this document*
3. *Prevalence of disease severity reported in the presentation was 12% for the Symphony IL-6 NPT cohort*
4. *Analysis of Clinical Performance was based on the respective cut-off data for the assays*
5. *This statement refers to the Method Comparison analysis reported in the AACC presentation*
6. *"r" refers to the [Coefficient of correlation](#), where possible values range from -1 to +1*

About the Symphony™ System and the Symphony IL-6 Test:

Bluejay's Symphony System is designed to address the need for simple, reliable, rapid, near-patient testing by providing quantitative measurements of specific biomarkers to determine the need for additional patient care and monitoring. The user-friendly system will not require any sample preparation or dedicated staff and was shown in published clinical studies to deliver results in less than 20 minutes.

The Symphony IL-6 Test is a development stage product candidate for investigational use only. It is limited by United States law to investigational use.

About Bluejay Diagnostics:

Bluejay Diagnostics, Inc. is a medical diagnostics company focused on improving patient outcomes using its Symphony System, a cost-effective, rapid, near-patient testing system for triage and monitoring of disease progression. Bluejay's first product candidate, an IL-6 Test for sepsis triage, is designed to provide accurate, reliable results in less than 20 minutes from 'sample-to-result' to help medical professionals make earlier and better triage/treatment decisions. More information is available at www.bluejaydx.com.

Forward-Looking Statements:

This press release contains statements that the Company believes are "forward-looking statements" within the meaning of the Private Litigation Reform Act. Forward-looking statements in this press release include, without limitation, the ability of the Company to submit a marketing application with the FDA in the fourth quarter of 2022 and whether the Company's cash position will be sufficient to fund operations beyond the date of its anticipated regulatory approval and initial commercialization of the Symphony IL-6 Test. Forward-looking statements may be identified by words such as "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "seeks," "should," "suggest," "will," and similar expressions. The Company has based these forward-looking statements on its current expectations and projections about future events, nevertheless, actual results or events could differ materially from the plans, intentions and expectations disclosed in, or implied by, the forward-looking statements the Company makes. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors, including those discussed under item 1A. "Risk Factors" in our most recently filed Form 10-K filed with the Securities and Exchange Commission ("SEC"), as updated by the Company's subsequent Quarterly Reports on Form 10-Q. You should not place undue reliance on these statements, as they are subject to risks and uncertainties, and actual results and performance in future periods may be materially different from any future results or performance suggested by the forward-looking statements in this release. This press release speaks as of the date indicated above. The Company undertakes no obligation to update any forward-looking statements, whether as a result of new information, future events, or otherwise. The Company expressly disclaims any obligation to update or revise any forward-looking statements found herein to reflect any changes in the Company's expectations of results or any change in events.

Investor Contact:

Alexandra Schuman

LifeSci Advisors

alex@lifesciadvisors.com

t: 646-876-3647