



Adaptive Biotechnologies Launches T-Detect™ Lyme, A New T-Cell Clinical Test for the Detection of Early Lyme Disease

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T-Detect Lyme enables patients and healthcare providers to detect early Lyme disease with greater sensitivity than leading antibody tests

SEATTLE, June 15, 2022 (GLOBE NEWSWIRE) -- Adaptive Biotechnologies Corporation (Nasdaq: ADPT), a commercial stage biotechnology company that aims to translate the genetics of the adaptive immune system into clinical products to diagnose and treat disease, today announced the launch of T-Detect™ Lyme. This is the company's second test to be made available from its growing T-Detect franchise. The T-Detect test detects an immune response by leveraging the body's unique T-cell response to disease-associated antigens. T-Detect Lyme identifies T cells activated by *Borrelia burgdorferi*, the bacterium that causes Lyme disease, to help diagnose early Lyme disease.

T-Detect Lyme, administered as a simple blood test, is intended to aid in the diagnosis of early Lyme disease in adult patients demonstrating signs and symptoms. These symptoms include, but are not limited to, the presence of an Erythema migrans (EM) rash, fever, chills, headache, fatigue, muscle and joint aches, and swollen lymph nodes.

"The T-Detect franchise leverages the immune system's natural abilities and the exquisite specificity of T cells to detect disease early. The availability of T-Detect Lyme may help shorten the time to accurate diagnosis for patients with early Lyme disease. Also, the addition of T-Detect Lyme will support scaling clinical operations to enable our growing T-Detect portfolio, including testing in autoimmune disorders with high unmet need," said Sharon Benzeno, Ph.D., chief commercial officer, immune medicine, Adaptive Biotechnologies. "T-Detect Lyme has demonstrated greater sensitivity than serology in early Lyme disease and may aid in the early diagnosis of up to two times more cases that may be missed by traditional serology testing. We aim to further improve the test sensitivity over time using new data sets from additional individuals to be able to help more patients."

In the U.S., Lyme disease is the most common tick-borne illness, with approximately half a million newly infected people per year.¹ An early diagnosis of Lyme disease facilitates treatment initiation to stop disease progression. However, today's standard antibody tests may miss up to 75% of Lyme disease cases in the acute, or early, phase of infection.²

In a clinical validation study among patients with early Lyme disease, the T-cell test was more accurate than leading antibody tests.³ T-Detect Lyme has a specificity of ~99% and showed more than 1.5 times greater sensitivity than standard two-tiered testing (STTT) in patients who presented with a bullseye rash (54% vs 30%, respectively).³ In a separate study, T-Detect Lyme showed three times greater sensitivity than STTT in the first four days after symptoms appeared (44% vs 14%, respectively).⁴

"Lyme disease is a particularly burdensome illness, and the areas where Lyme disease is common are expanding," said Dr. Shari Rozen, a doctor at Preferred Primary Care Physicians of Pittsburgh, and investigator for the ImmuneSense™ Lyme Study. "The development of antibodies takes time; however, the majority of serologic tests are requested in the early stages of infection, when STTT sensitivity is lower. A T-cell test can improve upon existing options for patients and healthcare providers by measuring a different aspect of the immune response, the T cell, which can arise earlier than antibodies to help identify recent infections."

T-Detect Lyme is the latest application of Adaptive's immune medicine platform, which uses Adaptive's TCR sequencing capabilities and Microsoft's cloud-scale AI to characterize the T-cell repertoire and identify a clinical signal for disease. Adaptive is applying this approach to enable earlier and more accurate diagnosis of many infectious diseases and autoimmune disorders. In early 2021, Adaptive Biotechnologies received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for the first diagnostic application of the platform, T-Detect COVID, which has been used by over 30,000 patients to confirm recent or prior SARS-CoV-2 infection.

T-Detect Lyme is available to patients with a prescription through a qualified healthcare professional as a Clinical Laboratory Improvement Amendments (CLIA) laboratory-developed test (LDT) service. Healthcare professionals interested in learning more about T-Detect Lyme or ordering it for their patients can contact T-DetectInquiries@adaptivebiotech.com or call 833-833-8328.

About T-Detect™

T-Detect™ is a clinical test from Adaptive Biotechnologies that uses the power of T cells to give us information about a person's adaptive immune response. [T-Detect COVID](#), the first-ever T cell-based clinical test to receive FDA emergency use authorization (EUA), can determine whether a person has had a recent or prior adaptive immune response to SARS-CoV-2. [T-Detect Lyme](#), available as a CLIA-validated LDT, is intended to aid in the diagnosis of early Lyme disease.

COVID-19 and Lyme disease are the first of many potential diseases Adaptive hopes to detect by looking at the T-cell response. It's our goal to use future versions of T-Detect to help diagnose many different illnesses, translating the natural diagnostic capability of T cells into clinical practice. In 2018, Adaptive and Microsoft partnered to build a map of the immune system called the TCR-Antigen Map. This approach uses immunosequencing, proprietary computational modeling, and machine learning to map T-cell receptor sequences to disease-associated antigens for infectious diseases and autoimmune disorders. From a simple blood draw, T-Detect aims to leverage the map to enable early disease diagnosis, disease monitoring, and critical insights into immunity.

About Adaptive Biotechnologies

Adaptive Biotechnologies is a commercial-stage biotechnology company focused on harnessing the inherent biology of the adaptive immune system to transform the diagnosis and treatment of disease. We believe the adaptive immune system is nature's most finely tuned diagnostic and therapeutic for most diseases, but the inability to decode it has prevented the medical community from fully leveraging its capabilities. Our proprietary immune

medicine platform reveals and translates the massive genetics of the adaptive immune system with scale, precision and speed to develop products in our Immune Medicine and Minimal Residual Disease (MRD) businesses. We have three commercial products and a robust clinical pipeline to diagnose, monitor and enable the treatment of diseases such as cancer, autoimmune conditions and infectious diseases. For more information, please visit adaptivebiotech.com and follow us on www.twitter.com/adaptivebiotech.

Forward Looking Statements

This press release contains forward-looking statements that are based on management's beliefs and assumptions and on information currently available to management. All statements contained in this release other than statements of historical fact are forward-looking statements, including statements regarding our ability to develop, commercialize and achieve market acceptance of our current and planned products and services, our research and development efforts, and other matters regarding our business strategies, use of capital, results of operations and financial position, and plans and objectives for future operations, including forward-looking statements contained in this press release or elsewhere related to products in the T-Detect franchise and their respective abilities to diagnose or detect diseases such as Lyme disease or recent or prior COVID-19 infection, as well as the potential application of T-Detect franchise products to additional disease states.

In some cases, you can identify forward-looking statements by the words "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements involve risks, uncertainties and other factors that may cause actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. These risks, uncertainties and other factors are described under "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in the documents we file with the Securities and Exchange Commission from time to time. We caution you that forward-looking statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. As a result, the forward-looking statements may not prove to be accurate. The forward-looking statements in this press release represent our views as of the date hereof. We undertake no obligation to update any forward-looking statements for any reason, except as required by law.

References

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3. Data on file. Adaptive Biotechnologies. 2022.
4. Greissl J, et al. Immunosequencing of the T-cell receptor repertoire reveals signatures specific for diagnosis and characterization of early Lyme disease. medRxiv. 2021 Aug 2. doi:10.1101/2021.07.30.21281353.

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