Advaite Deploys COVID-19 Rapid Antibody Test Kits To Chester County And Collaborates With Pennsylvania Companies To Scale Up Manufacturing

Company's diagnostic testing kit "Advaite RapCov™" offers the promise of a convenient and rapid solution for screening large populations for coronavirus (COVID-19)

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Advaite Inc. →
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CHESTER SPRINGS, Pa., April 7, 2020 /PRNewswire/ -- Advaite, an innovative biotech company focused on developing novel diagnostics, announced today that it has delivered antibody rapid test kits to Chester County Health Department. Advaite established a collaboration with several other Pennsylvania-based companies with the intention to accelerate the commercialization and distribution of Advaite's COVID-19 rapid antibody test kits, RapCov™, to support the nation's effort to contain the spread of coronavirus infection.

Advaite has worked to optimize its diagnostic reagent technology in developing its novel COVID-19 Rapid Antibody test kits. The RapCov Rapid COVID-19 Test is an in vitro diagnostic test for the qualitative detection of IgG or IgM antibodies to the COVID-19 virus in human whole blood fingerstick samples collected in CLIA certified laboratories and/or by healthcare workers at the point-of-care. Further, the test can show results in as early as 15-minutes, without the need to send blood specimens to a laboratory. This makes the RapCov™ Rapid Antibody test kits an ideal solution for quickly screening large populations.

Serological tests, such as RapCov™ Rapid COVID-19 Test, provide valuable information regarding the body's immune response to the presence of the COVID-19 virus. IgM antibodies appear in the blood as the initial immune response to the COVID-19 virus infection within the first week after symptom onset, therefore the presence of IgM antibodies suggests a recent COVID-19 infection. IgG antibodies appear in the blood after the first week of the disease and IgG antibody titers remain elevated as immunological memory, therefore, the presence of IgG antibodies suggest a non-recent (past) COVID-19 virus infection. If IgG antibodies are present, the patient may be immune to infection with COVID-19 virus. Individuals with immunity to COVID-19 may be able return to the workforce. Serosurveys may also help to determine the rate of infection in a community, which is essential to accurately determine the infection fatality rate and plan public health related interventions. While serological assays are not well suited to detect acute infections, they support a number of highly relevant public health and medical applications.

The other Pennsylvania based companies, Frontida BioPharm Inc., Frontage Laboratories Inc., and another local biotech have joined forces with Advaite to expeditiously facilitate availability of Advaite's RapCov™ kits throughout the United States. Frontida, a Philadelphia based pharmaceutical manufacturing company, collaborates with Advaite as its manufacturing partner for the mass production of the RapCov™ diagnostic kits. Within the next 4-6 weeks, Frontida is targeting a production scale of 40,000 to 60,000 RapCov™ tests per day to meet the unprecedented demand resulting from the coronavirus pandemic and will be hiring additional staff to meet this demand.

Frontage Laboratories, based in Exton, Pennsylvania is one of the region's leading biopharmaceutical laboratories and will provide its expertise to develop and validate necessary bioassays to support the release of reagents which are a critical component of the testing kits.

"The ADVAITE RapCov™ kit represents a significant public health resource in helping contain the spread of coronavirus disease. The combined expertise of Frontida and Frontage creates a more efficient pathway for Advaite to produce these kits rapidly. This will in turn provide healthcare workers a powerful tool for assessment of the attack rate and extent of COVID19 outbreak in their communities," said Karthik Musunuri, Chief Executive Officer of Advaite. “We are excited to join forces with Advaite and Frontage to provide this critical testing platform as one tool supporting our nation’s efforts in fighting the COVID-19 pandemic. Utilizing our team’s manufacturing and supply chain expertise, Frontida is committed to support Advaite’s commercialization and deployment of the RapCov™ kit to healthcare and government organizations in Pennsylvania and throughout the nation” said Ron Connolly, Executive Vice President and Cofounder of Frontida.

Speaking on behalf of the Chester County Board of Commissioners and the Chester County Health Department, Commissioners' Chair Marian Moskowitz said, "Chester County's is fighting the coronavirus crisis on many different fronts and undertaking the antibody blood test for our essential personnel is another weapon in that fight. We chose to work with Advaite because our evaluations showed that the company's test kits performed most efficiently and accurately. The fact that Advaite is part of the Chester County business community is a real bonus."

"When I learned of the tests from a conversation with Karthik Musunuri and saw how it would fit into the continuum of COVID-19 testing in Chester County, I spoke to the Chair of the Chester County Commissioners, Marian Moskowitz, to look into its value in achieving the testing's protocol. It did, and the county proceeded to order the test kits," said PA State Senator Andrew Dinniman.

About Advaite

ADVAITE Inc. is a biotech company focused on developing novel diagnostics and therapeutics to help patients suffering from a variety of debilitating diseases. The word 'Advaite' means 'one without a second', unrivaled or unique. At ADVAITE, we aspire to be just that. ADVAITE operates from two locations, Chester Springs, PA and Chicago, IL.

About Frontida

Frontida BioPharm, Inc. is a Contract Development and Manufacturing Organization for pharmaceuticals and drug diagnostics with facilities equipped to produce over 3 billion immediate and controlled release tablets and capsules annually. With its innovative and quality-oriented team, Frontida's primary goal is to provide life-saving medicines and diagnostic tools that can improve the lives of patients who receive them. Frontida operates facilities in Philadelphia, PA and Aurora, IL.

About Frontage

Frontage is a Contract Research Organization providing integrated, science-driven, product development services throughout the drug discovery and development process to enable life science companies to achieve their drug development goals. Frontage has enabled many innovator, generic and consumer health companies of all sizes to file regulatory submissions in global markets allowing for successful development of important therapies and products for patients.

About the Advaite RapCov™ Rapid COVID-19 Test

The Advaite RapCov™ Rapid COVID-19 antibody test kit was developed in collaboration with Dr.Jun Xing, Windsor, Canada using a proprietary technology (US IP pending). The COVID-19 rapid response test utilizes immunochromatography technique for presumptive detection of anti-COVID-19 IgM and IgG antibodies in their specific bands and verifies the validity of the test with a third control band. Based on the presence or absence of IgM and IgG antibody bands, the COVID-19 rapid response test may provide presumptive differentiation between recent and past infections. In a preliminary clinical performance study, the Advaite RapCov™ diagnostic test demonstrated accuracy of over 94% in blood samples obtained from COVID-19 infected patients.

Disclaimers: This test has not been reviewed by the FDA. FDA review for Emergency Use Authorization (EUA) for the RapCov Rapid COVID-19 Test is in progress (EUA # PEUA200048). Positive results are presumptive and must be confirmed by virus isolation or viral nucleic acid detection by RT-PCR for confirmation of COVID-19 virus infection. Positive results may be due to past or present infection with non-COVID-19 virus strains, such as coronavirus HKU1, NL63, OC43, or 229E. Negative results do not rule out COVID-19 infection, particularly in those who have been in contact with the virus. Results from antibody testing should not be used as the sole basis to diagnose or exclude COVID-19 virus infection or to inform infection status.

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