BD, BioMedomics Announce Launch of Rapid Serology Test to Detect Exposure to COVID-19

Point-of-care blood test detects evidence of present or past exposure in 15 minutes

FRANKLIN LAKES, N.J. and MORRISVILLE, N.C., March 31, 2020 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, and BioMedomics, a privately held, North Carolina-based clinical diagnostics company, today announced the release of a new point-of-care test that can detect antibodies in blood to confirm current or past exposure to COVID-19 in as little as 15 minutes.

The new test, developed and manufactured by BioMedomics, will be available through BD and distributed exclusively by Henry Schein, Inc. to health care providers throughout the United States.

The test does not require special equipment and may be used in a laboratory or at the point of care. The test detects antibodies in the blood that are produced by the body in response to coronavirus infection. These antibodies are typically present in the middle to later stages of COVID-19 infection, but may remain present after exposure, which helps clinicians determine who has been exposed to the coronavirus, even if a person didn't exhibit any symptoms of the COVID-19 disease. Data on past exposure is important for researchers to more accurately understand the likely true occurrence of SARS-CoV-2 infection across a population. This information will be helpful in informing future strategies for combatting COVID-19.

"Serology tests are important because they provide an additional piece of information to aid in characterizing possible prior exposure to SARS-CoV-2, especially since many infections are mild or asymptomatic in severity," said Dave Hickey, president of Integrated Diagnostic Solutions for BD. "Initial evidence suggests that nearly all patients infected with SARS-CoV-2 will have developed a detectable antibody response within days of symptom onset, at which time a negative serologic test, along with molecular diagnostics, could be helpful in ruling out COVID-19. Our agreement with BioMedomics adds a rapid serology test that can augment current tests already on the market, and we are pleased to collaborate in this effort with Henry Schein, which has extensive knowledge of the point-of-care test field."

The test is completed in four, simple steps. First, blood is collected through normal blood collection devices such as the BD Microtainer® Contact-Activated Lancet. A few drops of blood are then transferred to the test cartridge, followed by two to three drops of a buffer. The results can be read in 15 minutes, similar to how over-the-counter pregnancy tests show multiple lines for positive results and a single line for negative results.

"BioMedomics designed the test to be easy to use and provide results in minutes, with no special equipment necessary or the need to transport the sample to a laboratory for analysis," said Frank Wang, CEO of BioMedomics. "Our test has been clinically validated at several hospitals and clinical laboratories in both the U.S. and China, and our published clinical data in the *Journal of Medical Virology* was one of the world's first for a COVID-19 serology test. It has been used widely in China during the COVID-19 outbreak and is now ready to help combat coronavirus in the U.S. through our collaboration with BD. We are committed to doing our part to battle this disease and are excited to have BD as a partner to help deliver our high-quality rapid test to those who need it most."

The test analyzes blood, serum or plasma samples for the presence of immunoglobulin M (IgM) and Immunoglobulin G (IgG) antibodies associated with the coronavirus (SARS-CoV-2). IgM provides the first line of defense during viral infections, followed by the generation of adaptive, high-affinity IgG responses for long-term immunity and immunological memory. The detection of COVID-19 IgM antibodies tends to indicate a recent exposure to COVID-19, and detection of COVID-19 IgG antibodies indicates a later stage of infection, so this combined antibody test could also provide information on the stage of the disease in patients. Current guidance from the U.S. Food and Drug Administration (FDA) recommends that results from antibody testing should not be used as the sole basis to diagnose or exclude coronavirus infection. Depending on the clinical scenario, additional testing, such as those used on the BD MAX™ System may be considered to further evaluate the possibility of SARS-CoV-2 infection.

"We look forward to working with such an outstanding company as BD to help make the antibody test part of the standard of care," said Stanley M. Bergman, Henry Schein's chairman of the board and chief executive officer. "The test will help to identify people who have developed antibodies to the virus, which may inform future strategies regarding COVID-19."

The test has not been reviewed by the FDA but is permitted for distribution and use under the public health emergency guidance issued by FDA on March 16, 2020, and BD expects to begin shipping tests in April. BD will have capacity to supply more than one million tests over the coming months, with the ability to scale up based on market demand and is working with medical products distribution company Henry Schein to make these tests available to medical care facilities throughout the United States. Health care providers can order the test and all collection devices needed to perform the test by contacting their

BD or Henry Schein representatives.

About BD
BD is one of the largest global medical technology companies in the world and is advancing the world of health by improving medical discovery, diagnostics and the delivery of care. The company supports the heroes on the frontlines of health care by developing innovative technology, services and solutions that help advance both clinical therapy for patients and clinical process for health care providers. BD and its 65,000 employees have a passion and commitment to help enhance the safety and efficiency of clinicians' care delivery process, enable laboratory scientists to accurately detect disease and advance researchers' capabilities to develop the next generation of diagnostics and therapeutics. BD has a presence in virtually every country and partners with organizations around the world to address some of the most challenging global health issues. By working in close collaboration with customers, BD can help enhance outcomes, lower costs, increase efficiencies, improve safety and expand access to health care. For more information on BD, please visit bd.com.

About BioMedomics
BioMedomics is a point-of-care diagnostics company that aims to provide novel, rapid point-of-care tests to aid in the diagnosis of critical diseases. The company uses cutting-edge technology to create life-saving diagnostic solutions and address global health care needs. Its diagnostic tests produce rapid and accurate clinical results at the point-of-care without requiring complex and expensive lab equipment — placing immediate health care knowledge in the hands of providers. With that knowledge comes the power to make treatment decisions and save lives. Please visit biomedomics.com for more information.

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