BD Receives Emergency Use Authorization for Asymptomatic Screening for SARS-CoV-2 through Serial Rapid Antigen Testing

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BD Veritor™ Plus System supports return-to-school and return-to-work programs through serial testing

FRANKLIN LAKES, N.J., April 1, 2021 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced the U.S. Food and Drug Administration (FDA) has granted Emergency Use Authorization (EUA) for its rapid antigen test to be used for SARS-CoV-2 screening through serial testing of asymptomatic individuals.

Articles and studies in multiple peer-reviewed publications including the *New England Journal of Medicine*[1] and the *British Medical Journal*[2] have touted the benefits of serial, rapid antigen testing. In addition, a recent landmark RADx-funded study demonstrated that the serial use of diagnostic tests (at least twice per week), including rapid antigen tests, increased the ability to detect infection[3]. The BD Veritor™ Plus System supports this approach in everyday locations such as schools and businesses, along with serial testing in other situations, such as athletes and teams to ensure safe games and competitions.

The EUA for the BD Veritor™ Plus System includes SARS-CoV-2 screening through serial testing of asymptomatic individuals when tested twice over two or three days with at least 24 hours and no more than 48 hours between tests. Serial testing on the BD Veritor™ Plus System can be performed in any setting with a CLIA certificate of waiver.

"BD is supporting the global efforts to return to normalcy as soon as possible, and this additional authorization for the BD Veritor™ System to be used in screening through serial testing of asymptomatic individuals is a large step forward," said Dave Hickey, president of Life Sciences for BD. "Frequent testing of individuals without symptoms will enable those with negative results to resume their normal school or work routines and will help to identify and isolate positive cases of COVID-19 as early as possible to prevent further spread. Screening through serial testing is an important part of any back-to-school or back-to-work program, along with additional measures such as mask wearing and social distancing."

Serial COVID-19 testing in everyday settings presents challenges in managing test subject demographics and reporting results to public health authorities. To assist with this reporting in a mass testing program, BD recently announced a collaboration with ImageMover to provide a companion mobile app that enables organizations performing point-of-care testing to efficiently capture required demographic details of those being tested, upload COVID-19 test results, report results to appropriate stakeholders and automate reporting to public health agencies. This enables compliance with reporting requirements and significantly reduces manual documentation.

About BD Veritor™ Plus System for Rapid Detection of SARS-CoV-2
The BD Veritor™ Plus System for Rapid Detection of SARS-CoV-2 is intended for the qualitative detection of SARS-CoV-2 nucleocapsid antigens in direct anterior nasal swabs from individuals who are either suspected of COVID-19 by their health care provider within the first five days of the onset of symptoms, or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours and no more than 48 hours between tests. This product has not been FDA cleared or approved; but has been authorized by FDA under an EUA for use by authorized laboratories. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. This product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner. For more information, please see bdveritor.com.

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 70,000 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 or connect with us on LinkedIn at www.linkedin.com/company/bd1/ and Twitter @BDandCo.

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[1] New England Journal of Medicine. November 26, 2020; 383:e120. DOI: 10.1056/NEJMp2025631

[2] BMJ 2021;372:n208

[3] https://www.medrxiv.org/content/10.1101/2021.03.19.21253964v2.full.pdf

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