BD Announces Assay for Identification of COVID-19 Patients at Increased Relative Risks of Intubation with Mechanical Ventilation, Mortality at Hospital Admission Now Available in Europe

In conjunction with clinical findings and the results of other laboratory testing, BD Multitest™ 6-Color TBNK Reagent with BD Trucount™ Tubes may help clinicians determine the risks of Intubation with Mechanical Ventilation and also of mortality in COVID-19 patients, aiding in patient management decisions

EYSINS, Switzerland, (Feb. 3, 2021) – BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced the CE mark of **BD Multitest™ 6-Color TBNK Reagent with BD Trucount™ Tubes** with expanded clinical application to help clinicians identify COVID-19 patients at increased relative risk of intubation with mechanical ventilation (IMV) and mortality at hospital admission, in conjunction with clinical findings and the results of other laboratory testing. By providing deeper understanding of immune responses, clinicians can better understand an appropriate course of action for patients while also prioritizing the use of precious hospital resources.

As an industry leader in immunology research and clinical care, BD tools were utilized for research early in the pandemic and early publications showed that the **BD Multitest™ 6-Color TBNK Reagent with Trucount™ Tubes** was useful in assessing immune status for COVID-19 patients. Further clinical studies have demonstrated clinically validated cut-off levels and further refined the role **BD Multitest™ 6-Color TBNK Reagent with Trucount™ Tubes** has along with other testing in determining the COVID-19 patients' risk of IMV and mortality at hospitalization.

As shown in peer-reviewed clinical studies, some patients with COVID-19 may exhibit a decrease of specific lymphocyte T-cell subsets (CD4⁺ and/ or CD8⁺ T-cells), and this decrease is associated with increased risk of IMV and mortality. Knowing a patient's accurate T-cell count, therefore, can be instrumental in informing the right course of action, and the **BD Multitest™ 6-Color TBNK Reagent with BD Trucount™ Tubes** may aid in these types of determinations.

Results from a study conducted by BD have shown that a COVID-19 patient's risk for IMV and also mortality is five to six times higher for T-cell subsets below cut-off levels of: $CD4^+ < 250 \text{ cells/}\mu\text{l}$ and/or $CD8^+ < 100 \text{ cells/}\mu\text{l}$ compared to those that were above the cut-off.

"The BD Multitest™ 6-Color TBNK Reagent with BD Trucount™ Tubes assay's new claim related to risks of IMV and mortality may help clinicians better determine an appropriate course of action for hospitalized COVID-19 patients, which is a top priority for this population," said Puneet Sarin, worldwide president of BD Biosciences. "BD Biosciences has a long history of helping clinicians and patients understand immune function, and this new indication may help guide important care decisions while also prioritizing resources."

The BD Multitest™ 6-Color TBNK Reagent with BD Trucount™ Tubes is used in conjunction with the BD FACSLyric™ and BD FACSCanto™ II Clinical Flow Cytometers for COVID-19 clinical applications.

About the BD Multitest™ 6-Color TBNK Reagent with BD Trucount™ Tubes

The **BD Multitest™ 6-Color TBNK Reagent with optional BD Trucount™ Tubes** is a CE marked 6-color direct immunofluorescence reagent for use with a suitably equipped BD flow cytometer to identify and determine the percentages and absolute counts of T, B and natural killer (NK) cells, as well as the CD4 and CD8 subpopulations of T cells in peripheral blood. The **BD Multitest™ 6-Color TBNK Reagent with BD**Trucount™ Tubes can be used with the BD FACS™ Loader and the BD FACS™ Universal Loader.

In Oct. 2020, the following COVID-19 clinical application was added: determining counts of CD3⁺CD4⁺ and/or CD3⁺CD8⁺ lymphocytes may be useful in the immunological assessment of SARS-CoV-2 infected individuals with COVID-19 disease. Individuals with COVID-19 disease typically exhibit a decrease of CD3⁺CD4⁺ and/or

CD3⁺CD8⁺ lymphocyte counts with increasing disease severity.

New Clinical Application

CD3⁺CD4⁺ and/or CD3⁺CD8⁺ lymphocytes counts can also be used as an aid in determining the risk of IMV, and the risk of mortality, in confirmed COVID-19 patients, in conjunction with clinical findings and the results of other laboratory testing. For more information, visit www.bdbiosciences.com/Covid19-Tcell.

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 <u>bd.com</u>.

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Additional assets available online: Additional assets available online: Additional assets available online:

https://news.bd.com/2021-02-03-BD-Announces-Assay-for-Identification-of-COVID-19-Patients-at-Increased-Relative-Risks-of-Intubation-with-Mechanical-Ventilation-Mortality-at-Hospital-Admission-Now-Available-in-Europe