BD Onclarity™ HPV Assay for BD COR™ and BD Viper™ LT Systems Receive WHO Prequalification

FRANKLIN LAKES, N.J., Nov. 17, 2025 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced that the Conformité Européenne (CE) Marked BD Onclarity™ HPV Assay for the BD COR™ System and the BD Viper™ LT System have been accepted for the World Health Organization (WHO) list of prequalified in vitro diagnostic products, further expanding access to high-quality cervical cancer screening tools in low- and middle-income countries.

The newly prequalified assay detects 14 high-risk human papillomavirus (HPV) types, including individual identification of six high-risk types and three genotype groups. Extended genotyping enables more precise risk stratification and supports effective patient management in cervical cancer screening programs. The BD Onclarity™ HPV Assay is approved for self-collection, including at-home self-collection in countries that recognize the CE mark. By covering all available collection and testing modalities, the solution enables improved access, especially in settings with limited resources.

The ability to identify more individual types of HPV means that clinicians can more effectively manage high-risk cases and better guide follow-up for low-risk patients. This targeted approach helps ensure that women receive the most appropriate care for their situation and reduces demand for resources that support follow-up testing and procedures.

"Achieving WHO prequalification is an important step toward changing the future of cervical cancer screening, especially in low- and middle-income countries where the burden is greatest and access to screening is often limited," said Nikos Pavlidis, worldwide president of Diagnostic Solutions at BD. "Cervical cancer is a preventable disease, and by expanding access to potentially life-saving diagnostics, we're helping ensure that more women have the opportunity to be screened, treated, and protected. Together, with our global partners, we can accelerate progress toward eliminating cervical cancer worldwide."

The BD Onclarity™ HPV Assay is approved in the U.S. and in countries that recognize CE Marking for individually identifying high-risk HPV types and for self-collection in healthcare settings. In the U.S., it is the only assay approved for both extended genotyping of individual results beyond HPV 16, 18 and 45 and self-collection in healthcare settings, and in countries that recognize the CE mark, self-collection is also available in at-home settings. WHO prequalification is specific to the EU CE Marked BD Onclarity™ HPV assays.

The BD Viper™ LT System supports flexible testing indecentralized settings, offering a compact, benchtop design that enables molecular diagnostics in laboratories with limited space or infrastructure. It automates sample preparation and amplification, reducing manual steps and supporting consistent, reliable results. The system is designed for ease of use, with intuitive software and minimal hands-on time, making it well-suited for regional labs and public health screening programs where access to high-throughput platforms may be limited.

The BD COR™ System offers high-throughput automation for centralized laboratories, automating workflow with capacity for nearly 1,650 tests while delivering up to 1,000 sample results in 24 hours with barcode-driven traceability and remote system management. It offers up to seven hours of walk-away time, requires under 15 minutes to load, and uses room-temperature reagents that need no reconstitution, maximizing efficiency and minimizing manual interaction.

According to WHO, a woman dies of cervical cancer every 90 seconds. Cervical cancer is the fourth most common cancer in women worldwide, both in terms of incidence and deaths, but it is preventable with regular screening. WHO aims to eliminate cervical cancer as a public health issue. Global consensus is moving toward HPV primary screening with extended genotyping and self-collection, as reflected in WHO guidelines. WHO prequalification for HPV tests ensures those tests meet global standards for quality, safety, and performance for use in cervical cancer screening programs.

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 more than 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 atwww.linkedin.com/company/bd1/, X (formerly Twitter) @BDandCo or Instagram @becton_dickinson

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