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BD seeks FDA approval for its Onclarity HPV Test

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BD Onclarity™ HPV Assay detects 14 types of high-risk human papillomavirus (HPV) from specimens collected for cervical cancer screening in the BD SurePath™ Collection Vial

BD (Becton, Dickinson and Company), a leading global medical technology company, has announced that it has submitted a pre-market approval (PMA) supplement to the U.S. Food and Drug Administration (FDA) for an expanded version of its BD Onclarity™ HPV Assay.

The FDA-approved BD Onclarity™ HPV Assay detects 14 types of high-risk human papillomavirus (HPV) from specimens collected for cervical cancer screening in the BD SurePath™ Collection Vial. The BD Onclarity™ HPV Assay is the only FDA-approved assay to individually identify and report HPV genotypes 16, 18, and 45. These genotypes are associated with the majority of cervical cancers worldwide and are disproportionally responsible for up to 94 percent of glandular cervical pre-cancer cases. The prevalence of HPV genotypes 16 and 18, which are among those targeted by the FDA-approved HPV vaccines, are decreasing in vaccinated populations; thus shifting the prevalence of cervical pre-cancer cases to other HPV genotypes.

The PMA supplement seeks approval for genotype reporting beyond HPV genotypes 16, 18, and 45 to include types 31, 51, 52, and 8 additional types. The FDA submission includes data collected during a three year follow up of subjects from BD's prospective, multi-center clinical trial conducted in the U.S. that included more than 33,500 women, including those who received HPV vaccines and those who did not.

"Our goal is to provide laboratories and clinicians worldwide with comprehensive cervical cancer screening solutions that address the unique needs of individual healthcare providers and precision medicine for patients," said Dave Hickey, president, BD Integrated Diagnostic Solutions. "This PMA submission is the next step in our roadmap for the BD women's health and cancer portfolio as it brings us one step closer to expanding access to extended HPV genotyping capabilities in the U.S. market."