BD HPV assay gets premarket approval

March 8, 2018—Becton Dickinson received premarket approval from the FDA for the BD Onclarity HPV assay. The test detects 14 types of high-risk human papillomavirus from specimens collected for cervical cancer screening in the BD SurePath liquid based cytology vial. The assay also identifies HPV genotypes 16, 18, and 45, which are associated with the majority of cervical cancers and are responsible for up to 94 percent of glandular cervical cancer cases.

In evaluating the test, the FDA reviewed data collected during a multiyear, prospective, multicenter clinical trial conducted in the U.S. that included more than 33,500 vaccinated and non-vaccinated women. The assay may be used in accordance with clinical guidelines for cervical cancer screening and management to identify the presence of high-risk HPV types and is clinically validated for use as a primary screening test, for triaging patients with abnormal Pap test results, and in combination with a Pap test.

“The approval of the BD Onclarity HPV assay provides clinicians and laboratories an FDA-approved option for HPV primary screening with the BD SurePath liquid based cytology vial. The BD Onclarity HPV assay also aligns with clinical screening guidelines from the American Cancer Society, the American Society for Colposcopy and Cervical Pathology, and the American Society for Clinical Pathology,” Thomas C. Wright Jr., MD, professor emeritus of pathology and cell biology at Columbia, said in a release from BD.

The assay runs on the BD Viper LT system, a benchtop molecular platform.

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