FDA approves expanded version of BD HPV assay

July 28, 2020—Becton Dickinson received approval for a premarket approval supplement from the FDA for an expanded version of its BD Onclarity HPV Assay. The PMA supplement includes the expansion for genotype reporting beyond HPV genotypes 16, 18, and 45 to include types 31, 51, 52, 33/58, 35/39/68, and 56/59/66.

“With this FDA approval, BD can now offer laboratories, clinicians, and patients access to critical information in screening for cervical cancer in the United States and other countries recognizing the PMA supplement or CE mark,” Dave Hickey, president of integrated diagnostic solutions at BD, said in a press statement. “Our goal is to continue the global fight towards eliminating diseases and associated deaths due to cervical cancer with our comprehensive diagnostic solutions.”

The BD Onclarity HPV Assay is the only FDA-approved assay to individually identify and report the expanded genotype results.