Cytopathology in focus: BD Onclarity HPV assay now in CAP HPV Surveys

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August 2019—The BD Onclarity HPV assay is a human papillomavirus test approved by the Food and Drug Administration on Feb. 12, 2018. The assay is a qualitative test for detection of HPV in cervical specimens collected either with a broom or endocervical brush/spatula combination and placed in a BD SurePath liquid-based cytology vial. The assay is not approved for use with ThinPrep collection media (PreservCyt). The Onclarity HPV assay targets E6/E7 DNA oncogenes using the BD Viper LT system. The assay detects target DNA of 14 high-risk HPV types by use of PCR and nucleic acid hybridization. The assay specifically identifies HPV types 16, 18, and 45 separately while concurrently detecting the other high-risk HPV types (31, 33, 35, 39, 51, 52, 56, 58, 59, 66, and 68). Other genotyping data are also available and additional processing steps are not necessary.

The FDA-approved uses for this assay are as follows: 1) triage of specimens showing atypical squamous cells of undetermined significance (ASC-US) in women 21 years and older; 2) use as an adjunct to cervical cytology (cotesting) in women 30 years and older; 3) first-line primary cervical cancer screening in women 25 years and older. The BD Onclarity and Roche Cobas assays are the only HPV testing platforms that are approved by the FDA for primary cervical cytology screening (without cytology cotesting) in the United States. With the primary screening use, a positive HPV genotyping result for types 16 or 18 indicates that the woman should be referred for colposcopy, while women positive for the remaining HPV high-risk types should have cervical cytology evaluation. Genotyping results showing HPV types 16, 18, and 45 are also used for further patient management with the Onclarity cotesting indication, and may be helpful for patient management in women with ASC-US.

The CAP offers a high-risk HPV Survey (CHPV) consisting of three mailings per year with five challenges per mailing. The Survey modules include Digene (CHPVD), ThinPrep PreservCyt (CHPVM), SurePath (CHPVK), or a combination of transport media (CHPVJ). Laboratories are evaluated for the ability to detect high-risk HPV types, and those that perform testing on ThinPrep samples can also elect to provide genotyping results to include HPV types 16 and 18; this portion of the assay is for educational use only and the results are not reported to the Centers for Medicare and Medicaid Services.
More than 900 laboratories participate in the CHPV Survey. BD Diagnostics requested that the BD Onclarity HPV assay be added to the CAP proficiency testing menu for SurePath collections. As of the last mailing period, fewer than 10 laboratories participated in the BD Onclarity proficiency test. BD Diagnostics confirmed that the test had achieved satisfactory results with previous CHPV Surveys. In addition to several publications on the performance of Onclarity, there are now published data from the trial done in the United States leading to FDA approval.1,2 The Onclarity HPV trial consisted of nearly 34,000 enrolled women, with 22,383 having negative cytology results and 1,960 women having ASC-US cytology results.

1. Wright TC Jr, Stoler MH, Parvu V, et al. Detection of cervical neoplasia by human papillomavirus testing in an atypical squamous cells-undetermined significance population: results of the Becton Dickinson Onclarity trial. *Am J Clin Pathol*. 2019;151(1):53–62.
2. Stoler MH, Wright TC Jr, Parvu V, et al. HPV testing with 16, 18, and 45 genotyping stratifies cancer risk for women with normal cytolology. *Am J*

Clin Pathol. 2019;151(4):433–442.

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