FDA approves Cobas HPV Test with SurePath

Aug. 3, 2018—Roche has received FDA approval for the Cobas HPV Test to be used as the first-line screening test for cervical cancer in women 25 and older using specimens collected in SurePath preservative fluid.

The Roche test is now the only HPV test approved for use as a primary screening test with both SurePath and ThinPrep PreservCyt Solution. It is approved for all of the cervical cancer screening indications supported by guidelines—primary screening in women 25 and older, reflex testing of unclear Pap test results in women 21 and older, and cotesting with a Pap test in women 30 and older—with both of the primary collection media types.

“Before today, laboratories did not have an FDA-approved HPV test available that could cover all of the HPV screening options supported in professional guidelines and be used with both of the primary Pap test collection media,” Ann Costello, head of Roche Tissue Diagnostics, said in a press release. “With this additional approval for the Cobas HPV Test, laboratories and clinicians now have an approved option that can be used for all of their HPV screening indications and sample types, so they can more easily provide the most appropriate options for their patients.”

The test is approved for use with the Cobas 4800 system, which offers walkaway automation of nucleic acid purification, PCR setup, and real-time PCR amplification and detection.

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