

Roche gets FDA approval for HPV test on Cobas 5800 system

Nov. 6, 2023—[Roche](#) announced that the FDA has approved the Cobas HPV test for use on its next-generation Cobas 5800 molecular instrument. The HPV test is indicated for use for routine cervical cancer screening, as per professional medical guidelines, including triage of ASC-US cytology, cotesting with cytology, and HPV primary screening of women to assess the risk for cervical precancer and cancer. The test identifies the presence of the DNA of HPV genotypes 16 and 18 and reports the 12 other high-risk HPV types as a combined result from one patient sample.