

HPV AND CERVICAL CANCER DETECTION METHODOLOGIES

You have options

LabCorp offers the latest molecular tests and cervical cytology technologies to aid in the **detection of cervical cancer.**

Studies show that HPV is found in 99.7% of all cervical carcinomas.¹ When using Pap testing with HPV DNA, the combined sensitivity for detecting high-grade cervical disease and cancer has been reported as more than 99%.^{2,3} Several leading health organizations and governmental agencies have provided guidance on HPV testing together with a Pap test for women age 30 and older.

LabCorp offers three FDA-approved HPV screening test options.

These methods are approved (1) for Pap with HPV testing for women age 30 and older and (2) for women age 21 and older as a reflex option with an ASC-US Pap result.

Aptima® HPV mRNA Test

This test utilizes transcription-mediated amplification (TMA) technology and detects mRNA from 14 high-risk HPV types associated with cervical cancer.⁴ This technology also offers the latest generation of testing for HPV genotype analysis. Aptima detects HPV type 16 and HPV types 18/45 (18 is not differentiated from type 45).⁴

The cobas® HPV DNA Test

This test utilizes an amplified molecular technology known as "polymerase chain reaction" (PCR) to detect HPV type 16 and HPV type 18 individually while simultaneously detecting 12 additional oncogenic HPV types in a combined format on a single specimen.⁵

The digene® HPV DNA Test

This test utilizes an amplified molecular technology known as "Hybrid Capture® 2" (hc2) and detects 13 high-risk HPV types.⁶ hc2 is LabCorp's default method.

mRNA HPV Biomarker and Clinical Gaps in Cervical Cancer Screening

While HR HPV DNA testing has been shown to have excellent sensitivity and negative predictive value, the specificity has been shown to be much lower than cytology, affecting positive predictive value.^{7,8} mRNA testing for E6/E7 offers an improvement in specificity and positive predictive value for transforming infections (CIN2+ disease).^{7,9}

HPV E6/E7 QuantaSURE® – mRNA-based Test

The HPV E6/E7 QuantaSURE HPV test uses flow cytometry to differentiate cell types within a sample, measure the quantity of E6/E7 mRNA per cell, and calculate the percentage of cells that are overexpressing E6/E7 mRNA. The quantification of E6 and E7 in the cells helps to triage women for disease progression, helps to identify high-grade lesions, and to identify those women at increased risk for cervical disease.⁷⁻¹⁰ The detection of E6/E7 is not just a sign of virus within the cell but evidence of viral activity. Data have demonstrated that E6 and E7 mRNA may help in discriminating the presence of \geq CIN2 disease.⁷

HPV Test Method Options

Test Description	The <i>digene</i> HPV High-risk group <i>hc2</i> method ¹	The Aptima [®] HPV Assay High-risk group mRNA method ²	The Roche HPV High-risk group <i>cobas</i> method ³
Collection device	ThinPrep [®] / SurePath [™]	ThinPrep [®] / SurePath [™]	ThinPrep [®] only
Age-based Test Options based on ACOG guidelines^{11,12}			
Cervical Cancer and Chlamydia/Gonorrhea Screening	193030	193060	NA
Cervical Cancer Screening Only	193025	193065	NA
Cervical Cancer Screening plus <i>Chlamydia trachomatis</i> , <i>Neisseria gonorrhoeae</i>	193035	193070	NA
Cervical Cancer Screening plus <i>Chlamydia trachomatis</i> , <i>Neisseria gonorrhoeae</i> , and <i>Trichomonas vaginalis</i>	193045	193075	NA
Human Papillomavirus (HPV), High-risk Group	507301	507800	NA
HPV High-risk Group With Reflex to HPV Genotype 16 & 18 *(HPV Genotype 16,18/45)	507815*	507805	196305
HPV High-risk Group and HPV Genotype 16 & 18	NA	NA	507385
Image-guided Pap, HPV With Reflex to HPV Genotype 16 & 18	197146	199305	NA
Image-guided Pap, Ct/Ng, HPV With Reflex to HPV Genotype 16 & 18	197124	199310	NA
Image-guided Pap, Ct/Ng/Tv, HPV With Reflex to HPV Genotype 16 & 18	196599	199315	NA
Image-guided Pap, HPV High-risk Group and HPV Genotype 16 & 18	NA	NA	196210
Image-guided Pap, Ct/Ng, HPV High-risk Group and HPV Genotype 16 & 18	NA	NA	196215
Image-guided Pap, Ct/Ng/Tv, HPV High-risk Group and HPV Genotype 16 & 18	NA	NA	196220
Image-guided Pap With Reflex to HPV when ASC-U	194074	199300	196310
Image-guided Pap, Ct/Ng, With Reflex to HPV when ASC-U	194027	199320	196315
Image-guided Pap, Ct/Ng/Tv, With Reflex to HPV when ASC-U	196527	199325	NA
Image-guided Pap With Reflex to HPV High-risk Group and HPV Genotype 16 & 18 When ASC-U	NA	NA	196225
Image-guided Pap, Ct/Ng, With Reflex to HPV High-risk Group and HPV Genotype 16 & 18 When ASC-U	NA	NA	196230
Image-guided Pap, Ct/Ng/Tv, With Reflex to HPV High-risk Group and HPV Genotype 16 & 18 When ASC-U	NA	NA	196235
Image-guided Pap, Liquid-based Prep With Reflex to HPV High-risk DNA Detection When ASC-U, ASC-H, LSIL, HSIL, AGUS	196250	199345	NA
Image-guided Pap, Liquid-based Prep, Ct/Ng, NAA With Reflex to HPV High-risk DNA Detection When ASC-U, ASC-H, LSIL, HSIL, AGUS	196565	199355	NA
Image-guided Pap, Liquid-based Prep, Ct/Ng/Tv, NAA With Reflex to HPV High-risk DNA Detection When ASC-U, ASC-H, LSIL, HSIL, AGUS	196595	199360	NA

- The test provides qualitative molecular detection of 13 different human papillomavirus high-risk types: (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68) without differentiation of the individual type. Additional test options/test numbers (not listed above) are available for this method.
- The test detects the same high-risk HPV types listed above (#1) in addition to HPV type 66 for a total of 14 different HPV high-risk types. Genotype includes HPV types 16, 18/45.
- The test provides three test results for the detection of HPV type 16, HPV type 18, and a qualitative molecular detection of 12 different human papillomavirus high-risk types: (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68) without differentiation of the individual type. Alternatively, LabCorp offers three tests (196305, 196310, 196315) that provide one total result that includes the 12 different HPV types listed above (#3) and HPV types 16 and 18.

HPV E6/E7 QuantaSure[®]

199415	Image-guided Pap, Liquid-based Prep, HPV DNA With Reflex to Genotypes 16 and 18 and HPV E6/E7 (QuantaSURE [®])
199420	Image-guided Pap, Liquid-based Prep, Ct/Ng, NAA and HPV DNA With Reflex to Genotypes 16 and 18 and HPV E6/E7 (QuantaSURE [®])
199430	Image-guided Pap, Liquid-based Prep, HPV DNA With Reflex to HPV E6/E7 (QuantaSURE [®])

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