

Human Papillomavirus & Cervical Cancer

Overview

Human papillomavirus (HPV) is one of the most common causes of sexually transmitted disease (STD) in the world.¹ In the U.S., there are more cases of genital HPV infection (>20 million) than of any other STD.² HPV infection of several subtypes is associated with pre-malignant cervical lesions (dysplasias or “squamous intra-epithelial lesions”). The incidence of these cervical lesions is on the rise in the U.S. and is associated with a greatly increased risk for the development of invasive cervical cancer, one of the most preventable of all human cancers.³ HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59 and 68 are high- and intermediate-risk carcinogenic types.³ HPV infection with high-risk types increases relative risk for high-grade squamous intraepithelial lesions (HSIL) >300 times.⁴ High-risk HPV types are detected in 93-100% of HSILs and in 99.7% of cervical cancer cases.^{5,6} Low-risk HPV types 6, 11, 42, 43 and 44 typically do not proceed to cervical cancer.³

For effective screening and diagnosis, which can lead to prevention and control of cervical cancer, the American College of Obstetricians and Gynecologists (ACOG) and the American Cancer Society (ACS) recommend:

- ?? cervical screening 3 years after first sexual intercourse or age 21 (whichever comes first)
- ?? after first test, annual cervical screening with regular Pap tests until the age of 30
- ?? for women 30 and older, cervical cancer screening with an FDA-approved HPV DNA test in conjunction with a Pap test is recommended

- if both test results are negative (normal), neither test will need to be repeated more often than every three years
- if the Pap test is negative (normal) and the HPV DNA test is positive, then the HPV DNA test should be repeated in 6-12 months
- ?? women 70 and older who have had three or more normal Pap test results and no abnormal results in the last 10 years may choose to stop cervical cancer screening.^{7,8}

More frequent screening should be considered for high-risk women, including:

- ?? HIV-positive or immunosuppressed,
- ?? previously exposed to DES in utero
- ?? previously diagnosed with cervical cancer
- ?? hysterectomy AND a history of (cervical intraepithelial neoplasia grade 2) CIN2 or CIN3.^{7,8}

The majority of cervical cancer cases occur in women who have not had screening exams in the previous 5 years.⁶

Specialty offers HPV DNA testing for detection of high- and/or low-risk HPV types by Hybrid Capture 2; the most sensitive method available when combined with traditional or liquid-based Pap smears for detection of HPV.^{6,9} These tests also identify women with high- and low-grade squamous intraepithelial lesions³ and triage women with ASCUS equivocal Pap smear results to assess the need for colposcopy.^{10,11}

Clinical Utility

High-Grade Squamous Intraepithelial Lesions (HSIL)

- ?? Hybrid Capture 2 combined with Pap (combined testing) is 100% sensitive for HSIL^{6,9}
- ?? Combined testing has nearly a 100% negative predictive value for HSIL⁶

CIN2 & CIN3:

- ?? Combined HPV and Pap testing is 100% sensitive for CIN2¹²
- ?? Combined testing is 99.2% sensitive for CIN3¹³
- ?? Combined testing has 100% NPV for both CIN2 and CIN3¹²

Methodology

Hybrid Capture Type 2 by Digene (DNAwithPap?)

Ordering Information

Test Code	Test Name	Description
1821	HPV High Risk DetectR [?]	Detects high-risk types of HPV only: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68
1822	HPV High & Low Risk DetectR [?]	Differentiates between low-risk & intermediate/high-risk Types of HPV
1824	Human Papillomavirus DetectR [?] rflx to High & Low Risk DetectR [?]	If HPV is detected, tests for specific high- and/or low-risk types present in sample
1827	Human Papillomavirus DetectR [?] rflx to HPV High Risk DetectR [?]	If HPV is detected, tests for specific high-risk types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68

Specimen Requirements*

Cervical or anal swab specimens should be collected using the **Digene Specimen Collection Kit** and transported in **Digene Specimen Transport Medium**. Cervical Biopsy specimens should be 2-5 mm in cross-section and must be placed in 1 mL of Digene Specimen Transport Medium and shipped FROZEN. Collection kits are available from Specialty Client Supply.

***Sample Media also accepted for Cytoc ThinPrep[®], TriPath SurePath[?], AutoCyte[®] PREP Tube. Contact Client Services at 800-421-4449 for complete collection instructions.**

Related Tests

- 1820 Human Papillomavirus DetectR[?]
- 7432 *Chlamydia/Neisseria* rRNA/HPV DetectR[?]
- 7431 *Chlamydia/Neisseria* rRNA/HPV High Risk DetectR[?]
- 7430 *Chlamydia/Neisseria* rRNA/HPV High & Low Risk DetectR[?]
- 7436 *Chlamydia/Neisseria* rRNA/HPV reflex High Risk DetectR[?]
- 7434 *Chlamydia/Neisseria* rRNA/HPV reflex High & Low Risk DetectR[?]

References

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For complete information, please call Client Services at 800-421-4449 or visit our Web site at www.specialtylabs.com