

Women's Health *path*

Associates in Pathology: Guiding the Journey in Women's Health

Interpreting Positive HPV Results

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HPV types 16 and 18
*together account
for about 70% of
cervical cancers. [1]*



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

The Roche cobas® HPV Test

Associates in Pathology (AIP) uses the cobas® 4800 platform for HPV testing. This test provides three results.

1. HPV pooled subtypes: Including HPV high risk types: 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68
2. HPV subtype 16
3. HPV subtype 18

HPV 16 and 18 are pulled out of the group of high risk subtypes because, if left untreated, they are most likely to progress to gynecological cancers.

HPV 16 and 18 results are especially useful when managing women over the age of 30 with negative cytology and a positive HPV result. If the patient is either HPV 16 or 18 positive, colposcopy is recommended regardless of cytology diagnosis.

Who Should be Tested for HPV? — Current Screening Guidelines

Below, are the current screening guidelines supported by the American Society for Colposcopy and Cervical Pathology (ASCCP).

Note: These are guidelines, and should be used at each physician's discretion.

Screening Methods for Cervical Cancer: Joint Recommendations of the American Cancer Society, the American Society for Colposcopy and Cervical Pathology, and the American Society for Clinical Pathology [2]

Population	Recommended Screening Method	Comment
Women younger than 21 years	No screening	
Women aged 21-29 years	Cytology alone every 3 years	
Women aged 30-65 years	Cytology and HPV co-testing (preferred) every 5 years Cytology alone (acceptable) every 3 years	Screening by HPV testing alone is not recommended
Women older than 65 years	No screening is necessary after adequate negative prior screening results	Women with a history of CIN2, CIN 3 or adenocarcinoma in situ should continue routine age-based screening for at least 20 years
Women who underwent total hysterectomy	No screening is necessary	Applies to women without a cervix and without a history of CIN 2, CIN 3, adenocarcinoma in situ or cancer in the past 20 years
Women vaccinated against HPV	Follow age-specific recommendations (same as unvaccinated women)	

Abbreviations: CIN: cervical intraepithelial neoplasia; HPV: human papillomavirus

Managing Women with Discordant Cotesting Results [3]

Use cotesting management recommendations only for women ≥ 30 years of age.

HPV+/Pap– women can be managed in two ways (also demonstrated in the chart below):

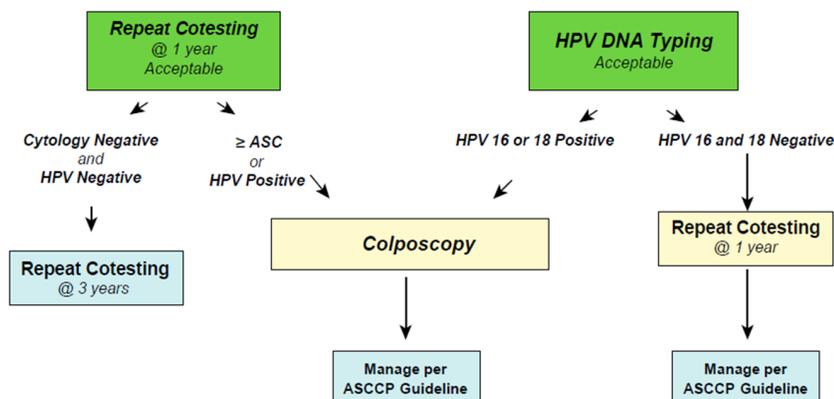
1. Repeat cotesting in one year, with colposcopy if HPV+ or ASCUS+ (including HPV-/ASCUS) and repeat cotesting in 3 years if cotest results are negative.
2. Genotyping, with colposcopy if HPV16+ or 18+ and repeat cotesting in one year if both HPV 16 and 18 are negative.

HPV-/ASCUS results should be followed up with cotesting in 3 years, not 5 years, as these women are at marginally higher risk for CIN3+ than women who are cotest negative.

Women with HPV-/LSIL results can be followed with cotesting in a year (preferred) or with colposcopy. Women with HPV+/LSIL or LSIL/no HPV result should have colposcopy.

Women with HPV-/AGC are at high risk and need colposcopy, often with endometrial sampling.

Management of Women \geq Age 30, who are Cytology Negative, but HPV Positive



Why AIP Offers the Roche cobas® HPV Test [4]

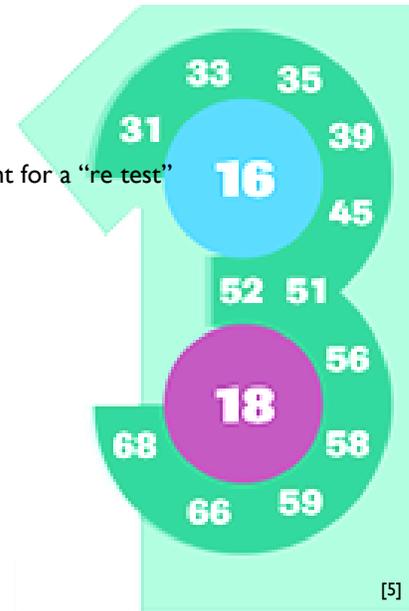
The cobas® HPV Test is the only clinically validated, FDA-approved assay that simultaneously provides individual results on the highest-risk genotypes – HPV 16 and HPV 18 – and a pooled result on the twelve other high-risk HPV (hrHPV) genotypes, all in one run from one patient sample.

HPV 16 and 18 are the two most prevalent oncogenic HPV types in both squamous cell carcinoma and adenocarcinoma and are responsible for more than two-thirds of all cervical cancer cases.

The cobas® HPV Test delivers 3 high-risk HPV results in one test, enabling clinicians to risk-stratify patients and help guide patient management decisions.

Benefits of the cobas® HPV Test include:

- No cross-reactivity with low-risk HPV types
- Results are positive, negative, or invalid with no gray zone—this reduces the warrant for a “re test”
- Reproducible results with real-time PCR
- Reduced false negatives
 - β-globin internal control for sample adequacy
- Reduced false positives
 - External control
 - No cross-reactivity with low-risk HPV genotypes



How to Order HPV Testing

To order an HPV test:

- Select the appropriate option from the “HPV Testing Options” drop-down
 - Drop-down is located in the “comments” field of the Pap smear pathology order
 - See example, below
- It is not necessary to place an additional order in EPIC

GYN CYTOLOGY
{AIP - THIN PREP OR # OF SLIDES:16619}
{AIP - ROUTINE PAP\HIGH RISK PAP\DIAGNOSTIC PAP:16621}

LMP: No LMP recorded.
OB/GYN Status: Recent pregnancy
Pertinent Positives: {OB/GYN Status Pertinent Positives:27410}

HPV Testing Options:

{HPV_TEST_OPTIONS:13783}

Gonorrhea/Chlamydia testing via
{GONORRHEA/CHLAMYDIA:25

No HPV testing
Reflex HPV testing on (may check more than one): {22242}
Regardless of diagnosis/co-testing
Other – the clinic may call the cytology department within one week of reviewing pap test results to order HPV testing

Contact Us

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REFERENCES

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2. Adapted from: Saslow D, Solomon D, Lawson HW, Killackey M, Kulasingam SL, Cain J, et al. American Cancer Society, American Society for colposcopy and Cervical Pathology, and American Society for Clinical Pathology screening guidelines for the prevention and early detection of cervical cancer. *CA Cancer J Clin* 2012;62:147-72.
3. Adapted from: "Updated Consensus Guidelines FAQs." Consensus Guidelines FAQs - ASCCP. N.p., 01 Jan. 2013. Web. 13 June 2017.
4. Adapted from: Confidence with the cobas® HPV Test. (n.d.). Retrieved June 26, 2017, from <https://www.hpv16and18.com/hcp/cobas-hpv-test/precise-results.html>
5. Roche Molecular Systems, Inc. (n.d.). Retrieved June 20, 2017, from <https://www.hpv16and18.com/labs/lab-efficiencies/3-results-1-test.html>



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