



## The Role of HPV Testing in Cervical Cancer Screening

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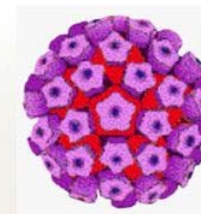
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## Genital HPV Infection

### Human Papillomavirus (HPV)

- Consists of double-stranded, circular DNA contained within a spherical protein coat (capsid)
- There are over 100 different strains of the human papillomavirus but only about 30 types affect the genital tract
- 14 genital types are highly oncogenic - these "high-risk" HPV types are found in **99.7%** of invasive cervical cancers.

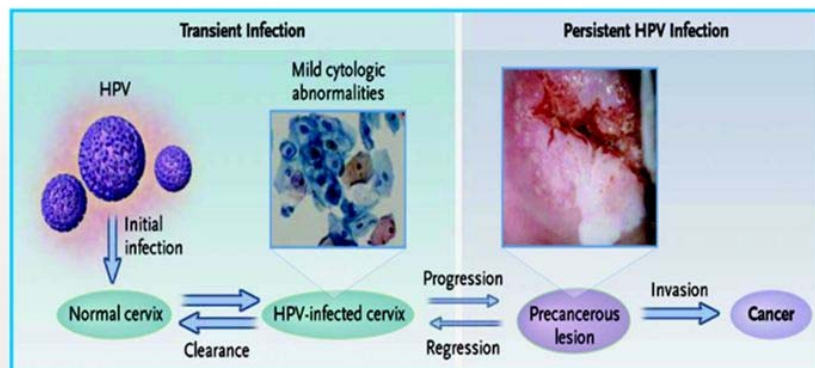


Capsid of HPV

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## Natural History of HPV infections

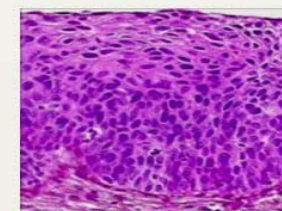
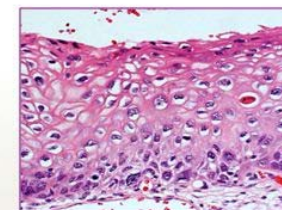


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## Cervical Intraepithelial Neoplasia

- All genital HPV infections induce low grade squamous cervical lesions (LSIL) which correlate with a productive viral infection
- Rarely, high-risk HPV induces a proliferative epithelial phenotype (HSIL) that is a precursor of invasive cervical carcinoma



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## HPV and Cervical Cancer

- Most sexually active men and women will become infected with at least one type of HPV during their lifetime
- High-Risk HPV genital infection is usually without symptoms, transitory and self-resolving. More than 90% of detected infections clear within two years.
- Concurrent infection with other HPV types is common and subsequent infection with the same type may occur
- The majority of CIN spontaneously regress, however, some have the potential to develop into invasive cancer

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## HPV and Cervical Cancer

- Less than 50% of CIN 3 progress to invasive carcinoma
- It usually takes 10 to 20 years (or longer) from the time of infection with a hr HPV before a cervical cancer develops.
- Persistence of an infection with a hr HPV virus beyond 12 months is associated with an increased risk of cervical cancer.
- But less than 10% of women with a persistent hr HPV infection are likely to develop CIN.

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## Role of HPV in Cervical Cancer

- High-Risk HPV is more significant if found in women over 30 years
- The negative predictive value (NPV) of hr-HPV is more clinically useful than the positive predictive value
- There is currently no effective treatment for HPV infection in the cervix
- HPV testing not able to detect endometrial disease

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## HPV Testing Applications in Cervical Screening

### HSIL Proof of Cure

Following treatment of HSIL, patient will have annual Pap and HPV Test until both tests are negative on two consecutive occasions. Then revert to routine screening

### Cessation of routine screening

After the menopause if a woman has been regularly screened and always cytologically negative

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## HPV Testing Applications in Cervical Screening

### Primary Screening

Adjunctive to Liquid Based Cytology screening

or

Reflex to Cytology if HR HPV +

### ASC-US Management

Reflex HPV Test out of ThinPrep vial

HPV + Colposcopy

HPV - Return to Routine Screening

## HPV Tests

### Signal Amplification Methods

Hybrid Capture II (Qiagen)  
Cervista (Hologic) }

FDA Approved

### Target Amplification Methods (PCR)

COBAS Amplicor (Roche)

Aptima (GenProbe)

RealTime HR HPV Test (Abbott)

## Signal Vs. Target Amplification

### Signal Amplification Methods

Less prone to cross contamination concerns

Full genotyping not yet available

16/18 genotyping available Cervista

### Target Amplification Methods (PCR)

Extremely Sensitive - ? detecting clinically irrelevant infections

Increased risk of false positive results due to cross contamination

Full genotyping

## HC2 USA Direct-to-Consumer Advertising

You're not failing your Pap test  
but it might be failing you.

About 80 percent of cervical cancers are caused by a virus—the human papillomavirus (HPV). A Pap test looks for the abnormal cells caused by HPV but may not find them until it is too late. Only the HPV test can check to detect the virus and to identify 100% precancer.

When used along with a Pap, the HPV test can help your doctor reduce your chance of developing cervical cancer and is approved for screening women 30 and over. Learn more before your next doctor's appointment. [www.fhlpvt.com](http://www.fhlpvt.com) 877HPVFACT

HPV TEST

If you're a gambling woman,  
then getting just a Pap test is fine.

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Figure 1. Cervix. When the HPV test returned HPV test for detection of high-risk HPV associated with cervical cancer. Availability only from your doctor. © 2011 Hologic, Inc. All rights reserved. Hologic, the Hologic logo and Cervista are trademarks of Hologic, Inc. and are used under license. All other trademarks are the property of their respective owners. For more information, visit [www.fhlpvt.com](http://www.fhlpvt.com) or call 877HPVFACT.

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## Concerns about HPV DNA Testing

- WHO recommends **not** using HPV-DNA testing in women below the age of 30 years because of the high prevalence of transient HPV infections in younger women, resulting in unnecessary follow-up and eventually treatment in this age (i.e. specificity in younger women is too low)
- Even a second positive test showing persistence of a hr HPV type gives no information about disease progression in that woman's cervix
- The best test for HPV neoplasia remains quality cytology-based testing

## Conclusion

- The value of HPV Testing lies in its high Negative Predictive Value
- The Positive Predictive value of HPV Testing is generally low
- Proven to be a cost effective approach to management of ASCUS
- The best test for HPV neoplasia remains quality cytology-based testing