

# When is a Double Negative a Positive Outcome?

## Pap with HPV DNA

### More than 99% sensitivity

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%.<sup>1,2</sup>

### Determine risk for informed and improved patient care

Research reports that about one in five women developed CIN 2/3+ within three years in the patient group who were persistently high-risk HPV-positive when using the Pap and HPV DNA test combination.<sup>2</sup>

### Accurate patient risk stratification

Women with persistent high-risk HPV infection are about 300 times more likely to develop HSIL.<sup>3,4</sup>

### Patient confidence— “negative means negative”

More than 99% negative predictive value for CIN3 and cancer, when **both** the liquid-based Pap and high-risk HPV DNA results are negative, was published in a major US study.<sup>5</sup> Pap with

HPV DNA can provide you greater confidence in your care decisions.<sup>2,5</sup> With a double negative, you can reasonably state to a patient that “negative means negative.”<sup>2</sup>

### Better risk assessment

A single-visit “double-negative” high-risk HPV DNA and Pap test result provides better assurance for patients 30 and over that the risk of developing CIN3 cervical disease within the next 2-3 years is extremely low (1 in 1000), earlier than waiting for three consecutive negative Pap smear results.<sup>5,7</sup> HPV DNA testing is a more sensitive indicator for prevalent high-grade CIN than either conventional or liquid cytology alone; a combination of HPV DNA and Pap testing has been shown to have more than a 99% sensitivity and negative predictive value for high-grade CIN.<sup>2</sup>

### Identify • Stratify • Provide Care

**By using the Pap with HPV DNA\* as a combined primary screening method for women age 30 and older, you are able to:**

- Identify women who are at greatest risk for cervical disease or cancer
- Identify women who may have a persistent infection that can be about 300 times more likely to develop HSIL<sup>3,4</sup>
- Offer appropriate and effective follow-up,<sup>6,7</sup> since the combined Pap with HPV DNA test is more sensitive in determining the presence of disease than a Pap test alone.<sup>2,8</sup>



**Pap with HPV DNA option  
for women age 30 and older**

**Order Test 199123 or 195050**



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# Order Pap with HPV DNA A Double Negative = Greater Confidence in Care Decisions

## Why select the Pap with HPV DNA option for women age 30 and older?

**While the Pap alone detects cellular changes associated with cervical disease and cancer, the Pap with HPV DNA test combination accurately detects the recognized necessary causal factor of the disease, human papillomavirus (HPV),<sup>6,9</sup> giving you and your patients a greater level of diagnostic confidence.**

Pap with high-risk HPV testing is a recommended screening approach for women age 30 and older.<sup>6,7</sup>

A positive high-risk HPV test result in women age 30 and older is more likely to represent persistent infection and increased risk of cervical disease.<sup>10</sup>

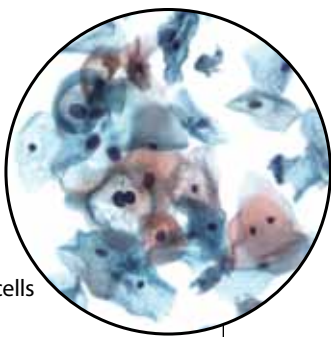
Persistent infection with high-risk HPV is necessary for the development and maintenance of CIN3.<sup>9</sup>

Studies show that HPV DNA is found in 99.7% of all cervical carcinomas.<sup>10</sup>

Cervical cancer incidence increases for women age 30 and older.<sup>8</sup>

There is a negative predictive value of greater than 99% when both results are negative in a combined Pap with high-risk HPV DNA test. The combined result is more sensitive than the Pap test alone, which aids in assessing the absence of cervical disease.<sup>2,5</sup>

\*The digene HPV DNA Test is also known to physicians as the "Hybrid Capture 2 High-Risk HPV DNA Test" and "DNAwithPap Test." This does not refer to the Qiagen product that tests for several types of the virus commonly referred to as "low-risk HPV," which are rarely associated with cervical cancer.



HPV infected cells

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Gynecologic Pap Test (Image-guided),  
Liquid-based Preparation and Human  
Papillomavirus (HPV), High-risk DNA  
Detection (Test 199123)

### References

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- 9 Nottenhuis MAE, Walboomers JMM, Helmerhorst TJM, et al. Relation of human papillomavirus status to cervical lesions and consequences for cervical cancer screening: a prospective study. *Lancet*. 1999; 354:20-25.
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Gynecologic Pap Test, Liquid-based  
Preparation and Human Papillomavirus  
(HPV), High-risk DNA Detection  
(Test 195050)

Ask your representative about out-of-the vial options available for human papillomavirus, *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Trichomonas vaginalis*, and Herpes Simplex Virus Types 1 and 2.

**The digene HPV Test**

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