HPV test sensitivity — why settle for less?

The *digene* HPV Test

Other HPV tests advertise equivalent sensitivity to the *digene*® HPV Test — but don’t reveal the fine print:

- HPV tests used for screening purposes should be compared using data from an NILM/cotested patient population to identify women at risk for cervical disease, not just women with disease (1).
- HPV test sensitivity data from an ASC-US patient population instead of cotested population will almost always be higher because Pap negatives have already been eliminated from the testing pool (1).
- Using data from a study that applied a different cutoff value than the FDA-approved version of the test is not an accurate representation of the test your patients will receive.

**ONLY** the *digene* HPV Test with a Pap has proven up to 100% sensitivity in a cotested population (see Figure 1).

![Figure 1. Clinical sensitivity of various cervical cancer screening methods.](image)

Other FDA-approved tests have not proven the same level of sensitivity — which can lead to false negatives.

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<thead>
<tr>
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<th>NILM</th>
<th>ASC-US</th>
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<tbody>
<tr>
<td></td>
<td>Alternative HPV DNA test</td>
<td>Alternative HPV RNA test</td>
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<tr>
<td>Sensitivity for CIN 3+</td>
<td>90.0% (6)</td>
<td>90.9% (7)</td>
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<tr>
<td>Sensitivity for CIN 2+</td>
<td>83.2% (6)</td>
<td>75.0% (7)</td>
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“Our general assumptions are that the sensitivity of HPV testing for CIN3+ and CIN2+ should be ≥90%, and the percent of women in the general population who test (screen) positive, as a measure of false positives, should be less than or equal to established thresholds from well-validated HPV DNA tests.” (8)
The **digene** HPV Test uses full genome detection to achieve higher sensitivity.

- Using the full genome to detect the presence of HPV increases sensitivity and the likelihood of early detection
- Technology that targets only a single region of the genome is more likely to miss disease or cancer
- In particular, the L1 region, used in one commercially available test, is prone to deletion which increases the risk of false negatives

“L1 primers may be associated with a 2–3% false negative rate due to integration events in the L1 open reading frame.” (9)

- mRNA HPV tests target the E6/E7 region of the HPV genome
- mRNA tests are highly specific because E6/E7 regions express as disease progresses toward cancer
- These tests are more susceptible to missing early stage disease that has not yet reached the targeted level of detection. This can result in an unidentified at-risk patient returning to a 3–5 year screening pool, allowing the disease to progress without being monitored

A negative HPV test that you can trust is more important than ever. Knowing you’ve chosen the only HPV test that has the necessary data to support recommended screening intervals offers additional peace of mind.

Trust your HPV result, because she trusts you. Ask for the **digene** HPV Test.

References: