Normal cervical epithelium
HPV-infected cervical cells
CIN1 or LSIL (low-grade intraepithelial lesions)
CIN2 or HSIL (high-grade intraepithelial lesions)
CIN3+ or HSIL (high-grade intraepithelial lesions)
Cervical carcinoma

**The APTIMA® HPV Assay detects E6/E7 viral mRNA from 14 high-risk types of human papillomavirus in cervical specimens (ThinPrep® Pap Test vials containing PreservCyt® Solution collected with broom-type or cytobrush/spatula devices). The test is indicated to screen women ≥21 years with ASCUS cytology to determine the need for colposcopy, and to screen women ≥30 years for high-risk HPV types.**

**With the FDA-approved APTIMA® HPV test, you can focus on more clinically relevant results**

**E6/E7 mRNA levels**

**HPV mRNA delivers significantly less false positives than DNA—up to 40% fewer.**

**The future of HPV testing is here**

**The APTIMA® HPV test**

**Models used for illustrative purposes only.**

**References:**

**The assay is not a substitute for regular cervical cytology screening. The results of this test are not intended to prevent women from proceeding to colposcopy. The assay has not been evaluated for managing HPV vaccine, women with prior ablative or excisional therapy, hysterectomy, who are pregnant, or have other risk factors.**

**The CLEAR Trial was a prospective, multicenter clinical study that analyzed more than 11,000 women undergoing routine Pap testing at 18 US clinics. The CLEAR Trial comprised two arms: 1. The ASCUS Study population included 939 women ≥21 years with ASCUS cytology results; 2. The NILM (Adjacent) Study population included 10,871 women ≥30 years with normal cytology results.**

**Out-of-the-Vial Testing**

- **Chlamydia trachomatis (CT), ThinPrep® Vial**
  - Test Code: 906394
- **Neisseria gonorrhoeae (NG), ThinPrep® Vial**
  - Test Code: 906395
- **CT/NG, ThinPrep® Vial**
  - Test Code: 803509
- **HPV mRNA**
  - Test Code: 718
- **HPV mRNA w/Reflex to Genotypes 16, 18/45 if HPV is Positive**
  - Test Code: 435
- **HPV Genotypes 16, 18/45**
  - Test Code: 906546
The APTIMA® HPV test

Highly sensitive and specific

Offers excellent sensitivity...
so you can help minimize false-negative results

The APTIMA® HPV Assay, utilizing mRNA, has shown sensitivity comparable to common DNA-based tests.

Clinical Sensitivity

<table>
<thead>
<tr>
<th>Clinical Sensitivity</th>
<th>Referral population</th>
<th>Screening population</th>
</tr>
</thead>
<tbody>
<tr>
<td>100%</td>
<td>75%</td>
<td>50%</td>
</tr>
<tr>
<td>75%</td>
<td>50%</td>
<td>25%</td>
</tr>
<tr>
<td>50%</td>
<td>25%</td>
<td>0%</td>
</tr>
</tbody>
</table>

Sensitivity for CIN3 and more severe lesions

The APTIMA® HPV Assay has been shown to produce up to 40% fewer false-positive test results:

- Decreasing difficult patient conversations
- Decreasing the potential for over-treatment

Offers increased specificity, decreasing potential harms

Fewer false-positive results

Published guidelines recommend the use of HPV co-testing in women ages 30–65. Persistent HPV infections occur more frequently in women age 30 or older.

Pap with HPV Co-testing for Women 30–65 Years of Age

The best way to identify women most at risk of cervical cancer

The HPV result serves as the gatekeeper in the decision to advance to colposcopy.

Co-testing with Confidence

The HPV mRNA assay provides clinicians greater confidence in patient management, helping reduce the complaints that arise from the performance of unnecessary colposcopies and costly medical procedures.

FDA-approved for use with ThinPrep®

Complies with cervical cancer screening guidelines

Offers excellent sensitivity

Offers increased specificity

Same price and coverage as DNA-based HPV tests

No increased costs to you or your patients
The APTIMA® HPV test

**Highly sensitive and specific**

**Offers excellent sensitivity... so you can help minimize false-negative results**

The APTIMA® HPV Assay, utilizing mRNA, has shown sensitivity comparable to common DNA-based tests.

![Clinical Sensitivity Graph]

**Offers increased specificity, decreasing potential harms**

Fewer false-positive results:

- Decreasing difficult patient conversations
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![False-positive results Graph]

**Pap with HPV Co-testing for Women 30–65 Years of Age**

The best way to identify women most at risk of cervical cancer

![Pap with HPV Co-testing Diagram]

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- Offers excellent sensitivity*
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*Data sources include clinical studies and published guidelines.

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HPV-infected cervical cells

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(low-grade intraepithelial lesions)

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(high-grade intraepithelial lesions)

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Cervical carcinoma

mRNA and Cervical Disease

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With the FDA-approved APTIMA® HPV test, you can focus on more clinically relevant results.

E6/E7 mRNA levels

HPV mRNA delivers significantly less false positives than DNA—
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References: