Comprehensive FDA Approvals/Clearances for Out-of-the-Vial Testing

- Aptima® HPV assay
- Aptima® HPV & Syphilis Genotype assay
- Aptima® HPV 3/4/8 Genotype assay
- Aptima® HPV 16/18 Genotype assay
- Aptima® HPV 45 Genotype assay
- Aptima® HPV 2/3/45 Genotype assay
- Cervista® HPV 16 assay
- Cervista® HPV 16/18 assay
- cobas® 4400 CT/NG test
- digene® HC2 HPV DNA test
- ProbeTec™ CT/GC Qx Amplified DNA assays

This is the test that stands the test of time.

Leading the Revolution in Cytology

For more than 20 years, healthcare providers have trusted ThinPrep® more than any other brand. The ThinPrep Pap test has shown to be significantly more effective than conventional Pap testing* and become the preferred choice in liquid-based cytology today, with more than 650 million ThinPrep Pap tests performed so far.1

* The ThinPrep 2000 System is significantly more effective than conventional Pap smear for detection of low-grade squamous intraepithelial (LSIL) and severe lesions in a variety of patient populations.3
A Wealth of Knowledge in a Single Vial

Trust the Track Record

- 97% higher HSIL detection than conventional Pap testing
- 90% of the Top 50 U.S. Best Hospitals for Gynecology use the ThinPrep® Pap test
- The only Pap test FDA-approved for improved ability to detect glandular disease compared to conventional Pap
- Significantly more effective than conventional Pap smear for the detection of LSIL and more severe lesions
- The first FDA-approved collection media for use with all FDA-approved HPV tests

The ThinPrep® Pap Test Collection Process Provides:

- Patient Comfort
  - Out-of-the-vat testing minimizes the number of samples required for multiple test results.
- Cervical Versatility
  - Multiple FDA-approved ancillary testing options available from a single vial.
- Chain of Custody Verification
  - Closed system lab processing limits opportunities for chain-of-custody errors.
- Sample Integrity Preservation
  - 100% VIRTUALLY FULL CONTENTS OF SAMPLE PREPARATION.

SurePath® Pap Test

Full contents of sample preserved in SurePath®

- Brush head removed in 90°
- Brush head discarded in 90°
- Full contents of sample preserved in SurePath®

HSIL and LSIL Categorization

The College of American Pathologists reported increased HSIL and LSIL categorization rates in labs that used the ThinPrep Pap test in 679 U.S. laboratories.

A Versatile Application, Increased Detection

<table>
<thead>
<tr>
<th>Multifaceted Functionality</th>
<th>ThinPrep®</th>
<th>Viper System®</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA Approval</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Improved Sensitivity (HSIL)</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Improved Specificity (LSIL)</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Standard Disease Labelling</td>
<td>YES</td>
<td>YES</td>
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<tr>
<td>FDA Approved for Roche HPV DNA Tests</td>
<td>YES</td>
<td>YES</td>
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<tr>
<td>Available in 1700 Approval Countries</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>TrustLine Specimen HPV assay</td>
<td>35 weeks</td>
<td>Exist &amp; Available</td>
</tr>
<tr>
<td>Confirm HPV assay</td>
<td>25 weeks</td>
<td>Exist &amp; Available</td>
</tr>
<tr>
<td>Target HPV assay</td>
<td>25 weeks</td>
<td>Exist &amp; Available</td>
</tr>
<tr>
<td>Multiple HPV assays</td>
<td>YES</td>
<td>YES</td>
</tr>
</tbody>
</table>

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A Thorough Approach to Cervical Cancer Detection

Cervical Adenocarcinoma is a Growing Concern

While squamous cell carcinoma has steadily decreased since the introduction of the Pap smear, adenocarcinoma is on the rise. The ability to detect adenocarcinoma is an essential part of comprehensive cervical cancer screening.

HSIL Reporting Rate % (95th-pctl)*

- 11
- 0.6%
- p=0.108

Cervical Adenocarcinoma

- 10
- 0.7%
- 0.25
- 1.0
- 1.25
- 1.75
- 2.0
- 2.5
- 3.0
- 3.5

LISL Reporting Rate % (95th-pctl)*

- 10
- 0.25
- 0.5
- 1.0
- 1.25
- 1.75
- 2.0
- 2.5
- 3.0
- 3.5

Increased specificity and sensitivity over manually reviewed ThinPrep Pap test results.

Improved standardization at each stage of sample processing.

Reduced false-negative fraction.

Targeted areas: margin of cytologic interest and darkest nuclei for review.

* Biopsy follow up showed that the significant increase in HSIL diagnoses in the Imager group was due to the detection of true disease rather than false positive cytologic diagnoses.

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# The ThinPrep Pap test... produces more reliable results in detecting abnormalities of glandular cells.

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Addressing a Dangerous Threat

The ThinPrep Pap test is the only Pap test with FDA-approved labeling stating citing multiple peer-reviewed publications supporting increased glandular disease detection.

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