



The one vial that is tested
and trusted.

ThinPrep[®]
PAP TEST **20** YEARS

Leading Advances 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



TESTED
AND
TRUSTED



* 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.²

A Wealth of Knowledge in a Single Vial

Trust the Track Record

- ▶ **Significantly more effective** than conventional Pap smear for the detection of LSIL and more severe lesions.^{2*}
- ▶ **59.7% higher HSIL detection** than conventional Pap testing.^{2*}
- ▶ **The only Pap test FDA-approved** for improved ability to detect glandular disease compared to conventional Pap.²
- ▶ **The only collection medium** approved for use with all FDA-approved and all CE-marked HPV tests.[§]

The ThinPrep® Pap Test Collection Process Provides:



Patient Comfort

Only one sample needed for cytology and molecular testing.



Efficiency

Scalable levels of automation to optimize lab efficiency.



Chain-of-Custody Verification

Closed-system processing supports strong chain-of-custody.

Overcoming Conventional Limitations

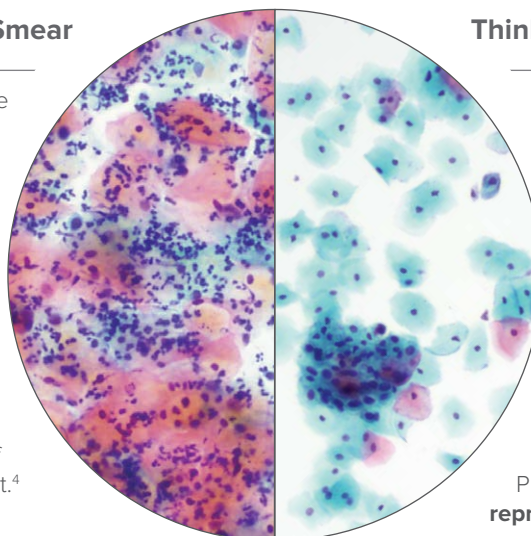
Conventional Pap Smear

Only a fraction of collected sample is used in slide preparation.³

Sample smearing factors often produce **poor cell quality**.³

Slide **may fail** to accurately represent sample and not reflect patient's actual condition.³

Cells on slide may overlap or be **obscured** by blood, mucus or other material, making visualization of cells difficult.⁴



ThinPrep® Pap Test

Nearly all of collected sample is retained in the ThinPrep vial.³

Immediate fixation **maintains cell quality**.³

Slides **accurately** represent sample for increased opportunity to detect abnormality.³

Cells on slide are **cleared** of obscuring elements and distributed evenly for ease of visualization.²

Produces multiple **representative** and **reproducible** samples.³

* 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.
§ Aptima® HPV assay, Aptima® HPV 16/18/45 Genotype assay, Cervista® HPV HR Test, Cervista® HPV 16/18 Test, Roche cobas HPV Test and Hybrid Capture 2 HPV DNA test.

Versatile Application

Multifaceted Functionality	ThinPrep [®] 2 PAP TEST	SUREPATH [®] 5 PAP TEST
FDA-Approved and CE-marked:	1996	1999
Improved Specimen Adequacy	✓	✓
Improved HSIL Detection	✓	✓
Glandular Disease Labeling Detection	✓*	—
FDA-Approved for Every Adjunctive HPV Test	✓	— [†]
Adjunctive CT/NG Approval / Clearance	For All FDA-Approved CT/NG Tests	Only Cleared on the BD ProbeTec Q CT and GC Assays with the Viper System
Adjunctive <i>Trichomonas vaginalis</i> Clearance	✓	—
Adjunctive <i>Mycoplasma genitalium</i> Clearance	✓	—
Shelf Life: Aptima [®] HPV assays ⁶	30 days [‡]	7 days [‡]
Digene [®] HC2 assay ⁷	90 days [‡]	28 days [‡]
cobas [®] HPV assay ⁸	180 days [‡]	14 days [‡]

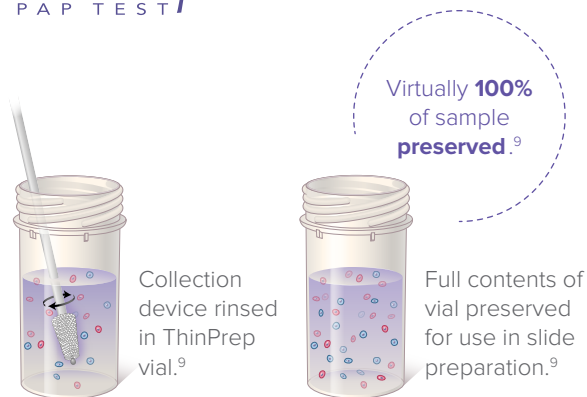
* The ThinPrep Pap test is the only Pap test with FDA-approved labeling supported by multiple peer-reviewed publications reporting increased glandular disease detection.


[†] Surepath is only approved for ASCUS Reflex and co-testing with Roche cobas.

[‡] At room temperature.

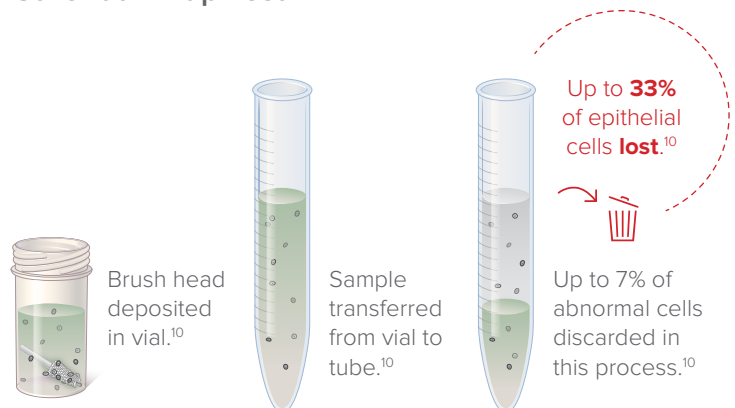
Sample Integrity Preservation


ThinPrep[®]
PAP TEST



20 mL Total Sample Volume
4 mL Pre-Aliquot Removal Volume: 
Extra volume for ancillary testing.²

SurePath[®] Pap Test



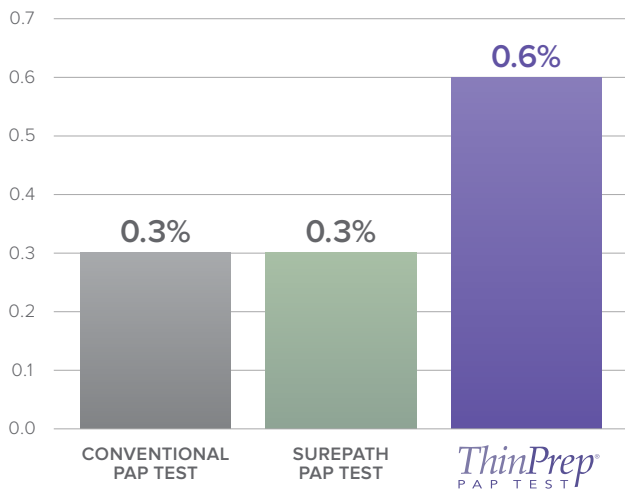
Just 10 mL Total Sample Volume
Only 0.5 mL Pre-Aliquot Removal Volume: 
Ancillary testing limited.

Increased Disease Detection

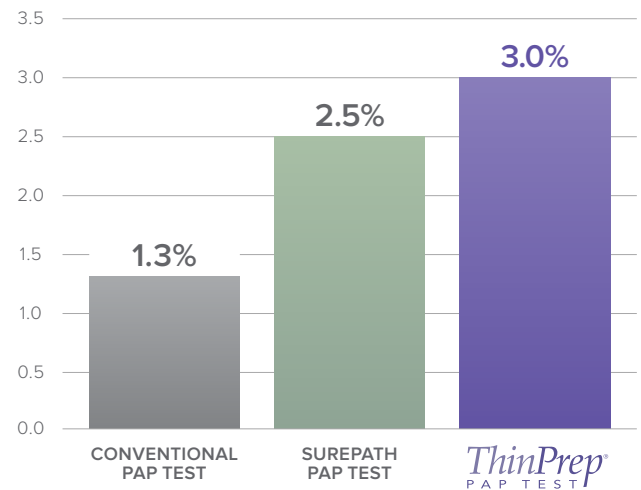
HSIL and LSIL Categorization

The College of American Pathologists (CAP) reported increased HSIL and LSIL categorization rates in labs that used the ThinPrep Pap test in 679 U.S. laboratories.¹¹

HSIL Reporting Rate % (50th pct)¹¹



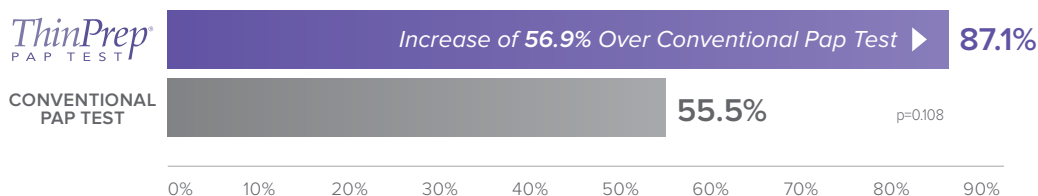
LSIL Reporting Rate % (50th pct)¹¹



Addressing a Dangerous Threat

The ThinPrep Pap test is the only pap test with FDA-approved labeling that is supported by multiple peer-reviewed publications reporting increased detection of adenocarcinoma (glandular disease).¹²⁻¹⁷

Sensitivity for Cervical Adenocarcinoma¹²



“The ThinPrep Pap test ... produces **more reliable results** in detecting abnormalities of glandular cells.”

The Society of Gynecologic Oncologists (SGO)¹⁸

Imaging-directed Cytology Means Improvements to Patient Results¹³



Increased sensitivity and specificity over manually reviewed ThinPrep Pap test slides.*



Improved standardization at each stage of sample processing and staining.



39% Reduced false-negative results.⁹



Targeted areas: Imager identifies largest 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.”¹⁹

* The Imager clinical trial results showed a statistically significant increase in ASCUS+ sensitivity of 6.4% [95% CI: 2.6-10.0], a statistically significant increase in HSIL+ specificity of 0.2% [95% CI: 0.06-0.4], and a reduction in false negative fraction of 39% (based on ASCUS+ sensitivity). The unsatisfactory rate was not evaluated for statistical significance, but a decrease was observed.

Imaging Raises the Bar in Pap Testing Results

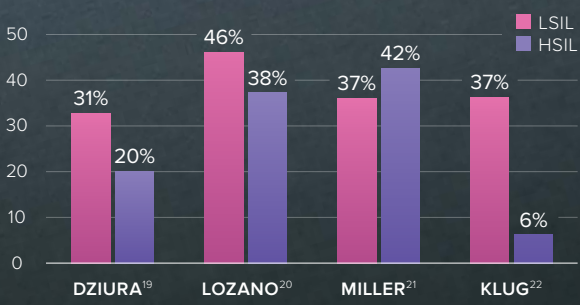
Imaging elevates workflow in your lab and **provides greater LSIL and HSIL categorization** versus non-imaged slides.



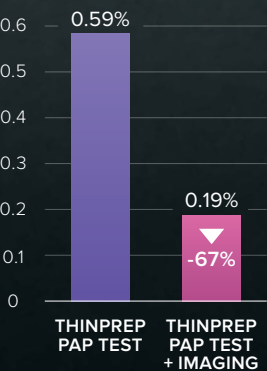
A Step Ahead with Imaging

Slides screened with the ThinPrep Imaging system showed greater LSIL and HSIL categorization versus non-imaged slides:

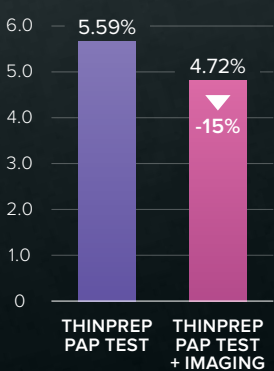
Independent Studies Show Increased LSIL and HSIL Cytology Categorization vs Manual ThinPrep Pap Test



UNSAT Rate²¹



ASCUS Rate²¹



The Complete Solution for Cervical Health Screening.



References 1. Hologic, Inc. Data on File. 2. ThinPrep 2000 System [package insert]. MAN-02060-002 Rev. 001. Marlborough, MA: Hologic, Inc.; 2011. 3. Hutchinson M, et al. Homogeneous Sampling Accounts for the Increased Diagnostic Accuracy Using the ThinPrep Processor. *Am J Clin Pathol*. 1994;101(2):215-9. doi:10.1093/ajcp/101.2.215. 4. Klinkhamer, et al. Liquid-based Cervical Cytology. *Cancer Cytopathol*. 2003;99(5):263-71. doi:10.1002/cncr.11673. 5. PrepStain System [product insert]. 779-07085-00, Rev. F. Burlington, NC: TriPath Imaging, Inc., 2011. 6. Aptima HPV Assay [package insert]. AW-1141-001, Rev. 003. San Diego, CA: Hologic, Inc.; 2015. 7. Hc2 High-Risk HPV DNA Test [package insert]. Gaithersburg, MD: QIAGEN; 2008. 8. cobas 4800 HPV Test [package insert]. 0564125001-14EN, Rev. 12.0. Branchburg, NJ: Roche Molecular Systems, Inc.; 2015. 9. FDA. Summary of Safety and Effectiveness Data: ThinPrep Imaging System. http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020002b.pdf. Approved June 6, 2003. Accessed March 21, 2016. 10. FDA. Summary of Safety and Effectiveness Data: The AutoCyte PREP System. http://www.accessdata.fda.gov/cdrh_docs/pdf/P970018b.pdf. Approved June 17, 1999. Accessed October 11, 2016. 11. Eversole GM, et al. Practices of participants in the college of American pathologists interlaboratory comparison program in cervicovaginal cytology, 2006. *Arch Pathol Lab Med*. 2010;134(3):331-5. doi:10.1043/1543-2165-134.3.331. 12. Schorge JO, et al. ThinPrep detection of cervical and endometrial adenocarcinoma: a retrospective cohort study. *Cancer Cytopathol*. 2002;96:338-343. 13. Bai H, et al. ThinPrep Pap Test promotes detection of glandular lesions of the endocervix. *Diagn Cytopathol*. 2000;23:19-22. 14. Carpenter AB, et al. ThinPrep Pap Test: Performance biopsy follow-up in a university hospital. *Cancer*. 1999;87:105-112. 15. Guidos BJ, et al. Detection of endometrial adenocarcinoma with the ThinPrep Pap Test. *Diagn Cytopathol*. 2000;23:260-265. 16. Ashfaq R, et al. ThinPrep Pap Test: Accuracy for glandular disease. *Acta Cytol*. 1999;43:81-85. 17. Wang N, et al. Histologic follow-up of atypical endocervical cells. Liquidbased, thin-layer preparation vs. conventional pap smear. *Acta Cytol*. 2002;46:453-457. 18. Medical Associations and Advocacy Groups Acknowledge Importance of New FDA Claims for ThinPrep Pap Test [press release]. Marlborough, MA: Cytec Corporation; September 15, 2005. 19. Dziura B, et al. Performance of an imaging system vs. manual screening in the detection of squamous intra epithelial lesions of the uterine cervix. *Acta Cytol*. 2006;50(3):309-11. 20. Lozano R. Comparison of computer-assisted and manual screening of cervical cytology. *Gynecol Oncol*. 2007;104(1):134-8. 21. Miller FS, et al. Implementation of the ThinPrep imaging system in a high-volume metropolitan laboratory. *Diagn Cytopathol*. 2007;35(4):213-7. 22. Klug SJ, et al. A randomized trial comparing conventional cytology to liquid-based cytology and computer assistance. *Int J Cancer*. 2012;132(12):2849-57. doi:10.1002/ijc.27955.

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