Imaging Raises the Bar in Pap Testing Results

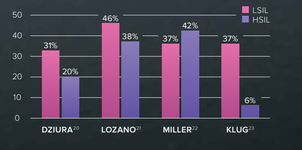
Imaging elevates workflow in your lab and **provides greater LSIL and HSIL categorization** versus non-imaged slides.

More Than **75%** of ThinPrep Pap Tests **Are Imaged**[1]

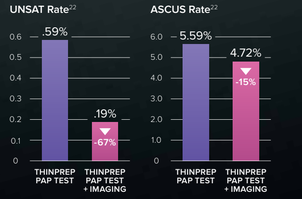
A Step Ahead with Imaging

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 Rate[22]



ASCUS Rate[22]

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

- Aptima® HPV assay
- Aptima® HPV 16 18/45 Genotype assay
- Aptima Combo 2® assay for CT/NG
- Aptima® Trichomonas vaginalis assay
- Cervista® HPV HR assay
- Cervista® HPV 16/18 assay
- cobas® HPV assay
- cobas® 4800 CT/NG test
- digene® HC2 HPV DNA test
- ProbeTec™ CT/GC Qx Amplified DNA assays

References 1. Hologic, Inc. Data on File. **2.** US News & World Report. Best Hospitals for Adult Gynecology. http://health.usnews.com/best-hospitals/rankings/gynecology. Published 2016. Accessed April 18, 2016. **3.** ThinPrep 2000 System [package insert]. MAN-02060-002 Rev. 001. Marlborough, MA: Hologic, Inc.; 2011. **4.** FDA. Summary of Safety and Effectiveness Data: ThinPrep Imaging System. http://www.accessdata.fda.gov/cdrh_docs/pdf/P970018b.pdf. Approved June 6, 2003. Accessed March 21, 2016. **5.** 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. **6.** PrepStain System [product insert]. 779-07085-00, Rev F. Burlington, NC: TriPath Imaging, Inc.; 2011. **7.** Aptima HPV Assay [package insert]. AW-11141-001, Rev. 003. San Diego, CA: Hologic, Inc.; 2015. **8.** Cervista [package insert]. 15-3053, Rev. 105. Wythenshawe, Manchester: Hologic, Inc.; 2015. **9.** Hc2 High-Risk HPV DNA Test [package insert]. Gaithersburg, MD: QIAGEN; 2008. **10.** cobas 4800 HPV Test [package insert]. 05641225001-14EN, Rev. 12.0. Branchburg, NJ: Roche Molecular Systems, Inc.; 2015. **11.** Evensole 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.** Adegoke O, et al. Cervical Cancer Trends in the United States: A 35-Year Population-Based Analysis. *J Women Health*. 2012;21(10):1031-1037. **13.** Schorge JO, et al. ThinPrep detection of cervical and a typical endocervical cells: a retrospective cohort study. *Cancer Cytopathol*. 2002;96:338-343. **14.** Bai H, et al. ThinPrep Pap Test promotes detection of glandular lesions of the endocervix. *Diagn Cytopathol*. 2000;23:19-22. **15.** Carpenter AB, et al. ThinPrep Pap Test: Performance biopsy follow-up in a university hospital. *Cancer*. 1999;87:105-112. **16.** Guidos BJ, et al. Detection of endometrial adenocarcinoma with the ThinPrep Pap Test. *Diagn Cytopathol*. 2000;23:260-265. **17.** Ashfaq R, et al. ThinPrep Pap Test: Accuracy for glandular disease. *Acta Cytol*. 1999;43:81-85. **18.** Wang N, et al. Histologic follow-up of atypical endocervical cells: Liquid-based, thin-layer preparation vs. conventional pap smear. *Acta Cytol*. 2002;46:453-457. **19.** Medical Associations and Advocacy Groups Acknowledge Importance of New FDA Claims for ThinPrep Pap Test [press release]. Marlborough, MA: Cytyc Corporation; September 15, 2005. **20.** 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. **21.** Lozano R. Comparison of computer-assisted and manual screening of cervical cytology. *Gynecol Oncol*. 2007;104(1):134-8. **22.** Miller FS, et al. Implementation of the ThinPrep imaging system in a high-volume metropolitan laboratory. *Diagn Cytopathol*. 2007;35(4):213-7. **23.** 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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ThinPrep® PAP TEST 20 YEARS

HOLOGIC® The Science of Sure

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]

20 YEARS

This is the test that stands the test of time.

TESTED AND TRUSTED

USED BY 90% OF THE TOP 50 U.S. BEST HOSPITALS FOR GYNECOLOGY.[1,2]

U.S.News & WORLD REPORT

ThinPrep® PAP TEST 20 YEARS

* 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

- **59.7% higher HSIL detection** than conventional Pap testing.[3*]
- **90% of the Top 50** U.S. Best Hospitals for Gynecology use the ThinPrep® Pap test.[1,2†]
- **The only Pap test FDA-approved** for improved ability to detect glandular disease compared to conventional Pap.[3]
- **Significantly more effective** than conventional Pap smear for the detection of LSIL and more severe lesions.[3‡]
- **The first FDA-approved** collection media for use with all FDA-approved HPV tests.[§]

The ThinPrep® Pap Test Collection Process Provides:

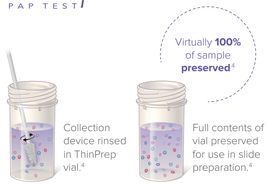
Patient Comfort
Out-of-the-vial testing minimizes the number of samples required for multiple test results.

Clinician 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

ThinPrep® PAP TEST

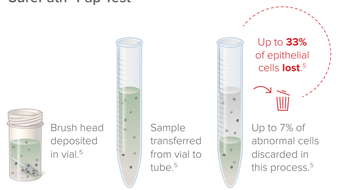


Collection device rinsed in ThinPrep vial.[4]

Virtually **100%** of sample **preserved**.[4]

Full contents of vial preserved for use in slide preparation.[4]

SurePath® Pap Test



Brush head deposited in vial.[5]

Sample transferred from vial to tube.[5]

Up to **33%** of epithelial cells **lost**.[5]

Up to 7% of abnormal cells discarded in this process.[5]

* 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.
† U.S. News & World Report data correlated with Hologic ordering data.
‡ 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, Increased Detection

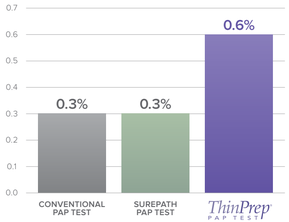
Multifaceted Functionality	ThinPrep® PAP TEST [3]	SUREPATH® PAP TEST [6]
FDA Approval	1996	1999
Improved Specimen Adequacy	✓	✓
Improved HSIL Detection	✓	✓
Glandular Disease Labeling Detection	✓*	—
FDA Approved for Every Adjunctive HPV Test	✓	—‡
Adjunctive CT/NG Approval / Clearance	For All FDA-Approved CT/NG Tests	Only Cleared on the BD ProbeTec Q CT and GC Assays with the Viper System
Adjunctive *Trichomonas vaginalis* Clearance	✓	—
Shelf Life: Aptima® HPV assays[7]	15 Weeks	Data Not Available
Cervista® HPV assays[8]	24 Weeks	Data Not Available
Digene® HC2 assay[9]	12 Weeks	Data Not Available
cobas® HPV assay[10]	24 Weeks	4 Weeks‡

* 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.

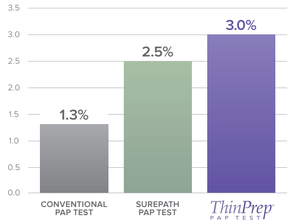
HSIL and LSIL Categorization

The College of American Pathologists reported increased HSIL and LSIL catergorization rates in labs that used the ThinPrep Pap test in 679 U.S. laboratories.[11]

HSIL Reporting Rate % (50th pctl)[11]



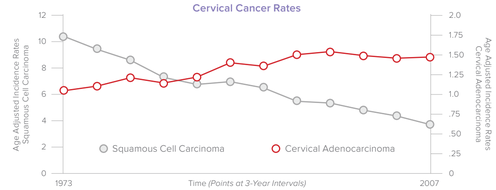
LSIL Reporting Rate % (50th pctl)[11]



A Thorough Approach to Cervical Cancer Detection

Cervical Adenocarcinoma is a Growing Concern[12]

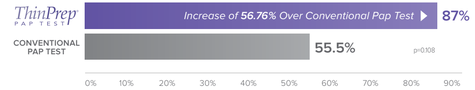
While squamous cell carcinoma has steadily decreased since the introduction of the Pap smear, adenocarcinoma remains an area of great concern. The ability to detect adenocarcinoma is an essential part of comprehensive cervical cancer screening.



Addressing a Dangerous Threat

The ThinPrep® Pap test is the only Pap test with FDA-approved labeling citing multiple peer-reviewed publications supporting increased glandular disease detection.[13-18]

Sensitivity for Cervical Adenocarcinoma[12]



> *"The ThinPrep Pap test ... produces **more reliable results** in detecting abnormalities of glandular cells."*
>
> *The Society of Gynecologic Oncologists (SGO)*[19]

Imaging-directed Cytology Means Improvements to Patient Results[14]

- **Increased sensitivity** and specificity over manually reviewed ThinPrep Pap test slides.*
- **Improved standardization** at each stage of sample processing.
- **Reduced false-negative** fraction.
- **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."*[20]

* 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.