

Imaging Raises the Bar in Pap Testing Results

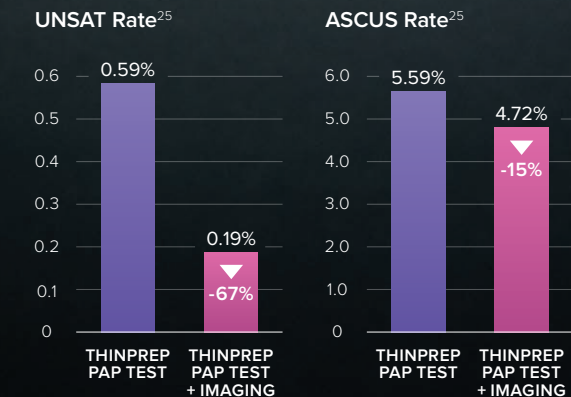
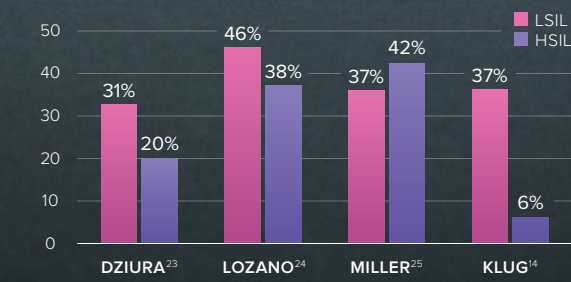
Imaging elevates workflow in your lab and **provides greater LSIL and HSIL categorization** versus non-imaged slides.



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



The Complete Solution for Cervical Health Screening.



References 1. Table 17, ThinPrep 2000 System [package insert]. MAN-02060-001 Rev. 006, Marlborough, MA: Hologic, Inc.; 2017. Hologic, Inc. 2. Data on File Hologic Report MAN-TPPTBR-001. 3. Schorge JO, Hossein Saboonian M, Hyman L, Ashfaq R. ThinPrep detection of cervical and endometrial adenocarcinoma: a retrospective cohort study. *Cancer Cytopathol.* 2002;96:338-43. 4. Bai H, Sung CJ, Steinhoff MM. ThinPrep Pap Test promotes detection of glandular lesions of the endocervix. *Diagn Cytopathol.* 2000;23:19-22. 5. Carpenter AB, Davey DD. ThinPrep Pap Test: performance and biopsy follow-up in a university hospital. *Cancer Cytopathol.* 1999;87:105-12. 6. Guidos BJ, Selvaggi SM. Detection of endometrial adenocarcinoma with the ThinPrep Pap test. *Diagn Cytopathol.* 2000;23:260-5. 7. Ashfaq R, Gibbons D, Veita C, Saboonian MH, Iliya F. ThinPrep Pap Test: Accuracy for glandular disease. *Acta Cytol.* 1999;43:81-5. 8. Data on File Hologic Report MAN-TPPTBR-002. 9. ThinPrep 2000 System [package insert]. MAN-02060-001 Rev. 006, Marlborough, MA: Hologic, Inc.; 2017. Hologic, Inc. 10. Hutchinson ML, Isenstein LM, Goodman A, Harley AA, Douglass KL, Mai KK, et al. Homogeneous Sampling Accounts for the Increased Diagnostic Accuracy Using the ThinPrep Processor. *Am J Clin Pathol.* 1994;101:215-9. 11. Powell N, Smith K, Fiander A. Recovery of human papillomavirus nucleic acids from liquid-based cytology media. *J Virol Methods.* 2006;137:58-62. 12. Kinkhimer PJ, Meerding WJ, Rosier PF, Hanselaar AG. Liquid-based cervical cytology. *Cancer Cytopathol.* 2003;99:263-71. 13. Kitchener HC, Gillies M, Desai M, Smith JH, Cook G, Roberts C, et al. A study of cellular counting to determine minimum thresholds for adequacy for liquid-based cervical cytology using a survey and counting protocol. *Health Technol Assess.* 2015;19(1):xxxi-64. 14. Papilio JL, Lagen D. Cell yield. *ThinPrep vs. cytocentrifuge.* *Acta Cytol.* 1994;38:33-6. 15. Biscotti CV, Shore JH, Gramlich TL, Easley KA. ThinPrep vs. conventional smear cytology preparations in analyzing fine-needle aspiration specimens from palpable breast masses. *Diagn Cytopathol.* 1999;21:137-41. 16. Dey P, Luthra UK, George J, Zubairy F, George SS, Haji BI. Comparison of ThinPrep and conventional preparations on fine needle aspiration cytology material. *Acta Cytol.* 2000;44:46-50. 17. Rana DN, O'Donnell M, Mallick A, Griffin M. A comparative study: conventional preparation and ThinPrep 2000 in respiratory cytology. *Cytopathology.* 2001;12:390-8. 18. Iwenberg H, Bergeron C, Schmidt D, Grieser H, Alameda F, Angeloni C, et al. Screening for cervical cancer precursors with p16/Ki-67 dual-stained cytology: results of the PALMS study. *J Natl Cancer Inst.* 2013;105:1550-7. 19. Klug SJ, Neis KJ, Harflinger W, Malter A, König J, Speith S, et al. A randomized trial comparing conventional cytology to liquid-based cytology and computer assistance. *Int J Cancer.* 2013;132:2849-57. 20. Wang N, Emancipator SN, Rose P, Rodriguez M, Abdul-Karim FW. Histologic follow-up of atypical endocervical cells: liquid-based, thin-layer preparation vs. conventional Pap smear. *Acta Cytol.* 2002;46:453-7. 21. Medical Associations and Advocacy Groups Acknowledge Importance of New FDA Claims for ThinPrep Pap Test [press release]. Marlborough, MA: Cytyc Corporation; September 15, 2005. 22. FDA. Summary of Safety and Effectiveness Data: ThinPrep Imaging System. http://www.accessdata.fda.gov/cdrh_docs/pdf2/PO20002b.pdf. Approved June 6, 2003. Accessed March 21, 2016. 23. Dziura B, Quinn S, Richard K. Performance of an imaging system vs. manual screening in the detection of squamous intraepithelial lesions of the uterine cervix. *Acta Cytol.* 2006;50:309-11. 24. Lozano R. Comparison of computer-assisted and manual screening of cervical cytology. *Gynecol Oncol.* 2007;104:134-8. 25. Miller FS, Nagel LE, Kenny-Moynihan MB. Implementation of the ThinPrep imaging system in a high-volume metropolitan laboratory. *Diagn Cytopathol.* 2007;35:213-7.

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Leading Advances in Cytology

The ThinPrep Pap test has shown to be significantly more effective than conventional Pap testing¹ and has become the preferred choice in liquid-based cytology today, with **more than 750 million ThinPrep Pap tests performed** so far.²



The one vial that is tested and trusted.

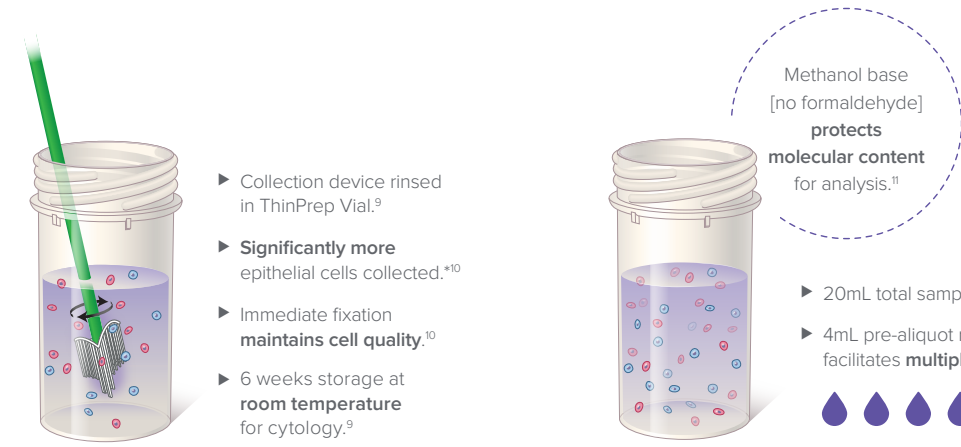


A Wealth of Knowledge in a Single Vial

Trust the Track Record

- ▶ **The only FDA-approved Pap test which is significantly more effective** than conventional Pap smear for the detection of LSIL and more severe lesions.¹
- ▶ **59.7% higher HSIL detection** than conventional Pap testing.¹
- ▶ **The only Pap test FDA-approved** for improved ability to detect glandular disease compared to conventional Pap.³⁻⁷
- ▶ **Approved** for use with all leading FDA-approved and CE-marked HPV tests.⁵
- ▶ **Used in more than 250 clinical studies**, with over 400,000 women tested with the ThinPrep® system.⁸

Sample Integrity Preservation



Multifaceted Versatile Application

FDA-Approved and CE-marked

- ✓ Improved Specimen Adequacy
- ✓ Improved HSIL Detection
- ✓ Improved Glandular Disease Detection
- ✓ For all leading HPV Tests⁵

Approved for Adjunctive use with Aptima Assays

- ✓ CT/NG¹
- ✓ *Trichomonas vaginalis*
- ✓ *Mycoplasma genitalium*

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.



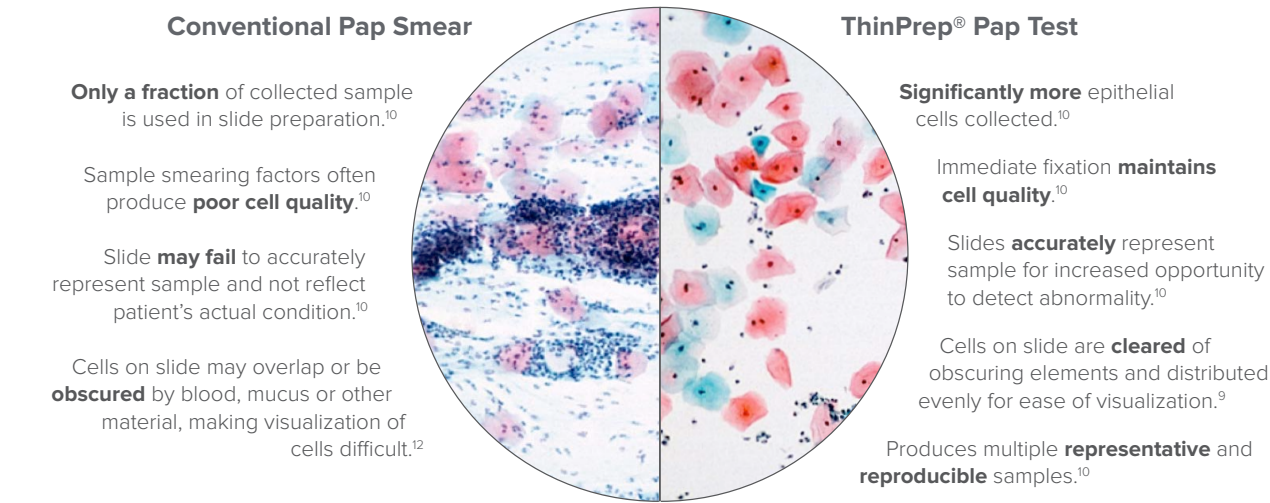
Chain-of-Custody Verification

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

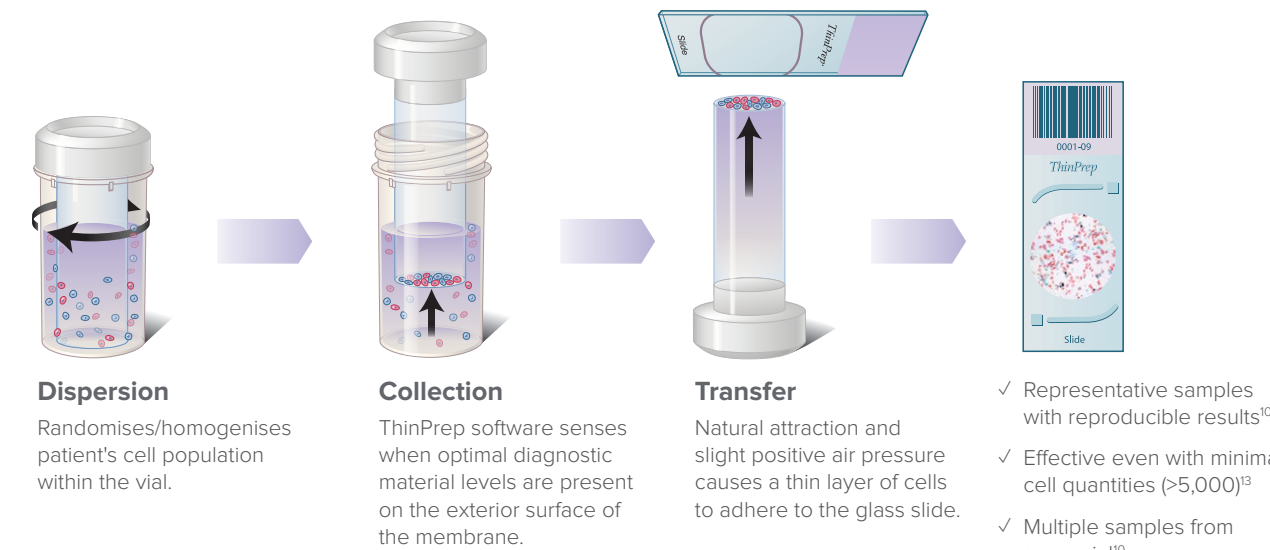
¹ Compared to conventional Pap
⁵ Aptima® HPV assay, Aptima® HPV 16/18/45 Genotype assay, Cervista® HPV HR Test, Cervista® HPV 16/18 Test, Roche cobas HPV Test and Hybrid Capture 2 HPV DNA test.
¹ Approved for all FDA-Approved CT/NG Tests

Versatile Application

Overcoming Conventional Limitations



Unique cell dispersion, collection & transfer technique⁹



Non-Gyn Applications with Standardized Workflow

Standardized process

- Controlled Membrane Transfer Technology automates and standardizes sample dispersion, cell collection and transfer for a wide variety of sample types – the same technology and process as gynae.
- **Fine Needle Aspirates** (Breast, Lung, Thyroid, Liver, Lymph nodes).
- **Body Fluids** (Ascitic, CSF, Pericardial, Pleural, Urine).
- **Respiratory Specimens** (Sputum, Bronchial brush/wash).

Improved slide quality and interpretation

- High cell yield.^{14,15}
- Thin layer technology reduces clumping and overlapping, preserves cell morphology and enhances nuclear detail.¹⁵⁻¹⁷
- Cells limited to smaller area (20mm diameter) and presented in a thin layer.¹⁶
- Easy interpretation.^{16,17}

Increased processing efficiency

- Scalable levels of automation.
- Minimal number of preparation steps.¹⁷
- Ancillary testing from the same sample.

Bronchial Wash – Adenoca Lung.

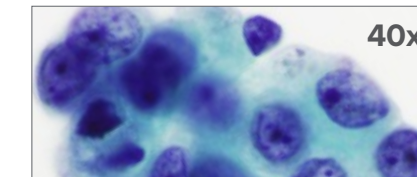


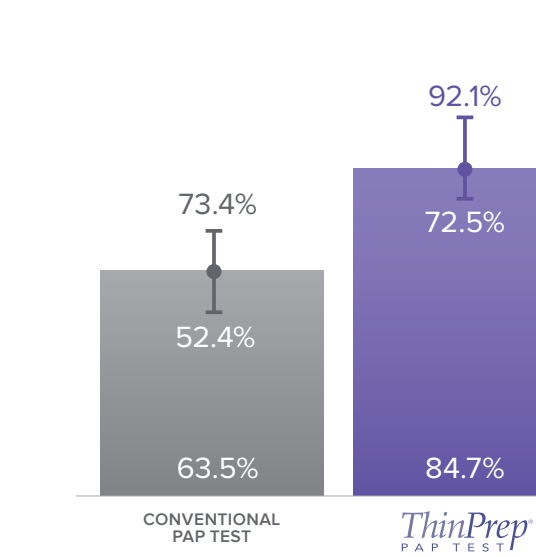
Image provided courtesy of Cytopathology Dept, Llandough Hospital, Wales

Increased Disease Detection

Significantly higher sensitivity for CIN (Cervical intra-epithelial neoplasia)

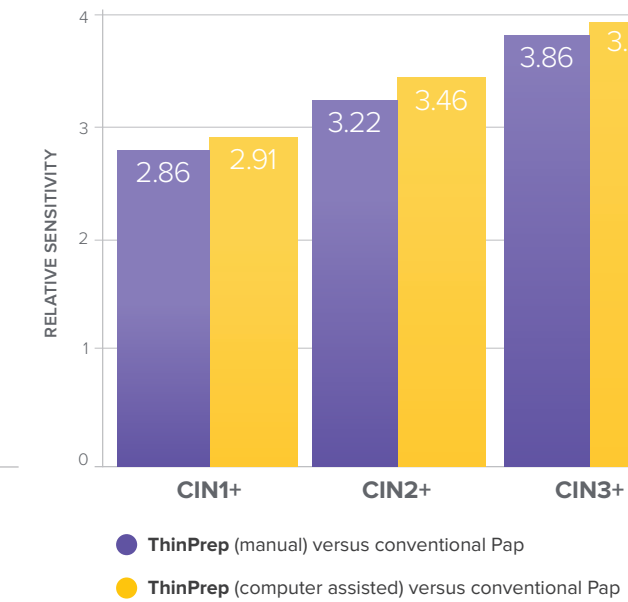
The highest sensitivity for Biopsy confirmed CIN2+ in the PALMS study.¹⁸

Sensitivity for CIN2+ (95% CI)



Significantly more sensitive for the detection of CIN in the Rhine-Saar study.¹⁹

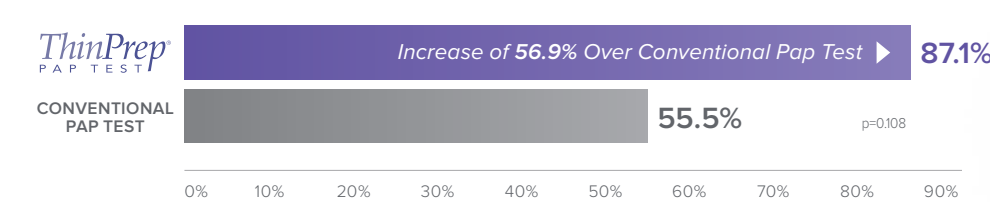
Relative sensitivity for CIN1+, CIN2+ and CIN3+ by HSIL+ cut-off



Significantly increased Glandular Disease Detection

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).^{3-7,20}

Sensitivity for Cervical Adenocarcinoma³



“ Specifically, the FDA recently approved a labeling change for the liquid-based cytology test, ThinPrep Pap Test, as a result of evidence that this technology produces **more reliable results** in detecting abnormalities of glandular cells. **These abnormalities are sometimes missed by conventional Pap test methods.** ”

The Society of Gynecologic Oncologists (SGO)²¹

Imaging-directed Cytology Means Improvements to Patient Results⁴

- 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.²²
- 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.”²³

* 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: 0.05-0.4], 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.