



The one vial that is
tested and trusted.



ThinPrep[®]
PAP TEST **20** YEARS

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



TESTED
AND
TRUSTED



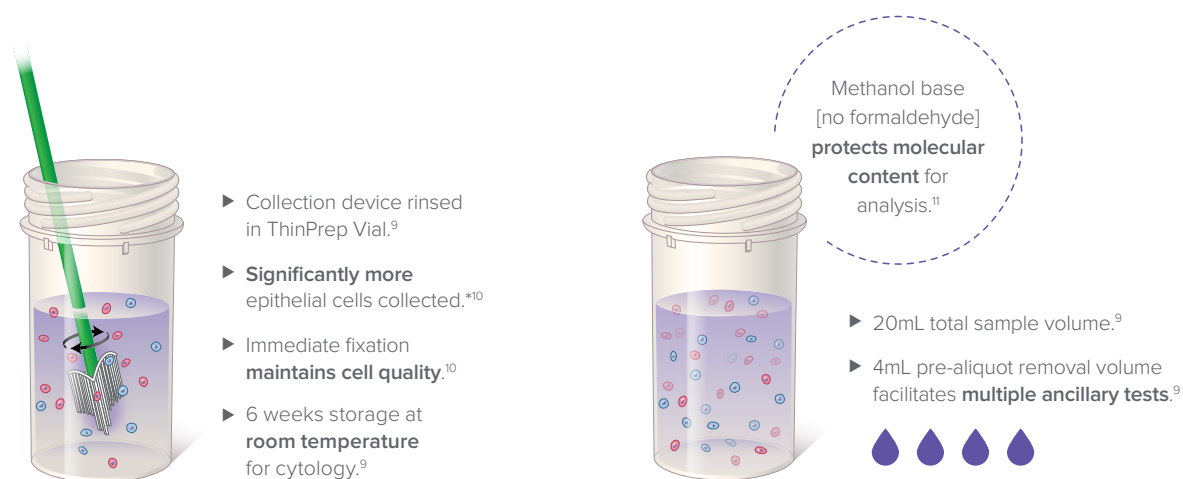
*

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/NG[†]
- ✓ *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.

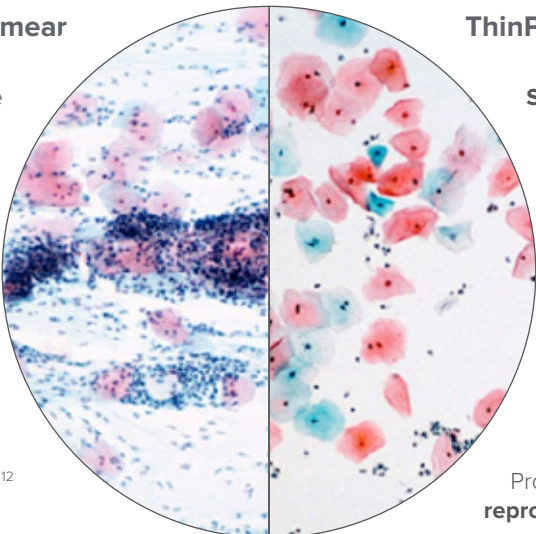
* Compared to conventional Pap

§ 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.

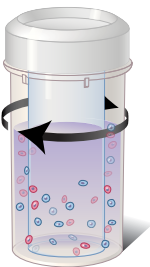
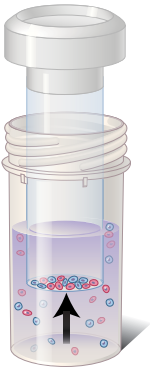
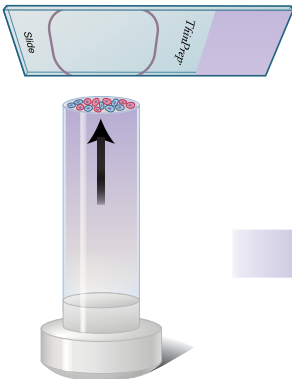

† Approved for all FDA-Approved CT/NG Tests

Versatile Application

Overcoming Conventional Limitations

Conventional Pap Smear		ThinPrep® Pap Test
<p>Only a fraction of collected sample is used in slide preparation.¹⁰</p> <p>Sample smearing factors often produce poor cell quality.¹⁰</p> <p>Slide may fail to accurately represent sample and not reflect patient's actual condition.¹⁰</p> <p>Cells on slide may overlap or be obscured by blood, mucus or other material, making visualization of cells difficult.¹²</p>		<p>Significantly more epithelial cells collected.¹⁰</p> <p>Immediate fixation maintains cell quality.¹⁰</p> <p>Slides accurately represent sample for increased opportunity to detect abnormality.¹⁰</p> <p>Cells on slide are cleared of obscuring elements and distributed evenly for ease of visualization.⁹</p> <p>Produces multiple representative and reproducible samples.¹⁰</p>

Unique cell dispersion, collection & transfer technique⁹

	➔		➔		➔	
Dispersion		Collection		Transfer		<ul style="list-style-type: none"> ✓ Representative samples with reproducible results¹⁰ ✓ Effective even with minimal cell quantities (>5,000)¹³ ✓ Multiple samples from same vial¹⁰
Randomises/homogenises patient's cell population within the vial.		ThinPrep software senses when optimal diagnostic material levels are present on the exterior surface of the membrane.		Natural attraction and slight positive air pressure causes a thin layer of cells to adhere to the glass slide.		

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.

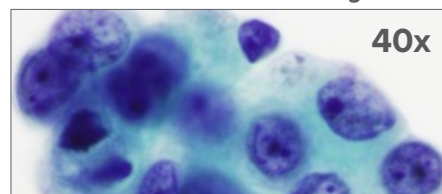


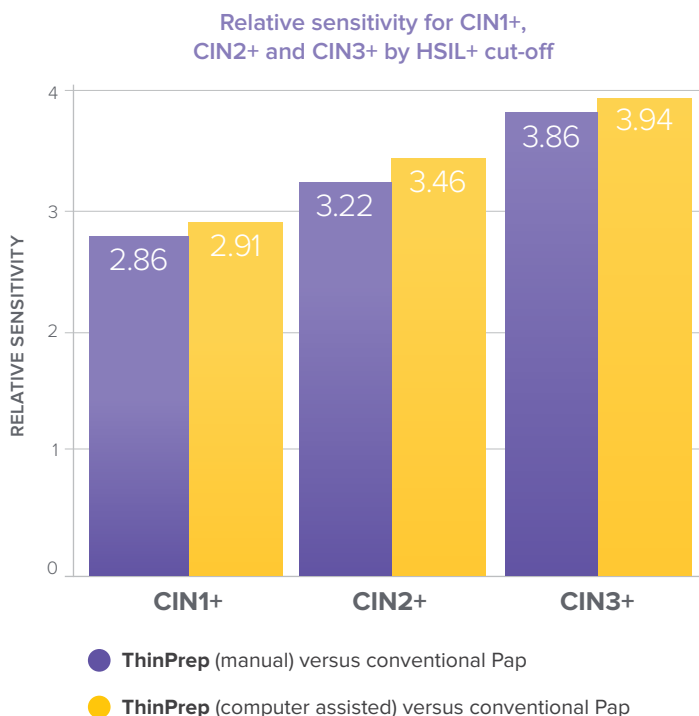
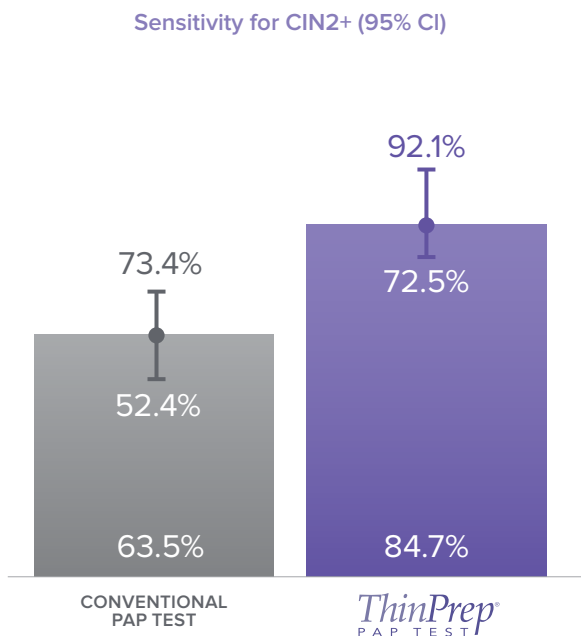
Image provided courtesy of Cytopathology Dept, Llandough Hospital, Wales

Increased Disease Detection

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

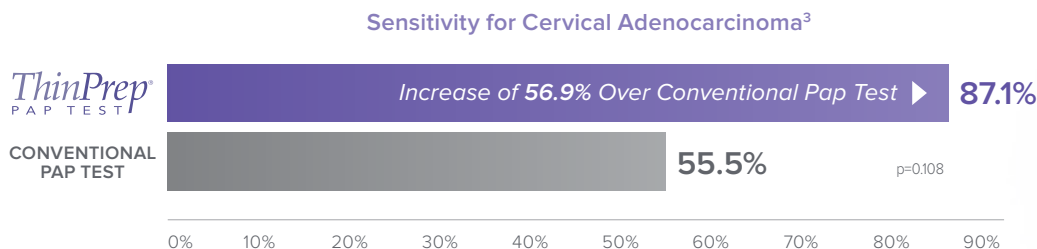
The highest sensitivity for Biopsy confirmed CIN2+ in the PALMS study.¹⁸

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



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}



“ 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

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 Saboorian M, Hynan 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, Vela C, Saboorian 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, Hurley AA, Douglass KL, Mui 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. Klinkhamer PJ, Meerding WJ, Rosier PF, Hanselaar AG. Liquid-based cervical cytology. *Cancer Cytopathol.* 2003;99:263-71. 13. Kitchener HC, Gittins 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:i-xix:1-64. 14. Papillo JL, Lapen D. Cell yield. ThinPrep vs. cytocentrifuge. *Acta Cytol.* 1994;38:33-6. 15. Biscotti CV, Shorie JH, Gramlich TL, Easley KA. ThinPrep vs. conventional smear cytologic preparations in analyzing fine-needle aspiration specimens from palpable breast masses. *Diagn Cytopathol.* 1999;21:137-41. 16. Dey P, Luthra UK, George J, Zuhairy 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, Malkin A, Griffin M. A comparative study: conventional preparation and ThinPrep 2000 in respiratory cytology. *Cytopathology* 2001;12:390-8. 18. Ikenberg H, Bergeron C, Schmidt D, Griesser 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, Harlfinger W, Malter A, König J, Spieth 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: Cytoc Corporation; September 15, 2005. 22. 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. 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.

Diagnostic Solutions | Hologic.com | euinfo@hologic.com

PB-00470-EUR-EN Rev 003 ©2019 Hologic, Inc. All rights reserved. Hologic, The Science of Sure, ThinPrep, Aptima Combo 2, Aptima and associated logos are trademarks and/or registered trademarks of Hologic, Inc. and/or its subsidiaries in the United States and/or other countries. This information is intended for medical professionals and is not intended as a product solicitation or promotion where such activities are prohibited. Because Hologic materials are distributed through websites, eBroadcasts and tradeshows, it is not always possible to control where such materials appear. For specific information on what products are available for sale in a particular country, please contact your local Hologic representative or write to euinfo@hologic.com.

