

Liquid Based Cytology Collection: Quick Reference Guide

ThinPrep® Pap Test Instructions for direct to vial specimen collection

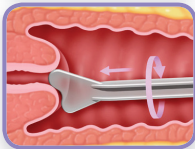
Liquid Based Cytology (LBC) is now MBS-listed as an interim arrangement until the renewed National Cervical Screening Program commences (Item 73069). For each patient a rebate is payable for one cytology test – either LBC or the conventional Pap test. For optimal specimen collection with the ThinPrep Pap test, please follow the instructions below.

ThinPrep Pap Test Plastic Spatula and Endocervical Brush Protocol

- Prepare all equipment before starting the procedure.
- Note expiry date on sample collection vial. Do not use expired vials.
- Ensure the entire plastic seal is removed from the lid of the vial and discarded.
- Remove the lid from the vial before taking the sample.
- If lubrication of the speculum is required, please use warm water. The use of lubricant may interfere with pathology tests. However, if necessary a small amount of water-soluble **carbomer-free** lubricant should be applied sparingly to the outer portion of the speculum only, avoiding the tip.
- Do not use an endocervical brush during pregnancy
- Do not use an endocervical brush in isolation



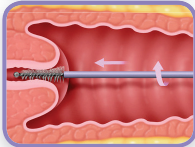
Record the patient's full name and date of birth on the vial as required by local regulations. The patient information and medical history should be recorded on the pathology request form.



Obtain an adequate sample from the ectocervix using a plastic spatula. Select the contoured end of the plastic spatula and rotate it 360° in a clockwise direction around the entire ectocervix, while maintaining tight contact with ectocervical surface.



Rinse the plastic spatula immediately into the vial by swirling the spatula **vigorously** in the vial 10 times. Discard the plastic spatula.



Obtain an adequate sampling from the endocervix using an endocervical brush device. Insert the Cytobrush into the endocervical canal until only the bottom-most bristles are exposed. Slowly rotate 1/4 or 1/2 turn in one direction. **Do not over-rotate the brush.**



Rinse the endocervical brush immediately in the same vial by rotating the device in the solution 10 times while pushing it against the vial wall. As a final step, swirl the brush **vigorously** to further release material. Discard the brush.



Tighten the cap so that the torque line on the cap passes the torque line on the vial. **Do not over-tighten.** Place the vial and pathology request form in a specimen bag for transport to the laboratory.

Note: Certain molecular tests, such as HPV, CT/GC, TV, M.gen, can be performed from the same material collected for the ThinPrep Pap Test. Contact your laboratory for more information.

Liquid Based Cytology Collection: Quick Reference Guide

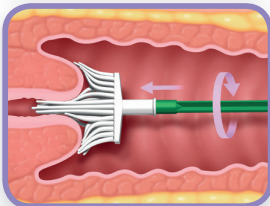
ThinPrep® Pap Test Instructions for direct to vial specimen collection

ThinPrep Pap Test Cervical Sampler Broom protocol

- Prepare all equipment before starting the procedure.
- Note expiry date on sample collection vial. Do not use expired vials.
- Ensure the entire plastic seal is removed from the lid of the vial and discarded.
- Remove the lid from the vial before taking the sample.
- If lubrication of the speculum is required, please use warm water.
The use of lubricant may interfere with pathology tests. However, if necessary a small amount of water-soluble **carbomer-free** lubricant should be applied sparingly to the outer portion of the speculum only, avoiding the tip.
- An endocervical brush may also be used in combination with the cervical sampler at the discretion of the practitioner. Both sampling devices should be rinsed in the same patient vial.



Record the patient's full name and date of birth on the vial as required by local regulations. The patient information and medical history should be recorded on the pathology request form.



Obtain an adequate sample from the transformation zone of the cervix using a cervical sampler (broom-like device). Insert the central bristles of the broom into the endocervical canal deep enough to allow the shorter bristles to fully contact the ectocervix. Push gently, and rotate the brush 360° in a clockwise direction 3–5 times.



Rinse the cervical sampler immediately into the vial by pushing it into the bottom of the vial 10 times, forcing the bristles apart. As a final step, swirl the brush **vigorously** to further release material. Visually inspect the cervical sampler to ensure that no material remains attached. Discard the collection device. **Do not leave the head of the cervical sampler in the vial.**



Tighten the cap so that the black torque line on the cap passes the black torque line on the vial. **Do not over-tighten.** Place the vial and pathology request form in a specimen bag for transportation to the laboratory.

Note: Certain molecular tests, such as HPV, CT/GC, TV, M.gen, can be performed from the same material collected for the ThinPrep Pap Test. Contact your laboratory for more information.

For more information please visit: www.thinprep.com.au

Diagnostic Solutions | hologic.com.au | australia@hologic.com | 1800 264 073 (Australia)

Hologic (Australia) Pty Ltd, Level 4, 2-4 Lyon Park Rd, Macquarie Park NSW 2113. Tel. +61 2 9888 8000. ABN 95 079 821 275.

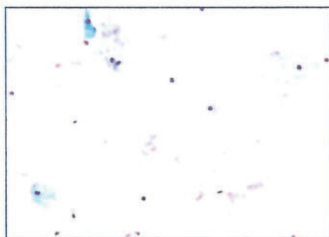
MED-00247-AUS-EN Rev 001 © 2017 Hologic, Inc. All rights reserved. Specifications are subject to change without prior notice. Hologic, Science of Sure, PreservCyt, ThinPrep and associated logos are trademarks and/or registered trademarks of Hologic, Inc. and/or its subsidiaries in the United States and/or other countries. All other trademarks, registered trademarks, and product names are the property of their respective owners. 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 Hologic representative or write to australia@hologic.com

This is a general information tool for medical professionals and is not a complete representation of the product(s)' Instruction for Use (IFU) or Package Insert, and it is the medical professionals' responsibility to read and follow the IFU or Package Insert. The information provided may suggest a particular technique or protocol however it is the sole responsibility of the medical professional to determine which technique or protocol is appropriate. At all times, clinicians remain responsible for utilizing sound patient evaluation and selection practices, and for complying with all applicable rules and regulations regarding accreditation, anesthesia, reimbursement, and all other aspects of in-office procedures. In no event shall Hologic be liable for damages of any kind resulting from your use of the information presented.

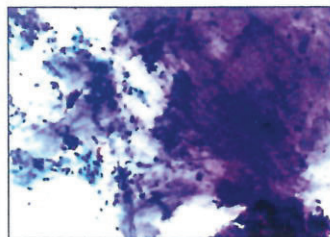
ThinPrep[®] Pap test: specimen collection

Training bulletin

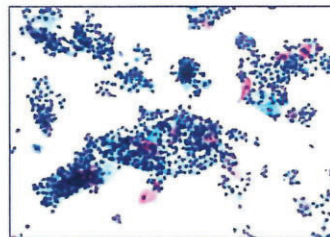
The detection of cervical cancer and its precursors as well as other gynecologic abnormalities is the primary purpose of obtaining a cervical cell sample. The following guidelines are referenced from CLSI Document GP15-A3¹ and are recommended in the collection process for obtaining a ThinPrep Pap Test (TPPT) specimen. In general, the guidelines state that it is important to obtain a specimen that is not obscured by blood, mucus, inflammatory exudate or lubricant.



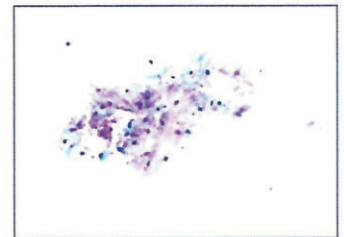
Unsatisfactory specimen
obscured by blood



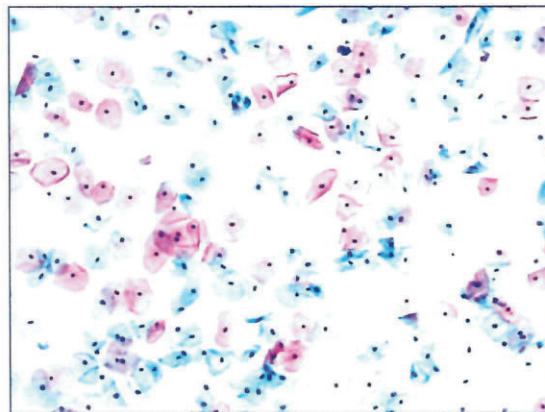
Unsatisfactory specimen
obscured by mucus



Unsatisfactory specimen
obscured by inflammation



Unsatisfactory specimen
obscured by lubricant



Satisfactory ThinPrep Pap Test specimen

Patient information

- The patient should be tested 2 weeks after the first day of her last menstrual period, and definitely not when she is menstruating.
Even though the TPPT reduces obscuring blood, clinical studies have demonstrated that excessive amounts of blood may still compromise the test and possibly lead to an unsatisfactory result.²
- The patient should not use vaginal medication, vaginal contraceptives, or douches for 48 hours before the exam.
- The patient should refrain from intercourse 48 hours prior to the exam.³

ThinPrep[®] Pap test: specimen collection

Training bulletin

Specimen collection preparation

- **Prepare the speculum.**

For patients without physical or physiological need for lubricant, use lukewarm water to warm and lubricate the speculum.

Water lubrication has the fewest risks to the quality of the Pap sample collected.⁴

When necessary, sparingly apply **carbomer-free** lubricant on the exterior of the speculum blades.

If lubricant is necessary due to patient discomfort or the use of a plastic speculum, sparingly apply a thin film of **carbomer-free** lubricant on the speculum's surface, avoiding the tip.

Do not use an excessive amount of lubricant jelly to lubricate the speculum.

Hologic[®] evaluated a variety of popular lubricants and found those containing carbomer or carbopol polymers (thickening agents) may interfere with obtaining a representative cervical sample or cause artifact in the alcohol-based transport medium.⁴ Hologic recognizes the varying availability of different types of lubricants and recommends that, if used, any lubricant should be applied sparingly.

- **Remove excess mucus or other discharge present before taking the sample. This should be gently removed with ring forceps holding a folded gauze pad.**

The excess cervical mucus is essentially devoid of meaningful cellular material and when present in the sample vial may yield a slide with little or no diagnostic material present.

- **Remove inflammatory exudate from the cervical canal before taking the sample. Remove by placing a dry 2-by-2-inch piece of gauze over the cervix and peeling it away after it absorbs the exudate or by using a dry procto swab or Scopette[®] swab.**

The excess inflammatory exudate is essentially devoid of diagnostic cellular material and, when present in the sample vial, may yield a slide with little or no diagnostic material present.

- **The cervix should not be cleaned by washing with saline or it may result in a relatively acellular specimen.**

- **The sample should be obtained before the application of acetic acid.**

Specimen collection

Refer to Hologic's ThinPrep Pap Test Quick Reference Guides, Part No.s DS-05867-001 and DS-05720-001, and ThinPrep Pap Test Specimen Collection Protocol Video.³

Collection device rinsing

Refer to Hologic's ThinPrep Pap Test Quick Reference Guides, Part No.s DS-05867-001 and DS-05720-001, and ThinPrep Pap Test Specimen Collection Protocol Video.³

hologic.com | diagnostic.solutions@hologic.com | +1.781.999.7300

1. Clinical Laboratory Standards Institute. GP15-A3 Cervicovaginal Cytology Based on the Papanicolaou Technique; Approved Guideline. November 2008.
2. Lee, et al. Comparison of Conventional Papanicolaou Smears and a Fluid-Based, Thin-Layer System for Cervical Cancer Screening. *Obstet Gynecol.* 1997;90(2):278-84. 3. Saslow D, et al. American Cancer Society guideline for the early detection of cervical neoplasia and cancer. *CA Cancer J Clin.* 2002;52:342-62. 4. Lubricant Use During Pap Sample Collection. MISC-00579 Rev. 006. 5. ThinPrep Specimen Collection Protocol Video. MOV-00052-001 Rev. 002. Hologic, Inc.