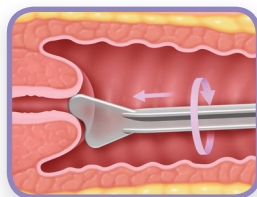


Protocol: endocervical brush/spatula

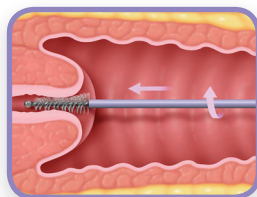
Quick reference guide



Obtain an adequate sample from the ectocervix using a plastic spatula. If desired, use lukewarm water to warm and lubricate the speculum. Apply water-soluble, carbomer-free gel lubricant sparingly to the posterior blade of the speculum if necessary.^{1,2} Select the contoured end of the plastic spatula and rotate it 360 degrees around the entire ectocervix, while maintaining tight contact with ectocervical surface.



Rinse the spatula as quickly as possible into the PreservCyt® Solution vial by swirling the spatula **vigorously** in the vial 10 times. Discard the spatula.



Obtain an adequate sampling from the endocervix using an endocervical brush device. Insert the brush into the cervix until only the bottom-most fibers are exposed. Slowly rotate 1/4 or 1/2 turn in one direction. **DO NOT OVER-ROTATE THE BRUSH.**



Rinse the brush as soon as possible in the PreservCyt Solution by rotating the device in the solution 10 times while pushing it against the PreservCyt vial wall. 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.



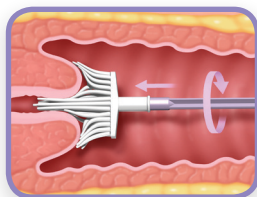
Record the patient's name and ID number on the vial.
Record the patient information and medical history on the cytology requisition form.



Place the vial and requisition in a specimen bag for transport to the laboratory.

Protocol: broom-like device

Quick reference guide



Obtain an adequate sampling from the cervix using a broom-like device. If desired, use lukewarm water to warm and lubricate the speculum. Apply water-soluble, carbomer-free gel lubricant sparingly to the posterior blade of the speculum if necessary.^{1,2} 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 broom in a clockwise direction for five complete, 360 degree turns.



Rinse the broom as quickly as possible into the PreservCyt® Solution vial by pushing the broom into the bottom of the vial 10 times, forcing the bristles apart. Swirl the broom **vigorously** to further release material. Do not leave the head of the broom in the vial. Discard the collection device.



Tighten the cap so that the torque line on the cap passes the torque line on the vial.



Record the patient's name and ID number on the vial.

Record the patient information and medical history on the cytology requisition form.



Place the vial and requisition in a specimen bag for transport to the laboratory.

Refer to the instructions provided with the collection device for warnings, contraindications, and limitations associated with specimen collection.

www.thinprep.com

Hologic provides this quick reference guide ("guide") as a general informational tool only and is not an affirmative instruction or guarantee. While the information provided in this guide may describe a particular technique or protocol, it is not intended as an endorsement and/or requirement by Hologic to utilize such technique or protocol. It is the sole responsibility of the laboratory to determine which specific technique and/or protocol to employ. Laboratories using ThinPrep or PreservCyt products must read and understand each product's Instructions for Use and comply with applicable local, state and federal rules and regulations.

1. Cervicovaginal Cytology Based on the Papanicolaou Technique; Approved Guideline – Third Edition (Clinical and Laboratory Standards Institute GP15-A3). 2. Hologic internal study, data on file.

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

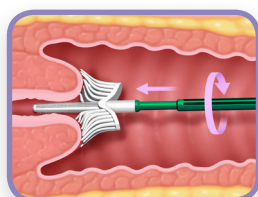
DS-05867-001 Rev. 002 © 2017 Hologic, Inc. All rights reserved. Hologic, Science of Sure, PreservCyt, ThinPrep and associated logos are trademarks and/or registered trademarks of Hologic, Inc. and/or its subsidiaries in the United States and/or other countries. All other trademarks are the property of their respective owners. This information is intended for medical professionals in the U.S. and other markets and is not intended as a product solicitation or promotion where such activities are prohibited. Because Hologic materials are distributed through websites, eBroadcasts and trade shows, 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 diagnostic.solutions@hologic.com.

ThinPrep
PAP TEST

Protocol: Rovers® Cervex-Brush® Combi device

Quick reference guide

Contra-indications: The Rovers Cervex-Brush Combi device should not be used during pregnancy.



Obtain an adequate sample from the cervix using a Rovers Cervex-Brush Combi device (a green, broom-like device with an integrated endocervical sampler). If desired, use lukewarm water to warm and lubricate the speculum. Sparingly apply water-soluble carbomer-free gel lubricant to the posterior blade of the speculum if necessary.^{1,2} Insert the endocervical sampler part of the device into the endocervical canal deep enough to allow the other bristles to fully contact the ectocervix. Push gently, and rotate the brush in a clockwise direction 2 times for 2 complete 360° degree turns.³



Rinse the Rovers Cervex-Brush Combi device immediately into the PreservCyt® Solution 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 Rovers Cervex-Brush Combi device to ensure that no material remains attached. Discard the collection device. **Do not leave the head of the Rovers Cervex-Brush Combi device in the vial.**

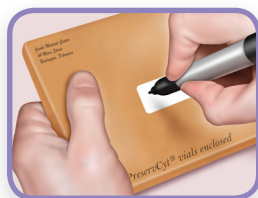


Tighten the cap of the PreservCyt Solution vial so that the torque line on the cap passes the torque line on the vial.



Record the patient's name and ID number on the vial.

Record the patient's information and medical history on the cytology requisition form.



Place the vial and requisition in a specimen bag for transport to the laboratory.

Hologic provides this Rovers Cervex-Brush Combi device protocol ("protocol") as a general informational tool only and is not an affirmative instruction or guarantee. While the information provided in this protocol may describe a particular technique or protocol, it is not intended as an endorsement and/or requirement by Hologic to utilize such technique or protocol. It is the sole responsibility of the physician to determine which specific technique and/or protocol to employ for obtaining an adequate sample. Physicians using the Rovers Cervex-Brush Combi Device must read and understand the product's Instructions for Use and comply with applicable local, state and federal rules and regulations.

1. Cervicovaginal Cytology Based on the Papanicolaou Technique; Approved Guideline – Third Edition (Clinical and Laboratory Standards Institute GP15-A3). 2. Hologic internal study, data on file. 3. Rovers Cervex-Brush Combi, Information For Use, 2010-11.

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

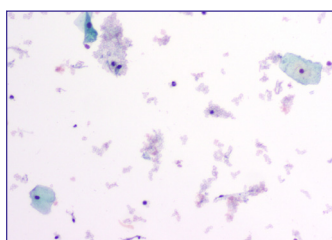
DS-05867-001 Rev. 001 © 2015 Hologic, Inc. All rights reserved. Hologic, Science of Sure, PreservCyt, ThinPrep and associated logos are trademarks and/or registered trademarks of Hologic, Inc. and/or its subsidiaries in the United States and/or other countries. All other trademarks are the property of their respective owners. This information is intended for medical professionals in the U.S. and other markets 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 **diagnostic.solutions@hologic.com**.

ThinPrep®
PAP TEST

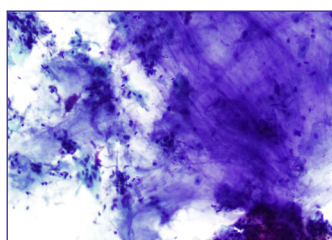
ThinPrep® Pap Test: specimen collection

Training bulletin

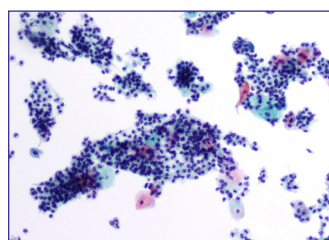
The detection of cervical cancer and its precursors as well as other gynecologic abnormalities is the primary purpose of obtaining a cervical cell sample. The following guidelines are referenced from CLSI Document GP15-A3¹ and are recommended in the collection process for obtaining a ThinPrep® Pap Test (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.



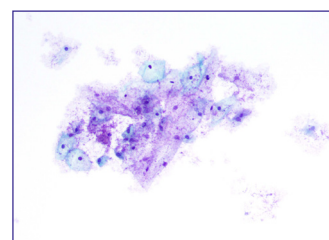
Unsatisfactory specimen
obscured by blood



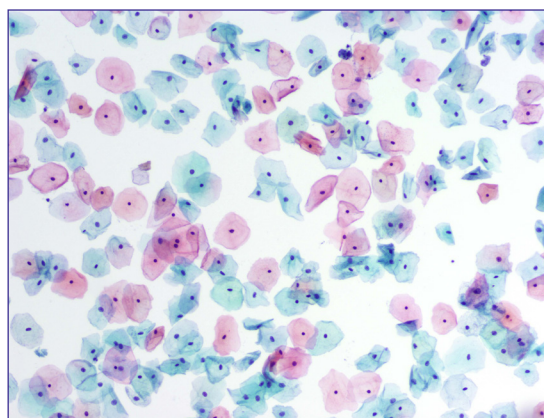
Unsatisfactory specimen
obscured by mucus



Unsatisfactory specimen
obscured by inflammation



Unsatisfactory specimen
obscured by lubricant



Satisfactory ThinPrep Pap Test specimen

Patient information

- The patient should be tested two 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, vaginal creams, vaginal jellies, or douches during the 48 hours before the exam.
- The patient should refrain from intercourse 48 hours prior to the exam³.

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 Video³.

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 Video³

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

1. Papanicolaou Technique Approved Guidelines (CLSI Document GP15-A3) 2. Lee et al. Comparison of Conventional Papanicolaou Smears and a Fluid-Based, Thin-Layer System for Cervical Cancer Screening. Ob Gyn 1997; 90: 278-284. 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, Part No. MISC-00579 Rev. 006 5. Specimen Collection Protocol Video, Part No. MOV-00052-001 Rev. 002.

MISC-02720-001 Rev. 001 ©2015 Hologic, Inc. All rights reserved. Hologic, Science of Sure, 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 are the property of their respective owners. This information is intended for medical professionals in the U.S. and other markets and is not intended as a product solicitation or promotion where such activities are prohibited. Because Hologic materials are distributed through websites, eBroadcasts and tradeshow, 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 **diagnostic.solutions@hologic.com**.

ThinPrep®
P A P T E S T