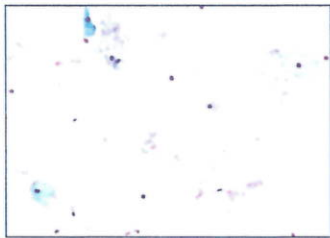


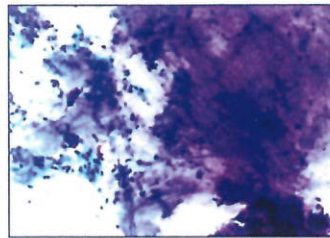
ThinPrep® Pap test: specimen collection

Training bulletin

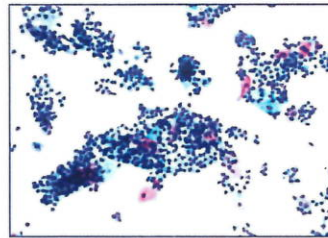
The detection of cervical cancer and its precursors as well as other gynecologic abnormalities is the primary purpose of obtaining a cervical cell sample. The following guidelines are referenced from CLSI Document GP15-A3¹ and are recommended in the collection process for obtaining a ThinPrep Pap Test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



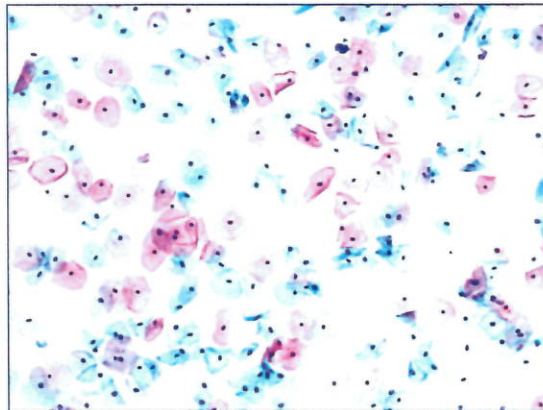
Unsatisfactory specimen
obscured by mucus



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

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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.

The use of lubricants with the ThinPrep Pap test is not recommended. However, if a lubricant is necessary, consult this list of common lubricant brands for compatibility.^{1*}

ThinPrep[®] Pap Test Lubricant Compatibility List

	Lubricant	Manufacturer	Contains Carbomer?
✓ Preferred [†]	PAP Test Lubricating Jelly	Aseptic Control Products	No
	Surgilube Surgical Lubricant	HR Pharmaceuticals	No
✓ Compatible [‡]	K-Y Jelly (Physician Formula)	Johnson & Johnson	No [§]
	Surgel	Ulmer Pharmacal	No
✗ Incompatible [§]	Aquagel Lubricating Gel	Parker Laboratories, Inc.	Yes
	Astroglide (Physician Formula)	BioFilm, Inc.	No
	Astroglide (Personal Formula)[¶]	BioFilm, Inc.	No
	Crystelle	Deltex Pharmaceuticals, Inc. - FDA injunction in 2011; no longer in operation	Unknown
	HR Lubricating Jelly	HR Pharmaceuticals, Inc.	Yes
	Lubricating Gel	Henry Schein	Yes
	Lubricating Jelly	McKesson	Yes
	MediChoice Lubricating Jelly	Owens & Minor	Yes
	PDI Lubricating Jelly I and II	PDI Healthcare	Yes
	PSS Select (also known as Triad)	PSS World Medical, Inc.	Yes
	Rite Aid Pharmacy Lubricating Gel[#]	Rite Aid Corp.	Yes
	Allegiance	Medline Industries, Inc. (formerly Triad/H&P Industries)	Yes
	Aplicare Sterile Lubricating Jelly (also known as Operand Lubricating Jelly)	Aplicare Inc./Clorox Professional	Yes
	Aqua Lube Personal Lubricant^{**}	Mayer Laboratories	No
	DynaLube Lubricating Jelly	Dynarex Corporation	Yes
	E-Z Lubricating Jelly	Chester Packaging	Yes
	IMCO Lubricating Jelly	Medline Industries, Inc. (formerly Triad/H&P Industries)	Yes
	Lubricating Jelly	DUKAL Corporation	Yes
	Lubri-Gel	Sheffield Pharmaceuticals	Yes
	Maxilube Personal Lubricant	Mission Pharmacal	Yes
	NovaPlus	Medline Industries, Inc. (formerly Triad/H&P Industries)	Yes
Pro Advantage Lubricating Jelly	National Distribution & Contracting, Inc.	Yes	
ReliaMed Lubricating Jelly	ReliaMed	Yes	

*The use of lubricants (e.g., KY Jelly) should be avoided prior to specimen collection. Lubricants can adhere to the filter membrane and may cause poor cell transfer to the slide. If its use is unavoidable, the lubricant should be used in minimum amounts. [†]Preferred: Lubricants have multiple lots run through periodic testing to ensure compatibility. [‡]Compatible: Lubricants have been tested at least once, but periodic testing is not regularly performed. [§]Incompatible: Lubricants have either been tested and deemed incompatible or excluded from testing because they contain carbomer. [¶]Carbomethylcellulose ingredient does not perform like carbomer-containing lubricants. ^{¶¶}Not recommended due to low viscosity and cell reduction percentage. [#]Not recommended due to borderline cell reduction percentage. ^{**}Not recommended due to low viscosity, personal lubricant.

1. ThinPrep 2000 System Operator's Manual. MAN-02585-001, Rev. 005. Marlborough, MA: Hologic, Inc.; 2014.

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