

February 3, 2014

**Re: Lubricant use during Pap sample collection**

Dear Colleague,

On occasion, Hologic personnel are asked to provide information concerning the use of lubricants when collecting a Pap sample using the ThinPrep® Pap Test. As part of Hologic's continuing education for clinicians and laboratorians, this bulletin addresses the proper preparation of the cervix for an adequate Pap sample collection pertaining to the ThinPrep Pap Test and the use of lubricants on the speculum. Steps taken by the clinician, from patient education to improved sampling technique, may ensure that the sample collected maximizes the potential of the Pap test.<sup>1,2</sup>

**Patient Education:**

Women should be counseled to refrain from intercourse, douching, using tampons, or using intravaginal medication for at least 48 hours before the examination to decrease the possibility that the number of exfoliated cells will be diminished or obscured by personal lubricants or spermicides.<sup>1,2</sup> In addition, the patient should avoid scheduling her appointment during heavy menstrual bleeding.<sup>1</sup> If you would like Hologic patient education materials for your office, please contact your Hologic representative.

**Sample Collection Options for Lubricating the Speculum:**

1. **Lukewarm Water:** For a patient without physical or physiologic reasons for needing lubricant, lukewarm water may be used to warm and lubricate the speculum. This protocol has the least risk to the quality of the Pap sample collected.<sup>1,3</sup> Professional organizations including ACOG and CLSI recognize that excessive use of lubricant may contaminate or obscure the Pap sample.
2. **Lubricant Gels:** If lubricant must be used due to patient discomfort or other circumstances, lubricant should be used sparingly and applied **only** to the exterior sides of the speculum blades, **avoiding contact with the tip of the speculum.**<sup>1,2,3,4</sup> (see pictures below) When a lubricant is used sparingly and appropriately, it poses little risk to the quality of the Pap sample. However, when a lubricant is used in excess, it can adversely affect the Pap sample. Hologic evaluated a variety of popular lubricants and found those containing carbomer or carbopol polymers (thickening agents) interfere with the ThinPrep Pap test when found in the sample vial.<sup>5</sup> Hologic recognizes the varying availability of different types of lubricants and recommends that, if used, any lubricant should be applied sparingly as described below.

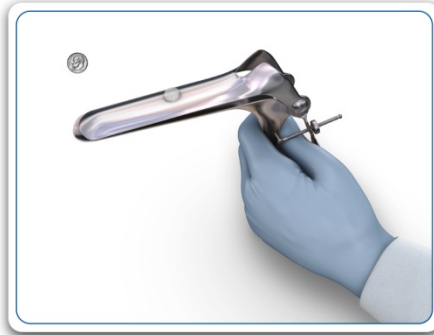


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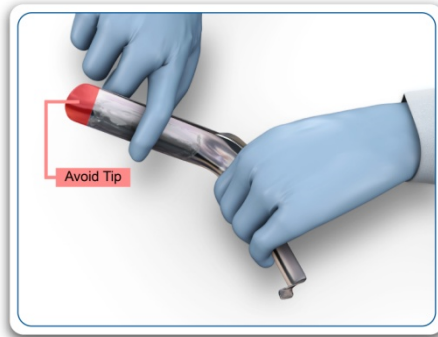
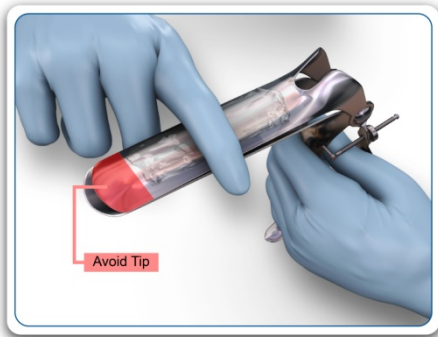
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# Appropriate Use of Lubricant for Pap Collection

Apply a dime-sized amount of lubricant gel.



Apply only to exterior sides of the speculum, avoiding the tip.



Should you have further questions regarding this topic, please refer to the CLSI guidelines or contact Hologic Technical Support Department at 1-800-442-9892, option 6.

Sincerely,

A handwritten signature in black ink, appearing to read "Edward Evantash".

Edward Evantash  
Medical Director

1. Davey *et al*, 2008, "Cervical Cytology Specimen Adequacy: Patient Management Guidelines and Optimizing Specimen Collection"; American Society for Colposcopy and Cervical Pathology Journal of Lower Genital Tract Disease, Volume 12, Number 2, 2008, 71-81
2. Amies, AE.; Miller, L; Lee, Shu-Kuang; Koutsky, L, The Effect of Vaginal Speculum Lubrication on the Rate of Unsatisfactory Cervical Cytology Diagnosis, Obstet Gynecol. 100(5, Part 1):889-892, November 2002.
3. "Cervicovaginal Cytology Based on the Papanicolaou Technique; Approved Guideline – Third Edition", Clinical and Laboratory Standards Institute (formerly NCCLS), Vol. 28 No. 28, 2008.
4. ACOG Practice Bulletin, Clinical Management Guidelines for Obstetrician Gynecologists, Number 109, December 2009, pg 2.
5. Hologic internal study, Data on file.

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MISC-00579 Rev. 006



May 2016

Dear Colleague:

Hologic strives to provide you with processes and products to help you deliver targeted care for your patients. As part of this effort, we are pleased to announce the approval of a second lubricant option for use with the ThinPrep® Pap test. Surgilube® lubricant is a carbomer-free lubricant and approved for use with the ThinPrep Pap test in accordance with our lubricant letter (see attached, #MISC-00579 Rev. 006).

Surgilube lubricant is the second carbomer-free lubricant approved for use with the ThinPrep Pap test, joining the previously approved Pap Test Lubricating Jelly from Aseptic Control Products, Inc. Both lubricants passed stringent testing by Hologic and meet established quality parameters without impacting ThinPrep Pap test results.

**Lubricants with carbomers, regardless of their quality, can affect test results and should not be used with ThinPrep Pap testing.**

Ultimately, healthcare providers are responsible for providing counsel to patients to refrain from using over-the-counter lubricants and vaginal medications 48 hours prior to the collection of any Pap sample. All healthcare providers should follow the guidelines for Pap collection as indicated in CLSI and ACOG guidelines.<sup>1,2</sup>

Surgilube lubricant is available for purchase through numerous medical distributors and GPOs, listed on their website at Surgilube.com. It is available in several packaging types:

MFR #	Item Description	Volume	Packaging
281020536	Screw/Fez Cap (Metal Tube)	4.25oz (120.49gm)	12 ea/bx – 6 bx/cs (72)
281020502	Screw/Fez Cap (Metal Tube)	2oz (56.7gm)	12 ea/bx – 12 bx/cs (144)
281020555	Metal Tube – Elongated Tip	5gm	48 ea/bx – 3 bx/cn – 4 cn/cs
281020537	Flip Top Cap (Laminated tube)	4.25oz (120.49gm)	12 ea/bx – 6 bx/cs (72)
281020512	Flip Top Cap (Laminated tube)	2oz (56.7gm)	12 ea/bx – 12 bx/cs (144)
281020543	Foilpac® (Foil laminated film)	3gm	144 ea/bx – 12 bx/cs (1728)
281020545	Foilpac® (Foil laminated film)	5gm	144 ea/bx – 6 bx/cs (864)

*Part numbers, packaging configurations, and pricing are set by HR Pharmaceuticals, Inc., and are subject to change without notice.*

Pap Test Lubricating Jelly is also available in several packaging options directly through its manufacturer or from various medical distributors:

Aseptic Control Products, Inc.  
3831 Industrial Ave. Unit D  
Rolling Meadows, IL. 60008  
P: (800) 448-0131  
P: (847) 342-1729  
F: (847) 342-1809  
info@acpmedicalinc.com  
www.acpmedicalinc.com

Description	ACP Item#	Packaging
Pap Test Lubricating Jelly, 3-gram packet, non-sterile	024-PKT	1,728/case
	024-PKT-BX	144/box
Pap Test Lubricating Jelly, 4-OZ flip top tube, non-sterile	024-4OZ	72/case
	024-4OZ-BX	12/case

*Part numbers, packaging configurations and pricing are set by Aseptic Control Products, Inc., and are subject to change without notice.*

For any support related to this topic, please contact Hologic Technical Support Department at 1-800-442-9892, Option 6.

The *Pap Test Lubricating Jelly* (PN#s 024-PKT, 024-PKT-BX, 024-4OZ, 024-4OZ-BX) tested by Hologic on August 21, 2013 and Surgilube Lubricating Jelly (PN#s 281020536, 281020502, 281020555, 281020537, 281020512, 281020543, 281020545) tested by Hologic on March 3, 2016, are the only lubricants approved by Hologic. If either vendor modifies the raw materials and/or the formulation is modified, approval by Hologic and this document shall be null and void.

REFERENCES: 1. CLSI. Cervicovaginal Cytology Based on the Papanicolaou Technique; Approved Guideline – Third Edition (GP15-A3). Wayne, PA: Clinical Laboratory Standards Institute; 2008. 2. American College of Obstetricians and Gynecologists. Cervical Cancer Screening and Prevention. Practice Bulletin No. 157. *Obstet Gynecol.* 2016;127:31-20. doi:10.1097/AOG.0000000000001256.

MISC-02811-001 Rev. 002

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.<sup>1\*</sup>

## ThinPrep® Pap Test Lubricant Compatibility List

	Lubricant	Manufacturer	Contains Carbomer?
Preferred <sup>†</sup>	<b>PAP Test Lubricating Jelly</b>	Aseptic Control Products	No
	<b>Surgilube Surgical Lubricant</b>	HR Pharmaceuticals	No
Compatible <sup>‡</sup>	<b>K-Y Jelly (Physician Formula)</b>	Johnson & Johnson	No <sup>§</sup>
	<b>Surgel</b>	Ulmer Pharmacal	No
Incompatible <sup>§</sup>	<b>Aquagel Lubricating Gel</b>	Parker Laboratories, Inc.	Yes
	<b>Astroglide (Physician Formula)</b>	BioFilm, Inc.	No
	<b>Astroglide (Personal Formula)<sup>¶</sup></b>	BioFilm, Inc.	No
	<b>Crystelle</b>	Deltex Pharmaceuticals, Inc. - FDA injunction in 2011; no longer in operation	Unknown
	<b>HR Lubricating Jelly</b>	HR Pharmaceuticals, Inc.	Yes
	<b>Lubricating Gel</b>	Henry Schein	Yes
	<b>Lubricating Jelly</b>	McKesson	Yes
	<b>MediChoice Lubricating Jelly</b>	Owens & Minor	Yes
	<b>PDI Lubricating Jelly I and II</b>	PDI Healthcare	Yes
	<b>PSS Select (also known as Triad)</b>	PSS World Medical, Inc.	Yes
	<b>Rite Aid Pharmacy Lubricating Gel<sup>#</sup></b>	Rite Aid Corp.	Yes
	<b>Allegiance</b>	Medline Industries, Inc. (formerly Triad/H&P Industries)	Yes
	<b>Aplicare Sterile Lubricating Jelly (also known as Operand Lubricating Jelly)</b>	Aplicare Inc./Clorox Professional	Yes
	<b>Aqua Lube Personal Lubricant<sup>**</sup></b>	Mayer Laboratories	No
	<b>DynaLube Lubricating Jelly</b>	Dynarex Corporation	Yes
	<b>E-Z Lubricating Jelly</b>	Chester Packaging	Yes
	<b>IMCO Lubricating Jelly</b>	Medline Industries, Inc. (formerly Triad/H&P Industries)	Yes
	<b>Lubricating Jelly</b>	DUKAL Corporation	Yes
	<b>Lubri-Gel</b>	Sheffield Pharmaceuticals	Yes
	<b>Maxilube Personal Lubricant</b>	Mission Pharmacal	Yes
	<b>NovaPlus</b>	Medline Industries, Inc. (formerly Triad/H&P Industries)	Yes
	<b>Pro Advantage Lubricating Jelly</b>	National Distribution & Contracting, Inc.	Yes
	<b>ReliaMed Lubricating Jelly</b>	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. <sup>†</sup>Preferred: Lubricants have multiple lots run through periodic testing to ensure compatibility. <sup>‡</sup>Compatible: Lubricants have been tested at least once, but periodic testing is not regularly performed. <sup>§</sup>Incompatible: Lubricants have either been tested and deemed incompatible or excluded from testing because they contain carbomer. <sup>¶</sup>Carbomethylcellulose ingredient does not perform like carbomer-containing lubricants. <sup>#</sup>Not recommended due to low viscosity and cell reduction percentage. <sup>\*\*</sup>Not recommended due to borderline cell reduction percentage.

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

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PAP TEST