

February 3, 2014

Dear Colleague:

Hologic is pleased to announce the availability of a new, carbomer-free lubricant on the market. Aseptic Control Product's *Pap Test Lubricating Jelly* has been tested and deemed acceptable for use with the ThinPrep® Pap test. This lubricant was tested by Hologic in a controlled environment and when used in accordance to our lubricant letter (see attached document #MISC000579-001 Rev. 006), does not impact the quality of the ThinPrep Pap Test. The use of any lubricant containing carbomers, regardless of the quality of carbomers used, is not recommended for use with the ThinPrep Pap Test.

It remains the healthcare provider's responsibility to counsel their patients on the appropriate use of over-the-counter lubricants and medications prior to the collection of any Pap sample. All healthcare providers should follow the guidelines for Pap collection as indicated in the CLIA and ACOG guidelines.

Pap Test Lubricating Jelly is available directly from:

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	Manufacturer's Suggested Retail Price	
			Per case or box	Per each
Pap Test Lubricating Jelly, 3-gram packet, non-sterile	024-PKT	1,728/case	\$230.00	\$0.13/each
	024-PKT-BX	144/box	\$22.00	\$0.15/each
Pap Test Lubricating Jelly, 4-OZ flip top tube, non-sterile	024-4OZ	72/case	\$140.00	\$1.94/each
	024-4OZ-BX	12/case	\$30.00	\$2.50/each

Part numbers, packaging configurations, and pricing are set by Aseptic Control Products, 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.

Legal Disclaimer: The *Pap Test Lubricating Jelly* (PN#'s 024-PKT, 024-PKT-BX, 024-4OZ, 024-4OZ-BX) tested by Hologic on August 21, 2013 is currently the only Hologic approved formulation. If the vendor modifies the raw materials vendor and/or the formulation is modified, Hologic's approval and this document shall be null and void.

MISC-02811-001 Rev. 001

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.^{1,2}

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.^{1,2} In addition, the patient should avoid scheduling her appointment during heavy menstrual bleeding.¹ 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.^{1,3} 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.**^{1,2,3,4} (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.⁵ Hologic recognizes the varying availability of different types of lubricants and recommends that, if used, any lubricant should be applied sparingly as described below.

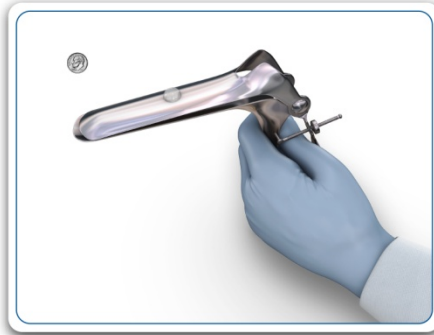


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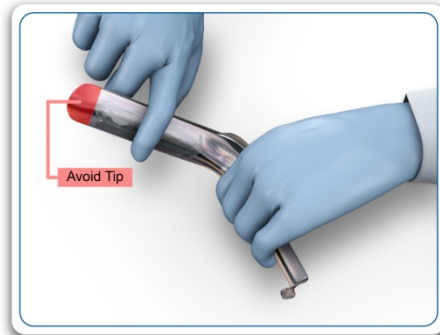
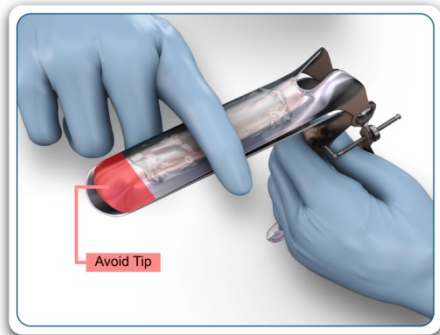
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Appropriate Use of Lubricant for Pap Collection

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