

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.

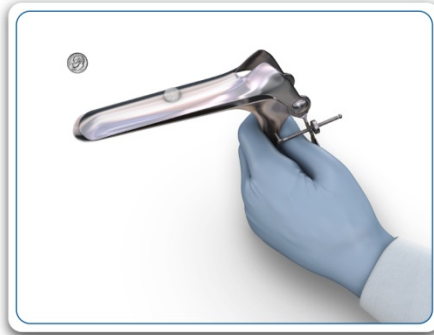


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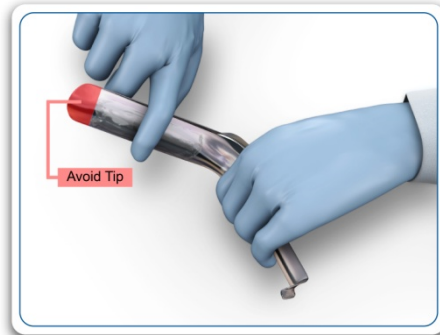
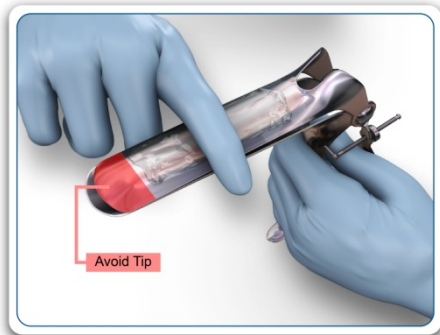
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Appropriate Use of Lubricant for Pap Collection

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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