

May 18, 2020

## 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 with 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 ThinPrep Pap test.<sup>1,2</sup>

## **Patient Education:**

Women should be counseled to refrain from intercourse, douching, using tampons or 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 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 poses 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, it should be used sparingly and applied *only* to the exterior sides of the speculum blades, *avoiding contact with the tip of the speculum* (see pictures below).<sup>1-4</sup> 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.

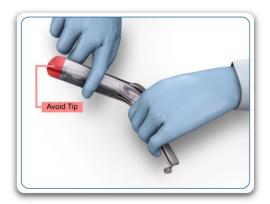
Hologic evaluated a variety of popular lubricants and found those containing carbomer or Carbopol polymers (thickening agents) interfere with the ThinPrep Pap test when found in the sample vial. Hologic recognizes the varying availability of different types of lubricants and recommends that, if used, any lubricant should be applied sparingly as described below.

## Appropriate Use of Lubricant for ThinPrep Pap Sample 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 the Hologic Technical Support Department at 1-800-442-9892, option 6.

Sincerely,

Philipp Mueller

Sr. Director Medical and Scientific Affairs

References: 1. Davey DD, et al. Cervical Cytology Specimen Adequacy: Patient Management Guidelines and Optimizing Specimen Collection.

J Low Genit Tract Dis. 2008;12(2):71-81. doi: 10.1097/LGT.0b013e3181585b9b 2. Amies AE, et al. The Effect of Vaginal Speculum Lubrication on the Rate of Unsatisfactory Cervical Cytology Diagnosis. Obstet Gynecol. 2002;100(5, Pt 1):889-892. 3. CLSI. Cervicovaginal Cytology Based on the Papanicolaou Technique; Approved Guideline – Third Edition (GP15-A3). Wayne, PA: Clinical Laboratory Standards Institute; 2008.

4. ACOG. Cervical Cancer Screening and Prevention. Practice Bulletin No. 168. Obstet Gynecol. 2016;128(4):e111-30. doi: 10.1097/AOG.000000000001708 5. Hologic, Inc. Internal study. Data on file.

MISC-00579 Rev. 007 © 2020 Hologic, Inc. All rights reserved. Hologic, ThinPrep and/or its subsidiaries in the United States and/or other countries. This information is intended for medical professionals in the U.S. 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 local Hologic representative or write to diagnostic.solutions@hologic.com.