

Use of lubricants with Cervical Screening tests

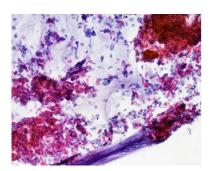
This bulletin addresses the proper preparation of the cervix for the collection of an adequate cervical screening test sample pertaining to the ThinPrep Pap Test and the use of lubricants on the speculum. It is important to obtain a specimen that is not obscured by blood, mucous, inflammatory exudate or lubricant.

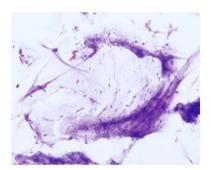
It is important to ensure that the sample collected maximises the potential of the cervical screening test.^{1,2}

As an aid for patient comfort, lubricants are frequently used during the pelvic examination. However, usage of lubricant is <u>NOT RECOMMENDED</u>, because their use can adversely affect the cervical screening test result in many ways including:

- Residual lubricant could interfere with the endocervical brush and spatula or cervical broom in the acquisition of cervical cells.
- Lubricants may have the potential to cause inhibition in certain molecular based tests.³
- Residual lubricant could create a potential immiscible interface in alcohol based liquid Pap solutions leading to potential agglutination and cellular loss.







Hologic, Inc. makers of ThinPrep, has evaluated a variety of popular lubricants and found that those containing an ingredient known as "carbomers" or "carbopol polymers" may be prone to interfere with cervical screening tests. Carbomers or carbopol polymers are used as thickening agents.

Those lubricant formulations which currently are listed as NOT CONTAINING carbomers include:

- KY Jelly medical grade as supplied by Dorevitch Pathology
- Pap Test Lubricating Jelly (as tested by Hologic Inc.)

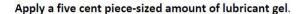


Sample Collection Options for Lubricating the Speculum:

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 cervical screening sample collected. ^{1,4}

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. 1.2.4.5 (refer to diagram). When a lubricant is used sparingly and appropriately, it poses little risk to the quality of the cervical screening test sample. However, when a lubricant is used in excess, it can adversely affect the sample.

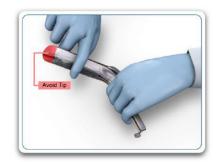
Appropriate Use of Lubricant for Cervical Screening Test Collection





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





References

- 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. http://www.health.gov.au/internet/main/publishing.nsf/Content/9B758F769B58B1A8CA258107001BB2DA/\$File/Reqs%20Cervical%20Screen%20-%20 31%20May%2017.pdf/
- 4. "Cervicovaginal Cytology Based on the Papanicolaou Technique; Approved Guideline Third Edition", Clinical and Laboratory Standards Institute (formerly NCCLS), Vol. 28 No. 28, 2008.
- 5. ACOG Practice Bulletin, Clinical Management Guidelines for Obstetrician Gynecologists, Number 109, December 2009, pg 2.



