Unsatisfactory ThinPrep[®] pap test results and lubricant usage for collection



On occasion, our Cytology laboratory notices an increase in the number of unsatisfactory results for ThinPrep[®] pap tests submitted by our clients which is often found to be related to lubricant usage during specimen collection. Below is a message from Hologic, Inc., regarding the usage of lubricants for pap test specimen collection. Please share this information with your providers who might be collecting ThinPrep[®] pap specimens.

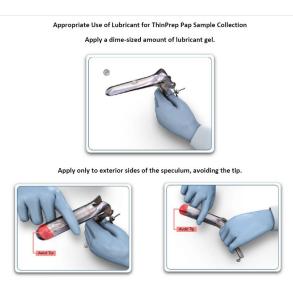
Patient Education:

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. In addition, the patient should avoid scheduling her appointment during heavy menstrual bleeding.

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 Pap sample collected. Professional organizations including ACOG and CLSI recognize that excessive use of lubricant may contaminate or obscure the Pap sample.

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*.) 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.



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Hologic has evaluated a variety of popular lubricants and found that those containing the thickening agents carbomer or Carbopol interfered with the test. Hologic recommends that if lubricants are used, it should be one of the validated lubricants lists below.

Purchasing details for the validated lubricants

• Surgilube lubricant is available for purchase through numerous medical distributors and GPOs listed on their website <u>Surgilube.com</u>. It is available in several packaging types:

MFR #	Item Description	Volume	Packaging
281020536	Screw/Fez Cap (Metal Tube)	4.25oz <mark>(12</mark> 0.49gm)	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 available in several packaging options directly through its manufacturer or from various medical distributors. Manufacturer location:

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	024-PKT/BX	144/box
packet, non-sterile	024-PKT/CS	1,728/case
Pap Test Lubricating Jelly, 4-oz flip	024-PKT/BX	12/box
top tube, non-sterile	024-PKT/CS	72/case

• Sion CerviLube lubricant is available in several packaging options directly through its manufacturer or from various medical distributors. Please contact their customer service for more information at the following:

Vanessa Palafox 832-761-3912 vanessa@sionbrands.com

Description	Packaging
CerviLube 3-gram CAR/PAR Free	144/box
	144x12/case
CerviLube 4-oz CAR/PAR free	6/box
	6x12/case