

May 18, 2020

Dear Colleague:

Hologic strives to provide you with processes and products to help you deliver targeted care to your patients. As part of this commitment, if lubricant must be used due to patient discomfort or other circumstances we recommend the use of Surgilube lubricant from HR Pharmaceuticals, Pap Test Lubricating Jelly from Aseptic Control Products and Sion CerviLube lubricant from Sion Brands — three carbomer-free lubricants that have all been validated by Hologic for use with the ThinPrep[®] Pap test.^{1*}

All three of these lubricants passed stringent testing by Hologic and meet established quality parameters without impacting ThinPrep Pap test results. We only advise using carbomer-free products because lubricants containing the synthetic polymers, regardless of their quality, can affect test results and should not be used with ThinPrep Pap testing.

Ultimately, healthcare providers are responsible for providing counsel to patients to refrain from using overthe-counter lubricants and vaginal medications 48 hours prior to the collection of any Pap sample. All healthcare providers should follow the guidelines for Pap collection as indicated in CLSI and ACOG guidelines.^{2,3}

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 (120.49gm)	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

* The Pap Test Lubricating Jelly (PN#s 024-PKT, 024-PKT-BX, 024-4OZ, 024-4OZ-BX) tested by Hologic on August 21, 2013, Surgilube lubricant (PN#s 281020536, 281020520, 281020555, 281020537, 281020512, 281020543, 281020545) tested by Hologic on March 3, 2016, and Sion CeviLube lubricant (3 g and 4 oz) tested on April 22, 2019, are the only lubricants validated by Hologic. If the vendor modifies the raw materials and/or the formulation is modified, approval by Hologic and this document shall be null and void.

References: 1. ThinPrep 2000 System Operator's Manual. MAN-02585-001. Marlborough, MA: Hologic, Inc.; 2017. **2.** CLSI. Cervicovaginal Cytology Based on the Papanicolaou Technique; Approved Guideline – Third Edition (GP15-A3). Wayne, PA: Clinical Laboratory Standards Institute; 2008. **3.** ACOG. Cervical Cancer Screening and Prevention. Practice Bulletin No. 168. *Obstet Gynecol.* 2016;128(4):e111-30. doi: 10.1097/AOG.00000000001708

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