

HOLOGIC®

29th September 2017

Bryan Jacobs
Chief Executive Officer
Medical Industries Australia
87 Mars Road
Lane Cove 2066
NSW, Australia

Dear Mr. Jacobs,

This letter is to provide confirmation from Hologic, Inc. (“Hologic”) to Medical Industries Australia (“MIA”) that *Pap Test Lubricating Jelly* (PN# 024-PKT-BX) manufactured by Sion Biotext Medical Ltd., Israel and distributed by MIA, has been tested and approved for use with the ThinPrep® Pap Test. The *Pap Test Lubricating Jelly* (PN# 024-PKT-BX) was tested by Hologic in a controlled environment and when used appropriately and accurately, this lubricant does not impact the quality of the ThinPrep® Pap Test.

It remains the healthcare provider’s responsibility to counsel their patients on the appropriate use of over-the counter lubricants and medications prior to the collection of any cervical screening test. All healthcare providers should follow the guidelines for cervical screening test collection as indicated by the Australian Government National Cervical Screening Program.

If you have any questions please feel free to contact me, or reference Hologic Australia’s Lubricant Bulletin, p/n MISC-04667-AUS-EN Rev. 001.

Kind regards,



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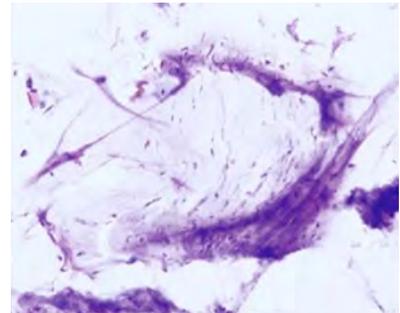
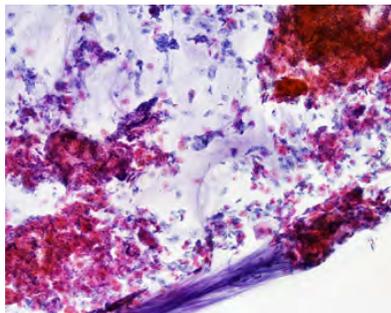
Legal Disclaimer: The *Pap Test Lubricating Jelly* (PN# 024-PKT-BX) tested by Hologic on August 21st 2013 is currently the only Hologic approved formulation. If the vendor modifies the raw materials, vendor and/or the formulations is modified. Hologic’s approval and this document shall be null and void.

LIQUID BASED CYTOLOGY TRAINING BULLETIN: USE OF LUBRICANTS WITH CERVICAL SCREENING TESTS*

On occasion, Hologic (Australia) is asked to provide information concerning the use of lubricants when collecting a cervical screening test sample using the ThinPrep[®] Pap Test. As part of Hologic's continuing education for healthcare providers and laboratory personnel, 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. Steps taken by the healthcare provider, from patient education to improved sampling technique, may 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 not recommended, 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. 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. Carbomers are large molecules prepared from relatively small monomers. The monomers used to make Carbomer polymers are acrylic acid and polyalkenyl polyethers. Carbomers are all chemically similar, differing from each other in molecular weight and viscosity. Carbomers have the ability to absorb and retain water, and these polymers can swell to many times their original volume. Carbomers help to distribute or suspend an insoluble solid in a liquid. Carbomers are often used to control the consistency and flow of cosmetics and personal care products.⁴

The detection of cervical disease and its precursors as well as other gynaecological abnormalities is the primary purpose of obtaining a cervical cell sample. Therefore it is important to obtain a specimen that is not obscured by blood, mucous, inflammatory exudate or lubricant.

If lubricant is necessary due to patient discomfort or the use of a plastic speculum, sparingly apply a thin film of carbomer-free lubricant on the speculum's surface, avoiding the tip. Do not use an excessive amount of lubricant to lubricate the speculum. Hologic[®] evaluated a variety of popular lubricants and found those containing carbomer or carbopol polymers may interfere with obtaining a representative cervical sample or cause artifact in the alcohol-based transport medium. Hologic recognises the varying availability of different types of lubricants and recommends that, if used, any lubricant should be applied sparingly.⁴

Please contact your local Hologic representative for more information on compatible lubricants.

Patients should be counselled 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

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.^{1,5}

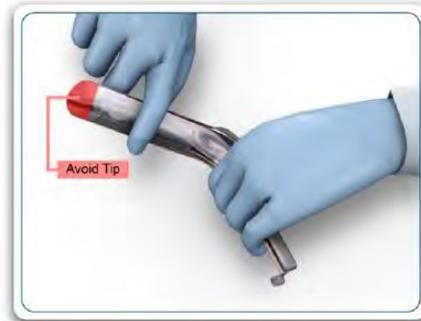
Lubricant Gels: If lubricant must be used due to patient discomfort or other circumstances, lubricant should be used sparingly and applied only to the exterior sides of the speculum blades, avoiding contact with the tip of the speculum.^{1,2,5,6} (refer to diagram). When a lubricant is used sparingly 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 a five cent piece-sized amount of lubricant gel.



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



ThinPrep Processor Observations

Note: Although not a determinant of specimen adequacy, a paucicellular, borderline or typical ThinPrep Pap Test may result in a **'sample is dilute'** message on the ThinPrep Processor. This message occurs when the entire liquid contents of the vial is used to create a ThinPrep slide. However, samples contaminated with incompatible lubricants often still have the majority of the specimen remaining after the ThinPrep slide is prepared - the slide is produced by the processor in a very short amount of time which is not typical. Troubleshooting steps should always be undertaken in instances where the ThinPrep slide appears unsatisfactory however the ThinPrep vial retains the majority of the specimen before a result is reported for that sample. **Please contact the Hologic team for more information.**

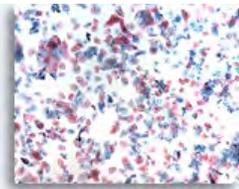
Cytologists may be asked to evaluate the cause of "unsatisfactory" cervical screening test samples. The following photographs illustrate the appearance of the different lubricants as seen in ThinPrep[®] Pap Test (TPPT) preparations. A TPPT vial containing epithelial cells of moderate to high maturation and devoid of visible lubricant was identified for use in this comparison presentation. The TPPT vial was divided equally into five new TPPT vials with subsequent addition of a lubricant.

Reminder: You may click on any slide image for an enlarged view (active internet connection required)



Limiting factor

Lubricant limiting the adequacy of the squamous cell component. 20X



Control vial

Superficial and intermediate cells evenly dispersed across the field of view. There is no visible evidence of lubricant or lubricant effect. Minimal degree of overlap and clearing is commonly seen in thin layer preparations. 4x



Lubricant A treated vial

The effect of excessive lubricant. Superficial and Intermediate cells are clumped into a three dimensional group. Cells are less evenly dispersed with scant amorphous material noted in the background suggestive of lubricant. 10x



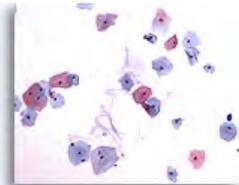
Lubricant B treated vial

The effect of excessive lubricant. The field of view has sparse cellularity with an increase in the amount open spaces. In this instance, the excessive lubricant interfered with the cell collection process during slide preparation. 10x



Lubricant C treated vial

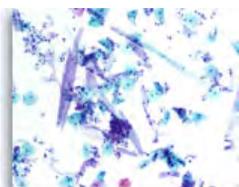
The lubricant staining a deep purple and resembling dense mucoid material in appearance. In this instance, the specimen had very scant cellularity and fragments of lubricant obscuring the epithelial cells. The decreased cellularity was most likely the result of excessive lubricant interfering with cell collection during slide preparation. 10x



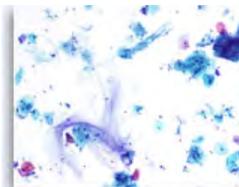
Lubricant D treated vial

Evidence of the lubricant present as a semi solid matrix resembling thin mucous. The lubricant stains a purplish hue in the background and is loosely associated with the epithelial cells. The cellularity is decreased as compared to the control. The lubricant effect in this case may not be as obvious to the observer. 10x

Note: The term lubricant is used to refer to medical and personal grade lubricants, spermicides and/or vaginal medications.



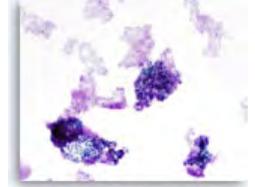
Lubricant E
10x



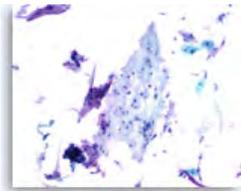
Lubricant F
10x



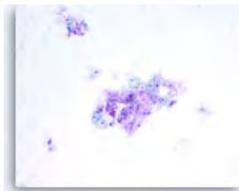
Lubricant G
10x



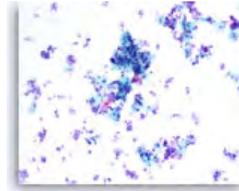
Lubricant H
10x



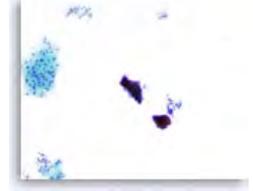
Lubricant I
10x



Lubricant J - Image 1
10x



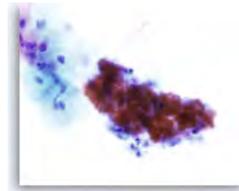
Lubricant J - Image 2
10x



Lubricant K - Image 1
10x



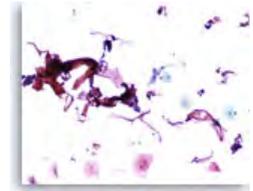
Lubricant K - Image 2
40x



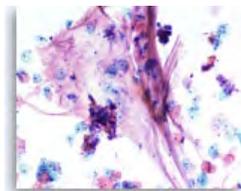
Lubricant K - Image 3
40x



Lubricant L
10x



Lubricant M - Image 1
10x



Lubricant M - Image 2
10x



Lubricant N
10x

For more information please visit:

CYTOLOGYstuff.com

www.cytologystuff.com is an educational resource for all things Cytology



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* Information contained in this bulletin has been sourced from <http://www.cytologystuff.com/study/indexlube.htm>

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-%2031%20May%2017.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/9B758F769B58B1A8CA258107001BB2DA/$File/Reqs%20Cervical%20Screen%20-%2031%20May%2017.pdf). 4. Hologic Data on File. 5. "Cervicovaginal Cytology Based on the Papanicolaou Technique; Approved Guideline – Third Edition", Clinical and Laboratory Standards Institute (formerly NCCLS), Vol. 28 No. 28, 2008. 6. ACOG Practice Bulletin, Clinical Management Guidelines for Obstetrician Gynecologists, Number 109, December 2009, pg 2.