OAML ONTARIO ASSOCIATION OF MEDICAL LABORATORIES

Community Laboratory Guidelines

OAML Guideline on the Investigation of Genital Tract Infections

November, 2015

1. Purpose

OAML

The purpose of this guideline is to provide ordering clinicians with a clear and concise reference for the investigation of genital tract infections for community patients. For detailed information, clinicians are encouraged to consult:

The Canadian Guidelines for the Sexually Transmitted Infections (CGSTI) available at <u>http://www.phac-aspc.gc.ca/std-mts/sti-its/cgsti-ldcits/index-eng.php</u> and

The Public Health Ontario Guidelines for Testing and Treatment of Gonorrhea in Ontario available at http://www.publichealthontario.ca/en/BrowseByTopic/InfectiousDiseases/Pages/Gonorrhea-Guideline.aspx.

OAML guidelines will not apply to every clinical situation, nor can they serve as a substitute for sound clinical judgment. In particular, this guideline does not apply to pre-menarchal and post-menopausal females, as specimens from these patients may require additional investigations and different interpretation of test results.^{1, p 1}

2. Clinical Situations that Warrant Screening

All sexually active persons who have signs and symptoms of gonorrhea should be tested for *Neisseria gonorrhoeae* (*N. gonorrhoeae*). Consideration should also be given to laboratory screening of asymptomatic persons who have risk factors for gonorrhea such as:

- sex workers and their partners;
- sexually active men who have sex with men;
- travelers to an endemic country who have sex with a resident of that country;
- sexually active youth and street youth (less than 25 years of age);
- patients with multiple partners;
- patients who have previously been infected with *N. gonorrhoeae* (reinfection rate projected to be at least 2 %); ^{2, p 29}
- patients with a recently diagnosed other sexually transmitted infection (e.g. syphilis, HIV) and
- sexual contacts of a confirmed case.

The CGSTI recommend rescreening for all who are diagnosed with gonorrhea six months after the initial diagnosis, as these patients are at high risk for reinfection as evidenced from Ontario data. If rescreening within six months is not possible, these patients should be rescreened when they next seek medical care within the next 12 months.^{2, p.29}

Since a high proportion of individuals with gonorrhea are at risk of co-infection with *Chlamydia trachomatis* (CT), when testing for *N. gonorrhoeae* patients should be concurrently tested for CT.

3. Clinical Investigation of Urethritis/Cervicitis, Vulvovaginitis, and Genital Lesions

a) Urethritis/cervicitis caused by Chlamydia trachomatis and/or N. gonorrhoeae (CT/GC)

i. Nucleic Acid Amplification Test (NAAT)

The NAAT is a superior test to culture and is the preferred test for detection of CT/GC. However, in women the urine NAAT for *N. gonorrhoeae* is less sensitive than the cervical NAAT for *N. gonorrhoeae*.

If clinical symptoms persist, a repeat specimen can be collected four weeks after the initial NAAT.

Appropriate specimen types include:

- females endocervical NAAT swabs, and vaginal NAAT swabs where available, or first void urine
- males urethral NAAT swabs or first void urine

Note:

- NAAT is not Health Canada approved for pharyngeal and rectal specimens, nor is it an acceptable test for medicolegal cases.
- Conventional culture swabs are not suitable for the NAAT; Swabs designed for NAAT must be used.

ii. Culture Method

The NAAT is superior to the culture method for detecting *N. gonorrhoeae*; however, in cases of treatment failure, the culture method must be used to obtain a antimicrobial susceptibility result. If the culture grows *N. gonorrhoeae*, then the isolate is sent to Public Health Ontario Laboratory (PHOL) for susceptibility testing.

For test of cure, regardless of the presence or absence of symptoms, the preferred testing method is culture. NAAT is an acceptable alternative test; however, it should only be performed 4 weeks after treatment and in situations where culture is not feasible.

Test of cure is recommended in a number of circumstances, such as pregnancy and when first-line antibiotic treatment* of *N. gonorrhoeae* is not used. The other circumstances are outlined in the Public Health Ontario Guidelines for Testing and Treatment of Gonorrhea in Ontario.^{2, p28}

For patients who receive appropriate treatment and are asymptomatic routine testing of a post-treatment specimen as a "test-of-cure" is NOT indicated.

*Note: At the time of publication, first line recommended therapy for *N. gonorrhea* include: Ceftriaxone (250mg IM) and Azithromycin (1g PO)^{2, p 24}

Appropriate specimen types for culture of *N. gonorrhoeae* include:

- females endocervical specimen using conventional swabs;
- males urethral specimen using conventional swabs and;
- pharyngeal or rectal specimens using conventional swabs.

b) Vulvovaginitis

Laboratories will investigate specimens for:

- Trichomonas vaginalis (T. vaginalis)
- morphotypes associated with bacterial vaginosis
- yeast

i. Microscopy

Appropriate specimen type:

• Conventional vaginal swab; swabs used for NAAT are not suitable for microscopic examinations.

A wet mount and a gram stain will be prepared from specimens labeled as vaginal swabs and examined microscopically. Laboratories that perform wet mount examination for *T. vaginalis* should receive the specimen within 2 hours of collection to allow the organism to be identified.^{3, p. 3.2.3.2}

Vaginal flora in pre-pubertal and post-menopausal females may be different than that of post-pubertal and pre-menopausal females and may impact the interpretation of results. Pre-pubertal and post-menopausal female patients will not be tested for bacterial vaginosis.^{1, p.3}

Pre-pubertal and post-menopausal female patients will be tested for yeast and trichomonas infections.

In pre-pubertal females, cultures for *N. gonorrhoeae* will also be set up routinely on vaginal swabs.

If a physician suspects toxic shock syndrome, this information should be clearly indicated on the requisition. Accordingly, the vaginal swab will be cultured for detection of *Staphylococcus aureus*.

Specimens for culture and microscopy should be maintained at room temperature and processed within a few hours of collection.

ii NAAT

The NAAT is a more sensitive method than microscopy for the detection of *T. vaginalis*.

Acceptable female specimen types include vaginal and cervical swabs, and first void urine in the appropriate NAAT specimen collection/transport kit.

Check with your laboratory for availability of NAAT for T. vaginalis.

c) Genital Lesions

Causative organisms include:

- Herpes simplex virus;
- Treponema pallidum (Syphilis);
- Human papilloma virus (HPV);
- Haemophilus ducreyi (chancroid) and,
- CT Lymphogranuloma venereum (LGV) serovar.

The PHOL should be contacted for advice on appropriate specimen collection/transport kit to test for these organisms.

Specimen collection instructions and requisitions for these tests are available on the PHOL's website at <u>http://www.publichealthontario.ca/</u>.

d) Urethritis Caused by Other Organisms

i. Urethritis caused by Mycoplasma genitalium, Ureaplasma urealyticum, and T. vaginalis

Appropriate specimen types:

- females urethral specimen using conventional swabs
- males urethral specimen using conventional swabs

Information on the appropriate testing method and collection/transport kit can be obtained by contacting your local laboratory.

Note: Testing for *T. vaginalis* is challenging in males, since wet mount microscopy is often negative in infected men. The NAAT is not currently licensed for detection of *T. vaginalis* in male patients.

ii Herpes simplex virus and other agents

For other etiologies, such as *Herpes simplex virus*, the PHOL should be contacted for advice on the appropriate specimen collection/transport kit.

Specimen collection instructions and requisitions for these tests are available on the PHOL's website at <u>http://www.publichealthontario.ca/</u>.

4. Specimen Collection

Specimens for culture and NAAT should be maintained at room temperature and transported to the laboratory for testing as quickly as possible, and processed within 24 hours.

Laboratories that perform wet mount examination for *T. vaginalis* should receive the specimen within 2 hours of collection to allow the organism to be identified.

5. Learning Points

- In females, urine, cervical or vaginal specimens can be tested simultaneously for CT/GC or CT/GC/T. *vaginalis* on the same specimen using the NAAT.
- In females, the urine NAAT for *N. gonorrhea* is less sensitive than the cervical NAAT; however, this specimen type has the advantage of being a less invasive than a cervical specimen.
- In males, urine or urethral specimens can be tested simultaneously for CT and GC on the same specimen using the NAAT. The urine specimen has the advantage of being less invasive.
- Culture for GC is recommended for test of cure and for medical/legal cases.
- The NAAT is not licensed for use in pre-pubertal patients or for pharyngeal or rectal sites.
- Conventional vaginal swabs will be used to diagnose bacterial vaginosis. Swabs will be routinely tested by microscopy for presence of *T. vaginalis* and yeast.
- Specimens for culture and NAAT should be maintained at room temperature and transported to the laboratory for testing as quickly as possible and processed within 24 hours.
- Laboratories that perform wet mount examination for *T. vaginalis* should receive the specimen within 2 hours of collection to allow the organism to be identified.
- Swabs used for NAAT are not suitable for culture or microscopic examinations.

Cited References

- 1. Institute for Quality Management in Healthcare. Consensus Practice Recommendation Female Genital Specimens. March 2015.
- Public Health Ontario. Guidelines for Testing and Treatment of Gonorrhea in Ontario, April 2013. Available at <u>http://www.publichealthontario.ca/en/BrowseByTopic/InfectiousDiseases/Pages/Gonorrhea-Guideline.aspx.</u> <u>Accessed February 2015.</u>
- 3. Garcia LS, Isenberg H. *Clinical Microbiology Procedures Handbook*, Volume. 1, 3rd ed. Washington, DC: ASM Press, 2010.

Additional References

- Public Health Agency of Canada. Canadian Guidelines on Sexually Transmitted Infections. Available at http://www.phac-aspc.gc.ca/std-mts/sti-its/cgsti-ldcits/index-eng.php. Accessed February 2015.
- Mandell G, Bennet J, Dolin R. *Principles and Practice of Infectious Diseases*. 7th ed. Philadelphia, PA: Mandell, Douglas, and Bennett's; 2010.

Acknowledgements

The OAML gratefully acknowledges the contribution of the following experts:

External Reviewer:

Cheryl Main, MD, FRCPC Associate Professor at McMaster University, Department of Pathology and Molecular Medicine, Medical Microbiologist, Hamilton Regional Laboratory Medicine Program and Infectious Diseases, Department of Medicine, based at Hamilton General Hospital

Internal Development Group:

Huda Almohri, M.D., FRCPC Deputy Ontario Medical Director, Discipline Head – Microbiology, Medical-Scientific Department, LifeLabs®

Anu Rebbapragada, Ph.D., D (ABMM), CIC	Julius Kapala Ph.D. , RSM (CCM), SM (ASCP)
Clinical Microbiologist,	Scientific Director Microbiology, Dynacare®
Associate Scientific Director for Microbiology, Dynacare®	

Laboratory Guidelines in Support of Clinical Practice

The OAML, through its Quality Assurance Committee, co-ordinates the development, dissemination, implementation and review of Guidelines for Clinical Laboratory Practice. Guidelines are reviewed every 5 years, or as the literature warrants. When consensus on the Guideline is achieved by the Committee, the Guideline is submitted to the OAML's Board of Directors for approval before distribution to Clinicians. The comments of end users are essential to the development of guidelines and will encourage adherence. You are strongly encouraged to submit your comments on this or any other OAML Guideline to: Chair Quality Assurance Committee Ontario Association of Medical Laboratories 5000 Yonge Street, Suite 1802 Toronto, Ontario, M2N 7E9 Tel: (416) 250-8464 E-mail: oaml@oaml.com Internet: www.oaml.com	Quality Assurance Committee Members Sheila Boss, Ph.D., FCACB Laboratory Director, LifeLabs [®] , Ontario Joel Goodman Ph.D., FCACB VP, Strategies and Innovation, Dynacare [®] Virginia Walley M.D., FRCPC Ontario Medical Director Medical-Scientific Department, LifeLabs [®] , Ontario Chair Judy Ash M.PP.A.L, B.Sc., ART, CQMgr, CQA (ASQ) Director, Programs & Member Services Ontario Association of Medical Laboratories
--	--

Warning & Disclaimer

This Guideline was prepared to assist clinicians who order tests from community laboratories. Users must ensure that their own practices comply with all specific government policies and specific legislative and accreditation requirements that apply to their organizations. The Guideline is not meant to be construed as legal advice or be all inclusive on this topic. Given the complexity of legal requirements, users are reminded that whenever there is uncertainty regarding whether some aspect of a Guideline is appropriate for their practice or organization, further direction should be obtained from the Laboratory Director, their own professional association, college and/or legal counsel or appropriate government ministry.