

# GUIDELINES & PROTOCOLS

## ADVISORY COMMITTEE

### Office and Laboratory Management of Genital Specimens

#### Scope

This protocol describes how genital specimens should be handled by the clinician and the laboratory once the decision to take a specimen has been made. It does not address which specimens are clinically appropriate in every situation or diagnostic tests performed in the office. It describes how clinicians should label genital specimens and delineates which tests will be routinely performed by the laboratory based upon the specimen submitted. Clinical conditions covered include urethritis, cervicitis, bacterial vaginosis, vulvovaginitis (including trichomoniasis and candidiasis), pregnancy, and patients at risk of STDs.

The protocol does not apply to other genital infections such as genital ulcer disease (including syphilis and herpes), PID, Bartholin's abscess, etc. For further information on sexually transmitted diseases, the clinician is referred to the Canadian STD Guidelines, 1998 edition.<sup>1</sup>

These recommendations do not apply to patients under 13 or over 70 years of age or to cases of suspected sexual abuse or assault.

Services covered include the following:

- Candida culture
- Candida/Trichomonas, direct examination
- Cervical culture
- Chlamydia antigen
- Chlamydia culture
- Chlamydia molecular techniques (MT)
- Stained smear
- Urethral culture
- Vaginal culture
- Vagino-anorectal culture for Group B Streptococcus

Note: Additional services for biochemical, serological and susceptibility testing will be performed when appropriate.

**RECOMMENDATION 1: Site of Origin and Clinical Condition**

The ordering physician must clearly indicate the site of origin and the clinical condition for each genital specimen to ensure proper processing. If neither site of origin nor clinical condition is indicated, the laboratory reserves the right to reject the specimen.

**RECOMMENDATION 2: Routine Testing**

The laboratory will perform the tests listed below based on the clinical condition and site indicated on the requisition. When other tests are considered clinically important, they may be requested through consultation with the laboratory physician or by specifying the circumstances on the requisition.

Clinical Condition	Site	Common Pathogens Sought	Tests Performed
Cervicitis	Cervix	<i>Neisseria gonorrhoeae</i> <i>Chlamydia trachomatis</i>	Cervical culture → Chlamydia examination*
Urethritis	Urethra	<i>Neisseria gonorrhoeae</i> <i>Chlamydia trachomatis</i>	→ Urethral culture & stained smear → Chlamydia examination*
STD Risk	Cervix/Urethra	<i>Chlamydia trachomatis</i> <i>Neisseria gonorrhoeae</i>	→ Chlamydia examination* → Cervical/urethral culture
Vulvovaginitis Initial Presentation	Vagina	Candida Bacterial vaginosis <i>Trichomonas vaginalis</i>	→ Stained smear → Stained smear → Trichomonas examination†
Vulvovaginitis Recurrent/Chronic‡	Vagina	Bacterial vaginosis Candida <i>Trichomonas vaginalis</i> Other pathogens	→ Stained smear → Candida culture§ → Trichomonas examination → Vaginal culture§

## Notes:

- \* Chlamydia examination: *C. trachomatis* examination may be performed by molecular, fluorescent microscopy, immunological or culture methods. Molecular methods are preferred.
- † Trichomonas: In an initial presentation, search for *T. vaginalis* by microscopy or culture will be performed only if specifically requested.
- ‡ Vulvovaginitis – Recurrent/Chronic: Patients presenting after a failure of self-treatment of vulvovaginitis should be regarded as ‘recurrent/chronic’ cases.
- § Vulvovaginitis – Candida and vaginal cultures: Candida culture and vaginal culture will only be performed if a clinical diagnosis of recurrent/chronic vulvovaginitis is provided on the requisition.

**RECOMMENDATION 3: Pregnancy Screen**

The laboratory will perform the following tests on genital specimens from pregnant patients\*:

Site	Common Pathogens Sought	Tests Performed
Vagino-Anorectal†	Group B Streptococcus	→ Vagino-anorectal culture
Vagina	Bacterial vaginosis	→ Stained smear
Cervix	<i>Chlamydia trachomatis</i> <i>Neisseria gonorrhoeae</i>	→ Chlamydia examination‡ → Cervical culture

Notes:

- \* When a genital infection is suspected in a pregnant woman, follow the instructions under Recommendation 2 for specific clinical conditions.
- † Vagino-anorectal specimens are preferred because collection from both sites significantly increases the likelihood of Group B Streptococcus (GBS) isolation. Although specimens collected from either vagina or rectum alone are recognized as clearly inferior to the combined vagino-anorectal specimen, they will still be examined for GBS. If a vaginal or rectal specimen is negative for GBS, the laboratory will advise the physician that the test should be repeated on a vagino-anorectal specimen.
- ‡ *C. trachomatis* examination may be performed by molecular, fluorescent microscopy, immunological or culture methods. Molecular methods are preferred.

**Rationale**

Genital specimens are usually taken to diagnose genital infection or to rule out specific sexually transmitted diseases. Information about the site of origin and clinical condition is critical for proper processing and identification of the putative pathogen(s).<sup>2</sup> This information helps the laboratory physician determine the appropriate testing and the significance of microbiological findings, thereby enhancing patient care and reducing costs. In the absence of such information, pathogens may be missed.

In the case of vulvovaginitis, the most common pathogens can usually be detected with a stained smear.<sup>3</sup> Yeast susceptibility tests may be useful in recurrent or chronic vulvovaginitis: consult with the laboratory physician.<sup>4,5</sup> Trichomonas examination will be performed only with recurrent/chronic vaginitis, or if specifically requested on initial presentation.

For *C. trachomatis* the preferred sites are the endocervix and urethra.<sup>6</sup> Urine may be an acceptable sample: contact your laboratory for details and availability of appropriate tests. Molecular techniques (nucleic acid amplification technology) are more accurate than antigen detection, but may not be available in all laboratories. Screening for *C. trachomatis* and other organisms may be indicated in pregnancy, in sexually active young people, and in women with a new sex partner in the last year.<sup>7-9</sup>

According to the Society of Obstetricians and Gynaecologists of Canada Statement on the Prevention of Early-Onset Group B Streptococcal Infection in the Newborn,<sup>10</sup> either of the following methods may be used to identify and manage women whose newborns might be at increased risk of GBS disease:

- a) Universal screening of all pregnant women at 35-37 weeks gestation with a single combined vagino-anorectal swab and the offer of intrapartum chemoprophylaxis to all GBS-colonized women.
- b) No universal screening, but intrapartum chemoprophylaxis for all women with identified risk factors. This strategy should also be used where universal screening is the policy, but either was not done or the test results are not available. Risk factors include:
  1. Pre-term labour (< 37 weeks gestation)
  2. Term labour ( $\geq$  37 weeks gestation)
    - a) Prolonged rupture of membranes. Chemoprophylaxis should be given if labour and/or ruptured membranes is likely to continue beyond 18 hours (neonatal benefits are optimally achieved if antibiotics are given at least 4 hours prior to delivery).
    - b) Maternal fever during labour ( $>$  38 °C orally)
  3. Previous delivery of a newborn with GBS disease regardless of current GBS colonization status
  4. Previously documented GBS bacteriuria

## References

1. Canadian STD guidelines 1998 edition. Ottawa (ON): Division of STD Prevention and Control, Bureau of HIV/AIDS, STD and TB, Laboratory Centre for Disease Control, Health Protection Branch, Health Canada;1998.
2. Isenberg H, editor. Clinical microbiology procedures handbook. 2nd ed. Herndon (VA): American Society for Microbiology Press;1992.p.1117.
3. Eschenbach DA. Vaginitis, cervicitis and endometritis. In: Gorbach SL, Bartlett JG, Zorab R, Blacklow NR, editors. Infectious Diseases. 2nd ed. Toronto: WB Saunders Co;1998.p.1040.
4. Sobel JD. Vulvovaginitis due to *Candida glabrata*. An emerging problem. *Mycoses* 1998;41 Suppl 2:18-22.
5. Sobel JD, Vazquez JA. Symptomatic vulvovaginitis due to fluconazole-resistant *Candida albicans* in a female who was not infected with human immunodeficiency virus. *Clin Infect Dis* 1996;22:726-7.
6. Borchardt KA, Noble MA, editors. Sexually transmitted diseases: epidemiology, pathology, diagnosis and treatment. Boca Raton (FL): CRC Press;1997.p.45.
7. Ramstedt K, Forssman L, Giesecke J, Granath F. Risk factors for *Chlamydia trachomatis* infection in 6810 young women attending family planning clinics. *Int J STD AIDS* 1992;3:117-22.
8. Sellors JW, Pickard L, Gafni A, et al. Effectiveness and efficiency of selective vs universal screening for chlamydial infection in sexually active young women. *Arch Intern Med* 1992;152:1837-44.
9. Scholes D, Stergachis A, Heidrich FE, et al. Prevention of pelvic inflammatory disease by screening for cervical chlamydia infection. *N Engl J Med* 1996;334:1362-6.
10. Statement on the prevention of early-onset group B streptococcal infections in the newborn. Ottawa: Society of Obstetricians and Gynaecologists of Canada; 1997 Jun. Policy Statement No. 61.

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- to encourage appropriate responses to common medical situations
- to recommend actions that are sufficient and efficient, neither excessive nor deficient
- to permit exceptions when justified by clinical circumstances.



## Collection of Genital Samples for Best Recovery of Sexually Transmitted Disease Pathogens

### Introduction

*Neisseria gonorrhoeae* and *Chlamydia trachomatis* are cell-associated bacterial pathogens associated with a spectrum of venereal diseases in a variety of anatomic locations. These bacteria can be difficult to detect by culture or other methods because they require precise collection techniques, do not survive well in transport, and may show cross-reactions with other bacteria. Test results therefore require careful interpretation. The following recommendations should be followed when collecting samples to be submitted for laboratory diagnosis:

RECOMMENDATION	EXPLANATION
<b>Use only the collection kit approved by the laboratory providing the assay</b>	<i>Neisseria gonorrhoeae</i> and <i>Chlamydia trachomatis</i> are sensitive to swabs or media not intended for collection of these pathogens. Collection kits are both technique and manufacturer specific. Collection kits provided for immunoassay cannot be used for culture or molecular diagnosis. Collection kits provided for one laboratory may be invalid for another laboratory if they use an assay from another manufacturer.
<b>Swabs must include cells from the patient in order to be an adequate sample</b>	<p>When collecting samples from the female genital tract, both <i>N. gonorrhoeae</i> and <i>C. trachomatis</i> are optimally collected by swabbing the cervical os. For women who have had a hysterectomy, submission of vaginal swab may be acceptable. Use only warm water for lubricating the speculum. It is important to remove excess mucus from the cervix with a dry swab before collecting the sample.</p> <p>For samples from males, the patient should be advised not to urinate for 2 hours prior to collection. Collect purulent discharge directly. If discharge is not present, insert swab 2 to 3 cm into the urethra, and allow to sit for 10-20 seconds. Gently rotate and remove the swab.</p>
<b>Separate tests require separate samples</b>	Because of the different technologies used, a single swab <b>cannot</b> be used for multiple tests. Currently, proper collection requires one swab for <i>C. trachomatis</i> and another for <i>N. gonorrhoeae</i> . A vagino-anorectal swab collected in pregnancy cannot be used to test for any organisms other than Group B Streptococcus. Specific examination for <i>T. vaginalis</i> requires yet another separate swab. Unfortunately this requires multiple samples being collected. Almost all laboratories will accept these multiple samples using a <b>single</b> requisition. If in doubt about a specific clinical situation, consult with the laboratory before collecting the samples.
<b>Some laboratories require both a swab and microscopic slide for examination</b>	Swab collection kits used for culture of <i>N. gonorrhoeae</i> often contain charcoal media to improve pathogen survival. This may obscure the ability of the laboratory to perform an adequate gram stain. Some laboratories request that the clinician also produce a smear for microscopic analysis at the time of sample collection. If both are requested, make the microscopic smear before putting swab in transport medium.

<p><b>Charcoal (black media) swabs collected for gonorrhea should never be refrigerated.</b></p>	<p>Follow the instructions provided by your laboratory for transport and storage of Amies (clear) or Stuart's (clear) media.</p>
<p><b>Ensure that samples are transported to the laboratory quickly</b></p>	<p><b>If samples for culture are unlikely to reach the laboratory within 24 hours they may not be worth collecting, unless special transport techniques are used.</b></p> <p>Some laboratories will provide fresh culture media for direct inoculation and a transport kit including a CO<sub>2</sub> generating tablet for the detection of <i>N. gonorrhoeae</i> by culture. These kits prolong the survival of <i>N. gonorrhoeae</i> and improve recovery.</p> <p><i>C. trachomatis</i> are sensitive to room temperature. Samples collected for culture must be transported at 4 °C.</p> <p>Samples for detection of <i>C. trachomatis</i> by immunoassay or by molecular techniques are stable for a longer period of time and are more likely to survive transport.</p>
<p><b>Urine samples can be used for <i>Chlamydia</i></b></p>	<p>First voided urine is the best sample for testing. Urine samples for <i>C. trachomatis</i> testing are approved for nucleic acid testing for both males and females. Urine samples cannot be used for culture techniques. Urine samples cannot be used for women if ELISA testing is performed.</p>
<p><b>Consult with the laboratory before collecting samples for <i>T. vaginalis</i></b></p>	<p>Diagnostic assays for <i>T. vaginalis</i> differ between laboratories. For best recovery of Trichomonas, samples intended for culture require inoculation into special transport medium at the time of collection. Samples intended for saline wet mount require rapid transmission to the laboratory. Samples for latex agglutination or microscopic slide examination are not affected by transport.</p>
<p><b>Vagino-anorectal samples that are taken for detection of Group B Streptococci can be collected using a single swab</b></p>	<p>Swabs that are not being transported immediately should be refrigerated, but not frozen. The value of collecting swabs should be questioned if they are not likely to be set up for culture within 3 days of collection.</p> <p>Some laboratories may provide special transport medium (LIM) for vagino-anorectal swabs for Group B Streptococcus search. This medium is highly selective, and must be used only for Group B Streptococcus search. LIM medium cannot be used for transport of any other samples, including vaginal or rectal swabs for any other pathogens.</p> <p><b>Vagino-anorectal swabs are significantly superior to vaginal or rectal swabs alone for the detection of Group B Streptococcus.</b></p> <p><b>Anorectal swabs collected for detection of <i>N. gonorrhoeae</i> are of no diagnostic value if contaminated with feces.</b></p>