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Canadian Guidelines for Screening for *Chlamydia trachomatis* Infection

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CANADIAN GUIDELINES FOR SCREENING FOR CHLAMYDIA TRACHOMATIS INFECTION

Bureau of Communicable Disease Epidemiology, Laboratory Centre for Disease Control (LCDC), Health Protection Branch, Department of National Health and Welfare, Ottawa, in collaboration with the Provincial and Territorial Directors of STD Control, and the College of Family Physicians of Canada

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Canadian Guidelines for Screening for Chlamydia trachomatis Infection

Background

These guidelines were produced by a Working Group created by the Provincial and Territorial Directors of Sexually Transmitted Disease (STD) Control in collaboration with the Division of STD Control, LCDC, Health Protection Branch, Department of National Health and Welfare, Ottawa.

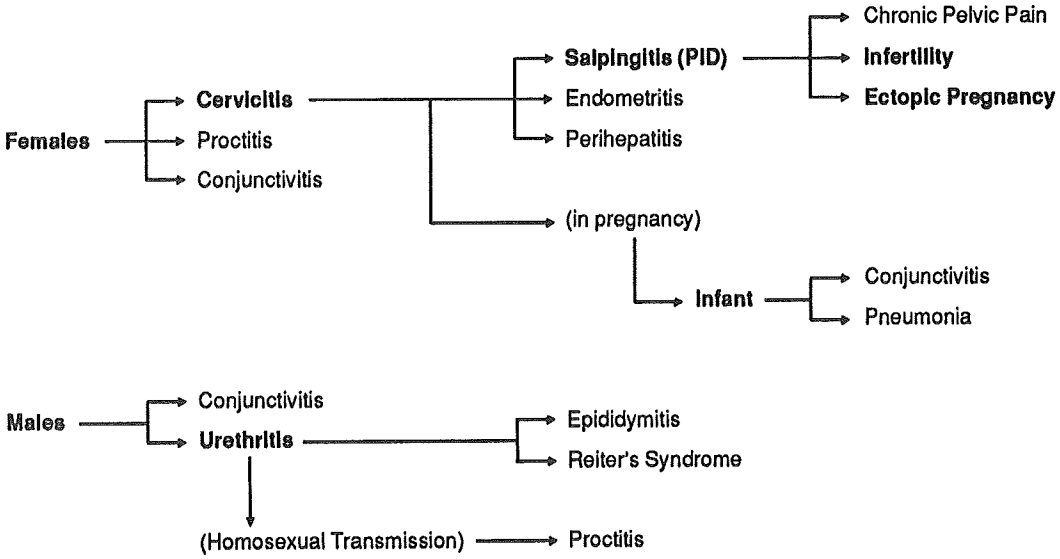
The recognition of *Chlamydia trachomatis* as an important genital pathogen and the development of new laboratory diagnostic technology prompted the preparation of these guidelines. As the technology continues to develop and improve, revisions will be necessary.

Introduction

Chlamydial infection is the most common and the most damaging treatable STD in industrialized countries. In Canada there are an estimated 100,000 infections annually. Although men and women are equally affected by this infection, women bear an inordinate burden of associated complications and consequences. In studies done in Europe and the United States, between 15% and 31% of acute salpingitis cases were culture positive for *C. trachomatis* when specimens were obtained from the lower genital tract[1]. Other serological studies have associated tubal factor infertility and ectopic pregnancy (EP) with chlamydial infection[2,3]. The prevalence of chlamydial infection in Canada is unknown but may be reflected in the incidence of EP which increased from one in 175 pregnancies to one in 77 between 1971 and 1984[4].

Figure 1

Spectrum of Common Clinical Presentations Associated with *C. trachomatis* Infection



The clinical manifestations of chlamydial infection vary with age. In infants, these are conjunctivitis and pneumonia. In men, the infection presents as urethritis, post-gonococcal urethritis, conjunctivitis, proctitis and epididymitis. In women, chlamydial infection is associated with mucopurulent cervicitis(MPC)[5], proctitis, conjunctivitis and the acute urethral syndrome. Complications of cervical infection include salpingitis, endometritis, pelvic peritonitis, perihepatitis, EP, infertility, and chronic pelvic pain (Figure 1).

C. trachomatis is responsible for up to 60% of non-gonococcal urethritis (NGU) in men[6]. In all populations studied, NGU due to *C. trachomatis* is approximately 2.5-3 times that of gonococcal urethritis.

Most infections in women are asymptomatic, but tubal damage may still occur in the absence of pelvic disease symptoms. Although the vast majority of infected men are symptomatic, up to 7% of asymptomatic men have been found to harbour the organism[7]. The true frequency of asymptomatic infection in sexually active males may be even higher.

Chlamydial infection is a major health problem in Canada. To prevent the further spread of infection and reduce the ensuing morbidity and complications, physicians need comprehensive guidelines for screening as well as sound diagnostic and therapeutic approaches. Screening for *C. trachomatis* cervicitis is cost-effective when the local prevalence of infection exceeds 7%[8]. The identification of risk factors predictive of chlamydial infection is necessary to establish cost-effective screening programs.

The Organism

Chlamydiae are unique bacteria with some biological similarities to viruses. They are obligate intracellular parasites growing only within living cells. However, the infections they cause respond to antimicrobial therapy.

Replication occurs through a complex life cycle resulting in the formation of an intracytoplasmic inclusion which, upon maturation and rupture, releases infectious elementary bodies.

Description of Laboratory Tests

C. trachomatis cannot be detected by routine Gram staining. Until recently, confirmation was limited to laboratories capable of undertaking tissue culture. Development of direct antibody testing methods has increased specimen handling capabilities and the number of laboratories offering *C. trachomatis* diagnostic services.

It is important that health-care workers recognize the performance, strengths and limitations, accuracy and fallibility of each test and which test to use in specific clinical situations (see Table 1).

Tissue Culture

This is the standard by which all other techniques are currently evaluated. When specimens are submitted under the appropriate transportation conditions, it is the universally accepted method for laboratory confirmation regardless of specimen site or patient risk situation.

The specificity is accepted as being 100%, i.e., there are no false-positive results, making it the method of choice in all medico-legal cases. The sensitivity is estimated to be 75-80%, i.e., there may be 20-25 false-negative results for every 100 positive tests.

Specimens for tissue culture must be transported to the laboratory on ice or other form of cooling (but not frozen). The total elapsed time should not exceed 24 hours. **If a refrigerated specimen, transported on ice, cannot be delivered to the laboratory within 24 hours of collection, another method of testing should be used.**

Table 1

Summary of the Attributes of Laboratory Tests for the Diagnosis of *Chlamydia trachomatis* Infection

Feature	Tissue Culture	DFA*	EIA**
Specimen site usage	all	cervix urethra conjunctiva	cervix urethra
Sensitivity	75-80%	65%	65%
Specificity	100%	70-95%	85-97%
Specimen transport temperature	refrigerate (do not freeze)	ambient	ambient
Maximum time to laboratory	24 hrs	7 days	48 hrs
Collection kits available from	tissue culture laboratory	testing laboratories	testing laboratories
Suitable for legal purposes?	yes (due to specificity)	no+	no
Report available in	minimum 48 hrs	24 hrs	24 hrs
Verification of specimen adequacy	no	yes	no
Stat testing possible?	no	yes	no
Costs - Labour - Per Test	high/increasing high	lower lower	lower lower
Test interpretation	subjective	subjective	objective

* DFA – Direct Fluorescent Antibody
** EIA – Enzyme Immunoassay
\+ May be suitable for clinical purposes, but may not satisfy legal requirements

Results are available after a minimum of 48 hours from the time the specimen is received by the testing laboratory.

Direct Antibody Testing

Presently, products for 2 direct antibody tests – direct fluorescent antibody (DFA) and enzyme immunoassay (EIA) – are widely used in Canada. These tests are similar in several ways. Unlike tissue culture techniques, viable organisms are not required. Therefore, specimens are less sensitive to transit conditions. Under ideal conditions tests can be completed in one normal working day.

Non-specific cross-reaction with other agents or cell components does occur. The degree of cross-reactivity varies with individual reagents. **The predictive value of positive results is high in high-risk groups and lower in low-risk groups.**

In sexual abuse cases, DFA testing can be used for clinical purposes but may not satisfy legal requirements; tissue culture is the method of choice. Direct antibody detection tests are not recommended for respiratory or rectal specimens. However, if culture of rectal specimens is impractical or unavailable, DFA is the best alternative.

1. Direct Fluorescent Antibody (DFA) (e.g., MicroTrak®*)

Specimens for DFA testing are submitted on special slides provided in the kit. The swab used to collect the specimen is rolled in the "well" of the slide, air dried (for at least 15 minutes) and the fixative provided is applied. The slides, shipped at ambient temperature, should be received by the laboratory within 7 days of collection.

Theoretically, results can be available within 30 minutes but, on a more practical basis, are available within 24 hours of receipt by the testing laboratory. A unique advantage to this method is that the adequacy of the specimen can be assessed by the microscopist.

This test is useful in high-risk populations, although some false results, both positive and negative, can be expected.

2. Enzyme Immunoassay (EIA) (e.g., Chlamydiazyme®*)

Specimens for EIA testing must be submitted to the laboratory using the specimen collection and transport tubes provided in the kits.

The occurrence of false positives and negatives indicates that this type of direct testing should be used only in high-risk or high-incidence situations.

After collection, specimens can be transported without refrigeration, but must reach the laboratory within 48 hours, and be tested within 7 days of collection.

The test takes approximately 4 hours to perform. Results will usually be available within 24 hours of receipt of the specimen in the testing laboratory. Laboratories dealing with smaller volumes of tests may batch specimens with a resultant delay in reporting time.

Risk Groups

Infection rates are high in persons with other STD. From 20-30% of heterosexual males[9,10] and 30-60% of females[10,11,12] with gonorrhea have co-existing chlamydial infections. Among males with NGU, 20-60% are infected[7], while 40-50% of males under 35 years of age with epididymitis have *C. trachomatis* infections[13].

The prevalence of chlamydial infection in Canada is unknown because it is not notifiable nationally. However, between 7% and 12% of women attending student health services[14,15] and 11.4% of women presenting for therapeutic abortion[16] were infected. Women attending prenatal clinics and family planning clinics had infection rates of 11% and 8%, respectively[17].

Risk Factors in Asymptomatic Women

Various studies[3,5,14,16,18,] have identified risk factors among women which lead to an increased index of suspicion for chlamydial infection. These risk factors should be sought during a careful sexual or pre-natal history and medical examination. They include the following:

- Age less than 25 years
- No contraceptive, or non-barrier method used
- STD clinic patient
- Intercourse with 2 or more partners in the past year
- Intercourse with new partner in previous 2 months
- Partner has/had NGU or gonorrhea

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* Use of commercial names is for reference purposes only

Table 2
Groups for Chlamydia Screening

Asymptomatic Women	
High Risk	Evidence of mucopurulent or purulent cervical discharge *OR* Under age 25, plus one or more of the following: • 2 or more sexual partners in the last year • a new sexual partner in the last 2 months • no contraception or use of non-barrier method • bleeding induced by endocervical swab *OR* STD clinic patient not given anti-chlamydial treatment *OR* Other groups (e.g. family planning clinic patients, juvenile centre detainees) if prevalence exceeds 7%.
Specimen site and test method	Endocervix. Any method.
Recommendation	Test • at least annually • prior to IUD insertion • prior to therapeutic abortion • in first trimester (1st prenatal visit) • in third trimester if risk continues.
Low Risk	Screening is not indicated.
Asymptomatic Heterosexual Men	Insufficient data at this time to make recommendations.
Asymptomatic Homosexual Men	Screening is not indicated.
Symptomatic Post-pubertal Patients	with ***C. trachomatis***-associated syndrome – e.g. MPC, pelvic inflammatory disease (PID), NGU or epididymitis (men 35 and under)[a,b].
Specimen sites and test methods	Endocervix or urethra: Any method. Anus or eye: Culture. DFA if culture is impractical.
Sexually Abused Person	
Specimen site	Endocervix if post-pubertal. Vagina if pre-pubescent. Urethra or anus.
Test method	Culture. DFA if culture is impractical[c].
Recommendations	Test at initial examination; repeat only if symptoms develop.
Sexual Contacts of Persons	with laboratory-confirmed chlamydial and/or gonococcal infection, or with ***C. trachomatis***-associated syndrome – e.g. NGU, MPC, PID or epididymitis (men 35 and under)[b].
Specimen sites and test methods:	Endocervix or urethra. Any method. Anus or eye. Culture. DFA if culture is impractical. Note: Pharyngeal testing is not indicated at this time.

All sexual partners of patients with ***C. trachomatis*** infection within 30[d] days of development of symptoms or diagnosis in the index case should be traced, examined, tested and treated for ***C. trachomatis*** infection. This group includes sexual partners of patients with sexually acquired chlamydial infection and mothers (plus their sexual partners) of infected neonates.

a) Testing in symptomatic patients is considered diagnostic rather than screening.
b) After examination, do not wait for laboratory results; treat immediately with anti-chlamydial regimen.
c) DFA results may not satisfy legal requirements.
d) 30 days has been selected arbitrarily. No reports are available on the optimal time for contact tracing in chlamydial infection.

- An observed mucopurulent cervical exudate
- Bleeding induced by the first endocervical swab or by the Pap test.

To assess individual risk, refer to Table 2, "Groups for Chlamydia Screening". With the exception of MPC, no single risk factor is sufficient to indicate who should be screened. Consideration of individual risk factors in combination with community factors (e.g., STD Clinic, Family Planning Clinic, the laboratory services available) will assist in reaching this decision and maximize the yield from screening.

Screening for chlamydial infection at the time of a Pap test is not indicated in women at low risk for STD[8,19]. A Pap test result indicating the presence of "non-specific cervicitis" is sufficient reason to recall the patient for chlamydia testing.

Risk Factors in Asymptomatic Men

Because risk factors in this group have not been identified, screening is not currently recommended.

Specimen Collection

The physician's decision to use a tissue culture or antibody test for diagnosis will dictate the type of transport media, the method of transport (wet ice vs ambient temperature) and the type of swab to be used. Wooden shafted swabs should be avoided as they may affect test results.

If the decision is to use an antibody test, the materials and transport methods employed will be determined by the kit supplied by the regional laboratory service. Swabs are provided with each kit, and a cytobrush for collecting endocervical specimens is supplied by some manufacturers for use **only in non-pregnant women.** Instructions are provided in each kit for the proper handling of the swab(s) after specimen collection.

If the decision is to use a tissue culture method, consultation with the laboratory is recommended in order to obtain appropriate materials.

The principles of specimen collection are independent of the type of test performed and must be followed in detail for accurate results.

1. Urethral Specimens

Adult and adolescent males and females

Ideally, the patient should not have voided for at least 1 hour. Voiding within this period may decrease the ability to detect organisms.

Tell the patient what you are going to do. Explain that most patients find the procedure uncomfortable and may experience dysuria at the next voiding.

An intraurethral specimen is required. It is best obtained by using a small swab on a flexible metal shaft.

Note: Some authorities recommend moistening the swab in sterile non-bacteriostatic saline before insertion to reduce discomfort.

Insert the swab gently (1-2 cm in females, 2-4 cm in males) into the urethra; rotate it slowly, by the shaft, in a clockwise direction for 3-5 seconds, and then withdraw it.

After collecting the specimen, the swab is placed in the appropriate transport tube for EIA testing or tissue culture. For DFA testing, the slide provided is prepared by pressing the swab against the slide well and rotating the shaft in a counter-clockwise direction. This should leave a visible specimen in the well. Allow the specimen to air dry for 15 minutes, then fix it with the fixative provided.

Pre-pubescent males and females

An intraurethral specimen is unkind in pre-pubescent individuals and should not be done. An adequate specimen may be obtained from the urethral meatus. Press the swab against the meatus for 10 seconds, attempting to collect any visible discharge by rotating the swab gently. Transfer to the DFA slide, EIA antigen transport tube, or transport medium for culture.

2. Endocervical Specimens

Adults and adolescents

To obtain endocervical specimens, the cervical os should be visualized. Vaginal secretions and any cervical mucus obstructing the os should be removed with a sponge.

*Note: To optimize the results of **C. trachomatis** testing, specimens from the cervix should be taken in the following order:*

*a) specimen for **Neisseria gonorrhoeae** culture,*

b) specimen for Pap test, if indicated, and

*c) specimen for **C. trachomatis**.*

A swab on a plastic shaft is used to obtain specimens for tissue culture and EIA testing and may be used for DFA testing. Insert it gently 1-2 cm into the endocervical canal and rotate it 6 complete turns; then leave it in place for at least 3 seconds. Withdraw it and place it in the appropriate transport tube for either *C. trachomatis* culture or EIA. For the DFA method, prepare the slide by pressing the swab firmly against the glass and rotating the shaft.

If the cytobrush is used (in the DFA method), insert it gently 1-2 cm into the endocervical canal and rotate it one complete turn; then leave it in place for at least 3 seconds. Withdraw it and prepare the slide by laying the cytobrush across the glass and rotating and twisting it while moving it back and forth.

Detection of *C. trachomatis* in women may be enhanced by taking an urethral swab.

Note: Do not use the cytobrush if the patient is pregnant.

Always examine slides to ensure that material is present. If not, repeat the pressing, rotating and twisting actions.

Pre-pubescent girls

Cervical specimens should not be taken from pre-pubescent girls.

3. Vaginal specimens

Infants and pre-pubescent children

For legal purposes, isolation of *C. trachomatis* by culture is essential.

If the vaginal orifice is open, swabs of pooled vaginal secretions can be collected on swabs moistened with non-bacteriostatic sterile saline, without a vaginal speculum. If necessary, a disposable aural or nasal speculum can be used to facilitate the process.

If the vaginal orifice is not open, gentle vaginal lavage with sterile saline through a soft Silastic® feeding tube may be employed. The saline is re-aspirated, and any overflow is collected by pressing moistened swabs against the vaginal orifice or collecting it in a sterile eye-dropper. The aspirate is sent to the laboratory on ice, while the swabs are placed in transport media and refrigerated at 4°C **(do not freeze).**

Endocervical specimens are **not** indicated in this group as infection is limited to the vulva and vagina.

Vaginal specimens are of no value in adults and adolescents **(See Section 2, "Endocervical Specimens").**

4. Rectal Specimens

Specimens may be obtained blindly, or through an anoscope. The latter is preferred for symptomatic individuals. For blind swabbing, the swab is inserted 2-3 cm into the anal canal, pressing laterally to try to avoid fecal matter. If there is visible fecal contamination of the swab, it should be discarded and another used.

Using an anoscope, specimens can be taken under direct vision, thereby avoiding fecal material.

Inadequate Specimens

Errors which may give inaccurate results or reports of "inadequate specimen" include the following:

- inadequate removal of mucus from the cervical os
- inadequate time of contact between the swab (or cytobrush) and the endocervix or urethra
- use of swabs on wooden shafts for culture specimens
- insufficient specimen collected or deposited on the slide
- insufficient "air-dry" time (minimum 15 minutes); fixative applied too soon washes specimen off the slide (DFA procedure only).

Note: *Blood on the swab does not affect test results.*

C. trachomatis Evaluation in Sexual Assault or Abuse

In sexual assault or sexual abuse cases, microbiological testing for *C. trachomatis* (and *N. gonorrhoeae*) should be carried out.

All specimens **for genital pathogens** should be taken during the same examination to minimize patient anxiety. Timing is important. Specimens taken too soon after the assault (e.g., when specimens for sperm counts, ABO antigens, etc. are being collected) may give false-negative results. **The ideal lapse time has not been determined, but it is recommended that STD specimen collection be delayed until 72 hours after the assault has occurred.** For *N. gonorrhoeae*, this timing appears reasonable; additional time may be required for recovery of *C. trachomatis*. In instances of chronic assault or abuse, specimens may be taken any time. For further information see the **"1989 Canadian Guidelines for Health Care Providers for the Examination of Children Suspected to Have Been Sexually Abused"**, a publication of the Department of National Health and Welfare (Can Dis Wkly Rep 1989; 15 (suppl. no. S3): 1-16).

Labelling of specimens as to patient and specimen site is essential and the collection sites should be recorded in the chart. The laboratory must be alerted to the potential medico-legal aspects of the specimens taken. Laboratory methods of isolation should be documented in these instances and the isolate saved for possible further studies and testing.

Public Health Aspects and Contact Tracing

Several provincial and territorial jurisdictions now include genital chlamydial infections, NGU and MPC in their lists of notifiable diseases.

Notification or reporting has 2 main functions; 1) to identify, examine and treat all sexual partners, and 2) to more accurately define high-risk groups for prevention and control programs.

The importance of examining and treating sexual partners cannot be over-estimated in genital chlamydial infection or chlamydia-associated syndromes. Failure to do so may result in re-infection of the index case, or the development of complications.

Physicians have a responsibility to their patients to ensure that sexual partners are examined and treated. Advice and assistance in tracing sexual partners can be obtained from public health authorities, who may undertake the task if requested.

Treatment Regimens

For uncomplicated urethral, endocervical, or rectal infection in adults and adolescents:

Drug Regimens of Choice

- Tetracycline: 500 mg, by mouth, 4 times a day for 7 days **or**
- Doxycycline: 100 mg, by mouth, 2 times a day for 7 days

Alternative Regimens (for patients in whom tetracyclines are contraindicated or not tolerated)

- Erythromycin: 500 mg, by mouth, 4 times a day for 7 days

Further Information

Physicians and other health-care providers requiring further information and details on treatment should consult the **"1988 Canadian Guidelines for the Treatment of Sexually Transmitted Diseases in Neonates, Children, Adolescents and Adults"**, a publication of the Department of National Health and Welfare (Can Dis Wkly Rep 1988; 14 (suppl. no. S2): 1-20).

Follow-Up

When taken as directed, the tetracycline and erythromycin regimens listed above are highly effective (95% cure rates). No tetracycline-resistant *C. trachomatis* has been described. Post-treatment cultures are not required if laboratory resources are limited.

If post-treatment testing is performed using DFA or EIA, sufficient time for the elimination of dead organisms must elapse. A complete menstrual cycle in women and 1 month in men is suggested. Otherwise false-positive results may be reported. Most "positive" post-treatment test results in asymptomatic persons are usually false positives.

A positive post-treatment culture most likely represents non-compliance with treatment, failure to treat sexual partners, or laboratory error rather than resistance to the antibiotic. Patients who do have positive post-treatment cultures should be treated again according to one of the above regimens, preferably tetracycline.

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Table 2
Groups for Chlamydia Screening

Asymptomatic Women	
High Risk	Evidence of mucopurulent or purulent cervical discharge *OR* Under age 25, plus one or more of the following: • 2 or more sexual partners in the last year • a new sexual partner in the last 2 months • no contraception or use of non-barrier method • bleeding induced by endocervical swab *OR* STD clinic patient not given anti-chlamydial treatment *OR* Other groups (e.g. family planning clinic patients, juvenile centre detainees) if prevalence exceeds 7%.
Specimen site and test method	Endocervix. Any method.
Recommendation	Test • at least annually • prior to IUD insertion • prior to therapeutic abortion • in first trimester (1st prenatal visit) • in third trimester if risk continues.
Low Risk	Screening is not indicated.
Asymptomatic Heterosexual Men	Insufficient data at this time to make recommendations.
Asymptomatic Homosexual Men	Screening is not indicated.
Symptomatic Post-pubertal Patients	with ***C. trachomatis***-associated syndrome – e.g. MPC, pelvic inflammatory disease (PID), NGU or epididymitis (men 35 and under)[a,b].
Specimen sites and test methods	Endocervix or urethra: Any method. Anus or eye: Culture. DFA if culture is impractical.
Sexually Abused Person	
Specimen site	Endocervix if post-pubertal. Vagina if pre-pubescent. Urethra or anus.
Test method	Culture. DFA if culture is impractical[c].
Recommendations	Test at initial examination; repeat only if symptoms develop.
Sexual Contacts of Persons	with laboratory-confirmed chlamydial and/or gonococcal infection, or with ***C. trachomatis***-associated syndrome – e.g. NGU, MPC, PID or epididymitis (men 35 and under)[b].
Specimen sites and test methods:	Endocervix or urethra. Any method. Anus or eye. Culture. DFA if culture is impractical. Note: Pharyngeal testing is not indicated at this time.

All sexual partners of patients with ***C. trachomatis*** infection within 30[d] days of development of symptoms or diagnosis in the index case should be traced, examined, tested and treated for ***C. trachomatis*** infection. This group includes sexual partners of patients with sexually acquired chlamydial infection and mothers (plus their sexual partners) of infected neonates.

a) Testing in symptomatic patients is considered diagnostic rather than screening.
b) After examination, do not wait for laboratory results; treat immediately with anti-chlamydial regimen.
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d) 30 days has been selected arbitrarily. No reports are available on the optimal time for contact tracing in chlamydial infection.

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