

Screening and Treatment Protocols

Due to restricted funding, the Project is not able to offer widespread screening and treatment services to males. Males, however, can receive treatment and/or testing if they are identified as a partner of an infected woman. In some locations, males in STD and family planning clinics are being tested using alternative funding resources.

Regarding screening of women, universal screening is neither economically feasible, nor is it cost-effective. As a result, the Region VIII Chlamydia Project uses selective screening criteria. These criteria were developed using universal screening data from clinics in the Region VIII Family Planning Program (Title X), as well as from the CDC screening criteria published in *Recommendations for the Prevention and Management of Chlamydia trachomatis Infections*, MMWR, 1993 and *CDC Sexually Transmitted Diseases Treatment Guidelines 2002*, MMWR, 2002.

A. SELECTIVE SCREENING CRITERIA FOR WOMEN

The regional set of minimum chlamydia screening criteria are given below. As indicated, these are minimum criteria; individual states and programs may do more based on their data and programmatic considerations.

1. All sexually active women under age 25
2. Women age 25 and older with one or more of the following:
 - (a) New sex partner in the last 60 days.
 - (b) Multiple sex partners in the last 60 days.
 - (c) MPC
 - (d) Cervical friability
 - (d) PID
 - (e) Positive for chlamydia in the last 12 months

B. PHYSICAL EXAMINATION

The definitive diagnosis of *Chlamydia trachomatis* (CT) infection can only be made by using one of several available laboratory tests. Two points should be understood when doing a physical exam:

- 1) Chlamydia infections can frequently be asymptomatic in both men and women;

- 2) The clinical signs of this disease closely parallel those caused by *N. gonorrhoeae*. Both organisms act by infecting cells within the cervical canal and may ascend to other pelvic organs, resulting in Pelvic Inflammatory Disease (PID).

Physical Exam Findings

1. Females

a. CERVICITIS

- Mucopurulent discharge from the cervical os (not vagina)—greenish or yellow as observed on a cervical swab.
- More than 10 Polymorphonucleocytes (PMNs) per field (x 1,000) on gram stain of cervix with NO GNIDC (gram negative intracellular diplococci).

Cervical friability—which is bleeding that easily induced by specimen collection, from the ectocervix or from the canal.

May be subtle with the only indication being "inflammation" reported by Pap smear.

b. PELVIC INFLAMMATORY DISEASE (PID)

Signs and symptoms of PID are varied and depend on actual site of infection, i.e., endometritis, salpingitis, pelvic peritonitis, perihepatitis.

Some minimal criteria are:

- Client history of pelvic pain or dyspareunia of recent onset.
- Uterine/Adnexal tenderness and/or fullness.
- Cervical Motion Tenderness - moderate to severe pain elicited when cervix is manipulated or palpated.
- May also exhibit fever (>101 F or >38.3 C) tachycardia, increased vaginal discharge, intermenstrual bleeding, uterine cramping, pain or bleeding with intercourse.
- Additional criteria that support a diagnosis of PID include the following: abnormal cervical or vaginal mucopurulent discharge; presence of white blood cells (WBCs) on saline microscopy of vaginal secretions; elevated erythrocyte sedimentation rate; elevated C-reactive protein; and laboratory documentation of cervical infection with *N. gonorrhoeae* or *C. trachomatis*.

Serious sequelae include infertility, ectopic pregnancy, chronic pelvic pain, dyspareunia, tubo-ovarian abscess formation.

c. OTHER

Swollen Bartholin gland with pustular exudate from Bartholin's duct.

Urethritis:

- Urine culture is negative, no hematuria, no suprapubic tenderness.
- On pelvic exam there is urethral discharge and the meatus is reddened and swollen.
- Fitz-Hugh-Curtis Syndrome (Perihepatitis)
- Association with right upper quadrant (RUQ) pain, fever, nausea, or vomiting.

2. Males

a. URETHRITIS

It is difficult to differentiate CT or GC urethritis on basis of signs and symptoms alone.

Frequently associated with dysuria and a complaint of a white or clear urethral discharge.

On examination no abnormality is seen other than the discharge, i.e. no adenopathy or penile lesions.

Gram stain of urethral discharge commonly shows 5 PMNs/high powered field (HPF), and NO GNIDC (gram negative intracellular diplococci).

b. EPIDIDYMITIS

Client presents with a history of fever, unilateral scrotal pain, swelling.

Exam confirms extremely painful testes and/or epididymis.

c. OTHER

Proctitis:

- Causes rectal pain, bleeding, mucous discharge, diarrhea and an intense urge to defecate.
- Acquired through receptive anal intercourse

Reiter's Syndrome:

- Uncommon but found more often in men.
- Men present with signs and symptoms of urethritis, joint pain (arthritis), inflammation in the eyes (conjunctivitis), and skin lesions.

C. CHLAMYDIA SPECIMEN COLLECTION

The sensitivity of chlamydia tests is dramatically influenced by the quantity of columnar epithelial cells since chlamydia live inside of these cells. The greater number of cells collected, the more likely a chlamydia infection, if present, will be detected. Careful and thorough specimen collection will increase the accuracy of test results.

1. Gen-Probe APTIMA Combo 2 – Endocervical

Equipment

Gen-Probe APTIMA Combo 2 Unisex Swab Collection Kit
1 Female Cleaning Swab
1 Unisex Collection Swab
1 Transport Tube
Laboratory Requisition

Procedure

Explain procedure to client

Prepare client for pelvic examination

Insert speculum exposing the cervix

Obtain specimens for chlamydia tests after obtaining specimens for Pap smear or other purposes

Remove excess mucus from the cervical os and surrounding mucosa using the white shafted cleaning swab. Discard this swab.

Insert the blue shafted specimen collection swab into the endocervical canal.

Gently rotate the swab clockwise for 10 to 30 seconds in the endocervical canal to ensure adequate sampling.

Withdraw the swab carefully; avoid any contact with the vaginal mucosa.

Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube.

Carefully break the swab shaft at the scoreline; use care to avoid splashing of contents.

Re-cap the swab specimen transport tube tightly.

Label specimen with client's first and last name, and date specimen collected.

Maintain specimen(s) at room temperature or refrigerate. DO NOT FREEZE.

Since the same APTIMA Combo 2 specimen can be used to test for both gonorrhea and chlamydia, please contact your lab to determine the protocol(s) for marking the laboratory requisition.

Follow specific instructions from the laboratory regarding when and how to transport specimens for testing.

2. Gen-Probe APTIMA Combo 2 – Urethral (male)

Equipment

- Gen-Probe APTIMA Combo 2 Unisex Swab Collection Kit
- 1 Unisex Collection Swab
- 1 Female Cleaning Swab -- not used - discard
- 1 Transport Tube
- Laboratory Requisition

Procedure

Explain procedure to client

The client should not have urinated for at least one hour prior to sample collection.

Insert the blue shafted specimen collection swab 2 – 4 cm into the urethra.

Gently rotate the swab clockwise for 2 to 3 seconds in the urethra to ensure adequate sampling.

Withdraw the swab carefully.

Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube.

Carefully break the swab shaft at the scoreline; use care to avoid splashing of contents.

Re-cap the swab specimen transport tube tightly.

Label specimen with client's first and last name, and date specimen collected.

Maintain specimen(s) at room temperature or refrigerate. DO NOT FREEZE.

Since the same APTIMA Combo 2 specimen can be used to test for both gonorrhea and chlamydia, please contact your lab to determine the protocol(s) for marking the laboratory requisition.

Follow specific instructions from the laboratory regarding when and how to transport specimens for testing.

3. Gen-Probe APTIMA Combo 2 – Male and Female Urine

Equipment

Urine Collection Cup, preservative-free
Gen-Probe APTIMA Combo 2 Urine Specimen Collection Kit
1 Transport Tube
1 Disposable Pipette
Laboratory Requisition

Procedure

Explain procedure to client.

The client should not have urinated for at least one hour prior to sampling.

Direct client to provide a first-catch urine (approximately 20 to 30 mL of the initial urine

stream) into a urine collection cup. *Note: Collection of larger volumes of urine may reduce test sensitivity. This is NOT a clean catch urine - female patients should not cleanse the labial area prior to providing the specimen.*

Remove the transport cap and transfer 2 mL of urine into the urine specimen transport tube using the disposable pipette provided. The correct volume of urine has been added when the fluid level is between the middle black lines on the urine specimen transport tube label.

Re-cap the urine specimen transport tube tightly. This is now known as the *processed urine specimen*.

Label processed urine specimen with client's first and last name, and date specimen collected.

Maintain specimen(s) at room temperature or refrigerate. DO NOT FREEZE.

Since the same APTIMA Combo 2 specimen can be used to test for both gonorrhea and chlamydia, please contact your lab to determine the protocol(s) for marking the laboratory requisition.

Follow specific instructions from the laboratory regarding when and how to transport specimens for testing.

4. BDProbeTek™ ET *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Amplified DNA Assays – Endocervical

Equipment

The **CULTURETTE DIRECT** Cleaning – Collection and Transport System and the Mini-Tip **CULTURETTE DIRECT** Collection and Transport System.

Procedure

Explain procedure to client

Remove excess mucus from the cervical os with the large-tipped cleaning swab provided in the **CULTURETTE DIRECT** Cleaning-Collection and Transport System and discard.

Insert the **CULTURETTE DIRECT** swab into the cervical canal and rotate 15 - 30 seconds.

Withdraw the swab carefully. Avoid contact with the vaginal mucosa.

Immediately place the cap/swab into the transport tube. Make sure the cap is tightly secured to the tube.

Label the tube with patient information and date/time collected.

The **CULTURETTE DIRECT** collection swab must be stored and transported to the laboratory and/or test site at 2-27⁰C within 4-6 days of collection. Storage up to 4 days has been validated with clinical specimens; storage up to 6 days has been demonstrated with seeded specimens.

5. BDProbeTek™ ET *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Amplified DNA Assays – Male Urethral

Equipment

The **CULTURETTE DIRECT** Cleaning – Collection and Transport System and the Mini-Tip **CULTURETTE DIRECT** Collection and Transport System.

Procedure

Explain procedure to client

Insert the Mini-Tip **CULTURETTE DIRECT** swab 2 – 4 cm into the urethra and rotate 3 - 5 seconds.

Withdraw the swab and place the cap/swab into the transport tube. Make sure the cap is tightly secured to the tube.

Label the tube with patient information and date/time collected.

The **CULTURETTE DIRECT** collection swab must be stored and transported to the laboratory and/or test site at 2-27⁰C within 4-6 days of collection. Storage up to 4 days has been validated with clinical specimens; storage up to 6 days has been demonstrated with seeded specimens.

6. BDProbeTek™ ET *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Amplified DNA Assays – Male and Female Urine

Equipment

Sterile, plastic, preservative-free specimen collection cup.

Procedure (Addition of the UPP at the Laboratory or Test Site)

Explain procedure to client

The patient should not have urinated for a least 1 h prior to specimen collection.

Collect specimen in a sterile, plastic, preservative-free specimen collection cup.

The patient should collect the first 15 – 20 mL of voided urine (the first part of the stream – NOT midstream). **NOTE:** During the clinical evaluation, testing urine volumes up to 60 mL was included in the performance estimates.

Label the tube with patient information and date/time collected.

Store and transport urine specimens to the test site at 2 – 8⁰C within 4-6 days of collection. Do not freeze the urine specimen.

8. Culture isolation (*Chlamydia trachomatis*)

Specimen:

Swab (Cotton, Rayon, Dacron, Cytobrush)

Transport:

Less or equal to 24 hours at 4⁰ C

If delayed > 24 hours, freeze to -70⁰ C

Transport media: Sucrose phosphate (2SP) or sucrose phosphate glutamate (SPG), supplemented with 5% fetal bovine serum, 10 ug/mL gentamicin, 100 ug/mL vanomycin, and 1ug/mL amphotericin B. Micro tests Multi-Microbe Media (M4; manufactured by Micro Test, Inc., Lilburn, GA).

Storage:

Frozen to -70⁰ C in transport media

Viability remains after two or more years, if frozen correctly

Avoid storage at -20⁰ C or in frost-free freezers

9. Culture isolation (*Neisseria gonorrhoeae*)

Specimen:

Swab (Rayon, Dacron, Calcium alginate)

Transport:

Less or equal to 5 hours

Inoculate selective or nonselective medium and incubate at 35⁰ C – 36.5⁰ C and place immediately in a CO₂–enriched atmosphere

5 – 48 hours : can be transported in ambient air and temperature if inoculated medium has been incubated at 35⁰ C – 36.5⁰ C in a CO₂–enriched atmosphere for 18 – 24 hours before

transport
Do not refrigerate

Storage:

Must be subcultured every 18 – 24 hours to maintain viability until frozen
Should be stored frozen at - 70⁰ C or less in trypticase soy broth plus 20% glycerine

ADD PCR

D. FOLLOW-UP OF CHLAMYDIA TEST RESULTS

The following are guidelines for follow-up on test results.

1. Facilitating Follow-Up

To facilitate follow-up procedures, agency staff should communicate to clients of all ages the need to collect accurate locating information. Clients should be encouraged to provide several ways to contact them including both phone and mail.

Agency staff need to have a way to contact clients concerning test results to make referrals for additional medical care as needed. Clients should be informed of the circumstances under which they may be contacted, and be assured that their cooperation is greatly appreciated by clinic staff.

Every effort should be made to protect the confidentiality of the client. Therefore, care should be taken to ensure that the receipt and disposition of test results are handled in a confidential manner.

2. Positive Test Results

As soon as a positive chlamydia test result is received, it should be signed and dated by appropriate clinic staff and matched with a medical record, the medical record should be identified in some way so that any staff person making contact with the client realizes that the client needs further medical care and transfers the client to an appropriate staff member to communicate the follow-up procedures.

For all positive chlamydia tests, follow-up should be attempted according to program or agency protocols. Follow-up methods may include using telephone contact, certified or regular mail, and/or health department staff. The first attempt to notify clients should occur within 3 business days of receipt of a positive test result. All attempts should be documented in the client's chart. Each clinic or program should comply with state STD reporting requirements.

3. Negative Results

Requirements regarding follow-up of negative test results will be at the discretion of each individual provider agency.

4. Borderline Results

Clients with borderline test results should be contacted and encouraged to return to the clinic for a repeat chlamydia test (unless they have been treated presumptively). The medical records of clients with borderline results should be identified in some way so that any staff person making contact with the client realizes the need for further medical care.

During the follow-up assessment, another specimen for chlamydia testing should be collected and submitted to the laboratory. Depending on clinical impression and an assessment of risk factors, the clinician may want to consider presumptive treatment for chlamydia infection.

E. CHLAMYDIA TREATMENT

Definitive diagnosis of chlamydia is by a positive laboratory test. Clients presumed to have chlamydia may be treated prior to receiving a test result from the laboratory according to the criteria given below. These criteria are based on CDC recommendations. As state-specific prevalence data becomes available and are reviewed, these criteria may be revised.

1. Presumptive Treatment Criteria for Females

The decision to treat presumptively should be based on local estimates of chlamydia prevalence and likelihood of client's compliance with follow-up visits.

- Signs and symptoms of PID
- History of recent sex partner with confirmed CT, GC and/or NGU (urethritis)
- MPC

NOTE: Treatment for PID is different than for chlamydia. Please refer to section on PID treatment, which follows.

2. Presumptive Treatment Criteria for Males

- History of recent sex partner with confirmed CT or GC
- Physical and laboratory examination consistent with NGU and/or GC

3. Treatment of Choice

Treatment for presumed or confirmed positive *Chlamydia trachomatis* in a **non-pregnant** female or any male is:

a. Recommended Regimens

- Azithromycin 1 g orally in a single dose
- **OR**-
- Doxycycline 100 mg orally 2 times a day for 7 days

b. Alternative Regimens

- Erythromycin base 500 mg orally 4 times a day for 7 days
- **OR**-
- Erythromycin ethyl succinate 800 mg orally 4 times a day for 7 days
- **OR**-
- Ofloxacin 300 mg orally 2 times a day for 7 days
- **OR**-
- Levofloxacin 500 mg orally, once daily, for 7 days

4. Treatment Options for Pregnant Women

a. Recommended Regimen for Pregnant Women

- Azithromycin 1 g oral suspension (single dose) or 4 X 250 mg. tabs in a single dose
- **OR**-
- Amoxicillin 500 mg orally 3 times a day for 7 days.

b. Alternative Regimens for Pregnant Women

- Erythromycin base 500 mg orally 4 times a day for 7 days
- **OR**-
- Erythromycin base 250 mg orally 4 times a day for 14 days
- Erythromycin ethyl succinate 800 mg orally 4 times a day for 7 days
- **OR**-
- Erythromycin ethyl succinate 400 mg orally 4 times a day for 14 days
- **OR**-

Clinical experience and studies suggest that azithromycin is be safe and effective.

Many pregnant women do not tolerate erythromycin well and may not comply with the prescribed treatment. Therefore, repeat testing of pregnant women 3 weeks after completion of therapy is recommended.

F. PID TREATMENT OPTIONS

Pelvic inflammatory disease (PID) comprises a spectrum of inflammatory disorders of the upper genital tract among women and may include any combination of endometritis, salpingitis, tubo-ovarian abscess, and pelvic peritonitis. No single therapeutic regimen has been established for persons with PID. Many experts recommend that all clients with PID be hospitalized so that supervised treatment with parenteral antibiotics can be initiated. PID therapy should provide empiric, broad-spectrum coverage of likely pathogens. Antimicrobial coverage should include *N. gonorrhoeae*, *C. trachomatis*, Gram-negative facultative bacteria, anaerobes, and streptococci.

1. Management of Clients

For women with PID of mild or moderate severity, parenteral and oral therapy appear to have similar clinical efficacy. The decision of whether hospitalization is necessary should be based on the discretion of the health-care provider. Clients who do not respond to oral therapy within 72 hours should be re-evaluated to confirm the diagnosis and to receive parenteral therapy.

Regimen A

- Levofloxacin 500 mg orally once daily for 14 days
 - **OR** -
 - Ofloxacin 400 mg orally 2 times a day for 14 days
 - **WITH OR WITHOUT** -
- Metronidazole 500 mg orally 2 times a day for 14 days.

*Quinolones should not be used in persons with a history of recent foreign travel or partners' travel, infections acquired in California or Hawaii, or infections acquired in other areas with increased QRNG prevalence.

Regimen B

- Ceftriaxone 250 mg IM in a single dose
 - **OR** -
 - Cefoxitin 2 g IM in a single dose and Probenecid, 1 g orally administered concurrently in a single dose
 - **OR** -
 - Other parenteral third-generation cephalosporin (e.g., ceftizoxime or cefotaxime),
 - **PLUS** -

- Doxycycline 100 mg orally 2 times a day for 14 days.
– **WITH or WITHOUT** –
- Metronidazole 500 mg orally twice a day for 14 days.

2. Management of Sex Partners

Sex partners of patients with PID should be examined and treated empirically with regimens effective against both *C. trachomatis* and *N. gonorrhoeae* if they had sexual contact with the patient during the 60 days preceding onset of symptoms in the patient. The evaluation and treatment are imperative because of the risk for reinfection and the strong likelihood of urethral infections of either of these organisms in the sex partner.

G. FOLLOW-UP TESTING

1. TEST OF CURE

Patients do not need to be retested for chlamydia after completing treatment with the recommended or alternative regimens unless therapeutic compliance is in question, symptoms persist, or reinfection is suspected, because these therapies are highly efficacious.

2. RESCREENING HIGH RISK CLIENTS FOR REINFECTION

Clinicians and health-care agencies should consider advising all women with chlamydial infection to be re-tested approximately 3 months after treatment.