

INFERTILITY PREVENTION PROJECT REGIONAL MANUAL & GUIDELINES – 2005

Developed by the Region X IPP Regional Advisory Committee

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TABLE OF CONTENTS

Section I: Overview

Section II: Screening, Specimen Collection & Treatment

Section III: Education & Counseling

Section IV: Laboratory Testing, Quality Assurance & Improvement Program

Section V: Lab Slip & Data Collection

Section VI: APPENDICES including Resources

Section I:

Introduction to the Region X Infertility Prevention Project

In 1988, a large-scale chlamydia screening demonstration project was initiated in Health and Human Services (HHS) Region X (Alaska, Idaho, Oregon, Washington). Introduction of chlamydia screening led to the reduction of *Chlamydia trachomatis* positivity rates among women attending family planning clinics by up to 60%. In 1993, the Centers for Disease Control and Prevention (CDC) expanded its chlamydia prevention demonstration projects to include federal HHS Regions III, VII, and VIII. Funding for this expansion was the result of legislation enacted by Congress (Preventive Health Amendments of 1992) that authorized activities for what is now known as the Infertility Prevention Program (IPP). The key components of the IPP as authorized by Congress in 1992 are:

- Screening women for disease and secondary conditions
- Providing treatment to women
- Providing counseling to women on prevention and control
- Providing follow-up services
- Providing partners of women with screening and treatment
- Providing outreach to inform women of services
- Providing the public with information and education about prevention and control and
- Training to health care providers.

Because resources were limited, CDC chose to phase in a national program of service delivery over several years. By 1996, 22 states had implemented screening and treatment programs in Title X family planning and STD clinics. By 1999, the program had expanded nationwide.

In 1992, CDC also entered into a memorandum of agreement with the Office of Population Affairs, the administrative agency for federal Title X family planning programs, to help organize the program. This partnership created one of the most distinctive features of the IPP by creating a regionally-based collaboration of state STD programs, Title X family planning and women's health programs, and the state public health laboratories. Representatives of these programs meet several times a year as a Regional Advisory Committee. Within each committee, the participants work together to formulate a common approach to the prevention of chlamydial infection and its sequelae. One focus within each regional infertility prevention program is on the expansion of screening and treatment services for women at risk. Although the long-term plan is to expand program activities beyond family planning and STD clinics, in many project areas there are still gaps in services to women being seen in family planning and STD clinics. Addressing this unmet need is one of the highest priorities. Where funds have been available, some programs have expanded screening and treatment to populations beyond STD and family planning clinics including prenatal clinics, school-based facilities, community health centers, adolescent health centers, Indian Health Service sites, and correctional facilities.

OVERVIEW OF THE DISEASE

Chlamydia trachomatis infection is considered to be the most prevalent reportable sexually transmitted disease in the United States. The wider availability of affordable, cost-effective laboratory diagnostic tests for chlamydia has allowed further exploration of the broad spectrum of disease caused by this organism. *C. trachomatis* is now recognized as the causative agent for a wide group of genital and neonatal infections, including many that were previously thought to be of unknown cause.

Chlamydial infections are among the most common reproductive tract infections health care providers see in men. It is estimated that *Chlamydia trachomatis* causes approximately 50 percent of reported cases of nongonococcal urethritis (NGU) among men. In most parts of the United States, chlamydia has an estimated incidence several times that of gonococcal urethritis. Chlamydia is also responsible for approximately 50 percent of the estimated 500,000 cases of acute epididymitis seen each year in the United States.

Even more important are chlamydial infections among women. *Chlamydia trachomatis* plays a significant role in causing mucopurulent cervicitis (MPC), acute pelvic inflammatory disease (PID), and maternal and infant infections during pregnancy and following delivery. Chlamydia accounts for one-quarter to one-half of the 1 million recognized cases of PID in the United States each year. These infections, in addition to sub-clinical *C. trachomatis* infections of the fallopian tube not clinically recognized as PID, contribute significantly to the increasing number of women who experience ectopic pregnancy or involuntary infertility. Approximately 17 percent of women treated for PID will be infertile; another 17 percent will experience chronic pelvic pain resulting from the infection. Ten percent of the women who do conceive after PID will have an ectopic pregnancy.

Besides its association with mucopurulent cervicitis and PID, chlamydia plays an important role in the urethral syndrome (dysuria-pyuria syndrome) and in perihepatitis (Fitz-Hugh-Curtis syndrome). Maternal chlamydial infection during pregnancy has been associated with preterm labor, premature rupture of membranes and postpartum endometritis.

Each year more than 155,000 infants are born to chlamydia-infected mothers. Almost two-thirds of the infants born vaginally to chlamydia-infected mothers become infected during delivery. These newborns are at high risk of developing inclusion conjunctivitis and pneumonia and are at slightly elevated risk of having otitis media and bronchiolitis. Chlamydia is the most common cause of neonatal eye infections and of a febrile interstitial pneumonia in infants less than six months of age.

Enormous cost is associated with chlamydial infections. Each year, more than \$2.4 billion is expended on these infections in the United States. Many of these costs result from the management of women with PID and its complications and from the management of infants hospitalized with chlamydial pneumonia. This estimated cost does not reflect the human suffering experienced by those with chlamydial diseases. Further growth in the economic burden of chlamydial infections will occur if these infections become more prevalent. Therefore, the legislation that funds this project emphasizes prevention services for women.

ETIOLOGY OF THE DISEASE

Chlamydia trachomatis (Ct) is a nonmotile, gram-negative bacterial pathogen with a two-phase life cycle. Once it invades a host cell, it is unable to synthesize its own adenosine triphosphate (ATP). Therefore, it uses exogenous energy resources (ATP) from the host cell to reproduce itself. This process occurs over 48-72 hours post exposure.

The infectious form of the organism is called the elementary body (EB); the EB attaches to and enters the host cell. The second phase of the life cycle begins when the EBs undergo a morphologic change and become metabolically active reticulate bodies (RBs). The RBs use host-derived ATP to replicate by binary fission. Up to several hundred progeny (offspring) are produced within a large inclusion; the inclusion may displace the entire cytoplasm of the host cell. These newly replicated RBs reorganize back into infectious EBs. The host cell ruptures and infectious particles are released to attack other cells. The life cycle is completed upon death of the host cell.

In females, the initial site of infection is usually the endocervical columnar epithelial cells. The presence of cervical ectopy (columnar epithelial cells on the ectocervix) increases susceptibility to CT infection. Ectopy can commonly be found among adolescents, pregnant women, and oral contraceptive pill (OCP) users. Infection leads to cervicitis in most women. Cervical infections may resolve spontaneously or continue as low-grade chronic infections with minimal signs of inflammation. Infections frequently ascend through the upper genital tract to involve the endometrium and fallopian tubes. The severity and the chronicity of chlamydia infections appear to be highly variable. Complications of untreated chlamydia infection in adult women include pelvic inflammatory disease (PID), ectopic pregnancy, and tubal infertility.

In males, infections usually remain localized to the urethra but can spread to cause epididymitis or prostatitis. Infections may resolve spontaneously but the natural course of untreated infection in men is not well known. Men are often asymptomatic and little screening occurs; men remain a large reservoir of infection in women.

PROJECT PRIORITY AREAS AND OBJECTIVES

Beginning in 2003, the Regional Advisory Committee developed a Regional Plan based on five national priority areas for the IPP. The Regional Plan follows the calendar year and as such provides a basis for related activities in each state/project area. In other words, the Regional Plan and the state IPP plans should have a connection.

At the July meeting of the RAC, the current Regional Plan is reviewed and revised as necessary to be operational in the coming year. The Regional Plan for CY2005 is available in the Resource Section.

Priority Areas

The following five areas are the priorities upon which the Regional Plan is built. As a region and as individual states we set objectives and activities under each priority in an effort to continue to meet the primary task of diminishing the prevalence of *Chlamydia trachomatis* in Region X.

1. **Target/expand chlamydia screening to young sexually active women and men at risk for infection in public and private settings.** Services should be expanded to sites that serve populations with known or expected high positivity. Sites can include traditional and non-traditional settings where young women and men access reproductive health care services. Examples of traditional settings might include Indian Health Service, migrant and community health centers, adolescent clinics, and school-based facilities. Non-traditional sites may include detention centers and homeless shelters.

2. **Incorporate analysis of regional prevalence monitoring data for regional and local data-directed program planning.** Data should help target chlamydia screening activities to assure that resources are being used in the most cost effective way and that adequate screening coverage is occurring for the highest risk populations of women.
3. **Improve appropriate and timely treatment for persons diagnosed with chlamydial infection and their partners.** Objectives should assure that adequate systems are in place to routinely monitor treatment timeliness and adequacy.
4. **Promote the use of high quality diagnostic tests for chlamydia.**
5. **Increase adoption of “best practice” prevention strategies to reduce efficiency of chlamydia transmission.** As new information is provided in this area, regional projects should address how to adopt best practice prevention strategies. Currently, several recent guidelines from CDC may assist this process including the *2002 STD Treatment Guidelines* and *2002 Screening Tests to Detect Chlamydia trachomatis and Neisseria gonorrhoeae Infections*.

SCREENING AND POSITIVITY IN REGION X IPP

The following table indicates the number of tests done in the IPP for 2003 and CT positivity, including females and males (primarily contacts of positive females). The first set of numbers represent the entire region, then by state, and then by clinic type (FP, STD, other).

| MEASURE | TEST | POSITIVITY | TOTALS |
|-----------------------|---------|------------|----------------|
| SEX | | | |
| Females | 136,860 | 5.4% | |
| Males | 26,796 | 11.7% | |
| | | | 163,656 |
| STATES | | | |
| Alaska | 13,941 | 10.3% | |
| Idaho | 16,139 | 6.0% | |
| Oregon | 56,289 | 4.6% | |
| Washington | 77,619 | 7.2% | |
| | | | 163,994 |
| CLINIC TYPE | | | |
| Family Planning | 109,049 | 5.7% | |
| STD | 23,420 | 10.6% | |
| Other Expansion Sites | 31,519 | 5.9% | |
| | | | 163,988 |

INFERTILITY PREVENTION PROJECT ADVISORY COMMITTEE STRUCTURE

The Region X Infertility Prevention Project Advisory Committee comprises representatives from state family planning and STD programs and state public health laboratories within PHS Region X, which includes the states of Alaska, Idaho, Oregon, and Washington. It also includes participants from Public Health Seattle & King County, Multnomah County, and other Title X grantees. The Regional Advisory Committee (RAC) meets twice a year, usually January and July..

There are three subcommittees: Data, Laboratory, and Clinical Services. These committees also meet two times a year, as part of the RAC. These subcommittees, as well as designated workgroups and teams, guide the progress of the project.

**SEE APPENDICES FOR REGIONAL ADVISORY COMMITTEE
REPRESENTATIVES
AND SUB COMMITTEE MEMBERSHIP.**

Section II: Screening, Specimen Collection & Treatment

FEMALE SELECTIVE SCREENING CRITERIA

It is neither economically feasible, nor cost effective, to screen all females. Furthermore, as the prevalence of disease decreases in a population, the likelihood of a false positive result increases. When screening low risk women in a lower prevalence population, the risk of false positive results may become unacceptably high. "If the prevalence of disease is low, even a highly valid test will yield a low predictive value (of a positive test)." [1] Therefore, selective screening criteria are used to identify the highest risk population in the project's family planning clinics and other (non-STD) clinics. These criteria were developed using published studies, data from clinics in the Region X Infertility Prevention Project (IPP), and from the CDC Screening Criteria published in 2002 Guidelines for Treatment of Sexually Transmitted Diseases, MMWR, May 2002; and Recommendations for the Prevention and Management of *Chlamydia trachomatis* Infections, MMWR, 1993.

In January 2002, female selective screening criteria were simplified in all sites except some STD clinics. Because of the presumption of exposure and higher positivity for most clients seen in STD clinics, universal screening of women will continue there.

Due to restrictions on federal funding, the Project does not cover widespread screening and treatment services for males unless they are identified as a partner of an infected woman. Some project areas are able to utilize local or state funds to screen males in STD clinics or other community sites. Even when funds other than Infertility Prevention Project Funds are used for screening, the data collected may be used to enhance the state or regional IPP chlamydia data set.

[1] Mausner, JS and Kramer, S, eds. Epidemiology: An introductory text. WB Saunders Co: Philadelphia; 1985,pp.222-3

FEMALE SELECTIVE SCREENING CRITERIA IN FAMILY PLANNING & EXPANSION SITES

1. Women 24 and under should be tested at least annually when undergoing a pelvic examination.
2. All women 25 and older who meet one of the following criteria should be screened:
 - a) Cervical findings of MPC, friable cervix, ectopy with inflammation or edema)
 - b) Pelvic Inflammatory Disease (PID)
 - c) Exposed to CT (in last 60 days)
 - d) Symptomatic sex partner (in past 60 days)
 - e) Pregnant
 - f) Seeking an IUD insertion
 - g) Prior chlamydial infection within the past 12 months

**FOR ADDITIONAL SPECIFIC INFORMATION,
MMWR MAY 10, 2002, VOL. 51/RR-6**

SYMPTOMS DIAGNOSTIC OF MPC – TESTING REQUIRED

Mucopurulent cervicitis (MPC)

MPC is a clinical syndrome, not diagnostic of chlamydia or any other specific infection. Thus, MPC is an indication to test for infection.

With a physical examination consistent with MPC, empiric treatment for chlamydia may be started without waiting for chlamydia test results only if:

- There is no herpes, vaginitis, or foreign body (IUD, lost tampon) complicating the diagnosis,
- The prevalence of chlamydia is high in the patient populations, AND
- The client reports she is unlikely to be able to be located for treatment or expresses reluctance to return for additional clinic visits.

Criteria for diagnosis of MPC:

- Mucopurulent secretion from the cervical os (not vagina)—greenish or yellow discharge (positive Q-tip test) from the cervical os in absence of vaginal infection or foreign body such as an IUD.
- Cervical friability—easily induced bleeding on the ectocervix or from the canal characterized by bleeding due to increased vascularity of the area.
- Absence of lower abdominal adnexal, uterine or cervical motion tenderness.

SYMPTOMS DIAGNOSTIC OF PID – TREATMENT REQUIRED

Pelvic inflammatory disease (PID)

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.

Minimum criteria for initiation of treatment in young, sexually active women includes one or more of the following:

(Perform pregnancy test to RULE OUT pregnancy. RULE OUT other causes, e.g., appendicitis.)

- Uterine/adnexal tenderness
- Cervical motion tenderness—moderate to severe pain elicited when cervix is manipulated or palpated

Additional criteria supportive of PID diagnosis:

- Client history of recent onset of pelvic pain or dyspareunia
- Presence of WBCs on wet mount
- Abnormal mucopurulent cervical or vaginal discharge.
- Intermenstrual bleeding or post-coital bleeding.
- Laboratory confirmation of cervical infection with gonorrhea or chlamydia
- Fever > 101°F, tachycardia
- Elevated erythrocyte sedimentation rate
- Elevated C-reactive protein

REFER TO CDC MMWR MAY 10, 2002 FOR MORE SPECIFIC CRITERIA.

SPECIMEN COLLECTION

The sensitivity of all types of *Chlamydia trachomatis* tests is dramatically influenced by the quantity of columnar epithelial cells. The greater the number of cells collected, the more likely a chlamydial infection will be detected. Careful and thorough specimen collection will increase the accuracy of patient test results. Additional information on specific laboratory tests is available under the laboratory tab in this manual. A video for clinicians, “Specimen Collection for CT: Cervix and Male Urethra” is available through each state’s IPP coordinator.

Collection of cervical specimen from the female

- Collect other specimens first
- Clean excess discharge from exocervix
- Always use sterile swab recommended by manufacturer
- Insert appropriate swab into endocervix until most of tip is not visible
- Rotate swab with firm pressure for at least 15 seconds (rotation time varies depending on type of specimen collection or test kit used)
- Carefully remove swab from vagina to avoid contamination
- Place swab in transport tube or bottle provided
- Break off shaft of swab (raise swab well off the bottom of tube or bottle before snapping shaft)
- Cap tube or bottle tightly

Collection of urethral specimen from the male

- Collect other specimens first
- Insert a sterile swab recommended by manufacturer into the urethra
- Insert the swab a minimum of 2.5 cm or 1 inch
- Rotate at least 2 complete revolutions for 5 seconds

Urine specimen collection (male and female)

- Instructions to client:
 - Do not void for at least one, preferably four hours before giving specimen
 - DO NOT cleanse perineum/urethral meatus as for “clean catch” specimens.
 - Catch urine from beginning of the urine stream, not mid-stream.
 - Collect only the first 20-30 ml voided. (Clients will need to be specifically told or shown how full the cup should be when 20-30 ml has been collected)
 - Clinic staff will then transfer a smaller amount of urine to the appropriate collection tube for transport.

NOTE: SPECIFIC INSTRUCTIONS MAY VARY ACCORDING TO TEST MANUFACTURER’S INSTRUCTIONS.

Specimen identification

Each transport tube or bottle label must identify, at a minimum, the client's name and date specimen was collected.

Special circumstances

Women without a cervix

- Use urine sample for amplified test (Aptima, TMA , etc.)
–OR– if amplified test is not available
- Use urethral swab sample for culture, or non-amplified test (EIA, DFA, etc.)

Suspect anal infection

- Preferred method of examination and specimen collection is use of anoscope to swab for culture.
- DFA is the nonculture test approved for rectal specimens. There is a risk of false positive result due to cross reactivity with fecal flora.

Oral infection – Ordinarily pharyngeal testing is not recommended.

TREATMENT OF UNCOMPLICATED CHLAMYDIAL INFECTION

Treatment for PID is different than for *uncomplicated* chlamydial infection. Refer to the following section on PID treatment.

Definitive diagnosis of chlamydial infection is by a positive test for *C. trachomatis*.

Presumptive diagnosis treatment criteria for females

Clients presumed to have chlamydial infection may be treated prior to receiving test result using the following criteria:

- History of recent sexual partner with confirmed CT or GC
- Confirmed gonorrheal infection
- Symptomatic partner
- Physical exam consistent with MPC

With a physical examination consistent with MPC, empiric treatment for chlamydia may be started without waiting for chlamydia test results only if:

- There is no herpes, vaginitis, or foreign body (IUD, lost tampon) complicating the diagnosis,
- The prevalence of chlamydia is high in the patient population, AND
- The client reports she is unlikely to be able to be located for treatment or expresses reluctance to return to for additional clinic visits

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

Treatment of choice (**Note:** *both* are equally effective in reasonably compliant clients)

- Doxycycline 100 mg orally 2 times a day for 7 days
- OR–
- **Azithromycin 1 gm orally in a single dose in compliance with project guidelines.

**** THE COST OF AZITHROMYCIN CAN BE AS MUCH AS TEN TIMES THE COST OF DOXYCYCLINE, THUS PROHIBITING ITS USE FOR ALL CLIENTS. A LIMITED AMOUNT MAY BE AVAILABLE FOR USE WITH “HARD TO TREAT” CLIENTS. PLEASE REVIEW CRITERIA REGARDING USE OF PROJECT-PURCHASED AZITHROMYCIN. (P. 2-24)**

Alternative regimens

- Erythromycin base 500 mg orally 4 times a day for 7 days
- OR–
- Erythromycin ethylsuccinate 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 a day for 7 days

General medication/treatment instructions

- Azithromycin
 - Single dose treatment should be directly observed
 - Tablets and sachet can be taken with food
 - Capsules must be taken on an empty stomach
 - Emphasize sexual abstinence for 7 days after treatment as it takes several days to kill all the organisms
 - Stress the importance of partner treatment
- Doxycycline
 - Emphasize importance of taking entire supply on twice-daily schedule
 - Take with plenty of water
 - Can be taken with food
 - Emphasize sexual abstinence during treatment week
 - Stress the importance of partner treatment

Test of cure (TOC)

- Doxycycline or azithromycin-resistant chlamydia has not yet developed, so patients do not need to be retested after completing treatment with doxycycline or azithromycin.
- Indications for test of cure are:
 - Persistent symptoms
 - Patient is pregnant,
 - Reinfection is suspected
 - Patient was noncompliant with doxycycline treatment.
- Post-treatment test of cures are not routinely covered through the project. TOC should not be done in any case less than 4 weeks after initiation of treatment because:
 - Culture may be false negative due to low number of organisms.
 - Amplified DNA tests may be false positive due to continued excretion of dead organisms.

Treatment Options for Pregnant Women

Recommended regimen

- Azithromycin 1 gm orally in a single dose

Alternative regimens

- Amoxicillin 500 mg orally 3 times a day for 7 days
–OR–
- Erythromycin base 500 mg orally 4 times a days for 7 days
–OR–
- Erythromycin base 250 mg orally 4 times a day for 14 days
–OR–
- Erythromycin ethylsuccinate 800 mg orally 4 times a day for 7 days
–OR–
- Erythromycin ethylsuccinate 400 mg orally 4 times a day for 14 days

Test of cure (TOC) or rescreening pregnant women

The project will cover a test of treatment efficacy for pregnant women. This should be done no sooner than 4 weeks after initiation of treatment.

A retest is recommended in the last 6 weeks of pregnancy.

NOTE: AT THIS TIME, AZITHROMYCIN, ERYTHROMYCIN BASE, ERYTHROMYCIN ETHYLSUCCINATE, AND AMOXICILLIN ARE ALL CLASSIFIED AS CATEGORY B DRUGS FOR USE DURING PREGNANCY. (SEE DEFINITION, PG. 2-23).

Treatment Options for Women Who are Breastfeeding

Recommended regimen:

- Azithromycin 1 gm orally in a single dose

Alternative regimen:

- Erythromycin base 500 mg orally 4 times a days for 7 days
–OR–
- Erythromycin base 250 mg orally 4 times a day for 14 days
–OR–
- Erythromycin ethylsuccinate 800 mg orally 4 times a day for 7 days
–OR–
- Erythromycin ethylsuccinate 400 mg orally 4 times a day for 14 days
–OR–
- Amoxicillin 500 mg orally 3 times a day for 7 days

**FDA ASSIGNED USE-IN-PREGNANCY RATING SYSTEM
DEFINITION CATEGORY B:**

“Adequate, well-controlled studies in pregnant women have not shown increased risk of fetal risk despite adverse findings in animals, or, in the absence of adequate human studies animal studies show no fetal risk. The chance of fetal harm is remote, but remains a possibility.”

SOURCE: PDR NURSE’S HANDBOOK, (1999) APPENDIX III, P. 1333.

Recommended criteria for selection of azithromycin as treatment medication

- Azithromycin is an effective antibiotic against chlamydial infection. Clinical trials have shown azithromycin and doxycycline to be equally efficacious (about 95%) when properly used by a reasonably compliant patient. While azithromycin has the compliance advantage of single dosing, it is considerably more expensive (up to \$20.00) than a comparable treatment regimen of doxycycline (\$2.00). Each state in the Region X Infertility Prevention Project makes its own decision regarding the medications to be provided based on budgetary constraints. It may not be possible to provide azithromycin for general use. Where a shortage exists, priority for treatment with azithromycin should be given to the following clients who have had positive test results:
 - those who probably won't take the meds consistently for seven days, e.g. homeless
 - pregnant women
 - clients with repeat infections (2 or more in 6 months)
 - clients who are doxycycline intolerant
 - developmentally disabled clients
 - teenagers
- **DO NOT** use project azithromycin
 - as general “take home” treatment for partners (its packaging does not meet regulatory standards for self-delivered therapy).
 - to treat PID
 - to treat MPC without a positive chlamydia test

PID Treatment options

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. PID therapy must provide empiric, broad-spectrum coverage of likely pathogens. Antimicrobial coverage should include *N. gonorrhoeae*, *C. trachomatis*, gram-negative facultative bacteria, anaerobes, and streptococci. Treatment options described here are for outpatient treatment only.

Consider physician consultation or referral, hospitalization, or IV antibiotics for patients who:

- are pregnant
- are not responsive to out patient regimens within 72 hours
- have a pelvic mass on examination
- have high fever (>38°C or 101°F)
- have acute nausea and vomiting

Options for outpatient treatment of PID

CAUTION: AZITHROMYCIN IN A SINGLE ORAL DOSE IS NOT INDICATED FOR TREATMENT OF PID.

The following regimen provides coverage against the common etiologic agents of PID. Patients who do not respond to outpatient therapy within 72 hours should have the PID diagnosis confirmed and be considered for parenteral therapy.

- Treatment of choice
 - Ceftriaxone 250 mg IM – *PLUS*
Doxycycline 100 mg orally 2 times a day for 14 days
 - OR–
 - Cefoxitin 2 g IM, concurrently with probenecid 1 g orally in a single dose
 - *PLUS* –
Doxycycline 100 mg orally 2 times a day for 14 days

NOTE: MANY EXPERTS RECOMMEND ADDING METRONIDAZOLE 500 MG ORALLY 2 TIMES A DAY FOR 14 DAYS TO EITHER OF THE ABOVE REGIMENS FOR BETTER COVERAGE OF ANAEROBES OR WHEN BACTERIAL VAGINOSIS (BV) IS PRESENT.

Alternative Regimen in extenuating circumstances only:

- Ofloxacin 400 mg orally 2 times a day for 14 days
- OR–
- Levofloxacin 500mg orally once a day for 14 days
- PLUS –
- Metronidazole 500 mg orally 2 times a day for 14 days

NOTE: THE OFLOXACIN REGIMEN IS CONSIDERABLY MORE EXPENSIVE THAN THE CEFTRIAXONE REGIMEN. THE PROJECT CANNOT BEAR THE EXPENSE OF THIS TREATMENT EXCEPT FOR EXTREME CASES. CONTACT YOUR STATE PROJECT DIRECTOR IF THIS IS INDICATED.

Instructions to patients given outpatient treatment

- NSAIDs PRN for pain. Some evidence suggests a reduction in inflammation and scarring with NSAID use.
- No intercourse throughout treatment
- Emergency or urgent care instructions
- Monitor temperature twice a day for two days
- Increased rest
- Push fluids by mouth
- All patients treated for PID must receive re-examination 48-72 hours after treatment is initiated or telephone call follow up.

Follow up of treated clients

- Clients must receive complete education (see Chlamydia Counseling/ Education Protocol).

Contact/partner notification and treatment

- Clients must be educated about the importance of partner notification and treatment (See Chlamydia Counseling/Education Protocol.)
- Sex partners exposed within 60 days of diagnosis for chlamydial infections should be promptly examined for STD, if possible, and treated with one of the regimens described above.

CASE REPORTING OF POSITIVE LABORATORY RESULTS

Clinical providers in each state are required by law to report chlamydia cases to public health authorities. Reporting procedures and case reporting forms are available from the states' Sexually Transmitted Disease programs. These procedures vary from state to state. It is important to follow your state's procedures. Report laboratory confirmed cases only, i.e. not presumptively treated cases.

PARTNER NOTIFICATION, EXAMINATION, AND TREATMENT

One of the goals of the Region X Infertility Prevention Project is to promote closer working relationships between the family planning and STD clinics. Partner notification is an area where collaboration should occur. STD services field staff could assist family planning staff in providing contact tracing for clients with a positive *C. trachomatis* test since most family planning clinics do not have any field staff. While resources may be limited in some areas, there should be an effort to reach high priority patients. Family Planning providers are strongly encouraged to seek out assistance as needed.

The purpose of partner notification is to ensure that sexual partners exposed to a client with a diagnosis of chlamydia (by a positive *C. trachomatis* test or a CT-related syndrome, i.e., MPC, PID, NGU, epididymitis) are examined and tested for *C. trachomatis*. They should also be tested for other STDs and offered HIV counseling and testing services if indicated by risk assessment. In addition, sexual partners should be presumptively treated at the time of their initial visit with one of the regimens for uncomplicated chlamydial infection.

The Centers for Disease Control and Prevention has set standards for the management of sex partners of individuals with diagnosed chlamydia. These are summarized in the 2002 Sexually Transmitted Disease Treatment guidelines. The standards include:

Refer All Sex Partners Within past 60 Days or Most Recent Sex Partner if Over 60 Days

- Two methods of partner notification are provider referral and patient self-referral. Only where there is staff available for conducting the referral process can provider referral be accomplished. All CT positive clients should be told to have their partners evaluated and treated. Clinics are strongly encouraged to establish systems whereby follow-up for partner treatment is tracked.
- Not only should sex partners of known CT positive clients be referred, but any woman diagnosed with PID should be told to refer her partner(s) for evaluation and treatment. A woman, whose sex partner is not treated, is at continued high risk for persistent or recurrent infection.

Evaluate and Treat All Sex Partners

- No person with chlamydia can be considered adequately treated until their sex partner(s) is also treated. Prevention of re-infection is critical to reducing the serious long term consequences of chlamydia, e.g., chronic pelvic pain, PID, infertility, and ectopic pregnancy.
- Clinics participating in the Region X project must provide for partner evaluation and treatment of CT positive clients. If such evaluation and treatment is not provided on site, the clinic must provide the client and any partners a referral and information to locations where evaluation and treatment will be provided.
- Examination and testing of a male partner of a CT positive female is strongly encouraged. Treatment of male partners without examination is preferable to no treatment. Dispensing of medication to partners without an interview for symptoms, medication allergies, and other contacts is not allowed in the project.

Instruct Clients to Abstain from Sex Until They and Their Partners are Cured

- All parties should be instructed to abstain from sex until all concerned have completed the full course of medication and any symptoms have subsided. Patients and their partners should also be counseled to complete the full course of medication, regardless of whether they have symptoms. Inadequate treatment may result in continuation of the infection. When treating with azithromycin advise to abstain or at least use condoms for 7 days after partners have been treated because the medication is actually working to kill bacteria for 5 to 7 days after the single dose.
- If a client cannot negotiate abstinence, explore the problem and help the client consider alternative behaviors with his/her partner:
 - Mutual masturbation
 - Penis in vagina sex with condom
 - Oral sex with protection

Contact/Partner Notification and Treatment

- Clients must be educated about the importance of partner notification and treatment (See Chlamydia Counseling/Education Protocol.)
- Sex partners exposed within 60 days of diagnosis for chlamydial infections should be promptly examined for STD and treated with one of the regimens described above.

Reporting

- Fill out and submit a Sexually Transmitted Disease Confidential Case Report and other forms as required by your state program.

RESCREENING WOMEN WITH POSITIVE CHLAMYDIA TESTS

NOTE: THE FOLLOWING POLICY AND PROCEDURES ON RESCREENING ARE RELEVANT TO ONLY CERTAIN PROJECT AREAS WITHIN THE REGION X IPP. THE DECISION TO IMPLEMENT A RESCREENING POLICY IS RESOURCE-BASED. CLINICIANS ARE URGED TO ADHERE TO THEIR STATE OR PROJECT AREA POLICY TO CONSERVE PROJECT RESOURCES. A RESCREENING PROGRAM SHOULD NOT DIVERT RESOURCES FROM AN AGGRESSIVE PARTNER MANAGEMENT EFFORT. IF THERE IS ANY QUESTION REGARDING A STATE'S POLICY ON RESCREENING, CLINICIANS SHOULD CALL THEIR STATE IPP REPRESENTATIVE OR THE REGIONAL PROJECT COORDINATOR.

Centers for Disease Control and Prevention (CDC) guidelines released May, 2002 discuss rescreening women treated for Chlamydial infection as a means to identify women with recurrent infection, thus preventing further adverse sequelae and interrupting disease transmission. Data show individuals with confirmed infection in the recent past are at especially high risk of reinfection. Region X IPP screening criteria already include screening individuals with infection in the past 12 months.

CDC STATEMENT ON RESCREENING

“A high prevalence of *C. trachomatis* infection is found in women who have had chlamydial infection in the preceding several months. Most post-treatment infections result from reinfection, often occurring because patient's sex partners were not treated or because the patient resumed sex among a network of persons with a high prevalence of infection. Repeat infection confers an elevated risk of PID and other complications when compared with initial infection. Therefore, recently infected women are a high priority for repeat testing for *C. trachomatis*. For these reasons, clinicians and health care agencies should consider advising all women with chlamydial infection to be rescreened 3-4 months after treatment.”

The rescreening effort is only directed at females. The effort is not yet shown to be cost-effective for males.

Rescreening women (as opposed to test-of-cure) is recommended at 3-4 months after original treatment of confirmed chlamydial infection, regardless of age, partner Rx, resumption of sex, or other risk factors.

Approaches to recalling patients

- At treatment visit, advise to return 3-4 months later for rescreening.
- Make a specific return appointment if clinic “books” that far ahead.
- Add rescreening message to client education materials and handouts.
- Send reminder letter if client has not returned by end of 4 months (if contact by mail will not violate client confidentiality).
- Phone call reminder if client has not returned by end of 4 months (if confidentiality is not breached).
- Flag chart and/or problem list and opportunistically test whenever the patient returns to clinic for any reason (refill contraceptive Rx, immunization, etc).

The following education protocols are meant to be used as guidelines for clinics to develop counseling protocols appropriate to their particular agency's needs, services, and resources. This information should be provided partially in verbal communication with the client, reinforced, and supplemented with written materials.

CHLAMYDIA COUNSELING/EDUCATION FOR CLIENTS & THEIR PARTNERS

- All clients must receive education about chlamydia, including the risks of untreated infections and STD/HIV risk reduction counseling to prevent re-infection. Key Counseling Points are outlined on the electronic link provided here. [a link will be inserted] and they can be found in the Resource Section on Page 87. These key counseling points may be used for client counseling, documentation of counseling or orientation of new staff.
- Patients with a presumptive diagnosis of chlamydia or a confirmed positive chlamydia test should be provided with the following information to assist them in understanding chlamydia, especially its treatment and prevention.

Education about Chlamydia includes:

- confidentiality and reporting requirements
- name of disease
- explanation of chlamydia (very common and treatable)
- signs and symptoms of the disease
- modes of transmission
- incubation period
- possibility of both partners having asymptomatic disease for a long period of time
- complications of untreated chlamydia for women, men, perinatal transmission
- options for prevention
- risk of co-infection with other STDs and HIV
- treatment options

Discussion of chlamydia treatment includes:

- the name of the drug(s) being used in treatment
- quantity and frequency of drug usage (explain that single dose takes several days to work; symptoms may last for a week or more after single dose treatment)
- probable efficacy of treatment
- potential side effects
- food, drugs, conditions (e.g., sunlight exposure) or behaviors that should be avoided (medications can be taken safely even if alcohol is used)
- what to do if side effects occur or symptoms develop or do not resolve
- stressing importance of abstinence or at least using condoms and spermicide for one (1) week after treatment has been initiated by self and partners;
- importance of completing medication, not missing doses
- partner and partner contact treatment is critical to prevent reinfection
- not sharing medication with partners: partial treatment may reduce symptoms but not cure disease, or make infection resistant to the medication

Discussion of partner(s) management includes:

- all partners must be treated (and ideally examined) to prevent re-infection
- meaning of partner's negative test results:
 - sensitivity of tests
 - likelihood of infection despite negative test
- need for contact treatment
- where partner can go for care – clinic, health dept, etc., give a referral card or letter to facilitate visit

- consequences to partner if not treated
- consequences to patient from re-infection if partner is not treated either from the partner or other people within the sexual network.
- suggestions of ways to approach/communicate with partner(s)
- discussion of possible partner reaction and effects upon relationship
- suggestions for alternatives to sexual intercourse until treatment completed

Discussion of correct condom use includes:

- discuss and demonstrate how to use (male & female condoms) with model
- use of water-based lubricants with latex condoms. Safe lubricants include commercial water based products, saliva and glycerin. Unsafe products include creams, petroleum jelly, oily products and medications.
- care and storage of condoms
- emphasis on latex use due to greater effectiveness and superior performance record
- polyurethane condom for latex allergy
- polyurethane condom has few studies and maybe less effective
- natural (gut) condoms have been shown to be less effective in preventing viral disease transmission

DEVELOPING A CLIENT-CENTERED PLAN

Discussion of Test Results with Clients

- As with all STD diagnosis, client counseling and treatment will depend on the impact of the test result on the client's situation.
- Younger adolescents with chlamydia should be evaluated for the possibility of sexual abuse or coercion.
- All patients with chlamydia should be considered at high risk for other STDs and HIV and should be offered HIV testing and STD/HIV risk reduction counseling

Negative Test

- It is important to recognize that with all tests currently available, some infections will be missed. (Region X Family Planning clinics utilize tests ranging from 82% to 98% sensitivity)*. A Negative test result does not always mean a client does not have chlamydia.
- If treatment for chlamydia was initiated because of signs, symptoms, or exposure, treatment should be completed regardless of the test result.

*Range includes sensitivity of all current testing methods.

Positive Test

- When a non-amplified CT test is positive, two tests (both the EIA and DFA) were run and were positive. The chance of both these tests being inaccurate is very, very small. Amplification tests (PCR, LCR, TMA) are highly sensitive and have over 99% specificity
- If a client with a Positive test requests another test because she/he does not believe the first tests, you may retest under the Region X project only if the test was non-amplified. However, due to built in test error in detecting infection (described above), especially at low infection levels, a repeat test may be Negative. Explain that the first Positive test has already been retested.

“Suspect” Test Results

- Suspect results are sometimes reported when EIA/DFA tests are used. Before notifying and/or talking to a client with a Suspect result, her/his chart should be read to review signs, symptoms, and risk behavior. Client counseling may include offering another test, as well as offering to test the partner. The repeat test of the client and testing of the partner will be covered under the Region X project funds. If presumptive treatment was initiated on the day the specimen was collected, do not retest the client.
- Because the treatment for chlamydia poses few risks compared to the risks of untreated chlamydia. Therefore, clients and partner(s) should generally be offered treatment. When there are some compelling adverse reasons not to treat, the clinician and client should discuss other treatment options.
- Women undergoing an abortion should be treated.

PARTNER EXAMINATION & TREATMENT

- One of the goals of the Region X Infertility Prevention Project is to promote closer working relationships between family planning and STD clinics. Partner notification is an area where collaboration should occur. STD services field staff could assist family planning staff in providing contact tracing for clients with a positive *C. trachomatis* test since most family planning clinics do not have any field staff.
- While resources may be limited in some areas, there should be an effort to reach high priority patients. Family Planning providers are strongly encouraged to seek out assistance as needed.
- The purpose of partner notification is to ensure that sexual partners exposed to a client with a diagnosis of chlamydia (by a positive *C. trachomatis* test or a CT-related syndrome, i.e., MPG, PID, NGU, epididymitis) are examined and tested for *C. trachomatis*. They should also be tested for other STDs and offered HIV counseling and testing services. In addition, sexual partners should be presumptively treated at the time of their initial visit with one of the regimens for uncomplicated chlamydia infection.
- The Centers for Disease Control and Prevention has set standards for the management of sex partners to chlamydia. These are summarized in the 2002 Sexually Transmitted Disease Treatment guidelines. The standards include:

Refer All Sex Partners Within past 60 Days or most recent sex partner if over 60 days

- Two methods of partner notification are provider referral and patient self-referral. Only where there is staff available for conducting the referral process can provider referral be accomplished. All CT positive clients should be told to have their partners evaluated and treated. Clinics are strongly encouraged to establish systems whereby follow-up for partner treatment is tracked.
- Not only should sex partners of known CT positive clients be referred, but any woman diagnosed with PID should be told to refer her partner(s) for evaluation and treatment. A woman, whose sex partner is not treated, is at continued risk for persistent or recurrent infection.

Evaluate and Treat All Sex Partners

- No person with chlamydia can be considered adequately treated until their sex partner(s) is also treated. Prevention of re-infection is critical to reducing the serious long term consequences of chlamydia e.g. chronic pelvic pain, PID, infertility.
- Clinics participating in the Region X project must provide for partner evaluation and treatment of CT positive clients.

If such evaluation and treatment is not provided on site, the clinic must provide the client and any partners a referral and information to locations where evaluation and treatment will be provided.

- Examination and testing of a partner of a CT positive client is strongly encouraged. Treatment of partners without examination is discouraged, but preferable to no treatment.
- Direct dispensing of medication to clients for delivery to their partners, without an interview for symptoms, medication allergies, and other contacts is not allowed by some state regulatory agencies.

Instruct Clients to Abstain from Sex Until They and Their Partners are Cured

- All parties should be instructed to abstain from sex until all concerned have completed the full course of medication and any symptoms have subsided. Patients and their partners should also be counseled to complete the full course of medication, regardless of whether they have symptoms. Inadequate treatment will result in continuation of the infection. When treating with Azithromycin advise to abstain or at least use condoms for 7 days after partners have been treated because the medication is actually working to kill bacteria for 5 to 7 days after the single dose.
- If client cannot negotiate abstinence, explore the problem and help the client consider alternative behaviors with his/her partner:
 - Mutual masturbation
 - Penis in vagina sex with condom
 - Oral sex with protection

Contact/Partner Notification and Treatment

- Clients must be educated about the importance of partner notification and treatment (See Manual Section II Page 30.)
- Sex partners exposed within 60 days of diagnosis for chlamydia infections should be promptly examined for STD and treated with one of the regimens described above.

Reporting

- Fill out and submit a Sexually Transmitted Disease Confidential Case Report and other forms as required by your state program.

GENERAL STD PREVENTION EDUCATION

All clients should be provided with information to assist them in judging their risk for contracting an STD infection, and modifying their behavior, if necessary, to reduce their risk.

A brief overview of STD should include

- prevention or means to reduce risks including sexual behavior and proper use of condoms
- identification of common diseases
- description of how STDs are transmitted (vaginal, anal or oral contact).
- discussion of various symptoms such as sores, discharge, pain, skin rashes, lumps or swollen glands
- stressing that many people, especially women, may have no noticeable symptoms
- untreated STDs can have serious complications including infertility, ectopic pregnancy, neonatal infection, and chronic pelvic pain
- some STDs are life-long or incurable and some can be fatal

Education aimed at reducing the risk of STD to those who are sexually active should include teaching a risk-based continuum of behaviors

- abstinence or limiting sexual contact to mutually monogamous relationships
- using condoms for all sexual contact (oral, genital, anal)
- avoid sexual contact with persons who have a genital discharge, genital warts, genital or oral herpes lesions or other genital lesions or with laboratory evidence of HIV infection or hepatitis B surface antigen
- avoiding multiple partners, anonymous partners, persons who exchange sex for money or drugs, and other persons with multiple sex partners
- avoid heavy use of alcohol or mind-altering drugs that may interfere with assessing or avoiding risky situations
- avoid IV drug use, especially sharing needles and avoid sexual contact with IV drug users
- be immunized for hepatitis B
- wash genitalia and hands before and after sexual contact; avoid douching
- use of lubrication may decrease STD transmission by reducing tissue trauma
- examine own and partner's genitals for evidence of infection before sexual contact
- discuss barrier methods, including spermicides to reduce bacterial STD transmission
- use of birth control pills or barrier methods to decrease PID (avoid use of an IUD when there are multiple sex partners)
- avoid oral and/or anal sex without a condom or other protection to prevent enteric infections
- avoid oral sex whenever there are sores in the mouth or bleeding gums
- have a periodic examination for sexually transmitted agents if at high risk for STD
- discuss sexual history and risk factors with potential partners

GENERAL STD COUNSELING/EDUCATION FOR CLIENTS & THEIR PARTNERS

Behavioral Risk Reduction/Prevention is an integral part of patient counseling

- Risk reduction counseling has a goal of promoting safer sex behaviors for prevention of future STDs and HIV. A distinction needs to be made between client 'education' and risk reduction 'counseling.' The goal of education is to enhance awareness and knowledge levels. However, knowledge alone is not sufficient to change behavior. Counseling should be client-centered and based on a behavior change model, recognizing that clients are in different stages of 'readiness' for change. Clients should be assessed for their readiness, and counseling interventions specific to that stage should be utilized (See Resource Section, Client Centered Counseling, for assistance).
- Client education and risk reduction counseling are designed to enhance compliance with treatment and partner notification interventions as well as to promote safer sexual behavior for future STD/HIV risk reduction.
- Remember that reactions of patients being told they have a STD may include anger, denial, depression and blame. Similar reactions may also occur with partners. The way in which the counseling and education session is handled may enhance compliance with partner referral and treatment.

Behavioral risk reduction/prevention includes:

- assisting patients in identifying personal risks for contracting/transmitting chlamydia, e.g., unprotected sex, multiple partners, having sex when drunk or high, etc.;
- assisting patients in developing realistic, personalized risk reduction plans, e.g., condom usage, monogamy, refraining from sex when drunk or high, etc.

PROGRAM GUIDELINES FOR TITLE X SERVICES

Federally funded family planning programs (Title X) are required to provide sexually transmitted disease and HIV counseling according to Section 8.2 of the Program Guidelines for Project Grants for Family Planning Services, January 2001.

“All clients must receive thorough and accurate counseling on STDs and HIV. STD/HIV counseling refers to an individualized dialogue with a client in which there is discussion of personal risks for STDs/HIV, and the steps to be taken by the individual to reduce risk, if necessary. Persons found to have behaviors which currently put them at risk for STD/HIV must be given advice regarding risk reduction and must be advised whether clinical evaluation is indicated. All projects must offer, at a minimum, education about HIV infection and AIDS, information on risks and infection prevention, and referral services. On an optional basis, clinics may also provide HIV risk assessment, counseling and testing by specially trained staff. When the project does not offer these optional services, the project must provide the client with a list of health care providers who can provide these services.”

Section IV:

Laboratory Testing, Quality Assurance & Improvement Program

INTRODUCTION

The laboratory committee of the Region X IPP has developed extensive measures which assist clinicians and laboratorians in monitoring quality assurance. These measures include (1) descriptions of the various diagnostic tests used; (2) a description of cell types found on slide samples; (3) a process for specimen collection evaluation; (4) a method for notifying all project labs as well as the national laboratory coordinator of any problems related to laboratory testing products or methodology. In collaboration with the training committee, a resource guide has been developed to assist any provider whose specimens do not meet the regional standard.

Clinicians are encouraged to participate in the specimen adequacy program. The Centers for Disease Control and Prevention (CDC) have established quality assurance indicators for this project. One such indicator is the monitoring of specimen collection proficiency by new clinicians as well as those who are seasoned clinicians. For additional information on this, please contact your state FP or CT Coordinator (listed in the Resource Section).

Laboratorians also have a process for evaluating each other through the sharing of specimens. Labs within Region X take turns preparing known (positive and negative) samples and send them to the other Region X labs that use the same test method for blind analysis. Results are compiled, shared and evaluated for consistency.

DESCRIPTION OF CHLAMYDIA TESTING TECHNOLOGIES

Nucleic Acid Probe (PACE II) Test for *Chlamydia trachomatis*

- Manufacturer
 - Gen-Probe, Inc.
- Collection Sites
 - Endocervical, male urethral and conjunctival.
- Specimen Handling
 - Transport and storage are 2-25° C. Test specimens within 7 days of collection, alternately, may be frozen until shipped.
- Principle
 - A direct specimen test where copies of a chemiluminescent labeled, single-stranded DNA probe combine with target organism's ribosomal RNA to form stable DNA:RNA hybrids. The labeled hybrids are separated from non-hybridized probe and are measured in a luminometer. The test results are calculated as the difference between the response of the specimen and the mean response of the negative reference.
- Turn Around Time (TAT) in Lab
 - 1-3 working days
- Sensitivity/Specificity
 - Varies with study parameters, population and anatomical site
- Test Comments
 - Can test for gonorrhea and chlamydia from a single swab, but not in a single/same run.

- Limitations

- Not approved for nasopharyngeal, urine, or rectal specimens.
- Not acceptable for medical/legal purposes.

Therapeutic success or failure cannot be determined as chlamydial DNA and antigen may persist following appropriate antimicrobial therapy. Follow up tests to determine success of treatment for pregnant women should not be collected until four (4) weeks following completion of treatment. Residual nucleic acid from dead organisms may persist, leading to false positive results for specimens collected sooner than four weeks post-treatment.

Adequacy of specimen cannot be determined. Grossly bloody specimens may interfere with test performance. Low-level (borderline) positives are currently repeated using the Probe Competition Assay (PCA). Both Ct and GC can be detected in the initial test and cannot be differentiated without a second test on the same specimen to determine which organism(s) is/are present.

- Result Interpretation

- *Positive*: A positive is reported as the difference greater than or equal to 350 RLU plus the mean of the negative reference. When the test result is marked positive, the PCA confirmation test is also positive.
- *Negative*: A negative is reported as the difference less than 350 RLU plus the mean of the negative reference.
- *Equivocal*: Anything that falls between 200 RLU and the positive cut off for the screening test.

Target Capture, Transcription-Mediated Amplification (TC-TMA)

Test for *Chlamydia trachomatis* – (APTIMA)

- Manufacturer
 - Gen-Probe Incorporated
- Collection Sites
 - Endocervical, urethral, male and female urine (first part of stream, 20 – 30 ml)
- Specimen Handling
 - *Swab*: Transport and store at 2° to 30°C in the APTIMA Combo 2 Swab Specimen Transport Tube until tested. Test swabs within 60 days of collection.
 - *Urine*: Transport and store at 2° to 30°C in the APTIMA Combo 2 Urine Specimen Transport Tube. (Urines must be transferred from the primary container to the urine transport tube within 24 hours of collection, however do not delay; transfer ASAP.) Test urines within 30 days of collection.
 - Swabs and urines may be frozen at -20° to -70°C for up to 90 days after collection.
- Principle
 - The assay combines the technologies of target capture (isolates the target nucleic acid strands), Transcription-Mediated Amplification (TMA), and Dual Kinetic Assay (DKA) for the amplified detection of rRNA molecules. The rRNA amplification product, amplicon, combines with labeled DNA probes to form stable RNA:DNA hybrids. During the chemiluminescent detection reaction, the hybrids emit light (Relative Light Units – RLU) measured as photon signals in a luminometer.
- Turn Around Time (TAT) in Laboratory
 - 1 – 3 working days

- Sensitivity/Specificity
 - Varies with study parameter, population and anatomical site
- Test comments
 - Can test for chlamydia and gonorrhea from a single swab or urine specimen in a single test run.
 - Swabs are not affected by blood, gynecological lubricants and spermicides. Urines are not affected by blood, vitamins, minerals and over-the-counter pain relievers.
- Limitations
 - Not approved for nasopharyngeal, eye or rectal specimens.
 - Not acceptable for medical/legal purposes in adults unless confirmed by a second NAAT assay OR culture. Not acceptable for medical/legal purposes in pediatric cases.
 - Adequacy of specimen cannot be determined directly from the test.
 - Therapeutic success or failure cannot be determined as chlamydial nucleic acid may persist following appropriate antimicrobial therapy. Follow up tests to determine success of treatment for pregnant women should not be collected until four (4) weeks following completion of treatment. Residual nucleic acid from dead organisms may persist, leading to false positive results for specimens collected sooner than four weeks post-treatment.
- Result Interpretation
 - *Positive*: 100 to < 3,000 RLU (x1000)
 - *Negative*: 1 to <25 RLU (x1000)
 - *Equivocal*: 25 to <100 RLU (x1000)

Digene Hybrid 2 Capture

- Manufacturer
 - Digene
- Collection Sites
 - Endocervical and male urethral specimens
- Specimen Handling

Specimens may be held for up to two weeks at room temperature and shipped without refrigeration to the testing laboratory. Specimens should be shipped in an insulated container using either an overnight or 2-day delivery vendor. At the testing lab, specimens should be stored at 2-8° C if the assay is to be performed within one week. If the assay will be performed later than one week, store specimens at 20°C for up to 3 months.

- Principle

The hc2 CT_ID DNA Test using Hybrid Capture 2 technology is a nucleic acid hybridization assay with signal amplification that utilizes microplate chemiluminescent detection. Specimens containing the target DNA hybridize with a specific Chlamydia RNA probe cocktail. The resultant RNA-DNA hybrids are captured onto the surface of a microplate well coated with antibodies specific for RNA-DNA hybrids. Immobilized hybrids are then reacted with alkaline phosphatase-conjugated antibodies specific for RNA-DNA hybrids, and detected with a chemiluminescent substrate. Several alkaline phosphatase molecules are conjugated to each antibody. Multiple conjugated antibodies bind to each captured hybrid resulting in substantial signal amplification. As the substrate is cleaved by the bound alkaline phosphatase, light is emitted, which is measured as relative light units (RLUs) on a luminometer. The intensity of the light emitted denotes the presence or absence of target DNA in the specimen.

- Turn Around Time (TAT) in Lab
 - Within three working days
- Sensitivity/Specificity
 - Varies with study parameters, population and anatomical site
- Test Comments
 - Can test for gonorrhea and chlamydia from a single swab, but not in a single/same run.
- Limitations
 - Not FDA approved for nasopharyngeal, urine, or rectal specimens.
 - Not acceptable for medical/legal purposes.
 - The hc2CT-ID DNA Test is not intended to determine therapeutic success.
- Result Interpretation
 - *Positive*: Specimens with RLU/Cutoff Value ratios ≥ 2.50 are considered positive for Chlamydia trachomatis DNA.
 - *Negative*: Specimens with RLU/Cutoff Value ratios < 1.00 do not contain Chlamydia trachomatis DNA or contain DNA below the detection limit of the assay.
 - *Equivocal*: Specimens with RLU/Cutoff Value ratios ≥ 1.00 and < 2.50 are considered equivocal. Repeat

Cell Culture Test for Chlamydia trachomatis

- Manufacturers
 - In house
- Collection Sites
 - Endocervical, urethral, conjunctival, nasopharyngeal, rectal, tissue biopsy, endometrial, tubal.
- Specimen handling
 - Transport and store at 4° C; test within 4 days of collection.
- Principle
 - Specimens are inoculated and centrifuged into a medium containing cycloheximide treated McCoy (mouse strain) cells. Specimens are incubated for 40-48 hours. Cells are fixed and stained with monoclonal fluorescent antibody (FA). FA stained cells viewed through a fluorescence microscope exhibit a fluorescent green inclusion if infected with the organism. Non-infected cells appear red.
- Turn Around Time (TAT) in Lab
 - 2-3 Working days
- Sensitivity/Specificity
 - Varies with study parameters, population and laboratory performing test.
- Test Comments
 - Culture is still considered the preferred test for medical/legal cases* Also, it is the only method recommended for specimen sites for which nonculture methods have not been developed or evaluated. (Prior to submission, consult lab about options on unlisted collection sites.)

- Limitations
 - Specimen transport and storage times and temperatures are critical; technically difficult procedure requiring expertise in tissue culture techniques.
- Result Interpretation
 - *Positive*: A positive is reported as greater than or equal to 1 inclusion forming unit. All positives are confirmed by a second analyst.
 - *Negative*: A negative is only considered negative in the absence of significant cell cytotoxicity.
 - *Equivocal*: Two readers can not agree upon results or suspect a nonviable organism.

*Contact lab for chain of custody procedures. Harborview Research & Training Lab at 206-341-5300

DEFINITION OF CELL TYPES FOUND ON SLIDE SAMPLES:

Columnar Epithelial Cells:

- A slide with these cells in the majority is IDEAL.
- Host Cells to Chlamydia trachomatis.
- Line the endocervical canal in a single layer.
- Have a basally located (eccentric or off-center) nucleus which is round to oval and may look “frothy” or “lacey”.
- When looking at columnar cells from above, the cytoplasm is seen as a narrow rim around the nucleus.
- May be seen in strips of parallel-arranged cells or in tight sheets (honeycomb pattern).

Atypical OR Metaplastic Columnar Epithelial Cells:

- It is not established that these cells can host an infection with chlamydial infectious particles. However, their presence on a slide indicates swab sample site is correct since these cells are found in the correct area of interest.
- Demonstrate changes from normal columnar epithelium; cells are extremely enlarged and nucleus contains excessive pigmentation (due to injury, repair).

Superficial/Intermediate Squamous Cells:

- Not a good slide if these cells are the majority.
- Not known to be host cells for chlamydial infectious particles.
- Line the vagina and the outer portion of the uterine cervix (ectocervix).
- Are large, flat, platelike cells with a small central nucleus.

Metaplastic Squamous Epithelial Cells:

- Not host cells for chlamydia, however their presence indicates correct area for swab collection.
- Lower organizational order than the mature cell.
- Are transformed squamous epithelial cells (due to noxious agents or processes) which are rounder than normal squamous cells, have dense cytoplasm and large nuclei with fine granular chromatin.

Erythrocytes (Red Blood Cells):

A slide with red blood cells as major cell type is acceptable for assessing specimen adequacy only if ten or more columnar epithelial or metaplastic cells are also found on the slide.

References

Reith, EDW. J., Ph.D, Michael H. Ross Ph.D., Atlas of Descriptive Histology, 3rd Edition, 1997.

Bibbo, Marluce, M.D., Sc.D., F.I.A.C., Comprehensive Cytopathology, Second Edition, 1997.

Acknowledgments

Cindy Fennel, STD Prevention/Training, Sue Szabo, STD Clinic, Harborview; Debbie Vernon, Cytology Lab, Harborview.

SPECIMEN ADEQUACY – PROCEDURE INFORMATION:

1. Enclosed are a set of 10 routine CT sample collection swabs AND 10 specimen adequacy swab/slides/slide-holder units.
2. The clinician collects all other specimens first then the CT samples as follows:
 - Routine CT swab: Collect sample and place the swab in the tube as indicated on the swab package.
 - Specimen Adequacy swab: Using the swab from the swab/slide/slide-holder set, collect the sample as done for the routine CT, then roll the swab over the circled area only on the slide. Do not drag or push the swab. Ensure that all surfaces of the swab come into contact within the circle and that the entire circled area is covered evenly with specimen. The result should be a thin even smear.
3. Label the slide. Using a pencil, write the patient's and clinician's identifier on the frosted area of the slide. Allow the sample on the slide to air dry completely before placing it inoculated side up into the slide holder.
4. Label the routine CT sample by your normal method plus add the clinician identifier to the bottom left area of the label.
 - *The collector's (clinician's) identifier needs to be consistent for all 10 patients.
5. Rubber band the CT swab tube and the slide-holder (containing the slide) together. Ship these along with the regular Region X Chlamydia form to your testing lab as normally done.
6. The routine CT sample will be tested and the result returned to your facility in the normal manner.
7. A "Chlamydia Specimen Adequacy Report" will be sent to your supervisor. A training fact/reference sheet will be included with results that do not meet the stated acceptable performance.
 - For training follow up, please call the contacts noted on the Training Fact/Reference Sheet.
 - To evaluate training needs, a copy of the clinician's results will be sent to your State's CT Infertility Prevention Project Coordinator.
 - For statistical purposes, non-identifiable data will be shared with the Region X Project Office at the Center of Health Training.

For questions or concerns regarding outcomes please call your testing laboratory at _____ (phone).

RESOURCES FOR CHLAMYDIA SPECIMEN ADEQUACY

Collection for the State Of _____

Your state offers the following resources to assist you in reaching the regional standard for specimen collection:

- Review “Specimen Collection for Chlamydia” video. If you do not have a copy within your agency, please contact your state FP or STD manager listed below.
- When feasible, ask a senior clinician who has met the proficiency standard to observe your collection technique.
- Attend a training offered by Seattle STD-HIV Prevention Training Center. Contact Anne Meegan at 206-685-9850, seaptc@u.washington.edu, or visit the website at <http://weber.u.washington.edu/~seaptc>.
- Review resources for improving specimen collection provided by your state Family Planning or CT/STD manager listed below.

ALASKA:

Susan Jones (CT Coordinator)
907-269-8061
907-561-4239 – fax
joness@health.state.ak.us

Municipality of Anchorage:

Cathy Feaster
907-343-4789
907-343-4633 – fax
feasterec@ci.anchorage.ak.us

IDAHO:

Anne Williamson (STD)
208-334-6526
208-332-7346 – fax
willia25@idhw.state.id.us

Susan Ault (FP)
208-334-5959
208-332-7346 – fax
aults@idhw.state.id.us

OREGON:

Doug Harger (STD)
503-731-4026
503-731-4082 – fax
DOUGLAS.R.HARGER@state.or.us

Carol Elliott (FP)
503-731-4363
503-731-4083 – fax
carol.j.elliott@state.or.us

WASHINGTON:

Katherine Gudgel (CT Coordinator)
253-395-6734
katherine.gudgel@doh.wa.gov
– OR –
Ellen Gish
360-236-3450
360-236-3470 – fax
Ellen.Gish@DOH.WA.GOV

Jane Wilson (FP)
360-236-3469
360-236-3400 – fax
jane.wilson@doh.wa.gov

PUBLIC HEALTH LABORATORIES

Public Health Laboratories approved to participate in the project include the following:

ALASKA

Alaska Public Health Laboratory
4500 Boniface Pkwy
Anchorage, AK 99507
907-334-2111
907-334-2161 Fax
Contact: Gregg Herriford

WASHINGTON

Washington State Public
Health Laboratories
1610 NE 150th ST
Shoreline, WA 98155-9701
(206) 361-2884
Contact: Mike McDowell

IDAHO

Bureau of Laboratories
Virology and Serology Section
2220 Old Penitentiary Road
Boise, ID 83712
(208) 334-2235
Contact: Colleen Greenwalt

Infectious Disease Laboratory

University of Washington
300 Ninth Ave., Rm. 627
Seattle, WA 98195
(206) 341-5304
Contact: Linda Cles

OREGON

Oregon Public Health Laboratory
1717 SW 10TH
Portland, OR 97201
(503) 229-5882
Contact: Chris Biggs

Spokane Regional Health Laboratory
1101 W. College, RM 210
Spokane, WA 99201
(509) 324-1440
Contact: Karen Crouse

LAB SLIP GENERAL INSTRUCTIONS

- Please be sure that all items are completed. If you forget to ask a question or don't know the answer, check Unknown.
- When filling in boxes with numbers (such as box for client number), write the numbers starting either from the left or the right. The computer will "right justify" and fill in the remaining boxes with zeroes. You do not have to zero-fill.
- When using a label to identify the patient, label all copies. Do not place label over lab result portion of the request form. Pink copy should not have a readable name.
- The top part of the slip is in triplicate; the bottom half is two pages. Please press firmly when completing the form.
- Send the entire lab slip (all three copies) with the client specimen to the laboratory. The lab retains the white 1/2 copy marked LAB COPY; Results are returned by the laboratory to the clinic on the green* copy marked CLINIC COPY; the laboratory sends the back pink copy without a client name marked AHLERS COPY to the data processor.

* University of Washington Chlamydia labslip CLINIC Copy is blue.

LAB SLIP DISTRIBUTION PROCESS

Public Health Laboratories or STD state managers maintain a supply of lab slips. When your clinic supply is running low, please call your laboratory or STD state manager to replenish the supply. Do Not Wait Until You Run Out of Lab Forms.

The laboratories and STD managers or IPP Coordinators responsible for stocking and distributing lab forms are:

WASHINGTON

| | |
|---|--------------|
| Washington State Public Health Laboratories | 206-361-2849 |
| Spokane County Health District Laboratory (for Eastern Washington) | 509-324-1440 |
| IPP Coordinator, Katherine Gudgel | 253-395-6734 |
| University of Washington Chlamydia Lab | 206-341-5300 |
| Public Health Seattle & King County, Donna Peterson | 206-296-4690 |

* Sites in Seattle-King County may have CT tests performed by UW lab or WA State lab.

It is important that you order from the lab that performs your site's tests.

OREGON

| | |
|---------------------------------------|--------------|
| Oregon State Public Health Laboratory | 503-229-5882 |
| STD Manager Doug Harger | 503-731-4026 |

ALASKA

| | |
|--|--------------|
| Public Health Laboratory/Anchorage, Alaska | 907-334-2111 |
| STD Manager, Susan Jones | 907-269-8061 |

IDAHO

| | |
|------------------------------|--------------|
| Idaho Bureau of Laboratories | 208-334-2235 |
| STD Manager, Anne Williamson | 208-334-6527 |

QUALITY ASSURANCE OF DATA COLLECTION INSTRUMENT

Fatal Data Errors

There are seven items on the lab slip which MUST be completed correctly or it will be returned to the clinic or your project state coordinator for required edits. These seven items are on the top third of the lab slip.

Items, which must be completed correctly, include:

- Sex
- Client number
- Date of birth
- Date specimen collected
- Service site number
- Provider/Clinic address
- Anatomical site from which specimen was collected
- Laboratory test result

If these data elements are missing or are inconsistent, (e.g. year of birth is "1900", or the same as date specimen collected; sex is male and anatomical site is cervix), the slip will be returned by the data processor, Ahlers and Associates, for correction.

Not So Fatal Errors

Monitoring for complete and consistent data occurs differently in each state. In some instances, the laboratory performing the test will review the bottom third of the lab slip on the copy to be sent to the processor to be sure all items are complete. If data are missing, the laboratory may call the clinic. OR, if several lab slips from the same agency have missing data, the lab may batch these with a memo to the clinic or State STD office.

When all lab slips are complete, they are sent to the data processor in batches, usually on a weekly or bi-weekly basis. The data processor must receive all lab slips for a month by the 20th of the next month in order to have sufficient time to enter the data and run the monthly or quarterly tables. It is imperative that corrected or revised lab slips be forwarded to your state coordinator or Ahlers and Associates as soon as possible. However, if there are significant delays in correcting lab slips you should still send them in for processing. Even if some data do not get into a monthly or quarterly report, all test data are entered in the project database and used for the annual reports.

LAB SLIP ITEM DESCRIPTIONS

Client Name

Please print clearly.

Print **LAST NAME FIRST**.

In many cases, client name is the only way clinics and laboratories have to identify the patient. Even where there is a numerical identifier, such as on this lab slip, the name is very important for a cross-reference (e.g. in case the numbers are copied wrong). Client name is also a requirement of CLIA regulations. If a patient is using a pseudonym, please try, if at all possible, to use only one name per client.

Client Number

This is a ten-digit number that is determined differently at each site. This is an important decision for this project as the client number will be the only way to identify a client when data are analyzed. In conjunction with date of birth, client number is used to ensure that the correct data are on file for each client. To ensure confidentiality, the client name has been deleted on the copy sent to the data processor. For this reason, the client number is a very important control field.

Avoid using duplicate client numbers. No two clients within a service site should have the same number. Each client number should be unique to one client (Social Security number, Medicaid number, business account number, chart number, chronological sequence, etc.). Please do not use the client's Date of Birth for a client number. If a client is new to your service site, a new number should be assigned. If the client is in for a return visit, use their number assigned at the earlier visit.

Please advise Center for Health Training and your state coordinator if your client numbers contain numbers and letters, and not just numbers. The client number cannot be longer than ten digits.

If an agency has multiple sites, it is helpful to assign a prefix for each site. Then, if each site consecutively numbers its clients, the numbers will not duplicate. For example: the first site assigns 1000000789; the second site assigns 2000000789. Regardless, each site should have a unique site number. Please contact your state's Infertility Project coordinator if you need a site number for any clinic.

Clinician Number

This four-digit number is to be determined within each clinic site. If a site uses fewer than four digits as a clinician identifier, the data processor will fill in the boxes with zeros. Many sites use the same clinician number being used for other projects (e.g. HIV project).

Date of Birth

The client's birth date is recorded as month/day/year. Importantly, the year is now a four digit field with "19" pre-printed in the appropriate boxes. The month, day and year are entered as two-digit numbers. The corresponding numerical values for the months are:

| | | | |
|----------|----|-----------|----|
| January | 01 | July | 07 |
| February | 02 | August | 08 |
| March | 03 | September | 09 |
| April | 04 | October | 10 |
| May | 05 | November | 11 |
| June | 06 | December | 12 |

For example, if a client is born on November 30, 1982, it should be recorded as 11301982. Do not use slashes (/) between month, day or year. The most frequent error is accidentally assigning today's year as a client's birth year.

Client birthdate is a control field and should match the date a client gave on previous visits to the service site.

Although a client may report different birthdates, it is recommended that the first date entered be used consistently (if at all possible).

Client Zip Code

This item is used to determine the location of the client's residence. Enter the five digits of the zip code. If the zip code is not answered during the visit, either it can be looked up later from the medical chart or it will be considered a 00000. This is an important control field to determine clinic utilization trends (e.g., Washington residents' use of Oregon clinics) and possible barriers to service delivery based on distances traveled.

Date Specimen Collected

This is the date the client was tested for CT at the service site. The date is recorded as month, day, year. Again, the year field is a four-digit result with the first three values ("200 ") pre-printed on the form. If the lab slip is completed after a visit is over, record the actual date the client was seen and tested in the clinic. This information is used to keep the client history in chronological order.

The most common errors are putting digits in the wrong order and writing the service date as the birth date.

Specimen

- Site – This field indicates the anatomical site from which the specimen is collected. In general, specimens will be collected in women from the cervix and male specimens from the urethra and urine from both sexes. If a woman has had a hysterectomy, it will be assumed that she does not have a cervix and a urine test with a NAAT is preferable. The Urine specimen site is for those clinics submitting urine samples for testing. The Other box is to be used for all other anatomical sites (e.g. rectal, ocular). You must write the specimen site beside Other in order for the specimen to be processed.

If multiple specimens are collected on a patient from different anatomical sites, the project will pay for cervical, urine and urethral site collections only.

Please Note: To date, the only tests approved for rectal collection are the DFA and culture.

- Specimen Frozen – This is the lower part of the Specimen box. This item should be completed by whoever stores and mails the specimens. Check the box “Yes” if the specimen is stored frozen until shipment; check “No” if it is not.

Client Sex

Determination of sex is made by observation or from the medical record. Check the appropriate box.

Service Site

This is a five-digit number that identifies the clinic at which the CT test was performed. Data are reported by service site on a monthly, quarterly and annual basis. This field is very important. If you have any questions about your site number, please contact CHT or your state project coordinator.

Each state is responsible for assigning a unique service site number to each clinic participating in this project.

Provider/Clinic Address

This space is to be filled in/stamped on all three copies of the lab slip. Many clinics pre-stamp their addresses on the form. In Washington, this address will appear in the window of the return envelope when the lab returns the results to the clinic.

Medicaid No.

If applicable, enter the client’s Medicaid number in the box provided. This identifier is being used in some states for reimbursing test costs.

ICD Code

If applicable, selected states and clinics are capturing diagnosis codes for this service based on the International Classification of Diseases. Consult with your state coordinator for additional information on acceptable responses. This field is completed by the clinic.

FOR OREGON ONLY

SUBMITTER CODE: OREGON AGENCIES WRITE THEIR SIX-DIGIT SUBMITTER CODE IN THE SPACES PROVIDED. THE LABORATORY ENTERS THIS CODE IN THEIR DATA SYSTEM TO MONITOR PROJECT ACTIVITIES. YOU STILL NEED TO COMPLETE CLINIC ADDRESS.

FPEP: OREGON AGENCIES PARTICIPATING IN THE FAMILY PLANNING EXPANSION PROJECT COMPLETE THIS ITEM. IF THE CLIENT IS AN FPEP PARTICIPANT MARK THE “YES” BOX; IF NOT, MARK “NO.”

FOR IDAHO ONLY

PROGRAM AREA: THIS SECTION IS USED BY INTEGRATED SERVICE SITES IN IDAHO ONLY. INTEGRATED SITES REFER TO CLINICS WHERE DIFFERENT TYPES OF PROGRAM AREAS EXIST WITHIN THE SAME SETTING (E.G. FAMILY PLANNING, PRENATAL, PRIMARY CARE OR STD). IT DOES NOT REFER TO THE PARTICULAR TYPE OF SERVICE REQUESTED BY THE CLIENT. FOR EXAMPLE, WITHIN AN INTEGRATED CLINIC, A FAMILY PLANNING CLIENT MAY RECEIVE STD OR PRIMARY CARE SERVICES BUT THE AGENCY IDENTIFIES HER AS A FP CLIENT. IN THIS CASE, BOX 1 (FAMILY PLANNING) WOULD BE MARKED.

FOR ALASKA ONLY

VISIT TYPE: THIS SECTION IS USED BY ALL SITES IN ALASKA. CHECK THE VISIT TYPE THAT REFLECTS THE MAJOR FOCUS OR PRIMARY ASSESSMENT OF THIS VISIT. WHEN A CLIENT IS PROVIDED MORE THAN ONE SERVICE, E.G., FAMILY PLANNING AND STD, CHECK THE TYPE OF SERVICES THAT WAS PREDOMINANT. THIS FIELD IS REPORTED BY THE PROVIDER.

FOR LAB USE ONLY

- **LAB NUMBER/DATE RECEIVED BOX IS STAMPED AT THE LAB UPON RECEIPT OF THE SPECIMEN.**
 - **CT/GC TEST OR CT TEST BOX CONTAINS THE TYPE OF TEST PERFORMED.**
 - **RESULTS BOX CONTAINS THE RESULTS OF THE TEST.**
 - **DATE REPORTED/BY BOX RECORDS DATE SPECIMEN REPORTED AND INITIALS OF PERSON COMPLETING THE REPORT.**
-

Ethnicity/Race

These are separate measures that conform to the recently revised U.S. Census categories. Only one box may be checked under Ethnicity. For the race measure, check all categories reported by the client; multiple responses are allowed.

Racial and ethnic classification should always be self-identified by the client. The client should always be asked ethnicity first. If the client is unable to determine race or ethnicity, it is suggested that you use the race of the client's mother.

For ethnicity, Hispanic includes Mexican-American, Puerto Rican, Cuban, Central or South American and other Spanish speaking origins.

For race categories, White includes any of the peoples of North America, Europe, the Middle East, or North Africa. Black includes any person identifying as African-American, African, or any other of the original peoples of Africa. Asian includes any person from Asia, including Japan, Korea, China, Taiwan, the Philippines, Southeast Asia and the Indian subcontinent. Hawaiian/Pacific Islander is a new census designation to be distinguished from Asian clients and refers to persons from Hawaii, Guam, Samoa, Fiji, Micronesia, Polynesia, or any other island in the Pacific. American Indian/Alaskan Native: American Indian includes any person having origins in any of the original peoples of North, Central or South America; Alaskan Native includes Alaska Indians, Eskimos, and Aleuts or any other persons having biological heritage with the original peoples of Alaska.

Reasons for Visit (Check All That Apply)

This information is reported by the client. Usually a client has one reason for coming to the clinic. However, if s/he provides multiple reasons, then please report all that are applicable. Since a client could present with symptoms and also exposure to CT, or other STDs, it is possible to present with two or more reasons for visit.

This question has undergone significant revision from earlier project lab slips. Please review closely the materials below concerning this updated measure.

[**Note:** the numbers listed on the left refer to the data entry codes used on the form.]

2. Routine Visit—refers to any reproductive health exam not specifically for STD screening; for example, initial or annual gynecologic exam, primary care visit, regular health check-up, or annual physical.
1. Symptoms—refers to patients that present primarily for a symptom check. This includes clients whose self-described symptoms may not sound like an STD.
13. STD Screening—refers to any person who states “just want to get checked” or “want an STD test” or receives routine CT screening, such as a urine test, without pelvic or genital examination.
4. Exposed to CT—refers to any person who indicates exposure to chlamydia, had sex with a partner known to have CT, or was notified by a health care provider that they were exposed or a contact to chlamydia in the past 60 days.
7. Exposed to Other STD—refers to any person who indicates exposure to another STD, such as gonorrhea, had sex with a partner with another STD, or was notified by a health care provider that they were exposed or a contact to another STD, not CT, in the past 60 days.

12. Any Pregnancy-Related Visit—refers to any female client requesting a pregnancy test, prenatal care, pregnancy management, or pre/post-abortion services.
11. Rescreening—refers to any person returning for another CT test because they tested positive for CT within the past 3-6 months. In some states, date of late positive test is requested, as a two-digit month, two-digit day (if known), and four-digit year.

EXAMPLE: A CLIENT MAY REPORT MULTIPLE REASONS FOR THAT DAY’S CLINIC VISIT. SHE MAY BE IN FOR A ROUTINE EXAM AND ALSO WANT A PREGNANCY TEST. IF SO, ONE WOULD MARK BOXES 2 AND 12. (HER ACTUAL PREGNANCY STATUS WILL BE REPORTED IN A DIFFERENT AREA OF THE LAB SLIP, SEE “OTHER ITEMS” BELOW.) SHE MAY BE SYMPTOMATIC FOR AN STD AND EXPOSED TO CT, LEADING TO CHECK MARKS IN BOXES 1 AND 4.

Symptoms (Check All That Apply)

This information is reported by the client. This section refers to clients that have a symptomatic complaint that has brought them to the clinic. Check boxes are gender-neutral. **Please check the appropriate box for the symptoms stated by the client.**

[**Note:** the numbers listed on the left refer to the data entry codes used on the form.]

1. Abnormal Vaginal/Urethral Discharge
2. Dysuria
3. Abdominal/Pelvic/Testicular Pain
4. Abnormal Vaginal Bleeding

Examination: Client Not Examined

Check this box if the client does not receive a gynecologic or genital examination or if the client only provides a urine sample to be tested for CT. Otherwise, indicate examination findings for women and men in the appropriate column.

Findings: Female (Check all that apply)

[**Note:** the numbers listed on the left refer to the data entry codes used on the form.]

1. Normal Appearance refers to a normal exam or an exam that does not include any of the CT-related signs/clinical impressions listed below. For women, this also includes the range of normal cervical ectopy.
3. Mucopurulence refers to yellow or green discharge from the cervix (not the vagina). This can be determined by color comparison of a white, dacron swab that has been introduced into the cervix.
4. Friability refers to easily induced bleeding with the first swab to touch the cervix. This is not usually the swab used to obtain the CT specimen. Bleeding after use of a brush is not considered friable bleeding.
5. Ectopy with inflammation refers to swelling and/or erythema in the area of visible ectopy.

WOMEN WITH SUSPECTED CERVICITIS BASED UPON THE PRESENCE OF MUCOPURULENT DISCHARGE, CERVICAL FRIABILITY AND EDEMA IN THE AREA OF ECTOPY SHOULD BE STRONGLY SUSPECTED OF HAVING INFECTION WITH CT. THESE WOMEN MAY BE PRESUMPTIVELY TREATED FOR CHLAMYDIA (I.E. TREATED BEFORE RECEIVING THE CT TEST RESULT).

6. PID (Pelvic Inflammatory Disease) refers to an upper genital tract infection that frequently involves the endometrium (endometritis), fallopian tubes (salpingitis), and pelvic peritoneum (peritonitis). Symptoms suggestive of PID include abdominal pain, pain with intercourse, vaginal discharge, excessive uterine bleeding, dysuria, onset of pain in association with menses, fever and sometimes nausea and vomiting. Signs associated with PID include cervical motion tenderness, uterine and adnexal fullness/thickening or pain.

Findings: Male (Check all that apply)

[**Note:** the numbers listed on the left refer to the data entry codes used on the form.]

8. Normal Appearance refers to a normal exam or an exam that does not include any of the CT-related signs/clinical impressions listed below.
9. Urethral Discharge is to be checked when there is discolored or unusual discharge from the urethral meatus.
11. GC on Gram stain refers to the presence of Gram-negative intracellular diplococci on a Gram stain.
21. ≥ 5 PMNs/hpf refers to the presence of five or more PMNs per high powered field ($\times 1000$).
12. Epididymitis refers to an infection of the epididymis caused by CT or GC and infection with Gram-negative bacilli such as *E. coli* or *Pseudomonas*. Men with epididymitis usually present with unilateral scrotal pain and swelling.

Other

The three items listed in this area of the lab slip refer to measures that are important for either tracking selective screening criteria, treatment or client status. As with the risk history measures, each of these items requires a response.

- **Is This Client Pregnant?**—refers to their pregnancy status at the time of the CT test. Complete this item for all female clients. If the client is pregnant, mark the box under “Yes;” if you know she is not pregnant, mark “No;” if it cannot be determined or the data are unavailable, mark “Unk.”

For male clients, must be marked “No”.

- **IUD insert planned**—a CT test should be performed prior to insertion of an IUD. Mark the “Yes” box if services at this visit were part of a clinical plan which will result in an IUD at some later visit. If an IUD is not part of this client’s service plan, then mark “No.” If it cannot be determined if an IUD insert is being planned, mark “Unk” (unknown).

For male clients, must be marked “No”.

- **Presumptive Tx for CT**—refers to the clinic providing medication to the client prior to an empirical (laboratory confirmed) finding of a disease. If this is done, mark “Yes.” If presumptive treatment is not indicated due to the lack of clinical findings and is not planned for this visit, mark “No.” If it is impossible to determine if presumptive treatment occurred, mark the box “Unk” (unknown).

Sex With

This information is the client’s self-reported sexual activity. If they have had sex in the last 60 days with only male partners, mark “Men;” with only female partners, mark “Women;” or with both male and female partners, then mark “Both.” However, if, for example, an older client notes that they had a homosexual experience during early adolescence then this historical information should not be reflected in recent sexual activity.

Risk History

Each risk history item requires a response—either Yes, No, or Unknown. Please ask clients each of the risk history items. One does not have to use the exact words listed on the lab slip; choose your vocabulary and syntax to fit the situation. If you forget to ask or don't know, or the client does not know, check Unknown.

- Positive CT last 12 months—refers to a positive Chlamydia test result during the 12 months preceding the current visit date. Use information from medical record or self-report from client.

If “Yes,” ask the client the number of sex partners s/he had in the 2 months prior to her/his last positive CT test. Write this number on the line marked “_____ # previous partners” under Positive CT last 12 months. Also, ask the client the number of those partners who were treated for CT. Write this number on the line marked “_____ # treated” under Positive CT last 12 months.

- 2 or more sex partners (60 days)—mark the box under “Yes” if the client has had sexual intercourse with two or more different individuals during the last 60 days. Mark the box under “No” if s/he has had none or one sex partner during this time period.
- New sex partner (60 days)—mark “Yes” if the client reports having a new sex partner, that is, someone they have never had intercourse with before.
- Symptomatic partner (60 days)—mark “Yes” if client reports having had sexual intercourse within the last 60 days with someone with a discharge or sores.
- Condom used during last sex—mark “Yes” if client reports having used a condom the last time s/he had sexual intercourse – regardless of when that last time occurred. If a client says s/he used condoms most of the times they had sex, but not during last sex, mark “No.” Similarly, if s/he rarely has used condoms but did so during their most recent sexual behavior, mark “Yes.” That is, the only event that matters for this item is last sexual encounter.
- Other STD last 12 months—refers to positive test results for an STD other than CT. STD is defined as the following: positive for gonorrhea, syphilis, trichomonas, or a primary case of herpes or warts in the 12 months preceding the current visit date.

RESOURCES & LINKS

1. Client-Centered Counseling
2. Key Counseling Points
3. Advisory and Subcommittee Members
4. Specimen Adequacy Forms
5. Selective Screening Criteria for FP and Expansion Sites
6. Website Links of Related Interest
7. Quick Reference To Acronyms and Abbreviations

CLIENT-CENTERED COUNSELING

Client-Centered Counseling

- Client-centered counseling allows the client to take responsibility and to set goals that she/he can embrace
- Client-centered counseling involves:
 - Attending to the client by listening to and affirming the client’s feelings, concerns, and needs
 - Asking the client open-ended questions to elicit information about her/his needs
 - Offering options not directives about her/his choices for healthier behaviors
 - Giving information simply that is related to the client’s needs and concerns

The shift from information-based client education to client-centered care can be summarized by the statement, “Listen. Don’t explain or justify.”

- STD prevention messages must be client-centered; i.e., tailored to the behaviors, circumstances, and special needs of the person being served. Risk-reduction messages must be personalized and realistic. Counseling should be:
 - Culturally competent (i.e., program services provided in a style and format sensitive to cultural norms, values, and traditions that are endorsed by cultural leaders and accepted by the target population)
 - Sensitive to issues of sexual identity
 - Developmentally appropriate (i.e., information and services provided at a level of comprehension that is consistent with the age and learning skills of the person being served)
 - Linguistically specific (i.e., information is presented in dialect and terminology consistent with the client’s language and style of communication)

-
- Client-centered care supports a client-centered value-neutral and non-directive counseling approach. This demands a personal awareness of one's own values and beliefs. A client's values may not mirror your own. By being aware of, and managing your personal and professional biases, you will be in a better position to reap the benefits of client-centered counseling strategies, as will your client.
 - Resources for more training on Client-Centered Counseling and Care:
 - Taking a Sexual History Video: available from Center for Health Training. This emphasizes a client-centered approach to gathering a client's sexual history.
 - Contraceptive Technology, 17th Edition: particularly chapter 10 on Education and Counseling
 - Writings on Behavior Change Theories, especially the Trans-theoretical model of Prochaska and DiClemente
 - Request training from Center for Health Training

 KEY COUNSELING POINTS FOR CLIENTS DIAGNOSED WITH CHLAMYDIA

1. Communication
 - culturally appropriate
 - language and reading level
 - client-centered education and counseling; use of open-ended questions
2. Introduction
 - clinician’s name and role
 - purpose of session
 - discussion of confidentiality
 - provide client with test results
3. Address Client’s Concerns
 - What questions can I answer for you at this time?
 - How can I help you at this time?
4. Chlamydia Information
 - sexual transmission of chlamydia
 - asymptomatic nature of disease
 - testing and meaning of results
 - complications and consequences
 - risk of reinfection
5. Disease Management
 - treatment plan
 - side effects and drug interactions
 - abstinence (or alternatives) for duration of treatment
 - risk of other STDs
6. Risk Reduction Counseling
 - limiting number of sexual partners
 - consistent use of condoms
 - limiting use of alcohol, drugs, intravenous exposures
 - assessing client’s safety or risk for relationship violence
7. Sex Partner Management
 - sexual history: # of sex partners last 60 days, date of last sex, protection
 - assessing client’s ability to effectively refer her/his sexual partner(s)
 - enhancing client’s ability to effectively refer partners by: modeling, role-play, providing strategies for partner notification and management
8. Closure
 - Any questions or other concerns?
 - medication
 - partner(s) management
 - safer sex/condoms
 - counseling
 - referrals
 - handouts and sources of further information
 - follow-up

INFERTILITY PREVENTION PROJECT ADVISORY COMMITTEE

VOTING MEMBERS

| | ALASKA | IDAHO | OREGON | WASHINGTON |
|-----------------|---------------|-----------------|----------------|--------------------|
| STD | Susan Jones | Anne Williamson | Doug Harger | Larry Klopfenstein |
| Family Planning | Cathy Feaster | Susan Ault | Carol Elliott | Jane Wilson |
| Lab | Shellie Smith | Sadika Kobic | Ed Schulmerich | Karen Crouse |
| Other | Anita Roth | Ella Gordon | Cate Wilcox | Katherine Gudgel |

NON VOTING MEMBERS

| REGION X INFRASTRUCTURE | |
|-------------------------|-------------------|
| Project Coordinator | Elizabeth Patrick |
| Data Analyst | Nancy Palmer |
| | |

| COMMITTEE CHAIRS | |
|-------------------|---------------|
| Lab | Karen Crouse |
| Data | Doug Harger |
| Clinical Services | Chris Knutson |

| CDC PROGRAM STAFF | |
|--|-----------------|
| National IPP Coordinator | Dorothy Gunter |
| National IPP Coordinator for Lab & Technology | Jim Newhall |
| National IPP Surveillance Coordinator | Debra Mosure |
| Program Consultant | Jan Hiland |
| Indian Health Services | Lori de Ravello |

INFERTILITY PREVENTION PROJECT SUBCOMMITTEES

| LABORATORY | DATA | CLINICAL SERVICES |
|--|--|---|
| Karen Crouse Chair – Spokane Lab | Doug Harger Chair – CHT | Chris Knutson Chair – AK |
| AK: Shellie Smith | Susan Jones Kathy Feaster | Anita Roth |
| ID: Sadika Kobic | Anne Williamson Susan Ault | Ella Gordon Annabeth Elliott Brenda VandenBeld |
| OR: Ed Schulmerich | Doug Harger | Margaret Lentell |
| WA: Mike McDowell Dolores Villareal | Larry Klopfenstein Katherine Gudgel | Jane Wilson Vivien Hanson, MD Lan Pham |
| UW Research/PHSKC Lina Cles | | Jeanne Marrazzo, MD |
| Project Partners | | Marjorie Witman – FP Nurse Consultant Public Health Region X Anne Meegan, Program Manager Seattle STD/HIV Prevention Training Center |

REGION X INFERTILITY PREVENTION PROJECT
SPECIMEN ADEQUACY PROGRAM

Registration Form

Purpose: This is a Quality Assurance process to help assess the quality of Chlamydia (CT) specimen collection. It is not meant as an immediate correlation of your current testing method results with the specimen adequacy result. It is offered to facilities participating in the Region X Project.

Registration:

1. Complete the following information and send it to your CT testing laboratory.

2. Clinician name: _____

Clinician identifier that will be used throughout the specimen adequacy process:

(name, initial, clinician number or other)

Facility: _____

Address: _____

Telephone: _____

Contact person to receive results: _____

(supervisor or other)

Date request submitted: _____

3. Copy this completed page and mail/FAX it to your CT testing Lab. The original is for your reference. If you choose to call the Lab, they will fill out the form from the information you give over the phone and send a copy to the contact person.

Your testing Laboratory is: _____

Address: _____

Phone: _____

FAX: _____

REGION X INFERTILITY PREVENTION PROJECT

Specimen Adequacy - Procedure Information:

1. Enclosed are a set of 10 routine CT sample collection swabs AND 10 specimen adequacy swab/slides/slide-holder units.
2. The clinician collects all other specimens first then the CT samples as follows:
 - Routine CT swab: Collect sample and place the swab in the tube as indicated on the swab package.
 - Specimen Adequacy swab: Using the swab from the swab/slide/slide-holder set, collect the sample as done for the routine CT, then roll the swab over the circled area only on the slide. Do not drag or push the swab. Ensure that all surfaces of the swab come into contact within the circle and that the entire circled area is covered evenly with specimen. The result should be a thin even smear.
3. Label the slide. Using a pencil, write the patient's and clinician's identifier on the frosted area of the slide. Allow the sample on the slide to air dry completely before placing it inoculated side up into the slide holder.
4. Label the routine CT sample by your normal method plus add the clinician identifier to the bottom left area of the label.

***The collector's (clinician's) identifier needs to be consistent for all 10 patients.**
5. Rubber band the CT swab tube and the slide-holder (containing the slide) together. Ship these along with the regular Region X Chlamydia form to your testing lab as normally done.
6. The routine CT sample will be tested and the result returned to your facility in the normal manner.
7. A "Chlamydia Specimen Adequacy Report" will be sent to your supervisor. A Training Fact/Reference sheet will be included with results that do not meet the stated acceptable performance.
 - For training follow up, please call the contacts noted on the Training Fact/Reference Sheet.
 - To evaluate training needs, a copy of the clinician's results will be sent to your State's CT Infertility Prevention Project Coordinator.
 - For statistical purposes, non-identifiable data will be shared with the Region X Project Office at the Center of Health Training.

For questions or concerns regarding outcomes please call _____ ,
 your testing laboratory at _____ (phone).

REGION X CHLAMYDIA PROJECT
Specimen Adequacy Program

| | | | |
|-----------------------|--|----------------|--|
| Evaluating Laboratory | | | |
| Submitter | | Site Number | |
| Site Supervisor | | | |
| Clinician ID | | | |
| Date Started | | Date Completed | |

| # Specs | Lab Number | Patient ID | Prove NAT EIA | Columnar Cells (adeq 10/slide) | | Comments | Tech ID |
|---------|------------|------------|---------------|--------------------------------|--------|----------|---------|
| | | | | Adeq | Inadeq | | |
| 1 | | | | | | | |
| 2 | | | | | | | |
| 3 | | | | | | | |
| 4 | | | | | | | |
| 5 | | | | | | | |
| 6 | | | | | | | |
| 7 | | | | | | | |
| 8 | | | | | | | |
| 9 | | | | | | | |
| 10 | | | | | | | |
| | | | Total: | | | | |

Scoring Criteria:

- 8 – 10 adequate slides is considered to be acceptable performance.
- 0 – 7 adequate slides indicates that additional training is necessary to ensure high quality specimens in the future.

The purpose of the proficiency testing is to improve the quality of specimens. Clinicians who score less than 80% are requested to repeat the proficiency testing until a satisfactory score is achieved. A Training Fact/Reference Sheet is attached for your use.

FOR HEALTHCARE PROVIDER USE

Comments _____

Supervisor: _____ Date Reviewed: _____

Employee: _____ Date Reviewed: _____

SELECTIVE SCREENING CRITERIA FOR FP & EXPANSION SITES

1. Women 24 and under
2. A woman with any of these findings:
 - Cervical Findings of:
 - Mucopurulence
 - Friability
 - Ectopy with inflammation/edema
 - PID
 - Exposure to chlamydia (in last 60 days)
 - Positive for CT in last 12 months
 - Symptomatic sexual partner [past 60 days]
 - Pregnant
 - Pre-IUD insertion

SELECTED REPRODUCTIVE HEALTH WEBSITES & LINKS

<http://www.cdc.gov/nchstp/od/nchstp.html>

The Centers for Disease Control and Prevention, the National Center for HIV, STD, and TB Prevention (NCHSTP) is responsible for public health surveillance, prevention research, and programs to prevent and control human immunodeficiency virus (HIV), infection and acquired immunodeficiency syndrome (AIDS), other sexually transmitted diseases (STDs), and tuberculosis (TB).

<http://www.plannedparenthood.org/STI/chlamydia.htm>

Planned Parenthood Federation of America.

<http://www.ucsf.edu/castd/>

Information on chlamydia and a variety of other Sexually Transmitted Diseases (STDs).

<http://www.afraidtoask.com>

Information on a variety of health information, including sexually transmitted disease (STD) photos.

<http://www.hopkins-id.edu/isstdr/isstdr.html>

The Johns Hopkins University STD Research Group. Research focus is on the epidemiology, prevention, and behavioral aspects of Sexually Transmitted Diseases (STDs).

<http://www.kff.org/>

The Henry J. Kaiser Foundation. The Foundation's work is focused on four main areas: health policy, reproductive health, HIV policy, and health and development in South Africa.

<http://www.aphl.org>

Association of Public Health Laboratories (APHL)

<http://www.4girls.gov>

HHS Office on Women's Health new website targets girls 10-16 years old with reliable health information to help them make healthy choices as they grow into adulthood.

<http://www.4women.gov>

This site is part of the National Women's Health Information Center. The gateway to Federal women's health information resources in the Department of Health and Human Services.

http://www.maq.org/content_homepage/homepage_in-the-news_hipaa.html

The Medical Association of Georgia website contains useful information and links to other websites with useful information on HIPAA (Health Insurance Portability and Accountability Act).

<http://www.vawnet.org>

The Violence Against Women Electronic Network (VAWnet) is an online resource for organizations and individuals working to end violence in the lives of women and their children. Started in 1995 through a cooperative agreement from the National Center for Injury Prevention and Control, VAWnet offers a wealth of online resources to enhance local, state and national prevention and intervention efforts.

NATIONAL PUBLIC HEALTH LINKS

<http://www.jsi.com>

JSI provides an extensive range of research and consulting services in the health care and service sectors by bringing creativity and innovation to all its endeavors. Assets include strong working teams on all projects; easy access to a broad range of disciplines; and flexibility and responsiveness to client needs.

<http://www.cdc.gov/nchstp/od/nchstp.html>

As part of the Centers for Disease Control and Prevention (CDC), the National Center for HIV, STD, and TB Prevention (NCHSTP) is responsible for public health surveillance, prevention research, and programs to prevent and control human immunodeficiency virus (HIV), infection and acquired immunodeficiency syndrome (AIDS), other sexually transmitted diseases (STDs), and tuberculosis (TB)

<http://www2a.cdc.gov/std101>

STD 101 In-a-Box: Includes nine ready-to-use and customizable presentations, a users guide with suggested agendas, discussion questions, and a script for an interactive group exercise. Useful for individuals in need of a basic presentation on STD prevention. New users must register before using.

<http://www.plannedparenthood.org/STI/chlamydia.htm>

Planned Parenthood Federation of America

<http://www.ippf.org>

International Planned Parenthood Federation

<http://www.afraidtoask.com>

Information on a variety of health information, including photos of sexually transmitted diseases (STDs).

<http://www.4women.org>

National Women's Health Information Center

<http://www.aphl.org>

Association of Public Health Laboratories (APHL)

http://www.aphl.org/chlamydia_lab.cfm

National Chlamydia Laboratory Committee Recommendations

<http://www.hipaadvisory.com>

Health Insurance Portability and Accountability Act (HIPAA). It mandates administrative simplification of several areas of health insurance, including the adoption of standard electronic transactions for basic business processes.

<http://www.ihs.gov>

The Indian Health Service (IHS), an agency within the Department of Health and Human Services, is responsible for providing federal health services to American Indians and Alaska Natives.

<http://www.stdhivtraining.org>

Find the ultimate online Chlamydia Course! The California STD/HIV Prevention Training Center is an integral part of a national network of training centers that offer dynamic continuing education courses. Clinical, behavioral interventions, partner services and program support courses are designed to enhance the STD/HIV knowledge and skills of medical, health, and community professionals. Browse through our course descriptions and register on-line!

<http://www.cdc.gov/std/gisp>

A website for the Gonococcal Isolate Surveillance Project (GISP). Includes information on the GISP sentinel surveillance system (protocol, data elements, among others).

Here are the web addresses for CDC's updated fact sheets:

- **BV** – <http://www.cdc.gov/std/BV/STDFact-Bacterial-Vaginosis.htm>
- **Chlamydia** – <http://www.cdc.gov/std/Chlamydia/STDFact-Chlamydia.htm>
- **Gonorrhea** – <http://www.cdc.gov/std/Gonorrhea/STDFact-gonorrhea.htm>
- **Herpes** – <http://www.cdc.gov/std/Herpes/STDFact-Herpes.htm>
- **HPV** – <http://www.cdc.gov/std/HPV/STDFact-HPV.htm>
- **PID** – <http://www.cdc.gov/std/PID/STDFact-PID.htm>
- **Syphilis** – <http://www.cdc.gov/std/Syphilis/STDFact-Syphilis.htm>
- **Trichomoniasis** – <http://www.cdc.gov/std/Trichomonas/STDFact-Trichomoniasis.htm>
- **STDs & Pregnancy** – <http://www.cdc.gov/std/STDFact-STDs&Pregnancy.htm>
- **MSM & Syphilis** – <http://www.cdc.gov/std/STDFact-MSM%26Syphilis.htm>
- **Sexually Transmitted Diseases & HIV Prevention** (in an updated format) – <http://www.cdc.gov/std/STDFact-STD&HIV.htm>.

QUICK REFERENCE TO ACRONYMS & ABBREVIATIONS

APC – Accelerated Prevention Campaign

ASTPHLD – The Association of State & Territorial Public Health Laboratory Directors

BID – Twice a day

CAP – College of American Pathology

CLIA – Clinical Laboratory Improvement Act

CMT – Cervical Motion Tenderness

CO – Cutoff

CSTE – Coalition of State and Territorial Epidemiologists

CT – Chlamydia Trachomatis

DFA – Direct Fluorescent Antibody Test

DIS – Disease Intervention Specialist

EIA – Enzyme Immunoassay

FP – Family Planning

GC – Gonococcus

GZ – Gray Zone

HCFA – Health Care Financing Administration

IM – Intramuscular

LCR – Ligase Chain Reaction

LPS – Lipopolysaccharide

MOA – Memorandum of Agreement

MOMP – Major Outer Membrane Protein

MPC – Mucopurulent Cervicitis

NCSD – National Council of STD Directors

NFPRHA – National Family Planning Reproductive Health Association

NGA – Notice of Grant Award

NGU – Non-gonococcal Urethritis

OPA – Office of Population Affairs

PCA – Probe Competition Assay

PID – Pelvic Inflammatory Disease

PCR – Polymerase Chain Reaction

PM – Partner Management

PN – Partner Notification

PO – Per os, i.e., by mouth

PT – Proficiency Testing

QA – Quality Assurance

QC – Quality Control

QD – Every day

QID – Four time a day

Rx – Prescription

STD – Sexually Transmitted Disease

TID – Three times a day

TMA – Transcription Mediated Amplification

TAT – Turnaround Time

Tx – Treatment and/or Therapy

TX – Title X

GLOSSARY OF TERMS

The terms below are defined in the context of the Region X Chlamydia Project. Some of these terms may be used in other settings, with different meanings.

Accuracy – The extent to which a measurement is close to the true value.

Amplification Test – A test which replicates the genetic material (DNA or RNA) of a microorganism such as Chlamydia from a few copies to millions within a few hours. These amplified (replicated) copies can then be detected, usually by photometry or fluorimetry.

Analytical Range – The range of accuracy of a test, e.g. the values (results) of a glucose blood test may range from 0 to 10,000 units, however test A used to detect glucose is only capable of detecting from 100 to 1,000 units, therefore the analytical range of this test is 100 to 1,000 units.

Antibiotics – A chemical substance capable of destroying microorganisms, specifically bacteria.

Antibody – A type of serum protein that is produced by the body in response to invasion by foreign proteins, e.g. viruses or bacteria, called antigens. Antibodies assist the body in removing or destroying foreign antigens.

Antigen – Foreign substances that stimulate the body to produce antibodies. Such substances may be used to detect antibodies in the blood serum.

Asymptomatic – A state where a person is infected with chlamydia but has no clinical symptoms (e.g. friable cervix and/or mucopurulence) of active disease.

ASTPHLD – The Association of State and Territorial Public Health Laboratory Directors. The national organization of public health laboratory directors working in state or territorial health departments.

Azithromycin – An antibiotic used to treat chlamydial infections that can be given in a single dose.

Bacteria – Any small one-celled (unicellular) microorganism. Bacteria vary in shape (morphologically), being spheric (cocci), rod-shaped (bacilli), spiral (spirochetes), or comma-shaped (vibrios).

Batch – A set of specimens, e.g. endocervical swabs, processed and tested during a single run (diagnostic test).

Cervical Motion Tenderness (CMT) – Moderate to severe tenderness elicited when the cervix is palpated or manipulated.

Cervicitis – Infection and/or inflammation of the cervix. Can be a sign of chlamydial infection.

Cervix – The narrow neck of the uterus, which extends into and can be partially visualized in the vagina. The cervix is a primary site of chlamydia infection and testing in females.

Chlamydia trachomatis – Chlamydia trachomatis is the bacterial agent which causes chlamydial infections, the most common sexually transmitted bacterial infection in the United States. While chlamydiae are classified as bacteria, they share some properties of both bacteria and viruses.

CLIA – Clinical Laboratory Improvement Act of 1967 (and amendments of 1988) which sets the guidelines for any clinical laboratory testing material obtained from human patients, i.e. blood, tissue, discharge, etc. CLIA is administered through the U.S. Health Care Financing Administration (HCFA).

Clinical Laboratory – A laboratory in which tests directly related to the care of patients are performed. Such laboratories use material obtained from patients for testing, as compared with research laboratories, where animal and other sources of test material are also used. Laboratories that accept specimens for testing by referral from separate medical facilities are often called reference laboratories.

Clinical Laboratory Procedure – Analytical procedure (test) performed on any specimens (samples) taken from humans and used to diagnose disease or infection.

Collection Sites – Locations in the body from which a chlamydia specimen may be taken. These sites include: cervix, urethra, rectum, throat, conjunctiva (eye). Different laboratory tests are sometimes indicated for use on different collection sites.

Confirmatory Test – A test which is used to confirm positive screening results thereby eliminating false positive results, improving test specificity. This test employs a different target molecule than screening tests, e.g. *C. trachomatis* enzyme immunoassays (EIA) typically detect specific lipopolysaccharide (LPS); while direct fluorescent antibody (DFA) test, used to confirm a positive EIA test, targets the major outer membrane (MOMP) of *C. trachomatis*. This method is preferred to using a supplemental test (see Supplemental Test).

Contact – A person who has had sexual contact with an individual having a confirmed sexually transmitted disease; often synonymous with “partner.”

Control – An artificial specimen with a known value (i.e. positive or negative) which is included in every test run in order to monitor the performance of the test. For example, if your positive control was negative it would invalidate the results of that particular test run and specimens would have to be re-tested.

CSTE – Council of State and Territorial Epidemiologist. This is the national organization for epidemiologists working in state or territorial health departments.

Culture – A laboratory test involving the cultivation of microorganisms or cells in a special growth medium.

Cutoff (CO) – A mathematically derived calculation in any given immunoassay which is used to determine which specimens are positive (reactive) or negative (unreactive), e.g. generally specimens with values above the CO are positive and those below are negative.

Detection Limit – The range (limits) of detection of any test methodology, e.g. *C. trachomatis* amplification test needs only 1-10 organisms to be presented in order to detect CT, whereas an enzyme immunoassay (EIA) needs 100,000 (10⁵) organisms to be present in order to detect CT.

Diagnostic Test – A test designed to detect chlamydia in a patient presenting with symptoms or history of exposure, as distinguished from a screening test.

Direct Fluorescent Antibody Test (DFA) – The direct detection of chlamydia (antigen) from a specimen (e.g. endocervical swab, etc.) which is placed on a microscope slide and stained using fluorescently labeled chlamydia specific antibody. After proper staining, the slide is viewed under a fluorescent microscope. Chlamydia positive specimens show apple-green elementary bodies in contrast to red background of counterstained cells.

Disease Intervention Specialist (DIS) – A trained individual working with test-positive patients and their partners to confirm treatment and identify all other potentially infected individuals. Usually employed by a health department.

DNA Probe – See Nucleic Acid Hybridization Test.

Doxycycline – An antibiotic used to treat chlamydial infections. The standard dosage is 100 mg, twice a day, for 7 days.

Ectopic Pregnancy – A pregnancy occurring anywhere except in the uterus, usually in the fallopian tubes. A serious, potentially fatal consequence of tubal damage from chlamydial infection.

Ectopy – Visible columnar epithelial cells that extend onto the outer surface of the cervix. In pregnant women, younger women or women using hormonal contraceptives, ectopy is considered normal. Ectopy increases the risk of acquiring chlamydia by exposing the more vulnerable columnar epithelial cells.

Enzyme Immunoassay (EIA) – A laboratory test that detects specific antigens or antibodies rather than the organism, e.g. chlamydia itself.

Erythromycin – An antibiotic used to treat chlamydial infection, especially for pregnant women. The standard dosage is 500 mg orally 4 times a day for 7 days.

Etiologic Agent – An agent, e.g., a bacteria or virus that causes disease.

External Quality Control – An external control (see control) specimen which is generally shared between multiple laboratories and the results compared for quality control purposes.

False Negative (Result) – A test result that indicates the absence of a condition when the condition is actually present (group “C” in Table I). The rate of occurrence of false negative results varies with the diagnostic accuracy and the specificity of the test or procedure. As the accuracy and specificity of a test increases, the rate of false negatives decreases. Certain tests are known to yield false negative results at a certain rate; in all tests, a small number of false negatives will occur by chance alone.

False Negative (Rate) – The rate of occurrence of negative test results in subjects known to have the disease or behavior for which the individual is being tested (see Table I).

False Positive (Result) – A test result that wrongly indicates the presence of a condition when the condition is not present (group “B” in Table I).

False Positive (Rate) – The rate of occurrence of positive test results in tests of individuals known to be free of a disease or disorder for which the individual is being tested (see Table I).

Friability – Fragile, easily irritated, especially prone to bleeding; for example, cervical surface tissue in some chlamydial infections.

Gonorrhea – A common sexually transmitted disease most often affecting the genitourinary tract and, occasionally, the pharynx, conjunctiva, or rectum. Infection results from contact with an infected person or by contact with secretions containing the causative organism *Neisseria gonorrhoea*. Sometimes referred to as GC (gonococcus).

Gray Zone (GZ) – An artificially established range (zone) below a diagnostic test’s cutoff (CO) value. The GZ generally ranges from 30-70% below the CO. Specimens in the established GZ are then re-tested by another methodology in order to increase the test sensitivity, i.e. to detect additional positive specimens.

Immunoassay – An assay (test) which detects antigens or antibodies.

Infertility – The inability to conceive or carry a fetus to term. Chlamydia related infertility is most often caused by scarring in the fallopian tubes.

Inhibitor – A substance that interferes with the test’s ability to detect the presence or absence of disease. Blood and mucous are examples of potential inhibitors for chlamydia testing.

Internal Quality Control – An internal control specimen made up and used by a particular laboratory (see control).

Kit – A package of test reagents, package insert, etc. which enable a laboratory to perform a particular test, i.e. a chlamydia kit would enable a laboratory to test for chlamydia.

Ligase Chain Reaction (LCR) – An amplification test for chlamydia and/or gonorrhea. A process whereby a strand of DNA can be cloned (replicated) millions of times within a few hours.

LPS – The lipopolysaccharide in the Chlamydia organism, a part of the organism. The same LPS is present in all chlamydia species, e.g. *C. trachomatis*, *C. psittaci*, *C. pneumonia*, and etc. Any test which detects chlamydia LPS would cross react with all chlamydia organisms.

Lot – Diagnostic kits are manufactured in large quantities (lots). As part of quality control, laboratories record all results from each kit and lot in order to monitor for any variations which may occur between lots.

Mean – The average of the numerical results obtained from a series of analyses.

Major Outer Membrane Protein (MOMP) – The major outer membrane protein on the Chlamydia organism. The MOMP is species specific, i.e. *C. trachomatis* is different from *C. psittaci*, etc. Any test which detects MOMP will only react with each separate species, i.e. *C. trachomatis* MOMP will not react with *C. psittaci*.

Mucopurulence – Bodily discharge composed of mucous, cellular debris and white blood cells as a result of an infection process such as chlamydia. Mucopurulent appears to have a green or yellow color when viewed on a white cotton swab that has been inserted into the cervical os. Slang: mucopus.

Mucopurulent Cervicitis (MPC) – Cervical infection/inflammation characterized by a mucoidpurulent (pus) discharge and friability. Often caused by chlamydia infection but may also occur with many other organisms.

Nucleic Acid Hybridization Test (DNA Probe) – Commercial name: Gen-Probe Pace 2 assay. A laboratory test which detects *C. trachomatis* ribosomal RNA.

Office of Population Affairs (OPA) – This is the federal office which administers the Title X family planning program. Part of the Department of Health and Human Services, US Public Health Service.

Package Insert – The written pamphlet in every diagnostic test kit which includes instructions for proper use (kit directions) of the kit. In addition, the package insert contains some or all of the following: information on intended use; summary and explanation of the test; principles of the procedure; reagents provided; special precautions; specimen collections, storage and transport; materials provided/not provided with kit; procedural limitations; performance characteristics; results; and quality control.

Partner Elicitation – Obtaining the names and means of contacting the sexual partners of an individual with a reportable, laboratory-positive sexually transmitted disease, usually by interviewing the diagnosed client.

Partner Management (PM) – A set of activities undertaken by a medical provider and patient aimed at ensuring appropriate clinical disposition of all possible contacts to a sexually transmitted disease. PM may include partner elicitation, notification, referral, treatment and tracking.

Partner Notification – The medical care provider advises the sexual partner of an individual with an STD of his/her contact status, usually providing anonymity for the patient.

Partner Referral – The provision of written or oral information on the sexual partner of an individual with a reportable, laboratory-positive sexually transmitted disease, about where to obtain medical care for the evaluation or treatment of the disease. Referral can be done by the provider, or, in the case of self-referral, the patient may provide the information to his/her partner.

Partner Tracking – The medical care provider provides and documents follow-up of the named sexual contacts of an STD patient (elicitation, notification, referral and/or treatment).

Partner Treatment – The sexual partner of an individual with an STD is given indicated treatment for the STD, with or without examination.

Pelvic Inflammatory Disease (PID) – A clinical syndrome identified by a range of symptoms including lower abdominal pain and tenderness, bilateral adnexal tenderness, low-grade fever, and cervical motion tenderness. Serious sequelae (consequences) can include infertility, ectopic pregnancy, and chronic pelvic pain. PID can be one of the serious consequences of chlamydial infection.

Polymerase Chain Reaction (PCR) – An amplification test for chlamydia. A process whereby a strand of DNA can be cloned (replicated) millions of times within a few hours.

Predictive Value Negative – The likelihood that a person with a negative test does not have the disease. See Table I.

Predictive Value Positive – The likelihood that a person with a positive test does, in fact, have the disease. See Table I.

Presumptive Treatment – Also known as epidemiologic treatment. The treatment of patients suspected of having a disease based on identified risk factors and/or clinical findings, without the confirmation of a positive test result.

Prevalence – the percentage of people in a given population that have a given disease, e.g. the prevalence of chlamydia in Clinic A is 5%, that is 5 out of 100 individuals in Clinic A are infected with chlamydia. See Table I.

Proficiency Testing (PT) – A process in which samples (artificial patient specimens) are sent from a quality assurance or certification organization to participating laboratories for analysis. The true value (results) of the samples are unknown to the participating laboratories. The results are tabulated and compared to all participating laboratories and reported to the enrolling laboratory. PT specimens are an indicator of laboratory performance. PT is a required quality assurance process under laboratory licensing law.

Qualitative – A test that is qualitative determines the presence or absence of a substance (antibody/antigen), e.g. an EIA detects the presence or absence of chlamydia.

Quantitative – A test that is quantitative determines the amount of a substance per unit volume or unit weight, e.g. blood glucose normal range 70-115 mg/dl-milligrams per deciliter.

Quality Assurance Program (QAP) – A comprehensive set of policies, procedures, and practices used to monitor the services provided in a clinical or laboratory setting. These plans should include protocols for proper record keeping, calibration and maintenance of equipment, monitoring of quality controls and proficiency testing results, and training.

Quality Control (QC) – The set of laboratory or clinical procedures designed to ensure the a test is working properly, e.g. test controls, monitor lot-to-lot variation, monitor/run CO values, and etc.

Reagent – A substance that produces a chemical reaction in a sample that allows an analyte (the substance being measured) to be detected and measured.

Reference Laboratory – See Clinical Laboratories, page 2.

Screening Criteria – A set of characteristics used to determine which patients in an asymptomatic population should receive a test for chlamydia.

Screening Test – A test performed to detect chlamydia in a patient presenting for a routine exam, with no symptoms or known exposure indicating chlamydia infection is likely, as distinguished from a diagnostic test.

Selective Screening – Testing for chlamydia in a population using screening criteria, as opposed to universal screening of an entire patient population, or diagnostic testing of patients with symptoms.

Sensitivity – The ability of a test to detect patients who have the disease or condition for which they are being tested. Expressed as the percent of positive cases where disease is correctly identified as present. See Table I.

Specificity – The ability of a test to accurately identify patients who do not have the disease or condition for which they are being tested. Expressed as the percent of negative cases correctly identified. See Table I.

Specimen – A small sample of something, intended to show the nature of the whole, such as a blood or urine specimen.

Specimen Adequacy – The quality of the specimen obtained from the patient judged by the number and type of cells sampled, e.g. in chlamydia testing, an endocervical specimen which contains any endocervical columnar/cuboidal epithelial cells or metaplastic cells (or greater than 100 erythrocytes (RBC's) per field at 200X).

Supplemental Test – A test which is used to confirm positive screening results.

This test employs the same target molecule as the original screening test, e.g. *C. trachomatis* enzyme immunoassays (EIA) typically detect specific lipopolysaccharide (LPS); the EIA blocking or neutralization assay also target this same molecule (LPS). As a general rule, results obtained from using one test should be confirmed using an alternate technology (see Confirmatory Test) in order to best decrease the incidence of false positive test results thereby increasing specificity.

Symptomatic – Presenting with clinical signs of disease.

Title X – The Federal legislation which supports federally funded family planning clinics; Title X of the Public Health Services.

Transcription Mediated Amplification (TMA) – An amplification test for the detection of chlamydia. A process whereby a strand of RNA can be cloned (replicated) millions of times within a few hours.

Turnaround Time (TAT) – The amount of time it takes to produce a test result from the time a specimen is received in the laboratory until it is reported out.

Universal Screening – Testing for chlamydia in an entire population, regardless of symptoms, risk history, or other factors.

Urethritis – Inflammation of the urethra.

CALCULATING DISEASE DISTRIBUTION BASED ON GOLD STANDARD TEST RESULTS

| | DISEASE PRESENT | DISEASE ABSENT | TOTAL |
|----------------------|-----------------|----------------|---------|
| Positive Test Result | A | B | A+B |
| Negative Test Result | C | D | C+D |
| | A+C | B+D | A+B+C+D |

Prevalence: $(A+C)/(A+B+C+D)$

Sensitivity: $A/(A+C)$

Specificity: $D/(B+D)$

Positive Predictive Value: $A/(A+B)$

Negative Predictive Value: $D/(C+D)$

False Negative Rate: $C/(A+C)$

False Positive Rate: $B/(B+D)$

REGION X INFERTILITY PREVENTION PROJECT

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