

## Section V:

### Lab Slip and Data Collection

#### 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 lab slip 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

Co - IPP Coordinators, Doug Harger and Lila Duncan 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, it can either 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 cervi

and male specimens from the urethra. If a woman has had a hysterectomy check **Urethral**. It will be assumed that she does not have a cervix. 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.

➤ **Customized Fields**

***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.  $\geq 5$  PMNs/hpf refers to the presence of five or more PMNs per high powered field (x1000).
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.