Dear IPP Health Care Provider(s),

The Region X Infertility Prevention Project's Clinical Subcommittee is pleased to offer you the enclosed *Chlamydia Toolkit.* The toolkit is designed to help clinical providers determine when women should be tested for Chlamydia and which specimen collection type is best suited to their clinical needs. These guidelines or considerations are not meant to replace good clinical judgment in client presentations. In the *Chlamydia Toolkit*, you will find:

- **Performing a Sexual Risk Assessment** is a sample set of sexual risk assessment questions, based, in part, on a document produced by the California STD/ HIV Prevention Training Center and California Department of Public Health, Center for Infectious Diseases, Division of Communicable Disease Control, STD Control Branch.
- **Female Selective Screening Criteria for Chlamydia in Family Planning and Expansion Sites** briefly describes when women need to be tested. **Considerations: Clinician-Obtained Vaginal (COV) vs. Self-Obtained Vaginal (SOV)** highlights considerations and advantages of COV and SOV**.** These documents are designed to be printed back-to-back on a 3x5 card that can be kept in a clinic jacket pocket for easy reference.
- **Clinician-Obtained Vaginal Chlamydia Specimen (COV)** includes considerations/key points for clinicians using vaginal swabs to collect specimens from clients
- **Client Self-Obtained Vaginal Chlamydia Specimen (SOV)** includes considerations/key points for clinic staff instructing clients on self-obtained vaginal specimen collection and tips for clients using self-obtained vaginal swabs
- **Frequently Asked Questions about Vaginal Swabs for Chlamydia and Gonorrhea Testing**
- **Bibliography – Vaginal Swabs**
- **Chlamydia Positive Follow-Up** is a sample medical record format used in some Region X IPP sites

We hope these materials will be helpful in your clinic setting. Your feedback is much welcomed through your state IPP contact.

Respectfully,

Sherrell Holtshouser, RN, MPH
Chair, Clinical Services Sub Committee
Region X Infertility Prevention Project Executive Committee

PERFORMING A SEXUAL RISK ASSESSMENT — 5 Ps

Past STDs/Personal risk	• Are you currently sexually active? If not, have you ever been sexually active? • Have you ever been diagnosed with an STI? • Have you ever been tested for HIV or other STIs? • Have you had sex with someone who has an STI? • Have you exchanged sex for drugs, money and/or other things?	
Partners	• Do you have sex with men, women or both? • Have you had a new sex partner in the last 60 days? • In the last 60 days, how many sex partners have you had? • Have you had sex with someone who may have had more than one partner in the last 60 days?	
Practices	• Do you have vaginal sex (penis in vagina)? • Do you have anal sex (penis in anus/butt)? • Do you have oral sex (penis in mouth or mouth on vagina/vulva)? • Have you ever used needles to inject/shoot drugs?	
Prevention	• What do you do to prevent STIs and HIV? • Do you and your partner(s) use any protection against STDs? • If so, what kind of protection do you use? • How often do you use this protection? • In what situations or with whom? • Tell me about your use of condoms with your recent partner.	
Pregnancy plans and prevention	• How would it be for you if you got pregnant now?	

Female Selective Screening Criteria for Chlamydia in Family Planning & Expansion Sites

1. Women 24 and under should be tested at least annually.*
2. All women 25 and older who meet one of the following criteria should be screened:
   - Cervical findings consistent with cervicitis (mucopurulence, friable cervix, or ectopy with inflammation or edema)
   - Pelvic inflammatory disease (PID)
   - Exposed to C. trachomatis (in last 60 days)
   - Exposed to N. gonorrhoeae (in last 60 days)
   - Symptomatic sex partner (in past 60 days)
   - Pregnant
   - IUD insertion
   - Prior chlamydial infection within the past 12 months

For Additional Specific Information, *MMWR* December 2010;59
www.cdc.gov/std/treatment

*CDC recommends that all women 25 and younger be screened using the listed criteria. Each state in Region X makes its own decision, depending on local data, resources, etc.

Region X IPP, May 2011

Advantages and Considerations of Client Self-Obtained Vaginal (SOV) vs. Clinician-Obtained Vaginal (COV) Chlamydia Specimen

SOV		COV
✓	Empowers client	
✓	Decreased latex exposure	
✓	Decreased equipment needs	
✓	Decreased staff time	
	Increased visual physical assessment	✓
✓	Asymptomatic client	
✓	Pelvic indicated	✓
✓	Pap/pelvic not indicated	
✓	Retest 3 months post treatment	

Region X IPP, May 2011

CLINICIAN-OBTAINED VAGINAL CHLAMYDIA SPECIMEN (COV)

Vaginal specimens are deemed the specimen of choice by the Centers for Disease Control and Prevention (CDC) when screening for *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) because they have the highest sensitivity of any available test method. When performing a speculum examination, both endocervical and vaginal swabs are equally acceptable options.

Clinicians may collect the vaginal specimen during a routine or non-routine client visit or may instruct the client to self-collect a specimen. The vaginal collection kit is FDA-approved for client self-collection within the clinical setting.

IMPORTANT INFORMATION TO CONSIDER

The clinician or designated clinic staff should consider other available testing options if:

- pregnancy is known/suspected
- the following signs/symptoms are present which may necessitate a pelvic exam:
  - Recent pelvic pain
  - Pain with sexual intercourse
  - Unusual vaginal discharge, bleeding or bad odor

The above signs/symptoms can be due to pelvic inflammatory disease (PID). A prompt diagnosis and treatment of PID can help reduce the risk of infertility and ectopic pregnancy associated with PID.

If at any time during the collection process:

- the inside of the cap and/or tube is contaminated, or
- the specimen swab is dropped and/or contaminated, or
- part of the transport liquid medium in the tube is spilled,

a new specimen collection kit must be used. Use **only** the swab that is provided in the collection kit; other swabs must not be used.

The Clinician-Obtained Vaginal Specimen is collected by swabbing the client's vaginal walls using the sterile swab provided in the vaginal specimen kit. It is not necessary to remove adherent or "excess" vaginal discharge from the vaginal canal prior to the actual specimen collection. Once the specimen is collected, place the swab into the collection tube. Holding the swab handle against the inside of the tube, break half of the swab stick off at the scored line, then securely place the cap on the tube.

Label the collection tube properly with the client's identifying information along with the appropriate IPP lab request form. The collected specimen is submitted along with the appropriate IPP lab request form to the designated lab for processing. Please contact your public health lab for more information and for specific instructions regarding labeling and mailing.

Federal requirements for packaging and mailing, as referenced in 42 CFR, Part 72, must be used. These federal requirements can be obtained from Centers for Disease Control and Prevention Office of Health and Safety in Atlanta, Georgia at 404-636-3883.

CLIENT SELF-OBTAINED VAGINAL CHLAMYDIA SPECIMEN (SOV)

Vaginal specimens are deemed the specimen of choice by the Centers for Disease Control and Prevention (CDC) when screening for *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) infection because they have the highest sensitivity of any available test method. Studies indicate clients prefer self-collection technique over traditional clinician-obtained specimens and are able to perform this function satisfactorily.

Client self-obtained vaginal swabs should be encouraged with clients for routine or non-routine visits. Clients may decline to self-collect for a variety of reasons. If the client agrees to self-collect, it is the responsibility of the clinician and/or her/his designee to review the proper specimen collection procedure with the client.

Clients may self-collect specimens only in the clinic facility, since self-obtained specimen kits have not been FDA-approved for off-site use, such as Juvenile Detention centers, homes, and so on. Validation studies are currently underway to remove this restriction.

IMPORTANT INFORMATION TO CONSIDER

The clinician or designated clinic staff should consider other available testing options if:

- pregnancy is known or suspected
- the following signs/symptoms are present which may necessitate a pelvic exam:
  - Recent pelvic pain
  - Pain with sexual intercourse
  - Unusual vaginal discharge/bleeding or bad odor

The above signs/symptoms can be due to pelvic inflammatory disease (PID). A prompt diagnosis and treatment of PID can help reduce the risk of infertility and ectopic pregnancy associated with PID.

The client should also be instructed that, if at any time during the collection process:

- the inside of the cap and/or tube is contaminated, or
- specimen swab is dropped and/or contaminated, or
- part of the transport liquid medium in the tube is spilled,

a new specimen collection kit must be used. Use **only** the swab that is provided in the collection kit; other swabs must not be used.

- The client should not attempt to remove "excess" vaginal discharge prior to obtaining the specimen.
- A specimen may be self-obtained even during menses. Tampons should be removed prior to attempting to insert a swab.
- Instruct the client to insert (without touching inner thighs) the sterile swab two inches past the introitus, gently rotating 10 – 30 seconds, ensuring the swab comes into contact with the vaginal walls in order to absorb the vaginal moisture.
- Once the specimen is collected, place the swab into the collection tube.
- Holding the swab handle against the inside of the tube, break half of the swab stick off at the scored line.
- Securely place the cap on the tube.

The client self-obtained vaginal specimen should be properly labeled by the clinician or her/his designee with the client's identifying information along with the appropriate IPP lab request form. The collected specimen is submitted along with the appropriate IPP lab request form to the designated lab for processing. Please contact your public health lab for more information and for specific instructions regarding labeling and mailing.

Federal requirements for packaging and mailing, as referenced in 42 CFR, Part 72, must be used. These federal requirements can be obtained from Centers for Disease Control and Prevention Office of Health and Safety in Atlanta, Georgia at 404-636-3883.

TIPS FOR THE CLIENT – SELF-OBTAINED VAGINAL SPECIMEN

- Add a test tube rack (or another container) in the bathroom to assist the client in handling swab and test tube upright
- Loosen the cap on the test tube before issuing to the client
- Remind client not to touch the inside of the tube or the cap, or handle the absorbent end of the swab with hand/fingers.
- Client should request a new collection kit if the inside of the cap, tube, or swab is dropped.
- Client should request a new collection kit if some of the transport media is spilled.
- Use the illustrated diagrams either from the package insert or from the Region X IPP illustrated, low literacy, "Vaginal Swab Guide" available in English and Spanish. Access it at:

  www.centerforhealthtraining.org/projects/pr_ippX.html

FREQUENTLY ASKED QUESTIONS ABOUT VAGINAL SWABS FOR CHLAMYDIA AND GONORRHEA TESTING

TEST PERFORMANCE

Q: Why is there variance between the sensitivity[1] of the provider-obtained swabs and the self-obtained swabs?

A: Not sure. This certainly deserves additional study. The higher positivity[2] found in the self-obtained specimens could be that the individual tends to leave the swab in longer or move it around more within the vagina than a clinician would. Certainly with a speculum in place, only the lateral vaginal walls could be swabbed by the clinician, so there would be opportunity for less saturation of the swab. When there is no speculum in place, the swab comes into contact with more of the vaginal wall surface area.

Q: If the clinician is doing a pelvic exam, is there enough evidence to support using a clinician-obtained vaginal swab over an endocervical swab?

A: There is slight but not a significant difference in positivity[2] to justify clinicians changing their practice. Also, there may be some advantage in using an endocervical swab when a speculum examination is done because one can better assess the cervix.

TEST TECHNOLOGY

Q: Are there are any differences between swab heads such as rayon or dacron as far as specimen quality or collection?

A: Studies report no differences in clients' reported comfort or in specimen quality with different swab head materials. The manufacturer recommends using the swabs provided in the kits.

Q: Is there any work being done for self obtained male testing?

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[1] 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.

[2] Positivity: The percentage of all chlamydia tests with a positive result. Positivity is calculated by the number of positive chlamydia tests divided by the total number of tests that were either positive or negative multiplied by 100

A: There have been some efforts to evaluate self-obtained male swabs (from the distal meatus). These have shown variable results. Males have generally not found swabbing the urinary meatus an appealing request as it is uncomfortable to some degree. Certainly self collection of urine and mail-in urine specimens is being studied; males find this approach much more acceptable.

Q: Is there the possibility that health districts or other providers' offices would be equipped to develop and obtain results like we currently do for pregnancy tests and rapid HIV tests?

A: Not in the foreseeable future. We are not aware of any efforts or advances in the "rapid test" technology for chlamydia screening. The current technology available to us is not an appropriate platform for rapid testing.

SPECIMEN COLLECTION/TRANSPORT

Q: I'm concerned that my patients might be afraid to use vaginal swabs or might use them incorrectly.

A: Studies indicate that clients actually prefer self-obtained over traditional clinician-obtained vaginal specimens and are able to perform this function satisfactorily.

Q: The urine CT/GC tests may be skewed if the client has voided within an hour of specimen collection, is this the same with vaginal self collected specimens?

A: No. This is one advantage of the vaginal swab. The time elapsed since the client last voided has no effect on the collection of the vaginal specimen.

Q: Often clients coming to clinic for a urine pregnancy test may have given us a urine specimen that doesn't meet the criteria for urine based chlamydia testing.

A: Again, this is a judgment call at the clinic location. If a client is able to give a urine sample and has not voided for an hour, certainly that sample could be used for the dual purpose of pregnancy and chlamydia screening, as discussed above. If a client has very recently voided and is unwilling to do a self-collected swab or is not capable of performing the technique, then the clinician would be well advised not to waste the opportunity to screen for chlamydia, and go ahead and use that urine sample even though the specimen may not be optimal. It might be months before there is another opportunity to screen, so seize the moment!

Q: Regarding possible reformulation of transport media to address temperature changes, are the manufacturers considering this? Our issue is freezing/thawing several times in transit.

A: The stability of mailed specimens is currently under investigation. Certainly transit issues such as temperature variability must be solved before over-the-counter, mail order, or out-of-clinic screening with self-collected specimens can be approved. Specimen stability to temperatures beyond the product insert will likely need to the verified by the laboratory during an establishment study for off-label testing.

CLINICAL ISSUES

Q: When I need a pregnancy test, I still have my patients do a self swab for GC/CT secondary to the higher specificity[3] of the vaginal swab. Is this correct?

A: This is an area where clinicians will have to use their own judgment and decide on local policy. Here are some considerations: The manufacturer's packaging information urges caution when advising clients to self-collect a specimen when pregnancy is known or suspected. Some feel there is potential liability should a pregnant client subsequently suffer a miscarriage. Others feel that giving clients two sets of instructions, one for urine collection and one for vaginal specimen collection, would be too confusing and therefore increase the odds of incorrect specimen handling. Still others are reasonably comfortable with advising a client about self-collected specimens in early pregnancy, with caution neither to insert the swab high in the vagina nor to "scrub" around too vigorously.

Q: Are you aware of studies that have evaluated the effect of self-collected vaginal swabs on the vagina, e.g., microabrasions?

A: No, we are not aware of any studies of the effect on the vagina of either the self-collection devices or processes. No studies have reported ill-effects or injuries from the devices or process.

Q: Does menstruation affect the test?

A: No. Studies carried out at the University of Washington indicate blood or cervical mucopurulence do not inhibit accurate results. However, when a client is performing a self-collected vaginal swab, she should be advised to first remove a menstrual tampon for her comfort and to maximize the contact of the swab head with the vaginal walls.

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[3]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.

OTHER

Q: What is the cost of the test? How are costs recovered?

A: The base cost to the IPP project is reportedly around $14 regardless of specimen type (urine, vaginal, endocervix). The client served by the IPP won't see this cost. If the client doesn't qualify for the IPP screening, then she might expect to pay up to $40, depending on whether the screening agency has a sliding fee scale in place.

Q: How long do you think it will take for the FDA to approve the self-collected swab for use outside the clinic setting?

A: This is unpredictable even though there are a lot of people working on it. The designated IPP labs are doing validation studies now on mailed specimens from outside the clinic setting. When individual laboratories validate the stability of out of clinic samples for their geographic area, it could begin regularly processing these even though the FDA has not given the manufacturer clearance to market the test for out of clinic use. A clinical trial has been proposed to extend the indication of some NAATs for home collection but such a trial has yet to commence. Laboratory Directors should discuss the local requirements for off-label testing with their regulatory agency.

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Chlamydia Positive Follow-Up

DATE	REPORT OF FOLLOW-UP SERVICES	SIGNATURE
_____ _____ _____ _____ _____ _____	Client tested/specimen site: _____ Lab reported + test result: _____ Client informed of + test result: _____ Phone call: _____ Phone call: _____ Letter: _____	_____ _____ _____ _____ _____ _____
	Clinic Visit: ☐ Discussed Chlamydia ☐ Discussed safer sex ☐ Advised to abstain or use condoms for 7 days ☐ Discussed treatment ☐ Discussed rescreening ☐ Written info given:	
	Discussed treatment of partner(s) _____ (#) of partners identified ☐ Partner management discussed ☐ Contact field record(s) completed ☐ Client will notify partners ☐ Client requests EPT: _____ (#) of partners ☐ Partner EPT education given	
	Treatment: ☐ Doxycycline 100 mg #14 sig 1 tab PO bid X 7 days ☐ Azithromycin 1 gm PO stat – single dose	
	Discussed Birth Control Plan: Condoms given # _____ Follow-up Plan:	
_____ _____ _____	**Rescreening:** Client notified to RTC for rescreening # or previous partners who received CT TX_____ Client RTC for Rescreening Test Result:	_____ _____ _____

Name _____

Client# _____ DOB _____

Chlamydia Positive Follow-Up

Presumptively Treated:

- ☐ Contact the client and advise of + test results
- ☐ Discuss regarding taking medication regularly (if Doxy was used)
- ☐ Discuss safe sex
- ☐ Discuss partner management
- ☐ Discuss rescreening
- ☐ Confirm contact information

Not treated at time of testing:

- ☐ Schedule time for client to RTC for TX, encourage partner to come also
- ☐ At time of clinic visit, provide client education re: disease, risk reduction, treatment, partner management, rescreening
- ☐ If partner(s) not with client, discuss partner management, develop plan
- ☐ Provide treatment
- ☐ Dispense condoms
- ☐ RTC of has symptoms/symptoms persist or has unprotected sex with untreated partner
- ☐ Confirm contact information
- ☐ Discuss rescreening