Why Three-Site (Extra-Genital) Testing?

- Chlamydia (CT) and Gonorrhea (GC) can occur in the genitals, pharynx, and/or rectum.
- Pharynx and/or rectum can be positive when genitals are negative.
- Different sites may be infected with different organisms.
 - Example: +CT/-GC genital, +CT/+GC pharyngeal, -CT/+GC rectal
 - Testing genitals only would miss GC infection, ineffective treatment.



Why Three-Site Testing?

"Look and you will find it - what is unsought will go undetected." -Sophocles

- More than half (53%) of *C. trachomatis* and 64% of *N. gonorrhoeae* infections were at non-urethral sites and would have been missed if the traditional approach to screening of men by testing only urethral specimens had been used.
- A US Military QI project found that 94% of GC/CT infections would have been missed before implementing 3 site testing for HIV positive service members.
- Extragenital GC infections contribute to growing antibiotic resistance.
- Untreated infections can result in infertility, PID
 - CT: proctocolitis, ocular infections, possibly reactive arthritis²

Medium Size Wyoming County Example

Of tests performed at County Public Health Office

<u>2016-2019</u>					
Individuals tested for CT/GC	615				
#CT/GC swabs collected	1,276				
Multi-site infections	2.93%				
Extra-genital infection only	1%				
Positive in all three sites*	0.33%				
Swab Percent Positive					
Vaginal	9%				
Urine	12%				
Pharyngeal	2%				
Rectal swab	13%				

*16yo female and 18yo female

Proportions of CT and CG infections amongst asymptomatic MSM that would be missed by different screening practices - San Francisco City Clinic 2008-2009



Urine vs. Vaginal Specimens for Females

- "For female screenings specimens obtained with a vaginal swab are the preferred type of specimen."¹
- ... "urine may detect up to 10% fewer infections"... ¹
- Transgender population: what anatomy is presence/absent, test accordingly



¹Recommendations for the Laboratory-Based Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* — 2014. https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6302a1.htm

Provider vs. Self-Collected Vaginal Swabs

This Changed My Practice: Indications and value of self-administered vaginal swabs for STIs and vaginitis – Dr. Roberto Leon

- British Medical Journal by Sarah Schoeman
 - 3,867 participants
 - Participant conducted self swabs upon arrival.
 - Provider collected swabs were then conducted during exam.
 - 10.2% infected with CT
 - Self Collected more sensitive than provider collected, 97% vs. 88%
- 67% of women preferred self collected





Clinician vs. Self-Collected Swabs

Considerations

- Patient preference
- If clinician is doing a vaginal or rectal exam, clinician could collect swabs if patient desires.
- Ask patient to self-collect if clinician will not be performing a vaginal or rectal exam.
- If clinic is unable to offer three-site testing and client has risk of infection in extra-genital sites, educate client on risk of infection in extra-genital sites and refer client to a location that provides extra-genital testing.

Self-Collected Vaginal and Rectal Swabs

- Label tubes
- When staff collects pharyngeal swab
 - Show patient how to keep liquid in bottle and unscrew vs. pierce lid

Patient:

- Wash hands
- Hold at or above scored line
- Insert 3-5cm
- Rotate for 10 seconds
- Remove and place in liquid
- Break off at scored line, re-cap
- Place in pass through
- Wash hands





Patient-Collected Vaginal Swab

Patient-Collected Vaginal Swab Specimen Collection

Wash hands before starting and undress from the waist down. Open the individual collection package (3) that contains the pink-capped Xpert® Swab Transport Reagent tube and individually wrapped collection swab. Set the tube aside before beginning to collect sample. Discard the larger swab ⁽¹⁾.



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Open the collection swab wrapper by peeling open the top of the wrapper.

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© 2017 Cepheid

Remove the swab, taking care not to touch the tip or lav it down. If the soft tip is touched, the swab is laid down, or the swab is dropped, request a new collection kit.



Gently rotate the swab for 10 - 30 seconds. Ensure the swab touches the walls of the vagina so that moisture is absorbed by the swab. Withdraw the swab and continue to hold it in your hand.



WARNING: If the contents of the tube are spilled on your skin, wash the affected area with soap and water. If the contents of the tube are splashed in your eyes, immediately flush your eyes with water. Notify your doctor, nurse or care-provider if irritation develops. If the contents of the tube are spilled, your test result may be invalidated. Do not take internally.



Hold the swab in your hand, placing your thumb and forefinger in the middle of the swab shaft



Identifying the scoreline on the collection swab shaft, carefully break the swab shaft against the side of the tube at the scoreline. If needed, gently rotate the swab shaft to complete the breakage. Discard the top portion of the swab shaft. Avoid splashing contents on the skin. Wash with soap and water if exposed.



- Re-cap the transport tube and tighten the cap securely.
- Return the tube as instructed by your doctor, nurse or care-provider.
- Note: Health care provider should invert or gently shake the tube 3-4 times to elute material from the swab. Avoid foaming. Label the transport tube with the sample identification information. including date of the collection, as required.







across the scoreline.

Carefully insert the swab into your vagina about 5 cm (two inches) inside the opening of the vagina.



In Vitro Diagnostic Medical Device



CE IVD

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Pharyngeal Swabs



- Five landmarks
 - Bilateral tonsils
 - Bilateral posterior walls
 - Uvula

Clinician-Collected Pharyngeal Swab

Clinician-Collected Pharyngeal Swab Specimen Collection For use with Xpert® Swab Specimen Collection Kit – Catalog #SWAB/G-50

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Wash hands before starting. Open the individual collection package () that contains the pink-capped Xpert Swab Transport Reagent tube and individually wrapped collection swab. Set the tube aside before beginning to collect sample. Discard the larger swab

Open the collection swab wrapper by peeling open the top of the wrapper. Remove the swab, taking care not to touch the tip or lay it down.

If the soft tip is touched, the swab is laid down, or the swab is dropped, use a new collection kit.

Hold the swab in your hand. placing your thumb and

forefinger in the middle of the





Instruct the patient to open mouth widely. Position the tongue toward the bottom of the mouth. Swab areas of the pharvnx (tonsil, posterior wall, uvula, posterior wall).



While holding the swab in the same hand. unscrew the cap from the Xpert Swab Transport Reagent tube. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new collection kit. Immediately place the collection swab into the transport reagent tube. WARNING: If the contents of the tube are

spilled on your skin, wash the affected area with soap and water. If the contents of the tube are splashed in your eyes, immediately flush your eyes with water.

Identifying the scoreline on the collection swab shaft, carefully break the swab shaft against the side of the tube at the scoreline and discard the top portion of the swab shaft. If needed, gently rotate the swab shaft to complete the breakage. Avoid splashing contents on the skin. Wash with soap and water if exposed.





Re-cap the transport tube and tighten the cap securely.

Invert or gently shake the tube 3-4 times to elute material from the swab. Avoid foaming. Label the transport tube with the sample identification information, including date of the collection, as required.

Specimen should be transported at 2-30 °C.

Prior to testing, specimen may be stored for up to 60 days at 2-30 °C.



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Clinician-Collected Endocervical Collection

Endocervical Specimen Collection

The Xpert Vaginal/Endocervical Specimen Collection kit contains Individual Collection Kit Cleaning Swab





Remove excess mucus from the cervical os and surrounding mucosa using the large individually wrapped cleaning swab 0. Discard the swab.

Open package O that contains the pink-capped Xpert Swab Transport Reagent tube and the individually wrapped collection swab. Set the tube aside before beginning to collect sample. Open the collection swab wrapper by peeling open the top of the wrapper. Remove the swab, taking care not to touch the tip or lay it down. If the soft tip is touched, the swab is laid down, or the swab

is dropped, use a new Xpert Vaginal/Endocervical Specimen

Hold the swab in your hand, placing your thumb and forefinger in the middle of the swab shaft.

Collection Kit.





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swab clockwise for 10-30 seconds in the endocervical canal. Withdraw the swab carefully.

Insert the collection swab into the

endocervical canal. Gently rotate the

While holding the swab in the same hand, unscrew the cap from the Xpert Swab Transport Reagent

tube. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new collection kit. Immediately place the collection swab into the transport reagent tube.

WARNING: If the contents of the tube are spilled on your skin, wash the affected area with soap and water. If the contents of the tube are splashed in your eyes, immediately flush your eyes with water. Notify your doctor, nurse or care-provider if irritation develops. If the contents of the tube are spilled, your test result may be invalidated. Do not take internally.

Identify the scoreline on the collection swab shaft. Carefully break the swab shaft against the side of the tube at the scoreline. If needed, gently rotate the swab shaft to complete the breakage. Discard the top portion of the swab shaft.

Use care to avoid splashing the contents. Wash with soap and water if exposed.

Re-cap the swab transport reagent tube and tighten the cap securely. Invert or gently shake the tube 3-4 times to elute material from the swab. Avoid foaming.

Label the transport tube with the sample identification information, including date of the collection, as required.











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Clinician-Collected Rectal Swab

Clinician-Collected Rectal Swab Specimen Collection For use with Xpert[®] Swab Specimen Collection Kit – Catalog #SWAB/G-50

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Wash hands before starting. Open the individual collection package (1) that contains the pink-capped Xpert Swab Transport Reagent tube and individually wrapped collection swab. Set the tube aside before beginning to collect sample. Discard the larger swab

Open the collection swab

the tip or lay it down.

kit.

3

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wrapper by peeling open the

top of the wrapper. Remove the

swab, taking care not to touch

If the soft tip is touched, the

swab is laid down, or the swab

is dropped, use a new collection



While holding the swab in the same hand. unscrew the cap from the Xpert Swab Transport Reagent tube. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new collection kit. Immediately place the collection swab into the transport reagent tube.

WARNING: If the contents of the tube are spilled on your skin, wash the affected area with soap and water. If the contents of the tube are splashed in your eyes, immediately flush your eyes with water.

Identifying the scoreline on the collection swab shaft, carefully break the swab shaft against the side of the tube at the scoreline and discard the top portion of the swab shaft. If needed, gently rotate the swab shaft to complete the breakage. Avoid splashing contents on the skin. Wash with soap and water if exposed.





Hold the swab in your hand, placing your thumb and forefinger in the middle of the swab shaft across the scoreline.



Carefully insert the swab approximately 1 cm beyond the anal sphincter (so that the fiber tips are no longer visible), and rotate gently.



Re-cap the transport tube and tighten the cap securely.

Invert or gently shake the tube 3-4 times to elute material from the swab. Avoid foaming. Label the transport tube with the sample identification information, including date of the collection, as required.

Specimen should be transported at 2-30 °C.

Prior to testing, specimen may be stored for up to 60 days at 2-30 °C.





Testing: How Often?

- After each partner/exposure
 - Repeat partner is a new partner
 - Exposure examples: needle stick, blood/body fluid exposure, drug use
 - Three-Site testing based on risk since last tested
- Frequent new partners or exposures
 - Every 1-3 months
- Monogamous relationship with one person
 - Annually, if desired





Wyoming Department of Health Communicable Disease Unit 6101 Yellowstone Road, Suite 510 Cheyenne, WY 82002 Phone: (307) 777-3562 Secure Fax: (307) 777-5279

Wyoming Department of Health Communicable Disease Snapshot of Screening Recommendations									
At Risk Populations	HIV	Hepatitis B*	Hepatitis C	Syphilis	Chlamydia	Gonorrhea	TB		
1945-1965 birth cohort (Baby Boomers)	X		X						
As indicated by employment (e.g. healthcare or congregate settings)							х		
Active tuberculosis (TB) disease	Х								
Recipient of blood transfusions, blood components, or organ transplant prior to July 1992	х	x	x						
Born in Asia, Africa or South America	Х	X					х		
Born in Latin America, Caribbean, Africa, Eastern Europe, and Russia	Х						х		
Current or past long-term hemodialysis	Х	X	х						
Current or past history of homelessness	Х						х		
Current or past history of injection drug use or other intranasal illicit drug use	Х	X	X				х		
Current or past resident of detention or correction facility	Х		X		X	х	х		
Hepatitis B or C positive sexual contact (as indicated)	Х	X	х		х	х			
Household contact to Hepatitis B positive individuals	Х	X							
History of prior sexually transmitted diseases (STD)	Х				х	х			
HIV infected		х	х	Х	X	x	х		
Household contact of patients with active TB disease							х		
Men who have sex with men (MSM)	Х	Х	х	x	х	х			
More than one sex partner in last 60 days	Х			Х	X	x			
New sex partner in the last 60 days	Х				х	х			
Parents born in Asia, Africa, or South America	х	X							
Pelvic inflammatory disease (PID)	Х				x	х			
Pregnant women	х	X		х	x	x			
Recipient of clotting factor or blood concentrate prior to 1987	Х		х						
Sexual contact with a STD positive individual (as indicated)	Х			х	X	x			
Sexually active males and females < 25 years old	Х				х	х			
Symptoms consistent with disease (as indicated)	X	x	х	х	x	х	Х		
Consistently abnormal liver tests		х	х						
Travelers with prolonged stays in countries where TB is endemic							Х		
Underlying immunocompromising conditions/immunosuppressive (including chemo) therapy	x	x					x		
DO NOT screen solely on risks listed; complete the resp *Prior to Hepatitis B testing, check WyIR for vaccination status. Fully vaccinate					-	ailure is suspec	ted.		

Updated 10/2018

https://health.wyo.gov/wp-content/uploads/2020/04/Wyoming-Department-of-Health-CommunicableDiseaseScreeningRecommendations_10-2018.pdf