STD Update

NC State Laboratory of Public Health

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STD Update Objectives

- Review progress of conversion to vaginal swabs for CT/GC NAAT testing and use of new request form
- Describe appropriate process for collecting and submitting vaginal swab specimens to the State Laboratory, including reasons for Unsatisfactory specimens
- Discuss status of technology for rectal and pharyngeal NAAT testing for CT/GC
- Provide updates in HIV and Syphilis testing areas

Conversion to Vaginal Swabs for Chlamydia/Gonorrhea Testing

- Per CDC 2010 Sexually Transmitted Diseases Guidelines, optimal specimen type for NAAT on females is vaginal swab
- Advantages include patient self-collection options
- Vaginal swabs also replaced the limited urine testing offered to select patient populations in Family Planning clinics
- SLPH began changing from endocervical swabs to all vaginal swabs in February 2011

Conversion to Vaginal Swabs for Chlamydia/Gonorrhea Testing

- Feb through Aug 2011 – SLPH accepted both endocervical and vaginal specimens as EC collection kits were depleted in field
- Effective Sept 1, 2011, vaginal swab specimens are the only acceptable specimen type at SLPH
- Test request form DHHS #4011 revised to replace "Endocervical" Specimen Source check off box with "Vaginal" Specimen Source check off box (new form available at http://slph.ncpublichealth.com/Forms/4011-20110608.pdf)
- New PPT "Chlamydia/Gonorrhea Vaginal Specimen Collection and Form Training" posted on SLPH website at http://slph.ncpublichealth.com

CHLAMYDIA / GONORRHEA

Vaginal Specimen Collection and Form Training

NC State Laboratory of Public Health

2011

Chlamydia / Gonorrhea Training Objectives

This training was developed to provide instruction in the collection of vaginal specimens for chlamydia/gonorrhea testing and the completion of test request form DHHS #4011.

At the conclusion of the training, participants should be able to:

- Determine if the patient meets the testing criteria established by the laboratory
- Correctly complete the test request form to accurately indicate testing eligibility
- Properly collect a vaginal specimen and submit the specimen to the laboratory using the GenProbe vaginal specimen collection kits
- Recognize reasons for unsatisfactory Chlamydia/GC test results because of improper collection or submission

Who is Tested?

- Women aged 24 years old and under
- Women of any age who have symptoms
- Pregnant women
- Women with a high-risk history (new partner or multiple partners)
- Women having an IUD inserted
- Women with contact to a known positive case
- Retest of a positive result three months later

Chlamydia / Gonorrhea Detection Request Form (DHHS #4011)

The top sections (1-8) contain patient demographics and submitter information. ►

The middle section (9) contains information about the patient visit. ►

The next section contains instructions and an area for laboratory use only. ►

Section 9: THIS SECTION MUST BE COMPLETED

- Fill in this section completely, including specimen source, signs/symptoms, pregnancy status, and reason for visit
- This information is required for all patients, regardless of the patient's age or the clinic in which the patient is seen
- Continuation of grant funding for testing is dependent upon complete and accurate collection of data

[9] **This Section Must Be Completed**

Test Requested:	Specimen Source:	Signs/Symptoms:	Pregnancy Status:
☒ Chlamydia Detection	❑ Vaginal	❑ Yes	❑ Yes
☒ Gonorrhea Detection	❑ Urine	❑ No	❑ No
	❑ Other _____		
Reason for Visit:			
❑ Volunteer/Medical Problem	❑ Annual Visit (FP)	❑ Prenatal Visit	❑ High Risk History
❑ Initial Visit (FP)	❑ Sex Partner Referral	❑ IUD Insertion	❑ Retest (3 months)

Vaginal Specimen Collection

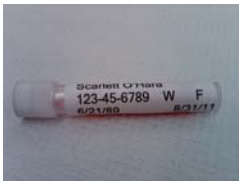
The video clip that follows will demonstrate the proper collection of a vaginal swab specimen.

Vaginal Specimen Collection
Important Reminders

- The vaginal collection kit consists of an orange-labeled tube and a pink-shafted swab
- The swab has a gray scoreline halfway up the shaft
- The swab **MUST** be broken directly on the gray scoreline or the specimen will not be acceptable for testing
- Specimen collection posters are available in English & Spanish – call lab to request

CT/GC Submissions
Important Reminders

- Adhere to testing criteria to ensure specimen will be tested
- Complete all sections of test request form
- Label specimen collection tube correctly



CT/GC Submissions
Important Reminders

- Store vaginal collection kits at room temperature prior to use
- Once collected, vaginal specimens are satisfactory for testing when held at room temperature for up to 60 days
- Check expiration dates on collection kits - sample will be deemed UNSAT if kit expiration date precedes collection date

Most Common Reasons for Unsat CT/GC Submissions

- Does not meet testing criteria
- Mislabeled sample/request mismatch
- Improperly collected sample – swab not broken correctly
- Transport medium leaked
- No submitter marked on request form

Status of CT/GC NAAT for Rectal/Pharyngeal Samples

- Per CDC 2010 Sexually Transmitted Diseases Guidelines, NAATs are recommended for detection of rectal and oropharyngeal infections caused by C. trachomatis and N. gonorrhoeae
- Testing of these specimen types have not been cleared by the FDA for use with NAATs
- Laboratories must establish performance specifications to satisfy CMS regulations for CLIA compliance prior to reporting results for patient management
- Testing not available yet at SLPH

HIV Update

- SLPH HIV test volume remains stable at approx. 240,000 screening tests/year
- FDA has approved two 4th generation HIV p24 Ag/Ab Combination assays - Abbott Diagnostics & BioRad
- Assays detect both acute & chronic infection; narrows "window period" between infection and detection
- Expected to replace existing test algorithms that use pooled NAAT for detection of acute cases
- Changes to HIV scannable form

Meet FANUC – Our Newest Employee!

☹ *Warning: Improperly submitted samples may cause FANUC to take a sick day*

Reminders for HIV Submissions

- Ensure that patient ID information on test request **exactly matches** information on sample tube label
  - Full first and last name and either SSN, DOB, or other unique ID number
- Correctly apply specimen labels to tubes
- Sample volume needed for HIV testing: **3.0 mL**
- Clerical errors
  - Continue to fax requests for corrections to reports

Syphilis Update

- SLPH uses traditional screening test algorithm
  - TRUST for non-treponemal screening
  - Titer if TRUST Reactive
  - Confirm with TrepSure EIA
- Since TrepSure detects both IgM and IgG antibodies, few "equivocal" confirmatory results (<0.3%)
- No plans at the present time to "flip" the algorithm

New DHHS #3446 Request Form

- Download from SLPH website http://slph.ncpublichealth.com/Forms/4011-20110608.pdf
- Print on white paper only (No pink paper, please)
- Include submitter information on all test requests


Syphilis Screening Serology

Reminders for Syphilis Submissions

- Provide two matching identifiers on sample and form
  (full first and last name and either SSN, DOB, or other unique ID)
- Indicate screening titer on requests for confirmatory testing
- Use correct mailers:
  white label/SYPHILIS for TRUST
  blue label/SPECIAL SEROLOGY for TrepSure
- Don't include Rubella samples with Syphilis samples

Questions???