DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

March 13, 2014

Dear Colleagues,

Today the U.S. Centers for Disease Control and Prevention (CDC) released *Recommendations for the Laboratory-Based Detection of Chlamydia trachomatis and Neisseria gonorrhoeae — 2014* in its *Morbidity and Mortality Weekly Report* (MMWR). This report updates CDC's 2002 recommendations for screening tests to detect *Chlamydia trachomatis* and *Neisseria gonorrhoeae* infections, and provides new recommendations regarding optimal specimen types, the use of tests to detect rectal and oropharyngeal *C. trachomatis* and *N. gonorrhoeae* infections, and circumstances when supplemental testing is indicated.

The recommendations in this report are intended for use by clinical laboratory directors, laboratory staff, clinicians, and disease control personnel who must choose among available tests, establish standard operating procedures for collecting and processing specimens, interpret test results for laboratory reporting, and counsel and treat patients.

The full recommendations can be found on CDC's STD Laboratory Information page, highlights of the recommendations include:

Nucleic acid amplification tests (NAATs) that are FDA cleared are recommended for detection of genital tract infections caused by *C. trachomatis* and *N. gonorrhoeae* infections in men and women with and without symptoms. Optimal specimen types for NAATs are vaginal swabs from women and first catch urine from men. Older non-culture tests and non-NAATs are no longer recommended.

NAATs have not been cleared by the U.S. Food and Drug Administration (FDA) for the detection of rectal and oropharyngeal infections caused by *C. trachomatis* and *N. gonorrhoeae* but are recommended based on increased sensitivity, ease of specimen transport and processing. Because NAATs are not cleared by the FDA for testing specimens collected from extragenital anatomic sites, laboratories must establish performance specifications according to Centers for Medicare and Medicaid Services (CMS) regulations for Clinical and Laboratory Improvement Amendments (CLIA) compliance and/or local or state regulations as applicable prior to reporting results for patient management.

Routine repeat testing of NAAT-positive genital tract specimens is not recommended since the practice does not improve the positive predictive value of the test.

Previous CDC recommendations to use NAATs for the detection of chlamydia and gonorrhea as the standard laboratory test remain. However, the recommendations advise against using NAATs in the following circumstances:

- in cases of child sexual assault involving boys;
- rectal and oropharyngeal infections in prepubescent girls; and
- when evaluating a potential gonorrhea treatment failure, in which case culture and susceptibility testing might be required.

Laboratory interpretation of test results should be consistent with product inserts for FDA cleared tests or have met all federal and state regulations for a modified procedure if the laboratory has changed the cutoff values or testing algorithm. This approach provides the most appropriate information to the clinician, who is ultimately responsible for assessing test results to guide patient and partner management. Despite the increased use of NAATs, it is still important to maintain the capability to culture for both *N. gonorrhoeae* and *C. trachomatis* in laboratories throughout the country. Data are insufficient to recommend nonculture tests in cases of sexual assault in prepubescent boys and extragenital anatomic site exposure in prepubescent girls. Further, *N. gonorrhoeae* culture is required to evaluate suspected cases of gonorrhea treatment failure and to monitor developing resistance to current treatment regimens. Chlamydia culture also should be maintained in some laboratories to monitor future changes in antibiotic susceptibility and to support surveillance and research activities such as detection of lymphogranuloma venereum or rare infections caused by variant or mutated *C. trachomatis*.

Questions about these recommendations should be directed to your local/state STD Director, or you can send an email to dstdpd@cdc.gov.

I'd like to thank staff across CDC, the Association of Public Health Laboratories, and the public health laboratorians, STD researchers, STD clinicians, STD Program Directors and representatives from FDA and CMS who served on an advisory panel to develop these recommendations.
Best Regards

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