Public Health Advisory

Reporting of Specimen Site for *Neisseria gonorrhoeae* and/or *Chlamydia trachomatis* Laboratory Testing

June 26, 2015

Situation:

Neisseria gonorrhoeae and/or *Chlamydia trachomatis* infections historically have been detected by either culture or nucleic acid amplification tests (NAATs). Most commercial NAATs have been cleared by the Food and Drug Administration (FDA) to detect *C. trachomatis* and/or *N. gonorrhoeae* in vaginal and endocervical swabs from women, urethral swabs from men, and first catch urine from both men and women[2]. Urine specimens have become the most common and easily collected specimen for NAAT testing. The Centers for Disease Control and Prevention (CDC) now recommends that, in addition to a urine specimen, asymptomatic patients in specific populations be tested using oropharyngeal and rectal specimens for these infections.[2] Disease from these specimen sites is often overlooked due to its asymptomatic nature, and medical providers who serve these populations are making efforts to increase this type of testing.[1]

The Southern Nevada Health District (SNHD) is requesting that laboratories include the specific specimen site, such as vaginal, endocervical, urethral, oropharyngeal (throat), rectal (anal), or urine, as ordered by the medical provider, with the test result that indicates the presence of *N. gonorrhoeae* or *C. trachomatis*. SNHD is making this request in accordance with Nevada Administration Code 441A.235(f), which states that the director or other person in charge of medical laboratory must provide "Any other information requested by the health authority, if available."

CDC is recommending NAATs to test for extra-genital infections based on increased sensitivity, ease of specimen transport and processing. Because these specimen types have not been cleared by FDA for use with NAATs, laboratories must establish performance specifications when using these specimens to meet Clinical Laboratory Improvement Amendments (CLIA) regulatory requirements and local or state regulations as applicable prior to reporting results for patient management.[2]

For Laboratories:

1. Include the specimen site when reporting results of any test indicating the presence of *N. gonorrhoeae* or *C. trachomatis*

References

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1. Full report Update to CDC's Sexually Transmitted Diseases Treatment Guidelines, 2015: Special Populations (MMWR Weekly, June 5, 2015 / 64(3); 9-17). Available at: http://www.cdc.gov/std/tg2015/default.htm
2. Papp JR, Schachter J, Gaydos C, et al. Recommendations for the laboratory-based detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*--2014. MMWR Recomm Rep 2014;63(No. RR-02).
3. Kent, Charlotte K., et al. "Prevalence of rectal, urethral, and pharyngeal Chlamydia and Gonorrhea detected in 2 clinical settings among men who have sex with men: San Francisco, California, 2003." Clinical Infectious Diseases41.1 (2005): 67-74.

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