DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Centers for Disease Control and Prevention (CDC), Atlanta, GA 30329

Atlanta, October 9, 2015

Re: Submission of specimens for CDC Laboratory confirmation of LGV infection

Dear Submitter,

The STD Laboratory Branch (Laboratory Reference and Research Branch) of the CDC Division of STD Prevention has capability to perform a real-time PCR test for confirmation of Lymphogranuloma Venereum (LGV) infection. This letter provides guidance for specimen submission for LGV-specific PCR testing

- The test purpose is epidemiologic research and outbreak investigation; is not a CLIA regulated test and therefore the results cannot be used for clinical management of patients
- Test specifications and validation data have been published previously (Chen et al, Sex Transm Infect. 2008 Aug; 84 (4):273-6)
- Only specimens from probable LGV cases (as per the case definition developed by MI DHHS in 2015) should be sent to the CDC for testing. This means presence of the described clinical findings, and the specimen must have tested positive for *C. trachomatis* by a commercial NAAT test prior to shipment to CDC.
- The test was developed for use on rectal specimens. Rectal/anal specimens will be accepted. The following specimens will also be considered but test performance has not been well established: Swabs of genital ulcers or suspected skin lesions in the proximity of the anogenital area, and bubo aspirates.
- Swabs in transport media used for all commercially available NAATs for *C. trachomatis* can be accepted (for a list, please see Centers for Disease C, Prevention. Recommendations for the laboratory-based detection of Chlamydia trachomatis and Neisseria gonorrhoeae--2014. MMWR Recomm Rep. Mar 14 2014;63(RR-02):1-19.). CDC prefers receiving an additional swab collected in AssayAssure transport medium for optimal assay performance. We can provide AssayAssure transport medium for LGV testing (contact Dr. Allan Pillay, email: AJP7@cdc.gov; phone 404-639-2140).
- For best results, submit specimens frozen (store at -20 ^{0}C, and submit on dry ice). Room temperature or refrigerated specimens (shipped with frozen ice packs) will be accepted if the commercial NAAT transport media is cleared for such temperature conditions.

- Specimen submissions must first be approved by the State or Local Public Health Laboratory and CDC (Dr. Allan Pillay, email: AJP7@cdc.gov; phone 404-639-2140).
- Use CDC Form 50.34 (http://www.cdc.gov/laboratory/specimen-submission/form.html) and test order CDC-10192 (*Chlamydia trachomatis*, Genital - Molecular Detection) for specimen shipment. Fill in "At CDC, bring to the attention of Dr. Allan Pillay (user ID AJP7@cdc.gov)". Please notify Dr. Pillay when sending a sample.
- Results will be communicated to the specimen submitter via encrypted email unless otherwise requested.
- Expected results include a) confirmation of LGV (includes genotypes L1, L2, or L3), b) absence of LGV with or without confirmatory detection of *C. trachomatis*, or c) inconclusive results due to insufficient sample quality as indicated by internal assay control performance.

We hope this information is helpful to your program, and look forward to serving you.

Sincerely,

Ellen Kersh

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