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, see enclosure) 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 (see enclosed table for a transport media list). 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

E. Kersh, PhD; STD Laboratory Branch Chief (LRRB, Laboratory Reference and Research Branch), Division of STD Prevention (DSTDP), NCHHSTP, CDC; 1600 Clifton Rd NE, MS A12, Bldg 23, rm 3-161, Atlanta, GA 30329; ph 404 639 2728; blackberry 404 784 9248

Enclosures

LGV case definition developed by the Michigan Department of Health and Human Services in October 2015

Transport media table

FDA Cleared Specimen Types and Requirements for the Transport and Storage of Specimens for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* by Nucleic Acid Amplification Test (NAAT) Type

FDA Cleared* NAAT	**FDA Cleared* Specimen Types**	**Specimen Transport and Storage Conditions**
Abbott RealTime CT/NG (Abbott Molecular Inc, Des Plaines, IL)	Asymptomatic women: clinician-collected vaginal swab, patient-collected vaginal swab in a clinical setting, and urine. Asymptomatic men: urine. Symptomatic women: endocervical swab, clinician-collected vaginal swab, patient-collected vaginal swab in a clinical setting, and urine. Symptomatic men: urethral swab and urine.	≤14 days at 2 to 30°C. ≤90 days at -10°C or lower. Thaw frozen specimens at 2 to 30°C. Specimens must not undergo more than four freeze/ thaw cycles.
APTIMA COMBO 2® Assay APTIMA® CT Assay APTIMA® GC Assay (Gen-Probe Incorporated, San Diego, CA)	Asymptomatic women: endocervical swab, clinician-collected vaginal swab, patient-collected vaginal swab in a clinical setting, gynecologic specimens collected in PreservCyt™solution and urine. Asymptomatic men: urethral swab and urine. Symptomatic women: endocervical swab, clinician-collected vaginal swab, patient-collected vaginal swab in a clinical setting, gynecologic specimens collected in PreservCyt™solution and urine. Symptomatic men: urethral swab and urine.	≤24 hours at 2 to 30°C (urine specimen in primary cup). ≤30 days at 2 to 30°C (urine specimen in Aptima urine transport tube). ≤60 days at 2 to 30°C (swab in Aptima swab transport tube). ≤12 months at -20 to -70°C (urine specimen and swab specimens in respective Aptima transport tubes).
BD ProbeTec™ ET CT/GC Amplified DNA Assay (Becton Dickinson and Company, Sparks, MD)	Asymptomatic women: endocervical swab and urine. Asymptomatic men: urethral swab and urine. Symptomatic women: endocervical swab and urine. Symptomatic men: urethral swab and urine.	≤30 hours at 2 to 30°C (urine specimen in primary cup). ≤7 days at 2 to 8°C (urine specimen in primary cup) ≤30 days at 2 to 30°C (urine specimen in urine processing tube) ≤60 days at -20°C or lower (neat urine specimen or urine in urine processing tube) ≤6 days at 2 to 27°C (swab specimens) ≤30 days at 2 to 8°C (swab specimens)

BD ProbeTec™ Q^X CT Amplified DNA Assay BD ProbeTec™ Q^X GC Amplified DNA Assay (Becton Dickinson and Company, Sparks, MD)	Asymptomatic women: endocervical swab, patient-collected vaginal swab in a clinical setting, gynecologic specimens collected in BDSurePath™ or PreservCyt™ solution and urine. Asymptomatic men: urethral swab and urine. Symptomatic women: endocervical swab, patient-collected vaginal swab in a clinical setting, gynecologic specimens collected in BDSurePath™ or PreservCyt™ solution and urine. Symptomatic men: urethral swab and urine.	≤30 hours at 2 to 30°C (urine specimen in primary cup). ≤7 days at 2 to 8°C (urine specimen in primary cup) ≤30 days at 2 to 30°C (urine specimen in urine processing tube) ≤180 days at -20°C or lower (neat urine specimen or urine in urine processing tube) ≤30 days at 2 to 30°C (endocervical and urethral swab specimens) ≤180 days at -20°C or lower (endocervical and urethral swab specimens) ≤14 days at 2 to 30°C (dry vaginal swab specimens) ≤30 days at 2 to 30°C (expressed vaginal swab specimens ≤180 days at -20°C or lower (dry or expressed vaginal swab specimens
Xpert® CT/NG Assay (Cepheid, Sunnyvale, CA)	Asymptomatic women: endocervical swab, patient-collected vaginal swab in a clinical setting, and urine. Asymptomatic men: urine. Symptomatic women: endocervical swab, patient-collected vaginal swab in a clinical setting, and urine. Symptomatic men: urine.	≤24 hours at room temperature (female urine specimen in primary cup). ≤3 days at room temperature (male urine specimen in primary cup). ≤8 days at 4°C (female and male urine specimen in primary cup). ≤3 days at 15 to 30°C (female urine specimen in Xpert CT/NG Urine Transport Reagent tube). ≤45 days at 2 to 15°C (female urine specimen in Xpert CT/NG Urine Transport Reagent tube).

		≤45 days at 2 to 30°C (male urine specimen in Xpert CT/NG Urine Transport Reagent tube). ≤45 days at 2 to 30°C (swab in Xpert CT/NG Swab Transport Reagent tube).
cobas® CT/NG test (Roche Diagnostics, Indianapolis, IN)	Asymptomatic Women: Patient-collected Vaginal swab in a clinical setting. Asymptomatic men: urine. Symptomatic Women: Self-collected Vaginal swab in a clinical setting. Symptomatic men: urine.	≤ 1 yr. at 2 – 30°C (swab or urine specimen in cobas PCR media) 24 hrs. 2 – 30°C (Neat male urine specimen prior to addition to cobas PCR media)

* FDA cleared NAATs and specimen types as of May 1, 2013