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Letter to the Editor

Update on the availability of commercialized real-time PCR assays for the diagnosis of Lymphogranuloma venereum

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To the Editor,

The diagnosis of Lymphogranuloma venereum (LGV) is of therapeutic interest because treatment requires 3 weeks of doxycycline compared with 1 week for an infection with a non-L genovar. The European guideline on the management of LGV recommends that all men who have sex with men with a *Chlamydia trachomatis* positive anorectal sample, irrespective of symptomology, should be tested for LGV [1]. Ideally, appropriate LGV routine molecular diagnostics should be available in all countries, which could also be centralized at some national reference centres or similar types of expert laboratories. Recently at the Fifteenth International Symposium on Human Chlamydial Infections (San Antonio, Texas, USA; June 2022), a talk about "the current landscape of chlamydia diagnostics" mentioned that "the largest missing laboratory-based diagnostic element specifically for chlamydia is a test that identifies LGV". In this letter, we wanted to remind the medical and scientific community that commercialized nucleic acid amplification tests exist for LGV diagnostic. There is a single-plex kit (RealCycler CHSL-U/CHSL-G [Progenie Molecular]) that is intended for use as a second-line diagnostic method, to detect LGV in *C. trachomatis* positive specimens, as recommended by European guidelines [1,2]. There are also multiplex nucleic acid amplification tests for genital ulcerative diseases: (a) the Real-Cycler Universal ULCGEN-U/ULCGEN-G (Progenie Molecular) allowing the detection of herpes simplex virus (HSV), *Treponema pallidum,* and *C. trachomatis* genovars L; (b) the Allplex Genital Ulcer Assay (Seegene) for the diagnosis of HSV-1, HSV-2, *Haemophilus ducreyi*, cytomegalovirus, *T. pallidum*, and *C. trachomatis* genovars L; and (c) the VIASURE *H. ducreyi* + *C. trachomatis* LGV Real-Time PCR Detection Kit (CerTest BIOTEC) detecting *H. ducreyi* and *C. trachomatis* genovars L. These four kits have been evaluated on *C. trachomatis* positive anorectal specimens and showed very good performance for LGV diagnosis [2,3].

Recently, the duplex VIASURE *H. ducreyi* + CT LGV Real-Time PCR Detection Kit (CerTest BIOTEC) was modified by the manufacturer and is currently only available in a single-plex format. The VIASURE *C. trachomatis* (LGV) Real-Time PCR Detection Kit is designed for the specific identification of DNA from LGV-associated strains of *C. trachomatis* in anorectal samples. It has the same technical specifications as its duplex counterpart, i.e. TaqMan real-time PCR with an internal control included. As no data were available in the literature about this kit, we evaluated its performances on 90 anorectal *C. trachomatis* positive specimens prospectively collected in 2022 by the French National Reference Centre for bacterial sexually transmitted infections. There were 45 LGV and 45 non-LGV anorectal specimens. LGV diagnostic was performed in our centre using a genovar L-specific real-time single-plex PCR assay targeting the *pmp*H gene [4]. Sequencing of the *omp*A gene for genovars L [5] showed a predominance of L2 genovar (44.4%, 20/45), followed by six different L2b genovariants (22.2%, 10/45) (L2b [n = 2], L2bv1 [n = 1], L2bv2 [n = 1], L2bv6 [n = 3], L2bv11 [n = 2], and L2b/D-Da [n = 1]) and L1 genovariant (15.5%, 7/45). Sequencing of the *omp*A gene was unsuccessful for eight samples. All the tests with the VIASURE *C. trachomatis* (LGV) Real-Time PCR Detection Kit were performed according to the manufacturer's instructions. Amplification was carried out on a LightCycler 480 II real-time PCR system (Roche diagnostics). Overall, the VIASURE *C. trachomatis* (LGV) Real-Time PCR Detection kit detected L genovars of *C. trachomatis* in all the 45 LGV-positive

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specimens, showing an overall agreement of 100% (95% CI, 95.9–100) with the reference methods used in the National Reference Centre and clinical sensitivity and specificity of 100% (95% CI, 92.1–100), respectively. Nevertheless, one limitation of this study is the small number of specimens tested.

All commercialized kits evaluated for LGV diagnosis target the unique 36-bp deletion of the *pmp*H gene, which is specific to all LGV genovars. For all these assays, IVDR approval is ongoing.

To improve routine LGV diagnostics, it is important to keep the chlamydial community updated regarding the availability of commercialized assays for the identification of L genovars of *C. trachomatis*. Expanded availability of LGV diagnosis will promote research and surveillance. Their widespread use in laboratories will provide results in a time frame that can influence clinical management.

Author contributions

All authors are listed in order of appearance in the author's list:

Conceptualization, methodology, formal analysis, and writing–original draft were done by A.T.

Writing–review and editing was done by C.B.

Methodology, writing–review and editing were done by O.P.

Transparency declaration

The authors declare that they have no conflict of interest. They certify that they have not received any contributions from industrials in the last 3 years.

References

[1] de Vries HJC, de Barbeyrac B, de Vrieze NHN, Viset JD, White JA, Vall-Mayans M, et al. 2019 European guideline on the management of lymphogranuloma venereum. J Eur Acad Dermatol Venereol 2019;33:1821–8. https://doi.org/10.1111/jdv.15729.

[2] Touati A, Laurier-Nadalié C, Bébéar C, Peuchant O, de Barbeyrac B. Evaluation of four commercial real-time PCR assays for the detection of lymphogranuloma venereum in *Chlamydia trachomatis*-positive anorectal samples. Clin Microbiol Infect 2021;27:909e1–5. https://doi.org/10.1016/j.cmi.2020.07.040.

[3] Bernal-Martínez S, García Sánchez E, Sivianes N, Padilla L, Martin-Mazuelos E. Evaluation of 2 commercial assays for the detection of Lymphogranuloma Venereum in rectal samples. Sex Transm Dis 2020;47:162–4. https://doi.org/10.1097/OLQ.0000000000001120.

[4] Morré SA, Spaargaren J, Fennema JS, de Vries HJ, Coutinho RA, Peña AS. Real-time polymerase chain reaction to diagnose lymphogranuloma venereum. Emerg Infect Dis 2005;11:1311–2. https://doi.org/10.3201/eid1108.050535.

[5] Lan J, Ossewaarde JM, Walboomers JM, Meijer CJ, van den Brule AJ. Improved PCR sensitivity for direct genotyping of *Chlamydia trachomatis* serovars by using a nested PCR. J Clin Microbiol 1994;32:528–30. https://doi.org/10.1128/jcm.32.2.528-530.1994.

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