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B-273 Lymphogranuloma Venereum: Validation of a Real-Time PCR Kit for Its Rapid Diagnosis

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BACKGROUND: *Chlamydia trachomatis* serovars L1, L2 and L3 are responsible for lymphogranuloma venereum (LGV), a sexually

transmitted infection that causes ulcerated lesions and adenopathy. Following the procedures in Clinical Microbiology recommendations, rectal samples positive for *C. trachomatis* are processed to detect the LGV-producing serovars in order to provide appropriate treatment. Since European regulations require for CE and IVD certification that an in vitro diagnostic product must be validated by an external body, the aim of this study was to validate the VIASURE *C. trachomatis* (LGV) Real Time PCR Detection Kit from Certest Biotec SL, using DNAs characterized as positive or negative for LGV extracted from clinical samples previously analyzed in the Laboratory.

METHODS: A total of 214 DNAs from clinical samples collected between January 2021 and November 2022 were analyzed. Based on the initial diagnosis performed with the Allplex™ Genital ulcer Assay (Seegene®), 37 samples were positive for LGV and 177 were negative. The use of all data and samples was approved by the Aragon research ethics committee (CEICA) (PI20/426). The clinical sensitivity and specificity of the kit and the positive and negative predictive values (95% CI) were calculated with MetaDisc 1.4 software.

RESULTS: Results are summarized in Table 1.

CONCLUSION: The comparative analysis of the “VIASURE *C. trachomatis* (LGV) Real Time PCR Detection Kit” proved to be as sensitive and specific as the reference molecular assay. The main advantage is that VIASURE products feature a stabilized, ready-to-use format, reducing the number of time-consuming laboratory steps, avoiding possible contamination and allowing transport and storage at room temperature.

Table 1. Summary of obtained results.

True positive results	True negative results	False positive results	False negative results	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value
37	177	0	0	1(0.90–1)	1(0.98–1)	1(0.88–1)	1(0.97–1)