

TITLE: THE LIMITATIONS OF USING SERA IN REAL-TIME PCR TO HUMAN DIAGNOSIS OF LEPTOSPIROSIS

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ABSTRACT:

Leptospirosis, an acute febrile disease, is one of the most common zoonoses occurring worldwide mainly in tropical and temperate areas. Diagnosis of the early stage of leptospirosis is difficult since it has varied symptoms. Thus, the development of rapid and specific diagnostic tools which can achieve early detection of the disease before complications occur are deemed highly desirable. Culture methods are well established for leptospires but are technically demanding and time consuming, often taking several weeks to achieve observable growth. The microscopic agglutination test (MAT) is the gold standard test for serological diagnosis of leptospirosis. However, it is considered insensitive, especially with initial sample acquisition near the time of diseases onset. Usually, ELISA-IgM is used as a screening test. Molecular diagnosis such as real-time PCR assay has been reported as an alternative to conventional methods for early detection of leptospires. However, a major limitation of this molecular method is the difficulty associated with the choice of clinical specimens. The aim of the study was to evaluate the performance of real-time PCR assay using serum samples from patients suspected of having leptospirosis. The results of serum samples from patients were compared with serological tests. The most common serovars of *L. interrogans* such as Copenhageni, Canicola, Pomona, Wolffi, Castellonis were used as positive control of the Real-time PCR. Prospective serum samples from 194 patients with clinical symptoms of leptospirosis were tested by Real-time PCR, ELISA-IgM and MAT. From these patients, 110 were not confirmed as leptospirosis. From 84 patients with leptospirosis, 46 were positive by ELISA-IgM, 37 were positive by MAT and ELISA-IgM and one was positive by MAT, ELISA-IgM and by real-time PCR. Sera samples are not the ideal material for detection of leptospires by real-time PCR.

Keywords: Leptospirosis, Real-time PCR, serology, serum samples

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