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Evaluation of a real time Polymerase Chain Reaction (PCR) assay for the early diagnosis of human leptospirosis

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Leptospirosis has the greatest impact on health in developing countries where it is often grossly under-recognized due to difficulties in clinical diagnosis and lack of diagnostic laboratory services. The disease is usually diagnosed in the laboratory by serological techniques or by culturing of bacteria from clinical specimens which results in delayed diagnosis. The objective of this study was to establish and evaluate a real time Polymerase Chain Reaction (PCR) assay using SYBR green for early, rapid and definitive laboratory diagnosis of leptospirosis. The assay was established and analytical specificity and sensitivity were determined using reference DNA samples. The accuracy of the real time PCR assay was determined using a panel of acute blood samples collected from leptospirosis (n = 60) and non leptospirosis (n = 51) confirmed patients based on serological assays. The analytical sensitivity of the assay was approximately 58.8 genome equivalents per reaction and no cross-reactivity was observed with saprophytic *Leptospira* spp. and other pathogenic micro organisms. The assay successfully detected leptospiral DNA from blood samples of clinically diagnosed patients with leptospirosis and showed high diagnostic sensitivity 82.05% (32/39) and specificity 80.55% (58/72). This study showed that real time PCR has the potential to facilitate rapid and sensitive diagnosis of acute leptospirosis during the early phase of infection.

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