TITLE: EVALUATION OF IGM DOT BLOT USING N-BUTANOL ANTIGEN FROM *LEPTOSPIRA* SPP. FOR SERODIAGNOSIS OF HUMAN LEPTOSPIROSIS

AUTORS: BLANCO, R. M. [1,2]; LIMA, E. S. [1]; ROMERO, E. C. [1,2].

INSTITUTION: 1. INSTITUTO ADOLFO LUTZ – IAL – SP, São Paulo – SP (Av. Dr. Arnaldo, 351, 9º andar, Pacaembu, São Paulo – SP. CEP: 01246-000) - BRASIL; 2. PROGRAMA DE PÓS-GRADUAÇÃO EM DOENÇAS INFECCIOSAS E PARASITÁRIAS – FMUSP – SP (Av. Dr. Enéas de Carvalho Aguiar, 470, térreo, Cerqueira César, São Paulo - SP. CEP 05403-907) – BRASIL.

ABSTRACT

Leptospirosis is an infectious disease that is widespread over global regions and could be deadly in some cases. More than 300 serovars have been identified among leptospires, including serovar Copenhageni, the most frequent serovar in Brazil. The development of rapid and specific diagnostic tools which can achieve early detection of the disease before complications occur are deemed highly desirable. The aim of this study was to develop a simple, rapid and inexpensive test for diagnosis of human leptospirosis. A total of 296 serum samples from 148 patients diagnosed with leptospirosis were analysed by IgM Dot Blot using n-butanol antigen from *Leptospira interrogans* serovar Copenhageni and anti-human IgM antibody conjugated with alkaline phosphatase. The results were compared with those obtained with microscopic agglutination test (MAT), the gold standard reference serological method. Serum samples from 60 healthy blood bank donors and 88 individuals with positive test results for diseases other than leptospirosis, selected randomly and screened negative by the MAT test were used as negative controls to establish the specificity of the assay. Cases of leptospirosis were considered confirmed by MAT when demonstrated seroconversion in paired serum samples from the acute and convalescent period. The IgM Dot Blot was inspected visually by two independent observers who were blind to all information. The IgM Dot blot test showed a sensitivity of 47.2% (95% CI 39.0 – 55.7%) and 95.2% (95% CI 90.5 – 98.1%) in serum samples from patients with acute and convalescent leptospirosis, respectively. The specificity was 92.5% (95% CI 87.1 – 96.2%) with serum samples from negative control. The agreement of visual results between two independent observers was considered almost perfect with a kappa value of 0.99 (95% CI 0.97 - 1.00). This IgM Dot Blot could be a good alternative method for the diagnosis of leptospirosis. It could be used as an initial screen for leptospiral infection in all laboratories, with subsequent confirmation by MAT.

Keywords: Dot blot; leptospirosis; n-butanol; serodiagnosis

Development Agencies: IAL/SES - SP