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Evaluation of Rapid Spot Tests such as Latex Agglutination Test and Dot ELISA based on Recombinant LigB Protein for Detection of Anti-Leptospira Antibodies in Humans in India

Sabarinath T., Behera, S.K., Deneke, Y., Atif Ali, S., Ashok Kumar, Med Ram Verma and Chaudhuri, P.

Abstract—*Human leptospirosis, which is often referred to as Weil's disease is presented with a wide spectrum of clinical manifestations ranging from chronic nephritis (renal involvement), severe pulmonary haemorrhage, hepatitis, myocarditis (cardiac arrhythmias), meningitis and uveitis. Human sera (n=340) collected from different Indian states such as Odisha (n=170), Uttar Pradesh (n=100) and Karnataka (n=70) were screened using Microscopic Agglutination Test (MAT). Out of 340 sera screened, agglutinins against various leptospiral serovars were present in 66 human sera samples (seropositivity 19.41%). Most predominant serovars reported in this study was Icterohaemorrhagiae 47 (13.82%), followed by Grippotyphosa 26 (7.65%), Australis 10 (2.94%), Hebdomadis 03(0.88%), Hardjoprajitno 01(0.29%) and Autumnalis 01(0.29%). The inherent pitfalls of MAT such as handling of live leptospiral antigens, cumbersome mechanisms of recording test results and the need for paired sera samples to confirm disease which delays disease diagnosis have forced researchers to search for alternative field oriented tests. Hence, in this present study, a truncated recombinant antigen of 46 KDa which represented the N terminal conserved region of LigA and LigB (rconLigA/B) was chosen as the diagnostic antigen to develop field oriented spot tests such as Latex Agglutination Test (LAT) and Dot-ELISA to detect human leptospirosis. All the human sera (n = 340) subjected to MAT were further screened using recombinant rconLigA/B based LAT and Dot ELISA. The sensitivity of rconLigA/B based LAT and Dot-ELISA for 66 MAT positive sera were 90.90% and 95.46% respectively while the specificity of rconLigA/B based LAT and Dot-ELISA for 274 MAT negative sera was 99.43% and 99.36% respectively. Further, Kappa value of 0.93 and 0.96 for rconLigA/B based LAT and Dot-ELISA respectively indicates high agreement with MAT. The results obtained with these two spot tests indicates direct field applicability of these tests in resource poor settings prevalent in tertiary levels of human health care system.*