Lept8. **A novel point-of-care test for leptospirosis based on Dual Path Platform (DPP) technology to differentiate IgM and IgG antibody responses**

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Introduction: Improved diagnostics for leptospirosis are urgently needed, especially for resource-poor countries where leptospirosis is a major public health problem. The gold standard serodiagnostic test, the microagglutination test or MAT, is complex, time-consuming, labor-intensive, and unavailable in remote settings. **Materials and Methods:** A rapid (20 minutes) serodiagnostic test for leptospirosis was developed using recombinant leptospiral immunoglobulin-like (Lig) protein fragments and a modification of the Dual Path Platform (DPP) technology, namely dual DPP (D-DPP). The distinct feature of this new immunoassay format was that the test detects separately IgM and IgG antibodies such that each response can be measured semi-quantitatively by a reflectance reader device. The test was evaluated in a pilot study using acute (n=91) and convalescent-phase (n=96) serum samples from patients with confirmed leptospirosis and control individuals (n=50) from Brazil. **Results:** In this evaluation study, the D-DPP assay detected 80% of patients with acute-phase leptospirosis and 100% of patients with convalescent leptospirosis. The specificity was 100%. Among acute-phase cases, 60% developed both detectable IgM and IgG antibodies, 13% had only IgM, while 7% produced only IgG antibodies. During convalescence, 77%, 0%, and 23% of leptospirosis patients developed IgM and IgG, only IgM, and only IgG antibodies, respectively. **Conclusions:** We designed a recombinant Lig protein-based D-DPP assay which can rapidly identify patients with acute-phase or convalescent leptospirosis with high accuracy. The ability to detect IgM and IgG antibodies separately improves diagnostic specificity as well as detection of patients who present at different times in the course of illness. The test therefore has the potential to provide effective point-of-care diagnosis in field settings in Brazil and resource-poor countries worldwide where leptospirosis is an emerging health problem. **E-mail:**klyashchenko@chembio.com