Recombinant LipL32 protein developed using a synthetic gene detects leptospira-specific antibodies in human serum samples

ABSTRACT

Background: Synthetic biology is emerging as a viable alternative for the production of recombinant antigens for diagnostic applications. It offers a safe alternative for the synthesis of antigenic principles derived from organisms that pose a high biological risk.Methods: Here, we describe an enzyme-linked immunosorbent assay (ELISA) using the synthetic recombinant LipL32 (rLipL32) protein expressed in Escherichia coli for the detection of Leptospira-specific antibodies in human serum samples. The rLipL32-based ELISA was compared with a microscopic agglutination test (MAT), which is currently used as the gold standard for the diagnosis of leptospirosis.Results: Our results showed that all the MAT-positive serum samples were positive for Leptospira-specific IgG in an ELISA, while 65% (n = 13) of these samples were also positive for Leptospira-specific IgM. In the MAT-negative serum samples, 80% and 55% of the samples were detected as negative by an ELISA for Leptospira-specific IgM and IgG, respectively.Conclusion: An ELISA using the synthetic rLipL32 antigen was able to distinguish Leptospira-specific IgM (sensitivity 65% and specificity 80%) and IgG (sensitivity 100% and specificity 55%) in human serum samples and has the potential to serve as a rapid diagnostic test for leptospirosis.