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Preparation of a K39sub Recombinant Antigen for the Detection of Leishmania infantum Antibodies in Human: a Comparative Study with an Immunochromatographic Test and Direct Agglutination

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### Abstract:

Background: The Mediterranean type of kala-azar is occurred in different parts of Iran and caused by Leishmania infantum. A rapid and valid test for early detection of visceral leishmaniasis in human would be highly desirable because it could decrease mortality rate of the disease. In this study, we aimed to compare the results of K39sub antigen with an commercial immunochromatographic dipstick rk39 test (Cypress Diagnostic Company, Belgium) for early detection of L. infantum infection in human. Methods: K39sub recombinant antigen of L. infantum LON49 was expressed in prokaryotic system and evaluated for the diagnosis of human visceral leishmaniasis. This study evaluated the performance of recombinant K39sub antigen by ELISA and an commercial immunochromatographic dipstick rk39 test for the detection of L. infantum antibodies in 43 clinically infected patients with direct agglutination test (DAT) at a 1:3200 cut off titer and higher. Controls included 69 healthy volunteers and 28 patients with other diseases including malaria (n=5), tuberculosis (n= 3), toxoplasmosis (n= 4), cystic hydatidosis (n= 5) and cutaneous leishmaniasis (n= 11). Results: The sensitivity of the K39sub antigen and an immunochromatographic dipstick rk39 test was 90.7%, and 97.7%, respectively, while the specificity was 95.6% and 97.9%, correspondingly. A good concordance was found between k39sub antigen and commercial dipstick rk39 strips (k= 96.4%). Conclusion: The accuracy of the K39sub antigen in the detection of L. infantum antibodies in human infection is confirmed.

### Keywords:

K39sub Antigen . Commercial dipstick rk39 . Human visceral leishmaniasis

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