ORT_04 - Evaluation of three antigens for the use in immunochromatographic rapid test for serological diagnosis of Human Visceral Leishmaniasis in Brazil

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Introduction: Leishmaniasis is a neglected vector-borne disease with a worldwide distribution. Among its different clinical manifestations, the Visceral Leishmaniasis (VL) is the most severe form, which is caused by *Leishmania infantum* in Brazil. When not treated properly, it can evolve to death and for this reason, early diagnosis followed by adequate treatment is of upmost importance. Currently, the gold standard diagnostic is the parasitological examination, but it has several disadvantages such as low sensitivity. It is known that diagnostic tests can play a major role in patient management, disease surveillance and epidemiological studies, however, accurate human VL diagnosis remains a world problem.

Objectives: Aiming to improve the national public health system, the objective of this study was to evaluate the performance of different antigens in immunochromatographic rapid test platform for serological diagnosis of human VL.

Methodology: Three recombinant proteins (A1, B1 and C1) that displayed good performance in the enzyme immunoassay (ELISA) in previous studies were tested in a lateral flow platform. The optimal membrane, buffer and protein quantity per test were assessed to identify the best test condition for each protein. The C1 protein was cut off of the study in this phase due to the incompatibility with all tested buffers. After establishing the parameters for proteins A1 and B1, an internal assessment was conducted. After that, a prototype of each test was sent to external evaluation.

Results: In the internal evaluation, 50 positive and 40 negative sera were tested. Another 10 samples positive for *Trypanosoma cruzi* and negative for VL were tested. The A1 protein obtained a sensitivity of 86% and specificity of 100%. The B1 protein obtained sensitivity of 88% and specificity of 100%. Both proteins did not cross reaction with *T. cruzi*. In the external evaluation, 48 negative and 52 positive sera were tested. The A1 protein obtained sensitivity of 98% and specificity of 90% and B1 obtained sensitivity of 98% and specificity of 92%.

Conclusion: These results indicate a potential applicability of the protein B1 in the field. The rapid detection of *L. infantum* infection will certainly improve the patient's prognosis, preventing fatal resolutions.

Keywords: Neglected diseases, Rapid Test