IVD_26 - Evaluation of two antigens for the diagnosis of Cutaneous Leishmaniasis using ELISA methodology

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Introduction: Cutaneous Leishmaniasis (CL) is a zoonotic disease caused by protozoa of the Leishmania genus and the three most important species in Brazil are *L. amazonensis*, *L. guyanensis* and *L. braziliensis*. Sandflies of the Lutzomyia genus are considered its main transmitting vector. It is characterized by ulcerated lesions on the skin and/or mucous membrane, frequently in the nose, mouth and throat, which may cause complications such as bleeding, dysphagia, dysphonia and secondary infections. The main form of diagnosis is based on clinical features and direct parasitological examination, but there are also serological methods that can be used, for example the Enzyme-Linked Immunosorbent Assay (ELISA). However, this method is not widely used to diagnose CL since its sensitivity thus low because of the poor immunological response in the body. In this scenario, the development of a highly sensitive and specific serological test for detection of CL antibodies is important as an alternative for the common methods. One of the antigens that will be evaluated in this project uses the extract of *Leishmania braziliensis* and the other one is a recombinant protein provided by the project collaborators.

Objectives: Therefore, this study aims to evaluate two different antigens to diagnose CL using the ELISA methodology.

Methodology: A comparison between the *L. braziliensis* extract and the recombinant protein was performed using 75 positive and 250 negative samples confirmed by direct methods. The sensitivity and specificity calculation were performed using a ROC curve made on GraphPad Prism 5 Software.

Results: Preliminary results obtained with the *L. braziliensis* extract showed satisfactory performance when it comes to sensitivity, presenting a result of 98% (CI 95% - 99%), however the specificity has not passed 81% (CI 70% - 89%). The recombinant protein has not reached better results, presenting sensitivity and specificity values of 72% (CI 66% - 78%) and 64% (CI 52% - 75%) respectively.

Conclusion: In conclusion, it is visible that the recombinant protein could not obtain the expected results and its values stayed below de acceptable ranges. The *L. braziliensis* extract was superior in both sensitivity and specificity parameters, however the specificity still needs to be improved. For prospects, new tests will be carried out.

Keywords: ELISA; Cutaneous Leishmaniasis; Recombinant protein