IVD_15 - Evaluation of a new chimeric recombinant protein with potential for serodiagnosis of symptomatic and asymptomatic dogs infected by *Leishmania infantum*

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Introduction: Visceral leishmaniasis (VL), a neglected disease caused by *Leishmania infantum*, is endemic in more than 76 countries and 90% of the Latin American cases are found in Brazil. Dogs represent one of the main reservoirs of VL infection and play an important role in maintaining this zoonosis, with its control depending on more efficient diagnostic methods. The gold standard for the VL diagnosis still is the parasitological confirmation, but the efficiency of the technique depends on the sample used, resulting in a variable sensitivity. Serological methods are a viable alternative and new antigens have been studied to provide better essays, with different recombinant proteins being investigated to improve the performance of various tests.

Objectives: This study reports the production and preliminary evaluation of a new chimerical recombinant protein, designed by joining fragments from five promising antigens previously described, with potential for the early diagnosis of canine VL.

Methodology: This recombinant protein was produced in bacteria, affinity purified and evaluated in an ELISA test. The assay was standardized, and the best concentrations of antigen and primary antibody were established. The test was evaluated with a total of 261 canine sera with VL positivity confirmed using the DPP rapid test, mostly from asymptomatic animals, some symptomatic or lacking clinical information. These samples were further tested with the EIE-CVL ELISA, the confirmatory test recommended by the Brazilian Ministry of Health, with 133 having a second positive result while 128 were found to be negative. A total of 28 DPP negative sera were used as controls, all from endemic regions from Pernambuco. A ROC curve was used to determine sensitivity and specificity.

Results: Values of 91.3% sensitivity and 100% specificity were observed for the new protein with the DPP and EIE-CVL positive sera, with 100% and 91.18% sensitivities observed within this group for the sera from symptomatic and asymptomatic dogs, respectively. A positive result was also observed for 48.4 % of the DPP positive, EIE-CVL negative sera.

Conclusion: Supporting the use of this new recombinant protein for the early CVL diagnosis and as an efficient alternative to the currently recommended EIE-CVL assay.

Keywords: ELISA, Canine Visceral Leishmaniasis, Recombinant protein