IVD_16 - Development and evaluation of an ELISA using recombinant proteins for the diagnosis of Canine Visceral Leishmaniasis

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Introduction: Canine Visceral Leishmaniasis (CVL) is a zoonotic disease caused by *Leishmania infantum* that has increased the number of cases in urban regions over the years in Brazil. This disease is of great epidemiological importance and has dogs as the main domestic reservoir, deeply influencing the maintenance of the biological cycle of the transmitting vector. Infected dogs may develop the disease either symptomatically or asymptomatically. Due to the proximity between humans and dogs, the early diagnosis of this neglected disease is of extreme importance for the well-being of both. The diagnostic test currently commercialized by the public service in Brazil is the EIE-LVC, which uses the extract of *Leishmania major* as capture antigen, conferring good sensitivity, however, its specificity can be variable since there is a possibility of cross-reaction with other species of the Trypanosomatidae family.

Objectives: In this scenario, the development of a highly sensitive and specific test for detection of CLV antibodies in animals is very urgent. Therefore, this study aims to develop and validate a recombinant ELISA to diagnose CVL.

Methodology: To achieve the objective, we selected a Q5 recombinant protein, provided by the project collaborators, and already described in literature by the research group. The Q5 recombinant test, in *in-house* experiments, demonstrated greater efficiency when compared to current commercial tests available on the market. A comparison between the Q5 recombinant protein assay and the EIE-LVC kit was performed using 68 positive and 77 negative samples confirmed in our Dual-Path Platform technology (DPP® CVL rapid test). The sensitivity and specificity calculation was performed using MedCalc Software.

Results: Preliminary results obtained with the Q5 recombinant protein showed satisfactory performance in the detection of CVL antibodies. The protein reached the same sensitivity and specificity values as the commercial kit presenting a result of 98% (92% to 99%) and 95% (87% to 98%) respectively.

Conclusion: As future prospects, it is planned to scale up the production of prototypes so that a multicentric validation of the kits can be carried out.

Keywords: ELISA, Canine Visceral Leishmaniasis, Recombinant protein