An ELISA immunoassay employing a conserved *Leishmania* hypothetical protein for the serodiagnosis of visceral and tegumentary leishmaniasis in dogs and humans

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In the present study, a conserved *Leishmania* hypothetical protein, namely LiHypA, was evaluated for the serodiagnosis of visceral and tegumentary leishmaniasis in dogs and humans. This protein showed a high amino acid sequence homology between viscerotropic and cutaneotropic *Leishmania* species. An enzyme-linked immunosorbent assay (ELISA) was developed using the recombinant antigen (rLiHypA), besides of A2 protein and two parasite antigenic preparations, which were used as controls. Regarding human diagnosis, results showed that rLiHypA was more sensitive and specific than ELISA-*L. braziliensis* SLA in detecting both cutaneous or mucosal leishmaniasis patients, but not those from Chagas disease patients or healthy subjects. Regarding canine diagnosis, this recombinant antigen showed higher sensitivity and specificity values, as well as a perfect accuracy to identify asymptomatic and symptomatic visceral leishmaniasis (VL) dogs, but not those from vaccinated animals or those developing babesiosis, ehrlichiosis or Chagas disease. However, using the rA2 protein or *L. braziliensis* SLA as controls, significant cross-reactivity was found when these samples were used, hampering their sensitivity and specificity values for the diagnosis. In this context, LiHypA could be considered a candidate to be evaluated for the serodiagnosis of visceral and tegumentary leishmaniasis in dogs and humans.

Keywords: Hypothetical proteins; leishmaniasis; ELISA; diagnosis; sensitivity; specificity.

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