Evaluation of performance of TR-DPP® test as a triage tool for canine visceral leishmaniasis in domiciled dogs in Natal, Rio Grande do Norte, Brazil.

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Canine visceral leishmaniasis (CVL) is a neglected zoonotic disease caused by parasites of the genus *Leishmania*, transmitted by the bite of an infected sandfly, which mainly affects the poor and vulnerable population. The city of Natal, in the state of Rio Grande do Norte, Brazil, is considered an endemic area for CVL. The surveillance service uses the TR-DPP® (Bio-Manguinhos/Fiocruz, BRA) as a triage test, as recommended by the Ministry of Health in Brazil. It works as an immunochromatographic test using a unique combination of *Leishmania* antigens for the detection of *Leishmania*-specific antibody in infected dogs, generating a qualitative result. Dogs negative in TR-DPP® are considered negative for CVL by the surveillance service, so it is essential to know the efficiency of the tool used for CVL triage tests. The aim of the present study was to evaluate the performance of the TR-DPP® test as a triage tool to identify cases of CVL. In this study, 1,073 domestic dogs were tested with TR-DPP® (Bio-Manguinhos/Fiocruz, BRA) by the Zoonosis Surveillance Unit (UVZ) in Natal, Rio Grande do Norte, during the year 2022. The subjects were evaluated by UVZ on spontaneous demand, when the tutors called UVZ to evaluate and test the animals. After evaluation and examinations, the samples of positive cases for TR-DPP® were sent to the State Central Laboratory (LACEN-RN) to carry out confirmatory tests by ELISA (Bio-Manguinhos/Fiocruz, BRA). The TR-DPP® tests showed positive and negative rates of 48% (N = 515) and 52% (N = 558), respectively, presenting equivalent results in the evaluated domestic dogs. TR-DPP®-negative dogs were considered CVL-negative (CVL-) cases. Samples of 360 out of 515 TR-DPP®-positive individuals were tested by ELISA, with 276 positive individuals. The remaining 155 TR-DPP+ samples were not tested by ELISA because database retrieval was not possible. TR-DPP+/ELISA- dogs were assigned as false positives (FP) and are excluded as CVL cases. Individuals with TR-DPP®+/ELISA+ were considered confirmed CVL cases (CVL+). TR-DPP® and ELISA had a high rate of agreement, with TR-DPP® showing a 77% rate of concordance with ELISA. The TR-DPP® has a high concordance rate with the confirmatory ELISA, presenting a high positive predictive value (PPV), making it a good triage tool for identifying cases of CVL in domestic dogs. Although TR-DPP®+ reveals the presence of *Leishmania* antibodies in samples, TR-DPP®- does not exclude possible *Leishmania* exposure or *Leishmania* infection, since a humoral response to infection takes time to reach identifiable levels, and this can also be observed in dogs submitted to certain medications. Therefore, it is interesting that future studies perform ELISA tests with TR-DPP®- subjects so that it is possible to calculate the Kappa concordance index between the immunodiagnostic tests used by the health surveillance service.