



SENSITIVITY AND SPECIFICITY OF **RAPIDE** - LEISHMANIA AB TEST KIT

Cuong Tu Ba, DVM, MS¹, Catherine Berezaie²

¹Modern Veterinary Therapeutics, LLC - Coral Gables, Florida - USA;
cuong.tuba@modernveterinarytherapeutics.com

²Modern Veterinary Therapeutics SAS - Saint-Lunaire - FRANCE

1. Abstract / Résumé

Rapide - Leishmania Ab Test Kit is a new *in-vitro* immunochromatographic one step assay for detection of Leishmania antibody in canine serum, plasma or whole blood. This study was conducted to check the sensitivity and specificity of this new diagnostic test.

Rapide - Leishmania Ab Test Kit was compared to Immuno-Fluorescence Assay (IFA). Results showed a sensitivity of 95.6% (22/23) and a specificity of 98% (98/100) compared to IFA.

Data from this study show that **Rapide - Leishmania Ab Test Kit** is highly sensitive and specific for detection of Leishmania antibody in serum, plasma or whole blood. Therefore, **Rapide - Leishmania Ab Test Kit** is recommended to be adopted in animal clinics for diagnosis of Leishmania infection.

***Rapide - Leishmania Ab Test Kit** est un nouveau test d'immuno-migration *in-vitro* pour la détection de l'anticorps de Leishmania dans le sérum, le plasma ou le sang total. Cette étude était conduite pour vérifier la sensibilité et la spécificité de ce nouveau test de diagnostic.*

***Rapide - Leishmania Ab Test Kit** était comparé au test d'immuno-fluorescence (IFA). Les résultats montrent une sensibilité de 95.6% (22/23) et une spécificité de 98% (98/100) en comparaison à IFA..*

*Les données de cette étude montrent que **Rapide - Leishmania Ab Test Kit** est extrêmement sensible et spécifique pour la détection des anticorps de Leishmania dans le sérum, le plasma ou le sang total. Par conséquent, **Rapide - Leishmania Ab Test Kit** est recommandé en clinique vétérinaire pour le diagnostic de l'infection due à Leishmania.*

2. Introduction

Leishmaniasis is caused by a protozoa of the genus *Leishmania*, The disease is endemic in many parts of the world including Central and South America, Africa, India, and the Mediterranean basin. The infection is transmitted by sandflies of the genus *Phlebotomus* in Europe, Asia, Africa and *Lutzomyia* in the America. Reservoir hosts vary within different geographic areas and can include domestic or wild animals. Dogs are reservoirs for *Leishmania infantum* infection. Visceral leishmaniasis, the most severe disease form, is a frequent cause of clinical illness in dogs in some regions. Canine Visceral leishmaniasis is a chronic systemic disease. The sign of disease are highly variable and often begin with slight but progressive dullness and insidious exercise intolerance.

2.1 **Background** - The **Rapide - Leishmania Ab Test Kit** is an *in-vitro* immunochromatographic one step assay designed for qualitative determination of Leishmania antibody in serum, plasma or whole blood.

2.2 **Objectives** - The primary objective was to determine the sensitivity and specificity of **Rapide - Leishmania Ab Test Kit**.

3. Study design

This is a parallel comparative study. Twenty-three (23) positive samples and hundred (100) negative samples from clinical cases were collected. The status of each sample was confirmed by Immuno-Fluorescence Assay (IFA), a laboratory reference standard test. All samples were then tested by **Rapide - Leishmania Ab Test Kit** to evaluate the sensitivity and specificity compared to IFA.

4. Materials & methods:

4.1 The **Rapide - Leishmania Ab Test Kit** is an *in-vitro* immunochromatographic one step assay designed for qualitative determination of Leishmania antibody in canine serum, plasma or whole blood. The study investigators were instructed to process the samples as indicated in the figure below:

<Serum or Plasma>

(1) One drop of specimen into sample hole "S"



Allow to stand for 1 min.



(2) 3 drops of developing buffer into buffer well



<Whole blood>

(1) 3 drops of the whole-blood diluent



(2) 1 drop of the whole-blood into the test tube



Mix & allow to stand for 1 min.



(3) 1 drop of the mixed sample into sample hole "S"



Allow to stand for 1 min.



(4) 3 drops of developing buffer into buffer well





4.2 The Interpretation of the test results is conducted as follows:

Negative Result:



Positive Result:



5. Analysis

5.1 Sensitivity and specificity will be determined by standard calculation:

$$\text{Sensitivity}(\%) = 100 \times \frac{\text{No. of specimens with positive results by Rapide - Leishmania Ab Test Kit}}{\text{No. of positive specimens confirmed by IFA}}$$

$$\text{Specificity}(\%) = 100 \times \frac{\text{No. of specimens with negative results by Rapide - Leishmania Ab Test Kit}}{\text{No. of negative specimens confirmed by IFA}}$$

6. Results:

| Sensitivity and Specificity | | Gold Standard: IFA | |
|---------------------------------|----------|--------------------|----------|
| | | Positive | Negative |
| Rapide - Leishmania Ab Test Kit | Positive | 22 | 2 |
| | Negative | 1 | 98 |
| Sensitivity | | 95.6% (22/23) | |
| Specificity | | 98% (98/100) | |

7. Discussion and conclusion:

These studies showed that **Rapide - Leishmania Ab Test Kit** is highly sensitive and specific for the qualitative detection of Leishmania antibody in serum, plasma or whole blood. Using **Rapide - Leishmania Ab Test Kit** is very simple, quick and it does not require any special equipments. Therefore, **Rapide - Leishmania Ab Test Kit** is recommended to be adopted in animal clinics for diagnosis of Leishmania infection.