



## SENSITIVITY AND SPECIFICITY OF RAPIDE - EHRLICHIA AB TEST KIT

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### 1. Abstract / Résumé

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

**Rapide - Ehrlichia Ab Test Kit** was compared to Immuno-Fluorescence Assay (IFA). Results showed a sensitivity of 97.6% (41/42) and a specificity of 99% (202/204) compared to IFA.

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

***Rapide - Ehrlichia Ab Test Kit** est un nouveau test d'immuno-migration in-vitro pour la détection de l'anticorps de *E. canis* 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 - Ehrlichia Ab Test Kit** était comparé au test d'immuno-fluorescence (IFA). Les résultats montrent une sensibilité de 97.6% (41/42) et une spécificité de 99% (202/204) en comparaison à IFA.*

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

### 2. Introduction

Ehrlichiosis, also known as "Tropical Canine Pancytopenia" or "Canine Rickettsiosis" is a tick-borne disease caused by obligate intracellular bacteria of the genus *Ehrlichia* (family rickettsiaceae). Clinical findings in dogs with Ehrlichiosis vary with the phase of the infection. During the acute phase, nonspecific signs such as fever, oculonasal discharge, anorexia, weight loss, dyspnea, and lymphadenopathy may occur. Clinical signs commonly seen during the chronic phase include depression, weight loss, pale mucous membranes, abdominal pain, hemorrhage, lymphadenopathy, spleno-megaly, dyspnea, increased lung sounds, hepatomegaly, arrhythmias, pulse deficits, polyuria, polydypsia, and stiff, swollen, painful joints.

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

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

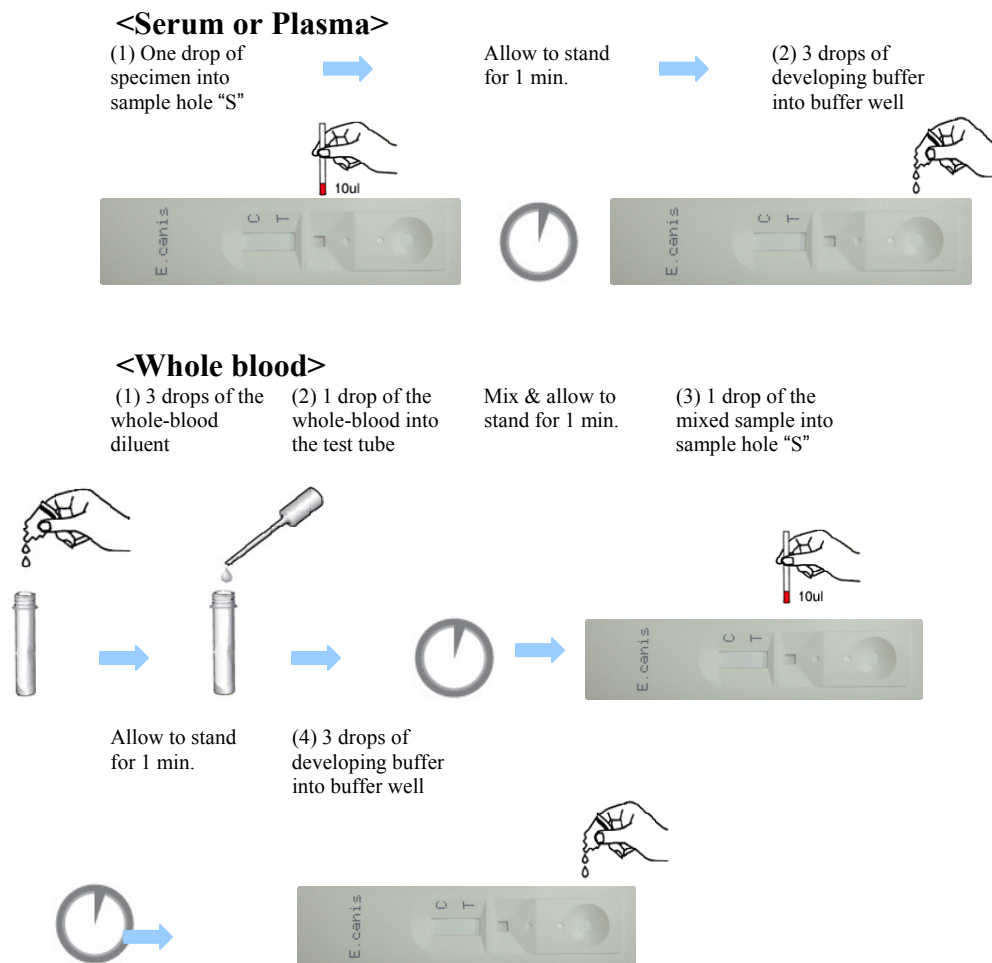
### 3. Study design

This is a parallel comparative study. Forty-two (42) positive samples and two hundreds and four (204) 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 - Ehrlichia Ab Test Kit** to evaluate the sensitivity and specificity compared to IFA.

#### 4. Materials & methods:

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



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:

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

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

## 6. Results:

Sensitivity and Specificity		Gold Standard: IFA	
		Positive	Negative
Rapide - Ehrlichia Ab Test Kit	Positive	41	2
	Negative	1	202
Sensitivity		97.6% (41/42)	
Specificity		99% (202/204)	

## 7. Discussion and conclusion:

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