



SENSITIVITY AND SPECIFICITY OF **RAPIDE** - GIARDIA AG TEST KIT

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1. Abstract / Résumé

Rapide - Giardia Ag Test Kit is a new *in-vitro* immunochromatographic one step assay for detection of giardia antigen in canine and feline feces. Two (2) studies were conducted to check the sensitivity and specificity of this new diagnostic test.

In the first study, **Rapide - Giardia Ag Test Kit** was compared to a competitive immunochromatographic assays on the market. Results showed a sensitivity of 100% (50/50) and a specificity of 100% (100/100).

In the second study, **Rapide - Giardia Ag Test Kit** was evaluated for potential cross-reactivity with canine parvovirus, canine distemper virus, canine parainfluenza virus, infectious canine hepatitis virus, porcine giardia, *Leptospira icterohaemorrhagiae*, *E. coli* spp., *Salmonella* spp., *Ascaris homogenates*, and *Giardia homogenates*. The results showed that **Rapide - Giardia Ag Test Kit** is highly specific for giardia antigen with no cross-reaction with other infectious pathogens which are commonly present in fecal materials.

Data from these studies show that **Rapide - Giardia Ag Test Kit** is highly sensitive and specific for detection of canine and feline giardia antigen in feces. Therefore, **Rapide - Giardia Ag Test Kit** is recommended to be adopted in animal clinics for diagnosis of canine and feline giardia infection.

***Rapide - Giardia Ag Test Kit** est un nouveau test d'immuno-migration in-vitro pour la détection de l'antigène du giardia dans les fèces du chien. Deux (2) études étaient conduites pour vérifier la sensibilité et la spécificité de ce nouveau test de diagnostic.*

*Dans la première étude, **Rapide - Giardia Ag Test Kit** était comparé test compétiteur d'immuno-migration déjà sur le marché. Les résultats montrent une sensibilité de 100% (50/50) et une spécificité de 100% (100/100).*

*Dans la deuxième étude, **Rapide - Giardia Ag Test Kit** était évalué pour des réactions croisées potentielles avec le parvovirus canin, le virus canin de la maladie de Carré, le virus du parainfluenza canin, le virus de l'hépatite infectieuse canine, giardia porcine, *Leptospira icterohaemorrhagiae*, *E. coli* spp., *Salmonella* spp. homogenates d'*Ascaris*, et homogenates de *Giardia*. Les résultats montrent que **Rapide - Giardia Ag Test Kit** est extrêmement spécifique pour l'antigène du giardia sans aucune réaction croisée avec d'autres pathogènes infectieux.*

*Les données de ces études montrent que **Rapide - Giardia Ag Test Kit** est extrêmement sensible et spécifique pour la détection de l'antigène du giardia dans les fèces canins et félins. Par conséquent, **Rapide - Giardia Ag Test Kit** est recommandé en clinique vétérinaire pour le diagnostic de l'infection de giardia chez les chiens et les chats.*

2. Introduction

2.1 Introduction – *Giardia* is a diarrhea causative protozoa infecting the small intestine of dogs and cats, and one of the most important pathogenic intestinal protozoa found in these animals. Young puppies tend to be highly infected especially in group breeding situations. No specific signs are seen in adult dogs and cats, but puppies and kittens show watery or foamy diarrhea with a bad smell due to malabsorption in the intestine. Usually, Giardiasis is diagnosed by finding cysts or trophozoites by fecal microscopy, but it has very low sensitivity. The **Rapide - Giardia**. Antigen Test Kit enables detection of vegetative stages and cysts of *Giardia* that are not detectable by microscopy.



2.2 Background - The **Rapide - Giardia Ag Test Kit** is an *in-vitro* immunochromatographic one step assay designed for qualitative determination of Giardia antigen in canine and feline feces.

2.3 Objectives - The primary objective was to determine the sensitivity and specificity of **Rapide - Giardia Ag Test Kit**.

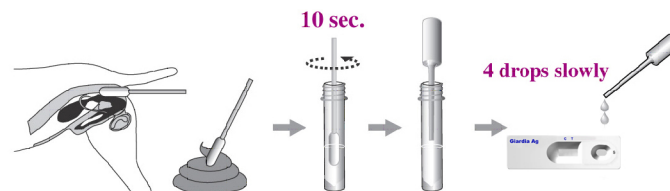
3. Study design

3.1 Study 1: This is a parallel comparative study. One hundred-fifty (150) fecal samples from clinical cases were collected and tested by both **Rapide - Giardia Ag Test Kit** and a competitive Giardia antigen test kit to evaluate the sensitivity and specificity.

3.2 Study 2: In this study, **Rapide - Giardia Ag Test Kit** was evaluated for potential cross-reactivity with other infectious pathogens which are commonly present in fecal materials: canine parvovirus, canine distemper virus, canine parainfluenza virus, infectious canine hepatitis virus, porcine parvovirus, *Leptospira icterohaemorrhagiae*, *E. coli* spp., *Salmonella* spp. and Ascaris homogenates.

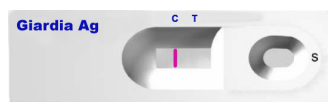
4. Materials & methods:

4.1 The **Rapide - Giardia Ag Test Kit** is an *in-vitro* immunochromatographic one step assay designed for qualitative determination of Giardia antigen in canine and feline feces. The study investigators were instructed to process the samples as indicated in the figure below:

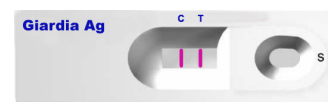


4.2 The Interpretation of the test results is conducted as follows:

Negative Result:



Positive Result:



5. Analysis

5.1 Sensitivity and specificity will be determined by standard calculation:

$$\text{Sensitivity(\%)} = 100 \times \frac{\text{No. of specimens with positive results by Rapide - Giardia Ag Test Kit}}{\text{No. of specimens with positive results by competitive Giardia Ag Test Kit}}$$

$$\text{Specificity(\%)} = 100 \times \frac{\text{No. of specimens with negative results by Rapide - Giardia Ag Test Kit}}{\text{No. of specimens with negative results by competitive Giardia Ag Test Kit}}$$



6. Results:

6.1 Study 1:

Sensitivity and Specificity		Competitive Test Kit	
		Positive	Negative
Rapide - Giardia Ag Test Kit	Positive	50	0
	Negative	0	100
Sensitivity		100% (50/50)	
Specificity		100% (100/100)	

6.2 Study 2:

Pathogens	Titer	Results
Canine Parvo virus	$10^{4.0}$ TCID ₅₀ /mL	Negative
Canine Distemper virus	$10^{4.0}$ TCID ₅₀ / mL	Negative
Canine Parainfluenza virus	$10^{6.0}$ TCID ₅₀ / mL	Negative
Infectious Canine Hepatitis virus	$10^{5.0}$ TCID ₅₀ / mL	Negative
Porcine Parvovirus	1,024 HAU	Negative
<i>Leptospira icterohaemorrhage</i>	OD 1.0 at 560nm	Negative
<i>E. coli spp</i>	$10^{8.0}$ CFU/ mL	Negative
<i>Salmonella spp.</i>	$10^{8.0}$ CFU/ mL	Negative
Ascaris homogenate	10% homogenates in PBS	Negative

7. Discussion and conclusion:

These studies showed that **Rapide - Giardia Ag Test Kit** is highly sensitive and specific for the qualitative detection of Giardia antigen in feces. Using **Rapide - Giardia Ag Test Kit** is very simple, quick and it does not require any special equipments. Therefore, **Rapide - Giardia Ag Test Kit** is recommended to be adopted in animal clinics for diagnosis of Giardia infection.