



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

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1. Abstract / Résumé

Rapide - FCoV Ab Test Kit is a new *in-vitro* immunochromatographic one step assay for detection of Feline Corona Virus (FCoV) antibody in feline serum, plasma or whole blood. Three (3) studies were conducted to check the sensitivity and specificity of this new diagnostic test. In the first study, **Rapide - FCoV Ab Test Kit** was compared to Immuno-Fluorescence Assay (IFA). Results showed a sensitivity of 96% (49/51) and a specificity of 97.9% (96/98). In the second study, the field robustness of **Rapide - FCoV Ab Test Kit** was evaluated by sending 20 blinded sera samples to three unrelated veterinary sites. The status of each sample was confirmed by IFA prior to the shipment to the study sites. Study investigators were requested to perform the test without knowing the status of each sample. Results show a 100% agreement between all study sites. The sensitivity was 100% (15/15) and the specificity was 100% (5/5). In the last study, **Rapide - FCoV Ab Test Kit** was evaluated for potential cross-reactivity with feline herpesvirus (FHV) type 1, feline panleukopenia virus, feline calicivirus, feline leukemia virus (FeLV), Chlamydia Psittaci and feline immunodeficiency virus (FIV). The results showed that **Rapide - FCoV Ab Test Kit** is highly specific for Feline Corona Virus (FCoV) antibody with no cross-reaction with any of the other common feline infectious pathogens. Data from these studies show that **Rapide - FCoV Ab Test Kit** is highly sensitive and specific for detection of FCoV antibody in serum, plasma or whole blood. Therefore, **Rapide - FCoV Ab Test Kit** is recommended to be adopted in animal clinics for diagnosis of FIP infection.

Rapide - FCoV Ab Test Kit est un nouveau test d'immuno-migration *in-vitro* pour la détection des anticorps du Coronavirus Félin (FCoV) dans le sérum, le plasma ou le sang total. Deux (2) études étaient conduites pour vérifier la sensibilité et la spécificité de ce nouveau test de diagnostic.

Dans la première étude, **Rapide - FCoV Ab Test Kit** était comparé au test d'Immuno-Fluorescence (IFA). Les résultats montrent une sensibilité de 96% (49/51) et une spécificité de 97.9% (96/98).

Dans la deuxième étude, la fiabilité sur le terrain de **Rapide - FCoV Ab Test Kit** était évaluée en aveugle en envoyant 20 échantillons de sérum masqués à trois sites vétérinaires indépendants. Le statut de chaque échantillon était confirmé par IFA avant l'envoi vers les sites de l'étude. Les investigateurs conduisaient l'étude en aveugle sans connaître le statut de chaque échantillon. Les résultats montrent 100% de corrélation entre les sites de l'étude. La sensibilité est de 100% (15/15) et la spécificité est de 100% (5/5).

Dans la dernière étude, **Rapide - FCoV Ab Test Kit** était évalué pour des réactions croisées potentielles avec le virus de l'herpes félin (FHV) type 1, le virus de la panleucopénie féline (FIPV), le virus de la leucose féline (FeLV), le calicivirus félin, Chlamydia psittaci et le virus de l'immunodéficience féline (FIV). Les résultats montrent que **Rapide - FCoV Ab Test Kit** est extrêmement spécifique pour les anticorps du Coronavirus Félin (FCoV) sans aucune réaction croisée avec d'autres pathogènes infectieux félins.

Les données de ces études montrent que **Rapide - FCoV Ab Test Kit** est extrêmement sensible et spécifique pour la détection anticorps du Coronavirus Félin (FCoV) dans le sérum, le plasma ou le sang total. Par conséquent **Rapide - FCoV Ab Test Kit** est recommandé en clinique vétérinaire pour le diagnostic de l'infection de la PIF.



2. Introduction

- 2.1 Introduction - Feline Infectious Peritonitis (FIP) is a fatal feline disease that is caused by a mutated Feline Enteric Corona Virus (FCoV). Apart of clinical symptoms, up until now, there is no way to differentiate FIP from Feline Enteric Corona Virus. Also there is no test that is not too invasive that might help in the diagnosis of FIP. It has been found that most cats that suffered from FIP were having high titer of antibodies against Feline Enteric Corona Virus, and that cats with no antibodies against Feline Enteric Corona Virus are unlikely to develop Feline Infectious Peritonitis The current standard antibody test is an Immuno-Fluorescence Assay (IFA), performed routinely in only few veterinary university laboratory sites.
- 2.2 Background - The **Rapide - FCoV Ab Test Kit** is an *in-vitro* immunochromatographic one step assay designed for qualitative determination of FCoV antibody in serum, plasma or whole blood.
- 2.3 Objectives - The primary objective was to determine the sensitivity and specificity of **Rapide - FCoV Ab Test Kit**.

3. Study design

- 3.1 Study 1: This is a parallel comparative study. One hundred-fifty-five (149) sera samples from clinical cases were collected and tested by Immuno-Fluorescence Assay (IFA), a laboratory reference standard test to confirm their positive or negative status for FCoV Antibody. All samples were then tested by **Rapide - FCoV Ab Test Kit** to evaluate the sensitivity and specificity.
- 3.2 Study 2: In this study, Five (5) positive and fifteen (15) negative feline sera samples were obtained from the Auburn University. All samples were tested by IFA to confirm their positive or negative status. Samples were divided and shipped to three veterinary sites for blind testing using **Rapide - FCoV Ab Test Kit**.
- 3.3 Study 3: In this study, **Rapide - FCoV Ab Test Kit** was evaluated for potential cross-reactivity with other common feline infectious pathogens: feline herpesvirus (FHV) type 1, feline panleukopenia virus (FIPV), feline calicivirus, Feline leukemia virus (FeLV), Chlamydia Psittaci and feline immunodeficiency virus (FIV).

4. Materials & methods:

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

(1) 1 drop of specimen



(2) 3 drops of assay diluent



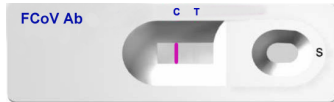
(3) Interpret at 10 mins.



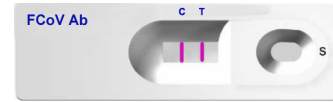


4.2 The Interpretation of the test results is conducted as follows:

Negative Result:



Positive Result:



5. Analysis

5.1 Sensitivity and specificity will be determined by standard calculation:

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

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

6. Results:

6.1 Study 1:

Sensitivity and Specificity		Gold Standard: IFA	
		Positive	Negative
Rapide - FCoV Ab Test Kit	Positive	49	2
	Negative	2	96
Sensitivity		96%	
Specificity		97.9%	

6.2 Study 2:

Sensitivity and Specificity			Gold Standard: IFA		Sensitivity	Specificity
			Positive	Negative		
Rapide - FCoV Ab Test Kit	Site A	Positive	5	0	100%	100%
		Negative	0	15		
	Site B	Positive	5	0	100%	100%
		Negative	0	15		
	Site C	Positive	5	0	100%	100%
		Negative	0	15		



6.3 Study 3:

Pathogens	Confirmation	Results
Feline herpesvirus (FHV) type 1 positive serum	ELISA Positive	Negative
Feline panleukopenia virus (FIPV) Positive serum	ELISA Positive	Negative
Feline calicivirus Positive serum	ELISA positive	Negative
Feline Leukemia virus Positive serum	VN Positive	Negative
Chlamydia felis (Chlamydia Psittaci)	ELISA Positive	Negative
Feline Immunodeficiency virus(FIV Ab)	Western blot Positive	Negative

7. Discussion and conclusion:

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

- A negative result is helpful in ruling out a diagnosis for FIP
- A positive result means that the cat has previously been exposed to FCoV and potentially FIP. A definitive diagnosis of FIP should be based only on complete clinical and laboratory findings
- Other indications: Testing before mating; screening a household or cattery for the presence of FCoV; screening a cat before introduction into a FCoV-free household or cattery.