



## SENSITIVITY AND SPECIFICITY OF **RAPIDE** - FELV AG TEST KIT

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### 1. Abstract / Résumé

**Rapide - FeLV Ag Test Kit** is a new *in-vitro* immunochromatographic one step assay for detection of FeLV antigen 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 - FeLV Ag Test Kit** and a competitive rapid test on the market were compared to Virus Isolation. Results showed a sensitivity of 100% (35/35) and a specificity of 100% (76/76) for both **Rapide - FeLV Ag Test Kit** and the competitive product.

In the second study, **Rapide - FeLV Ag Test Kit** and two other immunochromatographic assays on the market were compared to Virus Isolation. Results showed a sensitivity of 94.7% (18/19) and a specificity of 99.7% (300/301) for **Rapide - FeLV Ag Test Kit**. Competitor A and B have a sensitivity of 89.5% (17/19) and a specificity of 99.7% (300/301).

In the last study, **Rapide - FeLV Ag Test Kit** was evaluated for potential cross-reactivity with feline herpesvirus (FHV) type 1, feline panleukopenia virus, feline calicivirus, feline immunodeficiency virus (FIV) and Chlamydia Psittaci. The results showed that **Rapide - FeLV Ag Test Kit** is highly specific for FeLV antigen with no cross-reaction with any of the other common feline infectious pathogens.

Data from these studies show that **Rapide - FeLV Ag Test Kit** is highly sensitive and specific for detection of FeLV antigen in serum, plasma or whole blood. Therefore, **Rapide - FeLV Ag Test Kit** is recommended to be adopted in animal clinics for diagnosis of FeLV infection.

***Rapide - FeLV Ag Test Kit** est un nouveau test d'immuno-migration in-vitro pour la détection de l'antigène du FeLV dans le sérum, le plasma ou le sang total. Trois (3) études étaient conduites pour vérifier la sensibilité et la spécificité de ce nouveau test de diagnostic.*

*Dans la première étude, **Rapide - FeLV Ag Test Kit** et un test compétiteur étaient comparés à la technique d'isolation du virus. Les résultats montrent une sensibilité de 100% (35/35) et une spécificité de 100% (76/76) à la fois pour **Rapide - FeLV Ag Test Kit** et le test compétiteur.*

*Dans la deuxième étude, **Rapide - FeLV Ag Test Kit** et deux autres tests d'immuno-migration déjà sur le marché étaient comparés à la technique d'isolation du virus. Les résultats montrent une sensibilité de 94.7% (18/19) et une spécificité de 99.7% (300/301) pour **Rapide - FeLV Ag Test Kit**. Les tests compétiteurs A et B ont une sensibilité de 89.5% (17/19) et une spécificité de 99.7% (300/301).*

*Dans la dernière étude, **Rapide - FeLV Ag 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, le calicivirus félin, le virus de l'immunodéficience féline et Chlamydia psittaci. Les résultats montrent que **Rapide - FeLV Ag Test Kit** est extrêmement spécifique pour l'antigène du FeLV sans aucune réaction croisée avec d'autres pathogènes infectieux félins.*

*Les données de ces études montrent que **Rapide - FeLV Ag Test Kit** est extrêmement sensible et spécifique pour la détection de l'antigène du FeLV dans le sérum, le plasma ou le sang total. Par conséquent, **Rapide - FeLV Ag Test Kit** est recommandé en clinique vétérinaire pour le diagnostic de l'infection du FeLV.*

### 2. Introduction

2.1 Introduction – Feline Leukemia Virus (FeLV) is a retrovirus that can directly cause cancer. The virus is usually transmitted through contact with the saliva of an infected cat. Kittens



under 16 weeks are the most susceptible to the virus. Cats over 16 weeks who are dealing with an illness unrelated to FeLV, stress, or injury may also be more susceptible. Diseases caused by FeLV include lympho-sarcoma, myelogenous leukemia, thymic atrophy, nonregenerative anemia and panleukopenia-like disease. Because FeLV is immunosuppressive, it predisposes infected cats to a variety of secondary diseases. The FeLV is excreted in saliva and tears and possibly the urine and feces of infected cats. Prolonged, extensive cat-to-cat contact is required for efficient spread, because the virus is rapidly inactivated by warmth and drying.

2.2 **Background** - The **Rapide - FeLV Ag Test Kit** is an *in-vitro* immunochromatographic one step assay designed for qualitative determination of FeLV antigen in serum, plasma or whole blood.

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

### 3. Study design

3.1 **Study 1:** This is a parallel comparative study. Thirty-five (35) positive samples (15 sera and 10 whole blood) and seventy-six (76) negative samples (56 sera and 20 whole blood) from clinical cases were collected. Their status were confirmed by virus isolation, a laboratory reference standard test. All samples were then tested by **Rapide - FeLV Ag Test Kit** and another competitive rapid test on the market to evaluate the sensitivity and specificity of each test compared to virus isolation.

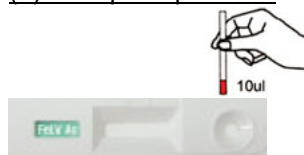
3.2 **Study 2:** This is a parallel comparative study. three hundred-twenty (320) serum samples from clinical cases were collected and tested by virus isolation, a laboratory reference standard test to confirm their positive or negative status for FeLV. All samples were then tested by **Rapide - FeLV Ag Test Kit** and two other competitive rapid tests on the market to evaluate the sensitivity and specificity of each test compared to virus isolation.

3.3 **Study 3:** In this study, **Rapide - FeLV Ag Test Kit** was evaluated for potential cross-reactivity with other common feline infectious pathogens: feline herpesvirus(FHV) type 1, feline panleukopenia virus, feline calicivirus, feline immunodeficiency virus (FIV) and Chlamydia Psittaci.

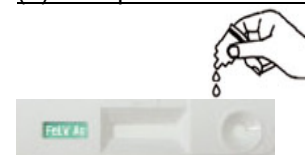
### 4. Materials & methods:

4.1 The **Rapide - FeLV Ag Test Kit** is an *in-vitro* immunochromatographic one step assay designed for qualitative determination of FeLV antigen 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) 2 drops of buffer solution





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:

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

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

## 6. Results:

6.1 Study 1:

Sensitivity and Specificity		Gold Standard: Virus Isolation	
		Positive	Negative
<b>Rapide - FeLV Ag Test Kit</b>	Positive	35	0
	Negative	0	76
Sensitivity		100% (35/35)	
Specificity		100% (76/76)	
<b>Competitor</b>	Positive	35	0
	Negative	0	76
Sensitivity		100% (35/35)	
Specificity		100% (76/76)	

6.2 Study 2:

Sensitivity and Specificity		Gold Standard: Virus Isolation	
		Positive	Negative
<b>Rapide - FeLV Ag Test Kit</b>	Positive	18	1
	Negative	1	300
Sensitivity		94.7% (18/19)	
Specificity		99.7% (300/301)	
<b>Competitor A</b>	Positive	17	1
	Negative	2	300
Sensitivity		89.5% (17/19)	
Specificity		99.7% (300/301)	
<b>Competitor B</b>	Positive	17	1
	Negative	2	300
Sensitivity		89.5% (17/19)	
Specificity		99.7% (300/301)	



### 6.3 Study 3:

Pathogens	Titer	Results
Feline herpesvirus(FHV) type 1	$5 \times 10^6$ TCID <sub>50</sub> /ml	Negative
Feline panleukopenia virus	$10^{5.0}$ TCID <sub>50</sub> /ml	Negative
Feline calicivirus	$10^{3.0}$ TCID <sub>50</sub> /ml	Negative
Feline immunodeficiency virus	$10^{3.0}$ TCID <sub>50</sub> /ml	Negative
Chlamydia Psittaci	$1.5 \times 10^{7.0}$ CFU/ml	Negative

### 7. Discussion and conclusion:

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