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SENSITIVITY AND SPECIFICITY OF RAPIDE - PARVOVIRUS AG TEST KIT

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1. Abstract / Résumé

Rapide - Parvovirus Ag Test Kit is a new in-vitro immunochromatographic one step assay for detection of parvovirus antigen in canine feces. Four (4) studies were conducted to check the sensitivity and specificity of this new diagnostic test.
In the first study, Rapide - Parvovirus Ag Test Kit was compared to Hemagglutination Assay (HA). Results showed a sensitivity of 100% (51/51) and a specificity of 100% (104/104).
In the second study, Rapide - Parvovirus Ag Test Kit and two other immunochromatographic assays on the market were compared to PCR. Results showed a sensitivity of 100% (51/51) and a specificity of 100% (104/104) for Rapide - Parvovirus Ag Test Kit and competitor A. Competitor B has a sensitivity of 100% (51/51) and a specificity of 99% (103/104).
In the third study, the field robustness of Rapide - Parvovirus Ag Test Kit was evaluated by sending 20 blinded fecal samples to three unrelated veterinary sites. The status of each sample was confirmed by PCR 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 - Parvovirus Ag Test Kit was evaluated for potential cross-reactivity with canine distemper virus, canine parainfluenza virus, infectious canine hepatitis virus, porcine parvovirus, Leptospira icterohaemorragiae , E. coli spp., Salmonella spp., Ascaris homogenates, and Giardia homogenates. The results showed that Rapide - Parvovirus Ag Test Kit is highly specific for the canine parvovirus antigen with no cross-reaction with any of the other common canine infectious pathogens.
Data from these studies show that Rapide - Parvovirus Ag Test Kit is highly sensitive and specific for detection of canine parvovirus antigen in feces. Therefore, Rapide - Parvovirus Ag Test Kit is recommended to be adopted in animal clinics for diagnosis of canine parvovirus infection.

Rapide - Parvovirus Ag Test Kit est un nouveau test d'immuno-migration in-vitro pour la détection de l'antigène du parvovirus dans les fèces du chien. Quatre (4) études étaient conduites pour vérifier la sensibilité et la spécificité de ce nouveau test de diagnostic.
Dans la première étude, Rapide - Parvovirus Ag Test Kit était comparé au test d'hémaglutination (HA). Les résultats montrent une sensibilité de 100% (51/51) et une spécificité de 100% (104/104).
Dans la deuxième étude, Rapide - Parvovirus Ag Test Kit et deux autres tests d'immuno-migration déjà sur le marché étaient comparés au test PCR. Les résultats montrent une sensibilité de 100% (51/51) et une spécificité de 100% (104/104) pour Rapide - Parvovirus Ag Test Kit et test compétiteur A. Le test compétiteur B a une sensibilité de 100% (51/51) et une spécificité de 99% (103/104).
Dans la troisième étude, la fiabilité sur le terrain de Rapide - Parvovirus Ag Test Kit était évaluée en aveugle en envoyant 20 échantillons fécaux masqués à trois sites vétérinaires indépendants. Le statuts de chaque échantillon était confirmé par PCR avant l'envoi vers les sites de l'étude. Les investigateurs conduisaient l'étude en aveugle sans connaitre le statut de chaque échantillon. Les résultats montrent 100%

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de corrélation entre les sites de l'étude. La sensibilit é est de 100% (15/15) et la spécificité est de 100% (5/5).
Dans la dernière étude, Rapide - Parvovirus Ag Test Kit était évalué pour des réactions croisées potentielles avec le virus canin de la maladie de Carré, le virus du parainfluenza canin, le virus de l'hépatite infectieuse canine, le parvovirus porcin, Leptospira icterohaemorragiae, E. coli spp., Salmonella spp. homogenates d'Ascaris, et homogenates de Giardia. Les ré sultats montrent que Rapide - Parvovirus Ag Test Kit est extrêmement spécifique pour l'antigène du par vovirus canin sans aucune réaction croisée avec d'autres pathogènes infectieux canins.
Les données de ces études montrent que Rapide - Parvovirus Ag Test Kit est extrêmement sensible et spécifique pour la détection de l'antigène du parvovirus canin dans les fèces. Par conséquent Rapide - Parvovirus Ag Test Kit est recommandé en clinique vétérinaire pour le diagnostic de l'infection du parvovirus canin.

2. Introduction

2.1 Introduction – Canine Parvovirus (CPV) is a member of the feline parvovirus subgroup. It is closely related to feline panleukopenia virus and mink enteritis virus, and is considered endemic to nearly all populations of domesticat ed and wild canines. CPV causes two forms of disease: myocarditis and enteritis. Due to mate rnal antibody protection, the myocardial form is rare. The enteric form, however, is preval ent and can be fatal to puppies and geriatric dogs. CPV enteritis causes severe, often bloody diarrhea, vomiting, leukopenia and dehydration. Transmission is fecal-oral and most infections occur from exposure to contaminated feces. CPV is highly contagiou s and stable under a variety of environmental conditions. Rapid diagnosis of CPV allows fo r quarantine and prompt treatment of infected dogs. Diagnosis may be difficult in milder cases.

2.2 Background - The Rapide - Parvovirus Ag Test Kit is an in-vitro immunochromatographic one step assay designed for qualitative determinatio n of Canine Parvovirus antigen in feces.

2.3 Objectives - The primary objective was to determi ne the sensitivity and specificity of Rapide - Parvovirus Ag Test Kit .

3. Study design

3.1 Study 1 : This is a parallel comparative study. One hundred-fifty-five (155) fecal samples from clinical cases were collected and tested by Hemagglutination Assay (HA), a laboratory reference standard test to confirm their positi ve or negative status for canine parvovirus antigen. All samples were then tested by Rapide - Parvovirus Ag Test Kit to evaluate the sensitivity and specificity.

3.2 Study 2 : This is a parallel comparative study. One hundred-fifty-five (155) fecal samples from clinical cases were collected and tested by P CR, a laboratory reference standard test to confirm their positive or negativ e status for canine parvovirus antigen. All samples were then tested by Rapide - Parvovirus Ag Test Kit and two other competitive rapid tests on the market to evaluate their sensitivit y and specificity compared to PCR.

3.3 Study 3 : In this study, fifteen (15) positive and five (5) negative canine fecal samples were obtained from the University of Wisconsin. All samples were tested by PCR to confirm their positive or negative status. Samples were divided and shipped to three veterinary sites for blind testing using Rapide - Parvovirus Ag Test Kit .

3.4 Study 4 : In this study, Rapide - Parvovirus Ag Test Kit was evaluated for potential cross-reactivity with other canine infectious pathogens which are commonly present in fecal materials: canine distemper virus, canine parai nfluenza virus, infectious canine hepatitis

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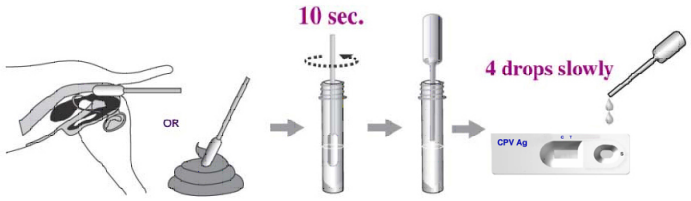
virus, porcine parvovirus, Leptospira icterohaemorragiae , E. coli spp., Salmonella spp., Ascaris homogenates, and Giardia homogenates.

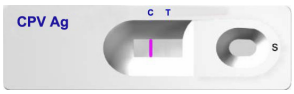
4. Materials & methods:

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

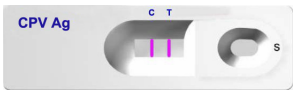


4.2 The Interpretation of the test results is conducted as follows:

Negative Result :



Positive Result:



5. Analysis

5.1 Sensitivity and specificity will be determined by standard calculation:

$$\text{Sensitivity}(\%) = 100 \times \frac{\text{No. of specimens with positive results by Rapide - Parvovirus Ag Test Kit}}{\text{No. of positive specimens confirmed by PCR or HA}}$$

$$\text{Specificity}(\%) = 100 \times \frac{\text{No. of specimens with negative results by Rapide - Parvovirus Ag Test Kit}}{\text{No. of negative specimens confirmed by PCR or HA}}$$

6. Results:

6.1 Study 1 :

Sensitivity and Specificity		Gold Standard: HA	
		Positive	Negative
Rapide - Parvovirus Ag Test Kit	Positive	51	0
	Negative	0	104
Sensitivity	100% (51/51)		
Specificity	100% (104/104)		

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6.2 Study 2 :

Sensitivity and Specificity		Gold Standard: PCR	
		Positive	Negative
Rapide - Parvovirus Ag Test Kit	Positive	51	0
	Negative	0	104
Sensitivity	100% (51/51)		
Specificity	100% (104/104)		
Competitor A	Positive	51	0
	Negative	0	104
Sensitivity	100% (51/51)		
Specificity	100% (104/104)		
Competitor B	Positive	51	1
	Negative	0	103
Sensitivity	100% (51/51)		
Specificity	99% (103/104)		

6.3 Study 3 :

Sensitivity and Specificity			Gold Standard: HA		Sensitivity	Specificity
			Positive	Negative		
Rapide - Parvovirus Ag Test Kit	Site A	Positive	5	0	100% (15/15)	100% (5/5)
		Negative	0	15		
	Site B	Positive	5	0	100% (15/15)	100% (5/5)
		Negative	0	15		
	Site C	Positive	5	0	100% (15/15)	100% (5/5)
		Negative	0	15		

6.4 Study 4 :

Pathogens	Titer	Results
Canine Distemper virus	5x10 ^{3}TCID $_{50}$/ml	Negative
Canine Parainfluenza virus	10 $^{6.0}$ EID $_{50}$/ml	Negative
Infectious Canine Hepatitis virus	10 $^{5.0}$ EID $_{50}$/ml	Negative
Porcine Parvovirus	1,024 HAU	Negative
Leptospira icterohaemorrhagiae	OD 1.0	Negative
E. coli spp	10 $^{8.0}$ CFU/ml	Negative
Salmonella spp.	10 $^{8.0}$ CFU/ml	Negative
Ascaris homogenate	10%	Negative
Giardia homogenate	10%	Negative

7. Discussion and conclusion:

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