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*FAST*est® C. perfringens Toxin

Internal study for sensitivity and specificity

01/2025

Introduction

The gram positive anaerobic bacterium *Clostridium perfringens* belongs to the intestinal flora of many pets and farm animals and is facultative pathogenic. Inconvenient endogeneous (other basic diseases, diarrhoea pathogens, antibiotic therapies with massive reduction of intestinal flora etc.) and exogeneous (farming conditions, extreme changes of the food, stress etc.) factors can disturb the floral balance within the gut enabling *C. perfringens* to reproduce actively leading to pathogenic effects by toxin production. Next to its ability to form extremely infectious and stable spores, the formation of lethal toxins is crucial for its pathogenicity. The classification into types A–E is based on the different toxins that are produced.

These toxins can cause extremely variable (mild to lethal progression forms) failures of the intestinal water and electrolyte balance in the different species like goat, sheep (e. g. dysenteria of lambs: type B; pulpy kidney disease: type D), cattle (haemorrhagic enteritis: type A–E), foal (haemorrhagic necrotising enteritis: type A & C) and piglet (e. g. serous-catarrhal enteritis: type A, necrotising enteritis: type C).

In the dog, especially serotype A occurs, producing 2 main toxins (toxin Alpha [α] and a Clostridia enterotoxin [CPE]), rarer serotype B (toxin Beta [β]). Both *C. perfringens* and its CPE can be detected also in healthy dog's feces. The CPE can be detected more often in dogs with diarrhoea compared to healthy dogs. For cats, to date reliable literature data concerning prevalence and clinical relevance are missing. Only by detection of *C. perfringens* in the feces, a disease caused by Clostridia is not diagnosable. Further investigation is necessary.

In a study in Switzerland, 54 % of the *C. perfringens* isolates showed a reduced sensitivity towards metronidazole or 18 % towards tetracycline. Because there is a general risk of resistance formation, it is recommended to identify the triggering pathogen in principle. By its high sensitivity and specificity, the use of ***FAST*est® C. perfringens Toxin** allows the veterinarian a rapid aetiological on-site diagnosis of a *C. perfringens* infection and subsequently the initiation of therapy as well as of necessary quarantine and prophylaxis measures.

To compare the performance of the ***FAST*est® C. perfringens Toxin** with ELISA, one of the gold standards to detect pathogenic levels of *C. perfringens*, we performed an internal study at our facilities.

Material and methods

Sampling:
In total, 100 fecal samples were collected from both healthy and diseased animals. Samples were collected, transported and stored according to the standard protocol.

Testing:
All 100 samples were each tested with ***FAST*est® C. perfringens Toxin** and ELISA.

Principle

The ***FAST*est® C. perfringens Toxin** is based on latest rapid immunochromatographic technique.

The *Clostridium perfringens* enterotoxin (CPE) in the feces sample will react in the conjugate pad area with mobile monoclonal anti-CPE antibodies (anti-CPE mAbs), which are bound to gold particles. Migrating ("lateral flow", LF) along the nitrocellulose membrane, these specific antigen-antibody complexes are bound by fixed anti-CPE mAbs producing a pink-purple TEST line (**TL**).

A correct test procedure will be indicated by a second, pink-purple CONTROL line (**CL**).

Results

Out of 100 samples, 45 were positive and 53 were negative in both ***FAST*est® C. perfringens Toxin** and ELISA. One sample was false positive in ***FAST*est® C. perfringens Toxin** (negative in ELISA) and one sample was false negative in ***FAST*est® C. perfringens Toxin** (positive in ELISA).

	ELISA positive	**ELISA** negative	
***FAST*est® C.p.T.** positive	45 A = RP	1 B = FP	46 A+B
***FAST*est® C.p.T.** negative	1 C = FN	53 D = RN	54 C+D
	46 A+C	54 B+D	

Sensitivity = A/(A+C) = **97.83 %**
Proportion of "really positive" (RP) in all sick animals

Specificity = D/(B+D) = **98.15 %**
Proportion of "really negative" (RN) in all healthy animals

Conclusion

The performance of ***FAST*est® C. perfringens Toxin** was very good with only one false positive and one false negative sample. In general, however, the proportion of false positive and false negative results with ELISA is also very high (Sakamoto et al., 2018). Consequently, we cannot say whether the ELISA or the ***FAST*est® C. perfringens Toxin** gave the wrong results. Overall, the ***FAST*est® C. perfringens Toxin** and the ELISA both show good accuracy in detecting *C. perfringens* as a pathogenic strain and cause of diarrhoea in animals.

The ***FAST*est® C. perfringens Toxin** is a good option for a rapid diagnosis of *C. perfringens*. It is very specific and detects only the pathogenic levels of *C. perfringens*, thus helping the veterinarian in much faster diagnosis and treatment of the animal.