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*FAST*est® C. perfringens Toxin

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***In vitro* diagnosticum**

Test-kit for the qualitative detection of *Clostridium perfringens* enterotoxin (CPE) in the feces of the dog, cat, goat and sheep lamb, calf, foal and piglet

INSTRUCTIONS FOR USE

Supplied Exclusively To The UK Veterinary Market By
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1. INFORMATION ON THE TEST-KIT

TEST-KIT COMPONENTS

1 test-kit ***FAST*est® C. perfringens Toxin** contains:
- 2 or 10 dipsticks coated with monoclonal antibodies
- 2 or 10 sample tubes with 2.0 ml buffer diluent each
- 1 instructions for use

STABILITY AND STORAGE

Store at 15–25 °C

Expiry date – see label

APPLICATION AND ABBREVIATIONS

For veterinary use only

LOT Lot number

In vitro diagnosticum

Do not use test-kit components from different kits, lot numbers or beyond stated expiry date.

Follow instructions for use precisely

TL – TEST line, **CL** – CONTROL line, **LF** – Lateral flow

LIABILITY

The entire risk due to the performance of this product is assumed by the purchaser. The manufacturer shall not be liable for indirect, special or consequential damages of any kind resulting from the use of this product.

ACCURACY

Sensitivity 99.83 %
Specificity 98.15 %
(Comparison Method: ELISA)

2. 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. 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 two 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.

3. INFORMATION ON THE SPECIMEN MATERIAL

Due to the normally inhomogeneous or nest-like dissemination of antigens in the feces, the specimen material has to be mixed up homogeneously (spatula, vortex-mixer) before sampling.

For the test, the required amount of feces as described in issue 4b/Specimen collection and preparation, is needed. The amount depends on the consistency of the sample. Use the attached spoon.

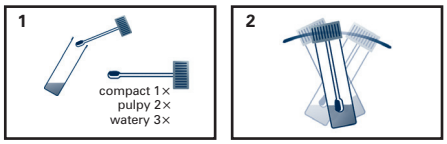
Non-cooled (**15–25 °C**), the sample should be tested within 4 hours! At **2–8 °C**, the sample can be stored up to 4 days, permanently **at minimum −20 °C**.

Keep in mind that the sample material, as well as all used test-kit components, should have reached **room temperature** at the time of application.

Endogeneous and exogeneous interfering substances of the sample (e.g. proteases, mucosa components, blood, but also viscosity, pH-value as well as grass and cat litter) **can cause interferences** (matrix effects) **that can influence the target measurement. These can lead to an impaired LF and/or unspecific reactions on TL and CL.**

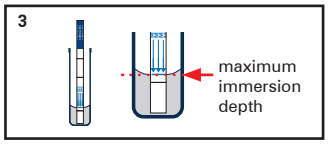
4. SPECIMEN COLLECTION AND PREPARATION

a. Open the sample tube with the buffer diluent.
b. Mix the feces sample homogeneously (applicator, vortexer). Then mix the required sample volume (**compact: 1 level spoon, pulpy: 2 level spoons, fluid-watery: 3 level spoons of feces**) steadily into the buffer diluent (fig.1).
c. Close sample tube tightly and rotate it easily to get the mixture as homogeneous as possible (fig.2).
d. For sedimentation of gross feces particles place the sample tube on a flat and horizontal surface for 1–5 minutes.



5. TEST PROCEDURE

1. Remove the dipstick from its foil pouch shortly before use.
2. Introduce the dipstick vertically and with the arrows pointing downwards into the sample tube for at least 1 minute. The liquid level (meniscus!) must not exceed the blue horizontal line below the blue arrowheads (fig.3).
3. Remove the dipstick from sample tube soonest the sample-buffer mixture (SBM) has reached the CL. If so, the pink-purple CL will appear slowly but surely (fig.4/5). If the CL will not appear after 5–10 minutes, a new SBM must be prepared and sedimented for at least 5 minutes. The dipstick must be held only in the supernatant until the LF has reached the CL (see also 7. Precautions for users*).
4. Place the dipstick on a flat and horizontal surface for incubation.



6. READING OF THE TEST RESULT

Read the test result **5 (max. 10) minutes**. Positive test results may be observed earlier, depending on the concentration of CPE in the sample.

POSITIVE TEST RESULT (fig.4)
A pink-purple TEST line **of any intensity** (varying from very weak to strongly intensive) and a pink-purple CONTROL line appear.

NEGATIVE TEST RESULT (fig.5)
Only a pink-purple CONTROL line appears. This line indicates, irrespective of its intensity, that the test has been performed properly.

INVALID TEST RESULT
No CONTROL line visible. The test should be repeated using a new dipstick *.

fig.4
POSITIVE TEST RESULT

fig.5
NEGATIVE TEST RESULT

7. PRECAUTIONS FOR USERS

- The guidelines for working in medical laboratories must be observed. It is recommended to wear disposable gloves and other personal protective equipment (protective clothing, possibly a face mask). Wash and disinfect hands after completing the test.
- Label sample material and associated sample tube to ensure a precise assignment.
- Use a new sample tube and a new dipstick for each sample.
- The buffer diluent contains low concentrations of toxic sodium azide as a preservative, therefore avoid skin/eye contact and/or ingestion.
- The sample material must be seen as potentially infectious and disposed of accordingly, together with the used test-kit components.

* To avoid an application error/external influence (e.g. too much sample material, too short sedimentation time, components in the faeces that clog the pores of the suction pad), the test can be repeated. Use a new dipstick and carefully observe the sample preparation. It is advisable to only hold the dipstick in the supernatant when repeating the test until the LF has reached the CL.

8. TEST 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**). These anti-CPE mAbs guarantee a high level of specificity for the aetiological detection of *Clostridium perfringens* enterotoxin. The intensity or width of TL depends on the concentration of *Clostridium perfringens* enterotoxin in the tested sample.

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

9. INFORMATION FOR THE INTERPRETATION

- The interpretation of the test result should always be based on anamnestic and clinical data as well as the therapy and prophylaxis possibilities.
- Any non-described colour or contour variation of TL and CL within the indicated incubation time or after more than 10 minutes (e.g. greyish, shadow-like lines) has to be considered as unspecific reaction and therefore as negative test result.
- TL can vary both in intensity (from weak to intense pink-purple) and width. Therefore, any pink-purple line appearing within the required incubation time is to be interpreted as a positive test result.