

FASTest® FOBT canine

ad us. vet.

In vitro diagnosticum

Test-kit for the qualitative detection of canine
haemoglobin in feces of the dog

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 **FASTest® FOBT** canine contains:

- 2, 5, 10 or 25 test cassettes coated with monoclonal antibodies
- 2, 5, 10 or 25 dropper bottles **A** with 1 ml buffer diluent each
- 2, 5, 10 or 25 disposable sample swabs
- 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 num-
bers or beyond stated
expiry date.



Follow instructions for
use precisely

T – TEST line, **C** – 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.

2. INTRODUCTION

Blood loss of any kind (e.g. gastrointestinal bleeding due to bacterial, viral or parasitic intestinal diseases, injuries, poisoning, ulcers, tumours, etc.) can occur without any visible changes in the feces. They can be quite significant. This is why we speak of occult blood – blood that is not visible to the eye. Currently, the most common detection method for FOB (faecal occult blood) in veterinary medicine is the modified Guaiac method. However, this test is said to have unspecific (false positive) reactions, especially to meat-based foods (including animal carcasses and blood meals), but also to drugs and peroxidases from plant-based foods. For this reason, a meat-free diet of at least 3 to 7 days is usually necessary before the guaiac FOB test, which is hardly ever complied with or adhered to by pet owners in practice.

As the **FASTest® FOBT** canine is based on the immunochromatographical detection of canine haemoglobin, it does not require this pre-test diet. The use of highly specific monoclonal antibodies against canine haemoglobin means that there is no cross-reaction with haemoglobin from other (food) animal species.

With the help of the **FASTest® FOBT** canine, the vet is able to detect occult bleeding in feces quickly, easily and reliably on-site and without the need for a meat-free diet.

3. INFORMATION ON THE SAMPLE MATERIAL

Freshly deposited feces, maximum 24 hours old.

For this test it is not necessary to follow a meat-free diet before taking fecal samples.

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

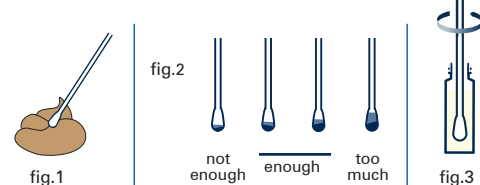
For the test, the required amount of feces as described in issue 4b/ Sample preparation or in fig.2 is needed.

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.

Endogenous and exogenous interfering substances of the sample (e.g. proteases, mucosa components, but also viscosity, pH-value and grass) **can cause interferences** (matrix effects) **that can influence the target measurement.** These can lead to an impaired LF and/or unspecific reactions on T and C.

4. SAMPLE PREPARATION

- a. Before opening the dropper bottle **A**, shake the entire buffer diluent down to the bottom of the bottle.

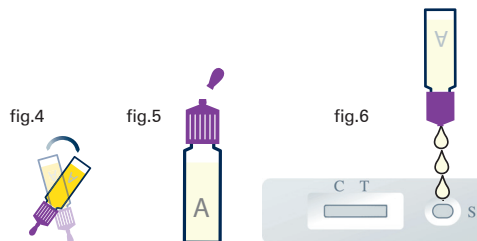


- b. Open the dropper bottle **A** with the buffer diluent.

- c. Mix the feces sample homogeneously (applicator, vortexer). Use the swab to collect some fresh feces (fig.1). Collect as much sample as indicated in fig.2. Place the swab into the buffer in the dropper bottle **A** and rotate the swab more than 10 times (fig.3). Remove the swab, discard it and close the dropper bottle **A**.

5. TEST PROCEDURE

1. Remove the test cassette from its foil pouch shortly before use. Place it on a flat surface.
2. Mix the sample-buffer mixture (SBM) thoroughly (fig.4).
3. Break the tip of the dropper bottle **A** (fig.5), hold the dropper bottle **A** vertically, discard the first drop and add 3 drops (approx. 90 µl) SBM into the sample window S of the test cassette (fig.6).
4. Add 1 additional drop of SBM into the sample window S if there is no beginning LF visible within 1 minute after adding the SBM.



6. READING OF THE TEST RESULT



Read the test result after **5–10 minutes**. Positive test results may be observed earlier, depending on the concentration of hemoglobin in the sample.

POSITIVE TEST RESULT (fig.7)

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.8)

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 test cassette.

fig.7
POSITIVE TEST RESULT



fig.8
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, associated dropper bottle and test cassette to ensure a precise assignment.
- Use a new dropper bottle, a new disposable sample swab and a new test cassette 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.

8. TEST PRINCIPLE

The **FASTest® FOBT** canine is based on latest rapid immunochromatographic technique.

Positive samples contain occult canine haemoglobin. This haemoglobin is used as antigen which will react in the conjugate pad area with mobile monoclonal antibodies (mabs), which are bound to gold particles. Migrating ("lateral flow", **LF**) along the nitrocellulose membrane, these antigen-antibody complexes are bound by fixed antibodies producing a pink-purple TEST line (**T**).

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

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 T and C (e.g. greyish, shadow-like lines) has to be considered as unspecific reaction and therefore as negative test result.
- To increase the reliability of detection, as occult blood is not excreted with every fecal sample, a single negative test result should be confirmed by testing a serial feces sample (individual testing of at least three consecutive feces samples) if clinical suspicion persists.