ScheBo® • Pancreas Elastase1 Quick™
Canine

Use

The ScheBo® • Pancreas Elastase1 Quick™ Canine is a visual immunochromatographic rapid test for detecting canine pancreatic elastase1 in stool samples for non-invasive exocrine pancreatic function testing.

Main indications:

- Diagnosis/exclusion of pancreatic involvement in association with Gastrointestinal Symptoms, Maldigestion, Steatorrhea, Poor Hair Coat, Diarrhea, Weight Loss
- Diagnosis/exclusion of exocrine pancreatic insufficiency caused by e.g. Chronic Pancreatitis, Diabetes Mellitus, Pancreatic Cancer, Pancreatic Acinar Atrophy, etc.

Advantages:

- Based on monoclonal antibodies, substitution therapy has no influence on the test result
- Absolutely pancreas-specific
- No blood sampling
- No starvation periods needed
- Intestinal inflammation and blockage of the pancreatic ducts do not interfere with the results
- High specificity and sensitivity

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Test Principle

Canine pancreatic elastase 1 (cPE 1) is a proteolytic digestive enzyme produced and secreted by the pancreas, which remains undegraded during intestinal transit and can be determined in stool. Its concentration in feces directly reflects the exocrine pancreatic function.

The ScheBo® • Pancreas Elastase1 Quick™ Canine test is based on an immunochromatographic method. Canine pancreatic elastase1 is detected by two specific monoclonal antibodies. Canine pancreatic elastase1 in the stool sample reacts with a monoclonal antibody bound to gold particles. This complex migrates along the test membrane and reaches the test line (T), which has a second monoclonal antibody against pancreatic elastase1 attached.

If the exocrine pancreatic function is normal (= high canine pancreatic elastase1 concentration), the gold-labeled antibody + canine pancreatic elastase1 complex binds to the test line (T) and a pink color becomes visible. In the event of an exocrine pancreatic insufficiency (= low canine elastase1 concentration) the sample contains no antibody + canine elastase1 complex that can bind to the test line (T) so no color becomes visible.

Development of a pink control line (C) guarantees that sample application and migration have taken place correctly and that the test was properly performed.

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Storage and Shelf Life

Test
The test must be stored at +4°C to +27°C and brought to room temperature just prior to use if necessary.

Stool sample
After taking the stool sample, it can be stored at room temperature for up to 5 days. Within these 5 days, either the test must be performed or the sample frozen at -20°C for longer-term storage. The deep-frozen sample is stable for up to 1 year.

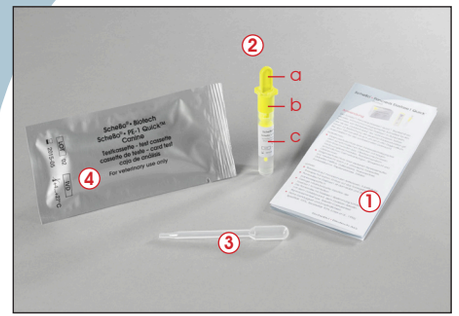
Interferences
Very watery stools can lead to false results due to a dilution effect.

⚠ In-vitro diagnostic test

Not for re-use

- Do not use after the expiry date.
- Do not use reagents from different lots.
- Only open the test cassette's packaging shortly before performing the test.
- Make sure the foil bag containing the test cassette is undamaged.
- All samples should be regarded as potentially infectious. Therefore, wear disposable gloves when conducting the test and dispose of the samples, extracts and test cassettes accordingly.
- The extraction buffer contains small quantities of sodium azide.

Contents of the kit



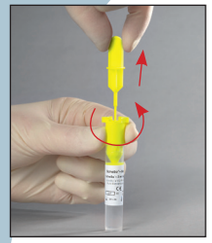
① 1 instructions for use

② 1 ScheBo® • Pancreas Elastase1 Quick™ Canine ready-to-use stool extraction system consisting of:
a) yellow dosing tip
b) yellow cone
c) pre-filled tube
(extraction buffer with detergent and sodium azide (< 0.05%))

③ 1 Pipette

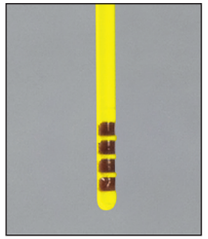
④ 1 ScheBo® • Pancreas Elastase1 Quick™ Canine cassette (packed in an aluminum sachet)

Test Procedure



1. Turn the yellow dosing tip of the extraction system anti-clockwise and remove the yellow dosing tip by pulling it up.

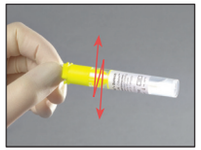
2. Insert the yellow dosing tip in three different places in the stool sample to a depth of 1cm (all notches must be filled with stool).



3. Please check that all notches of the yellow dosing tip are filled with stool.

Test Procedure

4. Insert the yellow dosing tip with the stool through the yellow cone into the extraction system and turn the tip clockwise to close it.



5. Shake well and tap the tube, if necessary, until all the stool has been removed from the notches in the dosing tip.

10 min.

6. Leave to stand for 10 minutes.

7. Give the tube a final shake. Caution: no stool should remain attached to the yellow dosing tip. If stool still remains stuck to the dosing tip, the extraction system can be left to stand for up to 1 hour in order to free the stool by repeated shaking.

8. Tear open the aluminum packaging and remove the test cassette.

9. Remove the stool sample extract from the extraction system with a pipette.

10. Using the pipette apply 4 drops of stool extract into the circular sample well on the cassette.

10 min.

11. Wait exactly **10** minutes and then read the results. Results which are read later may be false.

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Interpretation of the Test Results

Quality Control: The test contains an inbuilt control. When a pink band develops in the control region (C) the test has been performed correctly.

Normal Two pink bands develop, one in the control region (C) and one in the test region (T).
A high concentration of canine pancreatic elastase1 indicates a normal exocrine pancreatic function. The test stripe (T) must be clearly recognizable as a line, although it may be weaker than that of the control (C).

Low One pink band appears in the control region (C). No band develops in the test region (T). **A low concentration of canine pancreatic elastase1 indicates exocrine pancreatic insufficiency.**

Invalid If no pink band appears, the test has not worked.

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Application and Test Interpretation

The test is used to measure canine pancreatic elastase1 in stool samples. A low concentration of canine pancreatic elastase1 indicates exocrine pancreatic insufficiency.

Reference concentration:

- normal canine pancreatic elastase1 concentration (= Values > 10 µg elastase1/g stool) is an indicator for a normal exocrine pancreatic function.
- low canine pancreatic elastase1 concentration (= Values < 10 µg elastase1/g stool) can be an indicator for an exocrine pancreatic insufficiency.

Two pink lines:
A normal level of canine pancreatic elastase1 was found in the stool sample at the time the test was performed. High values of canine pancreatic elastase1 concentrations are standard values and are an indicator for a normal exocrine pancreatic function. In case of disease symptoms, further diagnostic investigations should be conducted.

One pink line:
A low level of canine pancreatic elastase1 was found in the stool sample at the time the test was performed. Low canine pancreatic elastase1 concentrations indicate exocrine pancreatic insufficiency.

Treatment Option:
An exocrine pancreatic insufficiency can be treated with enzyme substitution therapy.

Performance:
The Pancreas Elastase1 Quick Canine test has > 95% sensitivity and specificity when compared to the Pancreatic Elastase1 Canine ELISA.

References

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