ScheBo® • Pancreas Elastase 1 Quick™

Stool Test

Use

The ScheBo® • Pancreas Elastase 1 Quick™ stool test is a visual immunochromatographic rapid test for detecting pancreatic elastase 1 in stool samples. The Pancreatic Elastase 1 test is known as the gold standard for non-invasive pancreatic function testing. It is an in-vitro diagnostic test exclusively for professional use.

Main Indications:

- Diagnosis/exclusion of pancreatic involvement in association with gastrointestinal symptoms, abdominal pain, maldigestion, steatorrhea, diarrhea, Irritable bowel syndrome (IBS), Inflammatory bowel disease (IBD), obesity and osteoporosis
- Diagnosis/exclusion of exocrine pancreatic insufficiency caused by e.g. Chronic Pancreatitis, Diabetes Mellitus, Cholelithiasis (Gallstones), Cystic Fibrosis, Pancreatic Cancer, Papillary Stenosis, Coeliac Disease

Advantages:

- Based on monoclonal antibodies, substitution therapy has no influence on the test result
- Pancreatic elastase 1 is stable during intestinal transit and absolutely pancreas-specific
- Low intra-individual variation of pancreatic elastase 1 concentration
- Pancreatic elastase 1 determination correlates well with the invasive gold standard secretinpancreozymin test and the secretin-caerulein test
- High specificity: 93%, high sensitivity: 93% (Löser et al., 1996)

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Test Principle

Human pancreatic elastase 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 exocrine pancreatic function.

The ScheBo® • Pancreas Elastase 1 Quick™ stool test is based on an immunochromatographic method. Pancreatic elastase 1 is detected by two specific monoclonal antibodies. Pancreatic elastase 1 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 elastase 1 attached.

If the exocrine pancreatic function is normal (= high pancreatic elastase 1 concentration), the gold-labeled antibody + pancreatic elastase 1 complex binds to the test line (T) and a pink color develops. In the event of an exocrine pancreatic insufficiency (= low elastase 1 concentration) the sample contains no antibody + elastase 1 complex that can bind to the test band (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 one week. Within this week, 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

Watery stools can lead to false results due to a dilution effect.

⚠ In-vitro diagnostic test
for professional use only!

Not for re-use

- Do not use the test 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 cassette is undamaged.
- All patients' 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 doctor's kit

① 1 instructions for use

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

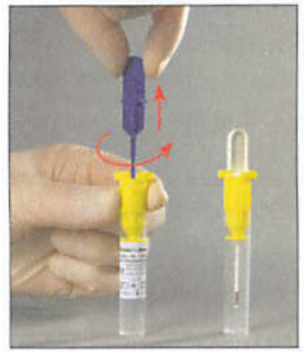
③ 1 Pipette

④ 1 ScheBo® • Pancreas Elastase 1 Quick™ cassette (packed in aluminium sachet)

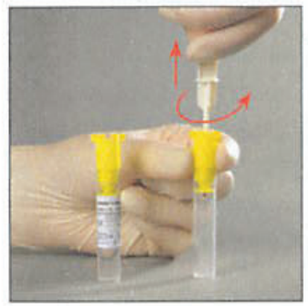
CE

Test Procedure

1. Before starting the test, check that all the notches in the **white** dosing tip of the patient's tube are filled with stool.

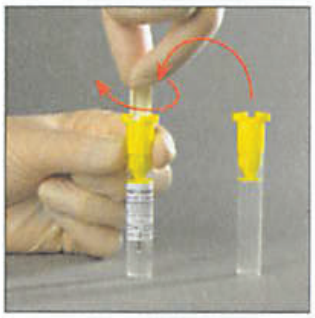


2. Turn the **blue** dosing tip of the extraction system anti-clockwise and withdraw it from the yellow cone. Dispose of the **blue** dosing tip.

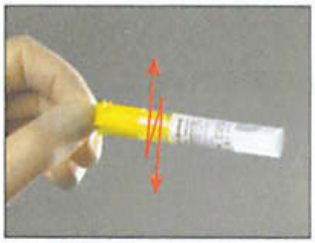


3. Turn the **white** dosing tip of the patient tube anti-clockwise and withdraw the tip with the stool through the yellow cone.

Test Procedure



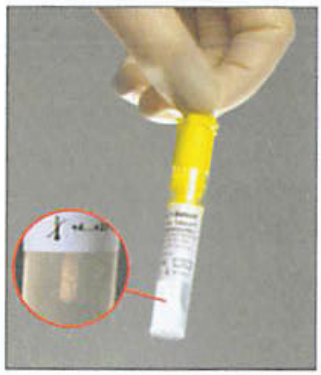
4. Insert the **white** dosing tip with the stool through the yellow cone into the extraction system and turn the tip clockwise to close it.



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

10min

6. Leave to stand for 10 minutes.



7. Give the tube a final shake. Caution: no stool should remain attached to the white 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 aluminium 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.

5min

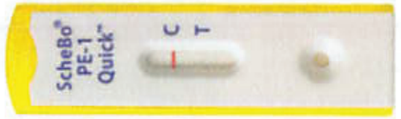
11. Wait exactly 5 minutes and then **read the results.** Results which are read later may be false.

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 pancreatic elastase 1 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 pancreatic elastase 1 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 pancreatic elastase1 in stool samples. A **low concentration** of pancreatic elastase 1 indicates ***exocrine pancreatic insufficiency.***

Reference concentration

(for adults and children more than one month old)

- **normal** pancreatic elastase1 **concentration** = Values > 200 µg elastase1/g stool is an indicator for a *normal exocrine pancreatic function*
- **low** pancreatic elastase1 **concentration** = Values < 200 µg elastase1/g stool can be an indicator of an *exocrine pancreatic insufficiency*.

Two pink **lines:**

A **normal level** of pancreatic elastase 1 was found in the stool sample at the time the test was performed. High values of 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 pancreatic elastase 1 was found in the stool sample at the time the test was performed. Low pancreatic elastase 1 concentrations indicate ***exocrine pancreatic insufficiency.***

Performance

The Pancreas Elastase1 Quick™ test has 92% sensitivity and 94% specificity when compared to the Pancreatic Elastase1 Stool Test ELISA.

References

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