PreventID® CC

Manual (FOR PROFESSIONAL USE)

→REF KST40110TP
KST40110GP

Intended Use

The **PreventID® CC** from Preventis is a simple immunochromatographic rapid test for the qualitative detection of human faecal blood.

Introduction

Faecal blood is an indicator for a variety of diseases. In the early stages, gastrointestinal disorders such as gastric ulcers, polyps, colitis, diverticulitis, fissures and colon cancer very rarely manifest themselves through visible symptoms – except for the presence of hidden traces of blood in the stool.
Tumours in the intestine bleed more often than a healthy intestinal mucosa. Intestinal polyps – which can be precancerous stages – also bleed sometimes. The blood is then often excreted with the stool – usually in very small quantities.
The **PreventID® CC** enables the detection of very small amounts of occult blood in stool. The specificity of **PreventID® CC** is very high: it only detects human haemoglobin. The test works independently of food components, i. e. no dietary restrictions on the day before sampling are necessary. Furthermore, the **PreventID® CC** is easy to interpret.

Test Principle

This test is based on a sandwich immunoassay whose unique combination of monoclonal antibodies permits the selective detection of blood traces in faecal samples. By this method, human occult blood can be detected with a high sensitivity.
Gold-labelled anti-hemoglobin antibodies bind to hemoglobin (if present) in the sample. These complexes migrate over the test membrane until they pass the test zone which consists of immobilised anti-hemoglobin antibodies. These secondary antibodies bind the gold-labelled antibody-hemoglobin complexes and thus generate a coloured (test) line (positive result).
In order to prevent false-negative results, an internal (control) line consisting of anti-IgG antibodies has been added. These bind excess gold-labelled antibodies and retain them on the control line. A coloured control line thus indicates that the test has run properly and the result is valid.

Materials

Materials Provided

- test devices, individually packed TEST
- folding boxes; each contains 1 sample collection tube (with buffer) TUBE , 1 paper stool catcher for faecal samples, 1 identification label, 1 instruction for stool sample collection
- manual

Materials Required but not Provided: timer or stop watch

Storage and Stability

The **PreventID® CC** test should be stored at room temperature (4–30 °C). The test device is susceptible to humidity and high temperatures. Therefore, this test should be protected from extreme temperature and should be run immediately after the opening of the pouch. This test should not be run after the expiry date.

Precautions

1. For *in vitro* diagnostic use only.
2. Do not eat or smoke while handling specimen.
3. Wear protective gloves and wash hands thoroughly after performing the test.
4. Avoid splashing or aerosol formation while handling specimen and performing the test.
5. All samples and materials used should be treated as potentially infectious and disposed in a biohazard container. Clean all contaminated objects and surfaces carefully.
6. Do not use test if the pouch is torn or if the membrane of the test device is visibly damaged. Note the expiry date.
7. Read the instruction carefully before performing the test.
8. Do not mix reagents from different lots.
9. If you have any questions please contact Preventis GmbH.

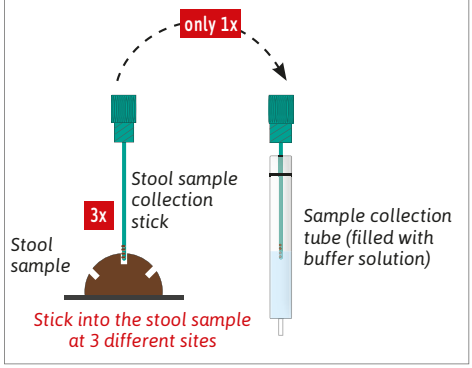
Sample Preparation

1. Sample collection should not be performed during or within three days of a menstrual period, or if the patient suffers from bleeding gums or haemorrhoids or blood in the urine. These may cause false-positive results.
2. No dietary requirements.
3. Alcohol, aspirin and some medications sometimes cause gastrointestinal irritation or bleeding. Advise your patient prior to the test to prescribe a temporary dose reduction if necessary.

Sample Collection

1. Collect a faecal sample with the paper stool catcher attached to your toilet according to the manual. Please note: The test result can be adversely affected when faeces come in contact with toilet water, urine or toilet bowl freshener.
2. Unscrew the cap of the sample collection tube and stick the attached sample collection stick **in one go at three different sites into the faeces** *(Fig. 1)*. Only the amount of stool that sticks to the grooves of the sample collection stick should be transferred to the sample collection tube.
3. Now retract the sample collection stick with the adhering faecal sample and insert it **only once** into the sample collection tube containing an extraction buffer solution.
   Please note: A repeated transfer of stool into the sample collection tube compromises the test performance!
4. Screw cap on firmly and shake well. This defined stool sample solution is now ready to use for the test.
5. The paper stool catcher can be flushed down the toilet.
6. If **PreventID® CC** rapid test is not run within one day of sample collection, the sample collection device should be stored at 2–8 °C, but not for more than 5 days.

Fig. 1: Sample collection (steps 2 + 3)



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Test Procedure

1. Remove the test device from its pouch and place it on a flat dry surface. The oval sample application window at the one end of the test device should be at the right side *(Fig. 2)*.
2. After the sample collection procedure has been completed, the sample collection tube should be brought to room temperature and shaken well.
3. Break off the tip of the sample collection tube carefully and avoid dripping by using a soft paper for the tip *(Fig. 2a)*. Squeeze the tube and apply **two drops** of the extracted sample into the sample application window on the right end of the test device by gently pressing the sample collection tube in the middle.
4. In a properly working test, a violet band will pass through the square result window in the middle of the test device.
5. The result should be interpreted **at 10 minutes**.

Beware: The above interpretation time is based on reading the test results at room temperature (15–30 °C). If your room temperature is significantly lower than 15 °C, then the interpretation time should be increased accordingly.

Test Interpretation

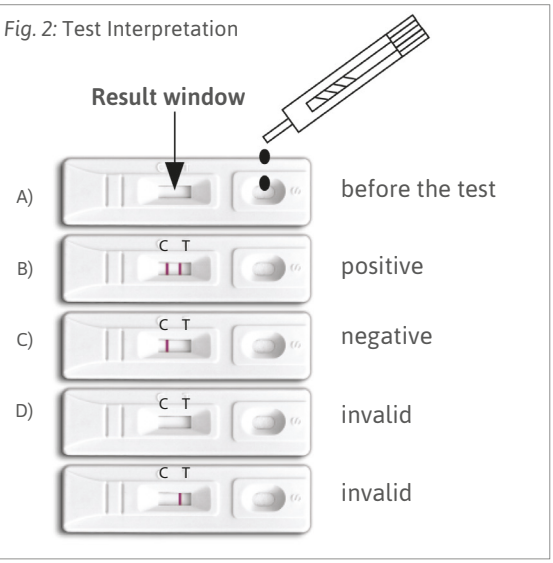
1. A coloured control line (C) at the left side of the result window indicates that the test has run correctly.
2. The test result is indicated by the appearance or non-appearance of a coloured test line (T) on the right side of the result window.

Positive Result: If both test (T) and control (C) lines appear in the result window, the test is positive *(Fig. 2b)*. Human occult blood was detected in the stool sample. This does not automatically indicate the presence of colon cancer! The causes of the bleeding must be clarified.

Negative Result: A solitary control (C) line in the result window indicates a negative result *(Fig. 2c)*. No human occult blood was detected in the stool sample.

Invalid Result: If no control (C) line is visible after performing the test, the test result is considered invalid. The test result is also considered invalid if only the test (T), but no control (C) line appears *(Fig. 2d)*.

Fig. 2: Test Interpretation



Test Characteristics

Analytical Sensitivity: 50 ng/mL – test shows postive results with hemoglobin higher then 50 ng/mL.

Analytical Specificity: samples were spiked with the following organisms and substances (e. g. bacteria, yeasts, drugs, food, food additives), tested with **PreventID® CC** and showed no cross-reactivities or interferences: Acinetobacter calcoaceticus, Proteus vulgaris, Salmonella typhi, Acinetobacter spp, Staphylococcus aureus, Candida albicans, Neisseria gonorrhae, Escherichia coli, Neisseria catarrhalis, Gardnerella vaginalis, Neisseria meningitidis, Streptococcus faecalis, Neisseria lactamica, Streptococcus faecium, Pseudomonas aeruginosa, Trichomonas vaginalis; hemoglobins from beef, fish, chicken, horse or sheep; broccoli, cantaloupe, horseradish, cauliflower, vitamin C, iron; Acetamiophen, Acetyl salicyl acid, Ascorbic acid, Atropine, bilirubin, caffeine, creatinine, gentesic acid, glucose, ketones, Mestranol, nitrite, Penicillin, sodium- and lithium heparin.
The high dose Hook effect (prozone effect) was not observed (false negative results) for hb concentrations up to 100,000 ng/mL.
PreventID® CC has a clinical sensitivity of 75 % and a specificity of 99 % relative to colonoscopy.

Test Limitations

The origin of blood of faeces may be other than from colorectal bleeding such as haemorrhoids, blood in urine or gastric irritations.
Negative results do not rule out bleeding because some polyps or adenomas bleed intermittent and blood is not distributed homogeneously within the faecal sample and may thus be missed during the sample collection.
Colorectal polyps may not bleed during very early stages.
Please note: Due to the intermittent bleeding of polyps, we recommend to use **PreventID® CC** at least once per year.
Other clinical tests are indicated in the case of unspecific results. As with other diagnostic tests, a definitive clinical diagnosis should not be based on a single test result, but should be made by a qualified professional after evaluation of all clinical and laboratory findings.

References

1. Hoepffner N et al. (2006) Comparative evaluation of a new bedside faecal occult blood test in a prospective multicentre study. Aliment Pharmacol Ther 23: 145-154
2. Schröder O et al. (2005) Klinische Validierung eines neuen immunologischen Bedside-Tests auf okkultes Blut im Stuhl. Z Gastroenterol 43:947 (P509)
3. Shastri Y M et al. (2005) Comparative evaluation of a new bedside fecal occult blood test in a prospective multicenter study. Abstract B6 of the 46th Ann. Conference of the Indian Society of Gastroenterology, November 11-15, Visakhapatnam
4. Trojan J et al. (2002) A New Immunological Test Strip Device for the Rapid, Qualitative Detection of Faecal Occult Blood. Z Gastroenterol 40: 921-924

US: all products: Research Use Only. Not for use in diagnostic procedures.

Temperature limitation	Manufacturer
In vitro diagnostic device	Lot number
Catalogue number	Expiry date
To be used with	Do not reuse
Read user instructions	Contains sufficient for <n> tests
Keep away from sunlight	

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