

Instructions for use for the physician

3-Hole Slide Test for fecal occult blood

REF005031-E (50) REF002531-E (25) REF005531-E (500)

SUMMARY

Method: modified guaiac test according to Greegor
 Readings: 30 seconds to 2 minutes after application of the developer solution onto each dried fecal specimen
 Evaluation: Any trace of blue colour development detectable 30 seconds to 2 minutes after application of the developer solution onto the dried fecal specimen is to be judged a positive test for fecal occult blood.
 Specimen: stool

REAGENTS

Natural guaiac resin impregnated into standardized, high quality filter paper.

Active reagent: cum guaiac; min. 0.05 mg per test.

Developer Solution:

Hydrogen peroxide in ethyl alcohol.

Active reagent: H₂O₂; 0.69 g/20 ml.

Keep bottles with developer solution capped tightly always. The developer solution evaporates quickly.



highly flammable liquid



causes skin irritation and serious eye irritation

Hazard and Precautionary statements:

H225: highly flammable liquid. H315: causes skin irritation. H319: causes serious eye irritation. P102: Keep out of reach of children. P233: Keep container tightly closed. P210: Keep away from heat – no smoking. P264: Wash hands thoroughly after handling. P280: Wear protective gloves / eye protection. P313: Get medical advice / attention.

STORAGE

Store hemoCARE test slides and developer solution at 4 – 28 °C (39 – 82 °F) and protected from light and heat. Do not use after expiration date. The test slide and the developer solution are ready to be used.

EVALUATION by the PHYSICIAN

1. Open lid at the back of the test slide (“To be opened by physician only”)
2. Apply 1 to 2 drops of hemoCARE developer solution directly onto the dried fecal specimens in the guaiac-impregnated testing areas.
3. Read results after 30 seconds to 2 minutes.

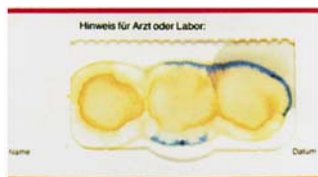
Each trace of **blue colour** development in or around a stool specimen is to be judged a **positive** test result and accordingly the reason for intestinal bleeding which has to be diagnosed.

The **absence** of a **blue colour** change is judged a **negative** test result for fecal occult blood in stool.

Example:



negative test result



positive test result

Attention:

In order to achieve reliable test results be aware of the following general notes concerning the test slides:

- protect from light and heat
- protect from direct sun light and UV-radiation
- never read results close to an opened window

TEST PRINCIPLE

By applying the hydrogen peroxide contained in the developer solution to the dried fecal specimen on the guaiac impregnated reaction paper, the guaiac is oxidised by the peroxidase like action of intact hemoglobin and therefore develops a characteristic blue color. The test only reacts with free hemoglobin of destroyed erythrocytes. In the presence of blood, hemolysis is promoted by substances contained in stool, primarily water and salts. hemoCARE is designed for an increased hit rate in the detection of fecal occult blood without having the problem to detect physiological bleeding.

PREPARATION of the PATIENT

For an initial screening special preparation of the patient is generally not necessary. However, the dietary restrictions given below and recommended in colon cancer screening programs should be considered and followed 3 days prior up to the end of specimen collection.

- Eat food rich in roughage (vegetables, salads, whole gran bread, nuts) to reveal silent lesions.
- Do not eat raw or rare meat or sausages, because food containing blood could give positive results, even though there is no intestinal bleeding.
- Do not take iron pills or the like because high iron concentrations may result in false-positive test results. Please also keep this in mind in the case of multivitamins- or iron pills.
- Do not take medication rich in ascorbic acid (Vitamin C) because in rare cases (more than 1 g ascorbic acid per day) it might result in false-negative results.

Give the patient an envelope containing 3 test slides, 9 cardboard applicators (for taking the fecal specimen) and 1 patient information sheet.

PREPARATION of the TEST SLIDE

1. The date of specimen collection and the patient's name and address are to be written on the back of the slide.
2. The patient opens the test slide at the front side (“patient - open here”). A pea-sized sample of the stool is taken with a cardboard applicator and is spread onto the left field “A”.
3. With a new cardboard applicator another sample is taken from a different location of the stool specimen and is smeared onto field “B”.
4. Again, with a new cardboard applicator a third sample from yet another location in the same stool specimen is taken and smeared on the right field “C” and the lid of the test slide is closed. The slide must always be protected from light and heat.
5. The same procedure is to be followed for the second and the third test slide during the next two days or after the next two bowel movements. After completing the third test slide, all the test slides are put into the envelope and should be returned to the physician or laboratory as soon as possible.

SPECIMEN

For the preparation of the test slide a pea-sized stool sample is necessary to be smeared within the test field. The test slides can be evaluated only after the stool samples have dried. Moist stool samples will result in decreased test sensitivity, also as with stool samples that were collected more than 12 days ago.

Hands, gloves and the working area should be free from blood. Some stool samples might show blood due to hemorrhoides or menstrual bleeding for example - such samples are not suitable for a reliable diagnosis.

Notes:

- (a) Gastro-intestinal lesions may bleed heavily or only intermittently.
- A positive test must not be repeated in order to double-check a test result.
- A negative test result does not rule out a carcinoma. In case of reasonable suspicion or stomach problems another diagnosis is necessary.

– it is recommended to take samples from 3 different bowel movements and to take the 3 samples from different portions of the stool from each bowel movement in order to increase the chances of detecting fecal occult blood.

(b) In the event hemorrhoids are detected after a positive test result, the test should be repeated after treatment and healing of the hemorrhoids. Positive test results may also arise due to another colon bleeding.

(c) The intake of medicines like aspirine, indomethacine, phenylbutazone, corticosteroides, reserpine and the like may cause gastro-intestinal irritations or bleeding. Whether or not the intake of such medication can be paused for the duration of the test phase should be evaluated.








(d) High iron concentrations, as in the case of iron therapies may cause false-positive results. A sample containing ~100 mg Iron⁺³-Chloride within 100 g of stool sample results in a clear blue color reaction of the test field. Therefore it is highly recommended to pause such therapies before and during the testing period.

(e) In rare cases the intake of vitamin-C medication (> 1 g ascorbic acid per day) may cause false-negative results due to the reducing action of ascorbic acid. Therefore vitamin-C medication should be paused before and during the testing period.

DIAGNOSTIC CONSEQUENCES

Patients with positive test results for fecal occult blood may require referral for colonoscopy.

ZEICHENERKLÄRUNG

-  „In-vitro diagnostic device“
-  „Read instructions carefully before use“
-  „Use only once“
-  „Order number“
-  „Expiration date“
-  „LOT number“
-  „CE Symbol“ – Dieses Produkt erfüllt die Anforderungen der Richtlinie 98/79/EC des europäischen Parlaments und der Ratsversammlung des 27. Oktober 1998 für IVD medizinische Apparate.

LITERATURE

1. Hammes, P.H., Gnauck, R. a Hawle, H., Nemecká klinika pre diagnostiku, Wiesbaden, FRG, Z gastroenterol. 1989, 27: 611-613.
2. Porschen, R., Kruis, W. a Strohmeyer, G., Medicínska klinika a poliklinika, Heinrich-Heine-Universität, Düsseldorf, FRG. Klin. Wochenschr. 1991, 69: Suppl. XXIII: 60

Contents:

hemoCARE

REF 005031-E (box containing 25x3, 50x3 or 500x3 tests)

- 25 / 50 / 500 envelopes, each with
 - 3 hemoCARE test slides
 - 9 cardboard applicators
 - patient information sheets
- 20 / 2x20 / 25x20 mL of hemoCARE developer solution
- 1 Instruction for use for the physician

Also available from CARE diagnostica:

immoCARE-C

REF 003630-E (25 tests)

Immunological detection of fecal occult blood

- 25 foil pouches with test cassette and desiccant
- 25 sample collection tubes with sample buffer and patient label
- 25 patient information sheets
- 25 plastic pouches
- 1 Instruction for use for the physician



Manufacturer and International Distribution:

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Rev06-2012-04-25

