User Guide

HEMOPLUS®

Screening test for occult blood in faeces

SARSTEDT

Test principle

The test card contains chromatographic filter paper impregnated with distilled guaiac resin as an indicator. A stabilised alcoholic peroxide solution acts as a developing reagent.

Addition of the developing reagent will produce a blue coloration if occult blood is present in the faeces sample.

The test principle is based on the peroxidase activity of haemoglobin which may be present in the faeces. Haemoglobin will catalyse the oxidation of the chromogen (guaiac resin) in the presence of hydrogen peroxide to form a blue colored compound. The intensity of the blue coloration is proportional to the concentration of haemoglobin in the specimen.

Test sensitivity

The test sensitivity of the HEMOPLUS® test is such that although there is a very high probability of detecting bleeding from colo-rectal disorders, physiological gastrointestinal blood loss is not detected. Field trials proved that it is within the ideal range (0.22–0.26 g Hb/100 g faeces) for screening for colo-rectal cancer.

Performing the test

The patient is allocated one HEMOPLUS® envelope containing 3 test cards, 12 cardboard spatulae and comprehensive instructions for use.

If the testing is to be done at home the patient's doctor should explain the reason for the test and the measures to be observed. The reliability of the test result depends on the patient observing the correct methodology.

Always inform the patient of the following:

1. Three days prior to the test period the patient should eat food which is high in fibre, e. g. vegetables, salads, nuts, wholemeal bread. This will encourage any carcinoma present to bleed.
2. Foods such as black pudding and raw meat should not be eaten as these may cause false-positive results.
3. Excessive consumption of vitamin C, peroxidase-containing vegetables e. g. kohlrabi, horseradish and soybeans should also be avoided for the 3 days before the test period. A daily intake of up to 2 g vitamin C will not affect the test.
4. The test should be postponed in the event of diarrhoea or menstruation in the patient. However, slight bleeding from the gums (after dental work) or nose will not affect the test.

There are precise instructions for the patient on the back of each card. The following must be observed:

- Three consecutive bowel motions are required for the test.
- 4 samples, from different areas of the stool, should be taken from each motion. Every sample must be taken with a clean spatula.
- The test positions 1–4 must each be filled completely with the sample.

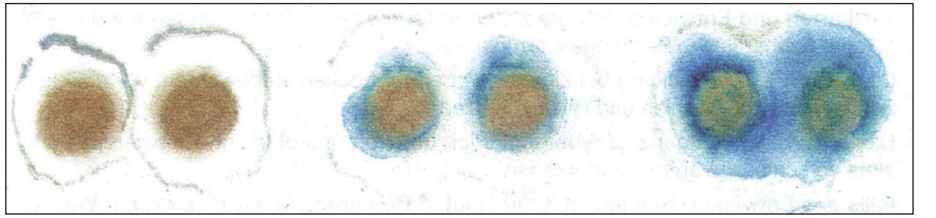
Returning the card

After the third day the patient should place the test card in the HEMOPLUS® envelope and return it to the laboratory for analysis. The envelope is made from a special non-permeable paper in the interest of microbial safety.

Analysis

Analysis should only be carried out on dry faeces samples, for up to 12 days after the last sample was taken, otherwise a loss of sensitivity must be expected. A reduced test sensitivity of HEMOPLUS® has been established for fresh stool samples.

- Remove the perforated flap labelled "open for test evaluation" from the back of the test card completely. Add 1 drop of developing reagent to each of the 12 test positions.
- The presence of occult blood is indicated by a blue coloration. The color is stable for 60 seconds, its intensity may then increase up to two minutes and then begin to fade slowly.
- If no blue coloration appears within 30 seconds the test is NEGATIVE.
  If the blue coloration appears within 30 seconds the test is POSITIVE.



example for a negative result

examples for a positive result

- Any blue coloration appearing within 30 seconds should be regarded as a POSITIVE result.
- Even if only one of the 12 test positions shows a blue coloration the test should be regarded as positive as occult blood is indicated in this particular sample.
- A weak, asymmetrical blue coloration may develop in a faeces sample. This should also be regarded as positive and investigated further.
- The test card should not be developed in direct sunlight or at an open window. Exposure to direct sunlight or U. V. light during developing can lead to a blue-green coloring of the test paper which would give a false-positive result.
- If the test paper shows a blue-green coloration before developing, the test card should be discarded and the test repeated on a new HEMOPLUS® card.

Further instructions

A positive test should not be repeated for confirmation as bleeding may be intermittent.

A negative result does not exclude the presence of a carcinoma as a carcinoma may not have been bleeding at the time of test.

If a carcinoma is suspected, particularly when the patient´s symptoms indicate such a diagnosis, further investigations should be carried out even in the event of a negative HEMOPLUS® test.

Haemorrhoidal bleeding may occasionally cause a positive test result. In such cases the test should be repeated when the haemorrhoids have healed as bleeding from the colo-rectal area can neither be eliminated nor confirmed.

Range of application

- Screening test for occult blood in faeces
- Diagnostic clarification of gastro-intestinal disorders
- Post-operative monitoring of the gastro-intestinal tract

Shelf life and storage

If stored under the conditions described below, the test cards and the developing reagent have a shelf life of 3 years.

Store HEMOPLUS® in a dry place at room temperature. Protect against direct sunlight, U. V. light and heat.

The developing reagent is inflammable and volatile. It should always be stored closed.

If the developing reagent comes in contact with the skin, rinse thoroughly with water immediately.

Kit contents

One HEMOPLUS® test kit contains 50 individual test cards (one test card and 12 card-board spatulae in an envelope), two bottles of developing reagent (for laboratory use only) and an instruction leaflet.

Literature

1. Mandel, J.S., et al., (1993): ”Reduction in the mortality for colorectal cancer by screening for fecal occult blood“, New Engl. J. Med. 328: 1365–1371.
2. Kewenter, J., et al. (1994): ”Results of screening, rescreening, and follow-up in a prospective randomized study for detection of colorectal cancer by fecal occult blood testing. Results for 68.308 subjects“, Scand. J. Gastroenterol. 29: 468–473.
3. Gnauck, R. (1995): ”Screening for colon cancer in Germany“, Tumori 81: 30–37.
4. Winawer, S.J., et al. (1995): ”Prevention of colorectal carcinoma: Improved WHO-guidelines for early detection of colorectal carcinoma“, Bulletin of the WHO 73 (1): 7–10.

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SARSTEDT
Aktiengesellschaft & Co.
D-51588 Nümbrecht

IVD CE