

OCCULT BLOOD - card

QUALITATIVE RESEARCH OF OCCULT BLOOD (HEMOGLOBIN)
WITH IMMUNOCHROMATOGRAPHIC METHOD IN FAECES
For in vitro diagnostic use only



Available kits:

20 tests
50 tests
100 tests

Code 4005
Code 4025
Code 4052

PRINCIPLE

OCCULT BLOOD cards combine monoclonal and polyclonal antibodies to selectively identify human hemoglobin in feces. During analysis the solution moves by capillarity into membrane. Hemoglobin, if present, binds to the monoclonal antibody-dye conjugate to form an antibody antigen complex. This complex binds to hemoglobin polyclonal antibody in the T (test) zone of the membrane. A pink colored band shows if hemoglobin concentration is over 150-200 ng/mL of buffer solution (40 µg/gr of feces). The reaction mixture continues to flow in the membrane toward the C (control) zone. The conjugate binds to a specific antibody and forms a pink colored band that shows that the test is functioning correctly.

REAGENTS

20/50/100 cards monoclonal and polyclonal antibodies immobilized on membrane

***20/50/100 collection vials (containing 2 ml of extraction solution);**

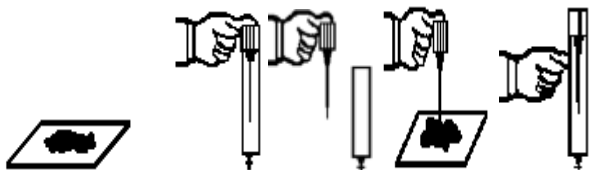
20/50/100 labels. STABILITY: stable at 4-30°C, inside the sealed envelope, up to the expiration date on the label.

TEST LIMITATIONS

Presence of blood in stools may be due to several causes: colorectal bleeding (precancerous or cancerous polyps, hemorrhoids), ulcer, stomach irritations and lesions in the mouth or digestive system. As is true with any in vitro diagnostic procedure, the physician should confirm data obtained by the use of this test with other clinical methods. Blending of the upper part of the digestive tract (for example in case of stomach or duodenal ulcers) may not be detected all the time due to the further hemoglobin proteolysis. Negative results do not exclude bleeding of colorectal polyps since it can be intermittent. Colorectal polyps at very early stage may not bleed. This is the reason why it is safe periodically check people over 45.

SAMPLE

The stool sample may be collected personally by the patient or by a laboratory person using the proper collection device vial. Collection device is composed of three parts: the collection stick, the device containing the extraction solution and the breaking cap. Collection device has been designed to dissolve exactly 10 mg of stool sample in 2 ml of extraction solution. Collect the stool sample in a clean and dry container. Unscrew the top of sample collection device and dip the stick at least three times in 3 different places of the sample. The excess sample, which is removed from the stick when passing through a calibrated hole inside the vial, deposits in a chamber without coming into contact with the extraction solution. Return the sample collection stick inside the collection device and screw it firmly. Shake well to facilitate sample dissolution. **Store the vial at room temperature and perform the test within a week from sample collection.**



Collect the sample, take the sample with the stick and put it inside the vial again.

PROCEDURE

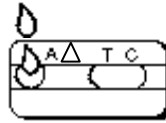
Shake the collection device vial. **WARNING:** to avoid accidental liquid overflow, hold it upright with the fracture point above while breaking it. Hold the cap with forefinger and thumb and break it: so it becomes a practical dropper. During the operation wear proper personal protection means.

Squeeze the vial, pipette a few drops and discard them.

Place the vial above well A on the card and pipette 4 buffer drops (100 µl) slowly.



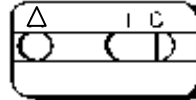
Discard a few drops and pipette 4 drops in well Δ



Result shows within **5 minutes**

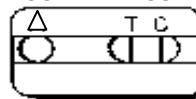
RESULT INTERPRETATION

NEGATIVE RESULT:



Only one colored band (C).

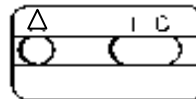
POSITIVE RESULT:



Two colored bands (C+T).

ATTENTION: read 'PERFORMANCE sensibility' section to obtain complete results interpretation.

INCONCLUSIVE RESULT:



No colored bands.

Reasons: wrong analysis procedure or improper card storage (for example: expired card, humidity).
Check and repeat the test.

PERFORMANCE

Sensitivity: >150-200 ng/mL of extraction buffer.

Results may be positive for Hb quantities from 100 to 150 ng/ml. This is due to many causes as: test conditions, temperature and air humidity, card characteristics, sample characteristics, operator handling ecc. For Hb quantity lower than 100 ng/ml a weak band can sometimes appear over 5 minutes reading time.

Hb absence in the sample always gives negative result.

Results may be negative for hemoglobin quantities >120 mg HB/gr of feces.

Specificity: the test is specific for human hemoglobin and does not require any restrictive diet.

Analysis on samples containing animal hemoglobin, have given negative result.

NOTES

1. The test is a rapid screening system to research hemoglobin in feces (occult blood) which may indicate gastrointestinal system disease associated with hemorrhages, as in case of colorectal cancer, colon polyps, Crohn's disease and ulcer.
2. The test cannot be used as the only unique diagnosis test for colorectal cancer and other specific diseases.
3. For a diagnostic investigation use the results of this test in addition to other assays.

BIBLIOGRAPHY

1. PARKIN, D.M. and al., Int. J. cancer, 1988, 41: 184-197



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