

SBio OCCULT BLOOD TEST KIT

(Standard Guaiac Method)
(For invitro diagnostic use only)

REF	95000100
	100 Tests



30°C 15°C Store at 15°C-30°C (R.T.)	Manufacturer	This way up	Standard Guaiac Standard Guaiac Method	
Use by (Last day of stated month)	Consult Instructions for use	L1 Developer Solution	T Test Cards	
Date of Manufacture	REF Catalogue Number	SA Sample Applicators	C Positive Control	
LOT Batch Number	IVD In vitro Diagnostic Medical Device	Contains sufficient for n- tests	EC REP Authorised Representative in the European Community	

INTENDED USE

Occult Blood Test is a two field test for occult blood in stool.

PRINCIPLE OF THE TEST

If blood is present in the stool sample, the hematin in the hemoglobin molecule catalyses the release of oxygen from the hydrogen peroxide, which in turn oxidizes the colourless phenolic components of gum guaiac to coloured quinones. During test, after the addition of the developer solution to the reactive surfaces of the result window, the reaction area turns blue if occult blood is present in the sample. If the reaction area does not change colour then, it indicates that there is no occult blood present in the sample.

CLINICAL SIGNIFICANCE

Fecal occult blood is a term for blood present in the feces that is not visibly apparent. This test can detect bleeding from almost anywhere in the digestive tract, and can come out positive for several conditions including colorectal cancer, esophagitis, gastritis, stomach cancer, ulcerative colitis and hemorrhoids. A fecal occult blood test is often used to detect colorectal cancer in its early stages, which has no other signs or symptoms. Early diagnosis and treatment of patients with colonic cancer results in a relative good prognosis for survival. Fecal occult blood test is recommended for use as an aid to routine physical examinations.

PRESENTATION

T : Test Cards	100 Tests
L1 : Developer Solution	100 Nos.
C : Positive Control	2 x 5 ml
SA : Sample Applicators	2 ml
	100 Nos.

COMPOSITION

Guaiac Resin 3mg; H₂O₂ 4.5% and Surfactant; Goat RBC 1.5%; Non Reactive Stabilizers; Detergents and Preservatives.

STORAGE / STABILITY

Contents are stable at R.T. (15-30° C) till the expiry mentioned on the labels.

SAMPLE REQUIRED

Stool is required.

Preparation of the patient before sample collection

1. As for all occult blood tests certain medications such as aspirin, indomethacin, phenylbutazone, reserpine, corticosteroids and nonsteroidal anti-inflammatory drugs can induce gastrointestinal bleeding and cause false positive results. These medications should be temporarily discontinued with the consent of the physician for 7 days prior to testing and during the test period.

2. Vitamin C when taken in amounts greater than 250 mg per day has been shown to induce false negative results. Rectal medications (suppositories) and iron containing medications may also interfere with these tests and should be discontinued two days before and during the test period with the consent of the physician.

3. For atleast 2 days before and during the test period all raw meat and red meat should be avoided. Raw broccoli, cauliflower, radishes and turnips may cause false positive results, hence should be avoided.

Sample collection

1. A clean dry detergent free glass or plastic container of a suitable size is ideal for collection of the specimen. Urine should not be passed simultaneously into the collection container. Clean pieces of plastic are convenient for transferring stool from the collection container to the transport vessel.

2. The stool samples should be collected from different areas of the formed stool. (Samples from the outside of stool are most likely to reflect the condition of the lower colon, while specimens taken from inside of the stool are more likely to reflect conditions of the upper gastrointestinal tract) and also provides a more representative sample to be tested.

3. The two test fields provided in SBio Occult Blood Test facilitate detection and localizing the source of bleeding. Because bleeding may be intermittent, it is preferable to collect specimens from different bowel movements, preferably consecutive ones.

REAGENT PREPARATION

Sbio Occult Blood Test Cards consisting of a filter paper impregnated with the guaiac resin (Reactive surface), the Developer solution and the Positive control are ready to use.

SAMPLE WASTE AND DISPOSAL

Do not reuse the reagent containers, bottles, caps or plugs due to the risks of contamination and the potential to compromise reagent performance.

This product requires the handling of human specimen. It is recommended that all human sourced material are considered potentially hazardous and are handled in accordance with the OSHA standard on blood borne pathogens.

Appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.

Handle specimen, solid and liquid waste and test components in accordance with local regulations and NCCLS guidelines M29, or other published biohazard safety guidelines.

MATERIALS REQUIRED BUT NOT PROVIDED

A clear, dry detergent free glass / plastic container of suitable size for sample collection, glove, stop watch.

TEST PROCEDURE

- Pierce the nozzle of the developer solution with a rust free sharp pin or needle.
- Retrieve the required number of test cards to perform the desired number of tests.
- Label the cards with correct patient identity.
- Open the sample application windows labelled A and B respectively, to expose the reactive surfaces of the test card.
- By using the sample applicator provided in the kit spread a very thin layer of stool on the reactive surfaces on the window A similarly on window B from a different part of the stool.
- Wait until the smeared sample has **dried completely**.
- Turn over the test card.**
- Open the result window and add one drop of developer solution to fields RA and RB (the reverse side of the sample smeared on the sample application windows) respectively.
- Observe for colour change **exactly at two minutes**.
- Even if one of the field's has a blue colour, the test is positive for occult blood.

INTERPRETATION OF RESULTS

No blue colour indicates absence of occult blood in the stool.

Trace blue colouration indicates presence of approximately 5 mg/dl of occult blood in the stool.

Strong blue colouration indicates significantly more than 5 mg/dl of occult blood in the stool.

QUALITY CONTROL

Positive control provided with the kit should be run occasionally to validate the performance of the test cards and reagent.

LIMITATIONS

- Stool samples collected during menstrual bleeding, constipation induced bleeding, bleeding hemorrhoids or when rectal medication is used may cause positive results.
- Hands, collection containers and test area should be kept free of blood as they may cause false positive results.
- Certain medications may induce gastrointestinal bleeding and cause false positive reactions hence should be avoided during and prior to the testing period.
- Diet containing exogenous peroxidases may induce false positive results.
- Dosages of Vitamin C more than 250 mg per day will cause a false negative result.
- If the test is developed before the sample smear dries completely on the test card, the results obtained may not be accurate.

SPECIFIC PERFORMANCE CHARACTERISTICS

The results obtained by Occult Blood Test correlated very well when run in parallel with another commercially available test for FOB, using known positive and negative specimen.

Sample Type	Total No. of Samples	Results Obtained	
		Positive	Negative
+ ve samples	30	30	0
- ve samples	50	0	50
Sensitivity = 100 %		Specificity = 100%	

Limit of detection

Occult Blood Test detects the presence of hemoglobin as low as 5 mg/dl in specimen (stool). Thus Occult Blood Test is diagnostically, a significant test, in uncovering and localizing bleeding from the gastrointestinal tract.

Method comparison:

Comparative studies were done to compare our reagent with another commercial Occult Blood Test. No significant differences were observed. Details of the comparative studies are available on request.

NOTE

- The kit contains hydrogen peroxide solution, which is irritant. Avoid contact with eyes, skin and clothing. In case of contact flush with large quantities of water.
- Do not expose the test cards and developer solution to direct sunlight, fluorescent light and U.V. rays.
- The positive control is derived from goat cells and not from human source, hence contamination due to HBsAg and HIV is practically excluded.
- The test is designed for preliminary screening and does not replace other diagnostic procedures. Negative results obtained cannot be considered conclusive as the blood in stool is not homogeneously distributed and also bleeding is intermittent.

WARRANTY

This product is designed to perform as described on the pack insert. The manufacture disclaims any implied warranty of use and sale for any other purpose.

REFERENCES

- Knight et. al. (1989) Occult blood screening for colorectal cancer, JAMA, Vol 261, No 4, 587-593
- Rockey D et. al. (1998) Relative frequency of upper gastrointestinal and colonic lesions in patients with positive occult blood tests. N Engl J Med 339; 153-159.
- Morris W.D. et. al. (1976) Reliability of chemical tests for fecal occult blood in hospitalized patients. Digestive diseases Vol 21, No 10, 845-852.
- Ostrow J.D. et. al. (1973) Sensitivity and reproducibility of chemical tests for fecal occult blood with an emphasis on false positive reactions. Digestive diseases Vol 18, No 11, 932-939.



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