

# SBio FOBT

Rapid test for detection of Faecal occult blood in human faeces.

REF	90700010
▼	10 T

	Temperature Limitation		Manufacturer		Contains sufficient for <n> tests	<b>DEVICE</b> Device
	Use by (Last day of stated month)		Consult Instructions for use		Do not reuse	
	Date of Manufacture		Catalogue Number		This side up	<b>BUF</b> Specimen Extraction Buffer
	Batch Number/ Lot Number		In vitro Diagnostic Medical Device		Do not use if package is damaged	
Xn						Harmful if swallowed. Do not breathe vapour. If swallowed, seek medical advice immediately and show this container or label. Avoid release to the environment. Refer to special instructions. NaH <sub>n</sub> R22 S23-46-61

## INTENDED USE

SBio FOBT is a rapid, qualitative, two-site sandwich immunoassay for the detection of Faecal Occult Blood concentration in human faeces.

## SUMMARY

Colorectal cancer (CRC) is a major cause of death from cancer. The risk of CRC increases with age, with an approximate doubling of the incidence in each decade from 40 to 80 yrs of age. It has been estimated that the lifetime risk of developing CRC is 1:50.

Faecal Occult Blood Test (FOBT) provides the most cost-effective way to screen for CRC. It has been reported that screening for CRC by FOBT decreases CRC mortality by 15-33%.

FOBT is the test to detect the presence of occult blood in the faeces. Small amounts of blood is present in the faeces of normal healthy individuals due to bleeding from the gastro intestinal tract like bleeding gums and bleeding from minor abrasions. The presence of small amounts of blood in faeces may not alter the colour or appearance of the stool. The detection of faecal occult blood can be useful in detecting bleeding resulting from gastro intestinal disorders such as colitis, polyps, colorectal carcinomas and diverticulitis.

Benzidine and guaiac tests for faecal occult blood detect the peroxidase activity of haeme, either as intact haemoglobin or as free haeme. Hence, to avoid false positives, for the week before the test, patients need to follow a diet that excludes red meat, turnips, horseradish, broccoli, radishes, cauliflower, cantaloupes and other melons and supplemental vitamin C. Unlike Guaiac tests,

SBio FOBT is a 3<sup>rd</sup> generation immunochromatographic test that is not affected by peroxidase activity.

## PRINCIPLE

SBio FOBT utilizes the principle of agglutination of antibodies/antisera with respective antigen in immuno-chromatography format along with use of nano gold particles as agglutination revealing agent. The conjugate pad contains two components - Agglutinating sera for human haemoglobin conjugated to colloidal gold and rabbit globulin conjugated to colloidal gold. As the test specimen flows through the membrane assembly of

the device, the highly specific Agglutinating sera for human haemoglobin -colloidal gold conjugate complexes with the human haemoglobin in the specimen and travels on the membrane due to capillary action along with the rabbit globulin-colloidal gold conjugate. This complex moves further on the membrane to the test region (T) where it is immobilized by another specific Agglutinating sera for human haemoglobin coated on the membrane leading to formation of a coloured band. If occult blood level is equal to or higher than the 200 µg/l of faeces suspension, the test is positive. The absence of this coloured band in the test region indicates a negative test result. The rabbit globulin - colloidal gold conjugate and unbound complex, if any, move further on the membrane and are subsequently immobilized by the Agglutinating sera for Rabbit globulin coated on the membrane at the control region (C), forming a coloured band. The control band formation is based on the 'Rabbit / Agglutinating sera for Rabbit globulin' system. Since it is completely independent of the analyte detection system, it facilitates formation of consistent control band signal independent of the analyte concentration. This control band acts as a procedural control and serves to validate the test results.

## REAGENTS AND MATERIALS SUPPLIED

SBio FOBT kit contains:

A. Individual pouches, each containing:

1. Test Device: Membrane assembly pre-dispensed with Agglutinating sera for human haemoglobin- colloidal gold conjugate, rabbit globulin-colloidal gold conjugate, Agglutinating sera for human haemoglobin and Agglutinating sera for rabbit globulin coated at the respective regions.
2. Desiccant pouch.
- B. Specimen Extraction Buffer in a dropper bottle.
- C. Package Insert.

## STORAGE AND STABILITY

The sealed pouches in the test kit & the kit components may be stored between 4°C to 30°C for the duration of shelf life as indicated on the pouch/ carton. DO NOT FREEZE.

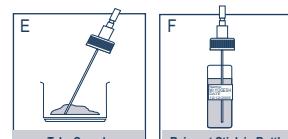
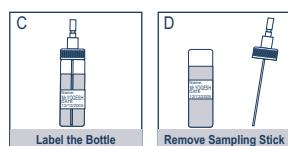
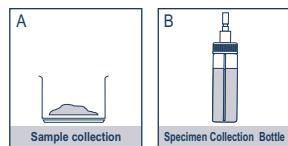
## NOTES

1. Read the instructions carefully before performing the test.

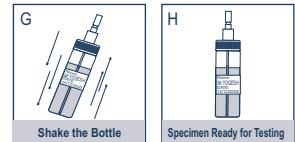
- For in vitro diagnostic use only. NOT FOR MEDICINAL USE. For professional use only.
- Do not use the kit beyond expiry date and do not re-use the test device.
- Do not intermix reagents from different lots.
- Contact with the contents of desiccant pouch containing, among other substances, cobalt chloride (CAS# 7646-79-9) should be kept to a minimum. Inhalation / swallowing may cause harm.
- Handle all specimens as if potentially infectious. Follow standard biosafety guidelines for handling and disposal of potentially infectious material.
- If desiccant colour at the point of opening the pouch has turned from blue to pink or colourless, another test device must be run.
- Specimen extraction buffer contains Sodium Azide (0.1%), avoid skin contact with this reagent. Azide may react with lead and copper in the plumbing and form highly explosive metal oxide. Flush with large volumes of water to prevent azide build-up in the plumbing.

#### SPECIMEN COLLECTION AND PREPARATION

- SBio FOBT uses human faeces as specimen.
- Collect faeces in a clean dry container.
- Though fresh specimen is preferable, in case of delay in testing, it may be stored at 2°C to 8°C for maximum up to 24 hrs.
- Refrigerated specimens must be brought to room temperature prior to testing.
- Label the specimen collection bottle with specimen identity.
- Unscrew and remove the cap (with attached sampling stick) of the specimen collection bottle ensuring that the extraction buffer is not spilt.
- Take representative amounts of faeces specimen from different portions of the sample by introducing the sampling stick at 3-4 different places in the faeces specimen.
- Wipe the sampling stick with an absorbent or tissue paper. The sample taken up by the grooves is sufficient for the test.
- Reinsert the sampling stick into the bottle and screw the cap tightly.

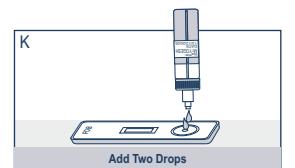


- Shake the specimen collection bottle so that there is proper homogenisation of faeces in buffer solution.



#### TESTING PROCEDURE AND INTERPRETATION OF RESULTS

- Bring the kit components of SBio FOBT device to room temperature prior to testing.
- Open a foil pouch by tearing along the "notch".
- Remove the testing device. Once opened, the device must be used immediately.
- Label the device with specimen certification.
- Place the testing device on a flat horizontal surface.
- Hold the specimen collection bottle in an upward position and break the tip off.
- Invert the bottle and holding the dropper vertically, carefully dispense exactly two drops of specimen-buffer mixture into the specimen port.
- Observe the development of visible coloured band at Test region (T).
- Positive results may be observed within 5 minutes, depending on the concentration of occult blood in the tested specimen.
- Do not read and interpret after 5 minutes.
- In negative specimens only the control band (C) would develop.



#### Negative Result

Presence of one coloured band at Control (C) region indicates absence of OCCULT BLOOD or the concentration of OCCULT BLOOD in the specimen is below the detection limit of 200µg/l of faeces suspension.



#### Positive Result

If concentration of OCCULT BLOOD in specimen is above 200µg/l of faeces suspension, two coloured bands appear at Test (T) and Control

(C) regions. The intensity of the test band may be more or less than the Control band, depending upon the concentration of OCCULT BLOOD in specimen.



#### Invalid Result

The test is invalid if no band is visible at five minutes. The test should also be considered invalid if only the test band appears and no control band appears. Verify the test procedure and repeat the test with a new SBio FOBT device.

#### PERFORMANCE CHARACTERISTICS

The detection limit of SBio FOBT is up to 200 $\mu$ g/l of faeces suspension i.e. equivalent to 100-200  $\mu$ g/gm of faeces.

#### Sensitivity

The detection limit of SBio FOBT device is up to 200 $\mu$ g/l faeces suspension (calibrated against Sigma Human Hemoglobin Cat No. H-7309). This corresponds to a concentration of 100 to 200 $\mu$ g/gm hemoglobin/gm of faeces. No Prozone Effect up to a hemoglobin concentration of 1000mg/l has been observed.

#### Specificity

SBio FOBT is highly specific to human hemoglobin and does not cross react with the following:

Chicken hemoglobin	500 $\mu$ g/ml
Pork hemoglobin	500 $\mu$ g/ml
Beef hemoglobin	500 $\mu$ g/ml
Goat hemoglobin	500 $\mu$ g/ml
Rabbit hemoglobin	500 $\mu$ g/ml
Horseradish peroxidase	2000 $\mu$ g/ml

#### LIMITATIONS OF THE TEST

1. SBio FOBT is a highly sensitive and specific test for human haemoglobin in faeces. Nonetheless, as with any in-vitro diagnostic test, occasional false positive and negatives may occur.
2. False negatives may occur due to improper faeces suspension preparation or the lesion did not bleed or bleed sufficiently to produce a positive result.
3. Blood secondary to aspirin use or use of other non-steroidal anti-inflammatory agents may cause GI bleeding and show false positive results.
4. Stool samples collected during menstrual bleeding, constipation induced bleeding, bleeding hemorrhoids and rectal medication may also cause false positive results.
5. Gloves, collection container and test area should be kept free of blood to avoid false positive results.

6. Since benzidine & guaiac-based tests suffer from non-specific interference of peroxidase activity, exact one-to-one correlation of the results of such tests with a 3<sup>rd</sup> Generation Immunochromatographic test like SBio FOBT may not be observed.
7. SBio FOBT should only be used as a screening test. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

#### WARRANTY

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

#### BIBLIOGRAPHY

1. McArdle CS. Faecal occult blood testing for colorectal cancer. Ann of Oncol 2002; 13: 35-39.
2. Niv Y et al., Protective effect of faecal occult blood test screening for colorectal cancer: worse prognosis for screening refusers.
3. Allison JE et al., A comparison of faecal occult-blood tests for colorectal - cancer screening. N Engl J Med 196; 334:155-9.

Manufactured by:

**Zephyr Biomedicals**

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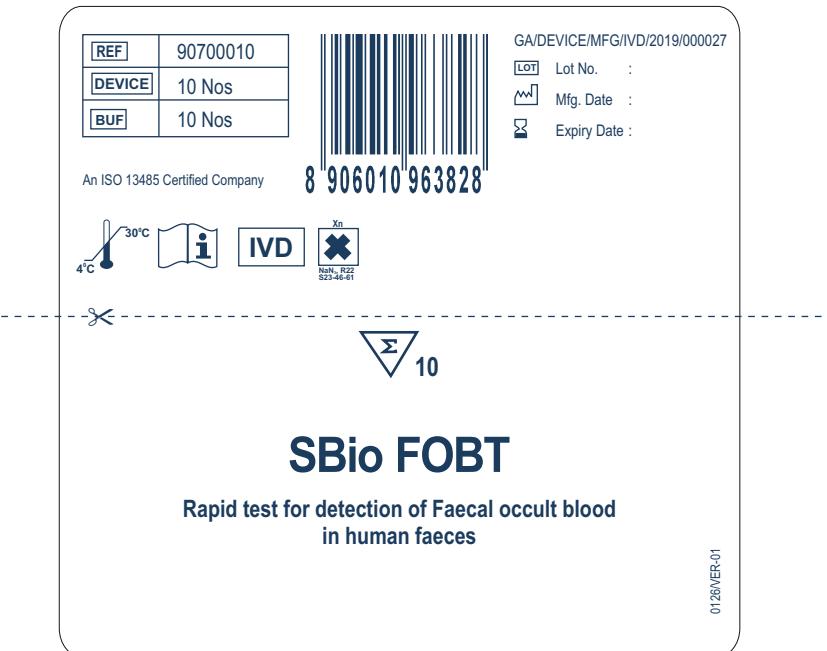
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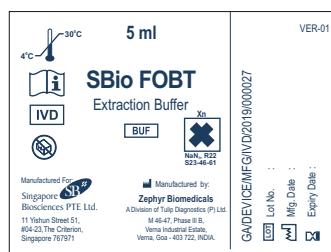
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90mm x 86mm



43 mm x 32mm



50mm x 80 mm

