

#### INTENDED USE

The TesTube Fecal Occult Blood Test is a convenient, rapid, qualitative immunochromatographic assay for the determination of human hemoglobin in feces at the cutoff of 50ng/ml or 10ug/g feces. The test is recommended for use in physical checkup and screening for gastrointestinal tract cancers.

#### INTRODUCTION

The presence of hemoglobin in feces can be indicative of gastrointestinal tract conditions associated with bleeding such as colorectal carcinoma, colon polyps, Crohn's disease, and ulcerative colitis.

The TesTube Fecal Occult Blood Test features a 2-in-1 sample preparation and test device. No liquid pipetting/transfer is required. The device is designed to detect lower levels of fecal occult blood than standard guaiac tests. The basis of the test is an immunochromatographic sandwich capture method, which yields results more specific to human hemoglobin and are easier to interpret than those of guaiac-based devices.

#### PRINCIPLE OF THE TEST

The TesTube Fecal Occult Blood Test is a convenient test method that employs anti-human hemoglobin antibodies that recognize human hemoglobin with no cross-reactivity with other animal blood components. In less than five minutes, elevated levels of human hemoglobin as low as 50ng Hb/ml (10ug/g feces) can be detected and positive results for higher levels of hemoglobin can be seen in the test as early as less than two minutes. This sensitivity level is equivalent to about 1/15,000 of blood in feces.

A fecal sample is collected and prepared for testing using the fecal collection probe attached to the cap; the resulting sample fluid is added directly to the test device, where a test buffer is pre-stored. By a simple operation, the device facilitates contact of the sample solution and the immunochemical test strip. The sample fluid mixes with anti-hemoglobin dye-conjugate in the test membrane forming an antigen-dye complex, which migrates through the test device. The complex is captured in the test (T) zone by immobilized anti-hemoglobin antibodies. The captured dye-complex becomes visible as a rose-pink band within the test zone, which indicates the test has detected human hemoglobin, a positive result. In the absence of hemoglobin, no line will form in the test zone.

A built-in procedural control indicates proper kit performance. The control result is viewable as a rose-pink band in the control (C) zone within the five-minute testing period. The control band is formed by a non-specific sandwich dye conjugate reaction and should appear regardless of the test result.

A rose-pink band in the test zone and in the control zone at or before five minutes is considered a positive result by the criteria of the test. A band only in the control zone at five minutes is a negative result.

#### REAGENTS AND MATERIALS PROVIDED

1. Test Device
2. Product Package Insert

#### STORAGE

Store test device at room temperature (15-28°C). Refer to the expiration date printed on the foil pouch for stability. Sample collection tube after collecting sample should be stored refrigerated (2-8°C) if not used immediately.

#### WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Do not use product beyond the expiration date.
3. Patient samples may contain infectious agents and should be handled accordingly. Dispose of all used test components in a biohazard container.

#### SAMPLE COLLECTION AND PREPARATION

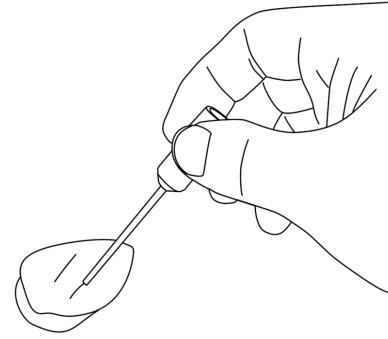


Figure 1. Stool Sampling

1. Collect a random sample of feces in a clean, dry receptacle.
2. Remove the cap of the tube device.
3. By holding the cap insert the applicator probe/ stick into the fecal specimen at several different sites (Fig. 1)
4. Collect a thin smear of specimen on the probe tip section only. Remove excess sample from the stick by gently wiping with an absorbent tissue.
5. Replace the stick in the tube and tighten securely.

#### TEST PROCEDURE

1. Shake the tube vigorously to ensure a good liquid suspension. (Fig. 2)
2. Holding the tube upright, loosen the bottom part of the TesTbe device for about 1 revolves (360°) (Fig. 3). This will allow the sample solution inside the tube contact the immunochemical test strip. **Do not remove the bottom part of the device.**
3. Keep the device in a upright position for 5 minutes.
4. Read the test result. A positive result may appear in as short as less than 2 minutes. A negative result must be confirmed between 5 and 10 minutes.

**IMPORTANT:** Waiting more than ten minutes may cause the reading to be inaccurate.

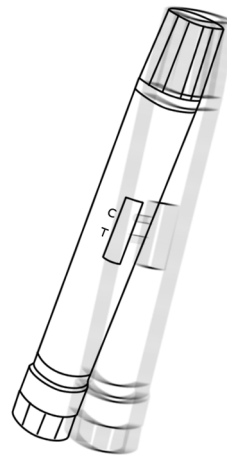


Figure 2. Shake the tube to suspend the specimen in the test buffer.

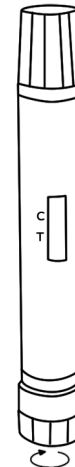


Fig. 3 Loosen the bottom part of the device to allow testing begin.

#### INTERPRETATION OF RESULTS

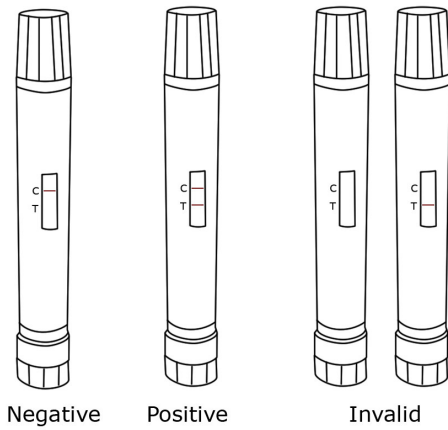


Fig. 3. Test results

**Negative:** At five minutes, one rose-pink color band appears in the control (C) zone indicating a negative result and that the specimen does not contain a detectable level of human hemoglobin.

**Positive:** At five minutes, two rose-pink color bands appear: one in the test (T) zone and one in the control (C) zone. A positive result indicates that the specimen contains human hemoglobin. A positive result may be read sooner than 5 minutes.

**Invalid:** At five minutes, no bands appear, or a test band appears without a control band, disregard the result, indicating the test is invalid. It is recommended that the specimen be re-tested.

*Note: There is no meaning attributed to line color intensity or width. A positive result may be read sooner than 5 minutes, however, a negative result must be read after 5 minutes.*

**QUALITY CONTROL**

An internal procedure control has been incorporated into the test to ensure proper kit performance and reliability.

The use of an external control is recommended to verify proper kit performance. Quality control samples should be tested according to quality control requirements established by the testing laboratory.

**LIMITATIONS**

- As with any diagnostic test, TesTube Fecal Occult Blood may not be considered as a conclusive diagnosis for gastrointestinal bleeding or pathology. It is not intended to replace other diagnostic procedures such as G.I. fibro scope, endoscopy, colonoscopy or other x-ray analysis.
- Although the test is very accurate in detecting human hemoglobin, there is a possibility false result may occur. In addition, because many bowel lesions, including some colorectal cancers and polyps, may bleed intermittently or not at all, occult blood may not be uniformly distributed throughout the fecal sample. Thus test results may be negative even when disease is present.

**PERFORMANCE CHARACTERISTICS**

- Sensitivity:** The analytical sensitivity of the test is 50ng hHb/ml buffer or 10 ug hHb/g feces.
- Specificity:** The TesTube Fecal Occult Blood Test is specific to human hemoglobin. Specimens containing the following substances have no effect on test result:

Substance	Concentration
Chicken Hemoglobin	1000 ug/ml
Pork Hemoglobin	1000 ug/ml
Beef Hemoglobin	1000 ug/ml
Goat Hemoglobin	1000 ug/ml
Horse Hemoglobin	1000 ug/ml
Rabbit Hemoglobin	1000 ug/ml
Horseradish Peroxidase	2000 ug/ml

**REFERENCE**

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