

Wondfo One Step Fecal Occult Blood (FOB) Test Cassette is a simple direct binding immunoassay for the rapid, qualitative detection of human occult blood in feces. The test is used as an aid to the diagnosis of gastrointestinal bleeding.

For *in vitro* use only. Suitable for self-testing use.

HOW DOES IT WORK?

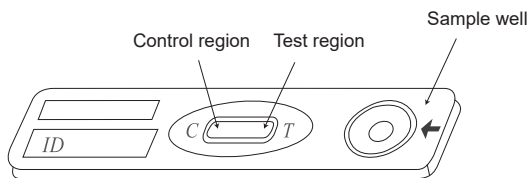
FOB (Fecal Occult Blood) is the trace amount of blood in feces which can not be seen with eyes. It could be the early clinical symptom of the common malignant tumor, the gastric cancer or colonic cancer, or the indicator or enteron ulcer. Ninety-five percent of enteron cancer patients are positive in OBT (Occult Blood Test). And about 50% to 80% of enteron ulcer patients could be positive in OBT. An early detection of FOB is vital in life saving for it can be check up out in the early stage of the diseases

One Step Fecal Occult Blood (FOB) Test adopts immunochromatographic sandwich method, which employs two specific monoclonal antibodies to selectively identify hemoglobin in test samples. When the specimen is added into the test device, capillary action carries the specimen to migrate along the membrane.

When the hemoglobin antigen levels are at or above the target cutoff, the antigens in the specimen bind to the antibody-dye conjugate and are captured by antibodies immobilized in the Test region (T) of the device. This produces a colored Test band and indicates a positive result.

When the hemoglobin antigen levels are zero or below the target cut off (the detection sensitivity of the test), there is no visible colored band in the Test region (T) of the device and it indicates a negative result.

To serve as a procedure control, a colored line will appear at the Control region (C), if the test has been performed properly.



CONTENT OF THE TEST KIT

1. One pouch containing a test and a desiccant. The desiccant is only for storage purposes only, and is not used in the test procedures.
2. Specimen collection tubes per test, each with 1.5 mL buffer solution.
3. Leaflet with instructions for use

WHAT ELSE DO YOU NEED?

1. Clean container
2. Timer

PRECAUTIONS

1. This kit is for external use only. Do not swallow.
2. Wear protective gloves while handling specimens and wash hands thoroughly afterward.
3. Avoid splashing or aerosol formation while collecting the sample.
4. Do not use test kit beyond the expiration date.
5. Do not use the kit if the pouch is punctured or not well sealed.
6. Discard after first use. The test device cannot be used more than once.
7. Keep out of the reach of children.
8. Do not eat, drink or smoke in the area where the specimens and kits are handled.
9. The used device, container have the infectious risk, disposing them as if they were infectious waste, in a biohazard container.

STORAGE AND STABILITY

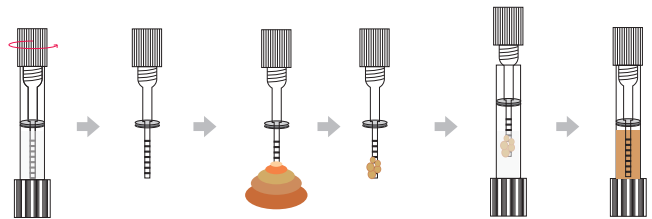
1. Store at room temperature (4°C~30 °C) in the sealed pouch up to the expiration date.

2. Keep away from direct sunlight, moisture and heat.
3. DO NOT FREEZE.
4. Do not remove the device from the pouch until ready to use.
The Test Device should be used within 1 hour once opened.

SPECIMEN COLLECTION AND PREPARATION

Collect stool sample from specimen caught by using the clean container (collection paper or clean cup). Contamination from toilet water and urine should be avoided.

1. Collect stool sample by using the sample collection tube provided. First, unscrew the smaller cap of the collection tube, take out the sampling stick.
2. Insert the sampling stick into stool sample at 6 different sites. Use only enough fecal material to cover the threaded portion of the sampling stick.
3. Put the sampling stick back to the sample collection tube and screw tightly, mix well.



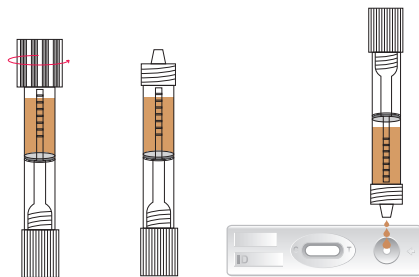
Note:

1. Test should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2°C~8°C for up to 2 days. For long-term storage, specimens should be kept below -20°C.
2. Specimen should not be collected during or within three days of a menstrual period, or if the patient suffers from bleeding hemorrhoids or blood in the urine.
3. Alcohol, aspirin, ibuprofen, dipyron, indomethacin, reserpin, phenylbutazone, corticosteroids and other medications may cause gastrointestinal irritation resulting in occult bleeding. With the physicians approval, such medication should be discontinued for 7 days before and throughout the test period. Rectal medication should be discontinued.

HOW TO DO THE TEST?

Test must be in room temperature (10°C to 30°C).

1. Remove the cassette from the foil pouch by tearing at the notch and place it on a level surface.
2. Holding a sample collector upright to make sure the bigger cap upwards. Carefully unscrew the bigger cap of the collection tube.
3. Squeeze 2~3 drops of sample solution to the sample well, as in the illustration.



4. Read the test results after 10 minutes. Do not read results after 30 minutes.

HOW TO READ THE RESULTS?

Positive (+)

If two color bands are visible both in the test (T) region and the control (C) region, the result is positive. It indicates a positive result for hemoglobin antigen.

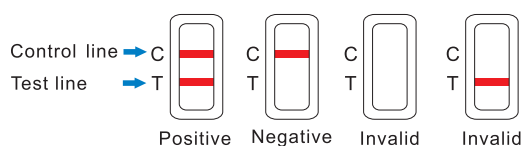
Negative (-)

If only one colored band appears in the control (C) region, no color band appears in the test (T) region, the result is negative. It indicates that the concentration of the hemoglobin antigen is zero or below 50 ng/ml.

Invalid

If a color band is not visible in the control region or a color band is only visible in the test region, the test is invalid. Another test should be run to re-evaluate the

specimen. If test still fails, please contact the distributor or the store where you bought the product, with the lot number.



Note: There is no meaning attributed to line color intensity or width.

LIMITATIONS

1. This test has been developed for testing fecal samples only. The performance of this test using other specimens has not been substantiated.
2. Heterophil antibody and human anti-mouse antibody, as well as sample of patients with hemoglobinopathies (e.g., sickle cell disease) may potentially influence this test.
3. Positive results indicate the presence of human hemoglobin in fecal samples; nevertheless, it can be also due to several causes besides colorectal bleeding, such as haemorrhoids, blood in urine or stomach irritations. A positive result should be followed up with additional diagnostic procedures to determine the exact cause and source of the blood in the stool.
4. Negative results do not exclude bleeding, as some polyps and colorectal cancers may bleed intermittently or not at all during certain stages of the disease. Additionally, blood may not be uniformly distributed in stool samples. Other clinically available tests are required if questionable results are obtained.
5. If the symptom persists, Wondfo One Step Fecal Occult Blood (FOB) Test is negative, it is recommended to re-test the specimen with an alternative test device.
6. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
7. Wondfo One Step Fecal Occult Blood (FOB) Test is designed for aiding to diagnose and should not replace other diagnostic procedures such as colonoscopy or sigmoidoscopy, etc.

PERFORMANCE CHARACTERISTICS

The analytical sensitivity of this test is 50 ng/mL.

The result from Wondfo One Step Fecal Occult Blood (FOB) Test is compared with FobCHECK, fecal occult blood test manufactured by NanoRepro AG. 108 stool specimens were obtained for testing, Wondfo One Step Fecal Occult Blood (FOB) Test showed 99.07% overall agreement when compared with that FOB test.

QUESTIONS & ANSWERS

1. What is fecal occult blood?

Fecal occult blood is blood in your feces that you cannot see in your stool or on your toilet paper after you use the toilet. Wondfo One Step Fecal Occult Blood (FOB) Test is designed to detect it.

2. Why should you do this test?

You should do this test, because blood in your feces may be an early sign of a digestive tract disorder, for example abnormal growths (polyps) or cancer in your colon.

3. How often should you test for fecal occult blood?

It is recommended that you test for fecal occult blood every year after you turn 50. Some doctors suggest that you start testing at age 40, if your family is thought to be at increased risk. Follow your doctor's recommendations about how often you test for fecal occult blood.

4. How many times the test should be performed?

Home collection of two samples from three consecutive bowel movements for a total of 6 samples is recommended.

5. What does it mean if the test is positive?

A positive result means that the test has detected blood. This does not mean you have tested positive for cancer or any other illness. So if the result shows the positive result, further testing and examinations should be performed by the physician to determine the exact cause and source of the occult blood in the stool.

6. My test is negative. Does that mean I have't a bowel condition?

No. You could still have bowel condition that you should know about.

You should use this test again after a while. This is necessary because if you have polyps, they may not bleed all the time.

Additionally, blood may not be uniformly distributed in fecal samples.

Colorectal polyps at an early stage may not bleed.

7. Can I read the test result more than 30 minutes?

No, test results must be read in 30 minutes. Though a positive result should not change for several days, but a negative result may change to a false positive within minutes after the end of the testing period, which would not be an accurate reading.

REFERENCES

1. Simon JB. Occult blood screening for colorectal carcinoma: a critical review. *Gastroenterology* 1985;88:820
2. Mandel JS, et al. The effect of fecal occult blood screening on the incidence of colorectal cancer. *N Engl J Med* 2000;343:1603
3. Sieg A, et al. Validity of new immunological human fecal hemoglobin and albumin tests in detecting colorectal neoplasma – an endoscopy controlled study. *Z Gastroenterol.* 1998;36:485
4. WALKER C.W., "Fecal occult blood tests reduce colorectal cancer mortality.", *Am Fam Physician.* 2007 Jun 1;75(11):1652-3.
5. CHIEN-HUA CHIANG, et al. « A comparative study of three fecal occult blood tests in upper gastrointestinal bleeding »; *Kaohsiung J. Med. Sci* May 2006, Vol 22, No 5: 223-228.
6. N. Segnan, J. Patnick, L. von Karsa. European guidelines for quality assurance in colorectal cancer screening and diagnosis. First edition. European Commission 2010; 1-21

MEANING OF SYMBOLS ON PACKAGE

	For In Vitro Diagnostic Use Only		See Instruction for Use		Expiry Date
	Tests per Kit		Manufacturing Date		Keep Dry
	Batch Number		Authorized Representative		Keep away from Sunlight
	Manufacturer		Do not reuse		Catalog #
	Store between 4~30°C				

Guangzhou Wondfo Biotech Co., Ltd.
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2440 Geel
Belgium

Rev. A1 Rel.:2022/05/16



物料编码：

项目名称： FOB粪便卡自测用1T说明书(210*285mm)70g双胶英文V01

尺寸(长*宽*高)：210*285mm

颜色：  K20  C100M40 材质：70g双胶

工艺：/

折页方式：长边风琴3折4页+短边对折

修改内容：☐文字 ☐颜色 ☐尺寸 ☐工艺 ☐材质 ☐其他 ☐无

修改内容截图

改稿前编码：

申请人：赵慧婷

设计师：杨晓洁

设计时间：2022.05.16

稿件确认签名：