Willi Fox – FOB Test

Fecal Occult Blood Test Package Insert

A rapid, one step test for the qualitative detection of human occult blood in feces.

For professional in vitro diagnostic use only.

1. Intended use

The Willi Fox - Fecal Occult Blood Test Device (FOB Test Device) is an immunochemical test intended for rapid qualitative detection of human hemoglobin from blood in fecal samples. Fecal occult blood tests are used as a screening tool for detecting lower gastrointestinal (GI) bleeding that may be related to iron deficiency anemia, peptic ulcer, ulcerative colitis, polyps, and colorectal cancer. The Willi Fox - FOB Test Device is recommended for use by health professionals in routine physical examinations and in monitoring for GI bleeding in patients in hospitals or in physicians' offices.

2. Summary

Many diseases may result in hidden blood in the feces. This is known as fecal occult blood (FOB), human occult blood, or human hemoglobin. In the early stages, gastrointestinal problems such as colon cancer, ulcers, polyps, colitis, diverticulitis, and fissures may not show any visible symptoms, only occult blood. Traditional guaiac based methods of occult blood testing lack sensitivity and specificity, and also require diet restrictions prior to testing.

The Willi Fox - FOB Test Device is a rapid immunochemical test intended for the qualitative detection of low levels of fecal occult blood. The test uses a double antibody sandwich assay to selectively detect fecal occult blood at 0.2µg/mL. The Willi Fox - FOB One Step Fecal Occult Blood Test does not require the patient to follow any special dietary restrictions.

3. Principle

The Willi Fox - FOB Test Device is a qualitative, lateral flow immunoassay for the detection of human occult blood in feces. The membrane is pre-coated with anti-hemoglobin antibody on the test line region of the test. During testing, the specimen reacts with the particle coated with anti-hemoglobin antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-hemoglobin antibody on the membrane and generate a colored line. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

4. Kit contents

Test Kit Contents:

- FOB Test Devices
- Sample collection tube
- Desiccant

5. Material required but not provided

- Timer

6. Reagents

The test contains anti-hemoglobin antibody particles and anti-hemoglobin antibody coated on membrane.

7. Precautions

- For professional *in vitro* diagnostic use only. Do not use kit after expiration date.
- Do not eat, drink or smoke in the area where the specimens and kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.

8. Storage and stability

The kit can be stored at room temperature or refrigerated (2-30℃). **DO NOT FREEZE.** The test devices are stable through the expiration date printed on the box. Do not use kit beyond the expiration date.

9. Patient preparation

No special drug or dietary restrictions are required for this test. However, patients should closely follow the Patient Instructions to assure the most accurate test results. Patients should not collect fecal samples three days before, during, or three days after their menstrual period, if they have bleeding hemorrhoids, blood in their urine, open cuts on their hands, or if they have strained during their bowel movement.

10. Specimen collection and preparation

Specimens collected may be stored up to 6 days at at room temperature, 6 months at 4℃,and at least 20 months at -20℃.

11. Directions for testing

Allow the Test Device and Sample collection tube to reach room temperature (15-30℃) prior to testing.

1. Remove cap and stick from the tube. Poke the stick into the fecal sample several times at different sites.

2. Secure the cap back onto the tube and shake well.

3. Remove the Test Device from the sealed pouch and use it as soon as possible.

4. Open the tip cover of the sample collection tube to dispense 3 drops to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S).

   - If the Device does not begin to flow within 1 minute, add an additional 1 drops of Buffer.
   - If the Device does not work after the additional drops of buffer, contact technical support.

5. Wait for colored line(s) to appear. Read results at 5 minutes.. Do not interpret results after 10 minutes.

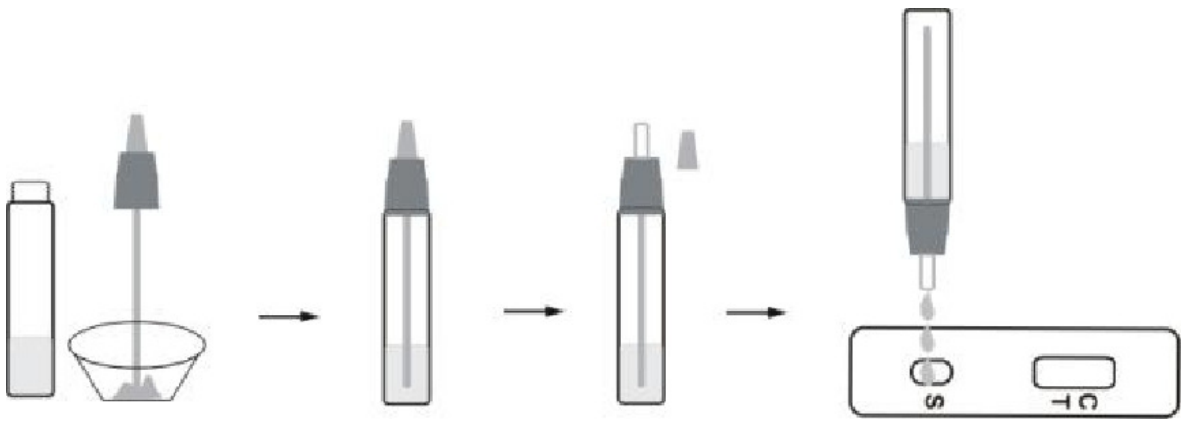

Figure 1: Test Procedure

12. Interpretation of results

POSITIVE:* Two distinct colored lines appear.

One line should be in the control line region (C) and another line should be in the test line region (T). A positive result indicates the level of hHb in the specimen is at or above the detection level of 0.2µg/mL.

> ***NOTE:** The intensity of color in the test line region (T) will vary depending on the concentration of fecal occult blood present in the specimen. Therefore, any shade of a line in the test line region indicates positive result.

NEGATIVE: One colored line appears in the control line region(C).

No apparent colored line appears in the test line region (T). A negative result indicates that hHb was not present in the specimen or is below the detection of level of the test.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

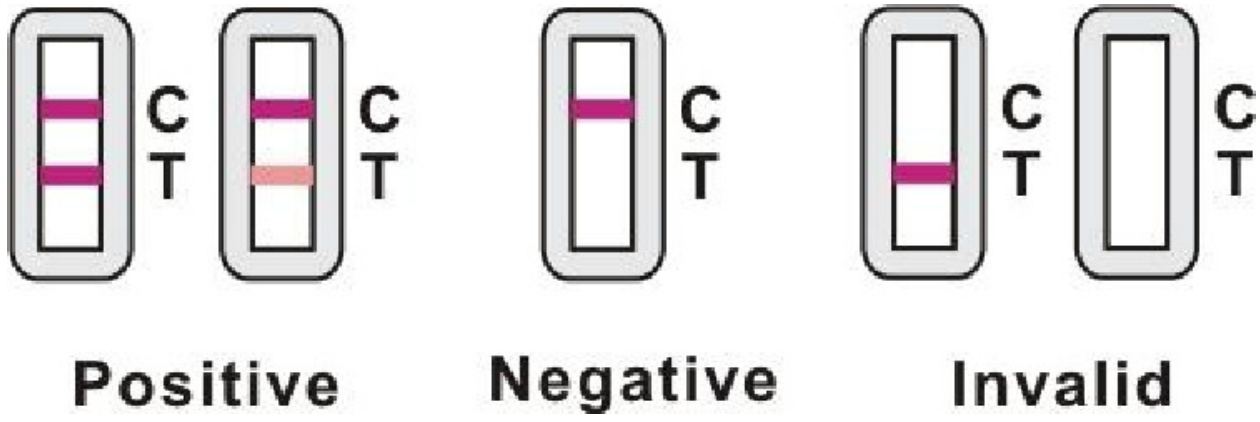

Figure 2: Interpretation of results

13. Limitations

1. The *Willi Fox* - FOB Test Device is for *in vitro* diagnostic use only.

2. The *Willi Fox* - FOB Test Device will only indicate the presence of fecal occult blood; the presence of blood in feces does not necessarily indicate colorectal bleeding.

3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.

4. Other clinically available tests are required if questionable results are obtained.

14. Expected values

Positive results with immunochemical fecal occult blood tests have been shown to vary in each patient population depending on the test used, age, ethnicity of the patient and the predisposition to colorectal disease. The *Willi Fox* - FOB Test Device will detect hemoglobin in feces at levels as low as 0.2µg/mL. The *Willi Fox* - FOB Test Device has been compared with a predicate device.

Analytical specifity

Specificity of the *Willi Fox* - FOB test was evaluated based on results from the cross reactivity studies. The *Willi Fox* - FOB test is specific to human hemoglobin.

Interefenrence testing

Studies were done to investigate the cross reactivity of other species of hemoglobin, tissue extracts and dietary substances on the *Willi Fox* - FOB test. Diluted extracts of the following substances were added to both positive and negative controls. The following table lists the substances tested.

No cross reactivity was detected:

Substance	Concentration
Bovine hemoglobin	1 mg/mL buffer
Chicken blood (1:10 in buffer)	0.1 mL/g feces
Pork hemoglobin	1 mg/mL buffer
Goat blood (1:10 in buffer)	0.1 mL/g feces
Horse hemoglobin	1 mg/mL buffer
Rabbit hemoglobin	1 mg/mL buffer
Fish blood (1:10 in buffer)	0.1 mL/g feces
Iron (Fe^{2+} /Fe^{3+})	5 mg/mL buffer

15. Bibliography

1. Simon JB. *Occult Blood Screening for Colorectal Carcinoma: A Critical Review*, Gastroenterology, 1985; 88: 820.

2. Blebea J, Mcpherson RA. *False-Positive Guaiac Testing With Iodine*, Arch Pathol Lab Med, 1985;109:437-40

16. Glossary of symbols

REF	Catalog number		Do not reuse
LOT	Batch code		Use by
	Temperature limitation		Content
IVD	*In vitro* diagnostic medical device		Consult instructions for use
	Manufacturer		

CE

The *Willi Fox* – FOB tests are manufactured in Switzerland and are provided by:

Willi Fox GmbH
CH - 4001 Basel
Tel. +41 (0)61 534 74 65
Fax +41 (0)61 535 14 80
willifox@willifox.com

www.willifox.com