

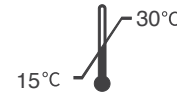
**Read all of the instructions before performing the test**

Simple one step self test for detection fo blood in feces.

Easy to use, rapid results in 4-7 minutes.

For external use only.

Store at Room Temperature. Do not expose the kit to extreme temperatures over 30°C (86°F).



**PART 1. CONTENTS (2 TESTS, DC-30-0017)**



**PART 2. INTENDED USE**

The iColon™ iFOB Test is a qualitative immunoassay for detection of Fecal Occult Blood. It is intended for over the counter use. Measurement of FOB is useful as an aid to detect human blood in stool as found in a number of gastrointestinal disorders, e.g., diverticulitis, colitis, polyps, and colorectal cancer.

**PART 3. WHAT ARE THE LIMITATIONS OF THE TEST**

1. This test should only be used for the detection of human blood in fecal samples.
2. A positive result indicates there is blood in the feces sample. It does not indicate the exact amount of blood or if the blood is a sign of serious disease. Therefore, talk to your doctor.
3. A negative result does not mean there is no problem with your digestive system. For example, some cancers of the intestines may not bleed all the time or blood may not be in the collected stool (false negative). If concerned, see your doctor.
4. Do not collect fecal samples if you have hemorrhoids, constipation, urinary bleeding, or menstrual period. These conditions may give positive results that are not due to bleeding in your digestive system (false positive).

**PART 4. WARNING AND PRECAUTIONS**

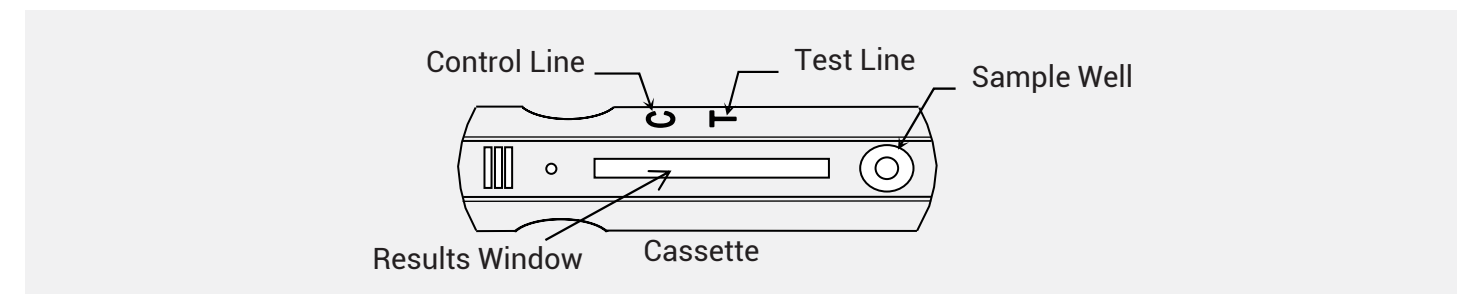
1. This test detects hidden blood (occult blood), blood not visible to the eyes, in fecal samples. This test will only give positive or negative results and does not tell how much blood is in the stool. Do not perform this test if you see blood in your stool, contact your doctor.
2. Bleeding in the digestive system may be intermittent (not continuous), We recommend performing the test on three different days using new stool samples each time. This would increase the chance of detecting fecal occult blood.

3. Taking Aspirin or non-steroidal, anti-inflammatory medications may cause bleeding in your digestive system and may make the FOB test positive. Prior to performing the test, tell your doctor if you are taking these medications.
4. Keep the buffer solution (contains 0.02% sodium azide) in the collection tube out of reach of children. If accidentally swallowed, call U.S. poison control at 1-800-222-1222 for help.
5. Do not perform the test with an expired device (see the expiration date on the pouch).

**PART 5. HOW THE TEST WORKS**

If an individual has blood in the feces, especially over several days, it could be a sign of a disease and should be investigated. The iColon™ iFOB Test uses antibodies to detect human blood in fecal samples. This test is good for monitoring the presence of blood in fecal samples by patients at home as ordered by a doctor or screening by healthy individuals to detect hidden blood in fecal samples.

**PART 6. THE STRUCTURE OF THE CASSETTE**



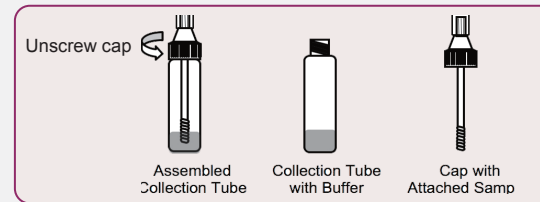
**PART 7. HOW TO COLLECT FECAL SPECIMEN**

**Step 1.** The stool (feces) samples may be collected on the collection paper provided. To use the collection paper, peel off the liner covering the adhesive tape on each end of the collection paper as shown. Then press the tape down on each side of the toilet seat. The paper must go across the opening as shown. Deposit feces on the collection paper.

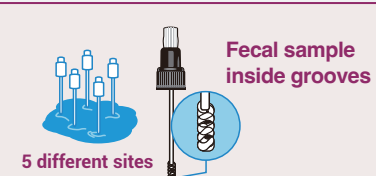


If preferred stool may be collected on regular toilet paper or caught in a clean cup. **Do not perform the test if stool comes in contact with toilet water.**

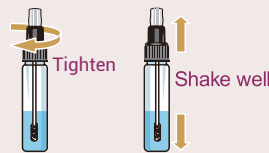
**Step 2.** Unscrew the sampler of the collection tube.



**Step 3.** Pierce the fecal sample with the end of the sampler in at least five (5) sites, randomly selected. Then insert the sampler into the collection tube.



**Step 4.** Once the sampler is inserted into the collection tube, firmly tighten it. Then shake the tube to mix the liquid.

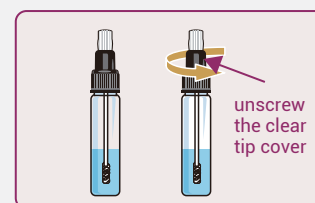


\*NOTE: Samples collected may be stored for two (2) days at room temperatures, 15-30°C (59-86°F).

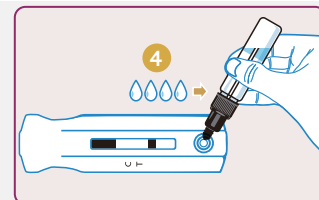
## PART 8. HOW TO DO THE TEST

**Step 1.** Remove the cassette from its pouch and place it on a flat surface.

**Step 2.** Holding the collection tube upright, unscrew the clear tip cover.



**Step 3.** Squeeze the collection tube to place **four drops** of fecal sample in the collection tube into the sample well of the cassette as shown.



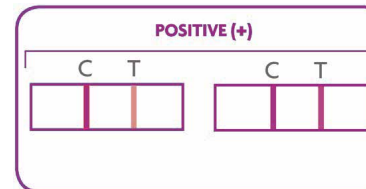
**Step 4.** Read the results in 4-7 minutes.

Do not read the test results before 4 minutes and after seven (7) minutes.

**Step 5.** After the test is done, discard the used kit (cassette and collection tube) into the regular trash, and flush the collection paper in the toilet bowl.

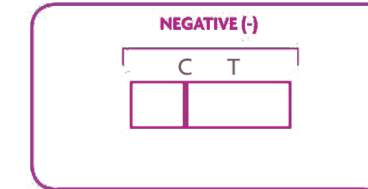
## PART 9. RESULTS INTERPRETATION

**POSITIVE:**



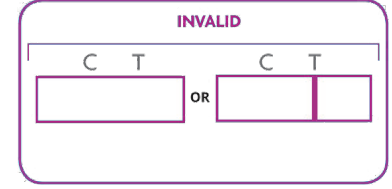
**POSITIVE:** If you see two lines in the result window, a control line (C line) and a test line (T line), the result is positive. It indicates that bleeding might have occurred in the intestinal tract. For positive results, consult a doctor.

**NEGATIVE:**



**NEGATIVE:** If only the control line (C line) appears, there may be no bleeding in the intestinal tract when the sample is collected.

**INVALID:**



**INVALID:** If neither control line (C line), nor Test line (T line) developed, please review the procedure carefully and repeat the test with a new cassette. In this case, there is no need to collect a new fecal sample. Each collection tube contains enough volume for at least three tests.

**What does it mean if the T line is very faint?**

A faint T line is still a positive result, consult your doctor.

**How do you know if the test worked ok?**

This test has an internal control feature, the C line. The C line should always be present. If the C line does not appear, the test result is invalid. In this case, review the section "How to do the test" and repeat the test with a new cassette.

**Is this test reliable?**

Yes, in a consumer study, 95% of the people with different ages and backgrounds were able to follow the test instructions and get correct results. This device has also been compared to another marketed fecal-blood test in laboratory studies. The accuracy of this device in laboratory studies is 100%.

**Do I need to see my doctor when the test is positive?**



Yes!

## PART 10. STORAGE

This test device is stable when stored at room temperature 15-30°C (59-86°F) for up to 2 years or until the expiration date printed on the label, whichever comes first. Do not expose the kit components to temperatures over 30°C (86°F).

## PART 11. TECH SUPPORT

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1-800-246-8878 (Toll-Free U.S.)  
9AM-5PM Pacific Standard Time  
Monday-Friday

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