

INDICAID™ OTC

iFOB IMMUNOCHEMICAL FECAL OCCULT BLOOD RAPID TEST

Catalogue No. See Box label

INTENDED USE

INDICAID™ iFOB Immunochemical Fecal Occult Blood Rapid Test is a rapid test for the qualitative detection of human occult blood in feces. It is used as an aid in the diagnosis of gastrointestinal (GI) bleeding.

It is intended for over-the-counter use. For *in vitro* diagnostic use only.

HOW DOES IT WORK?

INDICAID™ iFOB Immunochemical Fecal Occult Blood Rapid Test is a double antibody sandwich immunoassay. It is used for the detection of hemoglobin (Hb) in fecal samples. The result is very specific and easier to read than guaiac tests. It is able to detect 50 ng/ml Hb in feces.

When the sample is dropped into the test cassette, capillary action carries the sample along the membrane. When Hb in the sample reaches the Test Zone of the membrane, it will form a color line. Absence of this color line suggests a negative result.

To serve as a procedure control, a color line will appear in the Control Zone, if the test has been performed properly.

WARNINGS AND PRECAUTIONS

1. This kit is for external use only. Do not swallow.
2. Do not interchange materials from different product lots.
3. All specimens should be treated as potentially infectious materials. Protection gloves should be worn when handling the specimen.
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. **DISPOSAL OF THE DIAGNOSTIC:** The used device, container and collection tube have infectious risk. The process of disposing the diagnostic must follow the local infectious disposal law or laboratory rule.

CONTENT OF THE KIT

Material Provided

1. Test pouch(es). One pouch contains a test cassette and a desiccant. The desiccant is for storage purposes only, and is not used in the test procedures.
2. Collection tube(s) with 1.5 ml extraction buffer solution.
3. Flushable collection paper(s).
4. Package insert and Consumer Instruction.

Material Not Provided

1. Timer (watch or clock)

STORAGE AND STABILITY

1. Store at 39°F-86°F (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. The Test Device should be used within 1 hour once opened.

SPECIMEN COLLECTION AND PREPARATION

Subject preparation

1. Do not collect stool samples during your menstrual period (wait until three days after the bleeding stopped), or while you have bleeding hemorrhoids or blood in your urine. Hands and test area should be kept clean and free from blood to avoid false positive results.
2. Avoid the following drugs for the 7 days before the test they can make it look like you have hidden blood when you don't:
 - a. Aspirin or other non steroidal anti inflammatory medications (Ibuprofen, Naproxen, Indomethacin and Phenylbutazone)
 - b. Please ask your doctor about other medications you are taking.

Specimen collection

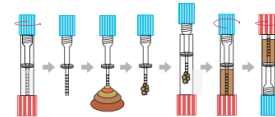
Note: Contamination from toilet water and urine should be avoided.

1. Prior to excreting, urinate first if possible. Flush the toilet bowl twice. If necessary, clean the toilet bowl.
2. Take out the collection paper. Peel covers to expose

- adhesive strips on collection paper.
3. Place the collection paper across the toilet bowl. Allow the paper to sag leaving room between buttocks and sample. Press the tape down on each side of the toilet bowl.
 4. Make bowel movement on the collection paper. Avoid urinating on the paper. If needed, urinate in the front of the bowl, missing the collection paper.



5. Collect stool sample by using the sample collection tube. Unscrew the smaller, blue cap of the collection tube with the sampling stick.
6. Poke the sampling stick into stool sample in 6 different places. Use only enough fecal material to cover the ridged end of the sampling stick.
7. Put the sampling stick back into the sample collection tube and screw tightly, mix well.

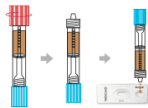


Note: Test should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 36°F-46°F (2°C-8°C) for up to 30 days. For long-term storage, specimens should be kept below -4°F (-20°C).

TEST PROCEDURE

- Test must be at room temperature 50°F-86°F (10°C-30°C).
1. Remove the test device from the sealed foil pouch by

- tearing at the notch and place it on a level surface.
2. Shake sample well to mix. Hold the collection tube upright and make sure the bigger red cap is facing upwards. Carefully unscrew the bigger red cap of the collection tube.
 3. Squeeze 3 drops of sample solution into the sample well, as in the illustration.
 4. Read the test results at 10 minutes. Some positive results may be seen earlier. Do not read results after 30 minutes.



READING THE RESULTS

Positive (+)

Rose-pink lines are visible in both the control region and the test region. It indicates a positive result for Hb. Please refer to QUESTIONS & ANSWERS 4 for further information.

Negative (-)

A rose-pink line is visible in the control region. No color line appears in the test region. It indicates that the concentration of the Hb is zero or below the detection limit of the test. Please refer to QUESTIONS & ANSWERS 5 for further information.

Invalid

If a color line is not visible in a control region, the test is invalid. Another test should be run to re-evaluate the sample. Please contact the distributor, with the lot number.



Note: Any shade of rose-pink line is acceptable. The intensity and width of the lines do not matter.

LIMITATIONS

1. This test is for testing human fecal samples only. The performance of this test using other samples has not been validated.
2. This test has not been validated for testing of samples

with heterophil antibody, as well as patients with hemoglobinopathies. Hemoglobinopathies is the medical term for a group of blood disorders and disease that affect red blood cells.

3. A positive result means that the test has detected blood. There are many GI conditions that may cause blood in your stool. False positive results may also be caused by diet and medications. Further examinations should be performed by a physician to determine the exact cause and source of the occult blood in the stool.
4. If the test result is negative, you could still have a bowel condition that you should know about. You should repeat the test again in a year.
5. If a suspicious result is obtained, it is recommended to re-test the specimen with another test.
6. The fecal occult blood test may be used to check for GI bleeding. However, it is never used to diagnose a condition. The test does not replace your regular physical or rectal examination by your doctor.
7. This device has not been validated for testing loose stool sample.

QUESTIONS & ANSWERS

1. What does this test do?

This is a home-use test kit to measure the presence of hidden (occult) blood in your stool (feces).

2. 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. INDICAID™ iFOB Immunochemical Fecal Occult Blood Rapid Test is designed to detect it.

3. Why should you do this test?

You should do this test, because blood in your feces may be an early sign of a digestive condition. For example abnormal growths (polyps) or other conditions in your colon.

4. 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. Further examinations should be performed by a physician to determine the exact cause and source of the occult blood in the stool.

5. My test is negative. Does that mean I do not have 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 polyps 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. Please seek guidance from your physician if you are having signs and symptoms of possible gastrointestinal bleeding. Signs and symptoms may include stomachache, diarrhea, melena and vomiting etc.

6. Can I read the test results after 30 minutes?

No, test results must be read in 30 minutes. A positive result should not change for several days. However, a negative result may change to a false positive within minutes after 30 minutes. This would not be an accurate reading.

7. How many times should the test be performed?

2 samples from three consecutive stools (total of 6 samples) at home is recommended.

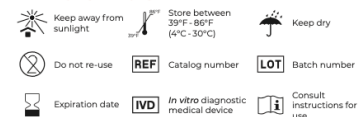
8. How often should you test for fecal occult blood?

It is recommended that you test for fecal occult blood every year after you turn 50 by The American Cancer Society. 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 should test for fecal occult blood.

ASSISTANCE

If you have any question regarding to the use of this product, please call our Technical Support Number 1-877-934-9344 (8:00 a.m. to 6:00 p.m. PST M-F). You may also reach us by email at care@indicaidhealth.com

INDEX OF SYMBOLS



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