Aid for Screening GI Disorders

COLONOX™ FIT

Easy as it seems.

Diagnox

BACKGROUND

Blood in the stool is not normal. It signifies bleeding somewhere in the digestive tract, which can result from various Gastrointestinal (GI) disorders. However, not all blood is visible. Hidden (or occult) blood in the stool may be a sign of colorectal cancer, colon polyps, diverticulitis, colitis, and many other lower GI conditions[1].

The **Colonox™ FIT** is an at-home screening test to find the tiniest traces of blood in stool that are not visible, as an aid in the diagnosis of gastrointestinal (GI) bleeding. The test is also commonly called Fecal Immunochemical Test (FIT) or immunochemical Fecal Occult Blood Test (iFOB or iFOBT).

FIT is the preferred annual colorectal cancer detection test recommended by the American College of Gastroenterology[3]. The US Preventive Services Task Force, a group of medical experts, recommends yearly screening for colorectal cancer for men and women between 45 and 75. But people with an increased risk, such as those with a family history of colon cancer, should consider screening sooner[2]. It is the same test healthcare professionals use for non-invasive screening of signs of GI disorders.

INTENDED USE:

The **Colonox™ FIT** 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. The device is suitable for over the counter use. For *in vitro* diagnostic use only. For over the counter use.

TEST PRINCIPLE:

The **Colonox™ FIT** uses antibodies to detect hemoglobin (Hb) in the stool. The test is a double antibodies sandwich immunoassay. The result is very specific and easier to read than those of guaiac test. It is sensitive enough to detect 50 ng/mL Hb in the stool.

When the sample is dropped into the test cassette, it migrates upward on the membrane and reacts with the chemicals. A positive result is indicated by a color line on the test region. The absence of this color line suggests a negative result. To serve as a procedural control, a colored line will always appear in the control region, indicating that the test was correctly performed.

TEST PROCEDURE

BEFORE YOU CONDUCT THIS TEST

Do not collect stool samples if you:

- ✓ are currently on your menstrual period (wait until three days after the bleeding has stopped)
- ✓ have bleeding hemorrhoids
- ✓ have blood in your urine
- ✓ have taken aspirin or other non-steroidal anti-inflammatory medications (Ibuprofen, naproxen, indomethacin, and phenylbutazone) in the 7 days before the test. They may cause the appearance of hidden blood when it is not actually present. Please consult your doctor regarding any other medications you are currently taking.

Keep your hands and the test area clean and free from blood to avoid false positive results.

The test does not require any special preparations, and it can be performed easily at home following the directions outlined in this insert.

1. SAMPLE COLLECTION

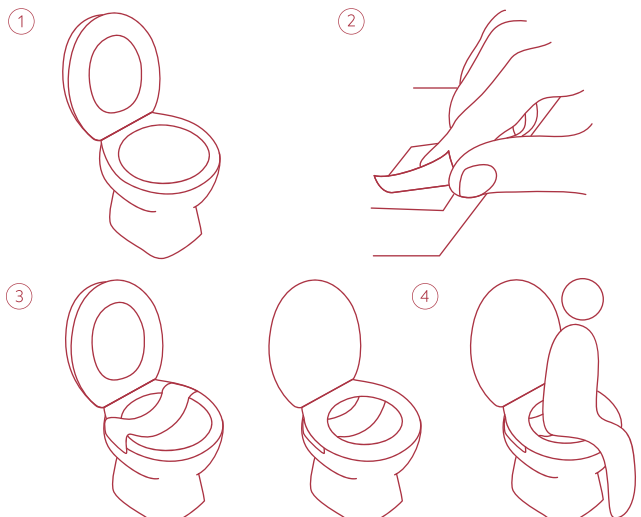
Note: Try to avoid contamination from toilet water and urine.

Make sure the toilet rim is clean and dry.

Take out the collection paper. Peel covers to expose adhesive strips on collection paper.

Place the collection paper across the toilet bowl. Allow the paper to sag, leaving room between the buttocks and the sample. Press the tape down on each side of the toilet bowl.

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.



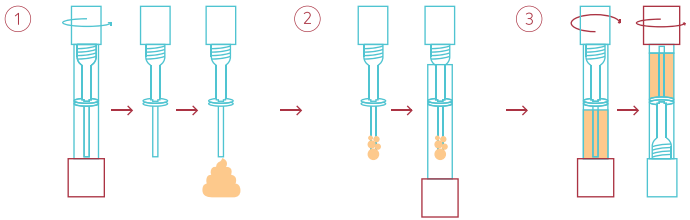
Test should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 36~46°F (2 ~ 8° C) for up to 30 days. For long-term storage, specimens should be kept below -4°F (-20° C).

2. SAMPLE DEPOSIT

Collect stool sample by using the sample collection tube. Unscrew the smaller blue cap of the collection tube with the sampling stick.

Poke the sampling stick into the stool sample in 6 different places. Use only enough fecal material to cover the ridged end of the sampling stick.

Insert the sampling stick back into the sample collection tube and firmly tighten it. Mix well.



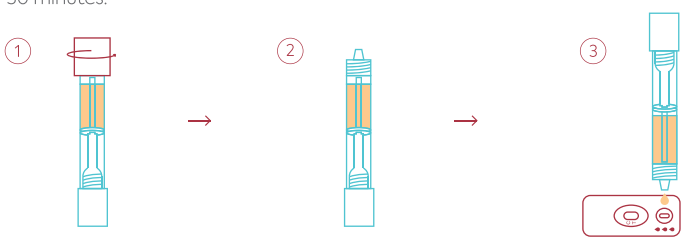
3. TEST PROCEDURE

Remove the test device from the sealed foil pouch by tearing it at the notch and placing it on a level surface.

Shake the 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.

Squeeze 3 drops of sample solution into the sample well, as shown in the illustration.

Read the test results at 10 minutes. Positive results may be seen earlier. Do not read the results after 30 minutes.



READING THE RESULTS

Positive (+)

Two rose-pink lines appear, one in the control region and one in the test region. It indicates a positive result. One line may be darker or lighter than the other, but even very faint lines remain valid.

A positive result means that the test has detected blood in the stool. 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.

Negative (-)

Only one rose-pink line is visible in the control region. No colored line appears in the test region. It indicates a negative result (i.e., no hemoglobin is detected, or the concentration is below the test's detection limit of 50 ng/mL).

You could still have a GI condition despite a negative test. Since polyps may bleed intermittently or not all the time (especially in their early stages), repeating the test at a different time is advised. Additionally, blood may not be uniformly distributed in fecal samples. Please seek guidance from your physician if you are having signs and symptoms of possible gastrointestinal bleeding. Signs and symptoms may include stomach ache, diarrhea, melena, vomiting, etc.

Invalid

If a color line is not visible in the control region, the test is invalid. The test line may or may not be present. Another test should be performed to re-evaluate the sample.

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, including loose stool samples has not been validated.
2. This test has not been validated for testing samples with heterophil antibodies or patients with hemoglobinopathies. Hemoglobinopathies is the medical term for a group of blood disorders and diseases that affect red blood cells.
3. The fecal occult blood test may be used to check for lower GI bleeding, not to diagnose a condition. A definitive clinical diagnosis should only be made by the physician after all clinical and laboratory findings have been evaluated.
4. A FIT test is not intended to replace other diagnostic procedures, such as colonoscopy, flexible sigmoidoscopy, or CT colonography, that are typically performed every 5 or 10 years. The U.S. Preventative Task Force recommends adults (45–75 years) use FIT for yearly colorectal screening.
5. Although the test is highly accurate in detecting human hemoglobin, a low incidence of fase positive results may occur. False positive results may be caused by diet and medications.
6. Many bowel lesions, including some polyps and colorectal cancers, may bleed intermittently or not at all. Also, occult blood may not be uniformly distributed throughout a fecal sample. These factors may yield a negative result even when the disease is present. Repeating the test at a different time can reduce the risk of false negatives.
7. If a suspicious result is obtained, it is recommended to re-test the specimen with another test.

QUESTIONS AND ANSWERS

1. ***Can I read the test result after 30 minutes?*** No, test results must be read within 30 minutes. A positive result should not change for several days. A negative result may change to a false positive within minutes after 30 minutes. That would not be an accurate reading.
2. ***How many times the test should be performed?*** 2 samples from three consecutive stools (total of 6 samples) at home are recommended.

Do not reuse	Keep dry	**REF** Catalog Number
IVD For *in vitro* diagnostic use only	Keep away from sunlight	**LOT** Batch Number
See instruction for use	Store between 39°F – 86°F	Expiry Date

KIT CONTENTS

SAMPLE COLLECTION TUBE(S)
COLLECTION PAPER(S)
TEST CASSETTE(S)
PACKAGE INSERT AND QUICK GUIDE

DESIGNED AND QC TESTED IN THE USA. MADE IN CHINA. DISTRIBUTED BY DIAGNOX LLC, PLANO, TX 75024 USA.

WARNING AND PRECAUTIONS

1. For *in vitro* diagnostic use only. For external use only. Do not swallow.
2. Keep out of the reach of children.
3. Read directions for use carefully before performing the test.
4. All specimens should be treated as potentially infectious materials. Nitrile or Latex gloves are recommended when handling potentially infectious fecal specimens.
5. Do not interchange materials from different product lots.
6. Do not use the test kit beyond the expiration date.
7. Do not use the kit if the pouch is punctured or poorly sealed.
8. Discard after first use. The test device cannot be used more than once.
9. Do not eat, drink or smoke in the area where the specimens and kits are handled.
10. DISPOSAL: The used device, container, and collection tube carry a risk of infection. Take care to dispose of materials properly in accordance with federal, state, and local requirements.

STORAGE AND STABILITY

- ✓ Store at 39°F~86°F (4°C~30°C) in the sealed pouch up to the expiration date.
- ✓ If the test is kept below room temperature, ensure that the test device is brought to room temperature before opening.
- ✓ Keep away from direct sunlight, heat, and moisture.
- ✓ Do not freeze.
- ✓ The test device should be used within 1 hour once opened.

COLONOX-1KT
COLONOX-2KT
COLONOX-3KT

CLX230801 – AUG 1, 2023

CARE TO KNOW

WHAT IS A FECAL OCCULT BLOOD TEST (FOBT)?

Fecal Occult (hidden) Blood (FOB) is blood that you cannot see in your stool or on your toilet paper after you use the toilet. Colonox™ FIT by Diagnox is designed to detect it.

WHAT DOES A FECAL OCCULT BLOOD SIGNIFY?

Blood in the stool means there's bleeding somewhere in the digestive tract. This type of bleeding isn't normal and is usually a sign of a health condition, such as:

- ✓ **Gastrointestinal (GI) disorders**, an umbrella term that refers to a broad range of conditions in the GI tract (that runs from the mouth to the anus). Lower GI disorders originate from the small or large intestines (colon), to the rectum and anus. FIT/iFOB tests primarily screen lower GI disorders that do not cause visible bleeding.
- ✓ **Anemia**, when your body doesn't have enough healthy red blood cells.
- ✓ **Colitis**, a type of inflammatory bowel disease that causes inflammation or irritation in the colon.
- ✓ **Colorectal cancer,** cancer that occurs in the lower part of the colon or rectum.
- ✓ **Diverticulosis**, small pouches or bubble-like formations in the inside wall of the colon.
- ✓ **Colon polyps**, a flat, raised or stalk-like abnormal growth on the colon or rectal lining.
- ✓ **Ulcers**, sores that develop in the lining of the digestive tract or rectum.

While FIT/iFOB test can be used as an aid for the diagnosis of these health conditions, it is most commonly used as a screening test for colorectal cancer[1]. It is essential to know that on its own, the FIT/iFOB test can't diagnose colorectal cancer or any digestive issues. Your healthcare provider will evaluate your physical symptoms and perform further tests to confirm a diagnosis.

[1]Kaur K, *et al.*, Fecal Occult Blood Test, StatPearls Publishing; 2023.
[2]US Preventive Services Task Force, Screening for Colorectal Cancer: US PSTF Recommendation Statement, JAMA. 2021; 325(19):1965–1977.
[3]Shaukat Aasma, *et al.*, American College of Gastroenterology Clinical Guidelines: Colorectal Cancer Screening 2021, The Am. J. of Gastroenterology, 2021, 116(3):458–479.

WHAT TYPES OF SCREENING TESTS ARE AVAILABLE FOR COLORECTAL CANCER?

Screening tests for colorectal cancer fall under two categories. First category of tests are non-invasive stool tests, while the second category of tests are advanced imaging tests.

STOOL TESTS:

1. **Guaiac Fecal Occult Blood Test (gFOBT):** Detects hidden blood in the stool using a chemical called guaiac. Requires dietary and medication restrictions prior to the test.

   How often: Once a year.

2. **Fecal Immunochemical Test (iFOBT or FIT):** Finds traces of blood in the stool using antibody tests.

   How often: Once a year.

3. **FIT-DNA or Stool DNA:** combines the FIT with a test that detects blood and DNA alterations associated with colorectal cancer. The sample is sent to the lab for analysis.

   How often: Once every three years.

Remember that a positive FOB test result isn't a cancer diagnosis. FOB test results will help your healthcare provider in making a diagnosis.

WHO SHOULD GET TESTED?

- ✓ Medical experts from various organizations recommend that men and women from 45 to 75 years should be screened for colorectal cancer annually with a FIT (and other imaging tests every 5 to 10 years).
- ✓ If you have a family history or are at an increased risk, you can start testing below the age of 45.
- ✓ The decision to be screened between ages 76 and 85 should be made on an individual basis. If you are older than 75, talk to your healthcare provider about getting screened.

IMAGING TESTS:

1. **Flexible Sigmoidoscopy:** A short, thin, flexible, lighted tube is inserted into the rectum to check for polyps or cancer inside the rectum and lower third of the colon.

   How often: Every 5 years, or every 10 years with a FIT every year.

2. **Colonoscopy:** A longer, thin, flexible tube with a camera is inserted in the rectum to image the rectum and the entire colon and visually check for polyps or cancer. Colonoscopy also is used as a follow-up test if anything unusual is found during one of the other screening tests.

   How often: Every 10 years (for people who do not have an increased risk of colorectal cancer) with a FIT every year.

3. **CT Colonography (Virtual Colonoscopy):** X-rays and computers produce CT images of the entire colon, which are displayed on a computer screen for the doctor to analyze.

   How often: Every 5 years with a FIT every year.

Each test has advantages and disadvantages. Your healthcare provider can guide you on the best test for you based on your preferences, medical condition, and personal/family history. Remember, the best test for you is the one you will take.

SCIENTIFIC EVIDENCE SHOWS THAT COLORECTAL CANCER SCREENING SAVES LIVES.[2]

Scan this code from your phone's camera to learn more.

ABOUT DIAGNOX

We believe that promoting and sharing knowledge can be a form of care. With this mission, we make it easy for people to take charge of their personal health.

Listen to your body and get to know yourself to own yourself!

Being the protagonist of your well-being is having information in the palm of your hand. With that in mind, we provide accurate results, simple-to-understand instructions, and all the support needed for you to connect the dots and be aware of your health. After all, **good decisions come from good information.**

It is knowledge from the inside out that guides us to look after ourselves and others around us, raising awareness and wellness for all.

We put you in the center so you can find your own.

Diagnox: Care to know. Know to care.

CONTACT US
contact@diagnoxhealth.com
(866) 342-4669 M-F 9-5 CT
Diagnox LLC, Plano, TX 75024 USA