

Intended purpose

The InSure® FIT™ test detects if there is any hidden blood in your stool. The presence of blood may be a sign of lower gastrointestinal disorders that should be treated. The sample is collected in the privacy of your home and the test is then developed at laboratories or medical professional offices. The InSure® FIT™ test is for In Vitro Diagnostic use only.

IVD Medical Device

InSure® FIT™ test complies with the IVD Medical Device Directive 98/79/EC and carries the CE mark.

Methodology

InSure® FIT™ test is used to detect bleeding in the lower intestine. Colorectal diseases, such as polyps, colitis, diverticulitis, hemorrhoids, fissures or colorectal cancer may leak small amounts of blood into the lower intestine. If there is hidden blood in your stool, it is then passed from the stool to the toilet bowl water. The InSure® FIT™ kit contains everything required to collect two samples of stool (from two different bowel movements) to test if there is blood in the samples. The collection is simple, does not require handling of stools and is completed in the privacy of your bathroom.

Composition

The test kit contains no reactive ingredients.

Kit contents

- Instructions for Use
- Test Card
- Brush Kit consisting of two brushes and two waste bags
- Return envelope

Storage and handling

The test card should be stored at room temperature. Protect from heat and direct sunlight. Use the kit prior to the expiration date printed on the Test Card.

Warnings and precautions

Some conditions may cause a wrong result, you should not perform this test if:

- The Test Card has passed its expiration date.
- Test Kit is damaged, dirty or appears to have been tampered with in any way.
- You have hemorrhoids that are bleeding.
- You have blood in your urine, or if you see blood in the toilet bowl. In this case, contact your doctor.
- It is three days before, during or three days after your menstrual period.
- You have any bleeding cuts or wounds on your hands.
- Your toilet bowl water is saltwater or rusty.

Preparing to collect samples

- Read all instructions before beginning your test.
- You do not have to avoid any foods or medications.
- Eating fruits and vegetables can increase test accuracy.
- Check the “Kit contents” list above to be sure you have all of the components.
- If you have any cleaners or bluing agents in your toilet bowl or tank, remove them and flush the toilet twice.

Limitation of the procedure

This test detects human blood in your stool. There are many gastrointestinal conditions that may cause blood in your stool. If you receive a “positive” test result, more testing and evaluation by a physician is necessary.

This test does not replace your regular physical or rectal examination by your physician.

A “negative” test result means that no human blood was found in the samples. However colorectal lesions, including some polyps and colorectal cancers, may bleed intermittently, or not at all. Additionally, blood may not be uniformly distributed in or on the stool and a test result may be negative even when blood or a lower gastrointestinal disease is present.

SAMPLING PROCEDURE: First sample - A



- Take these instructions, Brush Kit and Test Card into the bathroom.
- Flush the toilet **BEFORE** your bowel movement.



- After your bowel movement, **DO NOT PLACE USED TOILET PAPER IN THE TOILET BOWL.** Instead, use one of the waste bags provided.
- **DO NOT FLUSH** the toilet.



- Lift the flap marked “A” or “LIFT HERE FOR SAMPLE 1” on the Test Card to uncover the small white square underneath.



4 USING ONE OF THE BLUE BRUSHES, GENTLY BRUSH THE SURFACE OF THE STOOL FOR ABOUT 5 SECONDS.

- If the stool is loose, simply stir the water around the stool.
- Remove the brush from the water and gently shake it once to remove excess water and any clumps of stool.



● Transfer the **WATER** sample by gently dabbing the bristles of the brush onto the small white square on the Test Card for about 5 seconds (some staining of the square may occur).

- Put the used brush into the kit waste bag and throw away in your rubbish bin.

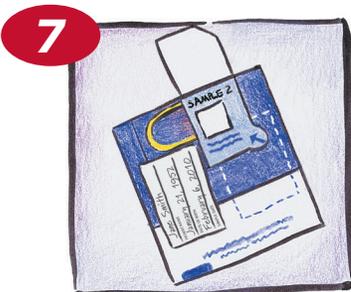


● For the first sample, **PRINT YOUR NAME, DATE OF BIRTH, AND THE DATE THE SAMPLE WAS COLLECTED** on one of the labels located on these instructions for use.

- Peel off the label and use it to reseal the flap marked “A” or “SAMPLE 1”. See diagrams above for the correct positioning of label.

Second sample - B

Your second sample must be from a different bowel movement. (Since bleeding may not occur all of the time, a second bowel movement is sampled to increase the chance of detecting blood.)



- Using the second blue brush, waste bag and the Test Card flap marked “B” or “LIFT HERE FOR SAMPLE 2”, repeat steps 1- 6 shown above. Use the other label to reseal the B flap or SAMPLE 2.
- Place the Test Card in the envelope.
- Return to the indicated laboratory or medical professional office either by post or personal delivery.

EC|REP

mdi Europa GmbH
Langenhagener Straße 71
D-30855 Langenhagen
Germany



Enterix Inc., Edison, NJ 08837 USA

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Test card must be returned to the indicated laboratory or medical professional office as soon as possible and within 14 days of first sample collection. Within the USA, if you have any questions or need help regarding the sample collection process, please call Enterix Inc. at 1-800-531-3681 or visit our website at www.InSureTest.com. Within all other countries please contact your local distributor.

Symbols used

European Community Authorized Representative	Attention, see instructions for use
Batch code	Manufacturer
Use by (Year Month Day)	In vitro diagnostic medical device
Limit of temperature	Biohazard
Do not reuse	This product is covered by one or more patents
CE Mark	Keep away from heat
Contents	Open when test is to be developed
Contains sufficient for (n) tests	Not for internal use Keep out of reach of children

Removable Labels

