Intended purpose

The InSure® ONE™ 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® ONE™ test is for *in vitro* diagnostic use only.

IVD Medical Device

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

Methodology

InSure® ONE™ test is used to detect bleeding in the lower intestine. Colorectal diseases, such as polyps and colitis, 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® ONE™ kit contains everything required to collect two toilet bowl water samples from ***one*** stool to test if there is blood in the sample. The collection is simple, does not require handling of the stool 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
- Reply form with label

Storage and handling

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

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, more testing and evaluation by a physician is necessary.

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

A "negative" test result means that no human blood was found in the sample. 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.

Symbols used

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

Entrix Inc., A Clinical Genomics Inc. Company
236 Fernwood Ave., Edison NJ 08837 USA

EC REP

mdi Europa GmbH
Langenhagener Straße 71
D-30855 Langenhagen
Germany

Instructions for Use

InSure® ONE™
One Day Fecal Immunochemical Test

For *in vitro* diagnostic use

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 to be sure you have all the components.
- If you have cleaners or bluing agents in your toilet bowl or tank, remove them and flush the toilet twice.

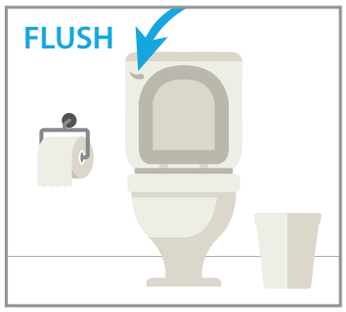
Warnings and precautions

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

- The Test Card has passed its expiration date.
- Collection 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 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.

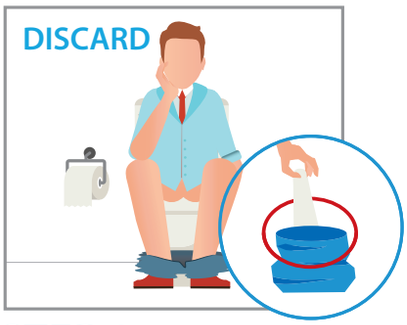
If you have any questions or need help regarding the sample collection process, please call us at 1-800-531-3681.

Read all instructions before beginning your test.



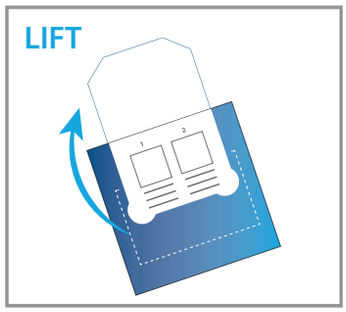
STEP 1

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



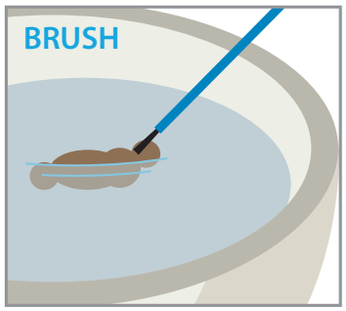
STEP 2

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



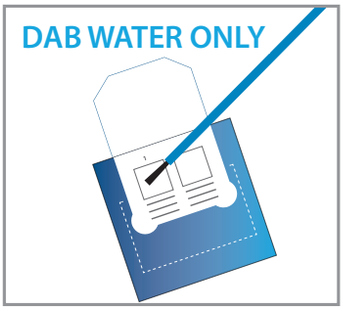
STEP 3

- Lift the flap marked "LIFT HERE FOR SAMPLE" on the Test Card to uncover the small white squares marked "1" and "2."



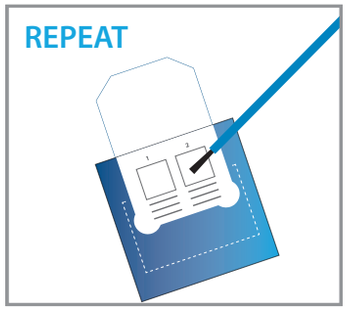
STEP 4

- ***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.



STEP 5

- Transfer a sample of the **WATER ONLY** by gently dabbing the bristles of the brush onto the small white square labeled "**1**" on the Test Card for about 5 seconds (some staining of the square may occur).
- Discard used brush in one of the blue waste bags and throw away.

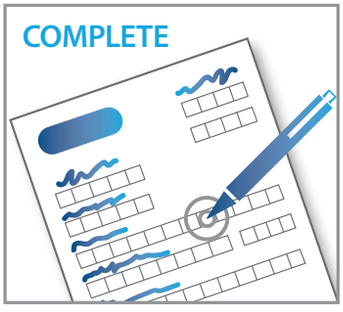


STEP 6

- Using the second blue brush, repeat step 4 and transfer a second **WATER** sample to the test card by gently dabbing the bristles of the brush onto the small white square labeled "**2**" for about 5 seconds.
- Discard used brush in the other blue waste bag and throw away in your trash.

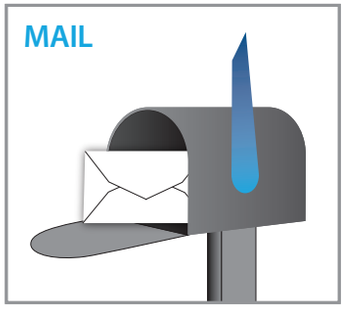
STEP 7

- ***Print your name, date of birth, and the <u>date the sample was collected</u>*** on the removable label.
- **REMEMBER TO INCLUDE DATE OF SAMPLE COLLECTION.**
- Peel off the label and use it to reseal the flap.



STEP 8

- Complete the Reply Form.
- Place the Test Card and Reply Form in the postage-paid mailing envelope provided.
- If your medical professional or the laboratory provided you with a pre-printed test requisition form include the form also in the return envelope.



STEP 9

- Return to the indicated laboratory or medical professional office either by mail or personal delivery.
- Test Card must be returned to the indicated laboratory or medical professional as soon as possible and within 14 days of sample collection.
- The results will be provided by your medical professional.

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