

FOBCHECK®

Rapid test for the detection of fecal occult blood in stool

Early detection can save...

INSTRUCTIONS FOR USE

INTRODUCTION

Risk of hidden (fecal occult) blood in stool increases with age. Fecal blood is an indicator for a variety of gastrointestinal disorders such as diverticulitis, colitis, polyps, and colorectal cancer.

FOBCHECK® is a qualitative rapid test for use at home to detect the presence of hidden (fecal occult) blood in stool.

FOBCHECK® is intended as an aid in the diagnosis of gastrointestinal disorders and detects the presence of human Hemoglobin (Hb) at the cut-off level of 40ng/ml.

FOBCHECK® uses antibodies directed against human hemoglobin to detect blood in the stool. If the sample contains this antigen, a colored Test line (T) will appear indicating a positive result. The final diagnosis must be confirmed by the physician.

An explanation of how to read and interpret the test results is given in the "Evaluation of test result" section. It is important to fully understand the entire instruction pamphlet before performing the test.

TEST CONTENTS

- 1 test cassette in a sealed pouch
- 1 sample collection applicator with sample dilution buffer
- 1 instruction pamphlet

Additionally required:

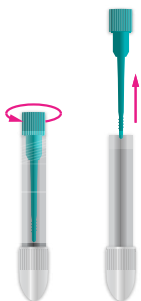
- 1 timer

TEST PREPARATION

Let test cassette and sample collection applicator with sample dilution buffer stand at a room temperature (15°C to 27°C) before performing the test. Contamination from urine and toilet water should be avoided as the test result can be adversely affected.

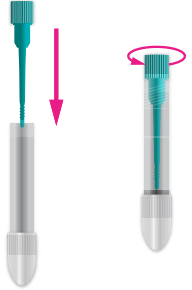
TEST PERFORMANCE

1. Collect a sample of feces in a clean, dry cup or toilet paper. Perform the immediately.
2. Take the sample collection applicator and open it by screwing the blue cap carefully. Be careful not to spill solution from the tube.

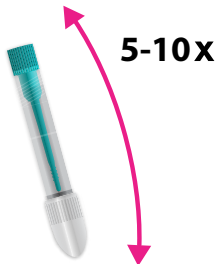


3. Using the blue sample collection applicator randomly poke the stool sample on different sites. Collect a stool on the end of applicator as much until the ribbed end of applicator will be covered.

4. Reinsert the sample collection applicator into the tube and close the cap carefully. Remove the test cassette from sealed pouch and begin the test performance immediately.



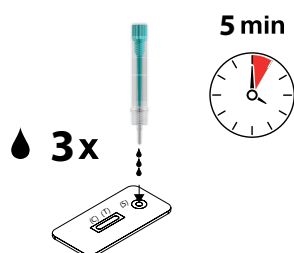
5. Shake the content of the solution bottle thoroughly (5-10 times) to ensure proper mixing of the stool sample with the dilution buffer. The "sample mixture" should not be "grainy".



6. Remove the white protective cap at the end of the tube. Using a piece of tissue paper, break the tip of the tube. Be careful not to spill or spatter the sample mixture from tube.



7. Hold the sample collection tube vertically and dispense 3 drops (approximately 150 µL) of sample mixture into the oval sample well of the test cassette. The test begins as soon as a red-dish migration on the test cassette will be recognized.



8. As the test begins to work, you may notice a light red flow moving across the Test and Control windows. **The test result should be read within 5 minutes. Do not read the result after 5 minutes.**

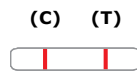
EVALUATION OF TEST RESULTS

To read the test results simply determine whether a line is present or absent at the control (C) position. It does not matter how strong or weak a Control line is.

POSITIVE TEST RESULT

If a **faint pink-to-red Control line (C)** is visible in the result window **along with a faint pink-to-read Test line (T)**, the test result is positive.

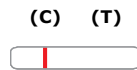
The test result indicates that hidden blood is present in the stool sample. The final diagnosis must be confirmed by the physician.



NEGATIVE TEST RESULT

If **only a faint pink-to-read Control line (C)** is visible in the result window with **no Test line (T)**, the test result is negative.

The test result indicates that hidden blood is not present in the stool sample. If there are any other gastrointestinal symptoms, please, visit the physician for further medical investigation.












INVALID TEST RESULT

If there is **no Control line (C)** or **only a Test line (T)** in the result window, the test did not run correctly and the results are not valid.

It is important that you carefully followed the instructions for the test. You should test again with a new stool sample and a new test.



Explanation of symbols:

 Follow instructions	 In vitro diagnostic medical device (for external use)	 Best before (See imprint on package)
 Store at 4°C - 30°C Do not freeze.	 Content sufficient for 1 test	 Do not reuse
 Manufacturer	 Catalogue number	 Batchnumber (See imprint on package)

CE0483

Instructions English
Revision from 2016-04 (Rev. 00)



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For the love of life.

For self-testing

WARNINGS AND IMPORTANT INFORMATION

- The test is intended for use outside the body.
- Not to be taken internally. Avoid sample buffer contact with skin and eyes.
- Keep out of the reach of children.
- Protect from sunlight, do not freeze. Store in a dry place between 4°C and 30°C.
- Do not use after the expiration date printed on the package.
- Not following the exact instructions can affect the outcome of the test. The final diagnosis must be confirmed by the physician.
- Do not use the test if the packaging is damaged. Do not use damaged test components.
- All test components are only intended to be used for this test. Do not reuse the test or test components.
- The test should be carried out immediately or within one hour after opening the foil pouch.
- Poor vision, color blindness or poor lighting may affect your ability to interpret the test correctly.
- All test components can be disposed in household waste.