

Interpretation of result



**Positive
Result**

**Negative
Result**

**Invalid
Result**

Please do note further explanations in the next coloured textblock for further information.

After more than 10 minutes, the test result can no longer be interpreted reliably. Please therefore discard the test cassette once you have assessed your test result.

The test is **positive** if, within the reaction time of five minutes, **two purple lines appear in the result window of the test cassette at both "C" and "T"**, even if the line shown at "T" is very faint. This means that blood has been detected in your stool. You should visit your doctor and ask for a more detailed medical examination to be undertaken.

The test is **negative** if **only one purple line appears in the result window at "C"**. This means that no blood was detected in your stool sample.




The test is **invalid** if, after 5-10 minutes, **no purple line appears at all, or if there is a line at "T" but no line at "C"**. Reasons for an invalid test result include a damaged foil pouch, improper storage, or a mistake when performing the test. Please keep all test components and contact the manufacturer of the test.

What should I do if the test result is positive?

Discuss the result with your doctor. Besides colon polyps and colon cancer, several other conditions may produce a positive test result. Inflammatory bowel conditions, haemorrhoids or changes in the digestive tract are some of the possible causes, and must be taken into consideration by your doctor. However, when blood was detected in your stool having a colonoscopy is highly recommended. It might be helpful to take these instructions with you to show your doctor, so you can give him or her a better idea of the type of test carried out.

What should I do if the test result is negative?

A negative result does not entirely exclude the possibility of a bowel condition, since some colon tumours only bleed intermittently. Around 25% of tumours do not bleed constantly. For this reason, it is important to test yourself or arrange to be tested annually from age 40 at the latest in order to keep your risk as low as possible.

 Read instructions carefully before use!
Keep out of reach of children.
Do not use the test after the expiry date.
 Store at 39° to 86°F (4° to 30°C).
Use test only once.
 Do not take the test cassette apart.
Do not ingest buffer solution.
For external use only.
In-vitro-diagnostic device for self-testing.


ZANL0002-GB
Rev08 2015-08-28

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Colon Polyps Health Care Test



General information:

Colon cancer is one of the most common forms of cancer and early detection is vital. The sooner it is detected, the greater are the chances of successful treatment. If it is treated at an early stage the survival rate exceeds 90%.

95% of cases of colon cancer develop from polyps, which are benign tumours growing inside the colon. Typically, they do not cause any pain, and often remain undetected for many years before becoming malignant. At this stage, the hidden early stages of colon cancer can be detected by a simple test for blood in the stool. The test enables you to increase your chances of early detection and thereby reduce your risk considerably.

Above the age of 40, if not sooner, everyone should perform an annual test for blood in the stool. It may be better to start testing before reaching 40 if for example, there is a history of colon cancer or polyps in your family. The test serves to identify blood in the stool which is not yet visible. Colon polyps bleed occasionally, and colon cancer will reveal blood at a very early stage. If, when performing this test, you detect blood in your stool, you should see your doctor in order for the medical reasons to be identified. What makes this test unique is that you do not need to restrict your eating habits in any way in order to perform it, and it can be conducted simply and easily at any time of day, giving you a result within just a few minutes.

Please note:

Do not allow your stool sample to come into contact with water in the toilet.

Women only: The test must not be performed during or for up to 3 days after your period.

**The test components can be disposed of with your normal household waste after use.
Always consult your doctor before making any important medical decisions.**

Performance data:

In a clinical trial with 138 participants who were scheduled for colonoscopy this test detected 91 % of all cancer cases.

Product information:

Alcohol and a number of medicines such as acetyl salicylic acid (aspirin), glucocorticoids, non-steroidal antiphlogistic / anti-rheumatic agents or cumarin derivatives may cause gastrointestinal bleeding (and therefore avoidable, positive results). Please consult your doctor before performing the test if you are taking such medication. Haemorrhoids or blood in the urine may also produce a positive test result.

This test is an immunological test for identifying blood in the stool by detecting human hemoglobin (hHB). Test components of animal origin (such as antibodies) are potentially infectious material, but present no risk to health provided that all test components are used in accordance with the instructions. The buffer solution contains harmless concentrations of sodium azide.

Preparation

Test components: Sample container, sealed foil pack with test cassette and desiccant, and instructions. Additionally required: a watch with a second hand and a clean paper tissue

Initially place the foil pack to one side **unopened**, since you will not need it until later.

Taking a stool sample

Attention: Make sure you do **not** spill any of the solution in the sample container as the solution is essential for performing the test. Take care that the opened bottle does not fall over.

After your bowel movement use the sample container as described below:



Carefully unscrew the cap with its attached test stick from the sample container.



Now, in a single procedure insert the stick vertically at 3 different areas of your stool. The stick will automatically retain the correct amount of sample.



However, it might happen, that too much stool sticks to the stick; remove excess stool with a piece of toilet paper. Excessive stool can lead to invalid results.



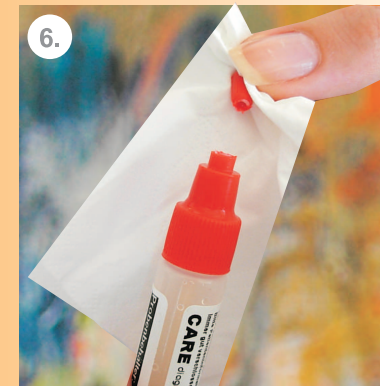
The correct amount of stool is shown on this picture. Place the test stick back in the container and screw the cap back on carefully and tightly. Shake the container well so as to thoroughly mix the contents.

Testing the sample

Please prepare the foil pack, a watch with a second hand and a clean paper tissue. Within just 5 more minutes you will get to know whether there is hidden blood in your stool.



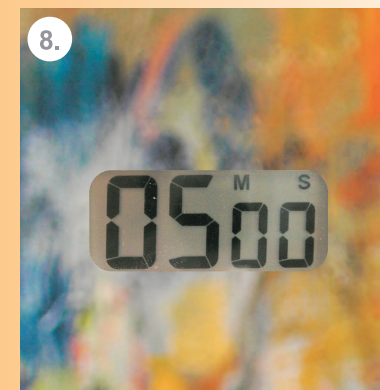
Tear open the foil pack where indicated, take out the test cassette and place it on a dry, even surface. The attached desiccant should be discarded unopened with your regular household waste.



As shown in the illustration cover the cap of the sample container with the paper tissue in order to avoid any splashing. Hold the sample container upright and exert pressure to **break off the dropper tip**.



As shown in the illustration, place two drops of sample onto the test field "S" of the cassette. It is essential to ensure that no liquid falls onto the result window.



Now wait five minutes. You might get an unreliable result if you wait considerably shorter or longer.

Result evaluation on following page