

Laboquick

FECAL OCCULT BLOOD TEST

Fecal occult blood Test Instructions

Intended Use:

Laboquick fecal occult blood test is used as a diagnostic tool to determine the fecal occult blood in humans. One step, quick test to determine the fecal occult hemoglobin. Only for professional use.
Product Code: LBOB.01

Introduction:

Colorectal cancer is the third type of cancers seen widely both in men and women. In most cases more than 90%, the colorectal cancers are observed in people over 50. If it is pre-determined, it can be taken under control possibly by 90%. However, at early stages, the colorectal cancer does not have an indicative symptom. The only way to be followed up in pre-determination phase is seen as to apply the scanning tests in most cases. American Association for Cancer Research suggests everyone who is above 50 to take the test.

Fecal Occult Blood Test determines the fecal blood related to the gastrointestinal disorders.

The rate of mortality in colorectal cancers decreases significantly due to the early action of predetermination and treatment accordingly by using the fecal occult blood test.

Test Principle:

One step cassette test is a rapid and easy immunochromatographic test to determine the fecal blood qualitatively. The test achieves to determine the human hemoglobin (hHB) of 10ng/ml within 10 minutes. The human hemoglobin (hHB) of 30 ng/ml in the samples can be detected easily within 10 minutes by the test. Thanks to this test, the colorectal bleeding at low levels is detected differently than the other type of biochemical test methods. The principle of the test is composed of immunochromatographical sandwich method containing two specific monoclonal antibodies that are able to detect the human hemoglobin in the test samples. The result is clear and more interpretable than the guaiac based tests. The sensitivity is also higher than the other methods of tests. It is not affected by any substance that may lead any crosswise reaction. Before the test, there is no need to apply a special diet.

Package content:

Fecal occult blood test device, disposable plastic pipette, silica gel bag as humidifier.

Storage Conditions:

The test must be stored between +4° to +30°C and must not be frozen. The test kit will provide valid results under these conditions provided that it is used prior to the expiry date and the package has not been opened.

Warnings and Cautions:

The following should be taken into consideration to get the correct results;

- 1- Before use, read the instructions carefully.
- 2- Never freeze the tests. If the test is stored in the refrigerator, you should provide the test come to the room temperature before use. The test should definitely be done at room temperature (between 4.....30 C degree)
- 3- Do not use the expired products.
- 4- You should use only the human stool as the sample.
- 5- Adjust the number of drops to be added carefully. Remember to add only 3-4 drops in the test.
- 6- Use the test device immediately after unpackaged.
- 7- If the package of the test is damaged or torn, do not use the test device.
- 8- In order to prevent any confusion in the samples, one disposable sample dropper should be used for each test.
- 9- During the test, any cosmetics should not be used; any food or beverage should not be consumed and smoking should be avoided.
- 10- The Device is just for in vitro diagnostic use.
- 11- It is for single use.

Sensitivity:

Laboquick Fecal Occult Blood Test is able to detect the human hemoglobin of 30 ng/ml in the sample.

Instructions:

- 1 Unpackage the aluminum bag of test device by tearing as shown.



- 2 Check the sample collecting part.

- 3 Shake the sampling bottle thoroughly.



- 4 Be sure that the sampling bottle is at the vertical direction in the manner that the top part is correctly positioned, then break off the plastic cover carefully.



- 5 Put 3-4 drops from the sample solution into the dropping hole as shown in the picture.



- 6 Read out the test result after 5-10 minutes. Do not take the result into consideration after 30 minutes.

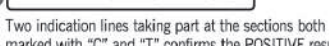
Results Evaluation:



NEGATIVE

The indication line taking part at the section marked with "C" in the result display confirms the NEGATIVE result.

- 7



POSITIVE

Two indication lines taking part at the sections both marked with "C" and "T" confirms the POSITIVE result.



INVALID

If any line is not appeared in the result display until the end of the testing time, the test is invalid. The test should be repeated.

Sample Collection:

Collect the sample of stool into the sampling device in the package of the test. Loosen the top part of sampling device and take the test stick out and take the samples from three different parts of the stool. Then place the stick into the sampling bottle and fasten strictly. If the sample is not analyzed instantly, keep it under 4°C degree. At the time of the test to be done, the sample should be brought to the room temperature.

Test Limits:

1- This test is used in-vitro by the purpose of detecting the occult blood in the human stool. This qualitative detection test is not used to detect the quantitative blood level whether the blood level increases or decreases.

2- The sole using purpose of the fecal occult blood test is to detect the occult blood in the stool. It should be remembered that the results do not bear the final and certain diagnosis. The test results should definitely be supported by the supplement diagnosis and diagnostic methods with the expert comments.

3- In case the defects continue even if the test results are found negative, other various tests should be done by using the other clinical methods. Any result seen as negative does not remove the risk and possibility of colorectal cancer.

4- Test device gives the best result under room temperature.

References:

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3. Schwartz S, Dahl J, Ellefson M, and Ahlquist D. "The Hemo Quant Test: A Specific and Quantitative Determination of Heme (Hemoglobin) in Feces and Other Materials", Clin. Chem., Vol.29 (1983):2061-67.
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