



# Atlas Slide Stool Blood Test

## INTENDED USE

Atlas Slide Stool Blood Test is a ready-to-use diagnostic aid designed for rapid and clean handling of fecal specimens to be tested for occult blood. This test is recommended for routine primary physical examinations of individuals aged 50 years or older, office practices and hospital testing, screening programs for colorectal cancer, and testing of newborns and postoperative patients. Since the test requires only a thin application of specimen, the transport and storage of fecal specimens are eliminated and unpleasant odors are minimized.

Clinical experiences demonstrate that this test for stool blood provides an established method for detecting a symptomatic gastrointestinal conditions including early detection of polyps and colorectal cancer. Additionally, this test is used to detect bleeding problems other than cancer that may come from digestive tract pathologies such as peptic ulcer, colitis, diverticulitis, and gastritis.

## SUMMARY AND EXPLANATION OF THE TEST

Although the concept of occult blood detection using gum guaiac as an indicator was first introduced by Van Deen in 1864, clinical tests for the recognition of small amounts of blood were first applied to fecal specimens in 1901 by Boas using guaiac test method. However, the application as a test for home use was not proposed until 1967 by Gregor with advent of a test that involved guaiac-impregnated paper slides.

Atlas Stool slide Test features ready-to-use, stabilized guaiac-impregnated, electrophoretic paper based on Gregor's classical approach.

When a fecal specimen containing occult blood is applied directly to the slide, the hemoglobin portion of the occult blood will exert a pseudoperoxidase reaction upon the addition of the developing solution. The oxidation reaction of alpha guaiacinic acid in the guaiac paper by hydrogen peroxide in the developing solution forms a quinone structure, guaiacum blue, which becomes visible as a blue or blue-green color change within 30 seconds in the presence of occult blood. Since the structure of hematin is similar in structure to that of peroxidase, it is probably the hematin fraction of hemoglobin in the occult blood specimen which catalyzes the oxidation of the guaiac in the test paper.

## Kit Contains :

Test Card  
Wooden Applicator  
Developing Solution  
Package Insert

## MATERIALS REQUIRED BUT NOT PROVIDED

Timer or watch.

## STORAGE AND STABILITY

This product will maintain its sensitivity for three years from manufacturing date if stored at room temperature and protected from light or heat. Do not refrigerate.

## CAUTIONS

1. For in vitro diagnostic use only
2. Keep testing area, hands, and specimen containers clean and free of blood.
3. The guaiac paper is light and heat sensitive and may discolor and/or lose sensitivity if not properly stored.
4. Do not use if blue discoloration of the normally cream colored test paper is observed prior to sample application.
5. Do not store in the vicinity of volatile oxidizing reagents such as iodine, chlorine, bromine or ammonia.
6. Do not use after the expiration date printed on the kit.

## SPECIMEN COLLECTION

A stool specimen may be collected from the toilet bowl. From toilet paper or caught in a clean cup. When stool is to be collected from the toilet, avoid use of bowl cleansers and continuous cleaning products. If tank cleanser is present, remove and flush toilet several times before bowl movement. Only a thin layer or smear of specimen is needed to conduct the stool blood test. The test may be prepared and developed immediately or stored at room temperature away from heat and light for up to seven days after development. Samples from the outside of the stool specimen will reflect conditions in the lower colon. Samples from the inside of the stool sample will be more representative of the upper gastrointestinal tract. So, it is recommended to take two stool samples from different locations. Also, since bleeding from intestinal lesions may be intermittent, it is recommended that specimens be collected for at least three consecutive days. It is suggested specimen collection be suspended if hemorrhoids, menstrual bleeding, nosebleeds, colitis, diverticulitis, diarrhea, or constipation occur during the test period or, if the patient has had recent dental work.

## TEST INSTRUCTIONS

1. Using the wooden applicator stick, collect a small sample from bowel movement on the end of the applicator.
2. Apply thin layer of specimen inside test window A.

3. Using same wooden applicator stick, collect another small sample from a different area of the same fecal specimen and apply a thin layer inside of test window B.
4. Close and reseal the test slide upon completion of specimen application and protect from heat and light.
  - a. Any trace of blue color is a positive result for occult blood.
  - b. No trace of blue color is indicative of a negative result for occult blood.

It is important that the slide test be read and interpreted thirty (30) seconds from application of the developing solution. Though the positive blue reactions are very stable and may persist for two hours or more, weak trace reactions may fade within one or two minutes.

## LIMITATIONS OF PROCEDURE

Extensive clinical studies have substantiated the diagnostic efficiency of the guaiac stool blood procedure to screen for bleeding symptoms common to many gastrointestinal pathologies. However, cancerous lesions, adenomatous polyps and other gastrointestinal lesions typically bleed intermittently, possibly allowing positive cases to go undetected. Further, blood in stool is not always homogeneously distributed, a phenomenon which can allow a false negative sample to be taken. Therefore all stool blood tests regardless of type are intended only to be used as adjuncts in combination with diagnostic procedures such as barium enema, sigmoidoscopy, colonoscopy, x-ray or other imaging studies.

Some authorities have recommended applying a few drops of water to thick, dry specimens to rehydrate the specimen or to increase the sensitivity of the test. This procedure can lead to false positive results. To avoid the need to rehydrate the test, it is recommended the patient be instructed to apply a thin smear and to return the specimen within seven days of completing the test.

## EXPECTED RESULTS

In vitro studies have shown that guaiac impregnated slide is capable of detecting 2 to 4 ml of blood in 150 grams of feces (equivalent to 2 mg hemoglobin per gram of stool), about twice the normal daily fecal blood loss in an adult.

A study of 900 patient showed a positive result of 5% utilizing barium enema examination, 1% of those patient were shown to have asymptomatic colon cancer. An additional 3% had some other type of bowel pathology. A false positive rate of only 1% was reported in this study, Gregor detailed 2000 physicians who had used the guaiac slides over a 6 month period; colon cancer was detected in 47 patients. These 47 patients were asymptomatic other than the positive guaiac slide test.

A collaborative test was conducted to compare this is stool blood test and 2 different hemocult slides. Hemoglobin was diluted in deionized water to the following concentrations: 1mg/ml, 2mg/ml, 4mg/ml, 6mg/ml and 12mg/ml ( equivalent to 0.1, 0.2, 0.4, 0.6, and 1.2 grams hemoglobin per 100 grams of stool, respectively). These dilutions were used to test the sensitivity of atlas test to compare the reactions to the reactions of the hemocult Tests. Atlas stool blood test gave a trace reaction at a hemoglobin concentration of 1mg/ml in less than one minute while the hemocult II and hemocult sensa produced a negative result. At 2mg/ml, a 1+ positive reaction was observed in less than two minutes with atlas test, while both hemocult II and hemocult sensa produced a trace reaction. At 4mg/ml, a 2+ positive reaction was observed in less than two minutes with atlas test system while both the hemocult II and hemocult sensa produced only a trace to a 1+ reaction. At 6mg/ml atlas test produced a 3+ positive reaction and at 12mg/ml a 4+ positive reaction was observed in less than two minutes whereas the hemocult II and hemocult sensa produced only a 1+ to 2+ reaction at the 6mg/ml dilution and only a 2+ to 3+ reaction at the 12mg/ml dilution.

In summary, data from numerous studies have shown the positive rate to be approximately 3%- 7.2% in screening programs. The false positive rate has been between 1% and 2% in patients who receive proper preparation. The guaiac stool blood test will detect 90% of all colorectal lesions that bleed provided that three consecutive bowel movements are tested.

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