A Schuman Company

propper Manufacturing Co., Inc.

SERACULT®

A TEST FOR FECAL OCCULT BLOOD
FOR IN VITRO DIAGNOSTIC USE

NAME _____

PHONE _____

Product Description and Instructions

Return to physician
Lift to open

Read directions for use
Protect from heat and light

Intended Use

The Seracult test is a rapid and aesthetically acceptable method of detecting fecal occult blood. It is used as a qualitative aid to the diagnosis of various gastrointestinal conditions which manifest themselves by the presence of fecal occult blood. Because of its design and ease of handling, this test lends itself to ready use in: routine physical examinations, routine hospital testing and mass screening programs for colorectal cancer.

Summary

The Seracult test provides, in kit form, a convenient version of the laboratory guaiac test for occult blood. The test consists of a special guaiac-impregnated paper available either as a tape, mounted in an individual cardboard slide, or mounted in a triple cardboard slide for serial determinations. A smear from a stool sample is applied to one side of the paper while the development of the impregnated reagents is performed on the other side. Aside from adding a few drops of developer solution to the paper, no other physical or chemical manipulations of the test components or reagents are necessary.

When a small smear from a stool sample containing occult blood is applied to the paper, the hemoglobin from the blood comes in contact with the impregnated guaiac on the slide. Upon addition of the developer (a stabilized solution of hydrogen peroxide and ethanol), a peroxidase-like reaction occurs which turns the paper blue within 30 to 60 seconds. Appearance of any blue color on the specimen area of the slide or tape is indication of the presence of occult blood.

It should be noted that results with the Seracult test, as with any fecal occult blood test, are not to be considered conclusive evidence for the presence or absence of any gastrointestinal pathology.

This test is designed for routine physical examinations and mass screenings as an aid to diagnosis. It is not a substitute for other diagnostic procedures such as endoscopy or proctosigmoidoscopic examinations, barium enema or other x-ray studies.

Basic Principles of Test

Alpha-guaiaconic acid, a component of natural guaiac resin[9], can be oxidized by hydrogen peroxide to yield a blue pigment. The rate of this reaction can be increased by the addition of peroxidase-like compounds. The hemoglobin component of whole blood is capable of exerting peroxidase-like activity and is thus able to catalyze the oxidation of alpha-guaiaconic acid. This oxidation produces the visible result of blue coloration.

This reaction between alpha-guaiaconic acid in the guaiac resin (on the slide or tape) and hydrogen peroxide (in the developer) catalyzed by the hemoglobin fraction of blood (if present in the stool) is the biochemical basis for the Seracult fecal occult blood test.

Reagents

A. Seracult Tape

Made of a special absorbent paper impregnated with natural guaiac resin, Seracult tape is ready for use as packaged.

Precautions:

For in-vitro diagnostic use only. Do not use product after its expiration date.

Storage and Stability:

Seracult tape is to be stored between 59°-86°F (15°-30°C) and is stable until the expiration date printed on each box. Do not refrigerate. Tape should be protected from heat, sunlight, fluorescent light and ultra-violet radiation. A light-blue discoloration of the normally light-amber paper may occur if tape is not stored under recommended conditions. This does not affect the performance of the test.

B. Seracult Slides with Performance Controls

Seracult slides are made of a special absorbent paper impregnated with natural guaiac resin. Each slide has two sides: one for the application of patient specimens and the other for specimen development.

The specimen development side is divided into two areas: the large Specimen Test Area and a smaller Performance Control Area. These areas are separated from each other by an impermeable inert hydrocarbon barrier which prevents the migration of developer from one area to the other. A Performance Control Line within the Performance Control Area consists of a hemoglobin derivative which is comparable to hemoglobin in its chemical reactivity. Seracult slides are ready to use as packaged.

Precautions:

For in-vitro diagnostic use only. Do not use product after the expiration date. Test is not valid if the performance control test does not yield a blue color.

Storage and Stability:

Slides are to be stored between 59°-86°F (15°-30°C) and are stable until the expiration date printed on each box. Do not refrigerate. Slides should be protected from heat, sunlight, fluorescent light and ultra-violet radiation. A light-blue discoloration of the normally light-amber paper may occur if slides are not stored under recommended conditions. This does not affect the performance of the test.

C. Seracult Developer

The developer is an aqueous solution of approximately 5% hydrogen peroxide and 75% ethanol and is ready for use as packaged.

Precautions:

For in-vitro diagnostic use only. Do not use product after the expiration date imprinted on each developer bottle. Do not ingest. The developer is flammable; keep away from open flame. The developer is an irritant; avoid contact with eyes and skin. If contact occurs, flush the affected area with water. Since the developer evaporates readily, keep the bottle tightly capped when not in use.

Storage and Stability:

Store the Seracult developer between 59°-86°F (15°-30°C). Do not refrigerate or freeze. Keep away from heat and light. If properly stored, developer will remain stable until the expiration date printed on each bottle.

Specimen Collection

The specimen required is a small stool sample which should be applied as a VERY THIN SMEAR to the tape or onto both windows of the Seracult slide. Slides may be developed immediately after specimen application or may be stored and developed up to 8 days after specimen application. Once they have been prepared with a specimen, keep the slides away from heat and light. Hands, gloves and the work area should be kept clean and free of blood to avoid accidental contact of blood with the slides or tape.

Patients experiencing hemorrhoidal bleeding, having a menstrual period, or bleeding from the nose, gums, etc. should delay testing for at least 48 hours from the time that all such bleeding has stopped. To increase the chances of detecting intermittent gastrointestinal bleeding, it is recommended that stool samples be collected from three consecutive bowel movements and that two smears be made from two different areas of each bowel movement.[3,4]

Patient Preparation

If possible, the patient should be placed on a meat-free low-peroxidase diet to reduce the possibility of false positive indications. This special diet

should be started two days before testing and continued through the testing period.

An alternative to this procedure is to omit the special diet for initial tests and to impose it on patients whose stools yield positive results and are to be retested.

Special Diet

Patient May Consume	Patient should not Consume
• Generous amounts of cooked and uncooked vegetables such as lettuce, corn and spinach	• Rare and lightly cooked meats, particularly beef
• Moderate amounts of high fiber foods such as bran cereal, peanuts and popcorn	• Cauliflower, horseradish, red radishes, turnips, broccoli and cantaloupe
• Plenty of fruits such as plums, grapes and apples	• Vitamin C in excess of 250 mg. per day
• Well cooked pork, poultry and fish	• Iron rich supplements
	• Aspirin and other medications which may cause gastrointestinal irritation

Note:

If any of the above dietary restrictions and recommendations are known to cause discomfort, patients should be instructed to inform their physician. The patient should always consult the physician before discontinuing or interrupting any prescription medication.

Interfering Substances

Ingestion of high doses of vitamin C (ascorbic acid) in excess of 250 mg per day has been linked to false negative results.[6] Intake should be discontinued two days prior to and during the testing period.

Oral iron preparations such as iron-rich supplements have been associated with a higher than normal percentage of false positive indications in healthy patients. Ingestion of therapeutic iron should be discontinued two days prior to and during the testing period.

Certain oral medications may cause gastrointestinal irritation and bleeding. Medications such as aspirin, indomethacin, phenylbutazone, corticosteroids & reserpine should, with the consent of a physician, be discontinued two days prior to and during the testing period.[6,11]

The physician should always assess the advisability of any changes to a prescription medication regimen.

Dietary catalases and peroxidases derived from various meats and vegetables may contribute significantly to the incidence of false positive indications. For this reason, certain dietary restrictions (described in the preceding Patient Preparation section) are frequently recommended.

Interpretation of Results

Specimen Test Area

Results must be obtained by visual observation 30 to 60 seconds after the application of the developer solution. *Any trace of blue color* in the Specimen Test Area is positive indication of occult blood. The absence of a blue color in the Specimen Test Area indicates a test negative for occult blood. Since any developed blue color may fade after two