




A Schuman Company

propper
Manufacturing Co., Inc.

SERACULT[®] PLUS



A MORE SENSITIVE TEST FOR
FECAL OCCULT BLOOD
FOR IN VITRO DIAGNOSTIC USE

NAME

AGE

STREET

Product Description
and Instructions

PHONE

Open flap-read directions for use
Return to physician

Intended Use

The Seracult Plus test is a rapid and aesthetically acceptable method of detecting fecal occult blood. It is a guaiac based slide test. 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 and routine hospital testing. It is suitable for the monitoring of post-surgical bleeding or patients with ulcerative colitis, peptic ulcers or iron deficiency anemia and other conditions resulting in increased presence of fecal occult blood. Seracult Plus may be used in screening programs for colorectal cancer if the Special Diet recommendations are followed. **The greater sensitivity of Seracult Plus renders it especially useful for monitoring patients at high risk for colorectal diseases.**

Summary

The Seracult Plus 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 in tape form, 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 physi-

cal or chemical manipulations of the test components or reagents are necessary. When a small smear from the 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 peroxide-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.

Seracult Plus is a more highly sensitive test than conventional guaiac slide tests, consequently, it will have both a higher sensitivity for possible diseases and also a higher than normal false-positive rate in normal patient populations. It should be noted that results with the Seracult Plus test, as with any fecal occult blood test, are not to be conclusive evidence for the presence or absence of any gastrointestinal pathology.

This test is designed for routine physical examinations and mass screenings when the Special Diet recommendations are followed or 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-guaiacetic acid, a component of natural guaiac-resin⁹, 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 Plus fecal occult blood test.

Reagents

Do not substitute reagents from other manufacturers, other product types, or from expired lots.

A. Seracult Plus Tape

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

Precautions:

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

Storage and Stability:

Seracult Plus 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 Plus Slides with Performance Controls:

Seracult Plus slides are made of a special absorbent paper impregnated with natural guaiac resin. Each slide has two sides: one for the application of the 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 contains a hemoglobin derivative, which is comparable to hemoglobin in its chemical reactivity. Seracult Plus slides are ready to use as packaged.

Precautions:

For in-vitro diagnostic use only. Do not use after the expiration date. Test is not valid if the performance control area 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. This does not affect the performance of the test.

C. Seracult Plus Developer

The developer is an aqueous solution of approximately 4% hydrogen peroxide and 84% ethanol with certain enhancing additives 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 Plus developer between 59° - 86° F (15° - 30° C). Do not refrigerate. 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 collection required is a small stool sample, which should be applied as a VERY THIN SMEAR on the tape or onto both windows of the Seracult Plus 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. Rectal suppositories or medications should be stopped before specimen collection. 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

Since Seracult Plus has a greater sensitivity, it is essential that the patient follow the red meat free, low peroxidase Special Diet for at least two days prior to, and during, the testing period to decrease the possibility of false positives.

