seracult®

PRODUCT DESCRIPTION & INSTRUCTIONS

A fecal occult blood test with performance control for in vitro diagnostic use

INTENDED USE

The Seracult test is a rapid and aesthetically acceptable method of detecting fecal occult blood. It is used as a qualitative aid in 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 in 3 variations: mounted in an individual cardboard slide, mounted in a triple cardboard slide for serial determinations and as a tape. 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 an 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 or as an aid to diagnosis. It is not a substitute for other diagnostic procedures such as endoscopy or proctosigmoidoscopy examinations, barium enema or other x-ray studies.

For patients at high risk for colorectal diseases, the use of the Seracult Plus fecal occult blood test, a more sensitive test, may be warranted.

All Seracult tests are CLIA Waived.

BASIC PRINCIPLES OF TEST

Alpha-guaiaconic acid, a component of natural guaiac-resin, 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.[7]

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.

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REAGENTS

A. SERACULT TAPE

Made of a special absorbent paper impregnated with natural guaiac resin, Seracult tape is ready for use as packaged. It is an economical method of testing, intended for use in office, clinic, and bedside examinations.

B. SERACULT SLIDES

Seracult slides are made of a special absorbent paper impregnated with natural guaiac resin mounted in an individual or triple cardboard slide. 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 slides are ready to use as packaged.

Seracult slides are available either as a single slide for testing one stool sample, or as a triple slide for testing stool samples from three consecutive bowel movements. Because gastrointestinal bleeding is intermittent, the testing of serial bowel movements increases the chances of detecting occult blood.[1]

Seracult slides may be prepared by the patient at home and then returned to the doctor for development. After applying the specimens, the slide can be returned either in person or by mail. For patients returning the slide by mail, the Seracult Mailing Kit should be used.

It includes a U.S. Postal Service approved envelope for convenient return of the prepared slide. Slides may not be mailed in regular envelopes: only the included approved envelope may be used. The Seracult Patient Kit is available to patients who will be returning the slide in person.

C. SERACULT DEVELOPER

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

In the event that the developer runs out before all slides are used, additional bottles of developer may be ordered separately. Any lot of Seracult developer may be used with any lot of Seracult slides, provided the expiration dates of both products have not lapsed.

Note: *Do not interchange Seracult agents with Seracult Plus agents. Seracult slides may only be developed with Seracult developer.*

PRECAUTIONS

Seracult slides and tape: For in-vitro diagnostic use only. Do not use product after the expiration date. For slides, test is not valid if the performance control area does not yield a blue color.

Seracult developer: For in-vitro diagnostic use only. Do not use after the expiration date. 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.

The Seracult developer is only to be used with Seracult slides. Do not replace any Seracult reagents with Seracult Plus test reagents.

STORAGE & STABILITY

Seracult slides, tape and developer are to be stored between 59° - 86° F (15° - 30° C) and are stable until the expiration date imprinted on each slide and bottle when stored as recommended. Do not refrigerate or freeze. Protect from heat, sunlight, fluorescent light and ultra-violet radiation. For tape and slides, a very faint blue or grey-green discoloration of the reactive paper may occur. This discoloration will not affect test performance. Storage of Seracult tape and slides under recommended conditions may help to prevent discoloration.

SPECIMEN COLLECTION

The specimen required is a small stool sample which should be applied as a 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 28 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.[1,2]

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PATIENT PREPARATION

If possible, the patient should be placed on a meat-free low-peroxidase diet to reduce the possibility of false positive results. 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. • Moderate amounts of high fiber foods such as bran cereal, peanuts and popcorn. • Plenty of fruits such as plums, grapes and apples. • Well cooked pork, poultry and fish.	• Rare and lightly cooked meats, particularly beef. • Cauliflower, horseradish, red radishes, turnips, broccoli and cantaloupe. • Vitamin C in excess of 250 mg. per day. • 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 results in healthy patients.[12] 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 and reserpine should, with the consent of a physician, be discontinued two days prior to and during the testing period.[5,18]

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

Dietary catalases and peroxidases derived from various meats and vegetables may contribute significantly to the incidence of false positive results.[13] 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 to four minutes; it is imperative that the developed slide or tape be read within the recommended time period.

PERFORMANCE CONTROL AREA

The performance control test allows the user to verify the reactivity of the paper and developer used in each Seracult slide test. Any blue color developed in the Performance Control Area acts as verification of correct product performance. (The shade or intensity of the blue color developed with the performance control test may not be indicative of the blue color that is obtained from a positive specimen test.)

The performance control test should only be performed after the patient specimen tests have been developed and interpreted to ensure the most objective interpretation of the patient specimen tests. If developer solution should accidentally cross over the barrier between the Performance Control Area and The Specimen Test Area, or if developer solution should inadvertently be applied to the Performance Control Area while the Specimen Test Area is being developed, the blue color developed in the Performance Control Area should not be considered positive indication for the presence of occult blood.

A lack of blue color in the Performance Control Area after proper development indicates that the slide test is not performing to product specifications. Specimen test results from a slide which fails the performance control test should be considered invalid and the test repeated.

LIMITATIONS OF PROCEDURE

The Seracult test is designed to detect the hemoglobin fraction of occult fecal blood in human stool specimens. Human fecal matter normally contains enough water and salts to induce hemolysis and release hemoglobin into the stool. This hemolysis and release of hemoglobin is an essential prerequisite to the proper performance of the Seracult test. Blood that is insufficiently hemolyzed, such as from hemorrhoids or a finger stick, may not yield a positive test result.

The Seracult test is intended for use as a diagnostic aid to the physician during routine physical examinations and for mass screening programs. It is specifically designed to determine the presence or absence of gastrointestinal

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bleeding. Results obtained with Seracult cannot be considered conclusive evidence for the presence or absence of any pathology. Seracult is intended only as an aid to diagnosis and not as a replacement for other diagnostic procedures.

PERFORMANCE CHARACTERISTICS

In vitro studies have shown that guaiac-impregnated slides and tape are able to detect 2 to 4 ml of blood per 100 g of feces – a loss of blood about twice the normal daily fecal loss in a human adult.[9]

The guaiac-impregnated paper test has been extensively studied.[3,4,11,14-17] In summary, these clinical studies show that the guaiac-impregnated slide test yields a positive rate of 3 to 5% in screening applications, while the false positive rate in patients receiving adequate preparation has been between 1 and 2%. Fecal occult blood screening tests with higher sensitivity levels than Seracult have exhibited higher false positive rates.

Seracult was designed to be a simple non-offensive version of the guaiac-impregnated paper test. The application of fecal specimens can be performed by patients or professional personnel, but development of the tests and interpretation should only be done by professional medical personnel.

Seracult's design makes it extremely valuable for use in mass colorectal cancer screening programs as well as routine physical examinations. Early diagnosis and prompt treatment can reduce deaths from colorectal cancer.

PROCEDURE

MATERIALS SUPPLIED

Professional Instruction Booklet; Seracult Single Slides (for single determinations) or Seracult Triple Slides (for serial determinations); Seracult Tape; Developer Solution; Specimen Applicators (supplied with slides);

Patient Instructions (supplied with Seracult Patient Kits and Mailing Kits); Flushable Collection Tissues and U.S. Postal Service Approved Mailing Envelopes (supplied with Seracult Mailing Kits).

The above materials are components of different kits. The materials included in a specific kit will vary depending on the particular kit ordered.

TEST INSTRUCTIONS FOR SERACULT SLIDES

A. Slide Identification
Identify each slide with the requested information.

B. Slide Preparation
(Patient or Professional Personnel)

1. Open front flap of slide.
2. Collect a small sample of stool on one end of the applicator stick. Apply a thin smear to one window. Wipe applicator clean.
3. From another part of the stool, collect another small sample using the same applicator as before and apply toother window.
4. Cover front flap of slide.

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C. Slide Development
(Professional Personnel Only)

1. Open perforated cover on back of slide.
2. Apply two drops of developer solution to each smear in the Specimen Test Area.
3. Read results within 30 to 60 seconds. ANY TRACE OF BLUE COLOR IS POSITIVE FOR OCCULT BLOOD. COLOR BEGINS TO FADE AFTER 2 TO 4 MINUTES.

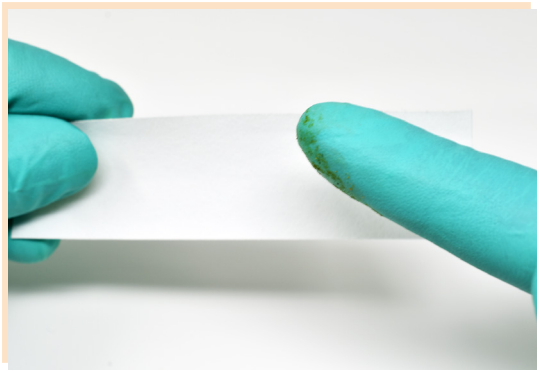
4. Develop the performance control area ONLY AFTER SPECIMEN TEST HAS BEEN COMPLETED AND INTERPRETED. Apply one drop of developer solution to the Performance Control Line. A blue color should appear within 30 seconds when the Seracult reagent test paper and developer are performing according to specifications.

SERACULT TAPE

A. Tape Preparation

1. Pull out the desired length of tape and tear strip from dispenser.

2. Use a gloved hand to apply a thin smear of stool to the tape.



B. Tape Development

1. Turn strip over to side not containing smear.
2. Apply 2 drops of developer solution to the tape.
3. Read results within 30 to 60 seconds. ANY TRACE OF BLUE COLOR IS POSITIVE FOR OCCULT BLOOD. COLOR BEGINS TO FADE AFTER 2 TO 4 MINUTES.

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READING & INTERPRETING THE SERACULT PLUS TEST

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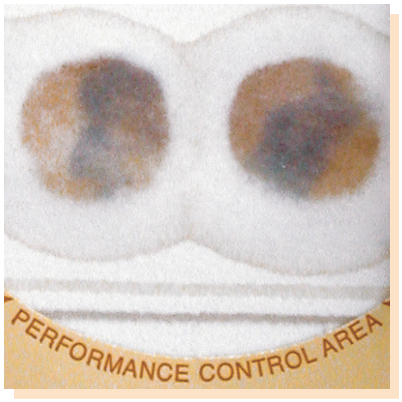
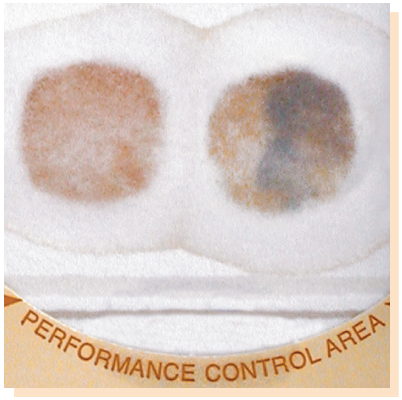


POSITIVE TEST RESULT

Development of smears in Specimen Test Area (or on tape) did yield a blue color and IS POSITIVE for the presence of occult blood.

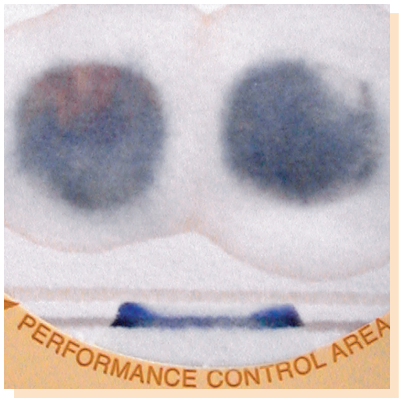


POSITIVE TEST RESULT

Presence of blue color even in only one smear IS POSITIVE for the presence of occult blood.

NEGATIVE TEST RESULT

Development of smears in Specimen Test Area (or on tape) did not yield a blue color. Absence of blue color after development IS NEGATIVE for the presence of occult blood.



PERFORMANCE CONTROL AREA

Development of blue color in the Performance Control Area confirms correct performance of both slide and developer reagents. The shade or intensity of blue color in Performance Control Area is not indicative of the blue color that may be obtained from a positive specimen.

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ORDERING INFORMATION

Seracult tests for fecal occult blood available as follows (please order by number):

Seracult Single Slides: Single slides of guaiac impregnated paper with performance controls. Box of 100 Seracult single slides with two 15 ml bottles of Seracult Developer and 100 applicators.
Reorder No. 37100100

Carton of 1,000 Seracult Single Slides: 10 boxes each with 100 slides, twenty 15 ml bottles of Seracult developer and 100 applicators.
Reorder No. 37100200

Seracult Triples: Three-unit of guaiac impregnated paper with performance control. Box of 102 slides (34 Seracult three-unit slides) with two 15 ml bottles of Seracult developer, and 102 applicators.
Reorder No. 37200400

Carton of 1,020 Slides: (10 boxes of 34 Seracult three-unit slides) with twenty 15 ml bottles of Seracult developer, and 1,020 applicators.
Reorder No. 37200500

Seracult Mailing Kits: 2 dispenser boxes, each with 40 kits and two 15 ml bottles of developer. Each kit contains one Seracult triple slide, collection tissues, applicators, U.S. Postal Service approved mailing envelope, U.S. Postal Service approved inner envelope and instructions for patient use.
Reorder No. 37200700

Seracult Patient Kits: 2 dispenser boxes, each with 50 kits and three 15 ml bottles of Seracult developer. Each kit contains one Seracult triple slide, applicators, envelope and instructions for patient use.
Reorder No. 37200300

Seracult Tape: Roll of guaiac impregnated paper tape dispenser. Box with two tape dispensers (each for 100 tests) and two 15 ml bottles of Seracult developer.
Reorder No. 37901000

Seracult Developer: Box of twenty 15 ml bottles of Seracult developer.
Reorder No. 37901500

Seracult Mailing Envelopes: Box of 100 envelopes (foil lined).
Reorder No. 37901600

Seracult Inner Envelopes: Boxes of 100 protective poly bags. Inner envelopes are intended for use either when returning the slide in person or as an inner envelope when mailing.
Reorder No. 37901700

Note: *Reorder numbers 37901600 & 37901700 combined meet all U.S. Postal regulations.*

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