Seracult® Plus Occult Blood – Stool

A. **PRINCIPLE:**
The Seracult® Plus test is a rapid method for 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.

B. **METHOD:**

\[
a\text{-guaiaconic acid} + 4\% \text{H}_2\text{O}_2 + 84\% \text{ETOH} \xrightarrow{\text{catalyst}} \text{guaiacum blue} \\
\text{Hgb}
\]

Guaiac-impregnated paper coated with a stool sample is developed with a solution consisting of 4% hydrogen peroxide and 84% ethanol giving a peroxidase-like reaction when hemoglobin from blood is detected in the stool sample turning the paper blue.

C. **REAGENTS AND MATERIALS:**


  **NOTE:** A very faint blue or grey-green discoloration of the reactive paper may occur. This discoloration will not affect test performance.

- **Seracult® Plus Developer** - Propper Mfg. Co., Inc. Aqueous solution of approximately 4% hydrogen peroxide and 84% ethanol with certain enhancing activities. The acceptable storage temperature is 15°-30°C. Flammable. Do not refrigerate or freeze. Protect from heat and light. Irritant; avoid contact with eyes and skin. Flush with water upon contact. Keep bottle tightly capped when not in use, as the developer evaporates readily. Stable until expiration date. Keep bottle tightly capped and protected from light.

  **NOTE:** Do not interchange Seracult® Plus reagents with Seracult® reagents. Seracult® Plus slides may only be developed using the Seracult® Plus developer.

D. **QUALITY CONTROL:**
A performance control area is incorporated onto each card (specimen development side) with a barrier between the performance test area and the specimen test area. A blue color verifies the reactivity of the paper and the developer. 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. It is developed after the patient sample has been developed and interpreted. A lack of blue color indicates that the slide test is not performing to product specifications. Patient test results from a slide which fails the performance control test should be considered invalid and the test must be rejected. If necessary, cancel the test and contact the provider.
E. SPECIMEN COLLECTION:

TYPE:
- Stool is applied as a thin smear onto both windows (patient application side) of the Seracult® Plus slide by the patient, nurse or provider.
- Stool container (grey cup) or urine collection cup (clear).
- Sample collected upon rectal exam.

This test is designed for routine physical examinations, 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 proctosigmoidoscope examinations, barium enema or other x-ray studies.

It is recommended that patients be placed on a meat-free low peroxidase diet two days before the testing period to reduce the possibility of false positive results. Special diet considerations include:

<table>
<thead>
<tr>
<th>Patient May Consume</th>
<th>Patient should not Consume</th>
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<tbody>
<tr>
<td>Cooked and uncooked vegetables (such as corn, lettuce, spinach)</td>
<td>Rare and lightly cooked meats, especially beef</td>
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<tr>
<td>High fiber foods (bran cereal, peanuts, popcorn)</td>
<td>Broccoli, cantaloupe, cauliflower, horseradish, red radishes, turnips</td>
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<tr>
<td>Fruits (plums, grapes, apples)</td>
<td>Vitamin C (&gt;250 mg/day)</td>
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<tr>
<td>Pork, poultry, fish (well cooked)</td>
<td>Iron rich supplements</td>
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<td>Medications, i.e. aspirin, indomethacin, phenylbutazone, corticosteroids, reserpine that may cause gastrointestinal irritation (consult physician)</td>
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<td>Excessive amounts of alcoholic drinks.</td>
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**Dietary catalases and peroxidases derived from various meats and vegetables may contribute significant positive results.**

Slides may be developed immediately after specimen application or may be stored and developed up to 21 days after specimen application. Once they have been prepared with a specimen, keep the slides away from heat and light.

F. PROCEDURE:

1) Label the Seracult® Plus card according to the Bassett Labeling Policy, using a patient label.

2) Open the front flap of slide card and apply a very thin smear of stool to the two windows of the cardboard slide.

3) For testing, open perforated cover on the back of the slide (testing) and apply two drops of developer to each smeared area in the Specimen Test Area.
Read results within 30-60 seconds. Any trace of blue color is Positive for occult blood. Color begins to fade after 2-4 minutes.

4) Once the specimen testing has been completed, develop the Performance Control Area by applying one drop to the Performance Control Line. The performance control yields a blue color in 30 seconds when paper and developer are performing according to product specifications. If the Performance Control Area does not work, the test is invalid and the specimen is rejected.

G. REPORTING RESULTS

- Any trace of blue color in the patient’s sample test area is considered a positive result. All traces of blue color are reported as POSITIVE. No blue color present is reported as NEGATIVE.
- Questionable results should be rejected and not reported. Notify the provider immediately and recollect the sample if possible.
- The occult blood test is ordered as POCT 13 (POCT Occult Blood Stool – Single Diagnostic).
- Results are reported in Unity after the test is ordered and released. Enter the required data through the Enter / Edit Results function under the Components tab. Complete all fields with a RED STOP SIGN.

See example below:
• Choose the Narrative tab and in the SmartText field enter POC. Select POC Stool Occult Blood Comment, enter.

See examples below:

• Accept filed data when completed.
H. SENSITIVITY
• Guaiac-impregnated slides are able to detect 2-4 ml of blood/100 g of feces (about twice the daily normal adult fecal loss).

• Seracult® Plus is a more 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 must also be recognized that the greater sensitivity of Seracult® Plus may yield false positive results in healthy patients. Such false positives may be due to the presence of interfering substances, inadequate compliance with the Special Diet or to the presence of low levels of occult blood in the feces that is common to healthy adults or to patients with gastrointestinal disease.

I. REFERENCE RANGE:
Negative.

J. REJECTION CRITERIA:
• Mislabeled or unlabeled samples.
• Seracult® Plus card not received within 21 days of collection.
• Seracult® Plus card is expired.
• Performance control area does not react positively.
• Specimen improperly placed on Seracult® Plus slide (i.e. sample applied to testing side).

K. INTERFERING SUBSTANCES:
• Ingestion of high doses of vitamin C (ascorbic acid, in excess of 250 mg/day) has been linked to false negative results. 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 higher than normal percentage of false positive results 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, and reserpine should, with the consent of a physician, be discontinued 7 days prior to and during the testing period.

• Dietary restrictions are recommended. Refer to chart under Specimen Collection.

L. LIMITATIONS OF PROCEDURE:
• The Seracult® Plus 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 test. Blood that is insufficiently hemolyzed, such as from hemorrhoids or a finger stick, may not yield a positive test result.
The Seracult® Plus test is specifically designed to determine the presence or absence of gastrointestinal bleeding. Results obtained with Seracult® Plus cannot be considered conclusive evidence for the presence or absence of any pathology. Seracult® Plus is intended only as an aid to diagnosis and not as a replacement for other diagnostic procedures.

The slide should not be rehydrated before applying the developer; this could result in false positives.

It must also be recognized that the greater sensitivity of Seracult® Plus may yield false positive results in healthy patients. Such false positives may be due to the presence of interfering substances, inadequate compliance with the Special Diet or to the presence of low levels of occult blood in the feces that is common to healthy adults or to patients with gastrointestinal disease.

M. REFERENCES: