Special Hematology/ 101 OCCULT BLOOD

Copy of version 1.0 (approved and current)

Last Approval or Periodic Review Completed	4/2/2024
Next Periodic Review Needed On or Before	4/2/2026
Effective Date	8/15/2021

Uncontrolled Copy printed on 4/22/2024 7:03 PM

Printed By Taneisha Wallace

Organization Howard University Hospital

Comments for version 1.0
Initial version

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Periodic review	Lab Director	4/2/2024	1.0	Ali Mousa Ramadan MD	
Periodic review	Medical Pathologist	3/22/2024	1.0	Lekidule Taddesse-Heath	
Approval	Lab Director	8/15/2021	1.0	Ali Mousa Ramadan	
Approval	Laboratory Operations Manager	8/13/2021	1.0	Wendell McMillan	
Approval	Quality Coordinator	8/1/2021	1.0	Lorraine Foster	Initial electronic version

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
1.0	Approved and Current	Initial version	7/22/2021	8/15/2021	Indefinite

HOWARD UNIVERSITY HOSPITAL
DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE

STANDARD OPERATING POLICY AND PROCEDURE MANUAL

Special Hematology/101 ColoScreen ES – Occult Blood

PURPOSE

ColoScreen-ES (Extra Sensitive) is a guaiac slide test for the qualitative detection of fecal occult blood. It is a useful aid in the diagnosis of a number of gastro- intestinal disorders and is recommended for use in:

- Routine physical examinations
- Routine hospital testing
- Mass screening for colorectal cancer

ColoScreen-ES is a simple, aesthetic, inexpensive test designed for collection and preparation of stool specimens.

ColoScreen-ES is an improvement over the traditional gum guaiac methods. It overcomes the instability of guaiac solution and the hypersensitivity of benzidine and ortho-tolidine. It offers increased sensitivity for the detection of blood in the stool. The increased sensitivity can be noted in the improved readability of the test because the color development is more intense and stable.

As with any occult blood test, results withColoScreen cannot be considered conclusive evidence of the presence or absence of gastrointestinal bleeding or pathology. The test is not intended as a replacement for other diagnostic procedures such as proctosigmoidoscopy examination, barium enema, and X-ray studies.

PRINCIPLE

ColoScreen-ES is composed of guaiac impregnated paper enclosed in a cardboard frame which permits sample application to one side, and development and interpretation on the reverse side. The process involves placing two specimens onto the guaiac paper which have been collected from each of three successive evacuations.

ColoScreen-ES, like all guaiac paper tests for occult blood, is based on the oxidation of phenolic compounds present in the guaiac (i.e. guaiaconic acids) to quinones resulting in production of the

blue color. Because of its similarity to the prosthetic group of peroxidase, the hematin portion of the hemoglobin molecule can functionin a pseudoenzymatic manner, catalyzing the oxidationof guaiac.

When a fecal specimen containing occult blood is applied to the test paper, contact is made between hemoglobin and the guaiac. A pseudoperoxidase reaction will occur upon the addition of the developer solution, with a blue chromagen formed proportionally to the concentration of hemoglobins. The color reaction willoccur after thirty seconds.

Hemoglobin + Developer

$Hb + 2H_2O_2 \longrightarrow 2H_2O + O_2$

Oxidation of Guaiac

O_2 + Guaiac $\longrightarrow$ Oxidized Guaiac

(Colorless) (Blue)

The ColoScreen-ES kits include ColoCheck Monitors which provide a quality control system for each test.The ColoCheck Monitors are incorporated into each slide.

REAGENTS

1. **ColoScreen-ES Slides and Monitors**

Reactive Ingredients: ColoScreen-ES Slides are made of quality controlled paper impregnated with guaiac resin. ColoCheck Positive Monitor contains animpregnated substance which will turn blue if product is functioning properly. The ColoCheck Negative Monitor consists of guaiac impregnated paper.

WARNING: FOR IN-VITRO DIAGNOSTIC USE.

Preparation for Use: The slide is ready for use as packaged.

Storage and stability:

- These products should be stored at room temperature (15 to 30°C) and are stable until the expiration date indicated on each slide.

- Do not use after expiration date.
- Both items should be protected from heat, humidity, light, fluorescent light, U.V. radiation, excessive air flow, or volatile chemicals (e.g. iodine or bleach).
- Do not refrigerate or freeze.

Signs of Deterioration:

- Discoloration of the normallylight tan paper may occur if exposed to sunlight, fluorescent or ultraviolet light.
- Failure of the control system to react as expected may be indicative ofdeterioration of the developer or the slide, and test results should be regarded as invalid.

2. ColoScreen-ES Developer

Reactive Ingredients: ColoScreen-ES Developer contains < 6% hydrogen peroxide in propanol.

WARNING:

- FOR IN-VITRO DIAGNOSTIC USE.
- DANGER: FLAMMABLE. NEVER PIPETTE BY MOUTH. VAPOR HARMFUL.
- DO NOT INGEST OR PLACE IN EYES**.** May cause blindness, or be fatal if swallowed.
- Keep away from heat, sparks, or an open flame.
- Avoid contact with eyes and skin. Should contact occur, flush the affected area with water and get immediate medical attention.

Preparation for Use: ColoScreen-ES Developer is ready for use as packaged.

Storage and Stability:

- ColoScreen-ES Developer should be stored tightly capped at 15 to 30°C protected from heat and light. Under these conditions, the developer will remain stable until the

expiration date indicated on the bottle.

- Do not use after the expiration date.
- Do not substitute reagents from othermanufacturers.

Signs of Deterioration:

- Failure of the ColoCheck Monitors to react as expected may be indicative of deterioration of the developer or the slide, and thetest results should be regarded as invalid.

SPECIMEN COLLECTION AND HANDLING

Patient Preparation:

A. It is recommended that the patient be placed on a high residue diet starting 2 days before andcontinuing through the test period.

DIET MAY INCLUDE:

- Meats: Only small amounts of well-cooked chicken, turkey and tuna.
- Vegetables: Generous amounts of both raw and cooked vegetables including lettuce, corn, spinach, carrots and celery. Avoid raw vegetables with high peroxidase activity such as those listed under "To Be Avoided"
- Fruits: Plenty of fruits, especially prunes and apples.
- Cereals: Bran and bran-containing cereals.
- Moderate amounts of peanuts and popcorn daily.If any of the above foods are known to cause discomfort, the patient is instructed to consult his/her physician.

TO BE AVOIDED:

- Meat: Diet should not include any red or rare or red meat.
- Raw fruits and vegetables containing highperoxidase activity:

Turnip	Cauliflower	Red radishes
Broccoli	Cantaloupe	
Horseradish	Parsnip	

B. Alternately, the special diet may be omitted initially with dietary restrictions imposed upon the retesting of all positive results. However, because gastrointestinal lesions may bleed intermittently and blood in feces is not distributed uniformly, all patients with positive tests regardless of diet, should have follow-up diagnostic procedures done.

C. Other factors which affect the test:

1. Medications: For 7 days prior to and during the testing, do not ingest aspirin or other anti- inflammatory medicines. For 2 days prior to and during testing, do not use rectal medicines, tonics, or vitamin preparations which contain Vitamin C (ascorbic acid) in excess of 250 mg per day.
2. Bleeding hemorrhoids or open cuts on hands.
3. Collection of specimen during menstrual cycle.
4. Improper specimen collection
5. Other diseases of the gastrointestinal tract such as colitis, gastritis, diverticulitis and bleeding ulcers.

Specimen Handling:

- Using the applicators provided, obtain a small sample of the stool from the toilet bowl. It is very important that the stool specimen be applied as a**very thin smear** to the ColoScreen-ES Slides.
- Obtain a second sample of the stool, from a different location, in the same manner. Apply a **very thin smear** to the slide. Allow the smears to air dry. The slide smears may be prepared and developed immediately or stored up to 12 days prior to development. Care should be taken so that anything coming into contact with the specimen is free of blood.
- Because of the nonhomogeneity of the stool, it is recommended that the test be performed

on three (3) consecutive evacuations, or ones as close together as possible.

- Patient specimens and all materials in contact with them should be handled as potentially infectious and shouldbe disposed of using proper precautions.
- Return the completed slide to your physician or laboratory as instructed. If the slide is returned by mail, use the foil-back envelope provided. DO NOT use a standard paper envelope, as they are not approved by U.S. Postal Regulations.

Interfering Substances:

- Ingestion of ascorbic acid (Vitamin C) in high doses has been shown to cause false negative results, and intake should be discontinued 2 days prior to, and during, the test period.
- Peroxidase from fruit and vegetables can cause false positive results.
- Elimination of red meat from the diet during the test period eliminates the source of hemoglobin which can cause false positive results.
- Oral medications (such as aspirin, indomethacin, reserpine, phenalbutazone, corticosteroids, etc.)
- Heavy alcohol consumption may cause irritation or bleeding of the gastrointestinal tract and should be discontinued for 7 days prior to and during the test period

PROCEDURE

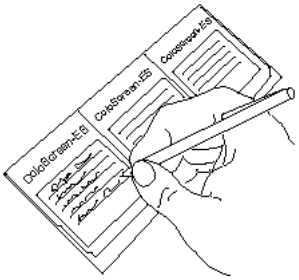
Materials Provided:

- ColoScreen-ES Slides with MonitorsColoScreen-ES Developer Specimen Applicators

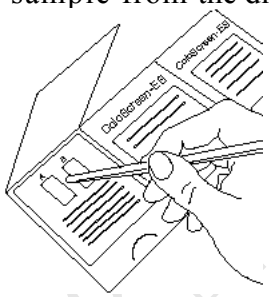
METHOD

ColoScreen Slide:

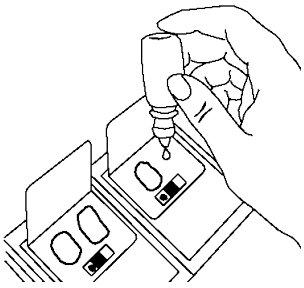
1. Supply all information listed on the front flap of the ColoScreen-ES Slide.
2. Open the front flap.



3. If provided, unfold oneof the collection tissues. Float it on the surface of the water so that the edges stick to the sides of the toilet bowl. The stool should fall onto the tissue. If the packet does not contain tissues, the stool should fall into the water.
4. Using the applicator sticks provided, collect a small sample from the different areas of the stool. Apply a **very thinsmear** in Box A.



5. Reuse applicator to obtain a second sample from a different part of the stool specimen. Apply a **very thin smear** inside Box B. (On subsequent bowel movements, repeat above steps on additional slides.) Flush tissue with stool, and discard stick in waste container.
6. Allow the specimen to air dry, then close the cover.
7. To develop, open perforated window on the backof the slide.
8. Apply two (2) drops ofC o l o S c r e e n - E SDeveloper to the backside of boxes A and B.



9. Read results after 30 seconds and within 2 minutes.
10. Record the results;

- Any trace of blue color, within or on the outer rim ofthe specimen, is positive for occult blood.

Stability of End Product: The color reaction is not permanent. Fading may occur after approximately 2 minutes.

QUALITY CONTROL

- ColoCheck Monitors are provided on each ColoScreen- ES Slide. This specially treated area provides assurance that the guaiac-impregnated paper and the ColoScreen- ES Developer are reacting according to product specifications.
- Positive ColoCheck Monitor is an impregnated substance in a base carrier and will turn blue within 30 seconds after application of ColoScreen-ES Developer if the test system is reacting according to product specifications.
- Negative ColoCheck Monitor consists of guaiac impregnated paper and will not turn blue upon addition of ColoScreen-ES Developer.

INTERPRETATION OF RESULTS

Any trace of blue color within the specimen application area is a positive for occult blood, if ColoCheck Monitors react properly. Remember always to develop the test, interpret, and record results before developing the ColoCheck Monitors

LIMITATIONS

- Results obtained with ColoScreen-ES cannot be considered conclusive evidence of the presence or absence of gastrointestinal bleeding or pathology.
- False negative results may be obtained, since most bleeding occurs intermittently.
- ColoScreen-ES tests are designedas a preliminary screen and are not intended to replace other diagnostic procedures such as proctosigmoidoscopy, barium enema or X-ray studies.
- ColoScreen-ES will detect only hemoglobin released upon hemolysis of the red blood cell. Should whole blood be applied to the test paper, it is necessary to hemolyze the red cells by the addition of a drop of water to the sample before adding the developer.

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Enter result in the computer

Operation on Novius LIS system

1. After signing on, activate TESTS by clicking once
2. Activate WORKLIST
3. Under WORKLIST ID box enter test profile

   UA STOOLS

   Additional worklist can be activated be entering the first letter of the profile and a list of all the profiles under this letter will be displayed. Use the up/down arrow to find activate profile
4. Once the profile is selected, activate ADD box to enter the profile in the WORKING BOX
5. Activate the SEARCH button all pending result for the activate profile will be activated in numerical order
6. Enter the number in the listed order
7. Activate the ENTER INDIVIDUAL REULTS button, and enter the results
8. Select COM/SAVE box to file the results
9. To activate the listing of all pending tests in a profile click on WORKLIST, then enter the code of the profile in the WORKLIST ID box, and then click on the ADD enter into the menu
10. From the sample ID VIEW box use the arrow to scroll and click on ordered test id view, then click on SEARCH. A listing of all tests in this profile be shown

References

- Helena Laboratories product insert. Cat. No. 5086
- Henry, J.B., et al: Clinical Diagnostics and Management by Laboratory Methods, 17th ed., Saunders, 1984.

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Replaces Core lab/Urinalysis/415/2006/2. Approval and revision of documentation maintained electronically