

Director Approval _____ Date _____

UCSF Medical Center Clinical Laboratories	Point of Care Testing
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ColoScreen© Guiac Slide Test

PURPOSE

ColoScreen is a guaiac slide test for the qualitative detection of fecal occult blood. It is a useful aid in the screening of a number of gastrointestinal disorders.

SCOPE

The presence of occult blood in fecal material may indicate gastrointestinal disorders such as hemorrhoids, diverticulitis, fissures, colitis, or colorectal cancer. ColoScreen is a simple and useful screening tool in both inpatient and ambulatory settings. It can be used for samples obtained from adults and children. It is recommended for use as a point of care test in:

- Routine physical examinations
- Routine hospital testing

PERSONNEL

Intended for use by clinical personnel who have demonstrated competency in this procedure. Staff who have difficulties with color discrimination must demonstrate their ability to interpret the test.

PRINCIPLE

ColoScreen is composed of guaiac impregnated paper enclosed in a cardboard frame which permits sample application on one side, and development and interpretation on the reverse side. When a fecal specimen containing occult blood is applied to the test paper, contact is made between hemoglobin and guaiac. A chemical reaction will occur upon addition of the developer solution, forming a blue discoloration after 30 seconds.

REAGENTS, EQUIPMENT, AND MATERIALS

- Gloves
- ColoScreen Slide
- ColoScreen Developing Reagent
- Applicator

The ColoScreen slides and developing reagents should be stored at room temperature (15 to 30° C). Do not refrigerate or freeze. Developer should be tightly capped. The products are stable until the expiration date and should not be used after the expiration date. Avoid exposure to heat, humidity, light, florescent light, radiation, and volatile chemicals, such as iodine and bleach.

SPECIMEN REQUIREMENTS

Preparation for Testing

For those patients using ColoScreen slides in the home setting, it is recommended that patients be placed on a high residue diet two days prior to and continuing through test collection. Alcohol, Vitamin C, and certain medications should be avoided prior to and during the testing period. Refer to the ColoScreen Patient Instruction Sheet in the Appendix.

Volume

The test is performed on a thin smear of stool obtained during a digital exam or from a stool sample.

Specimen Handling

As part of our Bloodborne Pathogen Exposure Control Plan, standard precautions must be followed when handling specimens. Gloves should be worn while obtaining and testing the specimen. Gloves must not be contaminated with urine, vaginal discharge, or other body fluids that may contain blood.

Stability of sample

Once the stool sample has been placed on the Coloscreen slide it is stable at room temperature for 12 days. Slides which are greater than 12 days old should not be tested.

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. Ingestion of red meat during the test period can cause false positives. Oral medications (such as aspirin, indomethacin, reserpine, phenalbutazone, corticosteroids, etc.) and 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

- 1) Using two patient identifiers, verify patient identification, and explain procedure to patient and/or family.
- 2) Check expiration dates of developer and slide
- 3) If testing is NOT performed immediately by person collecting the sample, then label coloscreen test slide with two forms of patient identification.
- 4) Don gloves; wear a mask and protective eyewear whenever the potential for a splash exposure exists.
- 5) To perform test, open front flap.
- 6) Using the gloved finger or applicator, apply a very thin smear of stool specimen to Box A and Box B from two different sites of the stool specimen.
- 7) Allow the specimen to air dry, then close the front flap.
- 8) Open the perforated window on the back of the slide.
- 9) Apply two drops of ColoScreen developer to the back of Boxes A and B.
- 10) Read results after 30 seconds and within 2 minutes.
- 11) Read results: any trace of blue color within or on the outer rim of the specimen is positive for occult blood.
- 12) Perform testing of quality control monitors.

QUALITY CONTROL

Note: The procedure for developing the sample test must be completed, and interpreted and results noted before proceeding with the development of ColoCheck monitors.

- 1) Place 1 or 2 drops of ColoScreen Developer between the Positive and Negative Monitor boxes on the reverse side of the slide.
- 2) Read the results after 30 seconds and within 2 minutes.
- 3) Positive ColoCheck Monitor should turn blue, but the Negative ColoCheck Monitor should not have any trace of blue.
- 4) If the Quality Control fails, do not report patient results. Discard the slide and developer and record this on the Point of Care Test QC Log.
- 5) Repeat the test on a new slide if there is still stool available for testing

When a new box of test cards is opened

- 1) Select one card from the box
- 2) Place 1 or 2 drops of Coloscreen Developer between the Positive and Negative Monitor boxes on the reverse side of the slide
- 3) Positive ColoCheck Monitor should turn blue, but the Negative ColoCheck Monitor should not have any trace of blue.
- 4) Record the QC results on the Point of Care Testing QC log sheet

5) Date the box and write "QC performed"

RESULTS AND REPORTING

After verifying the QC monitor results, record the patient test results on the ColoScreen Patient Results Log and/or in the patient's medical record. Any positive result must be reported to the patient's provider as soon as possible. Reporting of results indicates QC monitors reacted as expected and results are valid.

Test Areas	Positive Monitor	Negative Monitor	Result Reported
Blue	Blue	No Color	Positive result
No Color	Blue	No Color	Negative result
Any Color	No Color	No Color	Do not report
Any Color	Blue	Blue	Do not report

LIMITATIONS

Results obtained with ColoScreen 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 tests are designed as a preliminary screen and are not intended to replace other diagnostic procedures such as proctosigmoidoscopy, barium enema or X-ray studies. ColoScreen will detect only hemoglobin released upon hemolysis of the red cell.

REFERENCES

Product insert, ColoScreen 8/03 (11)
Helena Laboratories
Beaumont, Texas
800 231-5663

APPENDIX

(see attached patient instruction sheet for collecting specimens at home)

Patient Instructions for Using ColoScreen Slides

Do not collect specimen during a menstrual period or when suffering from bleeding hemorrhoids or open cuts on hands.

Protect the slides from heat, sunlight, ultraviolet light, and florescent light.

For two days prior to, and including the days when you are collecting specimens, a special diet must be followed:

The diet may include:

- Meats: Only small amounts of well-cooked chicken, turkey, and tuna. No red or rare meat.
- Vegetables: Generous amounts of both cooked and uncooked vegetables including lettuce, corn, spinach, carrots and celery. Avoid raw vegetables listed below under "To Be Avoided."
- Fruits: Plenty of fruits, especially prunes, grapes, plums, and apples.
- Cereals: Bran and bran-containing cereals.
- Other high fiber foods: moderate amounts of peanuts and popcorn.

If eating any of the above foods tends to cause you discomfort, please let your provider know.

Foods to Be Avoided:

- Meat: Diet should not include any red or rare meat.
- Horseradish
- Some fruit: canteloupe
- Some vegetables: raw turnips, cauliflower, broccoli, red radishes, parsnip.

Medications to Avoid:

For 7 days prior to and during the testing, do not take high doses of Vitamin C (more than 250 mg per day), aspirin or other anti-inflammatory medicines, such as ibuprofen or naproxen. For 2 days prior to and during testing, do not use rectal medicines, enemas, or tonics.

Identification / Labels:

The cards provided to you should already be labeled with your name, UCSF medical record number, and the name of your health care provider. If the cards are not labeled, please print the information requested on the front flap of each slide.

Sample Collection:

Using the applicator sticks provided, obtain a small sample of the stool from the toilet bowl. Use the applicator tip to apply a **very thin smear** to Box A of the slide. Reuse the applicator to obtain a second sample, from a different area of the stool. Apply a **very thin smear** to Box B of the slide.

Reseal the Slide:

Allow the smear to dry before resealing it or placing it in the envelope. As each slide is used, close the front flap by sliding tab beneath the tab holder. Print the date you collected the sample on the front flap of the slide.

Repeat the Steps:

On the next two subsequent bowel movements, repeat the above steps until all three slides have been used. Once you have collected all 3 samples, you may resume your regular diet and medications.

Mail the Slides:

Be sure that the slides have been labeled or that you have written your name, UCSF medical record number and the date each sample was collected on the front flap. When the three slides have been used, place them in the foil-lined envelope provided. **Be sure to include the laboratory requisition that you were given in the envelope.** Do not use standard paper envelopes. Immediately mail the envelope to:

UCSF Clinical Laboratories,
505 Parnassus Ave, Box M-521,
San Francisco, CA 94143

Samples must be received by the laboratory within **12 DAYS** of being collected. Samples over 12 days old when received will **NOT** be tested.