

## FECAL OCCULT BLOOD TESTS ENHANCED READABILITY

For use with McKesson Consult® FOBT MFR #'s 127-50ER, 127-100ER, 127-8DVER.

CLIA Category: Waived

### INTENDED USE

McKesson Consult® Fecal Occult Blood Test is a rapid, convenient, and non-offensive qualitative method for detecting occult blood in the stool. It is intended for professional use as an aid in the diagnosis of asymptomatic gastrointestinal conditions that may manifest themselves by the presence of occult blood in the stool. This test is recommended for use in routine hospital testing, mass screening programs for colorectal cancer, and in testing of postoperative patients and newborn infants.

### SUMMARY AND EXPLANATION

Clinical experience has shown that after proper dietary preparations, occult blood testing in the stool has provided both patients and physicians with a new parameter of detecting asymptomatic gastrointestinal conditions, such as colorectal cancer, ulcers, polyps, anemia, and diverticulosis. Cancer of the colon and rectum strikes over 123,000 men and women in the United States each year. It is second only to skin cancer as a killer. If the disease is localized, the number of patients who survive for five years approaches 70%. In localized asymptomatic disease 90% of patients survive five years. The American Cancer Society estimates that early diagnosis and prompt treatment could save two-thirds of 53,000 Americans who die annually of the disease<sup>2</sup>. "If guaiac screening, plus digital rectal examination and sigmoidoscopy were included in all annual physical examinations many more cases of colorectal cancer could be detected in a stage amenable to cure", Greigor<sup>3</sup>.

Van Deen<sup>1</sup> is generally credited with the discovery that gum guaiac, a natural resin extracted from the wood *Guaiacum Officinale*, is the method of choice for detecting occult blood in feces<sup>2</sup>. The basis of the test is that hemoglobin exerts a peroxidase like activity and causes the oxidation of a phenolic compound (alpha guaiaconic acid) by hydrogen peroxide to a quinone structure<sup>3</sup>. Since the structure of hematin is similar to peroxidase, it is probably this fraction of the hemoglobin which catalyzes the oxidation of guaiac. McKesson Consult Fecal Occult Blood Test slides feature special electrophoresis filter paper impregnated with guaiac. Since the guaiac is not in solution, it will remain stable indefinitely. Comparing the reactions obtained with guaiac paper slides and other chemical methods such as benzidine and orthotolidine<sup>9</sup>, for detecting fecal blood, the guaiac slide method was found to be about one-quarter as sensitive as the chemical tests, but overcomes both the instability of guaiac solutions and the hypersensitivity of benzidine and orthotolidine.

McKesson Consult Fecal Occult Blood Test in its original concept as slides and tape was designed to offer the hospital, mass screening programs and clinical laboratories a convenient rapid method for handling fecal specimens in testing for occult blood. McKesson Consult Fecal Occult Blood Test is especially useful for mass screening programs as it's enhanced readability feature facilitates the technicians' ability to make a determination.

McKesson Consult Fecal Occult Blood Test eliminates the mess and odors associated with the collection and transport of fecal specimens. Slides can be prepared at the patient's bedside and placed in a sealed envelope or by the patient at home and mailed to the hospital or laboratory in an inoffensive manner for development and evaluation.

McKesson Consult Fecal Occult Blood Test single slides are convenient for use when single stool specimens are to be tested. A single test is indicated when blood loss in the gastrointestinal tract is strongly suspected, for example; in persons with symptoms of ulcers, anemia, black stools or postoperative patients.

McKesson Consult Fecal Occult Blood Test Patient Packs are to be utilized so the patient can serially collect specimens at home over the course of three bowel movements. Patients should be instructed to follow the directions exactly, as the potential for false positive results exists due to improper diet, blood on the hands, hemorrhoids or if the test is used during menstrual bleeding. After all three slides are prepared, the slides may be sent back to the hospital laboratory for developing and evaluation. Preparation of three consecutive slides is recommended for screening asymptomatic patients by the American Cancer Society.

### PRINCIPLES OF THE TEST

When stool specimens containing occult blood are applied to McKesson Consult Fecal Occult Blood Test test paper, the hemoglobin portion of the occult blood comes in contact with the guaiac. When the McKesson Consult Fecal Occult Blood Test peroxide developing solution is added, a guaiac-peroxidase like reaction

occurs. The chemical reaction becomes visible by the appearance of a blue-green color between thirty (30) seconds and sixty (60) seconds if occult blood is present.

### MATERIALS PROVIDED

- McKesson Consult Fecal Occult Blood Test Slides – A special electrophoresis paper impregnated with natural guaiac resin. Contains both positive (+) and negative (-) performance standards. The positive (+) standard contains a hemoglobin derived catalyst on the slide.
- McKesson Consult Fecal Occult Blood Test Developing Solution (enhanced) - Contains a stabilized mixture of hydrogen peroxide (less than 6%) and 75% denatured ethyl alcohol with enhancing additives in aqueous solution.
- McKesson Consult Fecal Occult Blood Test Laboratory Pack – Instructions for use, one hundred (100) single slides with performance standards, two (2) 10 ml bottles of developing solution, and one hundred (100) applicator sticks.
- McKesson Consult Fecal Occult Blood Test Patient Pack – Instructions for use, fifty (50) patient slides with performance standards, three (3) 10 ml bottles of developing solution, one hundred fifty (150) applicator sticks, patient instructions, and fifty (50) foil-lined mailing pouches. See TEST INSTRUCTIONS.

### MATERIALS NEEDED BUT NOT PROVIDED

Clock or timer.

### STORAGE CONDITIONS

McKesson Consult Fecal Occult Blood Test Test Slides - Store at room temperature 59°-86°F (15°-30°C). Do not refrigerate or freeze. Protect from heat, humidity, and light. Do not store with volatile chemicals, e.g. iodine, chlorine (bleach), bromine or ammonia. When stored as recommended, slides will maintain sensitivity until kit expiration. The guaiac slides are beige in color. However, if not stored as recommended, they may discolor and turn blue. See "e" under Test Instructions. Do not use after expiration date.

McKesson Consult Fecal Occult Blood Test Developing Solution - Store at room temperature 59°-86°F (15°-30°C). Do not refrigerate or freeze. Protect from heat, humidity and light. When stored as recommended, solution will remain stable until kit expiration. Keep tightly capped when not in use.

PRECAUTION: Developing solution is flammable. Wash immediately with water if skin or eyes are contacted. Do not ingest. Do not use after expiration date.

For *in vitro* diagnostic use. Do not substitute reagents from kits from other manufacturers. You may interchange slides & reagent from McKesson Consult Fecal Occult Blood Test kits as long as they are within the expiration date. Patient specimens and all materials coming into contact with them should be handled as if capable of transmitting infections and disposed of with proper precautions.

### SPECIMEN COLLECTION AND PREPARATION

Prior to defecation, the toilet should be flushed. Using one end of the applicator stick collect a small stool sample from the toilet bowl by stabbing the stool and applying a thin smear to the center of the McKesson Consult Fecal Occult Blood Test slide. The tests may be prepared and developed immediately, or prepared and stored at room temperature, protected from heat and light for up to twenty-one (21) days before developing. Keep testing area, hands, etc. clean and free from blood to avoid false positive results.

It is recommended for screening of asymptomatic persons that stool smears for testing be collected from at least three consecutive bowel movements (i.e. McKesson Consult Fecal Occult Blood Test Patient Packs) since bleeding from gastrointestinal lesions may be intermittent. Greigor<sup>3,7</sup> recommends two samples per stool, with each test site (I,II) prepared from a different part of each day's stool to increase the probability of detecting occult blood in each stool.

### INTERFERING SUBSTANCES

There are some oral medications such as aspirin, corticosteroids, reserpine phenylbutazone, indomethacin, etc. that can cause gastrointestinal irritation and occult bleeding in some patients. Ascorbic acid (Vitamin C) taken in units greater than 250 mg per day may cause false negative results. Iron or preparations containing Iron may cause false positive results<sup>15</sup>. Two (2) days prior to and during the test period such medications should be avoided.

Patients with bleeding from other conditions such as hemorrhoids, dental work, constipation or menstrual bleeding should not be tested while such conditions are present. Do not collect a specimen if patient is using rectal preparations. The patient's physician should be consulted when discontinuing prescription medications.

### PATIENT PREPARATION

A red-meat-free, high residue diet is recommended, starting two days before testing and continuing through the test period. Raw fruits and vegetables which contain peroxidase-like substances (turnips, broccoli, horseradish, cauliflower, cantaloupe, parsnips, red radish etc.) should be avoided during the test period<sup>14</sup>.

### SUGGESTED DIET DURING TEST PERIOD

Vegetables. . . . .	Raw and cooked, especially lettuce, spinach and corn
Fruits. . . . .	Prunes, grapes, bran cereals, apples and plums
Peanuts . . . . .	Moderate amounts
Popcorn. . . . .	Moderate amounts

Well-Cooked Chicken. . . . . Moderate amounts  
Canned Tuna. . . . . Moderate amounts

A diet such as this helps reduce the number of false positive test results and at the same time provides roughage to help uncover silent lesions which may bleed only intermittently. If any of the above foods are known to cause patient discomfort, patient should be instructed not to eat them or to make appropriate substitutions.

In an initial three (3) test series, the patient may disregard the recommended diet. If patient has one or more positive tests, then he or she should be placed on the above suggested diet and retested for another three (3) test series. However, it should be remembered that bleeding may be intermittent and no positive test result should be disregarded.

#### TEST INSTRUCTIONS

McKesson Consult Fecal Occult Blood Test Slides:

- a. **Slide Identification:** (to be performed by the patient) Identify each slide with patient's name, phone number, address and date.
- b. **Slide Preparation:** (to be performed by the patient)
  1. With applicator, apply a thin smear of stool inside Area indicated with Roman numeral I. Using the same applicator repeat from a different portion of the stool for Area II. Discard the applicator in the trash after use.
  2. Repeat the procedure for a total of three bowel movements.
  3. Bring or send slides to a doctor immediately after preparing last test.
- c. **Slide Development:** (to be performed by the laboratory)
  1. On back of slide, open perforated section, marked 1 and 2.
  2. Apply two (2) or more drops of McKesson Consult Fecal Occult Blood Test Developing Solution to exposed test paper.
  3. Read results between thirty (30) seconds and sixty (60) seconds.
    - a) Any trace of blue is positive for occult blood.
    - b) No indication of blue is negative.
- d. **Performance Standards Development:** Performance standards on the slides allow for testing the function and stability of the slides and developer. A positive (+) performance standard and a negative (-) performance standard are located under the perforated flap on the back of the slide. It is important that the Performance Standards be developed after specimens to avoid interference or prejudice of test interpretation.
  1. Add one (1) drop of developer directly onto control area (between positive (+) and negative (-) performance standards.)
  2. Read results within thirty (30) seconds. The positive standard contains a hemoglobin derived catalyst. After addition of the developer, a blue color should appear within thirty (30) seconds. The negative standard should not show a blue color. If the standards do not react as expected, the test results should be regarded as invalid. Contact McKesson Medical-Surgical Inc. for assistance.
- e. A light blue discoloration may be noticed on the guaiac test paper, which does not affect the accuracy or test performance when interpreted according to the recommended procedure. When developer is added directly over the fecal smear on a discolored slide, the blue color migrates outward and forms a blue ring at the edge of the wetted area, this blue ring would be considered a negative result. The guaiac paper around the fecal smear will remain off white in color. Any blue on the edge of or within the fecal smear would be considered a positive result. Proper storage will prevent discoloration.

#### SPECIAL FINDINGS

Rarely, the fecal sample may appear greenish in color even before the developer is added or a green coloration may be observed after the addition of the developer. Sometimes this greenish color is "washed out" by the developer and moves to the periphery of the test area, such observations should be considered negative results. In contrast, when the greenish color does not wash out to the periphery, and remains fixed to its location, such findings should be considered positive results. Green colors are likely to be due to the presence of bile. Bile alone would not remain fixed in the fecal sample and the developer would wash the color out to the periphery of the test area. However, the fecal sample may contain occult blood in addition to bile. In such cases, the green color that may develop will not wash out of its location on the fecal sample.

#### EXPECTED VALUES

It is important that the McKesson Consult Fecal Occult Blood Test slides be read between thirty (30) and sixty (60) seconds after McKesson Consult Fecal Occult Blood Test developing solution has been applied. The color reaction will tend to fade after two to four minutes. Neither the intensity nor the shade of blue as seen in the positive performance standard should be regarded as an indication of what the blue from a positive fecal specimen should look like. **ANY TRACE OF BLUE WITHIN THE THIRTY (30) TO SIXTY (60) SECOND TIME INTERVAL, IS A POSITIVE TEST RESULT.** Any positive result should be followed up by further diagnostic procedures to determine the source of the occult bleeding.

#### LIMITATION OF THE PROCEDURE

Results obtained with McKesson Consult Fecal Occult Blood Test are designed for preliminary screening only and are not intended to replace diagnostic procedures such as barium enema, colonoscopy, proctosigmoidoscopy examination or other X-ray studies. The test should not be considered as conclusive evidence for the presence or absence of gastrointestinal bleeding or pathology. Individuals suffering from color blindness should not interpret this test. Gastrointestinal cancers and adenomas do not always bleed.

#### SPECIFIC PERFORMANCE CHARACTERISTICS

Independent studies have shown that McKesson Consult Fecal Occult Blood Test slides are capable of detecting 0.6 mg Hb/gm of feces<sup>10</sup>. Greigor<sup>3,7,12,13</sup> pioneered the use of guaiac paper slides like those supplied by McKesson Consult for the detection of colorectal cancer in office-practice patients. Screening nine hundred (900) patients, his reports show a positive rate of 5% (utilizing barium enema examination), 1% were shown to have asymptomatic colon cancer, 3% had some other type of bowel pathology, and 1% were false positive results. Other studies from two thousand (2000) physicians who had used the guaiac paper slides in their practices over a six month period, detected colon cancer in forty-seven (47) patients in which there were no signs other than the positive guaiac slide test. In these data which were collected by Greigor, there were no false negative results. Another study conducted on twenty (20) healthy volunteers by Ostrow et al<sup>8</sup>, involved instilling via nasogastric tube various quantities of radioactive chromium-tagged red cells (Cr51)<sup>11</sup>. The reactions obtained with guaiac paper slides were found to be about one-quarter as sensitive as the chemical tests such as benzidine and orthotolidine but overcomes both the instability of guaiac solutions and the hypersensitivity of benzidine and orthotolidine.

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