

## EXPECTED VALUES

IT IS IMPORTANT THAT THE **OneStep™ + ER** SLIDES BE READ BETWEEN THIRTY (30) AND SIXTY (60) SECONDS AFTER **OneStep™ + ER** 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 **OneStep™ + ER** are designed for preliminary screening only and are not intended to replace diagnostic procedures such as barium enema, colonoscopy, proctosigmoidoscopic 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 **OneStep™ + ER** guaiac impregnated slides are capable of detecting 0.6 mg Hb/gm of feces<sup>10</sup>. Greeger<sup>7,12,13</sup> pioneered the use of guaiac paper slides like those supplied by Henry Schein for the detection of colorectal cancer in office-practice patients. Screening 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 2000 physicians who had used the guaiac paper slides in their practices over a six month period, detected colon cancer in 47 patients in which there were no signs other than the positive guaiac slide test. In these data which were collected by Greeger, there were no false negative results. Another study conducted on 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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# OneStep™ + ER

## FOB ENHANCED READABILITY TEST KIT

### INTENDED USE

**OneStep™ + ER** 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", Greeger<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.

**OneStep™ + ER** 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>6</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.

**OneStep™ + ER** 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. **OneStep™ + ER** is especially useful for mass screening programs as its enhanced readability feature facilitates the technicians' ability to make a determination.

**OneStep™ + ER** 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.

**OneStep™ + ER** 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.

**OneStep™ + ER** FOB Triple Slide Kits 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 **OneStep™ + ER** test paper, the hemoglobin portion of the occult blood comes in contact with the guaiac. When the **OneStep™ + ER** 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 30 seconds and 60 seconds if occult blood is present.

## MATERIALS PROVIDED

**OneStep™ + ER 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.

**OneStep™ + ER Developing Solution (enhanced)** - Contains a stabilized mixture of hydrogen peroxide (less than 6%) and 75% denatured ethyl alcohol with enhancing additives in aqueous solution.

**OneStep™ + ER FOB Single Slide Kit** – Instructions for use, 100 single slides with Performance Standards, two (2) 10 ml bottles of Developing Solution, and 100 applicator sticks. Also available in 50 pack.

**OneStep™ + ER FOB Triple Slide Kit** – Instructions for use, 50 patient slides with a new and innovative “GRID” design for easy readability, Performance Standards, three (3) 10 ml bottles of Developing Solution, 150 applicator sticks, patient instructions, and 50 foil-lined mailing pouches. See “*Test Instructions*”.

## MATERIALS NEEDED BUT NOT PROVIDED

Clock or timer.

## STORAGE CONDITIONS

**OneStep™ + ER Test Slides** - Store at room temperature (15°-30°C or 59°-86°F). 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.

**OneStep™ + ER Developing Solution** - Store at room temperature (15°-30°C or 59°-86°F). 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 Henry Schein’s **OneStep™ + ER** 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 **OneStep™ + ER** 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. **OneStep™ + ER** FOB Triple Slide Kit) 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 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-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-test series. However it should be remembered that bleeding may be intermittent and no positive test result should be disregarded.

## TEST INSTRUCTIONS

**OneStep™ + ER 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. Without “GRID”: 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. With “GRID”: With applicator, apply a thin smear of stool inside Area indicated with Roman numeral I by pulling the applicator across the entire rectangle, making sure that all four circular cavities in the “GRID” are entirely filled and leveled. Using the same applicator repeat from a different portion of the stool for Area II. Discard the applicator in the trash after use.
3. Repeat the procedure for a total of three bowel movements.
4. 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 or more drops of **OneStep™ + ER** Developing Solution to exposed test paper.
3. Read results between 30-60 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 1 drop of developer directly onto control area (between positive (+) and negative (-) performance standards.)
2. Read results within 30 seconds. The positive standard contains a hemoglobin derived catalyst. After addition of the developer, a blue color should appear within 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 Henry Schein 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.