

# HEALTH-CHEM DIAGNOSTICS LLC

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## ONE STEP™ FECAL OCCULT BLOOD TEST

### INTENDED USE

The **One Step™ Fecal Occult Blood Test** is a rapid, qualitative immunochemical assay for the determination of human hemoglobin (hHgb) in feces by professional laboratories or physicians' offices. It is useful to determine gastrointestinal bleeding found in a number of gastrointestinal disorders such as colorectal carcinoma, colon polyps, diverticulitis and ulcerative colitis.

The **One Step™ Fecal Occult Blood Test** is recommended for use in (1) routine physical examination, (2) hospital monitoring for bleeding in patients, and (3) screening for colorectal cancer or gastrointestinal bleeding from any source.

### SUMMARY AND EXPLANATION

The gum guaiac method, developed by Van Deen in 1864, was useful in detecting blood. Building on this technique, Boas began searching in 1901 for a method of detecting occult blood as a means to diagnose gastric bleeding. The subsequent development of latex immunochemical agglutination by Adonis et al in 1974, single radial immune diffusion (SRID) by Songster et al in 1980, and reverse-passive hemagglutination (RPHAA) by H. Scito et al in 1984, have combined to produce test methods more sensitive to low concentrations of human hemoglobin in feces. The Fecal Occult blood test is designed to detect lower levels of fecal occult blood than standard guaiac tests. The basis of the test is an immunochromatographic sandwich capture method which yields results that appear more specific to human hemoglobin and are easier to interpret than those of guaiac-based devices. In addition, unlike guaiac assays, the accuracy of the test is not affected by interfering substances and does not depend on the status of the patient at the time the specimen is taken.

### PRINCIPLE OF THE TEST

The Fecal Occult Blood Test is a method that employs a unique combination of polyclonal and monoclonal antibodies to selectively identify hemoglobin in test samples with a high degree of sensitivity. In less than five minutes, elevated levels of human hemoglobin as low as 50 ng/Hb/ml can be detected, and positive results for higher levels of hemoglobin can be seen in the test as early as two or three minutes.

A fecal sample is collected and prepared for testing using the fecal collection tube, and then added directly to the test device. The sample fluid mixes with anti-hHgb-dye-conjugate in the test membrane forming an anti antigen-dye complex, which migrates through the test device. Fecal traces now in the form of an antibody-complex are captured in the test zone by immobilized anti-hHgb-antibodies. The captured dye-complex becomes visible as a pink-rose band, which indicates the test has detected human hemoglobin, a positive result. In the absence of hHgb, no line will form in the test zone.

A procedural control is built-in to the test device to indicate proper kit performance. It appears as a pink-rose band in the control zone within the five minute testing period. The band is formed by a non-specific reaction and will appear regardless of the test result.

### MATERIAL PROVIDED

1. Test Cassette  
(Packaged in foil pouch)
2. Extraction/Sample tube and buffer



3. Instructions for use.

### MATERIALS REQUIRED BUT NOT PROVIDED

1. A clock or timer
2. Sample collection containers
3. A sterile, absorbent cloth or tissue (preferably disposable)

### WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Do not use test kit after the expiration date indicated on the label.
3. Patient samples may contain infectious agents and should be handled accordingly. Dispose of all used test components in a biohazard container.

## One Step™ Fecal Occult Blood Test





### STORAGE

Store the test kits below 28°C; do not freeze. Refer to the expiration date for stability. After collecting sample, the collection tube should be stored refrigerated (2-8°C), if not used immediately.

### PATIENT PREPARATION



1. Specimen collection should not be performed during or within three days of a menstrual period, or if the patient suffers from bleeding hemorrhoids or blood in the urine; false-positive test results may be obtained.
2. Alcohol, aspirin and other medications taken in excess may cause gastrointestinal irritation resulting in occult bleeding. Such substances should be discontinued at least 48 hours prior to testing.

### SPECIMEN COLLECTION AND STORAGE

1. Collect a random sample of feces in a clean, dry receptacle. 
2. Unscrew the top of the collection tube and remove the applicator stick. 
3. Insert the stick into the fecal specimen at several different sites. 
4. Remove excess sample from the stick by gently wiping with an absorbent tissue.
5. Replace the stick in the tube and tighten securely. 

The specimen is now ready for testing, transportation or storage. Samples should be tested within one week of collection.

### ASSAY PROCEDURE

1. Shake the tube vigorously to ensure a good liquid suspension. 
2. Holding the tube upright, snap off the tip. 
3. Dispense 2-3 drops of solution into the sample well ("S").
4. Wait five minutes and read the result.



**IMPORTANT:** The result must be interpreted between 5 and 10 minutes. Waiting more than 10 minutes may cause the reading to be inaccurate.

### INTERPRETATION OF RESULTS

1. **Positive.** At five minutes, two rose-pink color bands appear: one in the test (T) zone and one in the control (C) zone. A positive result indicates that the specimen contains human hemoglobin. A positive result may be read sooner than 5 minutes.



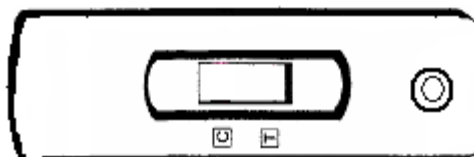
*Positive*

2. **Negative.** At five minutes, one rose-pink color band appears in the control (C) zone indicating a negative result and that the specimen does not contain a detectable level of human hemoglobin.



*Negative*

3. **Invalid.** At five minutes, no bands appear, or a test band appears without a control band. Disregard the result, indicating, as this indicates the test is invalid. It is recommended that the specimen be re-tested.



*Invalid*

*Note:* There is no meaning attributed to line color intensity or width. A positive result may be read sooner than five minutes. However, a negative result must be read after five minutes.

### LIMITATIONS OF THE TEST

1. The Fecal Occult Blood Test is designed for use as a diagnostic aid to physical examinations, and is not intended to replace other diagnostic procedures such as G.I. fibroscope, endoscopy, colonoscopy, or x-ray analysis. Test results should not be deemed conclusive with respect to the presence or absence of gastrointestinal disorders.
2. Although the test is highly accurate in detecting human hemoglobin, a low incidence of false positive results may occur. In addition, because many bowel lesions, including some polyps and colorectal cancers may bleed intermittently or not at all, occult blood may not be uniformly distributed throughout a fecal sample. Thus test results may be negative even when disease is present.

## QUALITY CONTROL

An internal procedure control has been incorporated into the test to ensure proper kit performance and reliability. The use of an external control is recommended to verify proper kit performance. Quality control samples should be tested according to QC requirements established by the testing laboratory.

## PERFORMANCE CHARACTERISTICS

### 1. Sensitivity:

The analytical sensitivity of the test is 50 ng hHb/ml buffer or 5 ug hHb/g feces.

### 2. Accuracy:

There were 120 human hemoglobin free feces extraction specimens collected over 10 days from in house and these were grouped into 6 in an evenly distributed number 20. The 6 groups of extraction samples were spiked with human hemoglobin for 6 different concentrations, respectively, 0 ng/ml; 20 ng/ml; 40 ng/ml; 50ng/ml; 100 ng/ml; and 2000ng/ml. The results obtained agreed 98% with the predicate device.

### 3. Specificity:

The Fecal Occult Blood Test is specific to human hemoglobin. Specimens containing the following substances, have no effect on the test result:

#### Substance Concentration

|                        |            |
|------------------------|------------|
| Chicken hemoglobin     | 500 µg/ml  |
| Pork hemoglobin        | 500 µg/ml  |
| Beef hemoglobin        | 500 µg/ml  |
| Goat hemoglobin        | 500 µg/ml  |
| Horse hemoglobin       | 500 µg/ml  |
| Rabbit hemoglobin      | 500 µg/ml  |
| Horseradish Peroxidase | 2000 µg/ml |

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