

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.

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 employs a pair of monoclonal antibodies to selectively identify hemoglobin in test samples with a high degree of sensitivity. In five minutes, elevated levels of human hemoglobin are detected.

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.

STORAGE





Store the test kits below 28°C; do not freeze. Refer to the expiration date for stability.

One Step™ Fecal Occult Blood Test

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. Dietary restrictions are not necessary.
3. 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.

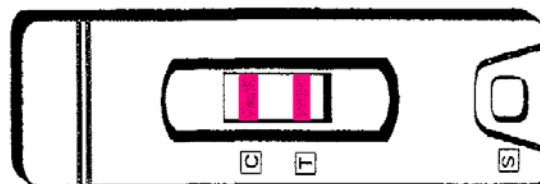
ASSAY PROCEDURE

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



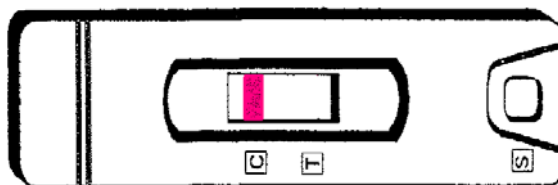
INTERPRETATION OF RESULTS

1. **Positive.** If there is a rose-pink color band in the control region (marked with a "C"), and a rose-pink color band in the test region (marked with a "T"). A positive result indicates that the specimen contain shuman hemoglobin.



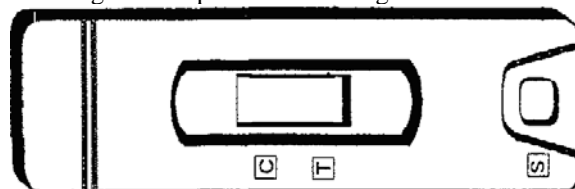
Positive

2. **Negative.** The absence of a color band in the test region next to the letter "T" indicates the absence of any detectable human hemoglobin.



Negative

3. **Invalid.** No pink-rose color band appears in the control zone ("C"), or a band appears in the test zone ("T") but not in the control zone. An invalid result may be due to improper testing procedure or deterioration of the liquid reagents. Repeat the test using a new device.



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 10µg/g feces.

2. Specificity:

The Fecal Occult Blood Test is specific to human hemoglobin. Samples containing the following interfering substances were tested on both positive and negative specimens with no effect on the test result.

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Manufactured in the USA by:
HEALTH-CHEM DIAGNOSTICS LLC
US FDA & ISO/CMDCAS/CE Approved Facilities
3341 SW 15th St
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FDA Establishment Registration: No.1048532

Substance Concentration

Chicken hemoglobin	500 µg/ml
Pork hemoglobin	500 µg/ml
Beef hemoglobin	500 µg/ml
Horse hemoglobin	500 µg/ml
Rabbit hemoglobin	500 µg/ml
Horseradish Peroxidase	500 µg/ml

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