RAPID FECAL OCCULT BLOOD TEST CARD

FOR THE QUALITATIVE ASSESSMENT OF HUMAN HEMOGLOBIN IN FECES

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For In Vitro Diagnostic Use Only

INTENDED USE

Rapid Fecal Occult Blood Test Card is a qualitative test that detects human hemoglobin in human fecal specimens. The test is a visual one step, in-vitro assay. It is intended for professional use to help diagnose gastrointestinal bleeding.

SUMMARY AND EXPLANATION

Colorectal cancer is the third most common cancer in the world. "Fecal occult blood" is generally defined as a blood loss of less than 50 mL/d. The appearance of occult blood in human fecal specimen is often associated with gastrointestinal diseases which might cause colorectal cancer if not treated promptly and properly. The traditional guaiac-based method lacks sensitivity and specificity, and has diet restrictions prior to the testing.

Rapid Fecal Occult Blood Test uses the technology of immunochromatographic sandwich assay. The test is more sensitive and more specific than the traditional guaiac assay. It is easier to interpret the result. In addition, unlike the guaiac assays, the accuracy of the test is not affected by the diet of the patients..

PRINCIPLE OF THE ASSAY

Rapid Fecal Occult Blood Test Card is composed of two units, a fecal collection tube and a test device. A fecal specimen is collected in the collection tube containing sample extraction buffer, and then added to the test device. When sample is added to sample pad, it moves through the conjugate pad and mobilizes the gold anti-h hemoglobin antibody conjugate that is coated on the conjugate pad. The mixture moves along the membrane by capillary action and reacts with anti-h hemoglobin antibody that is coated on the test region. If h hemoglobin is present at levels of 50 ng/mL or greater, the result is the formation of a colored band in the test region. If there is no h hemoglobin in the sample, the area will remain colorless. The sample continues to move to the control area where goat anti-mouse IgG antibody will capture gold-antibody conjugate to form a pink to purple color, indicating the test is working and the result is valid.

MATERIAL PROVIDED

1. Rapid Fecal Occult Blood Test Card
Test zone: contains mice monoclonal anti-hemoglobin antibody.
Control zone: contains goat anti-mouse IgG antibody.
Conjugate pad: contains gold-mice monoclonal anti-hemoglobin antibody conjugate.
2. Fecal specimen collection tube
The collection tube contains 2 ml of buffer
3. Instructions for use

MATERIALS REQUIRED BUT NOT SUPPLIED

Timer or clock.

STORAGE AND STABILITY

1. Store the test device in the original sealed pouch and the fecal specimen collection tube at 4 to 30°C. Do Not Freeze.
2. The expiration date given was established under these storage conditions.
3. The test device should remain in its original sealed pouch until ready for us.
4. The device is designed for single use. Once the pouch is opened, the device must be tested as soon as possible and cannot be reused.

PRECAUTIONS

1. For in-vitro diagnostic use only.
2. Do not use product beyond the expiration date.
3. Handle all specimens as potentially infectious.

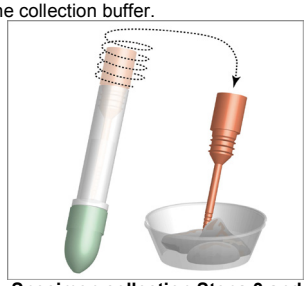
SPECIMEN COLLECTION AND PREPARATION

PATIENT PREPARATION

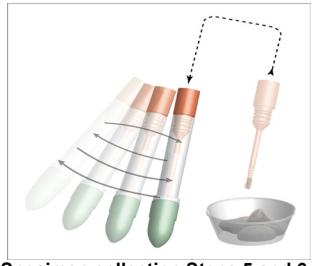
1. Specimen should not be collected during or within three days of a menstrual period, or if the patient suffers from bleeding hemorrhoids or blood in the urine.
2. Alcohol, aspirin and other medications, taken in excess, may cause gastrointestinal irritation resulting in occult bleeding. Such substances should be discontinued at least 48 hours prior to testing.
3. Dietary restrictions are not necessary.

SPECIMEN COLLECTION WITH SAMPLE TUBE TYPE I

1. Stool specimens can be collected at any time of the day.
2. Collect a random sample of feces in a clean, dry receptacle.
3. Unscrew the bottom cap (red end) of the collection tube and remove the applicator stick.
4. Insert the stick into the fecal specimen at several different sites.
5. Insert the sampled applicator back to the tube and tighten the bottom (red end) securely. The hold that only allows the stick goes through will prevent the access sample from getting into the tube.
6. Shake the tubes with bottom cap (red end) vigorously for about 5 seconds to release and disperse the stool sample into the collection buffer.



Specimen collection Steps 3 and 4

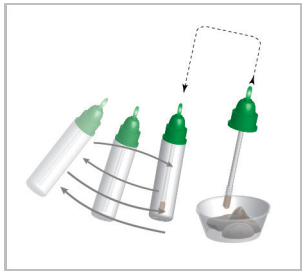


Specimen collection Steps 5 and 6

SPECIMEN COLLECTION WITH SAMPLE TUBE TYPE II

1. Stool specimens can be collected at any time of the day.
2. Collect a random sample of feces in a clean, dry receptacle.
3. Unscrew the cap of the collection tube and remove the applicator stick.
4. Insert the stick into the fecal specimen at several different sites.
5. Insert the sampled applicator back to the tube and tighten the cap securely.
6. Shake the tubes vigorously for about 5 seconds to release and disperse the stool sample into the collection buffer.

Specimen collection Steps 3 and 4



Specimen collection Steps 5 and 6

SPECIMEN STABILITY

The sample can be stored at room temperature (8-30°C) up to seven days if not immediately tested. If the condition allowed, the sample can also be refrigerated (2–8°C) for better storage.

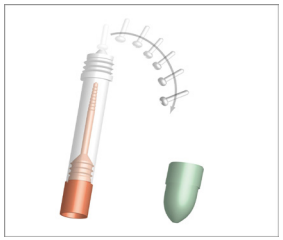
QUALITY CONTROL

1. It is recommended that a positive control, with a level between 50**–**200 ng/mL h hemoglobin and a negative control, 0 ng/mL h hemoglobin, be used. Control materials, which are not provided with this test kit, are commercially available.
2. The control band is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagents are reactive.

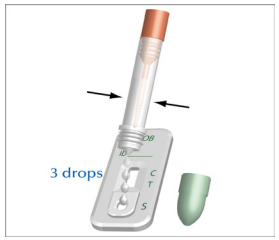
PROCEDURE

1. Bring all materials and specimens to room temperature (8–30ºC).
2. Remove the test card from the sealed foil pouch.
3.1 If collection tube Type I is used, remove the tip protection cap (green). Holding the tube upright with tip pointed toward the direction away from the test performer, Snap off the tip.
3.2 If collection tube Type II is used, hold the tube upright , put some paper between the performer's thumb and the tip, snap off the tip.
4. Hold the tube in a vertical position over the sample well of the test card and deliver 3 drops (120-150 μL) of sample into the sample well marked as "S" on the cassette.
5. Read the results at 5 minutes.

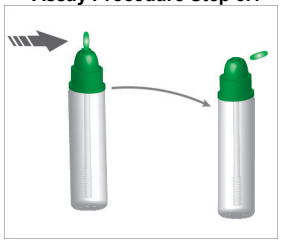
Note: Results read after 10 minutes may not be accurate.



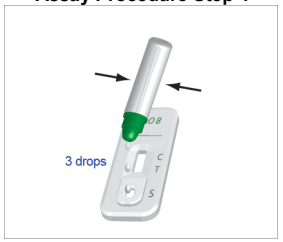
Assay Procedure Step 3.1



Assay Procedure Step 4



Assay Procedure Step 3.2



Assay Procedure Step 4

INTERPRETATION OF RESULTS

Positive:

If two colored bands are visible within 5 minutes, the test result is positive and valid.

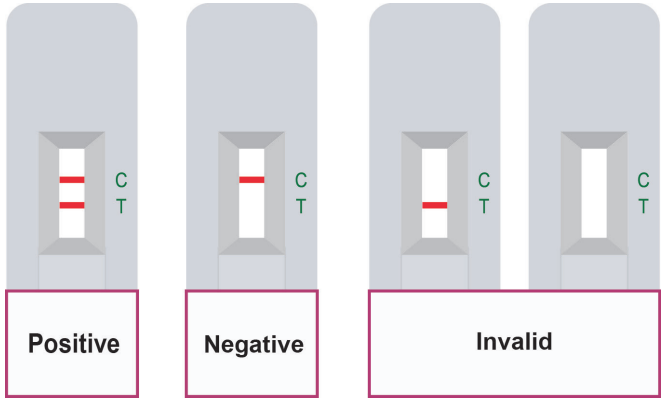
Note: Specimens containing very low levels of h hemoglobin may develop two colored bands over 10 minutes.

Negative:

If test area has no colored band and the control area displays a colored band, the result is negative and valid.

Invalid result:

The test result is invalid if a colored band does not form in the control region. The sample must be retested using a new test device.



LIMITATIONS OF THE PROCEDURE

1. A number of conditions, as mentioned in "Patient Preparation", can cause false positive results.
2. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

Sensitivity:

The analytical sensitivity of the test is 50 ng/mL h hemoglobin or 12.5 μg h hemoglobin/g feces.

Specificity:

The test is specific to human hemoglobin. Samples containing the following substances were tested on both positive and negative controls with no effect on test results.

Substances	Concentrations
Cattle hemoglobin	1 mg/mL
Chicken hemoglobin	1 mg/mL
Goat hemoglobin	1 mg/mL
Horse hemoglobin	1 mg/mL
Pig hemoglobin	1 mg/mL
Rabbit hemoglobin	1 mg/mL
Horseredish peroxidase	1 mg/mL

Accuracy:

Two hundred and fourteen (214) confirmed samples were used in the clinical evaluation of the Rapid Fecal Occult Blood Test. The clinical sensitivity, specificity and accuracy are respectively 98.4% (62/63), 100% (151/151) and 99.5% (213/214).

Interference testing:

The following substances were added to h hemoglobin free and 50 ng/mL controls. No interference was found with any of the substances at the following concentrations:

Acetaminophen	20 mg/dL
Acetylsalicyclic acid	20 mg/dL
Ampicillin	40 mg/dL
Ascorbic acid	40 mg/dL
Atropine	40 mg/dl
Bilirubin	20 mg/dL
Caffeine	40 mg/dL
Gentisic acid	40 mg/dL
Glucose	2000 mg/dL
Human albumin	2000 mg/dL
Urea	4000 mg/dL
Uric acid	10 mg/dL

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