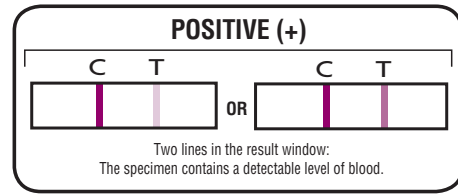


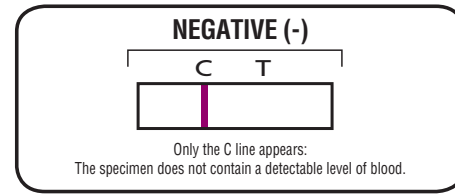
INTERPRETATION

POSITIVE:

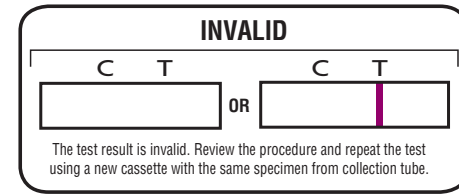


Many conditions may cause blood in your stool.
Contact your doctor right away.

NEGATIVE:



INVALID:



WHAT ARE THE LIMITATIONS OF THE TEST

1. This test is for testing human fecal samples only and loose stool samples have not been validated for this device to provide accurate results.
2. This test is not used to diagnose a condition or to replace other diagnostic procedures.
3. A positive result should be confirmed by a physician with additional confirmatory diagnostic procedures.
4. Occasionally, a negative result may be obtained even when a gastrointestinal disorder is present. For example, some polyps and colorectal cancers may bleed intermittently or not at all during certain stages of the disease.
5. Negative results may also occur when occult blood is not uniformly distributed throughout the bowel movement and the formation of a fecal sample. Repeat testing if a pathological condition is suspected.
6. Limit assay reading time to 1-10 minutes.
7. Specimen should not be collected or used with the following conditions that may interfere with the test results:
 - a. Menstrual bleeding
 - b. Bleeding hemorrhoids
 - c. Constipation bleeding
 - d. Urinary bleeding

WHAT DOES IT MEAN IF THE T LINE IS VERY FAINT

T stands for Test Line. It does not matter if the T-line is dark or faint, both indicate a positive result. Please consult your physician for further testing.

HOW DO I KNOW IF THE TEST WORKED?

The C stands for Control line, serving as an internal control feature. It should always be present. If the C-line does not appear, the test result is invalid. In this case, review the section "How to perform the test" and repeat the test with a new cassette. Return the used device to Reese Pharmaceutical Company for a free replacement.

IS THIS TEST RELIABLE?

Yes, the accuracy of the device is 98.8% from consumer studies.

ASSISTANCE

Customer Service
Phone: 1-877-204-5701
Hours: 8:30 a.m to 5 p.m. PST (Monday- Friday)

DISTRIBUTED BY:

REESE PHARMACEUTICAL COMPANY
10617 Frank Ave.
Cleveland, OH 44106- USA
Made in USA

REV 9/23 COLOIN

SYMBOL GLOSSARY

	Temperature limitation		Use by YYYY-MM
	Batch/Lot code		In vitro diagnostic medical device
	Manufacturer		Catalog number
	Contains sufficient for < n > tests		Consult instructions for use
	Do not reuse		Over the counter
	Caution, consult accompanying documents		Keep away from sunlight
	Keep dry		Unique device Identifier
	Do not use if package is damaged		

Please read all instructions before beginning the test.
Fast results as soon as 1 minute
For external use only
Store at room temperature
Do not expose the kit to extreme temperatures over 30°C (86°F)



INDICATIONS FOR USE

Reese's ColoTest® Immunochemical Fecal Occult Blood Test is a qualitative immunoassay for detection of fecal occult blood. Fecal occult blood is blood in your stool. It is intended for professional and over the counter use.

HOW THE TEST WORKS

This device uses antibodies to detect human hemoglobin (hHb) in fecal samples.

SUMMARY AND EXPLANATION

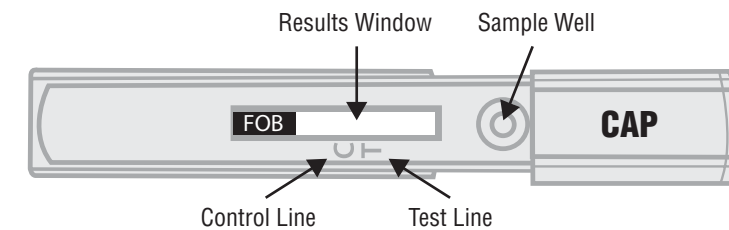
Reese's ColoTest® Immunochemical Fecal Occult Blood Test is an immunoassay that uses Driven Flow™ technology. The device consists of one test strip in a plastic cassette. The test strip consists of:

1. A pad treated with anti-human hemoglobin antibodies conjugated with colloidal gold.
2. A strip of nitrocellulose membrane with a Test line (T-line) and a Control line (C-line). The T-line is coated with anti-hHb antibodies, and the C-line is coated with IgG antibodies.

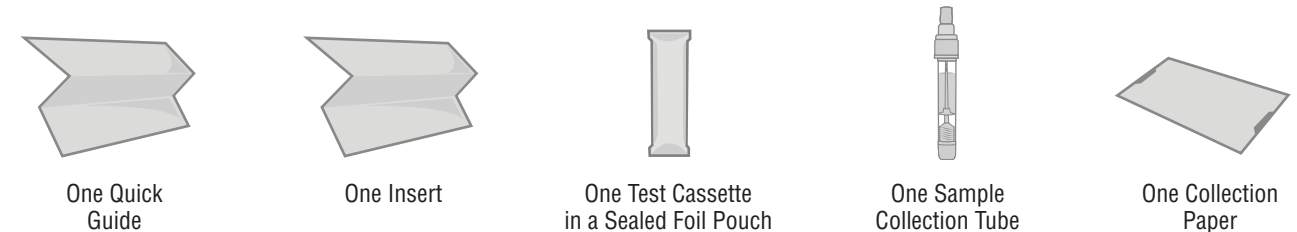
CHEMICAL, PHYSICAL, PHYSIOLOGICAL, OR BIOLOGICAL PRINCIPLES

When an adequate volume of test specimen is dispensed into the sample well of the cassette, the test specimen migrates across the test strip. If the concentration of hHb in the specimen is at or above 50 ng/mL, the T-line visibly appears as a burgundy line. The intensity of the T-line may vary according to the concentration of the hHb in the sample. If the concentration of hHb in the sample is below 50 ng/ml, a T-line does not visibly appear. The C-line is coated with goat anti-mouse IgG antibody, which binds to the conjugated monoclonal antibody, regardless of whether hHb is present in the sample, and migrates across the test strip.

THE STRUCTURE OF THE CASSETTE



CONTENTS



WARNINGS AND PRECAUTIONS

1. For In Vitro Diagnostic Use
2. Bleeding in the digestive systems may be intermittent (not continuous). If concerned, it is recommended to perform the test on three different days with new feces samples each time to increase the chance of detecting fecal occult blood.
3. Hands and test area should be kept clean and free from blood to avoid contamination.
4. Treat fecal samples and used test materials as if they are potentially infectious by using gloves and dispose according to federal, state, and local requirements.
5. Taking Aspirin or nonsteroidal anti-inflammatory medications may cause bleeding in your digestive system and may make the FOB test positive.
6. Keep the kit and test components out of the reach of children.
7. Do not use an expired device.

STORAGE

This test device is stable when stored at room temperature 8-23°C (46.4-73.4°F) for up to two (2) years or until the expiration date printed on the label, whichever comes first. Do not expose the kit components to temperatures over 30°C (86°F). Do not freeze. Collect specimen and test right away after opening test device.

HOW TO COLLECT FECAL SPECIMEN

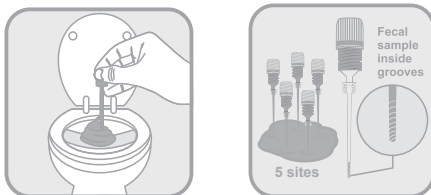
1. A collection paper is provided. Remove tape covers from the back side of the collection paper as shown. Loosely place the paper at the back portion of the toilet bowl, affix tape, and then lower the seat. Deposit feces on the collection paper.



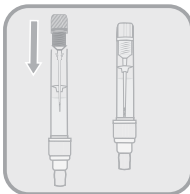
2. Unscrew and remove the sampler from the collection tube as shown.



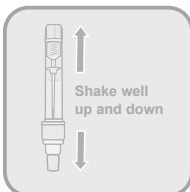
3. Using the grooved tip of the sampler, pierce the stool in at least five (5) different sites.



4. Insert the sampler with specimen back into the collection tube and firmly tighten cap.

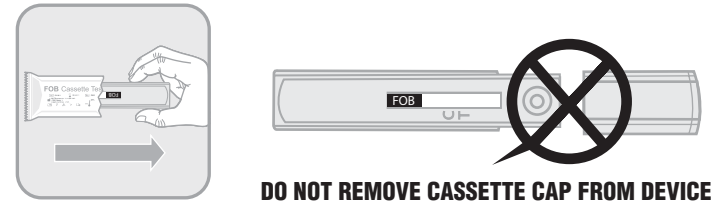


5. Shake the tube up and down to mix the liquid. Flush the remaining stool and paper.

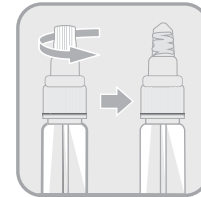


HOW TO PERFORM THE TEST

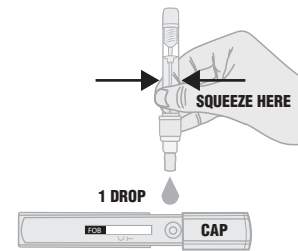
1. Open the sealed foil pouch, remove the test cassette, and place it on a flat surface.



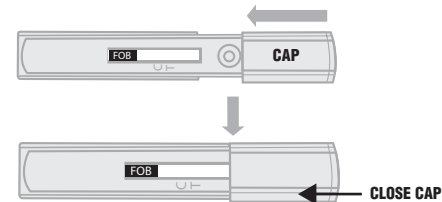
2. Holding the collection tube upright, unscrew the clear cap.



3. Squeeze the body of collection tube to deliver one drop of the sample into the sample well as shown.



4. Close cap over the sample well with force until it stops to ensure reaction.



5. Wait 1 minute and read results. Results should not be read after ten (10) minutes.

Note: A false negative or false positive result may occur if the test result is read before one (1) minute or after ten (10) minutes.

6. After the test is done, discard the used components into the regular trash.