

Diagnostic Kit for Fecal Occult Blood (Colloidal Gold)

Product Name

Fecal Occult Blood (FOB) Rapid Diagnostic Kit (Colloidal Gold)

Intended Use

The test kit is designed for the qualitative detection of human occult blood in feces according to the principle of gold immunochromatography assay.

Feces detection is a common indicator of digestive tract diseases, and is very important in the diagnosis of digestive tract diseases. The detection of gastrointestinal bleeding is an effective method to find occult blood and one of the important means for clinical diagnosis and monitoring of digestive tract hemorrhage disease. It is a cautionary tale for the early screening of the colorectal diseases in asymptomatic patients.

Test Principle

The test utilizes antibodies including a anti-human hemoglobin monoclonal antibody on the nitrocellulose membrane with colloidal gold marked Hb as an mark tracer. The reagent is used to detect the Hb in feces according to the principle of double antibody sandwich method and gold immunochromatography assay.

The specimen mixing up anti-human hemoglobin monoclonal antibody–marker move along the membrane to the T line, and form the T line when the specimen contains Hb, which a positive result. Conversely, it is a negative result.

Main Components

The testing kit is in the form of strip and cassette. Basic components: Sample pad, colloidal gold marked pad, nitrocellulose membrane, absorbent paper and PVC board. Colloidal gold marked pad coated with anti-human hemoglobin monoclonal antibody A, nitrocellulose membrane coated with anti-human hemoglobin monoclonal antibody B, control line coated with goat anti-mouse IgG antibody.

Description: different components of different batches cannot be used at the same time to avoid erroneous results

Storage and Expiry

Store as packaged in the sealed pouch at 4-30°C, avoid hot and sunshine, dry place, valid for 24 months. DO NOT FREEZE. Some protective measures should be taken in hot summer and cold winter to avoid high temperature or freeze-thaw. Do not open the inner packaging until ready, it must be used in one hour if opened (Humidity: 20%~90%, Temp: 10°C-50°C)

Sample Requirements

1. The samples were collected from different parts (at least six) of the feces, and the 1mL distilled

water was added to the mixture.

2. Fresh samples are suggested to use. The samples should be detected as soon as possible within 1 hour after dilution.

3. Specimens may be stored at 20~37°C for 12 hour, 2-8°C for 3 days, and at -20 °C for 1 year. Frozen refrigerated samples should be recovered to room temperature before detection and thoroughly mixed. Repeat freeze and thaw for no more than 3 times.

Test Methods

Instructions must be read entirely before taking the test. Allow the test device controls to equilibrate to room temperature for 30 minutes (20°C-30°C) prior to testing. Do not open the inner packaging until ready, it must be used in one hour if opened (Humidity: 20%~90%, Temp: 10°C-50°C)

Stripe:

1. Take off the outer packing, put the stripe onto the desk with the sample adding area up.
2. Drop 2 drops of diluted specimen (about 80μl) vertically onto the sample pad of stripe.
3. Observe the test results immediately within 5 minutes, the result is invalid over 5 minutes.

Cassette:

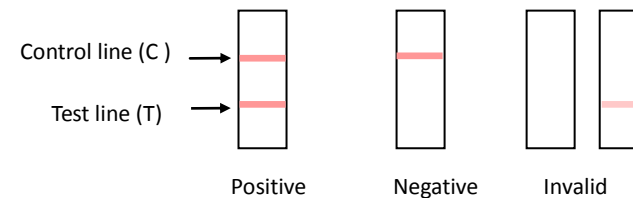
1. Take off the outer packing, put the cassette onto the desk with the sample window up.
2. Drop 2 drops of diluted specimen (about 80μl) vertically into the circular groove of cassette.
3. Observe the test results immediately within 5 minutes, the result is invalid over 5 minutes.

Interpretation of Results

POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and the other line should be in the test region (T).

NEGATIVE: One red line appears in the control region(C). No apparent red or pink line appears in the test region (T).

INVALID: No red bands appear or control line fails to appear, indicating that the operator error or reagent failure.



Reference value

The test kit has a sensitivity of 0.2μg/mL.

Limitations

1. The results of the reagent are only for clinical reference, which is not the only basis for clinical diagnosis and treatment. A confirmed diagnosis and treatment should only be made by a physician after all clinical and laboratory findings have been evaluated.
2. Limited by the detection method, the experimental personnel should pay more attention to the negative results. If faecal occult blood is still suspected, the specimen should be collected later and carry the detection with other methods.
3. Negative result may occur when detecting specimens with concentration exceed 2000µg /mL, indicate that the specimen should be diluted (50~100 times) before tested again.

Performance Characteristics

1. Using enterprise quality control specimens:

1.1 Analytical sensitivity: The results should all be negative when detecting specimens as follows: 500µg/mL Hb of goat, 500µg/mL Hb of chicken, 500µg/mL Hb of cattle, 500µg/mL Hb of swine, water and dilution of normal feces.

1.2 Limit of detection: The test kit has a sensitivity of 0.2µg/mL. when detecting Hb quality control specimens.

1.3 Repeatability: The results should be consistent and the coloration degree should be consistent when detecting the precision control specimens by 10 kits of 10µg/mL Hb.

1.4 Batch-to-batch variation: The results should be consistent and the coloration degree should be consistent when detecting the 10µg/mL Hb quality control specimens of 3 different batches.

2. Substance as follows has no effect on the detection result:

Substance	Concentration
Sheep hemoglobin	500µg/mL
Chicken hemoglobin	500µg/mL
Cattle hemoglobin	500µg/mL
Swine hemoglobin	500µg/mL
Bilirubin	600mg/L
Oxalic acid	10 mg/mL
Triglyceride	5mg/mL
Horseradish peroxidase	2000µg/mL
Fe ²⁺	60mg/mL
Vitamin C	250mg/mL

Attentions

1. Do not use after the expiration date.
2. The result is invalid over 5 minutes.

3. The strength of the quality control line doesn't indicate the quality problem of the reagent, a test result that is clearly visible demonstrates the reagent is effective.

4. Positive results may occur due to the gastrointestinal tract bleeding caused by taking drugs (such as aspirin).

5. A small amount of digestive tract bleeding cannot mix with feces evenly in the process of feces formation. To obtain accurate results, it is necessary to detect three times for hemorrhage of digestive tract is discontinuous process. One time of positive result can indicate the existence of hidden bleeding.

6. Positive result may occur according to menstrual period, hematuria and nasal bleeding.

7. Weakly positive or negative results may occur for the long time stay of Hb in digestive tract, and the enzyme may be secreted by the intestinal enzymes of the degradation. Another detection should be taken for 2~3 times to judge with clinical symptoms.

Note: Using slide method to detect tarry stools is not required.