Fecal Occult Blood Rapid Test Kit

PRODUCT NAME

Fecal Occult Blood Rapid Test Kit

PACKAGE SPECIFICATION

20 tests/kit

INTENDED USE

The kit is a rapid chromatographic immunoassay for the qualitative detection of human blood in feces samples, for early diagnosis of gastrointestinal bleeding.

SUMMARY AND PRINCIPLES OF THE PROCEDURE

Fecal occult blood test is an experiment used to check the hidden red blood cells or hemoglobin in feces. This is a very useful diagnostic index for gastrointestinal bleeding. Fecal occult blood is an early warning of gastrointestinal abnormalities. When the amount of gastrointestinal bleeding is small, the appearance of feces can not be abnormal and cannot be recognized by naked eyes. Therefore, fecal occult blood examination should be carried out in patients with suspected chronic gastrointestinal bleeding, which is of great significance for early screening of gastrointestinal malignant tumors (such as gastric cancer, colorectal cancer, polyps, adenomas).

Fecal Occult Blood (FOB) Rapid Test Kit is an assay for detection of human blood with using feces samples that utilizes immunochromatographic assay technology as its measurement principle. The test consists of a cassette device containing a separate region with immobilized mouse monoclonal anti-human blood specific monoclonal antibody and reagent pads with mouse monoclonal anti-human blood antibody binding gold colloid.The membrane is coated with monoclonal human IgM antibody the test line region of the device. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

KIT COMPONENTS

Each kit contains:

1. Test devices: 20 pieces test devices individually pouched.
2. Sample collection tubes: 20 pieces tubes and 1.0 ml collection solution in each tube.
3. Instructions For Use: 1 piece attached.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch.
- Biohazard disposal waste container.
- Disposable gloves and/or protective clothing.

WARNINGS

1. Read the Instructions For Use completely before using the product. The instructions must be followed carefully as not doing so may result in inaccurate results.
2. The kit is for diagnostic use only.
3. Perform test at room temperature.

PRECAUTIONS

1. The kit is for professional use only.
2. The Instructions For Use instructions must be followed to ensure optimum test performance.
3. The kit is intended for *in vitro* diagnostic use.
4. As with all screening assays, any results should be considered presumptive until confirmatory assays have been performed according to local practice or WHO guidelines.

Safety Precautions

1. Standard precautions for handling infectious agents should be observed when using this kit.
2. Wear protective clothing such as lab coat, safety glasses and disposable gloves when handling specimens and assay reagents.
3. Wash hands thoroughly after use.
4. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Bio safety Precautions

Appropriate bio safety practices should be used when handling specimens and reagents. These precautions include, but are not limited to the following:

1. Do not smoke, eat, drink, apply cosmetics or handle contact lenses in areas in which specimens are handled.
2. Dispose of all specimens, used devices and tubes as though they are capable of transmitting infection. The preferred methods of disposal are by autoclave at 121°C for a minimum of 60 minutes or by incineration. Disposable materials may be incinerated. Liquid waste may be mixed with appropriate chemical disinfectants. A solution of 10% bleach is recommended. Allow 60 minutes for effective decontamination. NOTE: Do not autoclave solutions containing bleach.
3. When disposing of sample collection tubes, avoid contact with acid to prevent liberation of a toxic gas.
4. All spills should be wiped thoroughly using a suitable disinfectant such as a sodium hypochlorite solution.
5. Use a separate tube and device for each specimen tested.

Handling Precautions

1. Do not use if the kit box safety seal is absent, damaged or broken.
2. Do not use any device if the pouches have been perforated.
3. Each device is for single use only.
4. Do not mix sample collection tubes/test devices from different kit lots.
5. Do not use the kit past the expiration date (this date is printed on the kit box).
6. Adequate lighting is required to read the test results.
7. The result should be read immediately after the end of the 10 minutes incubation time following the addition of collected specimen. Do not read results beyond 20 minutes.

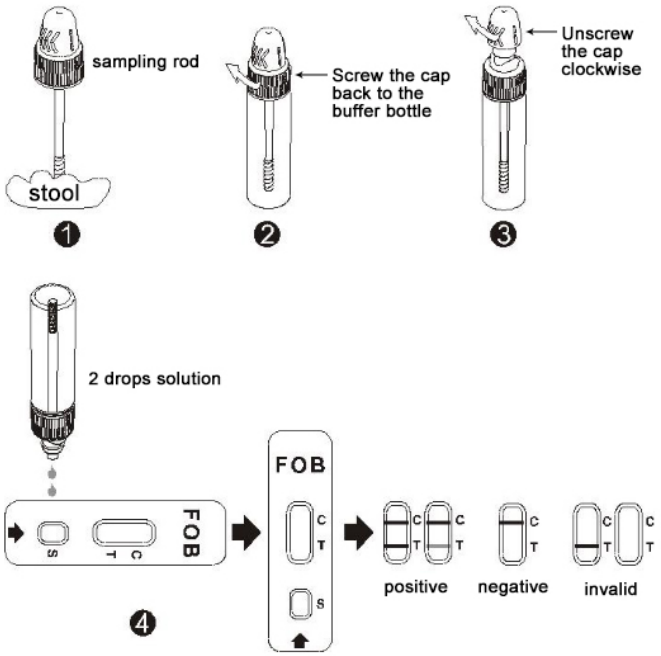
STORAGE INSTRUCTIONS

1. The kit should be stored between 2-30°C and the shelf life is 24 months.
2. The kit components are stable until the expiration date printed on the outer label, when stored as directed. The kit expiry date is determined by whichever of the components has the shortest expiry date. The kit expiry date is not impacted once the extraction Solution has been opened. Do not use kit components beyond overall kit expiry date.
3. If stored refrigerated, ensure that the pouched device is brought to room temperature before opening.
4. Do not freeze the kit.

TEST PROCEDURE

Allow the test device, specimen, extraction solution to equilibrate to room temperature (15-30°C) prior to testing.

1. Loosen the sample collection tube, take out the sampling rod, insert the feces sample, pick up 50 mg fecal sample (equivalent to the size of match head) and then put the sampling rod back into the tube, and rotate it tighten and shake well.
2. Place the test cassette on a clean and level surface. Break the tip of the sample collection tube, abandon the first two drops and draw two drops (approximately 90ul) into the sample well then start the timer. Avoid trapping air bubbles in the sample well.
3. Wait for the colored line(s)to appear. The test result should be read at 10 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

Negative result: if there is only a quality control line C, the detection line is colorless, indicating that human blood has not been detected and the result is negative.

Positive result: if both the quality control line C and the detection line appear, the human blood has been detected and the result is positive .

Invalid result: if the quality control line C is not observed, it will be invalid regardless of whether there is detection line (as shown in the figure above), and the test shall be conducted again.

LIMITATIONS

1. The kit is for professional in vitro diagnostic use only. The test should be used for the detection of human blood in feces samples. Neither the quantitative value nor the rate of increase in human blood can be determined by this qualitative test.
2. The kit will only indicate the presence of human blood in the specimen or not.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. A negative result may be obtained if the concentration of the human blood present in the specimen is not adequate or is below the detectable level of the test.
5. The accuracy of the test depends on the quality of the sample, avoid hematuria, haemorrhoids or menstruation contaminate feces samples. False negatives may result from improper sample collection or storage.
6. The use of over-the-counter and prescription medicine at high concentrations can interfere with results, leading to either invalid or incorrect test results.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The minimum detection limit for The kit is 50 ng/ml.

The kit specificity The detection results are not interfered by the substances whose concentrations are lower than those listed in the table below

Interfering substance	**Conc.**
Swine hemoglobin	500mg/mL
Bovine hemoglobin	500mg/mL
Chicken hemoglobin	500mg/mL
Sheep hemoglobin	500mg/mL
Rabbit hemoglobin	500mg/mL
HRP	2000mg/mL

INDEX OF SYBOML

IVD	In vitro diagnostic medical device		single-use,Please don't reuse it
	Use-by date		Consult instructions for use
	Cautions		Manufacturer
2°C	Temperature limit	LOT	Batch code
	Date of manufacture		Keep Dry
	Avoid overexposure to the sun		Don't use the product when the package is damaged
CE	CE mark		Biological risks

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INSTRUCTION APPROVAL AND REVISION DATE

Revision Date:
Date of Issue: