CE IVD

Haemoglobin Antigen Rapid Test Kit (Colloidal Gold)

Instruction for Use

Read this instruction carefully before use

A rapid test for the qualitative detection of Haemoglobin Antigen in human fecal specimens.For professional medical institutions use only,Not for self testing.

PRODUCT NAME

Haemoglobin Antigen Rapid Test Kit (Colloidal Gold)

SPECIFICATION

25 tests/kit, 5 tests/kit, 1 test/kit

INTENDED USE

The Haemoglobin Antigen Rapid Test Kit is a coloured chromatographic immunoassay (cut-off qualitative test) for the qualitative determination of human haemoglobin(hHb) in stool specimens.

INTRODUCTION

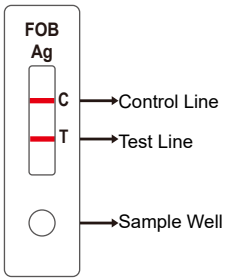
Colorectal cancer is the second leading cause of illness and death in Western word. The screening with faecal occult blood tests is based on the concept that important target colonic neoplasm,such as early-stage cancer and large adenomatous polyps,will bleed,for which may be detected by an occult blood test.Colorectal cancer is also associated with local acute inflammatory reaction being visualized,in some cases,by white cell neutrophil scanning.

Haemoglobin is the iron-containing oxygen-transport protein in the red blood cells of all vertebrates that maybe leaked into gastrointestinal tract and then dischanged with the feces in gastrointestinal bleeding diseases.

When gastrointestinal blood is lost,the stool will contain a combination of intact or nearly intact haemoglobin,intact heme and heme-derived porphyrins in amounts that depend on the site and amount of bleeding and the transit time through the gut. Immunochemical tests detect intact or nearly intact human haemoglobin,being a very specific technique for detecting loss of blood from the lower intestine,because blood from lower sites is less degraded during transit.

PRINCIPLE

The FOB Rapid Test Kit (Colloidal Gold) has been designed to detect human hemoglobin through visual interpretation of color development in the internal strip. The membrane was immobilized with anti - human hemoglobin antibodies on the test region. During the test, the specimen is allowed to react with colored anti - human hemoglobin antibodies colloidal gold conjugates, which were precoated on the sample pad of the test. The mixture then moves on the membrane by a capillary action, and interact with reagents on the membrane. If there were enough human hemoglobin in specimens, a colored band will from at the test region of the membrane. Presence of this colored band indicates a positive result, while its absence indicates a negative result. Appearance of a colored band at the control region serves as a procedural control. This indicates that proper volume of specimen has been added and membrane wicking has occurred.



COMPONENTS

Materials Provided

Components	25 tests/kit	5 tests/kit	1 test/kit
Cassettes	25 cassettes with dependent sealed foil pouch	5 cassettes with dependent sealed foil pouch	1 cassette with dependent sealed foil pouch
Sample Diluent Solution	1mL/bottle, 25pcs	1mL/bottle, 5pcs	1mL/bottle, 1pcs
Transfer tube	25 pcs	5 pcs	1 pcs
Package insert	1 pcs	1 pcs	1 pcs

Main ingredients of test cassettes:

Mouse anti-Haemoglobin antibody, Goat anti-rabbit IgG polyclonal antibody, Haemoglobin antibody, rabbit IgG, Colloidal gold conjugate, Other test device support; one desiccant.

Main ingredients of Sample Diluent Solution:

Neutral salt buffer

Reagents of different batch numbers cannot be used interchangeably.

MATERIALS REQUIRED BUT NOT PROVIDED

Timer for timing use

PRECAUTIONS

- Read this IFU carefully before use.
- Do not spill solution into the reaction zone.
- Do not use test if pouch is damaged.
- Do not use test kit after expiration date.
- Do not mix Sample Diluent Solution and Transfer Tubes from different lots.
- Do not open the Test Cassette foil pouch until ready to perform the test.
- Do not spill solution into the reaction zone.
- For professional use only.
- For in-vitro diagnostic use only
- Do not touch the reaction zone of the device to avoid contamination.
- Avoid cross-contamination of samples by using a new specimen collection container and specimen collection tube for each sample.
- All patient samples should be treated as if capable of transmitting disease. Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens.
- Do not use more than the required amount of liquid.
- Bring all reagents to room temperature (15~30°C) before use.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when testing.
- Evaluate the test result after 20 minutes and not beyond 30 minutes.
- Store and transport the test device always at 2~30°C.

STORAGE AND STABILITY

- The kit should be stored at 2~30°C, valid for 12months.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Cares should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND HANDLING

The FOB Rapid Test Kit (Colloidal Gold) is intended only for use with human fecal specimens.

•Patients should not collect samples during or within 3 days of their menstrual period, if they have bleeding hemorrhoids, blood in the urine, or if they have strained during bowel movement.

•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.

•No dietary restrictions are necessary before testing.

•Perform the testing immediately after the specimen collection. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2~8°C for up to 72 hours.

•Bring specimens to room temperature prior to testing.

•Pack the specimens in compliance with applicable regulations for transportation of etiological agents, in case they need to be shipped.

ASSAY PROCEDURE

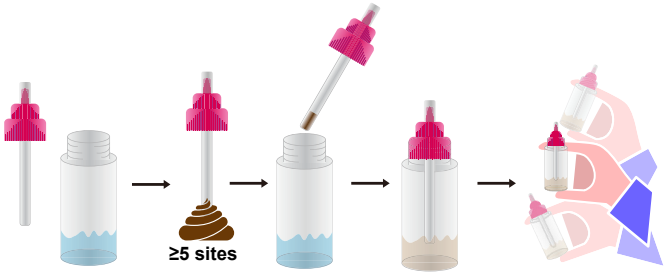
Bring tests, specimens, buffer and/or controls to room temperature (15□30°C) before use.

1.Specimen collection and pre-reatment:

1.1 Use the specimen collection container for specimen collection. Best results will be obtained if the assay is performed within 6 hours after collection.

1.2 Unscrew and remove the dilution tube applicator. Be careful not to spill or spatter solution from the tube. Collect specimens by inserting the applicator stick into at least 3 different sites of the feces to collect approximately 50 mg of feces (equivalent to 1/4 of a pea).

1.3 Place the applicator back into the tube and screw the cap tightly. Be careful not to break the tip of the dilution tube. Shake the specimen collection tube vigorously to mix the specimen and the extraction buffer. Specimens prepared in the specimen collection tube may be stored for 6 months at -20°C if not tested within 1 hour after preparation.



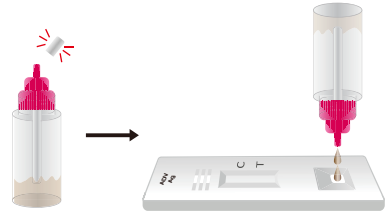
2.Testing

2.1 Remove the test from its sealed pouch, and place it on a clean, level surface. Label the test with patient or control identification. To obtain a best result, the assay should be performed within one hour.

2.2 Using a piece of tissue paper, break the tip of the dilution tube. Hold the tube vertically and **dispense 3 drops of solution** into the specimen well (S) of the test device.

Avoid trapping air bubbles in the specimen well (S), and do not drop any solution in observation window.

As the test begins to work, you will see color move across the membrane.



3.Wait for the colored band(s) to appear. The result should be read at 15 minutes. Do not interpret the result after 30 minutes.

QUALITY CONTROL

1.Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.

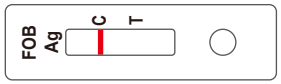
2.External controls are not supplied with this kit. It is recommended that positive and negative.

3.controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

INTERPRETATION OF ASSAY RESULT

Negative Control

If only the C band is developed, the test indicates that no detectable Haemoglobin antigen is present in the specimen. The result is non-reactive.



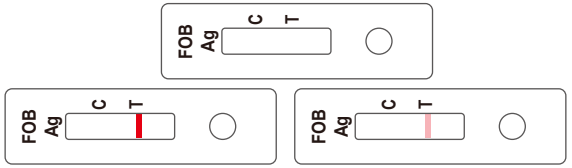
Positive Control:

If both C and T lines are developed, the test indicates the presence of Haemoglobin antigen in the specimen. The result is positive.

INVALID:

If no C line is developed, the assay is invalid regardless of any color development on the T line as indicated below. Repeat the assay with a new test device.

Excess fecal specimen can lead to invalid test results; if this is the cause, re-sample and re-test (see instructions for collection of specimen).



The appearance of any burgundy color in the test bands, regardless of intensity, must be considered as presence of the band.

Samples with positive or reactive results should be confirmed with alternative testing method(s) such as ELISA or PCR and clinical findings before a diagnostic decision is made.

PERFORMANCE CHARACTERISTICS

1. Sensitivity, Specificity and Accuracy:

Haemoglobin Antigen Test	BESTest		
Another Commercially Available	Positive	Negative	Total
Positive	325	9	334
Negative	16	1024	1040
Total	341	1033	1374
Relative Sensitivity: 97.31%; Relative Sp ecificity:98.46%; Overall agreement: 98.18%.			

A.Analytical Sensitivity

A sample containing human hemoglobin at concentration equal to or higher than 40 ng/ml produces a positive result. In some cases sample containing human hemoglobin at concentrations less than 40 ng/ml can also be tested as positive.

Hook or Prozone effect:

Sample containing as high as 0.5 mg/ml hemoglobin can still test positive. The tests do not show a Hook or Prozone Effect up to the maximal observed physiological concentration (0.5 mg/ml). Thus, the working range is 40 ng/ml up to 0.5 mg/ml.

B.Analytical Specificity:

The test is specific for human hemoglobin and does not show any cross-reaction with the hemoglobin from bovine, pig, horse and sheep concentrations up to 0.5 mg/ml.

Hemoglobin from rabbit and polecat may cause crossreactions.

The test also does not show any cross reaction with billirubin, vitamin C and horse radish peroxidase.

C.Clinical Specificity:

The following non-cancer related factors may cause blood in feces samples:

1) Iron

Food supplementation with iron leads to increased release of blood in the colon. Iron itself is not cross-reacting with the test.

2)Acetylsalicylic acid

ASA is main compound in a lot of drugs against headache (e.g. Aspirin® from Bayer), and is sometimes used to substitute macumar as a blood diluter. Almost always there are very small amounts of blood in fecal samples in case of healthy humans. This is far below the sensitivity of our test and has nothing to do with cancer or any other serious matter. If a patient takes blood diluters bleeding can be more intensive. Therefore the cut-off of the test may be reached.

3)Coumarin

Coumarines are used as drugs (e.g. Macumar®) for prevention of heart attacks, against thrombosis and stroke. Similar to ASA, cumarines are blood diluter. Almost always there are very small amounts of blood in fecal samples in case of healthy humans. This is far below the sensitivity of the test and has nothing to do with cancer or any other serious matter. If a patient takes blood diluters, bleeding can be more intensive. Therefore the cut-off of the test may be reached.

4)Hemorrhoids

Hemorrhoids may bleed. Therefore fecal sample may be contaminated with blood which is not associated with cancer.

5)Monthly period

Small amounts of blood released because of female's period may contaminate the fecal sample. This is blood which is not associated with cancer.

6)Urine samples

Several diseases may cause blood in urine samples. To avoid detection of urine-related blood, stool sample should not get in contact with urine.

TEST LIMITATIONS

1.The FOB Rapid Test Kit (Colloidal Gold) is for professional in vitro diagnostic use, and should be used for the qualitative detection of human hemoglobin only.
2.The presence of blood in stools may be due to several causes, besides colorectal bleeding, such as hemorrhoid, blood in urine or stomach irritations.
3.Negative results do not exclude bleeding since some polyps and colorectal region cancers can bleed intermittently or not at all. Additionally, blood may not be uniformly distributed in fecal samples. Colorectal polyps at an early stage may not bleed.
4.Urine and excessive dilution of sample with water from toilet bowl may cause erroneous test results.
5.This test may be less sensitive for detecting upper g.i. bleeding because blood degrades as it passes through the g.i. track.
6.All colorectal bleedings may not be due to precancerous or cancerous polyps. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

CAUTION

1.This product is used for in vitro diagnosis only.
2.Must strictly follow the instructions for operation and interpretation of the results.
3.The product is qualitatively tested, and the result cannot be used as a quantitative basis.should be tested using reagents within the validity period.
4.The cassetes, collectors,droppers,and tubes are for single person one-time use, cannot be reused.
5.Because the sample titer is different, the red lines of the test line will show different shades of color, all of which indicate positive results. The depth of the test line color cannot be used as the basis for determining the antibody titer in the sample.
6.The samples stored at low temperature should be balanced to room temperature and fully mixed before testing.
7.Samples and waste must be treated as a potential source of infection and the desiccant in the foil bag is not edible.

SYMBOLS

Symbol	Used For	Symbol	Used For
	Use-by date		Consult instructions for use
LOT	Batch code	IVD	In vitro diagnostic medical device
	Temperature limit		Manufacturer
	Please don't reuse it		Keep away from sunlight
	Don't use the product when the package is damaged		Keep dry
	Date of manufacture	Σ	Tests per kit
CE	CE Mark		Biological Risks
EC REP	Authorized representative in the European Community		

BASIC INFORMATION

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