LUNGENE® Fecal Occult Blood Rapid Test Strip/Cassette (Feces)

English

For professional and in vitro diagnostic use only.

[INTENDED USE]

The Fecal Occult Blood Rapid Test Strip/Cassette is a rapid chromatographic immunoassay for the qualitative detection of human hemoglobin (HB) from blood in fecal.

[SUMMARY]

Many diseases may result in hidden blood in the feces. This is known as fecal occult blood (FOB), human occult blood, or human hemoglobin. In the early stages, gastrointestinal problems such as colon cancer, ulcers, polyps, colitis, diverticulitis, and fissures may not show any visible symptoms, only occult blood. Traditional guaiac based methods of occult blood testing lack sensitivity and specificity, and also require diet restrictions prior to testing. Fecal occult blood tests are used as a screening tool for detecting lower gastrointestinal (GI) bleeding that may be related to iron deficiency anemia, pepti culcer, ulcerative colitis, polyps, and colorectal cancer. The Fecal Occult Blood Rapid Test is recommended for use by health professionals in routine physical examinations and in monitoring for GI bleeding in patients in hospitals or in physicians' offices. The Fecal Occult Blood Rapid Test Strip/Cassette is a simple, visual qualitative test that detects human hemoglobin from blood in fecal. The test is based on immunochromatography and can give a result within 5 minutes.

[PRINCIPLE]

The Fecal Occult Blood Rapid Test Strip/Cassette is a qualitative membrane strip based immunoassay for the detection of human hemoglobin from blood in fecal. In this test procedure, anti-hemoglobin antibody is immobilized in the test line region of the test kit. After an adequate volume of test specimen is placed in the specimen pad, it reacts with hemoglobin antibody coated particles that have been applied to the specimen pad. This mixture migrates chromatographically along the length of the test strip and interacts with the immobilized hemoglobin antibody. If the specimen contains hemoglobin antigen, a colored line will appear in the test line region indicating a positive result. If the specimen does not contain hemoglobin antigen, a colored line will not appear in this region indicating a negative result. 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.

[WARNINGS AND PRECAUTIONS]

- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens and kits are handled.
- Handle all specimens as if they contain infectious agents.
- Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Follow standard biosafety guidelines for handling and disposal of potential infective material.
- Humidity and temperature can adversely affect results.

[COMPOSITION]

The test contains a membrane strip coated with HB antibody on the test line, goat anti mouse antibody on the control line, and a dye pad which contains colloidal gold coupled with HB antibody.
The quantity of tests was printed on the labeling.

Materials Provided

•Test strip/cassette •Package insert
•Buffer

Materials Required But Not Provided

•Specimen collection container •Timer

[STORAGE AND STABILITY]

- Store as packaged in the sealed pouch at temperature (4-30℃ or 40-86℉). The kit is stable within the expiration date printed on the labeling.
- Once open the pouch, the test should be used within one hour. Prolonged exposure to hot and humid environment will cause product deterioration.
- The LOT and the expiration date were printed on the labeling.

[SPECIMEN]

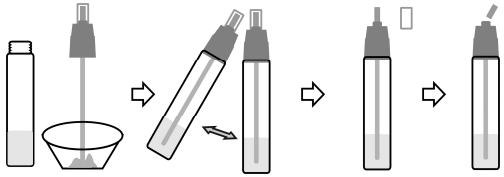
- The Fecal Occult Blood Rapid Test Strip/Cassette can be performed used on feces.
- Collect sufficient quantity of feces (1-2ml or 1-2g) in a clean, dry specimen collection container to obtain maximum antigens (if present). Best results will be obtained if the assays performed within 6 hours after collection.
- Specimen collected may be stored for 3 days at 2-8℃ if not tested within 6 hours. For long term storage, specimens should be kept below -20℃.
- Unscrew the cap of the specimen collection tube, then randomly stab the specimen collection applicator into the fecal specimen in at least 5 different sites to collect approximately 50 mg of feces (equivalent to 1/4 of a pea). Do not scoop the fecal specimen.
- Screw on and tighten the cap onto the specimen collection tube, then shake the specimen collection tube vigorously to mix the specimen and the dilution buffer. Leave the tube alone for 2 minutes.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

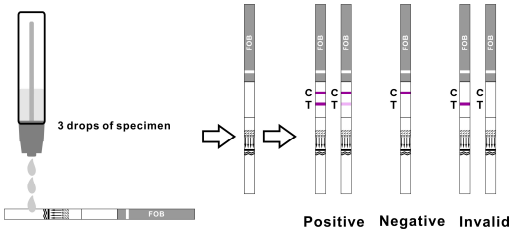
[TEST PROCEDURE]

Allow the test, specimen and/or controls to reach temperature 15-30℃ (59-86℉) prior to testing.

[For Strip]

1. Bring the pouch to room temperature before opening it. Remove the test strip from the sealed pouch and use it as soon as possible.
2. Place the test strip on a clean and level surface.
3. Holding the sample collection tube upright, carefully take off the tip of collection tube, then break off the tip of collection tube, transfer 3 drops (approximately 100µl) to the specimen pad of the test strip, then start the timer. See illustration below.
4. Wait for the colored line(s) to appear. Read results at 3~5 minutes. Do not interpret the result after 10 minutes.

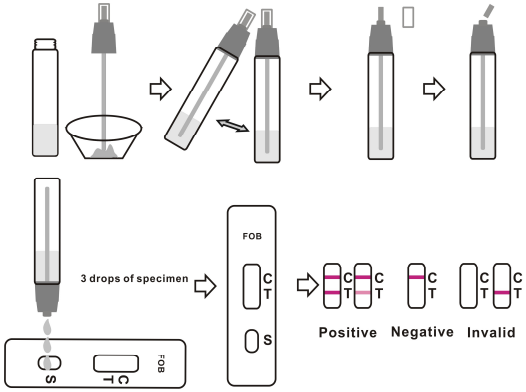




(The picture is for reference only, please refer to the material object.)

[For Cassette]

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. Place the test cassette on a clean and level surface.
3. Holding the sample collection tube upright, carefully take off the tip of collection tube, then break off the tip of collection tube, transfer 3 drops (approximately 100µl) to the specimen well(S) of the test cassette, then start the timer. See illustration below.
4. Wait for the colored line(s) to appear. Read results at 3~5 minutes. Do not interpret the result after 10 minutes.



(The picture is for reference only, please refer to the material object.)

[INTERPRETATION OF RESULTS]

Positive: Two lines appear. One colored line should be in the control region (C), and another apparent colored line adjacent should be in the test region (T).

Negative: One colored line appears in the control region (C). No line appears in the test region (T). This negative result indicates the absence of antigens to HB.

Invalid: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test strip/cassette. If the problem persists, discontinue using the lot immediately and contact your local distributor.

[QUALITY CONTROL]

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.
Control standards are not supplied with this kit. However, it is recommended

that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

[LIMITATIONS]

- The Fecal Occult Blood Rapid Test is for in vitro diagnostic use only. The test should be used for the detection of human hemoglobin from blood in fecal only. Neither the quantitative value nor the rate of increase in hemoglobin can be determined by this qualitative test.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended.

[PERFORMANCE CHARACTERISTICS]

Sensitivity

The Fecal Occult Blood Rapid Test will detect the concentration of human hemoglobin is equal to or greater than 200ng/ml.

Accuracy

A side-by-side comparison was conducted using the Fecal Occult Blood Rapid Test and commercially available FOB rapid tests. 241 clinical Specimens from three Professional Point of Care sites were evaluated with the Fecal Occult Blood Rapid Test and the commercial kit. The following results are tabulated from these clinical studies:

Agreement with Commercial FOB Rapid Test

		Commercial FOB Rapid Test		Total
		Positive	Negative	
CLUNGENE®	Positive	86	0	86
	Negative	0	155	155
Total		86	155	241

The agreement between these two test kit is 100% for positive specimens, and 100% for negative specimens. This study demonstrated that the Fecal Occult Blood Rapid Test is substantially equivalent to the commercial device.

Cross-Reactivity and Interference

Specimen containing the following substances at the standard concentration was tested on both HB positive and negative specimens and showed no effects on test results at standards concentration. No cross reactivity or interference was observed to the test kit.

Analytes	Conc. (mg/ml)	Specimens	
		Positive	Negative
Beef hemoglobin	0.5	+	-
Chicken hemoglobin	0.5	+	-
Pig hemoglobin	0.5	+	-
Goat hemoglobin	0.5	+	-
Horse hemoglobin	0.5	+	-
Rabbit hemoglobin	0.5	+	-
Horse radish peroxidase	2	+	-

Reproducibility

Reproducibility studies were performed for Fecal Occult Blood Rapid Test at three physician office laboratories (POL). Sixty (60) clinical serum specimens, 20 negative, 20 borderline positive and 20 positive, were used in this study. Each specimen was run in triplicate for three days at each POL. The intra-assay agreements were 99.4% at two sites, and 100% at one site. The inter-site agreement was 99.8%.

[Bibliography]

1. Ransohoff, D.F. and Lang, C.A.; Improving the Fecal Occult-Blood Test; The New England Journal of Medicine; (1996) 334 (3):189-190.
2. Yamamoto M., Nakama H., Cost-effectiveness analysis of immunochemical occult blood screening for colorectal cancer among three fecal sampling methods: Hepatogastroenterology, 2000 Mar-Apr, 47 (32) 396-399.
3. St. John, D.J.B., et al.; Evaluation of New Occult Blood Test for Detection of Colorectal Neoplasia; Gastroenterology; (1993) 104:1661-1668.

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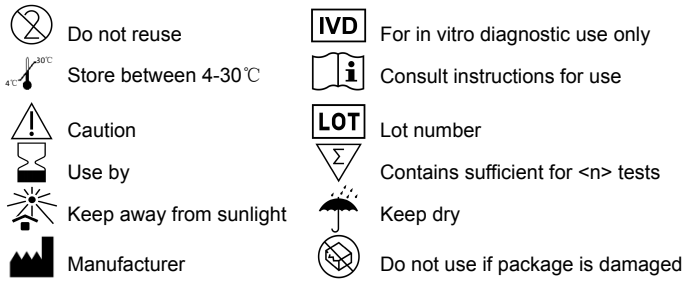

Version No.: 2.0
Effective Date: Jul. 30, 2018