Hb+Hb-Hp Combo Rapid Test Cassette (Feces)
Package Insert

REF THPB-625 | English

A rapid one step test for the qualitative detection of Hemoglobin and Haptoglobin-Hemoglobin complex in feces.
For professional in vitro diagnostic use only.

【INTENDED USE】

The Hb+Hb-Hp Combo Rapid Test Cassette (Feces) is a rapid chromatographic immunoassay for the qualitative detection of hemoglobin and/or haptoglobin-hemoglobin complex in feces.

【SUMMARY】

Bleeding in the digestive tract is a symptom of a disease rather than a disease itself. Bleeding can occur as the result of a number of different conditions, some of which are life threatening. Most causes of bleeding are related to conditions that can be cured or controlled, such as ulcers or hemorrhoids. The cause of bleeding may not be serious, but locating the source of bleeding is important. Common causes of occult blood are for ex-ample: esophagitis, gastritis, ulcers, cancer in the gastro intestinal tract (esophagus, sto-mach, colon), hemorrhoids, ulcerative colitis, colorectal polyps, diverticular disease etc.[1] In particular, early detection of colon cancer can significantly improve survival rate.Colorectal Cancer (CRC) detected at an early stage can be successfully treated with surgery. Malignancies and, to a lesser extent, polyps, bleed intermittently as the stool moves past them.[2] Performing an annual fecal occult blood test (FOBT) is one of several recommended options for colorectal cancer screening in the average risk population beginning at age 50.[3] Annual or biennial screening with guaiac-based FOBTs (gFOBT) has been shown in large, randomized trials to have a significant and beneficial effect on colorectal cancer incidence and mortality. However, while the specificity of these tests is generally high, sensitivity is poor. Complicated dietary restrictions prior to testing and sampling instructions may limit patient compliance. Newer, immunochemical FOBTs (iFOBT) are reported to have improved performance characteristics compared to guaiac tests, with no dietary restrictions.[4] Hemoglobin is used by iFOBT and gFOBT as the exclu-sive the blood protein of choice for detecting Occult Blood. The Diagnostik Nord HB-HP Rapid Test detects another blood protein complex: hemoglobin-haptoglobin in addition to Hemoglobin for the detection of occult blood. The hemoglobin-haptoglobin complex has a higher survival rate within the digestive tract than hemoglobin, thus the dual blood protein detection meaningfully increases the sensitivity of Occult Blood detection, inclu-ding bleeding from upper digestive tract.[5]

The colored C-line will always appear if the test has been performed correctly. The test sensitivity for Hb is 50ng/ml and Hb-Hp is 50ng/ml.

【PRINCIPLE】

The Hb+Hb-Hp Combo Rapid Test Cassette (Feces) is a qualitative, lateral flow immunoassay for the detection of hemoglobin or haptoglobin-hemoglobin in feces.

The Hb Rapid Test

The membrane is precoated with anti-hemoglobin antibody on the test line region of the test. During testing, the specimen reacts with the particle coated with anti-hemoglobin antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-hemoglobin antibody on the membrane and generate a colored line. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

The Hb-Hp Rapid Test

The membrane is precoated with anti-haptoglobin antibody on the test line region of the test. During testing, the specimen reacts with the particle coated with anti-hemoglobin antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-haptoglobin antibody on the membrane and generate a colored line. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The test contains anti-hemoglobin antibody particles and anti-hemoglobin, anti-haptoglobin coated on the membrane.

【PRECAUTIONS】

- For professional in vitro diagnostic use only. Do not use after expiration date.
- The test should remain in the sealed pouch until use.
- Do not eat, drink or smoke in the area where the specimens or 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.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

【STORAGE AND STABILITY】

The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

- Specimens should not be collected during or within three days of a menstrual period, or if the patient suffers from bleeding hemorrhoids or blood in the urine.
- 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 using the Hb+Hb-Hp Combo Rapid Test Cassette.

【MATERIALS】

Materials Provided

- Test cassettes
- Specimen collection tubes with extraction buffer
- Package insert

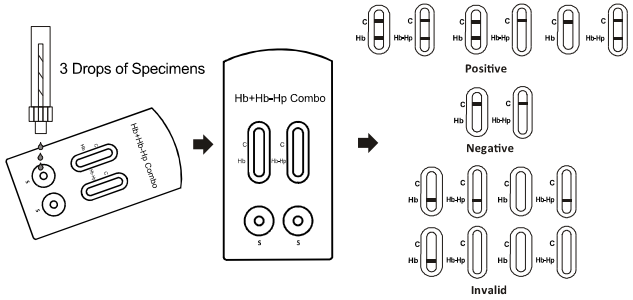
Materials Required But Not Provided

- Specimen collection containers
- Timer

【DIRECTIONS FOR USE】

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. To collect fecal specimens:
   Collect feces in a clean, dry specimen collection container. Best results will be obtained if the assay is performed within 6 hours after collection. Specimen collected may be stored for 3 days at 2-8°C if not tested within 6 hours.
2. To process fecal specimens:
   Unscrew the cap of the specimen collection tube，then randomly stab the specimen collection applicator into the fecal specimen in at least 3 different sites. 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 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.
3. Bring the pouch to room temperature before opening it. Remove the test cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch.
4. Hold the specimen collection tube upright and open the cap onto the specimen collection tube. Invert the specimen collection tube and transfer **3 full drops of the extracted specimen** (approximately 120µL) to the specimen well (S) of the test cassette, then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.
5. **Read results at 5 minutes.** Do not read results after 10 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

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

***NOTE**: The intensity of the color in the test line region (T) will vary depending on the concentration of hemoglobin or haptoglobin-hemoglobin complex present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

NEGATIVE: **One colored line appears in the control line region (C).** No line appears in the test line region (T).

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 with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

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

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

1. The presence of blood in stools may be other than colorectal bleeding, such as hemorrhoids, blood in urine or stomach irritations. If a positive result is obtained, additional diagnostic procedures should be performed to determine the cause and source of the occult blood in the fecal specimen.
2. Negative results do not exclude bleeding since it can be intermittent. False negative results may occur when occult blood is not evenly distributed throughout the bowel movement and fecal formation
3. Some colorectal polyps and coloreactal cancers may bleed intermittently or not at all at early stages.
4. Prozone Effects (high concentration that could cause false negative) for Hb and Hb-Hp are 100,000ng/ml and 75,000ng/ml respectively.
5. Patients taking blood thinning medications (warfarin) may have bleeding from the GI tract, especially if they take drugs like aspirin.

【EXPECTED VALUES】

The Hb+Hb-Hp Combo Rapid Test Cassette (Feces) has been compared with another leading commercial rapid test, demonstrating an overall accuracy of 99.2% for Hb, 98.8% for Hb-Hp complex.

【PERFORMANCE CHARACTERISTICS】

Accuracy

The Hb Rapid Test (Feces)

The Hb Rapid Test (Feces) has been compared with another leading commercial rapid test using clinical specimens.

Method		Other Rapid Test		Total Result
Hb Rapid Test Cassette (Feces)	Results	Positive	Negative	
	Positive	197	1	198
	Negative	3	299	302
Total Result		200	300	500

Relative sensitivity: 98.5% (95%CI*: 95.7%~99.7%);
Relative specificity: 99.7% (95%CI*: 98.2%~99.9%);
Accuracy: 99.2% (95%CI*: 98.0%~99.8%). *Confidence Intervals

The Hb-Hp Complex Rapid Test (Feces)

The Hb-Hp Complex Rapid Test (Feces) has been compared with another leading commercial rapid test using clinical specimens.

Method		Other Rapid Test		Total Result
Hb-Hp Complex Rapid Test Cassette (Feces)	Results	Positive	Negative	
	Positive	29	3	32
	Negative	1	297	298
Total Result		30	300	330

Relative sensitivity: 96.7% (95%CI*: 82.8%~99.9%);
Relative specificity: 99.0% (95%CI*: 97.1%~99.8%);
Accuracy: 98.8% (95%CI*: 96.9%~99.7%). *Confidence Intervals

Sensitivity

The Hb+Hb-Hp Combo Rapid Test Cassette (Feces) can detect levels of Hemoglobin as low as 50ng/ml or 6 µg/g feces and Haptoglobin-Hemoglobin complex as low as 50ng/ml or 6 µg/g feces.

Precision

Intra-Assay

Within-run precision has been determined by using 15 replicates of three specimens: 50ng/ml, 200ng/ml and 2µg/ml positive specimens. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 15 independent assays on the same three specimens: 50ng/ml, 200ng/ml and 2µg/ml positive specimens. Three different lots of the Hb+Hb-Hp Combo Rapid Test Cassette (Feces) have been tested using these specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The Hb+Hb-Hp Combo Rapid Test Cassette (Feces) is specific to human hemoglobin and haptoglobin-hemoglobin complex. Specimens containing the following substances were diluted in the extraction buffer to a concentration of 1.0 mg/ml, and tested on both positive and negative controls with no effect on test results: Bovine hemoglobin, Chicken hemoglobin, Pork hemoglobin, Goat hemoglobin, Horse hemoglobin, Rabbit hemoglobin and Turkey hemoglobin.

【BIBLIOGRAPHY】

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2. Blebea J and McPherson RA, “False-Positive Guaiac Testing With Iodine,” Arch Pathol Lab Med,1985, 109:437-40.
3. Block GE, “Colon Cancer: Diagnosis and Prognosis in the Elderly,” Geriatrics, 1989, 44(5):45-7,52-3.
4. Doyle AC, “A Study in Scarlet,” Philadelphia, PA: JB Lippincott Co, 1902.
5. Fleischer DE, Goldberg SB, Browning TH, et al, “Detection and Surveillance of Coleorectal Cancer,”JAMA, 1989, 261(4):580-5.

Index of Symbols

⚠	Attention, see instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged		Manufacturer		Consult Instructions for Use

Hangzhou AllTest Biotech Co., Ltd.
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www.alltests.com.cn

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