Fecal Occult Blood and Transferrin Combo Rapid Test Cassette (Feces)

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INTENDED USE

Fecal Occult Blood and Transferrin Combo Rapid Test Cassette (Feces) is a one step chromatographic immunoas-say for the qualitative determination of human hemoglobin (Hb) and human transferrin (Tf) in stool samples to detect gastrointestinal bleeding. The test is intended for use by health care professionals as an aid in the diagnosis of premature syndrome linked to the intestinal bleeding.

INTRODUCTION

Colorectal cancer is a leading cause of illness and death in the Western world. Screening with fecal 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. When gastrointestinal blood is lost, the stool will contain a combination of intact or nearly intact hemoglobin, intact heme, and heme-derived porphyrins in amounts that depend on the site, the amount of bleeding and the transit time through the gut. Immunochemical tests detect intact or nearly intact human hemoglobin, being a very specific technique to detect the loss of blood from the lower intestine, because blood from lower sites is less degraded during transit. The hemoglogin is unstable in feces, leading to false negative results. The detection of fecal transferrin, which is more stable than hemoglobin, provides an alternative way of diagnosing the disease in the upper digestive tract. Transferrin is a blood-derived component that may be leaked into gastrointestinal tract and then discharged with the feces in gastrointestinal bleeding diseases. Transferrin is stable in feces and a good marker to detect loss of blood from the upper and lower intestine (gastrointestinal bleeding). This immunochromatographic assay detects human hemoglobin and human transferrin in stool samples simultaneously, by obtaining more accurate testing results.

PRINCIPLE OF THE TEST

Fecal Occult Blood and Transferrin Combo Rapid Test Cassette (Feces) is a qualitative immunochromatographic assay for the determination of human hemoglobin and human transferrin in stool samples. The membrane is pre-coated with mouse monoclonal antibodies on both test bands (result region), against human hemoglobin and human transferrin.

During testing, the sample is allowed to react with the coloured conjugates (anti-human hemoglobin antibodies and anti-human transferrin antibodies) pre-dried on the test. The mixture then moves upward on the membrane by capillary action. As the sample flow through the test membrane, the coloured particles migrate. In the case of a positive result the specific antibodies present on the membrane will capture the coloured conjugate. Different bands will be visible, depending upon the hemoglobin or the transferrin content of the sample. These bands are used to interpret the result. The mixture continues to move across the membrane to the immobilized antibody placed in the control band region, a red band always appears. The presence of this red band serves as 1) verification that sufficient volume is added, 2) proper flow obtained and 3) an internal control for the reagents.

PRODUCT CONTENTS

Fecal Occult Blood and Transferrin Combo Rapid Test Cassette (Feces) contains coloured conjugates (anti-human hemoglobin antibodies and anti-human transferrin antibodies) and membrane (pre-coated with mouse monoclonal antibodies on both test bands (result region), against human hemoglobin and human transferrin) .

MATERIALS PROVIDED

20 Sealed pouches each containing a test cassette and a desiccant 20
Specimen collection tubes with extraction buffer, 3.0 mL
1 Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

Timer

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30ºC. The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **Do not freeze**.

PRECAUTIONS

1. For in-vitro diagnostic use only.Do not use beyond expiration date.
2. All the specimens should be considered as potentially hazardous and handled as if they were infectious agents.
3. Wear protective clothing (laboratory coats and disposable gloves) when assaying samples.
4. Do not eat, drink or smoke in areas where specimens and kit reagents are handled.
5. Avoid contact between hands and eyes or nose during specimen collection and testing.
6. Humidity and temperature can adversely affect test results.

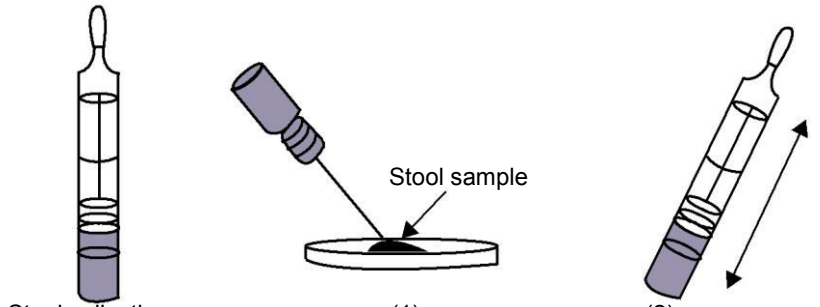
SPECIMEN COLLECTION AND PREPARATION

Note:Specimens prepared in the specimen collection tube may be stored at room temperature (15-30°C) for 3 days maximum, at 2-8°C for 7 days maximum or at -20°C for 3 months maximum if not tested within 1 hour after preparation.

Specimen preparation (see illustration):

(1) Unscrew the cap and use the stick by introducing four times into the fecal specimen to pick up the sample and adding the sample (approx.15mg) into the stool collection tube.

(2) Close the tube with the diluent and stool sample. Shake the tube in order to assure good sample dispersion. The stool collection vial with dilute sample can be stored for 5 days in the refrigerator (2-8ºC) prior to testing.



Precautions: Patients suffering from menstrual period, bleeding haemorrhoids, blood in urine or strain during bowel movement should not collect samples.

TEST PROCEDURE

Allow the test, stool samples and/or controls to reach room temperature (15-30ºC) prior to testing. Do not open pouches until ready to perform the assay.

1. Proceed to shake the stool collection tube in order to assure good sample dispersion.
2. Remove the test device from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
3. Place the test device on a clean and level surface.
4. Holding the sample collection device upright, carefully break off the tip of collection device.
5. Squeeze 3 drops (~90uL) of the sample solution in the sample well of the device and start the timer.
6. Wait for the colored line(s) to appear. Read results in 5 minutes. Do not interpret the result after 5 minutes.

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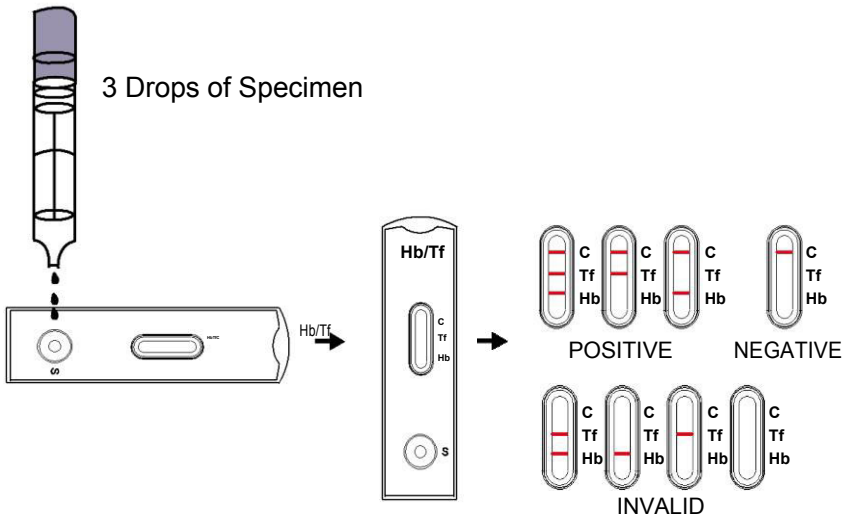

INTERPRETATION OF RESULTS

NEGATIVE: Only one red band appears across the central window in the site marked with the letter C (control line).
No occult blood presents: neither human hemoglobin nor human transferrin.

Tf and Hb POSITIVE: In addition to the control band, another two bands (Tf test line and Hb test line) also appear in the site marked with the letter Tf and Hb (result region). That probably would mean a lower gastrointestinal bleeding disease (colorectal cancer).

Tf POSITIVE: In addition to the control band, a red band (Tf test line) also appears in the site marked with the letter Tf (result region). That probably would mean an upper gastrointestinal bleeding disease (the human hemoglobin was probably degraded in the gastrointestinal tract).

Hb POSITIVE: In addition to the control band, a red band (Hb test line) also appears in the site marked with the letter Hb (result region). That probably would mean a lower gastrointestinal bleeding disease (the concentration of human transferrin in blood is 100 times less than human hemoglobin,therefore, Hb positive means not much blood present in feces).

INVALID: A total absence of the control band regardless the appearance or not of the result lines (Tf or Hb). Insufficient specimen volume, incorrect procedural techniques or deterioration of the reagents are likely the reasons for control line failure. Review the procedure and repeat the tests using a new test. If the problem persists, discontinue using the test kit and contact you local distributor.

NOTES ON THE INTERPRETATION OF RESULTS

The intensity of the Tf/Hb line in the result region will vary depending on the concentration of human hemoglobin or human transferrin in the specimen. However, neither the quantitative value, nor the rate of increase in hemoglobin or transferrin can be determined by this qualitative test.

QUALITY CONTROL

An internal procedural control is included in the test. A colored line appearing in the control line region (C) is 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 a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE ASSAY

1.The test must be carried out within 1 hours of opening the sealed bag.
2.An excess of stool sample could result in wrong results (brown bands appear or absence of the control band).
3.Patients suffering from menstrual period, bleeding hemorrhoids, blood in urine or strain during bowel movement should not collect samples.
4.Positive results confirm the presence of human hemoglobin and/or human transferrin in fecal samples; nevertheless, it can be also due to several causes besides colorectal bleeding, such as hemorrhoids, blood in urine or stomach irritations. A positive result should be followed up with additional diagnostic procedures to determine the exact cause and source of the blood in the stool.
5.Negative results do not exclude bleeding, as some polyps and colorectal cancers may bleed intermittently or not during certain stages of the disease. Moreover, blood may not be uniformly distributed in stool samples. 6.As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test , but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE

Sensitivity
A sample containing human hemoglobin at concentration equal to or higher than 5.1 ug/g feces and human transferrin at concentration equal to or higher than 1ug/g feces produces positive results when using FOB and Transferrin Rapid Test. Different hemoglobin and transferrin dilutions were tested directly in the extraction buffer or spiked in a negative stool sample in accordance with the kit instructions to determinate the detection limit of the test. Detection limit values: 50ng/mL of human hemoglobin and 10ng/mL of human transferrin.

Specificity
The Fecal Occult Blood and Transferrin Rapid Test is specific for human hemoglobin and human transferring, showing no cross-reaction with hemoglobin or transferrin from bovine and pig.

LITERATURE REFERENCES

1. Simon J.B. “Occult blood screening for colorectal carcinoma: a critical review”, Gastroenterology, Vol. 88 820, 1985.
2. Woo. H. and McDonald C. “Detection of fecal occult blood using monoclonal antibodies”, Gasteroenterology society of Australia, Annual general Meeting. Melbourne, Victoria, Australia, May 1986.
3. Adams, E.C. and Layman, K.M. “Immunochemical confirmation of gastrointestinal bleeding” , Ann. Elin. Lab. Sci., Vol. 4 343, (1974).
4. Ribet, A., et al. “Occult-blood test and colorectal tumors”, Lancet, Vol. 1, 417, (1980).
5. Taranen, M.J., et al. “Immunological detection of fecal occult blood in colorectal cancer”, Br. J. Cancer, Vol. 49 141, (1984).

INDEX OF SYMBOLS

	Consult 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	Cata log#

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