



# **C E** Revised 31 May 2011 rm (Vers. 1.1)



This kit is intended for Research Use Only.

Not for use in diagnostic procedures.

#### **INTENDED USE**

The Fecal Occult Blood test detects human hemoglobin in human fecal specimens. The test is a visual one step assay.

#### SUMMARY AND EXPLANATION

The Fecal Occult Blood Test uses the technology of immunochromatographic sandwich assay. The test is more sensitive and more specific than the traditional guaiac assay. It is easier to interpret the result. In addition, unlike the guaiac assays, the accuracy of the test is not affected by the diet of the donor.

## **TEST PRINCIPLE**

The Fecal Occult Blood Test is composed of two units, a fecal collection tube and a test device. A fecal specimen is collected in the collection tube containing sample extraction buffer, and then added to the test device. When sample is added to sample pad, it moves through the conjugate pad and mobilizes the gold anti-h hemoglobin antibody conjugate that is coated on the conjugate pad. The mixture moves along the membrane by capillary action and reacts with anti-h hemoglobin antibody that is coated on the test region. If hemoglobin is present at levels of 50 ng/mL or greater, the result is the formation of a colored band in the test region. If there is no h hemoglobin in the sample, the area will remain colorless. The sample continues to move to the control area where goat anti-mouse IgG antibody will capture gold-antibody conjugate to form a pink to purple color, indicating the test is working and the result is valid.

## **MATERIALS PROVIDED**

1. Fecal Occult Blood Test device

The amount of each coated antigen and/or antibody on the strip is less than 1.0 mg for antigen conjugate and is less than 1.0 mg for goat anti-mouse IgG antibody.

Test zone: contains mice monoclonal anti-hemoglobin antibody.

Control zone: contains goat anti-mouse IgG antibody.

Conjugate pad: contains gold-mice monoclonal anti-hemoglobin antibody conjugate.

- 2. Fecal specimen collection tube. The collection tube contains 2 ml of 50 mM Tris buffer, pH 7.6.
- 3. Instructions for use

## MATERIALS REQUIRED BUT NOT SUPPLIED

Timer or clock.

## STORAGE

- 1. Store the test device in the original sealed pouch and the fecal specimen collection tube at 4 to 30°C. DO NOT FREEZE.
- 2. The expiration date given was established under these storage conditions.
- 3. The test device should remain in its original sealed pouch until ready for use.
- 4. The device is designed for single use. Once the pouch is opened, the device must be tested as soon as possible and cannot be reused.

## **DRG International Inc., USA**

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## PRECAUTIONS

- 1. Do not use product beyond the expiration date.
- 2. Handle all specimens as potentially infectious.

## SUBJECT PREPARATION

- 1. Specimen should not be collected during or within three days of a menstrual period, or if the donor suffers from bleeding hemorrhoids or blood in the urine.
- 2. 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 resting.
- 3. Dietary restrictions are not necessary.

## SPECIMEN COLLECTION

- 1. Stool specimens can be collected at any time of the day.
- 2. Collect a random sample of feces in a clean, dry receptacle.
- 3. Unscrew the top of the collection tube and remove the applicator stick.
- 4. Insert the stick into the fecal specimen at several different sites.
- 5. Remove the excess sample from the stick by gently wiping with an absorbent tissue.
- 6. Replace the stick in the tube and tighten securely.

## SPECIMEN STABILITY

- 1. The sample can be stored at room temperature (8-30°C).
- 2. Remove the test card from the sealed foil pouch.
- 3. Shake the collection tube vigorously to ensure a good liquid suspension.
- 4. Holding the tube upright with tip pointed toward the direction away from the test performer; snap off the tip.
- 5. Hold the tube in a vertical position over the sample well of the test care and deliver 3 drops (120-150 mL) of sample into the sample well.
- 6. Read the result between 8 and 10 minutes.

## **INTERPRETATION OF RESULTS**

#### **Positive:**

If two colored bands are visible within 3 minutes, the test result is positive and valid. Note: Specimens containing very low levels of h hemoglobin may develop two colored bands over 10 minutes.

## Negative:

If test area has no colored band and the control area displays a colored band, the result is negative and valid.

## Invalid result:

The test result is invalid if a colored band does not form in the control region. The sample must be retested using a new test device.

## LIMITATIONS OF THE PROCEDURE

A number of conditions, as mentioned in "Subject Preparation", can cause false positive results.

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## 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, Mav 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).

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