

FOB Rapid Test Device

Lateral flow rapid test cassette for qualitative detection of hemoglobin in stool samples

Catalog #: AN1016C

FOB Rapid Test Device is an immunochromatographic *in vitro* assay for qualitative determination of human hemoglobin in feces. Hemoglobin in feces is an indication of internal bleedings associated with pathological conditions of gastrointestinal tract such as colon polyps, colorectal carcinoma, ulcerative colitis, and crohn's disease

Colorectal cancer is the third most common cancer in the world. "Fecal occult blood" is generally defined as a blood loss of less than 50 ml/d. The appearance of occult blood in human fecal specimen is often associated with gastrointestinal diseases, which might cause colorectal cancer if not treated promptly and properly. Traditional guaiac-based method lacks sensitivity and specificity, and has diet restriction prior to testing.

FOB Rapid Test Device uses technology of lateral flow double antibody sandwich assay. The test is more sensitive and more specific than the traditional guaiac assay does. 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 patients.

TEST PRINCIPLE

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

REAGENTS AND MATERIALS

FOB Device	25
Extraction Buffer	25
Instruction for use	1

PRECAUTION FOR USERS

- For in-vitro diagnostic use only.
- Handle all specimens as if they contain infectious agents. When the assay procedure is completed, dispose of specimens
- carefully after autoclaving for at least one hour. Alternatively, treat with a 0.5 or 1% solution of sodium hypochlorite for one hour before disposal.
- Wear protective clothing (laboratory coats and disposable gloves) when assaying samples.
- Do not eat, drink or smoke in areas where specimens and kit reagents are handled.
- Avoid contact between hands and eyes or nose during specimen collection and testing.

SPECIMEN COLLECTION

- Collect a random sample of feces in a clean, dry container.
- Trying not to spill the buffer, unscrew and remove the cap with attached applicator stick from the collection tube.
- Insert the stick into the feces a few times.
- Remove excess of feces from the stick by gently wiping it with an absorbent tissue.
- Reinsert the stick into the tube and tighten the cap thoroughly.

STORAGE OF TEST KIT

The FOB Device can be stored at any temperature between 4-30°C. **Do not freeze.** The stability of the kit under these storage conditions is 24 months. Use up the reagents as soon as possible after the kit is unpacked.

TEST PROCEDURE

- When you are ready to begin testing, open the sealed pouch by tearing along the notch. Remove the test from the pouch.
- Thoroughly shake the collection tube containing fecal sample, to ensure proper mixing of the sample with the buffer solution.
- Holding the tube vertically, carefully break the tip of the blue cap.
- Invert the collection tube carefully dispense 3-4 drops of the liquid into the sample well of the testing device.
- Read the test results at 3-10 minutes.

INTERPRETATION OF RESULTS



Negative: Only one colored band appears on the control region. No apparent band on the test region.

Positive: In addition to a pink colored control band, a distinct pink colored band will also appear in the test region.

Invalid: A total absence of color in both regions is an indication of procedure error and/or that test reagent deterioration has occurred.

LIMITATIONS OF THE ASSAY

As with all diagnostic, 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:

The analytical sensitivity of the test is 50ng/ml hemoglobin or 12.5ug hemoglobin/g feces.

Specificity:

The test is specific to human hemoglobin. Samples containing the following substances both positive and negative controls with no effect on the test results.

SUBSTANCES	CONCENTRATIONS
Beef Hemoglobin	1 mg/ml
Chicken Hemoglobin	1 mg/ml
Goat hemoglobin	1 mg/ml
Horse hemoglobin	1 mg/ml
Pork hemoglobin	1 mg/ml
Rabbit hemoglobin	1 mg/ml
Horseradish peroxidase hemoglobin	1 mg/ml

Interference testing:

The following substances were added to h Hemoglobin free and 50 ng/ml controls. No interference was found with any of the substances at the following concentrations:

Acetaminophen	20 mg/dl
Acetylsalicylic Acid	20 mg/dl
Ampicillin	40 mg/dl
Ascorbic Acid	40 mg/dl
Atropine	40 mg/dl
Caffeine	40 mg/dl
Gentisic acid	40 mg/dl
Glucose	2000 mg/dl
Human Albumin	2000mg/dl
Urea	4000 mg/dl
Uric Acid	10 mg/dl

REFERENCES

- Simon J.B. "Occult blood screening for colorectal carcinoma: a critical review", *Gastroenterology* Vol. 88 820, 1985.
- Woo. H and McDonald C. "Detection of fecal occult blood using monoclonal antibodies: *Gastroenterology society of Australia, Annual general Meeting. Melbourne, Victoria, Australia, May 1986.*

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