

FOB Rapid Test Kit

REF KT-111

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

This kit is an immunochromatographic assay for the qualitative determination of human hemoglobin in feces. It is for in vitro diagnostics use only.

TEST PRINCIPLE

This FOB Rapid Test kit contains a fecal collection tube and a test cassette. 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 colloid gold conjugated anti-human hemoglobin antibody. The mixture moves along the membrane by capillary action and reacts with another 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 colloid gold antibody conjugate to form a pink to purple color, indicating the test is working and the result is valid.

REAGENTS AND MATERIALS

FOB Cassette	REF Y0601	20
Sampling Tube	REF Y0602	20
Instruction for use	REF Y0603	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 sampling 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

- Unscrew the cap of the Sample Extraction Vial. Collect sample by immersing the sampling stick into the feces ensuring that the sample has impregnated the stick surface properly. (~ 50mg). For liquid or semi-solid stools add 100 microliters of stool using an appropriate pipette into the vial
- Reinsert the sampling stick into the vial and screw the cap tightly. Shake the vial to resolve stool into diluent.
- Break the tip off. Add **3 drops** to the sample well of the test device.
- Incubate the test at room temperature and read the test between **5-15 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 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
▪ Bovine 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.

Epitope Diagnostics, Inc.
San Diego, CA 92121, USA



MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

Manufacturer	No. of tests
Catalog Number	Keep away from heat and direct sun light
Concentrate	Store at
In Vitro Diagnostic Device	Use by
Read instructions before use	Lot No.
EC REP	Authorized Representative In Europe