









BIBLIOGRAPHY

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REF. CLZC81500

	<i>In vitro</i> diagnostic device		Lot (xxxx)
	Read the instruction's manual		Code
	Range of temperature		Manufacturer
	Use within (dd/mm/yyyy: year-month)		Contains sufficient for <n> tests

Code CND W0101060301



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Fecal occult blood

REF: CLZC81500

A visual one-step immunoassay for the qualitative detection of human blood hemoglobin in human fecal samples

INTRODUCTION AND PURPOSE OF USE

Hb Fecale is a rapid, visual immuno-chromatographic test for the qualitative detection of human blood hemoglobin in fecal samples. This test is intended as an aid in the diagnosis of lower gastrointestinal (g.i.) disorders. The test is recommended for professional use.

The principal use of the test is to screen for lower g.i. pathologies, such as colorectal cancers and large adenomas that bleed. Colorectal cancer is one of the most commonly diagnosed cancers and a leading cause of cancer death in the United States (Lieberman, 1994; MMWP, 1995). Screening for colorectal cancer probably increases the cancer detection at an early stage, therefore reduces the mortality (Dam et. al., 1995; Miller, 1995; and Lang, 1996).

Earlier commercially available FOB tests utilized the guaiac test, which requires special dietary restriction to minimize false positive and false negative results. Hb Fecale is specially designed to detect human hemoglobin in fecal samples using Immunochemical methods, which improved specificity for the detection of lower g.i. disorders, including colorectal cancers and adenomas (Frommer et. al., 1988; St. John et. al., 1993).

PRINCIPLE

Hb Fecale has been designed to detect human hemoglobin in fecal samples through visual interpretation of color development in the test device. The test device contains a membrane strip, which is pre-coated with anti-human hemoglobin antibody on the test line region (T) and goat anti-mouse antibody on the control line region (C).

An anti-human hemoglobin antibody-colloidal gold conjugate pad is placed at the end of the membrane. When human hemoglobin is present in the patient fecal sample dissolved in buffered saline, the mixture of colloidal gold conjugate and extracted sample moves along the membrane chromatographically by capillary action. This mixture then migrates to the test region (T) and forms a visible line as the antibodies complex with the human hemoglobin.

When human hemoglobin is absent in the extracted sample, no visible color band will form on the test region (T). Therefore, the presence of a color band in the test region (T) indicates a positive result.

A colored band will always appear at the control region (C) to serve as a procedural indicator for the proper performance of the test and the device.

STORAGE AND STABILITY

The test kit is to be stored at refrigerated (2-8°C) or at room temperature (up to 30°C) in the sealed pouch for the duration of the shelf-life.

REAGENTS AND MATERIALS SUPPLIED

- **Test Membrane - Hb Fecal:** Individually wrapped test devices (**CASSETTE**). Each test device (**CASSETTE**) contains one test strip with anti-human hemoglobin monoclonal antibody coated membrane and colored anti-human hemoglobin monoclonal antibody pad.
- **Extraction Liquid Tubes - FOB Diluent Buffer:** Sample collection tubes. Each contains 2 ml of 0.1 M Tris-HCl buffered saline, with BSA and 0.02 % sodium azide.
- Instructions for use.

SPECIMEN COLLECTION AND PREPARATION

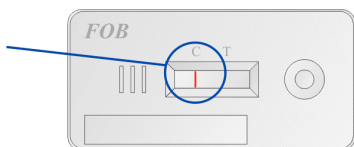
1. Collect a random sample of feces in a clean dry container or receptacle.
2. Unscrew and remove the collection tube applicator stick. Be careful not to spill or spatter solution from container.

3. Collect random sample by using the applicator stick. Take sample from various surfaces of the feces specimen
4. Re-insert the applicator stick into the tube and screw the cap tightly. Be careful not to break the tip of the sample collection tube.
5. The specimen is now ready to be stored at 2-30°C, transported or tested. Fecal samples in the buffered saline are stable for up to 15 days at room temperature.

TEST PROCEDURE

Quality Control / Internal Procedural Control

A procedural control is included in the test. A colored band appearing on the control region (C) of the membrane indicates proper performance of the test and the device.



A clear background in the observation window is considered an internal negative control. However, when the fecal samples are tested, the background may appear slightly yellowish due to the original color of the fecal samples. This is acceptable as long as it does not interfere with the interpretation of test result. The test is invalid if the background fails to clear and obscures the reading of the result.

Assay procedure

1. Test device, patient's samples, (extracted sample) should be brought to room temperature (20°C to 30°C) prior to testing.
2. Remove the test device from its pouch when ready to perform the test. Bring the device to room temperature to avoid condensation of moisture in the membrane. Label the device with patient or control identification.
3. Shake the collection tube thoroughly to ensure proper mixing of the fecal sample with the extraction solution.
4. Using a piece of tissue paper, break the tip of the collection tube using a twisting motion. Hold the collection tube vertically and dispense 3-4 drops (app. 120 µl) of solution into the sample well of the test device.
5. Observe the result in 5 minutes. Strong positive results may be observed sooner. Do not interpret results after 8 minutes.

INTERPRETAZIONE DEI RISULTATI

Positive

Two pink-red colored bands appear. One in the control region (C) and one in the test region (T). When testing with strong positive samples, the intensity of the control band may be lighter than expected. Comparison of the line intensities is not recommended.

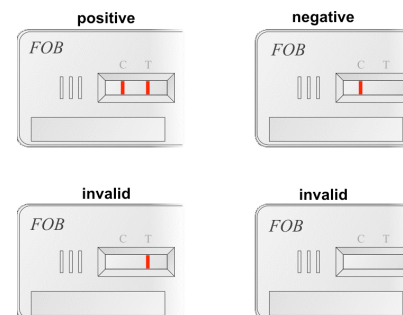
Negative

Only one pink-red colored band appears in the control region (C). No apparent faint pink to red colored band in the test region (T).

Invalid

A total absence of pink colored bands in both regions is an indication of procedural error or that test reagents may have deteriorated. Repeat the test with a new test device and if condition persists, contact the manufacturer for technical assistance.

The test lines may get darker after some time. This does not have any effect on the result.



PRECAUTIONS

- For in-vitro diagnostic use only.
- For professional use only.
- Do not use test kit beyond expiration date.
- Do not mix sample collection tubes from different lots.
- Do not open the test cassette foil pouch until you are ready to perform the test.
- All patient samples should be treated as if capable of transmitting disease.
- Buffered saline contains sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of buffered saline or extracted samples, always flush with copious quantities of water to prevent azide build up.
- Patients should closely follow the specimen collection procedures.
- Patients should not collect samples during their menstrual period, if they have bleeding hemorrhoids, blood in the urine, or if they have strained during bowel movement.

PERFORMANCE CHARACTERISTICS

A. Analytical Sensitivity

A sample containing human hemoglobin at concentration equal to or higher than 40 ng/ml produces a positive result. In some cases sample containing human hemoglobin at concentrations less than 40 ng/ml can also be tested as positive.

Prozone effect: sample containing as high as 0.5 mg/ml hemoglobin can still test positive.

B. Test Specificity

Hb Fecale is specific for human hemoglobin and does not show any cross-reaction with the hemoglobin from bovine, pig, rabbit, horse and sheep concentrations up to 0.5 mg/ml.

Hb Fecale also does not show any cross reaction with billirubin, vitamin C and horse radish peroxidase.