Immunochemical Fecal Occult Blood Test (Rx)

INDICATIONS FOR USE

The Instant-view® plus Immunochemical Fecal Occult Blood Test is a qualitative immunoassay for detection of Fecal Occult Blood. It is intended for professional and over the counter use.

SUMMARY AND EXPLANATION

Measurement of FOB is useful as an aid to detect human blood in stool as found in a number of gastrointestinal disorders. Colorectal cancer (CRC) is the third most common cancer diagnosed in men and women in the United States. CRC is the second leading cause of cancer death.[1] Studies proved that using FOB screening tests could save up to 33,000 lives nationwide every year. The American Cancer Society and Centers for Disease Control recommend a FOB test annually after age 50 as an aid in the early detection of CRC.[2]

This iFOB Test is designed to specifically detect low levels of human fecal occult blood. It is highly specific for human hemoglobin (hHb), that overcomes the false positive problem with Guaiac tests and Hemoporphyrin tests. The results of this iFOB test are not affected by dietary peroxidases, animal blood and ascorbic acid. A Japanese study demonstrated using iFOB tests reduced mortality by 60%.[3]

PRINCIPLE OF THE PROCEDURE

This assay is a *Driven* Flow™ chromatographic immunoassay. The device consists of one test strip in a plastic cassette. The test strip consists of:

1. a burgundy colored conjugate pad treated with mouse anti-hHb antibodies conjugated with colloidal gold; and
2. a strip of nitrocellulose membrane with a Test line (T-line) and a Control line (C-line). The T-line is coated with anti-hHb antibodies, and the C-line is coated with goat anti-mouse IgG antibodies.

When an adequate volume of test specimen is dispensed into the sample well of the device, the test specimen migrates across the test strip. If the concentration of hHb in the specimen is at or above 50 ng/ml, the T-line appears as a visible burgundy line. The intensity of the T-line may very according to the concentration of the hHB in the samples. If the concentration of hHb in the specimen is below the detectable level, no T-line develops. The C-line is coated with goat anti-mouse antibody, which binds to the conjugated antibody, regardless of the presence of hHb in the sample.

REAGENTS AND MATERIALS SUPPLIED

25	Collection tube contains 2 ml extraction buffer (1x PBS with 0.02% sodium azide)
25	Test devices sealed in a foil pouch
1	One insert (Instructions for Use)

MATERIALS REQUIRED BUT NOT PROVIDED

Timer

PRECAUTION

1. This kit is for *in-vitro* diagnostic use only.
2. Do not use expired kit components.
3. Dispose of all used components in a biohazard container, per clinical lab procedures

STORAGE

This test device is stable when stored in room temperature 20-23°C (68-73.4°F) for up to 2 years or until the expiration date printed on the label, whichever comes first. Do not expose the kit components to temperatures over 30°C (86°F).

SPECIMEN COLLECTION LIMITATIONS

1. A specimen should not be collected from a patient with the following conditions that may interfere with the test results:
   a. Menstrual bleeding
   b. Bleeding hemorrhoids
   c. Constipation bleeding
   d. Urinary bleeding

2. Alcohol and certain medications such as aspirin, indomethacin, reserpine, phenylbutazone, corticosteroids and nonsteroidal anti-inflammatory drugs may cause gastrointestinal irritation and subsequent bleeding in some patients.

SPECIMEN COLLECTION PROCEDURE

1. Refer to the Sample Collection Procedure.

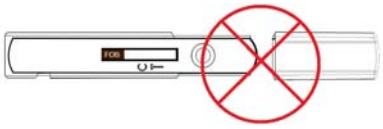
Note: Samples may be stored at least eight (8) days at ambient temperatures below 35°C (95°F), six (6) months at 2-8°C (26-48°F) and two (2) years at -20°C (-4°F).

ASSAY PROCEDURE

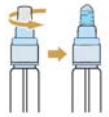
1. Refrigerated specimens or other materials, including the test cassette, must be equilibrated to room temperature before testing.

2. Remove the test cassette from its pouch and place it on a flat surface. Label the device with identification.

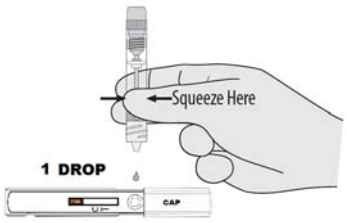
3. Do not remove the cap from the cassette.



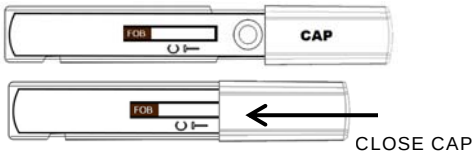
4. Holding the collection tube upright, unscrew the clear cap.



5. Squeeze the collection tube to deliver one drop of the sample into the sample well as shown.



6. Close cap of the device with force until it stops to ensure reaction.

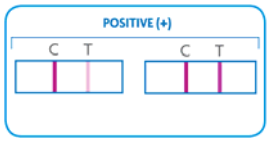


7. Read the result between one (1) to ten (10) minutes.

INTERPRETATION

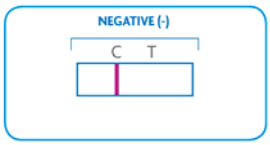
POSITIVE:

If both C-line and T-line are present, the result is positive. A positive result indicates the level of hHb in the specimen is over 50 ng hHb/ml.



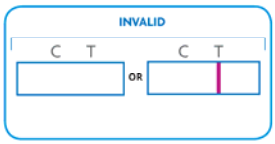
NEGATIVE:

If only the C-line develops in the control region of the test strip, the result is negative. A negative result indicates the hHb in the specimen is below 50 ng/ml.



INVALID:

If no C-line appears within two (2) minutes, the result is invalid and the assay should be repeated with a new device. *NOTE:* The test line may or may not be present. However, the absence of a control line indicates an invalid test.



QUALITY CONTROL

Internal Quality Control:

The Control line (C-line) is a built-in control feature, which indicates that an adequate sample volume was applied and that the reagents migrated properly. Without a C-line, the test result is invalid. In this case, review the entire procedure and repeat the testing with a new device.

External Quality Control:

Using external quality controls, positive and negative, are encouraged to check if the performance of the device is proper.

LIMITATIONS OF TEST

1. This is a screening test, positive results should be confirmed by a physician with additional confirmatory diagnostic procedures to determine the exact cause.
2. A negative result can be obtained even when a gastrointestinal disorder is present. For example, some polyps and colorectal cancers may bleed intermittently or not at all during certain stages of the disease.
3. False negative results may occur when occult blood is not uniformly distributed throughout the bowel movement and the formation of a fecal sample. Repeat testing is recommended if a pathological condition is suspected.

PERFORMANCE CHARACTERISTICS

1. **Sensitivity**

   The sensitivity of the test is 50ng hHb/ml.

2. **Accuracy and reproducibility**

A pool of hemoglobin free feces extraction were divided into 5 groups, each was spiked with human hemoglobin, separately, at different concentrations, to obtain the following fecal hemoglogin concentrations: 0 ng/ml, 25 ng/ml, 50 ng/ml, 48 ng/ml, 60 ng/ml, 72 ng/ml, and 500 ng/ml. Twenty aliquots of each of the seven concentrations of spiked stool test samples were tested in randomized order. Those specimens were blind labeled and tested for comparison studies, POL studies and consumer studies.

- The correlation between the Instant-view® plus iFOB Test and the predicate device is ~100%.
- The results obtained from the three (3) POL sites by personnel with diverse education backgrounds and work experiences agreed 100% with the expected results. Three (3) different lots were tested, separately, one (1) for each site.

Therefore, per the evaluation studies, the accuracy and reproducibility of Instant-view® plus iFOB Test is ~100%.

3. **Specificity**

The Instant-view® plus iFOB Test is specific to human hemoglobin. The following substances, when spiked in both positive and negative specimens, did not interfere with the test results.

Substance	**Concentration** (ug/ml)
Beef Hemoglobin	2,000
Chicken Hemoglobin	500
Fish Hemoglobin (meat extract)	100
Horse Hemoglobin	500
Goat Hemoglobin	500
Pig Hemoglobin	500
Rabbit Hemoglobin	500
Sheep Hemoglobin (meat extract)	100
Horseradish Peroxidase	20,000
Red radish	Aqueous extract
Raw turnip	Aqueous extract
Cauliflower	Aqueous extract
Broccoli	Aqueous extract
Parsnip	Aqueous extract
Cantaloupe	Aqueous extract
Vitamin C (ascorbic acid)	Dietary supplement
Iron	Dietary supplement

REFERENCES

1. https://www.cdc.gov/cancer/colorectal/statistics/
2. American Cancer Society, Inc. Cancer Reference Information: Can Colon and Rectum Cancer Be Found Early? [Online] Available: http://www.cancer.org
3. Saito H. Screening for colorectal cancer by immunochemical fecal occult blood testing (Review). Jpn J Cancer Res 1996;87:1011-1024.

Manufactured by:

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