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"See Now" FOB CassetteTest CE

Feces

For in vitro Diagnosis Use
Product Code: SN 3.7

INTENDED USE

The *"See Now"* Fecal Occult Blood(FOB) test is a rapid and convenient immunochromatographic. It is used for *in vitro* qualitative determination of FOB in feces at or above the cutoff of 50 ng/ml. This assay provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the results of the test.

.PRINCIPLE

Fecal Occult Blood (FOB) is intended for professional use for blood present in the feces that is not visibly apparent. Hemoglobin in feces is an indication of internal bleeding associated with pathological conditions of gastrointestinal tract such as colon polyps, colorectal carcinoma, ulcerative colitis and Crohn's disease.

The principle of FOB Test is a double antibody sandwhich, immunochromatographic assay. The specific antibody to human hemoglobin is conjugated with colloidal gold particles and immobilized on the nitrocellulose membrane respectively. When the sample is added, hemoglobin molecules in the specimen can be captured by specific antibodies conjugated to colloidal gold. Through capillary action, the antigen-antibody-gold complexes are migrated along the nitrocellulose membrane and captured by the specific antibodies immobilized on the membrane. Red color lines will appear on the test zone (T) if hemoglobin presents in the specimen. The complexes will be moved continually and captured in the control zone (C) where the second antibody is immobilized. To serve as an internal process control, a control band should always be seen after test is completed. Absence of a colored control line in the control region is an indication of an invalid result.

MATERIALS SUPPLIED

- Pouch Contents: Cassette, Sample Dropper, a Vial with Diluent buffer; Desiccant; Test instruction

MATERIALS REQUIRED BUT NOT SUPPLIED

- Clean, specimen collection container, clock or timer.

SPECIMEN PREPARATION

- Collect a random sample of feces in a clean, dry container.
- Insert the stick into the feces a few times.
- Remove excess of feces from the stick by gently wiping it with an absorbent tissue.
- Add the feces sample and small amount diluent into a sterile tube, and mix the feces sample with diluent. The supernatant will be used for the test.

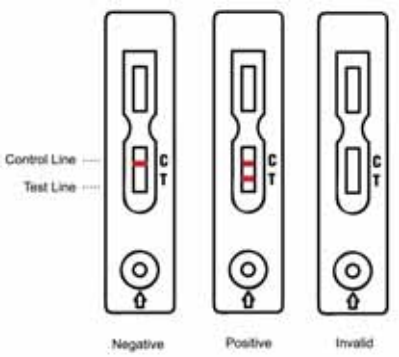
TEST PROCEDURE

- Remove the test device from the sealed pouch by tearing at the notch. Then place the testing device on a level surface. Thoroughly shake the collection tube containing fecal sample, to ensure proper mixing of the sample with the buffer solution.
- Holding the Sample dropper vertically, adds four full drops (0.2ml) of specimen without air bubbles into the sample well that is marked with an arrow on the testing device.
- Read the result at 15 minutes. Ensure that the background of the test area is white before interpreting the results. Do not read the results after 30 minutes.

INTERPRETATION OF RESULTS

Negative

Only one pink colored band appears at the control region.



Positive

Distinct pink colored bands appear at the control and test line regions.

Invalid

No visible band at the control region. Repeat with a new test device. If test still fails, please contact the distributor with the lot number.

STORAGE AND STABILITY

- Test device in the sealed pouch can be stored at 15-25ºC up to the expiration date. Do not freeze the test device.
- The test device should be kept away from direct sunlight, moisture and heat.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- Test device should remain sealed until use.
- Do not used after the expiration date shown on the pouch.
- Keep out of children's reach.

LIMITATION OF PROCEDURE

- This product is designed for in vitro diagnostic use only.
- There is always a possibility that false results will occur due to the presence of interfering substances in the specimen beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
- As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.