

Fecal Occult Blood (FOB) Test

Instructions For Use

Format: Cassette

Specimen: Fecal Extract

Catalog Number: A05-02-422

INTENDED USE

Artron One-Step Fecal Occult Blood (FOB) Test is a rapid and convenient immunochromatographic assay for the qualitative detection of hemoglobin in human fecal samples. It is intended for professional use as an aid in the diagnosis of colon polyps, colorectal carcinoma, ulcerative colitis and Crohn's disease. This assay provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the result of the test.

SUMMARY AND PRINCIPLE OF THE ASSAY

Fecal occult blood (FOB) refers to blood in the feces that is not visibly apparent. The presence of hemoglobin indicates internal bleeding associated with pathological conditions of gastrointestinal tract such as colon polyps, colorectal carcinoma, ulcerative colitis and Crohn's disease.

Artron One-Step FOB Test is an antigen-capture immunochromatographic assay, which detects the presence of hemoglobin in fecal samples. Monoclonal antibodies specifically against human hemoglobin are 1) conjugated with colloidal gold and deposited on the conjugate pad and 2) immobilized on the test line of the nitrocellulose membrane. When fecal sample is added the antibody conjugate is rehydrated and the hemoglobin, if any in the samples, will interact with the colloidal gold conjugated antibodies. The antigen-antibody-colloidal gold complex will migrate towards the test window until the Test Zone (T) where it will be captured by immobilized antibodies, forming a visible pink line (Test line), indicating a positive result. If hemoglobin is absent in the sample, no pink line will appear in the Test Zone (T), indicating a negative result.

To serve as an internal process control, a control line should always appear at Control Zone (C) after the test is completed. Absence of a pink control line in the Control Zone is an indication of an invalid result.

PACKAGE CONTENTS

- Pouch contents: Test Cassette, Desiccant.
- FOB Specimen Collection Vial (contains fecal specimen buffer 2 ml) PN A05-02-002.
- Test instructions.

MATERIALS REQUIRED (BUT NOT PROVIDED)

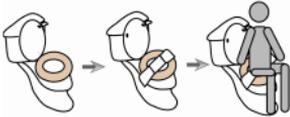
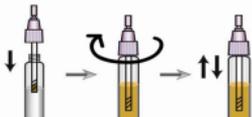
- Gloves.
- Clock or timer.

WARNINGS AND PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not reuse.
- Do not use if the pouch seal or its packaging is compromised.
- Do not use after the expiration date shown on the pouch.
- Do not mix and interchange different specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials or performing the assay.
- Wash hands thoroughly after finishing the tests.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Clean up spills thoroughly with appropriate disinfectants.
- Handle all specimens as if they contain infectious agents. Observe established precautions against bio-hazards throughout testing procedures.
- Dispose of all specimens and used devices in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations.
- Keep out of children's reach.

TEST PROCEDURES

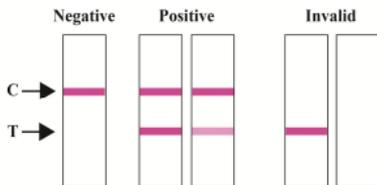
- Allow test, Specimen Collection Vial, specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing and collect a random sample of feces in a clean, dry specimen collection container.

<p>Place the sample collection pad on top of the toilet and deposit stool sample.</p>	
<p>Unscrew the cap of the fecal Specimen Collection Vial and take out specimen collection stick.</p>	
<p>Stab the specimen collection stick into the fecal specimen in at least 3 different sites (Do not scoop the fecal specimen).</p>	
<p>Insert the specimen collection stick into the tube and tighten the cap. Shake the tube vigorously to ensure thorough mixture of the specimen and the assay diluents reagent.</p>	
<p>Remove the test cassette from the sealed pouch and use it as soon as possible.</p> <p>Caution: Do not touch the test window and the membrane inside.</p>	
<p>Hold the fecal Specimen Collection Vial upright and break off the tip with hands. Invert the vial and add 3 full drops (120 µl) of specimen without air bubbles into the Sample Well of the cassette.</p>	
<p>Read the result within 15 minutes.</p> <p>NOTE: Specimens with high concentrations of FOB may produce positive results in as little as 1 minute and confirm negative results in 15-30 minutes.</p> <p>DO NOT INTERPRET RESULTS AFTER 30 MINUTES</p>	

Note:

- Best results will be obtained if the assay is performed within 6 hours after collecting fecal samples. The collected specimen may be stored for 3 days at 2-8°C if not tested within 6 hours.
- Specimens prepared in the Specimen Collection Vial may be stored for 3 days at room temperature (2-8°C) if not tested within 1 hour after preparation

RESULT INTERPRETATIONS



Negative

A pink colored band appears only at the control region (C), indicating a negative FOB result.

Positive

A clear pink control band (C) and a detectable test band (T) appear, indicating a positive FOB result.

Invalid

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

QUALITY CONTROL

Although the testing device contains an internal quality control (pink colored band in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

STORAGE AND STABILITY

- Test device in the sealed pouch should be stored at 2-30°C. Do not freeze the test device.
- The Specimen Collection Vial containing the buffer should be stored at 2-30°C.
- The test device should be kept away from direct sunlight, moisture and heat.

LIMITATIONS

- This product is an *in vitro* diagnostic test designed for professional use only.
- Humidity and temperature can adversely affect results.
- The instructions for the use of the test should be followed during testing procedures.
- There is always a possibility that false results will occur due to the presence of interfering substances in the specimen or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
- Although the test demonstrates superior accuracy in detecting hemoglobin in fecal extract, a low incidence of false results can occur. Therefore, other clinically available tests are required in case of questionable results. 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.

MANUFACTURER CONTACT INFORMATION



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