Fecal Occult Blood and Transferrin (FOB-TRF) Combo Test

Instructions For Use

Format: Cassette
Specimen: Fecal Extract
Catalog Number: A05-07-422

CE

* Please read the instructions carefully before use

INTENDED USE

Artron One-Step Fecal Occult Blood and Transferrin (FOB-TRF) Combo Test is a rapid and convenient immunochromatographic assay for the qualitative detection of human hemoglobin and transferrin in human faeces specimens. It is intended for professional use as an aid in the diagnosis of gastrointestinal bleeding caused by gastrointestinal diseases such as 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) test is a very specific and sensitive test for hidden (occult) blood in the feces. Fecal occult blood testing can provide clues as to subtle blood loss in the gastrointestinal tract. Positive tests warrant further investigation for a malignancy such as colorectal cancer or gastric cancer.

However, the presence of human haemoglobin in faeces is inadequate as a screening test for stomach cancer (upper gastrointestinal disorders), because of human haemoglobin derived from the upper digestive tract is broken down in the intestinal tract. Detection of fecal transferrin, which is more resistant to the metabolism in the intestine than hemoglobin, provides the best complementary way of diagnosing the disease in the upper digestive tract.

Transferrin is a blood plasma protein for iron ion delivery.Transferrin imbalance can have serious health effects for those with high serum transferrin levels. A patient with an increased serum transferrin level suffers from iron deficiency anemia that is one of the most important symptoms when a tumor has caused chronic occult bleeding.

Artron One-Step FOB-TRF Combo Test is an antigen-capture immunochromatographic assay, detecting the presence of transferrin and/or fecal occult blood in fecal samples. Monoclonal antibodies specifically against human transferrin and hemoglobin, respectively, are 1) conjugated with colloidal gold and deposited on the conjugate pad, and 2) immobilized on the Test Zone (T1 and T2) on the nitrocellulose membrane. When a fecal extraction sample is added, it rehydrates the gold-antibody conjugate and the transferrin and/or hemoglobin, if any in samples, interact with the colloidal gold conjugated antibodies. The antigen-antibody-colloidal gold complex will migrate towards the test window until the Test Zone (T1 and T2) where they are captured by immobilized antibodies, forming a visible pink line (indicate positive results). If transferrin and hemoglobin is absent in the sample, no pink line will appear in the Test Zone (T1 and T2), indicate negative results.

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.

Artron One-Step FOB-TRF combo Test can detect human hemoglobin at 30 ng/ml and transferrin at 10n g/ml diluted in extraction buffer provided

PACKAGE CONTENTS

- Pouch contents: Test Cassette, Desiccant.
- Fecal Specimen Collection tube with sample buffer (2 ml/tube).
- Test instructions.

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Gloves.
- Clock or timer.

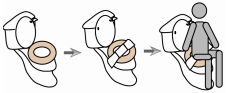
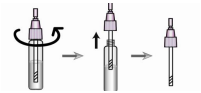
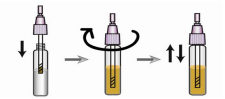
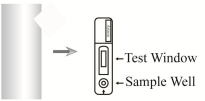
WARNINGS AND PRECAUTIONS

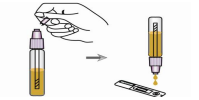
- For professional *in vitro* diagnostic use only.
- Do not reuse.
- Do not use if the pouch seal or its packaging is compromised.
- Do not use after the expiration date shown on the pouch.
- Do not mix and interchange different specimens.

- 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 tube, 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.

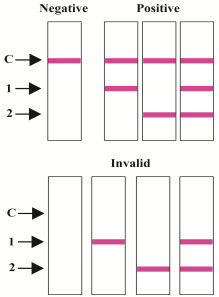
Place the sample collection pad on top of the toilet and deposit stool sample.	
Unscrew the cap of the fecal specimen collection tube and take out specimen collection stick.	
Stab the specimen collection stick into the fecal specimen in at least 3 different sites (Do not scoop the fecal specimen).	
Insert 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.	
Remove the test cassette from the sealed pouch and use it as soon as possible. Caution: Do not touch the test window and the membrane inside.	

Hold the fecal specimen collection tube 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.	
Read the result within 15 minutes. NOTE: Specimens with high concentrations of FT and/or FOB may produce positive results in as little as 1 minute and confirm negative results in 15-30 minutes. DO NOT INTERPRET RESULTS AFTER 30 MINUTES	

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 tube 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 result for FT and FOB

Positive
A clear pink control band (C) and a detectable test band (T1 and/or T2) appears, indicating a positive result:
T1: TFT positive
T2: FOB positive

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

RESULT REFERENCE

The reference below are given for orientation purpose only:

TRF	FOB	Digestive tract: Haemorrhage Level
+	+	Upper/lower, acute blood loss
+	-	Upper part, acute blood loss
-	+	Lower part, slight blood loss
-	-	No gastrointestinal bleeding

PERFORMANCE DATA

- Sensitivity is >99% compared to another commercial rapid test and the results of that guaiac assay.
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- Cross reactivity: there is not cross reactivity with common intestinal pathogens and substances occasionally present in feces: Rotavirus, Astrovirus, Campylobacter, Adenovirus, Escherichia coli, Giardia, Lactoferrin.

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 2-30ºC. Do not freeze the test device.
- The Fecal Specimen Collection Device containing the buffer should be stored at 2-30ºC.
- 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 transferring and 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

Artron

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Artron Laboratories Inc.
3938 North Fraser Way
Burnaby, BC
V5J 5H6 Canada

Ph: 604.415.9757
Fax: 604.415.9795
www.artronlab.com
info@artronlab.com

Wellkang Ltd
Suite B
29 Harley Street LONDON,
W1G 9QR
United Kingdom

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