



DRG[®] Fecal Occult Blood Rapid Test (RAP-3528)

As of 14 June 2005

RUO in the USA

**For the rapid detection of human hemoglobin in feces
For in vitro use only**

Summary

The DRG FOB Rapid Test is an immuno-chromatography rapid test designed for detection of fecal occult blood (FOB) in human feces. Detection in specimens as low as 50 ng/ml of human hemoglobin (hHB) with results within 10 minutes. A relative level of hHB in feces is important in the accurate diagnosis and treatment of diseases that can cause gastrointestinal bleeding.

Test Principle

The DRG FOB Rapid Test utilizes two site sandwich immunoassay technology and specific antibodies to hHB for the qualitative detection of FOB in human feces. Human hemoglobin (hHB) specific antibodies are precoated onto membrane as a capture reagents on the test band region. During the assay the specimen is allowed to react with anti-hHB gold-conjugate. The mixture then moves laterally on the membrane chromatographically to the test region with immobilized anti-hHB on the membrane. If hHB is present in the specimen, a color band is formed in the test region. The color band in the control region will always appear regardless the presence of hHB in feces.

Reagents Provided

The DRG FOB Rapid Test device and a vial with Running Buffer.

Storage and Stability

The DRG FOB Rapid Test device is to be stored refrigerated or at room temperature (2-25°C) for the duration of the shelf life. Under this condition, the test is stable for 12 months.

Precaution

1. The test is for *in vitro* diagnostic use only. In the United States, this kit is intended for Research Use Only.
2. Do not use beyond the expiration date.
3. Test device should remain sealed until ready for use.
4. Specimen collection should not be performed during or within three days of menstrual period, or if the patient suffers from bleeding hemorrhoids or blood in the urine; false positive test results may be obtained.
5. Alcohol, aspirin and other medications taken in excess may cause gastrointestinal irritation resulting in occult bleeding. Such substance should be discontinued at least 3 days prior to testing.

Specimen Collection and Storage

1. The One Step FOB Test is performed using human feces specimen.
2. Take a freshly collected specimen (about 0.5 grams in weight) with a plastic pipette or a wood stick) and add the sample into a glass vial with 2.0 ml running solution.
3. Close the cap of the vial tightly and shake the vial vigorously up and down for at least 10 times. Then let the vial sit for 1 minute to let the insoluble feces precipitates settle down.
4. If storage period greater than 3 days are anticipated, the specimens should be frozen. If samples are to be shipped, they should be packed in compliance with federal regulation covering the transportation of infectious agents.



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Assay Procedure

Before you begin:

1. Read through this entire description carefully.
2. Find a watch or timer to time the reaction of the test.
3. Do not use the test beyond the expiration date.
4. Do not open the protective pouch until just prior to performing the test,

Assay:

1. Bring tests and samples to room temperature (18-25°C) prior to use. DO NOT heat samples.
2. Remove the device from pouch by tearing and label the device with specimen identification.
3. Add three (3) drops (150 ul) of prepared/diluted specimen to sample (S) well.
4. Within 5 minutes, a pink-colored band will appear at the control (C) area of the test region, indicating the reaction is completed.

Sensitivity

The DRG FOB Rapid Test detects hHB at the concentration of about 50ng/ml of specimen solution as indicated by the development of a pink band in the test region of the test device.

Specificity

The DRG FOB Rapid Test is specific to human hemoglobin. The specimen contain the following interfering substances were tested on both positive and negative specimens with no effect on test results.

Substance	Concentration
Chicken Hemoglobin	500 ug/ml
Pork Hemoglobin	500 ug/ml
Beef Hemoglobin	2000 ug/ml
Goat Hemoglobin	500 ug/ml
Horse Homoglobin	500 ug/ml
Rabbit Hemoglobin	500 ug/ml
Horseradish Peroxidase	2000 ug/ml

Interpretation of Result

Positive: In addition to the control band, a distinct colored band will appear in the test (T) region indicates presence of hHB with 50 ng/ml or higher in feces.

Negative: Presence of a single pink colored band in the control region (C) indicates absence of hHB or the concentration

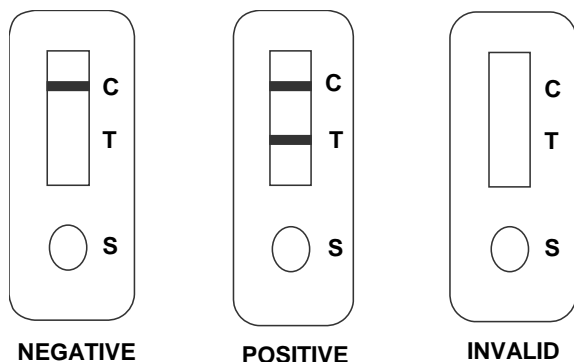
Invalid: If after 10 minutes no band is visible, the result is invalid. The protocol may not have been followed correctly or the test unit may have deteriorated. The test should be repeated with a new kit.

Note: Do not interpret result after 10 minutes.

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After testing:

Decontaminate area by disposing samples and all potentially contaminated materials appropriately as if they contained infectious agents.

Limitation

1. The DRG FOB Rapid Test is not reusable. The test works only if the instructions are followed precisely. Do not use the test after the expiration date shown on the package or if the moisture absorbent pack is wet.
2. Direct prolonged exposure to sunlight may cause spontaneous activation of the chromogen. For this reason, the test should be conducted or read in bright sunlight.
3. The rapid test result should be used as an aid in diagnosis and should not be interpreted as diagnostic by themselves.

Reference:

1. Schwautzm S., Dahl, J. Ellefson, M, and Ahlquist, D. "The Homo Quant Test: A Specific and Quantitative Determination of Heme (Hemoglobin) in Feces and Other Materials", Clin. Chem., Vol. 29 (1983):2061-67.
2. Saito, H., et al. "An Immunological Occult Blood Test for Mass Screening of Colorectal Cancer by Reverse-Passive Hemagglutination (RPHA)", Japanese Journal. Vol. 81 (1984):2831.
3. Tarranen, M.J., Lienwendahl, K. Paranen. P, and Aldercreutzl, H. "Immunological Detection oof Fecal Occult Blood in Colorectal Cancer", Br. J. Cancer, Vol. 49 (1984):141-48.
4. Simon, J.B. "Occult Blood Screening for Colorectal Critical Review.