



Diagnostic Automation/Cortez Diagnostics, Inc.

I M M U N O D I A G N O S T I C S

OneStep Fecal Occult Blood RapiDip™ InstaTest

REF 13020

PIC TM13020VV86



Fecal Occult Blood RapiDip™	
Principle	Chromatographic Immunoassay
Detection	Qualitative
Specificity	99.5%
Sensitivity	95.0%

PRODUCT FEATURES

✓ High Sensitivity and Specificity

✓ Built in Internal Controls

✓ Simplified Workflow, Non-invasive, and Safe

✓ Rapid and Faster Results

INTENDED USE

Cortez Diagnostics, Inc. Fecal Occult Blood RapiDip™ InstaTest (Feces) is a rapid chromatographic immunoassay for the qualitative detection of Human Occult Blood in feces.

SIGNIFICANCE AND SUMMARY

Many diseases can cause hidden blood in the feces. This is also known as Fecal Occult Blood (FOB), Human Occult Blood, or Human Hemoglobin. In the early stages, gastrointestinal problems such as colon cancer, ulcers, polyps, colitis, diverticulitis, and fissures may not show any visible symptoms, only occult blood. Traditional guaiac-based methods lack sensitivity and specificity, and also have diet restrictions prior to testing.^{1,2}

The FOB RapiDip™ InstaTest (Feces) is a rapid test to qualitatively detect low levels of Fecal Occult Blood. The test uses a double antibody sandwich assay to selectively detect Fecal Occult Blood at 50ng/ml or higher, or 6µg/g feces. In addition, unlike guaiac assays, the accuracy of the test is not affected by the diet of the patients.

ASSAY PRINCIPLE

The FOB RapiDip™ InstaTest (Feces) is a qualitative, lateral flow immunoassay for the detection of Human Occult Blood in feces. The membrane is precoated with anti-hemoglobin antibody on the test line region of the test. During testing, the specimen reacts with the particle coated with anti-hemoglobin antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-hemoglobin antibody on the membrane and generate a colored line. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region,

indicating that the proper volume of specimen has been added and membrane wicking has occurred.

REAGENT

The test contains anti-hemoglobin antibody particles and anti-hemoglobin antibody coated on the membrane.

SPECIMEN COLLECTION AND PREPARATION

1. Specimens should not be collected during or within three days of a menstrual period, or if the patient suffers from bleeding hemorrhoids or blood in the urine.
2. Alcohol, aspirin and other medications taken in excess may cause gastrointestinal irritation resulting in occult bleeding. Such substances should be discontinued at least 48 hours prior to testing.
3. No dietary restrictions are necessary before using the FOB RapiDip Test.

MATERIALS AND COMPONENTS

Materials provided with the test kit

1. Fecal Occult Blood Test device.
2. Specimen collection tubes with extraction buffer.
3. Instruction for use.
4. Reaction Tubes

Materials required but not provided

1. Specimen collection containers
2. Timer

ASSAY PROCEDURE

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. **To collect fecal specimens:** Collect feces in a clean, dry specimen collection container. Best results will be obtained

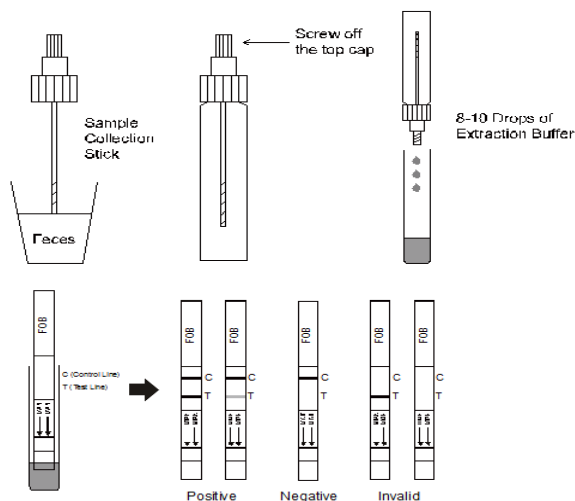


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if the assay is performed within 6 hours after collection. Specimen collected may be stored for 3 days at 2-8°C if not tested within 6 hours.

2. **To process fecal specimens:** Unscrew the cap of the specimen collection tube, then randomly stab the specimen collection applicator into the fecal specimen in at least 3 different sites. Do not scoop the fecal specimen. Screw on and tighten the cap onto the specimen collection tube, then shake the specimen collection tube vigorously to mix the specimen and the extraction buffer. Specimens prepared in the specimen collection tube may be stored for 6 months at -20°C if not tested within 1 hour after preparation.
3. Bring the pouch to room temperature before opening it. Remove the test dip from the foil pouch and use it as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch.
4. Fix the reaction tube, hold the specimen collection tube upright and break off the tip of the specimen collection tube. Invert the specimen collection tube and transfer 8-10 full drops of the extracted specimen (approx. 500µL) to the reaction tube, then with arrows pointing toward the extraction buffer, immerse the dip and start the timer. Do not immerse the dip past the maximum line. See illustration below.
5. Read results at 5 minutes. Do not read results after 10 minutes.



RESULTS

(Please refer to the illustration above)

- **Positive:** *Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T). ***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of Fecal Occult Blood present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.
- **Negative:** One colored line appears in the control line region (C). No line appears in the test line region (T).
- **Invalid:** Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

PERFORMANCE CHARACTERISTICS

Accuracy

The Cortez Diagnostics, Inc. FOB RapiDip™ InstaTest (Feces) has been compared with another leading commercial rapid test using clinical specimens.

Method	Results	Other Rapid Test		Total Result
Cortez, FOB RapiDip Test (Feces)	Positive	189	4	193
	Negative	10	802	812
Total Result		199	806	1005

Relative sensitivity: 95.0% (95%CI*: 91.0%~97.6%);

Relative specificity: 99.5% (95%CI*: 98.7%~99.9%);

Accuracy: 98.6% (95%CI*: 97.4%~99.0%).

*Confidence Intervals

Sensitivity

The FOB RapiDip™ InstaTest (Feces) can detect levels of Fecal Occult Blood as low as 50 ng/mL or 6 µg/g feces.

Precision

Intra-Assay

Within-run precision has been determined by using 15 replicates of three specimens: 50ng/ml, 100ng/ml and 10µg/ml positive specimens. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 15 independent assays on the same three specimens: 50ng/ml, 100ng/ml and 10µg/ml positive specimens. Three different lots of the FOB RapiDip™ InstaTest (Feces) have been tested using these specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The FOB RapiDip™ InstaTest (Feces) is specific to human hemoglobin. Specimens containing the following substances were diluted in the extraction buffer to a concentration of 1.0 mg/ml, and tested on both positive and negative controls with no effect on test results: Bovine hemoglobin, Chicken hemoglobin, Pork hemoglobin, Goat hemoglobin, Horse hemoglobin, Rabbit hemoglobin and Turkey hemoglobin.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal valid procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF PROCEDURE

1. The Cortez Diagnostics, Inc. FOB RapiDip™ InstaTest (Feces) is for in vitro diagnostic use only.

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2. The Cortez Diagnostics, Inc. FOB RapiDip™ InstaTest (Feces) will only indicate the presence of mFecal Occult Blood, the presence of blood in feces does not necessarily indicate colorectal bleeding.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. Other clinically available tests are required if questionable results are obtained.

PRECAUTIONS

1. For professional in vitro diagnostic use only. Do not use after expiration date.
2. The test should remain in the sealed pouch until use.
3. Do not eat, drink or smoke in the area where the specimens or kits are handled.
4. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
6. The used test should be discarded according to local regulations.
7. Humidity and temperature can adversely affect results.

STORAGE

The kit can be stored at room temperature or refrigerated (2-30°C). The Dip test is stable through the expiration date printed on the sealed pouch. The test Dip must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

REFERENCES

1. Simon JB. Occult Blood Screening for Colorectal Carcinoma: A Critical Review, Gastroenterology, 1985; 88: 820.
2. Blebea J, Mcpherson RA. False-Positive Guaiac Testing With

Iodine, Arch Pathol Lab Med, 1985;109:437-40.

MANUFACTURER AND BRAND DETAILS

ISO 13485:2016  ISO 13485 Quality Management for Medical Devices CERTIFIED	
 Diagnostic Automation/Cortez Diagnostics, Inc. 21250 Califa Street, Suite 102 and 116, Woodland Hills, California 91367 USA	
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