



## CORTEZ DIAGNOSTICS, INC.

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See external label



2°C-30°C



Σ=25 or 50 tests



Cat. #13010

# OneStep FOB RapiCard InstaTest

Cat. No. 13010

## INTRODUCTION

The One Step Cassette Style Fecal Occult Blood Test is a simple, direct binding immunoassay for the rapid and qualitative detection of human occult blood in feces. The assay is designed to detect lower levels of colorectal bleeding than other biochemical detection methods. The test principle is an immunochromatographic sandwich method, which employ two specific monoclonal antibodies to selectively identify hemoglobin in test samples. The result is very specific, and easier to interpret than those of guaiac-based test. The sensitivity is very high with the ability to detect 20 ng/mL hemoglobin in feces. In addition, the accuracy of the test is not affected by interfering substances, and dietary restriction is not necessary.

## SPECIMEN COLLECTION

Collect stool sample by using the special sample collection device provided. First, unscrew the top of the sample collection device, take out the sample collection stick, and collect the sample by dipping the stick into 3 different places of the stool sample. Then, put the sample collection stick back in the sample collection device and screw together tightly.

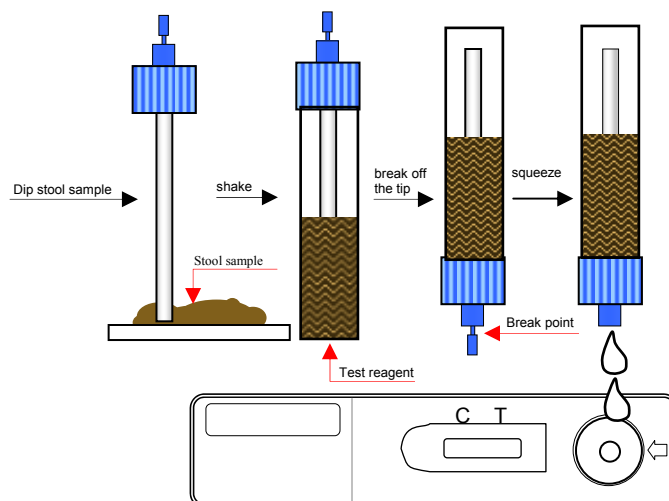
If the sample cannot be tested on the day of collection, store the stool sample at 4°C. Bring the specimen to room temperature before testing.

## MATERIALS PROVIDED

1. Test kit
2. Sample collection device

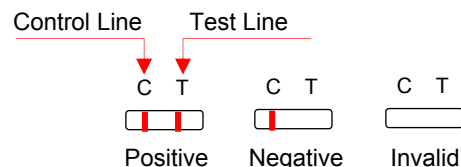
## TEST PROCEDURE

1. Remove the test device from its foil pouch by tearing along the notch.
2. Specimen collection. See also **SPECIMEN COLLECTION**
3. Shake the sample collection device several times.
4. Holding the sample collection device upright, carefully break off the tip of collection device.
5. Squeeze 4 drops of the sample solution on the test sample pad, as in the illustration.
6. Read the test results after 5-10 minutes. Do not read results after more than 30 minutes.



## INTERPRETATION OF RESULTS

- **Negative:** Only one colored band appears on the control region. No apparent band on the test region.
- **Positive:** In addition to a pink colored control band, a distinct pink colored band will also appear in the test region.
- **Invalid:** A total absence of color in both regions is an indication of procedure error and/or test reagent deterioration.



## STORAGE AND STABILITY

The test kit can be stored at temperatures between 2 to 30°C in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat.

## PRECAUTION

1. For *in vitro* diagnostic use only.
2. Patient specimens may contain infectious agents and should be handled as though capable of transmitting disease. Wear disposable gloves throughout the specimen collection and assay procedures.
3. Do not use the test kit beyond the expiry date.
4. The test device should not be reused.



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