



# CORTEZ DIAGNOSTICS, INC.

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		See external label		2°C-30°C
	Σ=25 or 50 tests		Cat. #13020-50	

## OneStep Fecal Occult Blood RapidDip InstaTest™

Cat. No. 13020-50 (50 tests)

### INTRODUCTION TO HemoStrip

**HemoStrip** is an immunochromatographic *in vitro* assay for qualitative determination of human hemoglobin in feces. Hemoglobin in feces is an indication of internal bleedings associated with pathological conditions of gastrointestinal tract such as colon polyps, colorectal carcinoma, ulcerative colitis, Crohn's disease.

**HEMOSTRIP** detects human hemoglobin at 88 mg/100 g feces (corresponds to final concentration 0.2 µg/ml in the collection buffer). The test kit allows performing 50 tests. It contains 50 sealed foil pouches, each containing one immunochromatographic test dipstick, 50 sample collection tubes with buffer, 50 test cups and a cup holder. A testing device is a test membrane with anti-hemoglobin antibodies and conjugates in a stabilizing matrix containing proteins and sodium azide, enclosed in plastic casing.

The result is read visually by observing the symbols developing in the test ("T") and control ("C") zones of the membrane. Distinctive control line serves as an indicator of proper performance of the test device.

**HemoStrip** is for *in vitro* diagnostic use only.

### Storage conditions

Store below 28°C; do not freeze.

### TEST PROCEDURE AND INTERPRETATION OF RESULTS

#### IMPORTANT

Do not open the foil pouch until you are ready to perform the test. If the test kit was stored refrigerated, bring the test components to room temperature before performing the test. During sample collection, be careful not to break the tip of the red cap of the tube.

### Sample collection

1. Collect a sample of feces in a clean, dry container.
2. Trying not to spill the buffer, unscrew and remove the cap with attached applicator stick from the collection tube.
3. Insert the stick into the feces a few times.
4. Remove excess of feces from the stick by gently wiping it with an absorbant tissue.
5. Reinsert the stick into the tube and tighten the cap thoroughly.

### Test procedure

1. Thoroughly shake the collection tube containing fecal sample, to ensure proper mixing of the sample with the buffer solution.
2. Place a test cup into a cup holder.
3. Holding the collection tube vertically, carefully break the tip of the red cap. Invert the tube and dispense six drops of the liquid into the test cup.
4. Open a foil pouch by tearing along the "notch". Remove a test dipstick and place it into the test cup, so that the arrows point down.
5. Read the test results at 5 minutes.

### Interpretation of the test results

The result is indicated by the two color lines (bands): the control line in the control (upper) region of the test membrane, and the test line in the test (lower) region of the membrane.



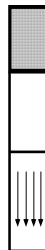
#### Positive

Two pink-rose lines (bands) are visible in the control (upper) and test (lower) areas of the membrane. The intensity of the test line may be less than that of the control line; this still means positive result: hemoglobin concentration in the sample liquid is 0.2 µg/ml or more.



#### Negative

The control line appears on the membrane, but the test line is not visible. Hemoglobin level in the sample liquid is below the **HemoStrip** sensitivity of 0.2 µg/ml.



#### Invalid

The test is invalid if the control line is not visible at five minutes. The test failed, or the test procedure was not followed properly. Verify the test procedure and repeat the test with a new test dipstick.

#### NOTE

Do not interpret **HemoStrip** results after more than five minutes. To avoid confusion, discard the test dipstick after registering the test result at five minutes.



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