

CORTEZ DIAGNOSTICS, INC.

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OneStep HbcAb IgM RapiCard InstaTest

Cat. No. 176578-1

INTRODUCTION

One Step Cassette Style anti-HBc-IgM Test is a rapid direct binding test for the visual detection of anti-hepatitis B core IgM in serum as an aid in the diagnosis of hepatitis B infection. One Step anti-HBc-IgM Test is based on the principle of inter-second antibody immunoassay for determination of anti-HBc-IgM in serum. Synthetic and recombinant HBcAg antigens are employed to identify anti-HBc-IgM specifically. This one step test is very sensitive and only takes about 10-20 minutes. Test results are read visually without any instrument.

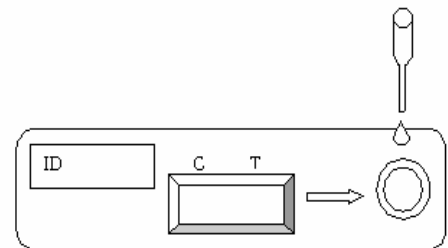
SPECIMEN COLLECTION

For serum, collect blood into a container without anticoagulant. Allow the blood to clot and separate the serum from the clot. Use the serum for testing.

If the specimen cannot be tested on the day of collection, store the serum specimen in a refrigerator or freezer. Bring the specimens to room temperature before testing. Do not freeze and thaw the specimen repeatedly.

TEST PROCEDURE

1. When you are ready to begin testing, open the sealed pouch by tearing along the notch. Remove the test from the pouch.
2. Dilute serum specimens (1:100) with Diluent Solution (which is ready to be used, no more further dilutions).
3. Draw 0.2ml (about 4 drops) diluted sample into the pipette, and dispense it into the sample well on the cassette.
4. Wait 10-20 minutes and read result. Do not read results after 30 minutes.



INTERPRETATION OF RESULTS

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



STORAGE AND STABILITY

The test kit can be stored at room temperature (18 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. Do not use test kit beyond expiry date.
3. The test device should not be reused.



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