

CORTEZ DIAGNOSTICS, INC.

23961 Craftsman Road, Suite E/F,
Calabasas, CA 91302 USA
Tel: (818) 591-3030 Fax: (818) 591-8383
E-mail: onestep@rapidtest.com
Web site: www.rapidtest.com

OneStep HBcAb RapiCard InstaTest

Cat. No. 176579-1

INTRODUCTION

Anti-HBc is one of the clinical Hepatitis B diagnostic indicators. The membrane is pre-coated with Anti-HBc antibodies on the test line region (T). During the test, the serum or plasma specimen reacts with the gold colloid conjugated HBcAg. The mixture migrates upward on the membrane chromatographically by capillary action and the Anti-HBc in serum will compete with Anti-HBc Antibodies on T line.

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.

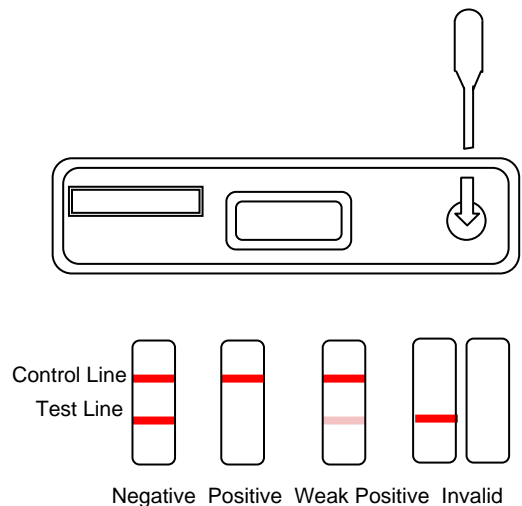
If the specimen cannot be tested on the day of collection, store the serum specimen in a refrigerator or freezer. Bring the specimens to room temperature before testing. Do not freeze and thaw the specimen repeatedly.

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. Draw 0.2 mL (about 4 drops) sample into the pipette, and dispense it into the sample well on the cassette.
3. Wait 10-20 minutes and read result. Do not read results after 30 minutes.

INTERPRETATION OF RESULTS

- **Positive:** Only one distinct pink colored band will appear in the control (C) region. No pink colored band appeared in the test (T) region. Test result shows that specimen has Anti-HBc.
- **Weak Positive:** In addition to a pink colored control band (C), there will be a faint pink band appearing in the test region (T). Test result shows that specimen has trace of Anti-HBc.
- **Negative:** Two colored bands appear in both test (T) and control (C) region. Test result shows that specimen has no Anti-HBc.
- **Invalid:** No band appearing in control region (C) is an indicator of procedural error and/or the test reagent has been deteriorated. Specimen should be re-tested again. If problem persists, stop using products from this lot.



STORAGE AND STABILITY

The test kit can be stored at temperatures between 4 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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