

CORTEZ DIAGNOSTICS, INC.

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OneStep HBcAb RapiDip InstaTest

Cat. No. 176587-1, 176580-1

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.

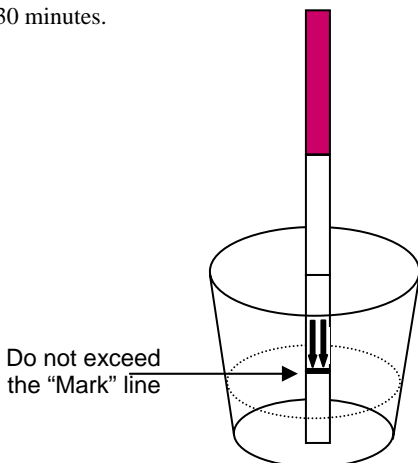
SPECIMEN COLLECTION & PREPARATION

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. Stir and 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 kit and use it as soon as possible.
2. Following the illustration, dip the test strip with the arrow side pointing down into the vessel of serum for about 10 seconds. Do not immerse past the marker line. Take the strip out and lay it flat on a clean, dry and non-absorbent surface.
3. Wait for 10 to 20 minutes and read results. Do not read results after more than 30 minutes.



PRECAUTION

1. For in vitro diagnostic use only.
2. Do not use test kit beyond expiry date.

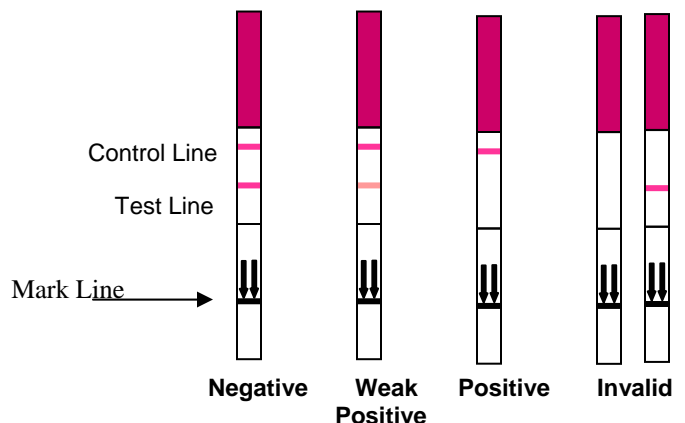
3. The test device should not be reused.

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.

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.



LIMITATIONS

1. Only test serum and plasma samples.
2. Interfering substance in the sample and technical error will affect the results; further testing is required.
3. Only detect the presence of Anti-HBc, it cannot show the concentration of Anti-HBc in the sample.
4. As with all diagnostic tests, all results must be considered with other clinical information available to the physician. A definite clinical diagnosis should only be made by the physician after all clinical and laboratory findings have been evaluated.



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