



DIAGNOSTIC AUTOMATION, INC.

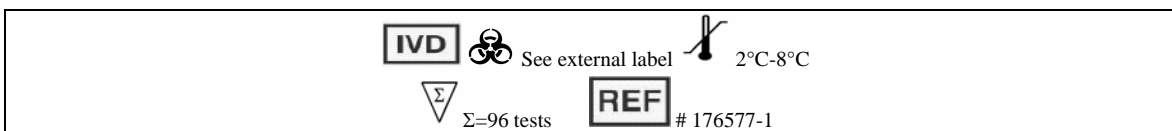
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OneStep HBeAb RapiCard™ InstaTest *Catalog No. 176577-1*

INTRODUCTION

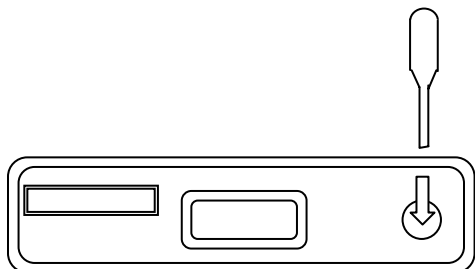
The OneStep HBeAb RapiCard™ InstaTest is a colloidal gold enhanced immunoassay for the determination of antibodies to Hepatitis B e antigen (ANTI-HBe) in serum. The nitrocellulose membrane is immobilized with mouse ANTI-HBeAg Mc-Ab on the test region. During the assay, the mixture of HBeAg and serum specimen is allowed to react with the colored conjugate (antibody-colloidal gold conjugate). The mixture then migrates on the membrane through capillary action.

SPECIMEN COLLECTION & PREPARATION

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 serum cannot be tested on the day of collection, it should be stored in a refrigerator or freezer. Stir and bring the serum to normal 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 from the pouch. Once the test kit is taken out from the pouch, use it as soon as possible. Label the device with patient or control identifications.
2. Add 3-4 drops of specimen mixture into the sample well by using the pipette provided. For each sample or control, use a separate pipette and device.
3. Wait 10-20 minutes and read results. It is important that the background is clear before the result is read. And do not read results after 30 minutes.



PRECAUTION

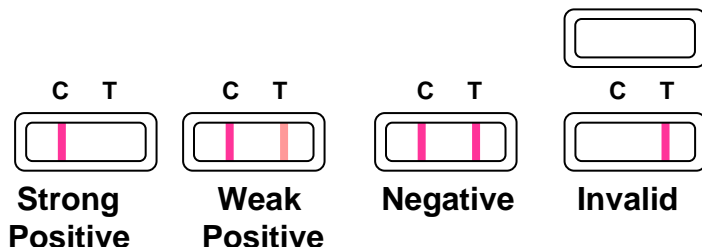
1. For in vitro diagnostic use only.
2. Do not use test kit beyond expiry date.
3. The test device should not be reused.

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

- **Negative:** In addition to one pink colored control (C) line in the control region, a distinct pink colored line will also appear in the patient test (T) region.
- **Strong Positive:** Only one colored lines appear in the control (C) region. No apparent line in the patient Test (T) region.
- **Weak Positive:** One colored line appears in the control (C) region, one colored test line appears in the test (T) region. The test line is lighter color than the control line.
- **Invalid:** A total absence of color in both regions or no colored line appears on the control (C) region is an indication of procedure error and/or test reagent deterioration.



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-HBe, it cannot show the concentration of Anti-HBe 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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