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OneStep HBsAg RapiCard InstaTest

Cat. No. 176571-1

INTRODUCTION

The One Step Cassette Style HBsAg Test is a rapid, direct binding test for the visual detection of hepatitis B surface antigen (HBsAg) in serum. It is used as an aid in the diagnosis of hepatitis B infection. One Step HBsAg Test is based on the principle of sandwich immunoassay for determination of HBsAg in serum. Monoclonal and polyclonal antibodies are employed to identify HBsAg specifically. This one step test is very sensitive and only takes about 10-20 minutes. Test results are read visually without any instrument.

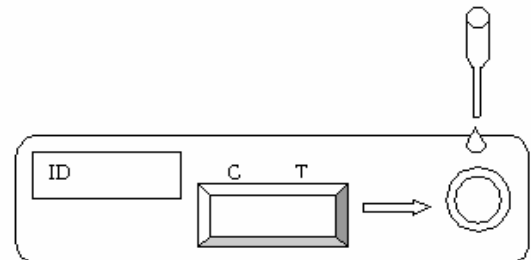
SPECIMEN COLLECTION & PREPARATION

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 from the pouch.
2. Draw 0.2ml (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

- **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.

LIMITATIONS

1. 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.
2. This test should be used for the detection of HBsAg in serum specimen.
3. This test kit will only indicate the presence of HBsAg in the specimen and should not be used as the sole criteria for the diagnosis of Hepatitis B viral infection.
4. This test kit cannot detect less than 1 ng/mL of HBsAg in specimens. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of Hepatitis B infection.



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