

INTRODUCTION

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

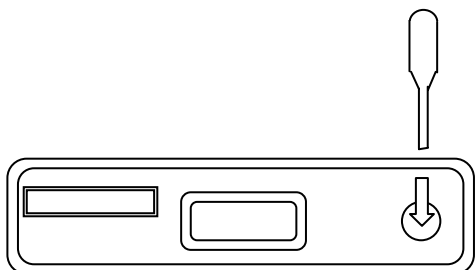
SPECIMEN COLLECTION & PREPARATION

Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.

If the specimen cannot be tested on the day of collection, store the 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, remove the test device from its protective 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 4 drops (~120uL) of specimen 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

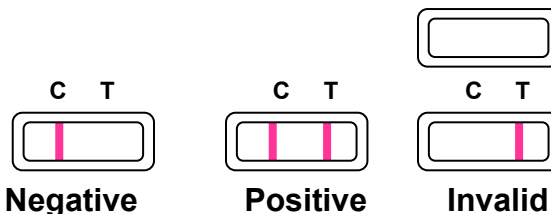
1. For in vitro diagnostic use only.
2. Do not use test kit beyond expiry date.
3. The test device should not be reused.
4. Do not compare results from a different device.
5. Serum/plasma specimens may be infectious; insure proper handling and dispose of all used reaction devices into a biohazard container.
6. Using a new specimen collection container and specimen pipette for each sample to avoid cross-contamination of samples.

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:** Only one colored band appears on the control region. No apparent band on the test region.
- **Positive:** In addition to a pink colored control band, a distinct pink colored band will also appear in the test region.
- **Invalid:** None of line appears or no line appears in the control (C) region. An invalid result may be due to improper testing procedures or deterioration of the kit components. Repeat the assay sequence using a new device.



LIMITATIONS

1. Only test serum and plasma samples.
2. 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.
3. This test is for in vitro diagnostic use only.
4. Interfering substance in the sample and technical error will affect the results; further testing is required.