

One Step Cassette Style HBsAg Test

INTRODUCTION

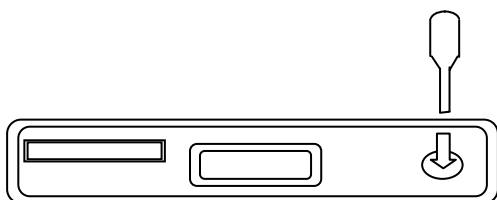
The One Step Cassette Style HBsAg Test is a rapid, direct binding test for the visual detection of hepatitis B surface antigen (HBsAg) in serum. It is used as an aid in the diagnosis of hepatitis B infection. One Step HBsAg Test is based on the principle of sandwich immunoassay for determination of HBsAg 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 kit from the pouch and use it as soon as possible.
2. Draw 120 mL (about 3-4 drops) sample using the pipette, and dispense it onto the sample well of the cassette.
3. Wait for 10-20 minutes and read results. It is important that the background is clear before the result is read. Do not read results after more than 30 minutes.



PRECAUTION

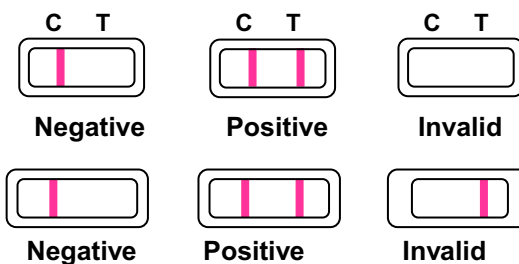
1. For in vitro diagnostic use only.
2. Do not use test kit beyond expiry date.
3. The test device should not be reused.
4. Keep out of the reach of children.

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.

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 colored control (C) band, a distinct pink colored band will appear in the test (T) region.
- ⌚ **Invalid:** A total absence of color in both regions or no colored line appears in the control (C) region is an indication of procedure error and/or test reagent deterioration. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



SENSITIVITY:- up to 1ng/ml

SPECIFICITY:- 99.8%

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.

SPECIFICITY:

Cross reactivity has been tested with Anti-HIV, AntiHCV, Anti-HBc positive serums, no cross reactivity was found with the above

Clinical Trials: (Comparative Evaluation with other Leading International Brands).

Another commercially available qualitative test kit (Abbott HBsAg) was used to compare with IND Diagnostic One-step HBsAg test kit for relative sensitivity and specificity in 605 serum samples. Only 2 samples were discordant, the agreement is 99.7%. The detailed results are shown in Table 1.

	Results of IND kits			Sub total
	+	-		
Results of Abbott kits	161	1	162	162
Subtotal	1	442	443	443
Subtotal	162	443	605	605

References:

1. Kim,C.Y, Tilles,J.G. Purification and biophysical characterization of hepatitis antigen. J. Clin Invest. 52:1176-1186(1973).
2. Rubin, E. Acute and chronic viral hepatitis. Federation Proceedings: 38(13): 2665-2673(1979).
3. Magnus L,O., Lindhoim, A., Lundin, P., Iwarson, S.A. New antigen-antibody system. Clinical significance in long-term carriers of hepatitis B surface antigen. J. Am. Med. Assoc. 231:356359(1975).