

EXPLANATION OF THE TEST

The ASAN EasyTest[®] Anti-HBs is a chromatographic immunoassay for the rapid qualitative determination of antibodies to the HBs surface antigens in serum, plasma. Anti-HBs is allowed to react with the colloidal gold-HBs Ag conjugate on the test line, which has been pre-dried on the test strip. The mixture then moves upward on the membrane by the capillary action. For positive result, a visible line appears in the test line region of the membrane.

MATERIALS PROVIDED

The ASAN EasyTest[®] Anti-HBs kit contains following items to perform the assay.

1. Test device individually foil-pouched with a desiccant
2. Instruction manual for use

PRECAUTIONS

The ASAN EasyTest[®] Anti-HBs should be stored at room temperature 2-30°C. The test device is sensitive to humidity as well as to heat. Perform the test immediately after removing from the pouch. Do not use it beyond the expiration date.

SPECIMEN COLLECTION AND STORAGE

1. Should be performed using human serum or plasma.
2. Should be stored at 2~8. For prolonged storage, freezing is recommended.
3. Should be clarified prior to assay for the specimens containing precipitation. It may precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

WARNINGS

1. For *in vitro* diagnostic use only.
2. Do not eat or smoke while handling specimens.
3. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
4. Avoid splashing or aerosol formation.
5. Clean up spills thoroughly using an appropriate disinfectant.
6. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.

TEST PROCEDURE

1. Add 100μl of serum or plasma sample in a Sample well.
2. Interpret test results at 20 to 30 minutes. Do not interpret after 30 minutes.

※ **CAUTION** : The above interpretation time is based on reading the test results at room temperature of 15 to 30 °C . If your room temperature is significantly lower than 15 °C , then the interpretation time should be properly increased.

INTERPRETATION OF THE TEST

1. A color band will appear in the upper section of the strip to show that the test is working properly. This band is the Control Band.
2. The down section of the strip indicates the test results. If another color band appears in the down section of the strip, this band is the Test band.

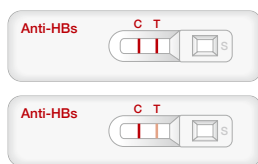
A. NEGATIVE RESULTS:

The presence of only one purple color band(control band) within the window indicates a negative result .



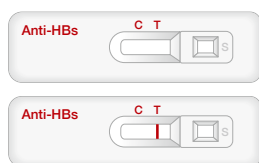
B. POSITIVE RESULTS:

The presence of two color bands ("T" band and "C" band) within the result window regardless of which band appears first indicates a positive result .



C. INVALID RESULTS:

If no band is visible within the window after performing the test the result is considered invalid . Some causes of invalid results are: not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test kit.



LIMITATIONS OF THE TEST

A negative result does not preclude the possibility of infection with HBV. Other clinically available tests are required if questionable results are obtained. As all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but be made by the physician after all clinical and laboratory findings have been evaluated.

STORAGE & EXPIRATION

1. ASAN EasyTest[®] Anti-HBs Ab should be stored between 2 to 30°C (35.6~86 °F).
2. Expiration date of this kit is 24 months after its manufacture date.

REFERENCES

1. Aubuchon JP, Sandler SG, Fang CT, et al, "American Red Cross Experience With Routine Testing for Hepatitis B Core Antibody," *Transfusion*, 1989, 29(3):230-2.
2. Chambers LA and Popovsky MA, "Decrease in Reported Posttransfusion Hepatitis. Contributions of Donor Screening for Alanine Aminotransferase and Antibodies to Hepatitis B Core Antigen and Changes in the General Population," *Arch Intern Med*, 1991, 151(12):2445-8.
3. Bortolotti F, Calzia R, Cadrobbi P, et al, "Long-Term Evolution of Chronic Hepatitis B in Children With Antibody to Hepatitis B Antigen," *J Pediatr*, 1990, 116(4):552-5.
4. Edwards MS, "Hepatitis B Serology Help in Interpretation," *Pediatr Clin North Am*, 1988, 35:503-15.
5. Jackson JB, "Polymerase Chain Reaction Assay for Detection of Hepatitis B Virus," *Am J Clin Pathol*, 1991, 95(4): 442-4.
6. Repp R, Rhiel S, Heermann KH, et al, "Genotyping by Multiplex Polymerase Chain Reaction for Detection of Endemic Hepatitis B Virus transmission , *J Clin Microbiol*, 1993, 31(5): 1095-102.
7. Lee HS and Vyas GN, "Diagnosis of Viral Hepatitis," *J Clin Microbiol*, 1987, 7:741-57.