



ASAN EASY TEST[®] Anti-HBs Strip

Diagnostic Kit for Detection of Hepatitis B Virus antibody

1. EXPLANATION OF THE TEST

The ASAN Easy Test Anti-HBs Strip is a chromatographic immunoassay for the rapid qualitative determination of antibodies to the HBs surface antigens in serum. HBs antibodies in serum are 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. The sensitivity of the ASAN Easy Test Anti-HBs Strip is 10mIU/ml.

2. MATERIALS PROVIDED

The ASAN EASY TEST Anti-HBs Strip kit contains following items to perform the assay.

1. ASAN EASY TEST Anti-HBs Strip
2. Instructions for use

3. PRECAUTIONS

The ASAN EASY TEST Anti-HBs Strip should be stored at room temperature 4–30°C (40–86°F). The test Strip is sensitive to humidity as well as to heat. Perform the test immediately after removing from the plastic tube. Do not use it beyond the expiration date.

4. SPECIMEN COLLECTION AND STORAGE

1. The test may be performed using human serum.
2. If specimens are not immediately tested they should be refrigerated at 2–8°C. For prolonged storage, freezing is recommended. They should be brought to room temperature prior to use.
3. Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

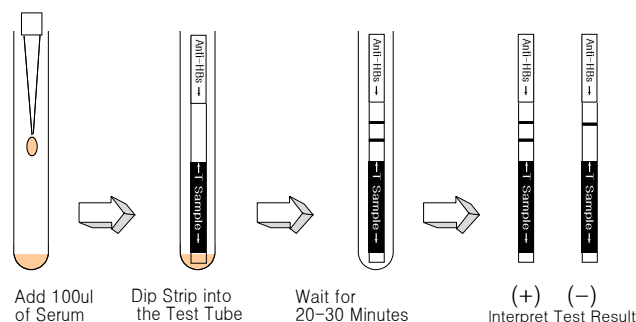
5. WARNINGS

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.
7. Do not use the test kit if the pouch is damaged or the seal is broken.

6. TEST PROCEDURE

1. Add 100 ul) of serum sample in a test tube .
2. Holding the strip vertically carefully dip it into the test tube.
3. 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.



7. 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 tube band.

A. 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 . Note: Generally, the higher the analyte level in the specimen, the stronger the "T" band color will be.

B. NEGATIVE RESULTS:

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

C. INVALID RESULTS:

If after performing the test no band is visible within the strip, 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.



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8. 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 with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

9. PERFORMANCE CHARACTERISTICS

Accuracy

Multi-site studies were performed using a total of 200 patients. Each specimen was tested with the ASAN EASY TEST Anti-HBs Strip and a commercially available test (ELISA). The results are summarized in the following tables.

	<u>Anti-HBs Positive</u>	<u>Anti-HBs Negative</u>
<u>ELISA Positive (87)</u>	85	2
<u>ELISA Negative (113)</u>	2	111

The overall relative sensitivity is 98.0% (85/87), and the overall relative specificity is 98.0% (111/113).

10. REFERENCES

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4. Edwards MS, "Hepatitis B Serology Help in Interpretation," *Pediatr Clin North Am*, 1988, 35:503-15.
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