

EXPLANATION OF THE TEST

The ASAN EasyTest[®] Anti-HBe is a chromatographic immunoassay for the rapid qualitative determination of anti-hepatitis e virus antigen antibody(anti-HBe) in human serum or plasma. For diagnosis of anti-HBe, the specific antibodies to HBeAg were used as a capture materials and gold conjugate. Also, The ASAN EasyTest[®] Anti-HBe contains recombinant HBeAg (rHBeAg) in sample pad. Therefore, anti-HBe of human serum or plasma competes with the rHBeAg. The antibody-antigen mixture then moves upward on the membrane by capillary action. For positive result, a non-visible line appears in the test band region. The control line will always appear and verify proper performance of the test. The ASAN EasyTest[®] Anti-HBe minimizes the possibility for the false positive and places high confidence in the test result using high quality of antibodies.

MATERIALS PROVIDED

The ASAN EasyTest[®] Anti-HBe 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-HBe should be stored at 2~30 °C. The test device is sensitive to humidity as well as to heat. Perform the test immediately after removing from the foil 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. Refrigerated specimens or other materials should be equilibrated to room temperature right before performing the test.
2. Remove the device from its protective pouch.
3. Add 100µl/test of serum or plasma specimens into the sample well.
4. Interpret test results within 15-20 minutes. Do not interpret after 20 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("C" zone) of the window to show that the test is working properly. This band is the Control Band.
2. The down section("T" zone) of the window indicates the test results, this band is the test band.

A. NEGATIVE RESULTS:

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



B. POSITIVE RESULTS:

The presence of only one purple color band(control band) within the window 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

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-HBe should be stored between between 2 to 30°C (35.6~86 °F). 
2. Expiration date of this kit is 24 months after its manufacture date.