IVD

Asan Easy Test® AFP

Diagnostic Kit for Alpha Fetoprotein Detection

Immunochromatography

EXPLANATION OF THE TEST

AFP (α-feto protein) is a glycoprotein with molecular mass of 70,000 Da, produced by both the yolk sack and the fetal liver, but not adult. However, its considerable increase in the plasma of adults is the hallmarker of the development of hepatomacellular carcinoma or hepatitis. Its normal concentration in serum is below 10ng/ml. The Asan Easy Test® AFP is an immunochromatographic assay for the rapid quantitative detection of α-feto protein (AFP) in human serum, plasma, and also has advantages of easy handling, and cost-effective with no special equipment.

MATERIALS PROVIDED

The Asan Easy Test® AFP contains following items to perform the assay.

1. Test device in aluminium pouch with a desiccant.
2. Instruction manual for use.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. The test kit should remain in the sealed pouch until ready for use.
3. The test kit is sensitive to humidity and to heat.
4. Do not smoke, eat or drink in areas where specimens or kit component are handled.
5. All specimens and reagents should be considered potentially hazardous and handled in the same manner as an infection agent.
6. Wear protective gloves while handling samples and wash hands thoroughly after the assay is complete.
7. Avoid any contact with the eyes, broken skin or mucous membranes.
8. The test device and all materials should be discarded in a proper biohazard container after testing.

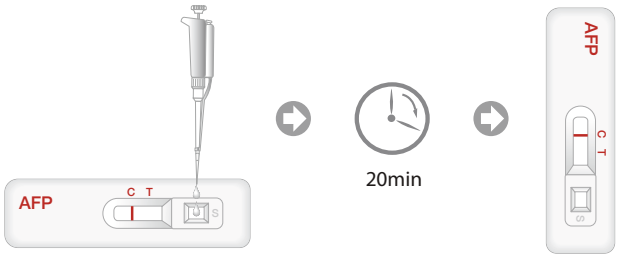
SPECIMEN COLLECTION AND STORAGE

1. The test should be performed using human serum or plasma.
2. If specimens are not immediately tested, they should be refrigerated at 2~8℃ . For storage periods more than three days, freezing is recommended.
3. Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assay.

TEST PROCEDURE

1. All materials should be equilibrated to room temperature before performing test.
2. Remove the device from its protective pouch.
3. Add 100㎕ of serum or plasma into the sample well(S).
4. Interpret test results within 20 minutes. Do not interpret after 30 minutes.

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



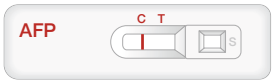
Add 100㎕ of serum or plasma — Reading

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 a control band.
2. The down section ("T" zone) of the window indicates the test results, test band. If another color band appears in the down section of the window, this band is a test band.

A. NEGATIVE RESULTS:

The presence of only one purple color band ("C" band) within the result 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 .

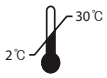
C. INVALID RESULTS:

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

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 be made by the physician after all clinical and laboratory findings have been evaluated.

STORAGE & EXPIRATION



1. Asan Easy Test® AFP should be stored at 2 ~ 30℃ (35.6 ~ 86 ℉).
2. Expiration date of this kit is 24 months after its manufacture date.

PERFORMANCE CHARACTERISTICS

This clinical test was performed using a total of 154 specimens. Each specimen was tested with Asan Easy Test® AFP and Commercial AFP. The results are summarized in the following tables.

n= 154		Commercial AFP		Total
		Positive	Negative	
Asan Easy Test® AFP	Positive	29	1	30
	Negative	0	124	124
Total		29	125	154

※ Relative Sensitivity : 100%, Relative Specificity : >99.2%

※ Detection limit : 20 ng/ml

ISO13485:2003

Manufactured & Sold by
ASAN PHARMACEUTICAL CO., LTD
Factory1 : 163, Yeongcheon-ro, Hwaseong-si, Gyeonggi-do 18462, Korea
Factory2 : 122-26, Gieopdanji-ro, Gongdo-eup, Anseong-si, Gyeonggi-do, 17551, Korea

Tel: +82-31-376-5990~2
Fax: +82-31-376-5993
http://www.asanpharm.com

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