Humasis

AFP card

One Step AFP Test

For professional use

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Please read the instructions carefully before use!

[INTENDED USE]

Humasis AFP Card is a one step in vitro diagnositc test based on immunochromatographic assay. It is designed for qualitative determination of human AFP in serum or plasma specimen.

[SUMMARY AND EXPLANATION]

Alpha-fetoprotein(AFP) is a glycoprotein with a molecular weight of approximately 70 kilodaltons. AFP is synthesized primarily in the liver and yolk sac of the fetus. It is secreted into fetal serum, reaching a peak at about 13 weeks gestation and gradually declining thereafter. Elevated serum AFP levels reappear during pregnancy and in conjunction with several malignant diseases such as testicular cancer, hepatocellular carcinoma, viral hepatitis and cirrhosis. The amount of AFP in the blood of a pregnant woman can help diagnose whether the fetus may have such problems as spina bifida, anencephaly, or Down syndrome. An AFP test can be done to detect others, more are conditions, such as chromosome(trisomy) syndromes or omphalocele, a congenital defect in which portion of a fetus`s intestines protrude through the abdominal wall.
Normal AFP value in healthy men and nonpregnant women is less than 20ng/mL but in pregnant women, it varies according to the age of fetus and woman`s weight and race.

[PRINCIPLE OF THE TEST]

Humasis AFP Card utilizes two site sandwich immunoassay technology and specific antibodies to AFP for the qualitative detection of AFP concentration in serum or plasma specimen. AFP specific antibodies are coated on the membrane as a capture reagent on the test region.
During the assay, the specimen reacts with the anti-AFP gold conjugate. then moves laterally on the membrane towards the other end of the test device. If AFP level is close to or higher than 20ng/mL in the specimen, a color line is appeared in the test region, indicating a positive result. If no line is formed in the test region, the result is negative. The line is in the control region should always appear and serve as an internal qualitative control.

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Test devices
Instruction manual

[COMPOSITION]

Anti-mouse immunoglobulin G ..... 0.25±0.4ug(Control Line)
Goat anti-AFP polyclonal antibody ..... 0.64±0.3ug(Test Line)
Mouse anti-AFP monoclonal antibody ..... 0.14±0.05ug(Gold Conjugate)

[STORAGE AND SHELF-LIFE]

1. Store the test device packaged in a sealed foil pouch at 2~30℃(36~86℉). Do not freeze.
2. Shelf-life : 24 months from manufacturing date

[PRECAUTIONS]

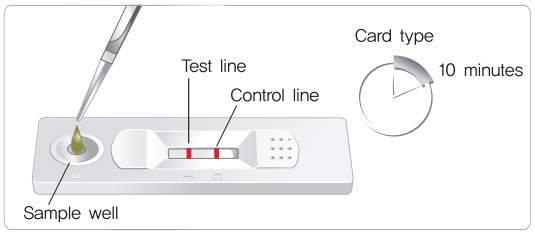
1. For in vitro diagnostic use only.
2. Do not use the test device after the expiry date.
3. Handle all specimens as potentially infectious.

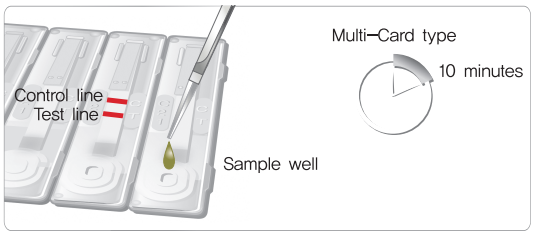
[SPECIMEN COLLECTION AND PREPARATION]

1. The serum or plasma specimen may be used as samples.
2. The serum or plasma specimen should be collected under standard laboratory conditions.
3. If plasma or serum samples must be stored for more than 24 hours, they should be frozen at -20℃ or below.
4. Bring all specimens to room temperature before testing.
   Note : - Heat inactivation of specimens, which may cause hemolysis and protein denaturation, should be avoided.
   - The blood cells or clotting substance of specimen should be removed, Do not test specimens which are heavy hemolysis of have high lipid concentration.

[TEST PROCEDURE]

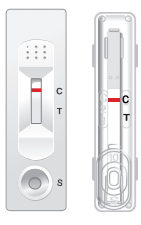
1. Bring all materials and specimens to room temperature before beginning the test, and then open the foil pouch and place the device on a clean, dry and level surface.
   Note : Once the test device is removed from the pouch, it should be used as soon as possible.
2. Write the specimen ID on the test device
3. Holding the pipette vertically, add exactly 100㎕ of blood specimen into the sample well.
   Note : Use a fresh pipette or tip for each sample in order to prevent cross -contamination.
4. Wait for 10 minutes and then read the results. Do not interpret the results after 15 minutes.





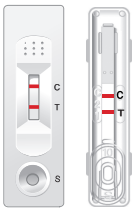
[INTERPRETATION OF RESULTS]

1. Negative



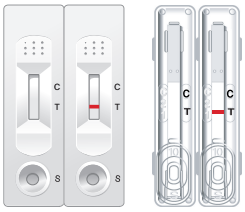
If the test region(T) has no color line and the control region(C) displays a colored line, the result is negative.

2. Positive



If the test region(T) has a colored line and the control region(C) displays a colored line, the test result is positive.

3. Invalid



If there is no distinct red line in the control region(C), the result is invalid. This is due to deterioration of the test device or improper test procedure. Repeat the test with a new testing device.

[QUALITY CONTROL]

The control line is an internal control of the test reagents and procedure. It will appear if the test has been performed correctly and the reagents are reactive.

[LIMITATION OF THE TEST]

1. For samples that test positive by Humasis AFP Card, more specific confimatory testing should be done.
2. A clinical evaluation of the patient`s situation and history should also be made before a final diagnosis is established.

[EXPECTED VALUES]

Humasis AFP Card is designed to yield a positive result for AFP concentration at 20ng/mL or greater.

[PERFORMANCE CHARACTERISTICS]

Humasis AFP Card	Commercial AFP EIA		Total
	Negative(〈20ng/mL)	Positive(〉20ng/mL)	
Negative	146	2	148
Positive	0	92	92
Total	146	94	240

Relative Sensitivity : 97%(92/94)
Relative Specificity : 〉99%(146/146)
Accuracy : 99%(238/240)

[INTERFERING SUBSTANCES]

The following substances do not interfere with the Humasis AFP test result

• Ampicillin	• EDTA	• Pyridoxine HCl
• Amoxicillin	• Ethanol	• Rivoflavin
• Ascorbic acid	• Glucose	• Salicylic acid
• Acetaminophen	• Heparin	• Sodium citrate
• Bilirubin	• Hemoglobin	• Sodium chloride
• Brompheniramine	• Human albumin	• Triglycerides
• Cyanocobalamine	• Nicotinic acid amide	• Thiamine HCl
• Calcium pantothenate	• Oxalic acid	

[REFERENCES]

1. Sizaret P et al., Equivalence between international units and mass units of alpha-foetoprotein. *Clin Chim Acta*. 1979, 96(1-2):59~65.
2. Melbye M et al., Alpha-fetoprotein levels in maternal serum during pregnancy and maternal breast cancer incidence. *J Natl Cancer Inst*. 2000, 92(12):1001~1005.
3. Bock JL et al., Current issues in material serum alpha-fetoprotein screening. *Am J Clin Pathol*. 1992, 97(4):541~554

IVD : For *in vitro* diagnostic use
LOT : Lot number
REF : Catalogue number
: Consult instructions for use
: Store at 2~30℃
: Do not reuse
EC REP : Authorized Representative
: Manufactured by
EXP : Use by / Expiry date
CE : This product fulfills the requirements for Directive 98/79/EC on *in vitro* diagnostic medical devices

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