(AFP)Alpha-Fetoprotein Rapid Diagnostic Kit

(Immunochromatography)

Product Name

(AFP)Alpha-Fetoprotein Rapid Diagnostic Kit (Immunochromatography)

Intended Use

It is used as an aid in the diagnostic of primary hepatocellular carcinomas, testicular teratocarinomas and neural tube defects.

Test Principle

The test utilizes antibodies including anti-mouse antibodies on the nitrocellulose. The reagent is used to detect the AFP according to the principle of double antibody sandwich method and gold immunochromatography assay.

Main components

Sample pad, colloidal gold marked pad, nitrocellulose membrane, absorbent paper and PVC board.

Sample requirement

1. Collect venous blood a clean and dry container according to the standard method. Separate the serum or plasma for testing. EDTA, sodium citrate, sodium oxalate, heparin can be used as the anticoagulants

2. After collection, separate the serum and plasma as soon as possible, in order to avoid hemolysis.

3. Use fresh samples. Samples may be stored in a refrigerator or freezer. Do not freeze and thaw the sample repeatedly. Frozen refrigerated samples should be recovered to room temperature before detection.

Storage and Expiry

Store as packaged in the sealed pouch at 4-30°C, avoid hot and sunshine, dry place, valid for 24 months. DO NOT FREEZE. Some protective measures should be taken in hot summer and cold winter to avoid high temperature or freeze-thaw.

Test Procedure

Instructions must be read entirely before taking the test. Allow the test device controls to equilibrate to room temperature for 30 minutes (20℃-30℃) prior to testing. Do not open the inner packaging until ready, it must be used in one hour if opened (Humidity: 20%~90%, Temp: 10℃-50℃)

Strip and Cassette:

1. Take off the outer packing, put the strip/cassette onto the desk with the sample adding area of the strip/ the sample window of the cassette up.

2. Drop 3 full drops of serum/plasma/whole blood (approx.80- 100μl) vertically into the sample adding area of the strip/sample hole of the cassette.

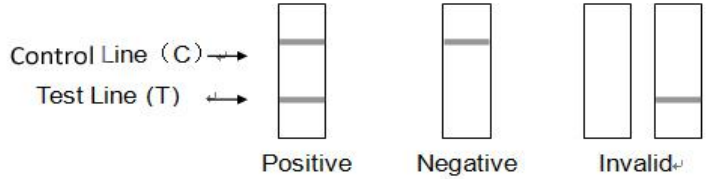
3. Observe the test results within 15-20 minutes the result is invalid over 30 minutes.

Result Judgment

POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and the other line should be in the test region (T).

NEGATIVE: One red line appears in the control region(C). No apparent red or pink line appears in the test region (T).

INVALID: No red lines appear or control line fails to appear, indicating that the operator error or reagent failure. Verify the test procedure and repeat the test with a new testing device.



Limitation

The results of the reagent are only for clinical reference, a confirmed diagnosis should be made only by a physician after all clinical and laboratory findings have been evaluated.

Precaution

1. For IN VITRO diagnostic use only. For AFP detect in human serum/plasma/whole blood only.

2. Do not use after the expiration.

3. All samples and reagents should be considered potentially hazardous and handled in the same manner as an infectious agent after use.

4. Do not use other kinds of quality control sample to test the reagent. Components of different batches cannot be exchanged for use to avoid erroneous results.