One Step Rapid Diagnostic Kit
AFP/CEA/PSA Rapid Test Cassette
(Immunochromatography)

Intended Use

Based on the fundamentals of GIA (Gold Immunochromatography Assay), this reagent puts AFP, CEA, and PSA recombined antigen and anti-human monoclonal antibody in practice and uses specific sensitive capturing to detect the AFP, CEA, and PSA antibody of human's serum/plasma.

Principle

AFP can used for primary hepatocellular carcinoma (HCC) and abnormal fetal neural tube development (such as spina bifida, hydrocephalus) the early auxiliary diagnosis.

CEA detection can be used as a reference for cancer clinical monitoring index, high concentration of CEA indicated that have potential to metastasize or residual. The CEA level rise may be associated with progressive cancer or bad treatment. The CEA value usually said treatment or good prognosis.

PSA testing can be used in the clinical auxiliary diagnosis of prostate cancer, also can be used as a testing index of prostate condition change and curative effect judgment.

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.

Sample Requirement

1. Sample collection

Serum: Use disposable syringe(vacuum blood collection tube) to extract a certain amount of venous blood, and place at room temperature for blood coagulation, take the supernatant after centrifugation of blood for detection.

Plasma: Use vacuum blood collection tube with anticoagulation to extract a certain amount of venous blood, and rock repeatedly, take plasma separation for detection. EDTA, sodium citrate, sodium oxalate, heparin can be used as the anticoagulants

2. Use fresh samples. Samples can be stored stored at 2-8℃ for 3 days. Do not freeze and thaw the sample repeatedly. Frozen refrigerated samples should be recovered to room temperature before detection.

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℃)

1. Take off the outer packing, put the cassette onto the desk with the sample window up.

2. Drop 3 drops of serum or plasma (80μl-100μl) vertically into the sample hole of cassette.

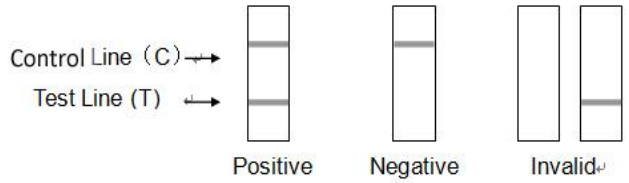
3. Observe the test results immediately within 15~20 minutes, the result is invalid over 30 minutes.

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

1. 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.

2. This reagent is designed for the qualitative screening test. Concentration of PSA/PSA/CEA cannot be determined by this qualitative test.

3. Negative results may occur due to short time infection or the window period. The antibody did not exist at that time or the concentration is too low.

Precaution

1. For IN VITRO diagnostic use only.

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 at 4℃ for 3 days, and should be stored at -20 ℃ if cannot be detected immediately. Do not freeze and thaw the sample repeatedly.

3. The strength of the quality control line doesn't indicate the quality problem of the reagent, a test result that is clearly visible demonstrates the reagent is effective.

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.