(CEA) Carcinoma Embryonic Antigen Rapid Diagnostic Kit

(Immunochromatography)

Product Name

(CEA) Carcinoma Embryonic Antigen Rapid Diagnostic Kit (Immunochromatography)

Intended Use

It is used to qualitative detect CEA of in human serum/plasma. The limit of detection concentration of the CEA is 5ng/ml.

Test Principle

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

Main components

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

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:

Remove the test device from the sealed pouch, put the end of the test strip print with arrow into the sample, the interface of sample should not exceed the max line, take it out and place the test device on a clean and level surface after 10 seconds. Observe the test results immediately within 15~20 minutes, the result is invalid over 30 minutes.

Cassette:

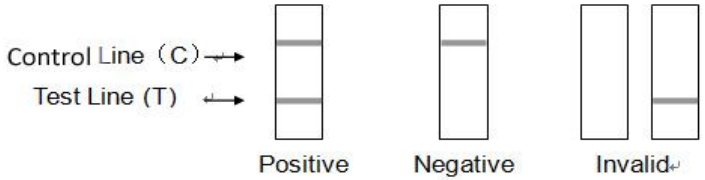
1. Take off the outer packing, put the cassette onto the desk with the sample window up.
2. Drop 3 drops of serum or plasma (80μl-100μl) vertically into the sample hole of cassette.
3. Observe the test results immediately within 15~20 minutes, the result is invalid over 30 minutes.

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. For detection CEA in human serum/plasma only.
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. 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.