(PSA) Prostate Specific Antigen Rapid Diagnostic Kit

(Immunochromatography)

Product Name

(PSA) Prostate Specific Antigen Rapid Diagnostic Kit (Immunochromatography)

Intended Use

One Step PSA Test is a rapid, direct binding test for the detection of Prostate Specific Antigen in serum /plasma. It is used as an aid in the diagnostic of prostate cancer.

Principle

The test utilizes antibodies including a PSA monoclonal antibody B and goat anti-rat IgG on the nitrocellulose membrane with colloidal gold marked PSA monoclonal antibody A as an mark tracer. The reagent is used to detect the PSA in serum /plasma according to the principle of double antibody sandwich method and gold immunochromatography assay

Main components

PSA monoclonal antibody A, PSA monoclonal antibody B, goat anti-rat IgG antibody

Storage and Expiry

Store as packaged in the sealed pouch at room temperature (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. 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.

2. EDTA, sodium citrate, sodium oxalate, heparin can be used as the anticoagulants.

3. Serum and plasma samples may be stored at 2-8℃ for 3 days prior to assay, and at -20 ℃ for 2 years. Repeat freeze and thaw for no more than 3 times.

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:

1. Remove the test device from the sealed pouch, put the end of the test strip print with arrow into the spample, 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.

2. Observe the test results immediately within 10-20 minutes, the result is invalid over 30 minutes.

Cassette:

1. Collect the serum/plasma, remove the test device from the sealed pouch, drop 3 full drops of sample (approx. 80~100μl) vertically to the sample hole of the test device.

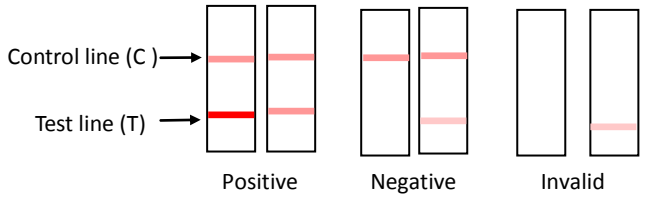
2. Observe the test results immediately within 15-20 minutes, the result is invalid over 30 minutes.

Result Judgment

POSITIVE: Two distinct red lines appear. And the color of testing line is stronger than or equal to the control line.

NEGATIVE: One red line appears in the control region(C). Or both red line appear with the color of testing line is weaker than the control line.

INVALID: No red lines appear or control line fails to appear, indicating that the operator error or reagent failure.



Limitation

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

2. The results of the reagent are only for clinical reference, which is not the only basis for clinical diagnosis and treatment.

3. A confirmed diagnosis and treatment should only be made by a physician after all clinical and laboratory findings have been evaluated.

4. If negative results occur with clinical symptoms at the same time, other clinical test methods are suggested to use.

Performance Characteristics

1. Positive specificity: The results should all be positive when detecting 10 kits of PSA positive quality control samples.(Including strong, medium and weak positive samples)

2. Negative specificity: The results should all be negative when detecting 10 kits of PSA negative quality control samples.

3. Limit of detection: Positive results may occur when detecting PSA of 4 ng/ml.

4. Repeatability: The results should be consistent and the coloration degree should be consistent when detecting the PSA standards by 10 kits of the same concentration.

5. Diagnostic specificity and sensitivity

A clinical evaluation was conducted on 412 samples (including 134 positive samples and 278 negative samples). The results are as follows:

Positive samples	76	PSA test kits of MR	PSA test kits of control group
		131/134（97.7%）	130/134（97.0%）
Negative samples	169	PSA test kits of MR	PSA test kits of control group
		276/278（99.3%）	276/278（99.3%）

Precaution

1. Do not use after the expiration date.

2. The test result is invalid over 30 minutes.

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. Samples with high lipid and high bilirubin show no effects on the test results. Samples with slight hemolysis (less than10g/L) show no effects on the test results, but may have an effect on observation of the results, so that other test methods are suggested.

5. CA-125, CA19-9, AFP and CEA show no effects on the test results.

6. 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.