Prostate Specific Antigen Cassette Rapid Test

(Serum/Plasma)

INTENDED USE

The Prostate Specific Antigen (PSA) Rapid Test is a colloidal gold/antibody complex-based immunoassay designed for the qualitative determination of human prostate specific antigen in serum or plasma. ***For professional in vitro diagnostic use only.***

INTRODUCTION

Prostate cancer is the one of the most common types of cancer found in man. The incidence of prostate cancer increases with age and accounts for a growing number of newly diagnosed patients. Prostate specific antigen (PSA) is produced primarily in the prostate gland and is secreted into the prostate ducts and at ejaculation serves to liquefy the seminal coagulum. Virtually all healthy males under 50 years of age have PSA concentration under 4.0 ng/ml. If PSA level is above 10 ng/ml, the patient most likely to have prostate cancer. Some studies indicated that elevated total PSA levels are found in serum from patients who have prostate cancer cells metastasized throughout their bodies. Other studies indicated that Free PSA, which cannot form a complex with serine protease, tends to be more abundant in patients with benign prostatic hyperplasia.

PRINCIPLE

The Prostate Specific Antigen (PSA) Rapid Test consists of a chromatographic absorbent device and a unique combination of monoclonal antibodies that selectively detect PSA in test samples with a high degree of sensitivity. In ten minutes, elevated levels of PSA as low as 4 ng/mL are detected.

Sample migrates through the absorbent area and along the test membrane, PSA present in the sample is bound by antibody-dye conjugate forming antibody-antigen complex. The complex is captured by the anti-PSA antibody immobilized in the test zone (T) of the membrane forming a color band (in the absence of PSA, no line will form in the test zone). Dye conjugate is captured by the antibody immobilized in the control zone (C) of the membrane producing a pink/rose color band regardless of the test sample composition. The clearly visible control band serves for evaluation of the test band intensity, and as an indicator of the assay validity.

REAGENTS

Coated Antibodies

Control region: Goat anti-mouse (IgG) polyclonal antibody

Test region: Goat anti-PSA antibody

Labeled Antibodies:

Colloidal gold conjugate of monoclonal anti-PSA antibody

MATERIALS SUPPLIED

1.Test Device 2.Desiccant 3.Pipette dropper 4.Package Insert

MATERIAL REQUIRED BUT NOT PROVIDED

1. Clock or Timer
2. Specimen collection containers
3. Centrifuge.

STORAGE AND STABILITY

All reagents are ready to use as supplied.Store unused test device unopened at 2□-30□.

If stored at 2□-8□, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30□.

WARNINGS AND PRECAUTIONS

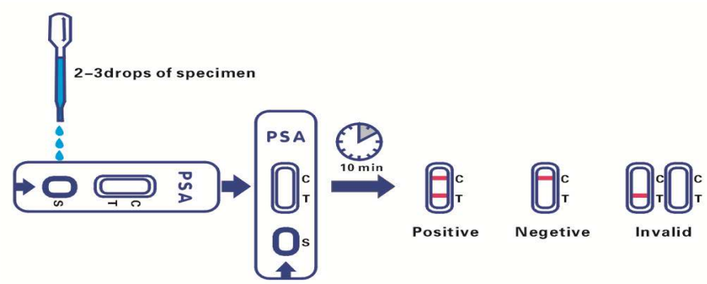
1. For professional In Vitro diagnostic use only.
2. Do not use it if the tube/pouch is damaged or broken.
3. Test is for single use only. Do not re- use under any circumstances.
4. Serum or plasma specimens may be infectious; Insure proper handing and dispose of all used reaction devices into a biohazard container.

SPECIMEN COLLECTION

1. The serum or plasma specimen should be collected under standard laboratory conditions.
2. Heat inactivation of specimens, which may cause hemolysis and protein. denaturation, should be avoided.
3. Serum specimens can be stored at 20□ to 80□ for 8 hours, at 2-8□ for up to 7 days, and at -20□ or lower for long term storage. Repeatedly frozen and thawed specimens are not recommended for this assay.
4. Any sediment in serum specimens should be removed by centrifugation. Avoid using any turbid specimens, which may be contaminated by microorganisms.

TEST PROCEDURE

1. Bring all materials and specimens to room temperature.
2. Remove the test card from the sealed foil pouch.
3. Place the transfer pipette in the specimen and depress the bulb to withdraw a sample.
4. Hold the pipette in a vertical position over the sample well of the test card and deliver 3 drops (approx. 75 µl) of sample into the sample well.
5. Read the result in 10 minutes. **Do not interpret the result after 10 minutes.**



INTERPRETATION OF RESULTS

Positive: Two lines appear. One coloured line should be in the control line region (C) and another apparent coloured line should be in the test line region (T). The test indicates a positive result: the level of tPSA in the specimen is above 4 ng/ml.

Negative: One coloured line appears in the control line region(C) and no line appears in the test line region (T).The test indicates a negative results: the concentration of tPSA in the specimen is below 4 ng/ml.

Invalid: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line and reference failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

Each reaction device has its own built-in quality control indicator. After performing the test and no line in either the (T) or (C) region of the reaction device is visible, the sample has been added in the wrong window or the test device may have deteriorated. External controls are recommended, positive and negative, to monitor the proper performance of the assay.

LIMITATIONS

1. The test is for in vitro diagnostic use only. This test is limited to the detection of PSA in human serum or plasma specimen and should not be used as the sole criteria for the diagnosis of Prostate Cancer.
2. A significant numbers of patients with BPH (more than 15%) and less than 1% of healthy individuals have elevated PSA. Even if the test results are positive, further clinical evaluation should be considered with other clinical information available to the physician.
3. PSA levels may be unreliable in patients who receive hormone therapy or prostate gland manipulation.

PERFORMANCE CHARACTERISTICS

1. Analytical Sensitivity: The analytical sensitivity of the Prostate Specific Antigen (PSA) Rapid Test is 4 ng/mL.

2. Accuracy: A study was performed using positive and negative serum specimens assayed with the Prostate Specific Antigen (PSA) Rapid Test and another leading commercially PSA EIA test according to the respective package insert procedures.

Method		EIA		Total Results
PSA Rapid Test	Results	Positive	Negative	
	Positive	143	3	146
	Negative	2	278	280
Total Results		145	281	426

Relative Sensitivity: 98.6%
Relative Specificity: 98.9%
Accuracy: 98.8%

3. **Dose Hook**

No dose hook effect was observed with PSA concentration up to 30,000 ng/ml.

4. Precision

Intra-Assay

Assay were carried out to determine assay reproducibility using replicates of 10 tests in three different runs for each of three lots using PSA specimen levels at 0 ng/mL,2 ng/mL, 4 ng/mL, 10 ng/mL and 20 ng/mL. The specimens were correctly identified > 99% of the time.

Inter-Assay

Between-run precision has been determined by using the five PSA specimen levels at 0 ng/mL, 2 ng/mL, 4 ng/mL, 10 ng/mL and 20 ng/mL of PSA in 3 independent assays. Three different lots of the PSA Plasma/Serum Cassette have been tested using these specimens. The specimens were correctly identified > 99% of the time.

5. Interfering Substances

The following substances do not interfere with the test results at the inicated concentrations:

Heparin at 30IU/ml, EDTA at 0.3%，Natrium Citricum at 0.6%, Bilirubin at 10ug/ml, Hemoglobin at 15mg/ml, Albulin at 20mg/ml,Lipids at 20mg/ml. And the Prostate Specific Antigen (PSA) Rapid Test has no cross reactivity with other tumor markers such as AFP, CEA, Ca125, Ca199, etc.

BIBLIOGRAPHY

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