# One Step Prostate Specific Antigen (PSA) Serum Test Strip

Cat.No.: PSA521

## 1. INTENDED USE

One-Step Prostate Specific Antigen (PSA) Test is a rapid and convenient immunochromatographic assay for the qualitative detection of human Prostate Specific Antigen in serum or plasma samples at or above the cutoff level of 4 ng/ml. It is intended for professional use as an aid in the diagnosis of prostate cancer. This assay provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the results of the tests.

## 2. SUMMARY AND PRINCIPLE OF THE ASSAY

Prostate specific antigen (PSA) is a signal chain glycoprotein containing two hundred forty amino acid residues and four carbohydrate side chains. The complete gene encoding PSA has been sequenced and localized to chromosome 19. PSA functions as a kallikrein-like serine protease and is produced exclusively by the epithelial cells lining the acini and ducts of the prostate gland. It is secreted into the prostatic ducts and at ejaculation it serves to liquefy the seminal coagulum. Many studies confirm that PSA is the most useful and meaningful tumor marker known for prostate cancer. Quantitative PSA detection by enzyme linked immunosorbent assay (ELISA) indicates the range of normal human serum PSA concentration is between 0.1 and 2.6 ng/ml, and the half-life of serum PSA is between 2.2 and 3.2 days.

One Step PSA test device is an antigen-capture immunochromatographic assay, detecting the presence of PSA in blood samples. Monoclonal antibodies specifically against PSA are 1) conjugated with colloidal gold and deposited on the conjugate pad and 2) immobilized on the Test Zone on the nitrocellulose membrane. When adequate volumes of the test sample is added the antibody conjugate is rehydrated and the PSA, if any in the samples, will interact with the colloidal gold conjugated antibodies. The antigen-antibody-colloidal gold complex will migrate towards the test window until the Test Zone (T) where they are captured by immobilized antibodies, forming a visible pink line (Test line), indicating a positive result. If PSA is absent in the sample, no pink line will appear in the Test Zone (T), indicating a negative result.

To serve as an internal process control, a control line should always appear at Control Zone (C) after the test is completed. Absence of a pink control line in the Control Zone is an indication of an invalid result.

## 3. PACKAGE CONTENTS

1) Pouch contents: Test Strip, Desiccant.
2) Test instruction.

## 4. WARNINGS AND PRECAUTIONS

1) For professional in vitro diagnostic use only.
2) Do not reuse.
3) Do not use if the pouch seal or its packaging is compromised.
4) Do not use after the expiration date shown on the pouch.
5) Do not mix and interchange different specimens.
6) Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials and performing the assay.
7) Wash hands thoroughly after finishing the tests.
8) Do not eat, drink or smoke in the area where the specimens or kits are handled.
9) Clean up spills thoroughly with appropriate disinfectants.
10) Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
11) Dispose of all specimens and used devices in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations.
12) Keep out of children's reach.

## 5. SPECIMEN PREPARATION

1) The One-Step PSA test is performed on human serum and plasma.
2) For serum samples, collect blood in a tube without anticoagulant and allow it to clot.
3) For plasma samples, collect blood in a tube containing anticoagulant.
4) Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
5) The blood may be stored at 2oC to 8oC for up to three days if the tests cannot be performed immediately. Ensure that the blood samples be brought to room temperature prior to use.
6) Do not use heat-inactive specimens.

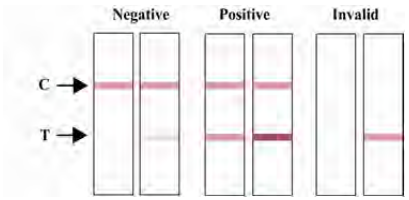
## 6. TEST PROCEDURE

1) Remove the testing device from the foil pouch by tearing at the notch. Hold the strip at the colored end. (Do not touch the arrow end; Do not touch test window, the middle part of the strip)
2) Holding the strip vertically, immerse the strip into the specimen with the arrow end pointing towards the specimen. Do not immerse past the MAX line.
3) Take the strip out when the sample has migrated to the test window (about 10 seconds). Lay the strip (MAX side facing up) flat on a clean, dry, non- absorbent surface.
4) Read the result in 10 minutes, following instructions under the "Result Interpretations" section
5) NOTE: Specimens with high concentrations of PSA may produce positive result in 3- 5 minute. Confirm weak positive and negatives in 20 minutes.
6) Do not read results after 30 minutes.

## 7. RESULT INTERPRETATIONS

**Negative**

Only one pink colored band appears at the control region (C), or the test band (T) is lighter than the control band (C), indicating negative result.




**Positive**

Distinct pink colored bands appear at the control and test regions, and the test band (T) is equal to or darker than the control band (C), indicating positive result.

**Invalid**

No visible band at the control region (C). Repeat with a

new test device. If the test still fails, please contact the distributor with the lot number

## 8. QUALITY CONTROL

Although the testing device contains an internal quality control (pink colored band in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

## 9. STORAGE AND STABILITY

1) Test device in the sealed pouch can be stored at 2-30$^{o}$C up to the expiration date. Do not freeze the test device.

2) The test device should be kept away from direct sunlight, moisture and heat.

## 10. PERFORMANCE CHARACTERISTICS

1) Analytical Sensitivity

One Step Prostate Specific Antigen (PSA) Test detects PSA in blood at concentrations equal to or greater than 4 ng/ml.

2) Analytical Specificity

The effect of tumor marker or proteins with similar structures associated with unrelated medical conditions of the specificity of One Step Prostate Specific Antigen (PSA) Test was assessed with a panel of serum specimens. The tumor markers or proteins studies were Carcinoembryonic Antigen (CEA) positive, Transferrin (TRF) positive, Alpha Fetoprotein (AFP) positive and human Kallikrein 2 (hK2) positive. The test panel consists of 100 PSA negative specimens. Of the 100 specimens, 80 contained one or more of the above tumor markers or proteins while 20 were healthy negative specimens. The results demonstrated that One Step Prostate Specific Antigen (PSA) Test has no cross-reactivity with these substances.

3) Diagnostic Sensitivity and Specificity

Accuracy of the One Step PSA Test has been evaluated by a comparison study with a currently marketed PSA test device and was conducted at external clinical sites. 90 clinic samples were studied. The detailed results are shown in the table below:

| | | Results of PSA test | | Subtotal |
|---|---|---|---|---|
| | | Positive | Negative | |
| Results of Commercial Kits | Positive | 49 | 1 | 50 |
| | Negative | 2 | 38 | 40 |
| Subtotal | | 51 | 39 | 90 |

Diagnostic Sensitivity: 49/50 = 98.0%
Diagnostic Specificity: 38/40 = 95.0%
Overall Agreement: (49+38)/(50+40) = 96.7%

4) Interference Studies

The following conditions were found not to interfere with the test. List of potentially interfering chemical/biological analytes and concentrations tested:

| | |
|---|---|
| Acetaminophen | 20 mg/dl |
| Acetylsalicylic acid | 20 mg/dl |
| Ascorbic acid | 20 mg/dl |
| Caffeine | 20 mg/dl |
| Gentesic acid | 20 mg/dl |
| Phenylpropanolamine | 20 mg/dl |
| Salicylic acid | 20 mg/dl |
| EDTA | 80 mg/dl |
| Benzoylecgonine | 10 mg/dl |
| Atropine | 20 mg/dl |
| Cannabinol | 10 mg/dl |
| Ethanol | 1% |
| Methanol | 1% |
| Albumin | 2,000 mg/dl |
| Glucose | 2,000 mg/dl |
| Bilirubin | 1,000 mg/dl |
| Hemoglobin | 1,000 mg/dl |

5) Reproducibility

The reproducibility was determined by replicate assays of both positive and negative urine samples with devices from three different production lots. The resultant data indicated no appreciable inter lot variation when testing both positive and negative samples across three different lots of devices.

## 11. LIMITATIONS

1) This product is an in vitro diagnostic test designed for professional use only.

2) Humidity and temperature can adversely affect results.

3) The instructions for the use of the test should be followed during testing procedures.

4) There is always a possibility that false results will occur due to the presence of interfering substances in the specimen or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.

5) Although the test demonstrates superior accuracy in detecting PSA, a low incidence of false results can occur. Therefore, other clinically available tests are required in case of questionable results. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test but should only be made by the physician after all clinical and laboratory findings have been evaluated.

## MANUFACTURER

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