One Step PSA Rapid Test

For detection of human prostate specific antigen (PSA) in Human Serum, Plasma.

IVD *In-vitro diagnostic use only* *Not reuse*

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 20 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 can not foam a complex with serine protease tends to be more abundant in patients with benign prostatic hyperplasia. The PSA test use antibodies which can equally recognize both free PSA and PSA-ACT complex.

Intended Use

The One Step PSA test is an immunochromatography based one step in vitro test

Principle

The One Step PSA Prostate Specific Antigen Rapid Test Strip (Whole Blood/Serum/Plasma) is a semiquantitative, membrane based immunoassay for the detection of PSA in whole blood, serum or plasma. The membrane is pre-coated with PSA antibodies on the test line region. During testing, specimen reacts with the particle coated with anti-PSA antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-PSA antibodies on the membrane and generate a colored line. A test line (T) of weaker intensity than the reference line (R) indicates that the PSA level in the specimen is below 4 ng/mL. A test line (T) intensity equal to the reference line(R) indicates that the PSA level in the specimen is approximately 4 ng/mL. A test line (T) intensity stronger than the reference line (R) indicates that the PSA level in the specimen is above 4 ng/mL. To serve as a procedural control, a colored line will always appear in the control line region (C) indicating that proper volume of specimen has been added and membrane wicking has occurred.

Materials Included and Active Ingredients

1) One Step PSA rapid test device.
2) Instruction for use.

Kit Precautions and Storage Instructions

1) For best results, adhere to instructions provided
2) All specimens should be handled as potentially infectious
3) The test device should be stored at room temperature
4) The test device is sensitive to humidity as well as heat
5) Do not use beyond expiration date
6) Do not use test kit if pouch is damaged or seal is broken
7) Use test device immediately after removing from the pouch
8) The components (test device and assay diluents (if provided)) in this kit have been quality control tested as a standard batch unit. Do not mix components from different lot numbers.

Warnings

1) For in vitro diagnostic use only. DO NOT RE-USE test device
2) The instructions must be followed to obtain accurate results. Anyone performing an assay with this product must be trained in its use and laboratory procedures.
3) Do not eat or smoke while handling specimens
4) Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
5) Avoid splashing or aerosol formation
6) Clean up spills thoroughly using an appropriate disinfectant
7) Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
8) Do not mix with other specimens.

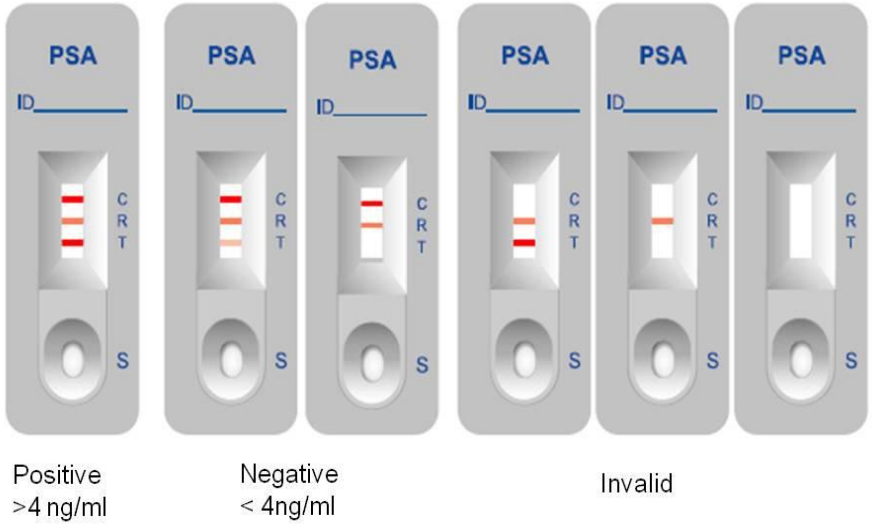
Specimen Collection, Storage and Precautions

1) Serum (S): Collect the whole blood into a collection tube (NOT containing anticoagulants such as heparin, EDTA, and sodium citrate) by venipuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant
2) Plasma (P): Collect the whole blood into a collection tube (containing anticoagulants such as heparin, EDTA, and sodium citrate) by venipuncture and then centrifuge blood to get plasma specimen.
3) If serum or plasma specimens are not tested immediately, they should be refrigerated at 2-8℃. For storage periods longer than 2 weeks, freezing is recommended. They should be brought to room temperature (1-30℃) prior to use.
4) Serum or plasma specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.
5) Anticoagulants such as heparin, EDTA and sodium citrate do not affect the test results.
6) Use separately disposable capillary pipettes or pipette tips for each sample in order to avoid cross-contamination of either samples which could cause erroneous results.
7) As known relevant interference, hemolytic samples, rheumatoid factors-contained samples and lipaemic, icteric samples can lead to impair the test results.

Test Procedure

1) Allow all test components and specimen to come to room temperature prior to testing
2) Remove the test device from the foil pouch, and place it on a flat, dry surface
3) With a micropipette (not provided) or a disposable dropper, add about 2-3 drops (80-100 µL) of serum, plasma specimen into the sample well marked “S”
4) As the test begins to work, you will see red color move across the result window in the center of the test device.
5) Interpret test results at 15-20 minutes. Caution: Do not read test results after 20 minutes. Reading too late can give false results.

Interpretation of Test Results (Refer to Figure)



1) Negative
The control line and reference line are visible line on the test device, but no test line appears or the intensity of the test line is weaker than the intensity of reference line. This indicates PSA level is below the cut-off value 4 ng/ml.

2) Positive
The control line and reference line are visible line on the test device, and the intensity of test line is equal or greater than that of the reference line. This indicates PSA level is above the cut-off value 4 ng/ml.

3) Invalid
If the "C" line (control) is not visible within the result window after performing the test. The result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested.

Limitations of the Test

1. The PSA Test Device is for in vitro diagnostic use only. This test should be used for the detection of PSA in whole blood, serum or plasma specimen.
2. The PSA Test Device will only indicate the semi-quantitative level of PSA in the specimen and should not be used as the sole criteria for the diagnosis of Prostate Cancer.
3. A significant numbers of patients with BPH (more that 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.
4. PSA levels may be unreliable in patients who receive hormone therapy or prostate gland manipulation.
5. High concentrations of PSA may produce a dose hook effect, resulting in false negative results. High dose hook effect has not been observed with this test up to 30,000 ng/mL PSA.

Suggested Readings

1. Wang MC, Valenzuela LA, Murphy GP, et al., Purification of human prostate specificity antigen. Invest Urol 1979; 17: 159163.
2. Christens A, Laurell CB, Lilja H. Enzymatic activity of prostate –specific antigen and its reaction with extracellular serine proteinaseInhibitors. Eur J Biochem 1990; 194:755763.
3. Catalona WJ, Southurick PC, Slawin KM, et al., Comparison of percentfree PSA, PSA density and agespecific PSA cutoffs for prostate cancer detection and staging. Urology 2000 Aug 1:56(2):25560.
4. Vancangh PJ, De Nayer P, Sauvage P, et al., Free to total prostatespecific antigen (PSA) ratio is superior to total PSA in differentially benign prostate hypertrophy from prostate cancer. Prostate Supplement, 1996, 7:3034.

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