PSA Serum/Whole Blood Rapid Test (Cassette)

Cat. No.: DTS218
Pkg. Size:

Intended use

PSA Serum/Whole Blood Rapid Test is an immunochromatography based one step in vitro test.

General Description

Prostate cancer is 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. PSA Serum Rapid Test use antibodies which can equally recognize both free PSA and PSA-ACT complex.

Principle Of The Test

It is designed for the rapid semi-quantitative determination of human prostate specific antigen (PSA) in human blood or serum specimens.

Reagents And Materials Provided

1. Instruction for use.
2. PSA Rapid Test device. The amount of each coated antigen and/or antibody on the strip is less than 1.0 mg for antigen conjugate and is less than 1.0 mg for goat anti-mouse IgG antibody.
Test zone: contains mice monoclonal anti-PSA antibody.
Control zone: contains goat anti-rabbit IgG antibody.
Conjugate Pad: contains gold-mice monoclonal anti-PSA antibody conjugate.

Materials Required But Not Supplied

1. Whole blood or plasma: Vacutainer tube, or other appropriate tube, containing heparin or EDTA as an anticoagulant.
2. Serum: Vacutainer tube, or other appropriate tube, without anticoagulant.
3. Micropipetter (0-200µl range) and pipette tips.
4. Timer or clock.

Specimen Collection And Preparation

1. The serum, whole blood 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. Patient samples performed best when tested immediately after collection. If specimens are to be stored, the red blood should be removed to avoid hemolysis. If the sample cannot be tested within 24 hours, specimen may be refrigerated at 2-8°C or frozen up to 7 days. Frozen samples should be thawed and brought to room temperature before proceeding.
4. Whole blood samples should be refrigerated at 2-8°C instead of being frozen. Whole blood samples must be tested within 24
hours.
5. Sodium azide can be added as a preservative up to 0.1% without affecting the test results.

**Assay 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 (120-150µl) of sample into the sample well.
5. Read the result at 8 minutes.
Note: Results after 8 minutes may change and cause false interpretation.

**Quality Control**

Good Laboratory Practice recommends the daily use of control materials to validate the reliability of device. Control materials should be assayed as a clinical specimen and challenging to the assay cut-off concentration, e.g., 25% above and below cut-off concentration. If control values do not fall within the established range, assay results are invalid. Control materials, which are not provided with this test kit are commercially available.

The PSA Serum/Whole Blood Rapid Test provides a built-in process control with a different antigen/antibody reaction at the control region (C). This control line should always appear regardless of the presence of drug or metabolite. If the control line does not appear, the test device should be discarded and the obtained result considered invalid. The presence of this control band in the control region serves as:
1. Verification that sufficient volume is added and that proper flow is obtained.
2. The build-in control also serves as reference line for color comparison. It represents the color intensity of 4ng/ml of PSA.

You should always follow local, state and federal guidelines for running QC.

**Interpretation of Results**

1. Positive: If the color of test band is equal or stronger than that of control band, it indicates the PSA level is equal or higher than the cut-off, 4.0 ng/ml.
2. Negative: If only a colored control band appears or the color intensity of the test band is less than that of control band, it indicates the PSA level is less than cut-off, 4.0 ng/ml.
3. Invalid Result: The test result is invalid if a colored band does not form in the control region. The sample must be re-tested, using a new test device.

**Expected Values**

PSA Serum/Whole Blood Rapid Test is a semi-quantitative assay. It identifies if the PSA in human serum is higher than 4 ng/ml or not. The exact concentration of the PSA cannot be determined by this assay. The test is intended to distinguish a normal PSA level result from a presumptive positive result. All positive results must be confirmed using a quantitative PSA assay.

**Precautions**

1. Do not use test kit beyond expiration date.
2. Do not use the product if the pouch is damaged or the seal is broken.
3. Handle all specimens as potentially infectious.
4. Store the test device at 2 to 30°C in the original sealed pouch. Do Not Freeze.
5. The expiration date given was established under these storage conditions.
6. The test device should remain in its original sealed pouch until ready for us.
7. The device is designed for single use. Once the pouch is opened, the device must be tested as soon as possible and cannot be reused.

**Limitations**

1. The test is limited to the semi-quantitative detection of PSA levels in human blood or serum specimen.
2. Although the test is very accurate in detecting elevated PSA, a low incidence of false positive results can occur.
3. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

**Analyte Gene Information**

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<th>Gene Name</th>
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