First Romanian rapid tests manufacturer !

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"See Now" PSA Strip Test

Serum/ Plasma

For in vitro Diagnosis Use
Product Code: SN 3.5

INTENDED USE

The *"See Now"* Prostate Specific Antigen (PSA) test is an immunochromatographic assay it is designed for detection of human PSA in serum or plasma specimen.

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PRINCIPLE

Prostate Specific Antigen (PSA) is an intracellular glycoprotein (34kDa) synthesized only by the prostate gland. PSA a normal constituent of prostate tissue, is also present in benign hyperplastic and malignant prostatic tissue, in metastatic prostatic carcinoma, and in prostatic fluid and seminal plasma. However, it is not detected in cancers of lung, breast, rectum, pancreas, stomach or thyroid.

The amount of PSA in the blood normally increases as a men's prostate enlarges with age. However, normal total PSA concentration of men, age 40 to 50, is less than 2.5ng/ml. The concentration of PSA is elevated in blood of prostate cancer patients. The predictive value of PSA test is superior to that of either rectal examination or ultrasound alone. Since elevated levels of PSA are also seen in BPH (Benign prostatic Hyperplasia) and other inflammation of urogenital tissues, measurement of blood PSA concentration is not recommended as a sole test procedure for diagnosis of cancer. But the combination of PSA test with ultrasonography provides a better method of detecting prostate cancer than rectal examination or ultrasonography alone. The PSA test is effective in screening men for prostate cancer or monitoring its development and the response to treatment.

"*See Now*" PSA test is an immunochromatographic assay. When sample is added to sample pad, it moves through the conjugate pad and mobilizes gold anti-PSA conjugate that is coated on the conjugate pad. The mixture moves along to the membrane by capillary action and reaction with anti-PSA antibody that is coated on the test region. If PSA presents in the sample at levels of 4.0ng/ml or greater, a color line is appeared in the test region. If PSA is present at lover level, or not present in the sample, the test region will remain colorless.

The sample continues to moves to the control region and forms a colored line, indicating the test is working and its result is valid

.MATERIALS SUPPLIED

Test Strip, Desiccant, Test instruction

MATERIALS REQUIRED BUT NOT SUPPLIED

Specimen collection container, Timer

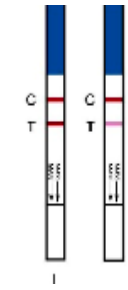
SPECIMEN PREPARATION

- The serum or plasma may be used as samples and should be collected under standard laboratory conditions.
- Plasma collection : Collect blood in a tube containing anticoagulant such as heparin or EDTA and centrifuge the blood to get plasma specimen
- Serum collection: Collect blood in tube without anticoagulant and allow clotting.
- It is recommended that fresh samples be used as soon as possible, whole blood sample should be tested within 3 hours of collection. If specimens must be stored, the blood cells should be removed. Plasma or serum samples may be refrigerated for 24 hours at 2-8ºC. If plasma or serum must be stored for more than 24 hours, they should be frozen at -20ºC or below.
- Heat inactivation of specimens, which may cause hemolysis and protein denaturation, should be avoided.
- Sodium azide can be added as a preservative up to 0.1% without affecting the test results.

TEST PROCEDURE

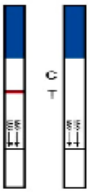
- Bring all materials and specimens to room temperature, and then open the foil pouch and place the device on a clean, dry and level surface.. NOTE: Once the foil pouch is opened, the device should be used as soon as possible.
- Immerse the strip into the tube sample with the arrow end pointing towards the sample. Let it stay immersed until you see liquid traveling up past the MAX word.
- Take the strip out after a minimum of 10 seconds. Lay the strip (MAX side facing up) flat on a clean, dry, non-absorbent surface.
- Wait for 15 minutes and then read the results. Do not interpret the results after 30 minutes.

INTERPRETATION OF RESULTS



Positive: Two colored lines should be observed. The line in the test region (T) is the probe line; the line in the control region (C) is the control line, which is used to indicate proper performance of the device. The color intensity of the test line may be weaker or stronger than that of the control line.

Negative: The control line appears in the test, but the test line is not visible.



Invalid: No line appears in the control region. Under no circumstances should a positive sample be identified until the control line forms in the viewing area. If the control line does not form, the test result is inconclusive and the assay should be repeated.

STORAGE AND STABILITY

- Test device in the sealed pouch can be stored at 2-30ºC up to the expiration date. Do not freeze the test device.
- The test device should be kept away from direct sunlight, moisture and heat.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not reuse.
- Test device should remain sealed until use.
- Do not used after the expiration date shown on the pouch.
- Keep out of children's reach.

LIMITATION OF PROCEDURE

- This product is designed for in vitro diagnostic use only.
- There is always a possibility that false results will occur due to the presence of interfering substances in the specimen beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
- 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.

QUALITY CONTROL

The control line is an internal control of the test reagents and procedure .It will appear if test has been performed correctly and the reagents are reactive. The absence of control line may indicate that insufficient sample added or the test device is inactivated.

EXPECTED VALUES

"*See Now*" PSA test is designed to yield a positive result for PSA concentration at 4.0ng/ml or greater. PSA concentration of normal healthy subject is less that 2.5ng/ml The concentration of PSA is elevated 4.ng/ml or greater in blood of prostate cancer patients