ACCUCARE™
ONE STEP PSA RAPID TEST
(Serum, Plasma)

A rapid and sensitive test for the qualitative detection of Prostate specific antigen (PSA) in serum or plasma

Only for *In vitro diagnostic* use

ORDER INFORMATION

REF	Cont.
PSA 10	10 Test
PSA 25	25 Test

CLINICAL SIGNIFICANCE

Prostate-specific antigen (PSA) is an intracellular glycoprotein (MW: 34 kDa) generated only in the prostate gland. Normal level of PSA concentration is 4ng/ml in human serum. However, the level of PSA concentration can be elevated in the case of prostate affection, for example, benign hyperplasma (enlarged Prostate), malignant prostatic tissue, metastatic prostatic carcinoma. So that, many reports have suggested that the elevated level of serum PSA is the best marker in the diagnosis of prostate cancers.

PRINCIPLE

Accucare PSA is a chromatographic immunoassay kit for rapid qualitative and semi quantitative detection of PSA in serum or plasma from human blood. The nitrocellulose membrane of ACCUCARE is immobilized with mouse anti-PSA monoclonal antibodies in “T” line; anti mouse IgG in “C” line and PSA 4 ng/ml in “R” line. Rabbit anti-PSA antibodies are conjugated with colloidal gold particles. This conjugate is placed on a polyester or glass pad as conjugate pad. When the sample is dropped into the sample well on the device, the solubilized conjugate migrates with the sample by passive diffusion and both the conjugate and sample come into contact with the monoclonal antibodies(C&T) and antigen(R) immobilized onto nitrocellulose. Test line intensity is weaker then Reference line(R) indicates that PSA level in the specimen is approximately below 4ng/ml. A test line (T) intensity is equal to Reference line(R) indicates that PSA level in the specimen is approximately equal to 4ng/ml. Test line(T) intensity is stronger than Reference line(R) indicates that PSA level in the specimen is approximately more than 4ng/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.

MATERIAL PROVIDED

Accucare PSA kit contains the following components:

1. Test devices individually foil-pouched with a desiccant.
2. Instruction manual for use.
3. Sample Dropper

MATERIAL REQUIRED BUT NOT PROVIDED

1. Specimen collection container
2. Micropipette
3. Watch or Timer

PRECUATIONS

1. The presence of humidity may decrease the stability of the reagents. Thus, please carry out the test immediately after removing the device from the foil pouch.
2. Do not use the kit after the expiration date and do not freeze the kit.
3. For in vitro diagnostic use only.
4. Wear protective gloves while handling samples and wash hands thoroughly after the test.
5. Dispose all the specimens and kits properly after test is over, in accordance with GLP.

SPECIMEN COLLECTION AND STORAGE

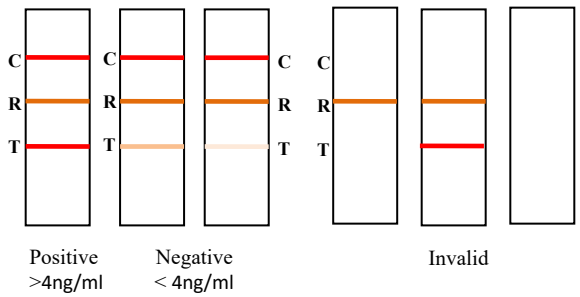
1. Specimen to be tested should be obtained and handled by standard methods for their collections.
   - Serum: allow the blood to clot, then centrifuge to separate the serum
   - Plasma: collect the whole blood into the tube contained anticoagulants such as heparin, citrate, or EDTA. Centrifuge the blood and separate the plasma.
2. All specimens should be tested as soon as they are prepared. If necessary, they may be stored at 2-8°C for up to 24 hours at -20°C for longer periods.

TEST PROCEDURE

1. Place all specimens and test devices and allow them to room temperature prior to testing (15-30 min).
2. Prepare the test device as you need, and then mark the patient’s ID onto the device. Please perform the test immediately after removing the device from foil pouch.
3. Load 3 drops (60-80μl) of serum /plasma into the sample well (S) in the test device.
4. After 20 minutes, read the results.
   Please do not read the results after 30 minutes of the test.

INTERPRETATION OF THE RESULTS

1. Negative result: Control line (C) and reference line(R) are visible on the test device but no test line appears or the test line intensity is weaker than intensity of reference line. This indicates that PSA level is below the cutoff value(4ng/ml)
2. Positive result: The control and reference line are visible in test device. And the intensity of the test line is equal or greater than reference line. This indicates that PSA level is above the cut off value (4ng/ml).
3. Invalid result: If the control line 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

ACCUCARE PSA is designed for primary screening of PSA level in the serum or plasma. This kit can provide fast and easy way to get a result, but do not completely exclude the possibility of false positive or false negative result caused by various factors. So, refer to the result of this kit, please make a final decision with clinical manifestation, other test results, and doctor’s view, collectively.

REFERENCE

1. Liedtke R.L. and J.D.Bajter (1984) Measurement of prostate-specific antigen by radioimmunoassay Clin.Chem.30, p649-652.
2. Barak M. et al (1989) Evaluation of prostate-specific antigen as marker for adenocarcinoma of the prostateJ.Urol. 145, p907-923.

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