ACCUCARE®
ONE STEP PROSTATE-SPECIFIC ANTIGEN (PSA) RAPID TEST (Serum/Plasma)

One step rapid Card Test for detection of Prostate specific antigen (PSA) in human Serum/Plasma

Store at 2-30°C. DO NOT FREEZE.
For *In-Vitro Diagnostic* Use only

ORDER INFORMATION

Pack Size	REF
10 Tests	PSAC 10
25 Tests	PSAC 25

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 4 ng/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® ONE STEP PROSTATE-SPECIFIC ANTIGEN (PSA) RAPID TEST 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.

CONTENTS

Test Device
Instruction for Use (IFU)
Disposable (Dropper) 25 µl sampling device
Desiccant

STORAGE & STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed aluminum pouch until use. DO NOT FREEZE.
2. Do not use beyond the expiration date.
3. Do not use the test device, if the pouch is damaged or seal is broken.

PRECAUTIONS

1. For professional *In-vitro* diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all the specimens as potentially infectious. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens and tested device.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
5. Read the Instruction for use carefully before performing the test.

LIMITATIONS

ACCUCARE® ONE STEP PROSTATE-SPECIFIC ANTIGEN (PSA) RAPID TEST 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.

SPECIMEN COLLECTION & PREPARATION

1. The ACCUCARE® ONE STEP PROSTATE-SPECIFIC ANTIGEN (PSA) RAPID TEST can be performed using either serum or plasma.
2. Separate the serum or plasma from whole blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
   - 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.
3. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
4. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
5. If specimens are to be shipped, it should be packed in compliance with federal regulations for transportation of etiologic agents.

PROCEDURE

1. Allow test device, Assay Buffer and specimen equilibrates to room temperature (15-30°C) prior to testing.
2. Remove the test device from the aluminum foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
3. Place the test device on a clean and flat surface. Carefully dispense 3 drops (75 µl) of Serum/Plasma in the sample well “S” using the dropper provided.
4. Allow reaction to occur and read the results at 20 minutes. Do not interpret the results after 30 minutes.

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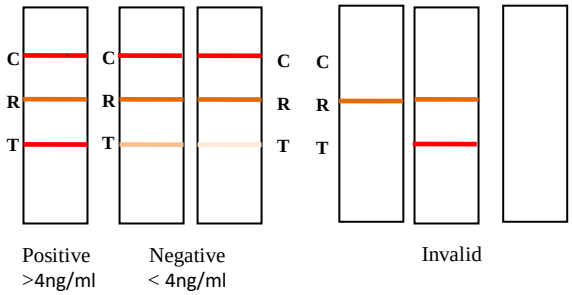
INTERPRETATION OF RESULTS

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 test line. This indicates that PSA level is below the cutoff value (4 ng/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 (4 ng/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.



PERFORMANCE CHARACTERISTICS

The ACCUCARE® ONE STEP PROSTATE-SPECIFIC ANTIGEN (PSA) RAPID TEST has been evaluated with positive and negative samples and data are as below:

Specimen	Positive	Negative	Sensitivity
PSA Positive	203	5	99.0 %

Specimen	Positive	Negative	Specificity
PSA Negative	2	351	99.2 %

BIBLIOGRAPHY

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.

GLOSSARY OF SYMBOL

	Consult Instruction for Use	LOT	Lot Number
REF	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer		Do not reuse
IVD	For *in vitro* Diagnostic use only		Keep Dry
Σ	Tests per Kit		Do Not Use if Damaged

ISO 13485:2016

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