PROFESSIONAL SERIES

Prostate Cancer (PSA) *Screening Test*

Detects PSA Levels
Quickly & Easily in Blood

Safe | Simple | Accurate

Detects PSA Levels
Quickly & Easily in Blood

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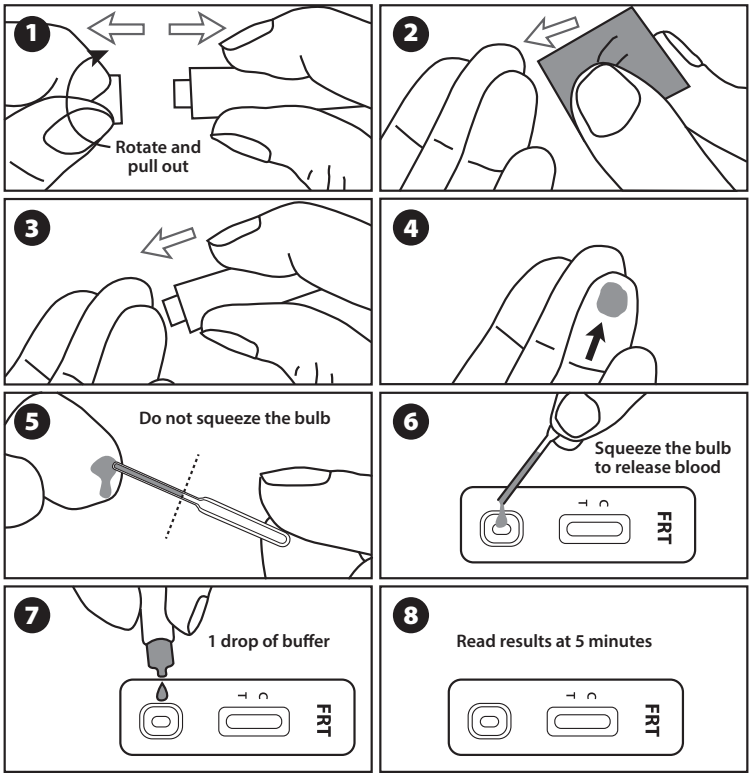
The Prostate Cancer (PSA) Rapid Test Cassette is a rapid test for the qualitative detection of Prostate Specific Antigen (PSA) in human fingerstick blood.



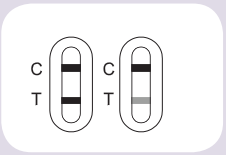
SUMMARY

Prostate specific antigen (PSA) is produced by prostate glandular and endothelial cells. The PSA level in serum of healthy men is between 0.1 ng/mL and 2.6 ng/mL. It can be elevated in malignant conditions such as prostate cancer, and in benign condition such as benign prostatic hyperplasia and prostatitis. A PSA level of 4 to 10ng/ml is considered to be in the "grey-zone" and levels above 10ng/ml are highly indicative of cancer. Patients with PSA values between 4-10ng/ml should undergo further analysis of the prostate by biopsy.

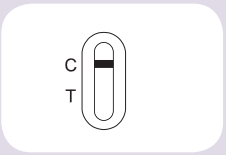
The prostate specific antigen test is the most valuable tool available for the diagnosis of early prostate cancer. Many studies have confirmed that the presence of PSA is the most useful and meaningful tumor marker known for prostate cancer and prostate infection of Benign Prostatic Hyperplasia (BPH).

The PSA Quantitative Rapid Test Cassette (Whole blood /Serum / Plasma) utilizes a combination of colloidal gold conjugate and anti-PSA antibodies to selectively detect total PSA in whole blood, serum or plasma. **The test has a cut-off value of 4ng/ml.**

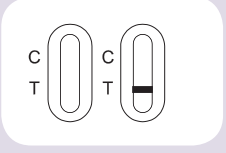
INTERPRETATION OF RESULTS



Positive: Three distinct colored lines appear. A test line (T) intensity weaker than the reference line (R) indicates a PSA level between 3-10 ng/ml. A test line (T) intensity equal or close to the reference line (R) indicates a PSA level of approximately 10ng/ml. A test line (T) intensity stronger than the reference line (R) indicates a PSA level more than 10ng/ml.



Negative: Color lines appear in both the control (C) and reference (R) regions. No apparent colored line appears in the test line region (T). This indicates a PSA level below 3ng/ml.



Invalid: Control line (C) or reference line (R) fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

PRECAUTIONS

Please read all the information in this package insert before performing the test.

1. For professional in vitro diagnostic use only. Do not use after the expiration date. **2.** The test should remain in the sealed pouch until ready to use. **3.** Do not eat, drink or smoke in the area where the specimens or kits are handled. **4.** Do not use the test if the pouch is damaged. **5.** All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent. **6.** Humidity and temperature can adversely affect results.

PROCEDURE - HOW TO DO THE TEST

1. Wash your hands with soap and rinse with clear warm water. **2.** Open the foil pouch and get out the Cassette-place on a flat surface. **3.**Use the provided alcohol pad to clean the fingertip of the middle or ring finger as the puncture site. **4.**Carefully twist and pull off and dispose the round cap of the lancet. **5.** Press the lancet, against your fingertip on the side from where the cap was extracted. This will allow the lancet to pierce the skin. The tip of the lancet retracts automatically and safely after use. **6.** Keeping your hand down massage the end of the finger to obtain a blood drop. **7.** Without squeezing the capillary dropper bulb, put it in contact with the blood. The blood will migrate into the capillary dropper through the capillarity to the line indicated on the capillary dropper. You may massage your finger to obtain more blood if the line is not reached. **8.**Put the blood collected into the sample well marked 'S' of the cassette, by squeezing the dropper bulb. **9.** Wait for all the blood to be in the well then unscrew the cap of the buffer bottle and add 1 drop of buffer into the same sample well of the cassette. **10.** Wait for the coloured line(s) to appear. Read results at 5 minutes. Do not interpret the result after 10 minutes.

What do I have to do if the result is positive? If the result is abnormal, it means that the PSA level is higher than the normal (4ng/mL) and that you should consult your doctor and show the test result to him/ her. Your doctor will then decide whether additional analysis should be performed.

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