

 PSA Test Device	
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A rapid test for the semi-quantitative detection of prostate specific antigen (PSA) in whole blood, serum or plasma.

For professional in vitro diagnostic use only.

INTENDED USE

The PSA Test Device (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for semi-quantitative detection of Prostate Specific Antigen in whole blood, serum or plasma.

SUMMARY

Prostate specific antigen (PSA) is produced by prostate glandular and endothelial cells. It is a single chain glycoprotein with a molecular weight of approximately 34 kDa.¹ PSA exists in three major forms circulating in the serum. These forms are free PSA, PSA bound to $\alpha 1$ – Antichymotrypsin (PSA-ACT) and PSA complexed with $\alpha 2$ –macroglobulin (PSA-MG).²

PSA has been detected in various tissues of the male urogenital system but only prostate glandular and endothelial cells secrete it. 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 10 ng/mL is considered to be in the “gray-zone” and levels above 10 ng/mL are highly indicative of cancer.³ Patients with PSA values between 4-10 ng/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).⁴

The PSA Test Device 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 4 ng/mL and a reference value of 10 ng/mL.

PRINCIPLE

The PSA Test Device is a semi-quantitative, membrane based immunoassay for the detection of PSA in whole blood, serum or plasma. The membrane is pre-coated with PSA antibodies on the test line region. During testing, the specimen reacts with the particle coated with anti-PSA antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-PSA antibodies on the membrane and generate a colored line. A test line (T) intensity weaker than the reference line (R) indicates that the PSA level in the specimen is between 4-10 ng/mL. A test line (T) intensity equal or close to the reference line (R) indicates that the PSA level in the specimen is approximately 10 ng/mL. A test line (T) intensity stronger than the reference line (R) indicates that the PSA level in the specimen is above 10 ng/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.

REAGENTS

The test contains PSA monoclonal antibody particles and PSA monoclonal antibody coated on the membrane.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- The test must remain in the sealed pouch until use.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves or eye protection when specimens are being tested.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- The PSA Test Device can be performed using whole blood (from venipuncture or fingerstick), serum, or plasma.
- To collect **Fingerstick Whole Blood specimens:**
 - Wash the patient’s hand with soap and warm water or clean with an alcohol swab. Allow to dry.
 - Massage the hand without touching the puncture site by

rubbing down the hand towards the fingertip of the middle or ring finger.

- Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
- Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Add the Fingerstick Whole Blood specimen to the test by using **a capillary tube:**
 - Touch the end of the capillary tube to the blood until filled to approximately 80 μ L. Avoid air bubbles.
 - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood onto the specimen well (S) of the test device.
- Add the Fingerstick Whole Blood specimen to the test by using **hanging drops:**
 - Position the patient’s finger so that the drop of blood is just above the specimen well (S) of the test device.
 - Allow 2 hanging drops of fingerstick whole blood to fall onto the specimen well (S) of the test device, or move the patient’s finger so that the hanging drop touches the specimen well (S). Avoid touching the finger directly to the specimen well (S).
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- 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.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

MATERIALS

Materials Provided

- Test devices
- Droppers
- Buffer
- Package insert

Materials Required But Not Provided

- Timer
- Specimen collection containers
- Lancets (for fingerstick whole blood only)
- Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)
- Centrifuge

DIRECTIONS FOR USE

Allow the test, specimen, buffer and/or controls to

equilibrate to room temperature (15-30°C) prior to testing.

1. Bring the pouch and buffer to room temperature before opening pouch. Remove the test device from the sealed pouch and use it as soon as possible.

2. Place the test device on a clean and level surface.

For **Serum, Plasma** or **Venipuncture Whole Blood** specimens:

Hold the dropper vertically and transfer 1 drop of serum, plasma (approximately 40 µL) or 2 drops of venipuncture whole blood (approximately 80 µL) to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.

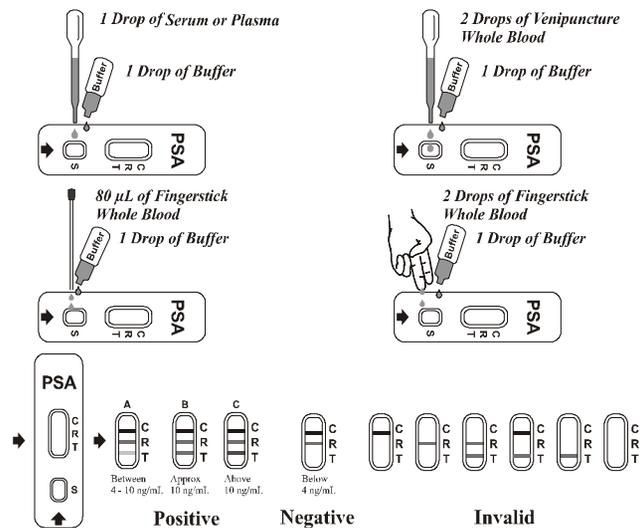
For **Fingerstick Whole Blood** specimens:

•To use a capillary tube: Fill the capillary tube and transfer approximately 80 µL of fingerstick whole blood specimen to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.

•To use hanging drop: Allow 2 hanging drops of fingerstick whole blood specimen (approximately 80 µL) to fall into the center of the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.

3. Wait for the colored line(s) to appear.*
Read the result at 5 minutes. Do not interpret the result after 10 minutes.

*Note: If migration is not observed in the result window after 30 seconds, add one or two extra drops of buffer.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE: Three distinct colored lines appear.

A. Test line (T) intensity weaker than the reference line (R) indicates a PSA level between 4-10 ng/mL.

B. A test line (T) intensity equal or close to the reference line (R) indicates a PSA level of approximately 10 ng/mL.

C. A test line (T) intensity stronger than the reference line (R) indicates a PSA level above 10 ng/mL.

NEGATIVE: Colored 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 4 ng/mL.

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

QUALITY CONTROL

A procedural control is included in the test. The appearance of colored lines in the control line region (C) and reference line region (R) is considered procedural controls. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The PSA Test Device is for *in vitro* diagnostic use only. This test should be used for the detection of PSA in whole blood, serum or plasma specimen.

2. The PSA Test Device will only indicate the semi-quantitative level of PSA in the specimen and should not be used as the sole criteria for the diagnosis of Prostate Cancer.

3. A significant numbers of patients with BPH (more than 15%) and less than 1% of healthy individuals have elevated PSA. Even if the test results are positive, further clinical evaluation should be considered with other clinical information available to the physician.

4. PSA levels may be unreliable in patients who receive hormone therapy or prostate gland manipulation.

5. High concentrations of PSA may produce a dose hook effect, resulting in false negative results. High dose hook effect has not been observed with this test up to 30,000 ng/mL PSA.

EXPECTED VALUES

The minimum indicative level of PSA for Prostate Cancer is generally agreed to be 4 ng/mL and the warning level is generally agreed to be 10 ng/mL.³ The PSA Test Device has been compared with a leading commercial PSA enzyme immunoassay (EIA) test. The correlation between these two results is 98.6%.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The PSA Test Device has been tested with leading commercial PSA EIA Test using clinical samples.

Method	EIA		Total	Relative Sensitivity: 98.5% (96.3%-99.6%)*	Relative Specificity: 98.6% (97.0%-99.5%)*
	Result	Positi			
PSA Test Device	Positi	154	4	158	95% Confidence Intervals
	Negati	2	266		
Total Results			156	270	426

Precision

Intra-Assay

Assays were carried out to determine assay reproducibility using replicates of 10 tests in three different runs for each of three lots using PSA specimen levels at 0 ng/mL, 2 ng/mL, 4 ng/mL, 10 ng/mL and 20 ng/mL. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by using the five PSA specimen levels at 0 ng/mL, 2 ng/mL, 4 ng/mL, 10 ng/mL and 20 ng/mL of PSA in 3 independent assays. Three different lots of the PSA Test Device have been tested using these specimens. The specimens were correctly identified >99% of the time.

Interfering Substances

The following substances do not interfere with the test results at the indicated concentrations: Ascorbic Acid at 200 mg/L, Hemoglobin at 10 g/L, Triglyceride at 30 g/L, Bilirubin at 1,000 mg/dL, Uric Acid at 200 mg/L.

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