PSA Cassette

for human whole blood, serum or plasma

REF **Content**

Z08010BN
- 1 test individually packed, disposable pipette
- 1 vial buffer, sufficient for 30 tests
- 1 package insert

* minimum order amount 30 tests or multiples thereof

For professional in vitro diagnostic use only

GENERAL INFORMATION

Method	sandwich type immunochromatographic assay
Shelf life	24 months from date of production
Storage	2 – 30 °C
Sample	human serum, plasma or whole blood
Results	after 5 minutes at room temperature, do not read after 10 minutes!
Sensitivity	3.0 ng / mL

INTENDED USE

The PSA Cassette is a rapid chromatographic immunoassay for the semi-quantitative detection of Prostate specific Antigen (PSA) 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 approx. 34 kDa.[1] PSA exists in three major forms circulating in the serum. These forms are free PSA, PSA bound to α-1 Antichymotrypsin (PSA-ACT) and PSA complexed with α-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 10ng/ml is considered to be in the "grey-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 tumour marker known for prostate cancer and prostate infection of Benign Prostatic Hyperplasia (BPH).[4]
The PSA Cassette 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 3 ng/mL and a reference value of 10 ng/mL.

TEST PRINCIPLE

The PSA Cassette 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 coloured 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 approx. 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 coloured 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, as well as 0.03 % Proclin 300.

WARNINGS AND PRECAUTIONS

- For professional in vitro diagnostic use only.
- Do not use kit beyond the expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Do not use test if pouch is damaged.
- 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.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- 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 at room temperature or refrigerated (2 – 30 °C). The kit is stable within 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.

MATERIAL PROVIDED

- test cassettes
- disposable pipettes
- buffer
- instructions for use

MATERIAL REQUIRED BUT NOT PROVIDED

- specimen collection container
- timer
- centrifuge (for plasma only)
- lancets (for fingerstick whole blood only)
- heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

SPECIMEN COLLECTION AND PREPARATION

- The PSA Cassette (whole blood/serum/plasma) can be performed using whole blood (from venipuncture or fingerstick), serum, or plasma.
- To collect **Venipuncture Whole Blood specimens**:
  Collect anti-coagulated blood specimen (sodium or lithium heparin, potassium or sodium EDTA, sodium oxalate, sodium citrate) following standard laboratory procedures.
- 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 approx. 80 µL. Avoid air bubbles.
    - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen well (S) of the test cassette.
  - 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 cassette.
    - Allow 2 hanging drops of fingerstick whole blood to fall into the specimen well (S) of the test cassette, 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 haemolysis. Use only clear, non-haemolysed 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.

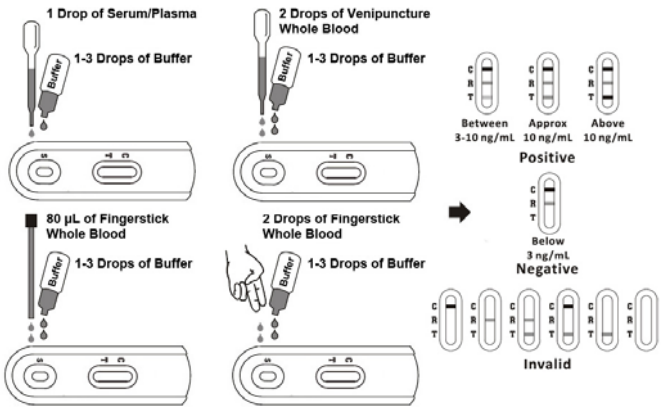
If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

ASSAY PROCECURE

Allow the test cassette, specimen, buffer, and/or controls to equilibrate to room temperature (15 – 30 °C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. Place the test cassette on a clean and level surface.
   For **Serum, Plasma or Venipuncture Whole Blood specimens**: Hold the dropper vertically and **transfer 1 drop of serum or plasma** (approx. 40 µL) or **2 drops of venipuncture whole blood** (approx. 80 µL) to the specimen well (S) of the test cassette, then **add 1 drop of buffer** (approx. 40 µL).
   For **Fingerstick Whole Blood** specimen:
   - To use a capillary tube: Fill the capillary tube and **transfer approx. 80 µL of fingerstick whole blood specimen** to the specimen well (S) of the test cassette, then **add 1 drop of buffer** (approx. 40 µL).
   - To use hanging drops: Allow 2 **hanging drops of fingerstick whole blood specimen** (approx. 80 µL) to fall into the centre of the specimen well (S) on the test cassette, then **add 1 drop of buffer** (approx. 40 µL).
3. Start the timer and wait for the coloured line(s) to appear. **Read results at 5 minutes.** Do not interpret results 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

POSITIVE:* Three distinctly coloured lines appear.
- A test line (T) intensity weaker than the reference line (R) indicates a PSA level between 4 – 10 ng/mL.
- A test line (T) intensity equal or close to the reference line (R) indicates a PSA level of approximately 10 ng/mL.

NEGATIVE: Coloured lines appear in both the control (C) and the reference (R) region. No coloured line appears in the test line region (T). This indicates a PSA level below 3 ng/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.

QUALITY CONTROL

A procedural control is included in the test. A coloured line appearing in the control line region (C) is considered an internal procedural control. 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 Cassette 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 Cassette 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 (> 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 < 30,000 ng/mL PSA.
6. As with any assay employing mouse antibodies, the possibility exists for interference by human anti-mouse antibodies (HAMA) in the specimen. Specimens from patients who have received preparations of monoclonal antibodies for diagnosis or therapy may contain HAMA. Such specimens may cause false positive or false negative results.

EXPECTED VALUES

The minimum indicative level of PSA for Prostate Cancer is generally agreed to be 3 ng/mL and the warning level is generally agreed to be 10 ng/mL.[3] The PSA Cassette has been compared with a leading commercial PSA ELISA test. The correlation between these two results is more than 98.0 %.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity
The PSA Cassette has been tested with a leading commercial PSA EIA Test using clinical samples.

Method		EIA		Total Results
	Results	Positive	Negative	
PSA Cassette	Positive	178	4	182
	Negative	2	282	284
Total Results		180	286	466

Relative Sensitivity: 98.9% (96.0 % - 99.9 %)*
Relative Specificity: 98.6 % (96.5 % - 99.6 %)*
Accuracy: 98.7 % (97.2 % - 99.5 %)*
* 95% Confidence Intervals

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, 3 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, 3 ng/mL, 10 ng/mL and 20 ng/mL of PSA in 3 independent assays. Three different lots of the PSA Cassette have been tested using these specimens. The specimens were correctly identified >99% of the time.

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

LITERATURE

1. Wang MC, Valenzuela LA, Murphy GP, et al., Purification of human prostate specificity antigen. Invest Urol 1979; 17: 159-163.
2. Christens A, Laurell CB, Lilja H. Enzymatic activity of prostate –specific antigen and its reaction with extracellular serine proteinase Inhibitors. Eur J Biochem 1990; 194:755-763.
3. Catalona WJ, Southurick PC, Slawin KM, et al., Comparison of percent free PSA, PSA density and age-specific PSA cut-offs for prostate cancer detection and staging. Urology 2000 Aug 1:56(2):255-60.
4. Vancangh PJ, De Nayer P, Sauvage P, et al., Free to total prostate-specific antigen (PSA) ratio is superior to total PSA in differentially benign prostate hypertrophy from prostate cancer. Prostate Supplement, 1996, 7:30-34.