

HEALTH-CHEM DIAGNOSTICS^{LLC}

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ONE STEP PSA™ PROSTATE SPECIFIC ANTIGEN TEST

(Whole Blood/Serum Plasma)

INTENDED USE

The HCD **One Step PSA™ Prostate Specific Antigen Test*** is a rapid semi-quantitative chromatographic immunoassay designed for the detection of human Prostate Specific Antigen (PSA) in human blood. It is intended for professional use as an aid in the diagnosis of prostate cancer, and for monitoring response to therapy.

SUMMARY

Prostate specific antigen (PSA) is a single chain glycoprotein containing two hundred forty amino acid residues and four carbohydrate side chains. The complete gene encoding PSA has been sequenced and localized to chromosome 19.¹ PSA functions as a kallikrein-like serine protease and is produced exclusively by the epithelial cells lining the acini and ducts of the prostate gland.²⁻⁴ It is secreted into the prostatic ducts, and at ejaculation it serves to liquefy the seminal coagulum.⁵ The detection of PSA by enzyme-linked immunosorbent assay (ELISA) has been demonstrated. The range of normal serum PSA concentration is 0.1 to 2.6 ng/ml, and the half life of serum PSA has been determined to be 2.2 to 3.2 days.⁷⁻⁸ Many studies have confirmed that PSA is the most useful and meaningful tumor marker known for prostate cancer.⁹

PRINCIPLES OF THE PROCEDURE

The HCD **One Step PSA™ Prostate Specific Antigen Test** is a chromatographic immunoassay which utilizes monoclonal antibodies to selectively detect PSA in serum with a high degree of sensitivity.

HCD's One Step PSA™ Prostate Specific Antigen Test strip consists of a chromatographic absorbent device, which uses a unique combination of monoclonal antibodies to selectively detect PSA in test samples. In five minutes, elevated levels of PSA as low as 4 ng/ml can be detected.

In the test procedure, the strip is dipped into a serum specimen. The specimen migrates through the absorbent area and along the test membrane. In the presence of PSA, labeled antibody-dye conjugate in the membrane binds to the PSA in the specimen, forming an antibody-antigen complex. This complex then binds to anti-PSA antibody in the test zone, producing a magenta (red-purple) line. In the absence of PSA, no line will form in the test zone. In either case, the reaction mixture continues to flow past the test zone into the control zone. Unbound conjugate binds to the reagents in the control zone, producing another magenta (red-purple) line, demonstrating that the reagents and the device are functioning correctly.

REAGENTS AND MATERIALS PROVIDED

1. HCD's **One Step PSA™ Prostate Specific Antigen Test** strip: an absorbent device consisting of a membrane containing lyophilized mouse monoclonal antibody and a pad treated with a protein matrix of polyclonal mouse antibody-dye conjugate and 0.1% sodium azide.

2. Test Instructions

NOTE: Sample collection materials and a clock or timer are required but are not supplied. Positive and negative controls are also available from HCD.

* A *membrane-based test strip covered under US Patent 4,774,192. Other patents pending.*

STORAGE CONDITIONS

Store the kit refrigerated between 4° and 8°C upon receipt and when not in use. Prior to use, bring the reaction kit to room temperature. Do not freeze. The expiration date is marked on the kit box label. When stored and transported properly, the strips are stable for a minimum of 12 months.

QUALITY CONTROL

The daily use of a control is recommended to verify proper kit performance. Quality control samples should be tested according to quality control requirements established by the testing laboratory.

Use the control in the same manner as a specimen by following the test procedure. The expected results should be obtained when using the control. Positive and negative controls are available from HCD.

PRECAUTIONS

1. Follow proper laboratory procedures for handling and disposal of specimens and test strips.
2. Do not use test strips after their expiration dates.
3. For in vitro diagnostic use only.

SPECIMEN COLLECTION AND STORAGE

1. For Serum or Plasma:

Collect blood aseptically by venipuncture into a clean test tube without anticoagulants. Permit blood to clot for twenty to thirty minutes at room temperature. Centrifuge, to obtain clear serum and transfer serum into a plastic or glass test tube. Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

If serum specimens are not tested immediately, they should be refrigerated at 4°- 8°C. For storage periods greater than three days, freezing is recommended. If specimens are to be shipped, they should be packed in compliance with applicable regulations covering the transportation of etiologic agents.

2. For fingerstick whole blood, see collection procedure.

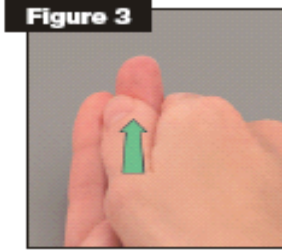
Blood Collection:

Figure 1

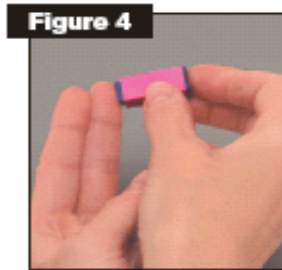


Figure 2

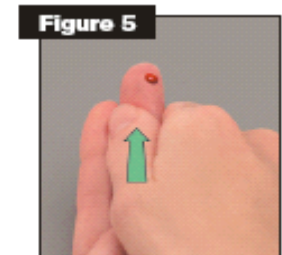


Figure 3

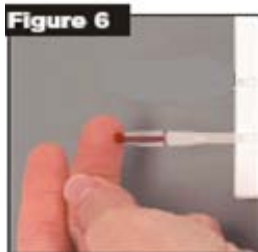


Figure 4

a. Place selected finger flat on the tabletop. With the thumb of your opposite hand, massage or “milk” the selected finger, five or six times, to push blood to the tip (Figure 3).

b. Place the raised end of the lancet firmly against the side of the selected finger.

Press the lancet against your finger until you hear a “click”. You may feel a slight sting. (Figure 4).

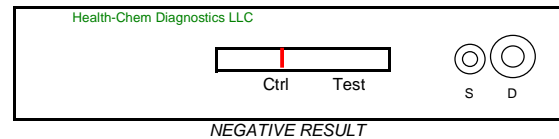
c. With the thumb of your opposite hand, massage or “milk” your finger until a large drop of blood forms. (Figure 5).

d. Gently touch the drop of blood to the tip of one dropper (Figure 6). Be sure to touch the drop of blood directly over the puncture site. The dropper will start to fill with blood.

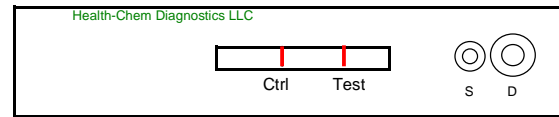
e. Fill the dropper until the blood reaches the black line.

If necessary, massage your finger to get more blood.

NOTE: The dropper **WILL NOT** fill past the black line.



NEGATIVE RESULT

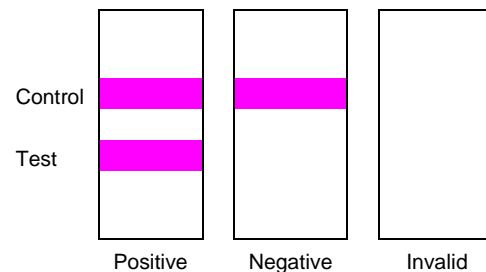


POSITIVE RESULT

- Wait 1-5 minutes until the plasma appears in the test window. If no visible flow appears, add an additional drop of serum/plasma.
- Read the results at 10 minutes.

B. For Fingerstick Blood:

- Using the enclosed pipette, add 25 µl of whole blood from a finger stick into the Sample Well (S) of the device, as shown in picture;
- Add 2 drops of sample diluent immediately to the Diluent Well (D).
- Wait 1-5 minutes until the pink color appears in the test window.
- Read the results at 10 minutes.

INTERPRETATION OF RESULTS

1. Positive: Two magenta (red-purple) lines appear - a control line (the line closer to the top of the strip) and a test line below it. The intensity of the test line is greater than the control line indicating that the PSA concentration in the serum specimen is elevated above the cutoff concentration of 4 ng/ml.

2. Negative: One magenta (red-purple) line appears in the control zone, with no visible second line in the test zone; this result indicates that the PSA concentration in the serum specimen is below the cutoff concentration of 4 ng/ml. (If a test line appears in the test zone and the intensity of the test line is less than the control line, then this result also indicates that the PSA concentration in the serum specimen is below the cutoff concentration of 4 ng/ml.)

3. Invalid: No magenta (red-purple) line is visible in the control zone. The test result is invalid, and the specimen should be retested.

Test Procedure:**A. For Serum or Plasma-**

- Remove the test strip from its foil wrapper by tearing along the “notch”.
- Add 2 drops of serum/plasma into the Sample Well (S) of the device, as shown in picture, from the enclosed pipette.

TEST PERFORMANCE

- Sensitivity:** The analytical sensitivity of the HCD **One Step PSA™ Prostate Specific Antigen Test** strip is 4 ng/ml.
- Accuracy:** A study was performed on 101 patient samples, comparing positive and negative sera as assayed with the HCD **One Step PSA™ Prostate Specific Antigen Test** strip versus another commercially available and FDA-approved ELISA test.

		ELISA TEST		TOTAL
		+	-	
HCD's ONESTEP PSA™	+	36	1	37
	-	0	64	64
		36	64	101

Sensitivity 100%
Specificity 98.5%

The data demonstrate the excellent correlation between the HCD **One Step PSA™ Prostate Specific Antigen Test** and a commercially available ELISA test. The clinical significance of the two tests is comparable.

- Specificity:** The specificity of the HCD **One Step PSA™ Prostate Specific Antigen Test** strip was determined in two ways: first by assessing the cross reactivity in PSA-free serum, and second, by measuring interference in normal serum containing PSA. No cross reactivity or interference was observed in sera containing the indicated concentrations of the following materials: triglycerides (500 mg/100 ml), bilirubin (10 mg/100 ml), Albumin (20 mg/ml), transferrin (5 mg/ml), prolactin (1 ug/ml), Prostatic Acid Phosphatase or PAP (1 ug/ml), and chorionic gonadotropin (900,000 mIU/ml). In addition, hemolyzed specimens with hemoglobin concentrations up to 10 mg/ml did not cross react or interfere with the **One Step PSA™ Prostate Specific Antigen Test**.
- Precision:** The precision of the HCD's **One Step PSA™ Prostate Specific Antigen Test** strip was determined using replicate assays of samples from three different patient serum pools, with kits from three different production lots. Each serum specimen was run through ten parallel assays. The data demonstrated 100% precision for the duplicates of each sample and 100% precision using the test kits from different lots.

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