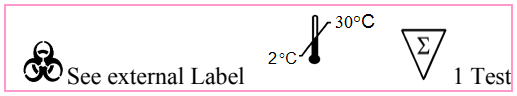
Diagnostic Automation / Cortez Diagnostics, Inc.
IMMUNO DIAGNOSTICS

OneStep PSA (Serum/Plasma/WB) RapiDip™ InstaTest

REF 13080-1-44

A Qualitative Rapid test for the qualitative detection of Prostate Specific Antigen (PSA) in whole blood, serum or plasma. For professional in vitro diagnostic use only.



INTENDED USE

The OneStep PSA Qualitative RapiDip™ (Whole Blood/Serum/Plasma) is a Qualitative Rapid chromatographic immunoassay for qualitative detection of Prostate Specific Antigen in whole blood, serum or plasma.

SUMMARY AND EXPLANATION

Prostate specific antigen (PSA) is produced by prostate glandular and endothelial cells. It is a single chain glycoprotein with a molecular weight of approximate 34 kDa.[1] PSA exists in three major forms circulating in the serum. These forms are free PSA, PSA bound to α1 – Antichymotrypsin (PSA-ACT) and PSA complexed with α2–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 3 to 10ng/ml is considered to be in the "gray-zone" and levels above 10ng/ml are highly indicative of cancer.[3] Patients with PSA values between 3-10ng/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).[4]
The PSA Qualitative RapiDip™ (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 3ng/ml and a reference value of 10ng/ml.

TEST PRINCIPLE

The OneStep PSA Qualitative RapiDip™ (Whole Blood/Serum/Plasma) is a qualitative, 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. 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.

SPECIMEN COLLECTION AND PREPARATION

- The PSA Qualitative RapiDip™ (Whole blood/Serum/Plasma) 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 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 area of the test dipstick.
  - 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 area of the test dipstick.
    - Allow 2 hanging drops of fingerstick whole blood to fall into the center of the specimen area on the test dipstick, or move the patient's finger so that the hanging drop touches the center of the specimen area. Avoid touching the finger directly to the specimen area.
- 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 the specimens have been collected. 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 AND COMPONENTS

Materials provided with the test kit

- Test dipsticks
- Droppers
- Buffer
- Package insert
- Test cards

Materials required but not provided

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

ASSAY PROCEDURE

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

1. Bring the pouch to room temperature before opening it. Remove the test dipstick from the sealed pouch and use it as soon as possible.
2. Place the dipstick on a clean and level surface.

For Serum, Plasma or Venipuncture Whole Blood specimens:

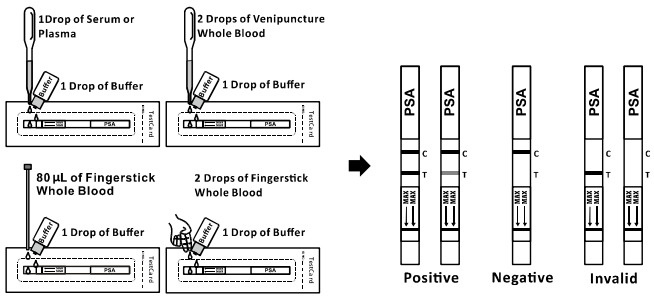
- Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 40µL) or 2 drops of venipuncture whole blood (approximately 80µl) to the specimen area of test dipstick, then add 1 drop of buffer (approximately 40µL) and start the timer. See illustration below.

For Fingerstick Whole Blood specimen:

- To use a capillary tube: Fill the capillary tube and transfer approximately 80µL of fingerstick whole blood specimen to the specimen area of test dipstick, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.
- To use hanging drops: Allow 2 hanging drops of fingerstick whole blood specimen (approximately 80 µL) to fall into the specimen area of test dipstick, 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 results 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.



RESULTS

(Please refer to the illustration above)

POSITIVE:* Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the test region (T).

***NOTE: The intensity of the color in the test line region (T) will vary depending on the concentration of PSA present in the specimen. Therefore, any shade of color in the test region (T) should be considered positive.**

NEGATIVE: One colored line appears in the control region (C). No apparent colored line appears in the test region (T).

INVALID: Control line 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 dipstick. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The PSA Qualitative RapiDip™ (Whole blood/Serum/Plasma) has been tested with leading commercial PSA ELISA Test using clinical samples.

Method		EIA		Total Results
PSA Qualitative Rapid Test Dipstick	Results	Positive	Negative	
	Positive	205	4	209
	Negative	2	459	461
Total Results		207	463	670

Relative Sensitivity: 99.0% (95%CI:*96.6%-99.9%)
*Confidence Intervals
Relative Specificity: 99.1% (95%CI:*97.8%-99.8%)
Overall accuracy: 99.1% (95%CI:*98.1%-99.7%)

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 0ng/ml, 2ng/ml, 3ng/ml, 10ng/ml and 20ng/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 0ng/ml, 2ng/ml, 3ng/ml, 10ng/ml and 20ng/ml of PSA in 3 independent assays. Three different lots of the PSA Qualitative RapiDip™ (Whole Blood/Serum/Plasma) 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 200mg/l, Hemoglobin at 10g/l, Triglyceride at 30g/l, Bilirubin at 1,000mg/dl, Uric Acid at 200mg/l.

REAGENTS

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

QUALITY CONTROL

A procedural control is included in the test. The appearance of colored lines in the control line region (C) is considered a 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 OF PROCEDURE

1. The PSA Qualitative RapiDip™ (Whole Blood/Serum/Plasma) 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 Qualitative RapiDip™ (Whole blood/Serum/Plasma) will only qualitative indicate the PSA antigen 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 that 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 30,000ng/ml PSA.

EXPECTED VALUES

The minimum indicative level of PSA for Prostate Cancer is generally agreed to be 3ng/ml and the warning level is generally agreed to be 10ng/ml.[3] The PSA Qualitative RapiDip™ (Whole blood/Serum/Plasma) has been compared with a leading commercial PSA ELISA test. The correlation between these two results is 99.1%.

PRECAUTION

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 or closed canister 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. Wear protective clothing such as laboratory coats, disposable gloves or eye protection when specimens are being tested.
7. The used test should be discarded according to local regulations.
8. Humidity and temperature can adversely affect results.

STORAGE

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 after the expiration date.

REFERENCES

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.

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