



ONE STEP Prostate Specific Antigen (PSA) TEST

(Whole Blood / Serum / Plasma)

FOR IN VITRO DIAGNOSTIC USE ONLY

INTENDED USE

THE ADVANCED QUALITY ONE STEP PSA TEST IS A RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR THE SEMI-QUANTITATIVE DETECTION OF PROSTATE SPECIFIC ANTIGEN (PSA) IN HUMAN SERUM, PLASMA AND WHOLE BLOOD. THE TEST IS INTENDED FOR HEALTHCARE PROFESSIONAL USE.

PRINCIPLE OF THE ASSAY

The One Step PSA Test is a colloidal gold enhanced immunoassay for the determination of Prostate Specific Antigen in human serum, plasma and whole blood. The nitrocellulose membrane was treated with mouse anti-human PSA McAb in the test region. During the assay, the serum, plasma and whole blood specimen is allowed to react with the colored conjugate (antibody-colloidal gold conjugate); the mixture then migrates on the membrane chromatographically by the capillary action. If PSA is present in the specimen, the specific antibody-PSA-colored conjugate complex will form in test region on the membrane. Absence of this colored band in the test region suggests a negative result. To serve as a procedural control, a colored band at control region should always appear in the test area.

MATERIALS PROVIDED

FOR CARD TEST

- Test cards individually foil pouched with a desiccant
- Plastic dropper
- Package insert.

FOR STRIP TEST

- Test strips individually foil pouched with a desiccant.
- Package insert.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer/clock
- Pipette
- Controls

PRECAUTIONS

1. For in vitro diagnostic use only.
2. All serum, plasma and whole blood specimens should be treated as infectious material. Do not contact the test strip without wearing safety gloves.
3. Devices used for the assay should be sterilized before being disposed.
4. Do not use the test beyond expiration date.

STORAGE CONDITION

The test device should be stored at 2-30°C.

SPECIMEN COLLECTION AND STORAGE

1. Collect serum, plasma and whole blood specimens following regular clinical laboratory procedures.
2. Only those serum, plasma and whole blood specimens that are clean, clear and with good fluidity can be used for the assay.

3. Those serum, plasma and whole blood specimens that are apparently hemolyzed, extremely thickened or with very high fat level are NOT suitable for the assay.
4. Storage: A specimen should be refrigerated if not used in the same day of collection; a specimen should be kept frozen if not used within 3 days after being collected. Do not thaw-and-freeze the specimens many times before using. Up to 0.1% of sodium azide can be added to specimen as preservative without affecting the results of assay.

ASSAY PROCEDURES

Bring all materials and specimens to room temperature before testing.

FOR CARD TEST:

1. Remove test device from sealed pouch.
2. Dispense 100µl (3 drops) serum, plasma or whole blood to the sample well.

FOR STRIP TEST:

1. Remove test strip from the sealed foil pouch.
2. Dip the test strip into serum, plasma or whole blood sample with the arrows pointing toward the specimen. *Note: The serum, plasma and whole blood level should reach the maximum line marked on the strip, but must not exceed the maximum line.*
3. Hold the strip in the sample until a reddish color appears at the lower edge of the test membrane (approximately 10 seconds).
4. Withdraw the strip and place it face-up on a clean, dry surface.

INTERPRETATION OF TEST RESULTS

Read the test result between 5 to 10 minutes. Do not interpret the result after 15 minutes.

1. *Negative:* Only one colored band appears in the control region.
2. *Positive:* In addition to the control band, a distinct colored band also appears in the test region.

This assay is designed to detect PSA at the cutoff level of 4 ng/ml. When the concentration of PSA in the specimen is equal to or greater than 4 ng/ml, the test band will appear with intensity that is equal to or stronger than control band. The appearance of a test band that is weaker than the control band indicates the presence of PSA in the specimen at a level lower than 4 ng/ml.

3. *Invalid:* Neither test band nor control band appears. Retest using a new test device.

BIBLIOGRAPHY:

1. Lange P.H.: the Value of Serum, plasma and whole blood Prostate Specific Antigen Determinations Before and After Radical Prostatectomy. J. Urol., 141:873-879, 1989.
2. Staney T.A.: Prostate Specific Antigen in the Diagnosis of and Treatment of Adenocarcinoma of the Prostate Untreated Patients. J. Urol., 141:1070-1075, 1989.
3. Schfman R. B. Analytical and Physiological Characteristics of Prostate Specific Antigen and Prostatic Acid Phosphates in Serum, plasma and whole blood Compared, Clin. Chem. 33:2086-2088, 1987.