e-mail : sales@campmedica.ro
http:// www.campmedica.ro

"See Now" PSA CassetteTest

Serum/ Plasma

For in vitro Diagnosis Use

Product Code: SN 3.6

INTENDED USE

The *"See Now"* PSA is a rapid direct binding test for the detection of Prostate Specific Antigen (PSA) in serum, plasma as an aid in the diagnosis of prostate cancer. The test is based on the principle of sandwich immunoassay for determination of PSA in serum or plasma. Monoclonal and polyclonal antibodies are employed to identify PSA specifically. This one step test is very sensitive and only takes about 5-8 minutes. The sensitivity of the test can reach to 4ng/ml.

PRINCIPLE

The *"See Now"* PSA has been designed to detect human Prostate specific antigen in serum, plasma samples through visual interpretation of color development in the test device. The test device contains a membrane strip, which is pre-coated with anti PSA antibody on the test line region (T) and goat anti-mouse antibody on the control line region (C). An anti-PSA colloidal gold conjugate pad is placed at the end of the membrane. When PSA is present in the patient sample dissolved in buffered saline, the mixture of colloidal gold conjugate and extracted sample moves along the membrane chromatographically by capillary action. This mixture then migrates to the test region (T) forms a visible line as the antibodies complex with the PSA. For a positive result, two pink-rose lines (bands) are visible in the control and test areas of the test window. The intensity of the test line is stronger than that of the control line; this means a PSA concentration is more than 4ng/ml. For a negative result, the intensity of the test line is less than that of the control line; this means a PSA concentration is less than 4ng/ml.
A colored band will always appear at the control region (C) to serve as a procedural indicator for the proper performance of the test and the device.

REAGENTS AND MATERIALS SUPPLIED

- Individually wrapped test devices.
- One Instruction Sheet.

MATERIALS REQUIRED BUT NOT SUPPLIED

- A clean container for the collection of serum or plasma sample.
- Timer

STORAGE AND STABILITY

The test kit is to be stored at temperature (4-30℃) in the sealed pouch for the duration of the shelf-life.

PRECAUTIONS

- *FOR IN-VITRO DIAGNOSTIC USE.*
- For professional use only.
- The test device should remain in the sealed pouch until use. Do not use it after the expiration date.
- All patient samples should be treated as if capable of transmitting disease.

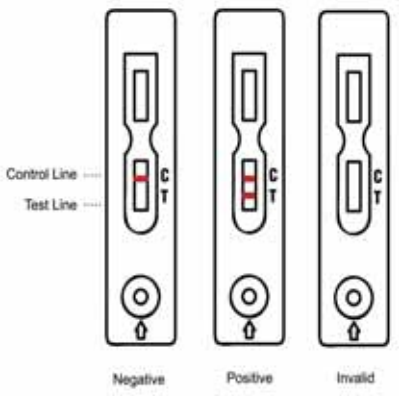
SPECIMEN COLLECTION AND STORAGE

- The *"See Now"* is performed on human serum, plasma.
- Remove the serum or plasma from the clot or red cells, respectively, as soon as possible to avoid hemolysis. Lipemic ， icteric, or hemolyzed specimens may give inconsistent test result. Specimens, of containing precipitate, should be clarified prior to testing.
- PSA is thermo-labile. If specimens are not to be tested they should be refrigerated immediately at 4 to 8℃ ， if storage periods greater than 5 days are anticipated, the specimen should be frozen.
- Do not use heat-inactive specimens.

TEST PROCEDURE

- Review "Specimen Collection" instructions. When you are ready to begin testing, open the sealed pouch by tearing along the notch. Remove the test from the pouch.
- Draw 0.2 ml sample into the pipette, and dispense it into the sample well on the cassette.
- Wait 15 minutes and read results. Do not read results after 30 minutes.

INTERPRETATION OF RESULTS



Negative

Only one pink colored band appears at the control region.

Positive

Distinct pink colored bands appear at the control and test line regions.

Invalid

No visible band at the control region. Repeat with a new test device. If test still fails, please contact the distributor.

QUALITY CONTROL

- A procedural control is included in the test. A colored band appearing on the control region (C) of the membrane indicates proper performance of the test and the device.

Sensitivity

The PSA Test detects Prostate specific antigen (PSA) concentration in human serum, plasma specimens higher than 4ng/ml as indicated by the intensity of the test line is as the same as or stronger than that of the control line.

Specificity

The clinical specimens were tested with a commercial EIA kit. In a side by side comparison using the PSA test and commercial EIA kit, test results rendered 100% agreement.