# INSTRUCTIONS FOR USE
# ONE STEP TEST
## Semi-Quantitative Prostate Specific Antigen (PSA) Detection In Whole Blood / Serum / Plasma

Only for professional *in vitro* diagnostic use.

**Product Code : TPSA01**
Semi-Quantitative PSA Detection Cassette Test.

## BACKGROUND INFORMATION

Prostate specific antigen (PSA) is the best serum marker currently available for the detection of prostate cancer and is the forensic marker of choice for determining the presence of azoospermic semen in some sexual assault cases.
Prostate cancer is a common malignancy in Western populations and a growing public health problem globally. Although the prevalence of prostate tumors becomes very high with age, only a small proportion of tumors are potentially lethal (aggressive) and their identification is an enduring challenge. Established risk factors include age, family history, and race, but, until the causes are better understood, prevention is impossible. In some populations, the widespread use of prostate-specific antigen (PSA) tests to increase early detection has inflated incidence, often by more than twofold, and shifted the disease spectrum toward less aggressive forms, that is, small tumors of low to moderate grade. Given the virtually ubiquitous presence of small low-grade tumors in the prostates of older men, the principal research question now is to identify factors that cause progression to advanced disease.
The human kallikrein (hk) family, located on chromosome 19, encodes prostate-specific antigen (PSA [or hK3]), hK2, hK4, and hK15 (prostin), as well as other serine proteases. Although PSA has been used in the detection of prostate cancer for several years, much remains unknown about its function and forms. The regulatory mechanisms of PSA are vital to its understanding.
Testing for prostate-specific antigen (PSA) has profoundly affected the diagnosis and treatment of prostate cancer. PSA testing has enabled physicians to detect prostate tumours while they are still small, low-grade and localized. This very ability has, however, created controversy over whether we are now diagnosing and treating insignificant cancers. PSA testing has also transformed the monitoring of treatment response and detection of disease recurrence. Much current research is directed at establishing the most appropriate uses of PSA testing and at developing methods to improve on the conventional PSA test.

## INTENDED USE

The Semi-Quantitative PSA Detection Test Device is a rapid chromatographic immunoassay for semi-quantitative detection of Prostate Specific Antigen in whole blood, serum or plasma.

## REAGENTS

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

## METHOD

The Semi-Quantitative PSA Detection Test Device uses solid-phase immunochromatographic technology for the semi-quantitative detection of prostate specific antigen in whole blood / serum / plasma. The test is a two-site immunometric assay in which a combination of monoclonal PSA antibodies and PSA monoclonal antibody coated particles are used to selectively detect prostate specific antigen in samples with a high degree of sensitivity. Monoclonal PSA antibodies were immobilized on the test area "T" of the nitrocellulose membrane. PSA monoclonal antibody coated particles were dried on a conjugate pad. Sample is introduced from sampling pad. If there is PSA in the sample, PSA binds to the mobile PSA monoclonal antibody coated particles. Together they move to the test area "T". PSA molecules bind to the immobilized Monoclonal PSA antibodies and as a result of this, PSA molecules that have already bound to PSA monoclonal antibody coated particles become immobilized in the test area "T" thus creating a visible colored signal indicating positive test result. Test area "T" intensity weaker than the reference line "R" indicates that the PSA level in the specimen is between 4-10 ng/mL. Test area "T" intensity equal or close to the reference line "R" indicates that the PSA in the specimen is approximately 10 ng/mL. Test area "T" intensity stronger than the reference line "R" indicates that the PSA level in the specimen is above 10 ng/mL. If there is no PSA in the sample then sample moves to the test area "T" together with free PSA monoclonal antibody coated particles. Immobilized Monoclonal PSA antibodies cannot bind to mobilized PSA monoclonal antibody coated particles, therefore no visible colored signal in test area "T" (no colored test line) can be obtained, indicating negative test result. Regardless of PSA content of the liquid sample, a visible colored signal is produced in the control area "C" (a colored control line), indicating a valid test result. Colored line should be visible in the control area "C" in every case; if no visible colored line in control area "C", test result should be indicated as invalid.

## PRECAUTIONS AND LIMITATIONS

1. For professional and *in vitro* diagnostic use only.
2. Do not use test kit beyond expiry date. The test device is single use. Do not reuse.
3. The test device should remain in its original sealed pouch until usage. Do not use the test if the seal is broken or the pouch is damaged.
4. Wear disposable gloves while performing the test.
5. Use a new dropper for each sample.
6. All patient samples should be handled as taking capable of transmitting disease into consideration. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of samples.
7. PSA levels may be unreliable in patients who receive hormone therapy or prostate gland manipulation.
8. 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 30,000 ng/mL PSA.
9. This test will indicate only the presence or absence of PSA in the sample, and should not be used as the only basis for the diagnosis of Prostate cancer.
As with all diagnostic tests, it should be kept in mind that an identification diagnosis can't be based on a single test result. Diagnosis can only be reached by an expert after the evaluation of all clinical and laboratory findings.

## STORAGE

Test device should be kept away from direct sunlight, moisture, heat and radiation sources. Store at 4 - 30°C (39 - 86°F). Do not freeze.
The test in the original packaging retains stable until expiry date at storage conditions. The test device should be used in maximum one hour after the foil is opened.

**Kit components:** Test devices, droppers, diluents and instructions for use.

**Additional materials required but not provided :** Sample collection tube, centrifuge and timer, lancet (for only fingerstick whole blood), heparinized dispensing bulbs and capillary tubes (for only fingerstick whole blood).

**Additional materials recommended but not provided :** Micropipettes to deliver mentioned amount of sample in the test procedure, negative and positive control materials.

## SAMPLE COLLECTION AND PREPARATION

The test can be performed using whole blood, serum or plasma. To avoid hemolysis, serum or plasma should be separated from blood as soon as possible.

**For Whole Blood Samples:** Test should be performed immediately with whole blood samples. Otherwise, whole blood samples should be stored at 2 - 8 °C with anticoagulants (EDTA, heparin, citrate should be used) to avoid coagulation until they are being tested in a period of 2 days after collection.

**For Serum Samples:** Collect blood into a collection tube without anticoagulant, leave to settle for 30 minutes for blood coagulation and then centrifuge the blood. At the end of centrifuge period remaining supernatant is used as serum.

**For Plasma Samples:** Collect blood into a collection tube with anticoagulants (EDTA, heparin, citrate should be used) to avoid coagulation of blood sample and then centrifuge the blood. At the end of centrifuge period supernatant is used as plasma.

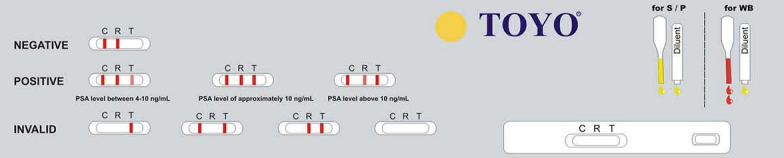
Do not use turbid, hemolyzed samples. If the sample cannot be tested on the day of collection, store the serum, plasma samples in a refrigerator or freezer. Do not freeze and thaw the serum, plasma samples repeatedly. Do not freeze whole blood sample. Bring the samples to room temperature before testing. Frozen samples must be completely thawed and mixed well prior to testing. Turbid test samples should be centrifuged. Using of frozen and thawed samples should be avoided whenever possible, due to the blocking of the membrane by the debris.

## TEST PROCEDURE

1.Take the test device out of its pouch. Bring the tests and whole blood / serum / plasma samples to room temperature,
2. **For Serum / Plasma Samples:** Draw serum / plasma into dropper and put 1 drop (40 µl) into the sample well of the cassette. Immediately after, 1 drop (40 µl) of diluent is added into the sample well and allowed to soak in.
**For Whole Blood Samples:** Draw whole blood into dropper and put 2 drops (60 µl) into the sample well of the cassette. Immediately after, 1 drop (40 µl) of diluent is added into the sample well and allowed to soak in.
Avoid the formation of any air bubbles.
3.Depending on the anti-PSA concentration in the sample, the test can react even in 2 - 3 minutes. Results should be read at 5 minutes as shown below. Do not interpret results beyond 10 minutes, results forming after 10 minutes should be regarded as invalid.
*Note: If migration is not observed in the result window after 30 seconds, add one or two extra drops of diluent.

## INTERPRETATION OF RESULTS

**Negative** : Two colored lines are visible in control area "C" and reference line "R" indicating that PSA level is below 4 ng/ml.
**Positive:** Three distinct colored lines appear
A. Test area "T" intensity weaker than the reference line "R" indicating that PSA level between 4-10 ng/mL.
B. Test area "T" intensity equal or close to the reference line "R" indicating that PSA level of approximately 10 ng/mL.
C. Test area "T" intensity stronger than the reference line "R" indicating that PSA level above 10 ng/mL.
**Invalid :** No colored line is visible in control area "C" or reference line "R" or only one colored line is visible in test area "T"; test should be repeated using a new test device.




## QUALITY CONTROL

Tests have built in procedural quality control features. When the test is complete, the user will see a colored line in the "C" and "R" areas of the test on negative samples and a colored line in the "T", "R" and "C" area on positive samples. The appearance of the control area "C" and reference line "R" is considered as an internal procedural control. This line indicates that sufficient volume of sample was added as well as valid test result. It is recommended that a negative control and a positive control be used to verify proper test performance as an external control. Users should follow appropriate federal, state and local guidelines concerning the external quality controls.

## PERFORMANCE EVALUATION

PSA Detection Test Device has been performed using below samples. Results were shown at below table and evaluated by Tietz Method.

- 300 PSA positive samples
- 100 clinical PSA negative samples
- 30 potentially interfering PSA negative samples (Bilirubin)
- 30 potentially interfering PSA negative samples (Triglycerides)
- 30 cross reactivity samples (hK2)
- 300 PSA negative samples
- 30 potentially interfering PSA negative samples (Ascorbic acid)
- 30 potentially interfering PSA negative samples (Hemoglobin)
- 30 potentially interfering PSA negative samples (Uric acid)
- 120 PSA positive calibrated samples
- 50 PSA positive samples (hook effect)

| Tietz method | | Reference | | Total |
|---|---|---|---|---|
| | | + | - | |
| Turklab PSA Test | + | 470 | 0 | 470 |
| | - | 0 | 580 | 580 |
| Total | | 470 | 580 | 1050 |

**Sensitivity: 100 %** **Specificity: 100 %**
**+ Predictive V: 100 %** **- Predictive V: 100 %**

**Cut-off value:** 6 different PSA concentrations (2ng/ml, 4 ng/ml, 10 ng/ml, 20 ng/ml, 40 ng/ml and 100 ng/ml) were tested with Turklab PSA IVD tests and cut-off value was observed 4 ng/ml according to performed study by Turklab.

**Cross reactivity:** Cross reactivity has been tested with hK2 positive samples, no cross reactivity was found with Turklab PSA rapid test.

**Interferences:** Potentially interfering substances; Ascorbic acid, bilirubin, hemoglobin, triglycerides, uric acid were tested with PSA IVD Medical devices. In each case, no interference with the expected PSA test results was observed.

**Hook effect:** No significant hook effect was detected when samples containing 30 000 ng/ml of PSA were assayed.

Haemolytic samples can interfere and can cause to invalid or false test results.

## REFERANCES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## SYMBOLS USED

CE 1434 — Manufacturer — Consult instruction for use — Attention, see instruction for use — *In vitro* diagnostic medical device — For single use only — Number of test — REF Catalog number — Storage temperature — LOT Lot number — Expiry date