Chemtrue™

One-Step PSA Test

For in vitro Diagnosis Use

Product Code: 9002C

INTENDED USE

Chemtrue™ One-Step PSA Test is a rapid direct binding test for the detection of Prostate Specific Antigen (PSA) in serum or 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.

SUMMARY

Prostate specific antigen (PSA) is a serine protease that is found only in the prostate within the epithelial cells of the acini and ducts. Normal PSA concentration in serum or plasma is 0.1-2.6ng/ml. Reports have suggested that elevated level of serum or plasma PSA is the most useful tumor markers in diagnosis of prostate cancers. Chemtrue™ One-Step PSA Test is designed to detect PSA concentration in serum or plasma as low as 4ng/ml within 5 minutes.

PRINCIPLE

The Chemtrue™ One-Step PSA Test has been designed to detect human Prostate specific antigen in serum or plasma samples through visual interpretation of color development in the test cassette. The test cassette contains a membrane strip, which is pre-coated with anti PSA antibody on the test region (T) and goat anti-mouse antibody on the control 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, 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 red lines are visible in the control and test regions of the test window. The intensity of the test line is as the same as or stronger than that of the control line; this means a PSA concentration is as the same as or 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 line will always appear at the control region (C) to serve as a procedural indicator for the proper performance of the test and the cassette.

REAGENTS AND MATERIALS SUPPLIED

- Individually wrapped test with disposable transfer pipette. Each test cassette contains one test strip with anti PSA antibody and goat anti-mouse antibody coated membrane, colored anti-PSA antibodies pad.
- Disposable transfer pipette
- Test instruction.

MATERIALS REQUIRED BUT NOT SUPPLIED

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

STORAGE AND STABILITY

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

PRECAUTIONS

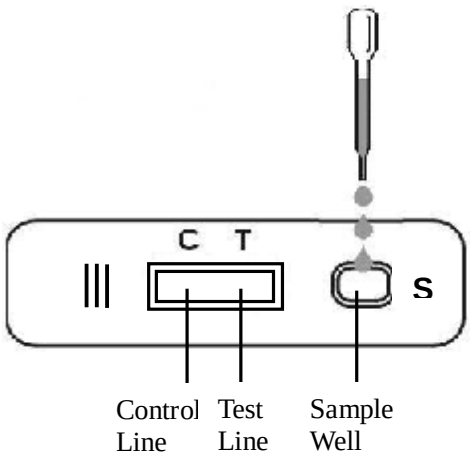
- *FOR IN-VITRO DIAGNOSTIC USE.*
- For professional use only.
- The test cassette should remain in the sealed pouch until use. Do not use the cassette beyond the expiration date.
- All patient samples should be treated as if capable of transmitting disease.
- Discard the used kit to right trashcan.

SPECIMEN COLLECTION AND STORAGE

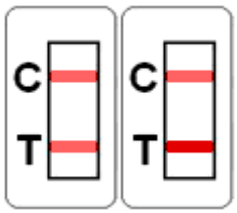
- The Chemtrue™ One-Step PSA Test is performed on serum or plasma.
- **Serum:**
  Collect blood into a collection container (containing no anticoagulants) by vein puncture.
  Allow the blood to clot.
  Seprate the serum by centrifugation.
  Carefully withdraw the serum for testing, or store at 2 to 8℃, if storage periods greater than 5 days are anticipated, the specimen should be frozen.
- **Plasma**:
  Collect blood into a collection container (containing EDTA, heparin or citrate, respectively) by vein puncture.
  Seprate the plasma by centrifugation.
  Carefully withdraw the plasma for testing, or store at 2 to 8℃, if storage periods greater than 5 days are anticipated, the specimen should be frozen.
- The specimens should preferably be examined immediately after collection. Lipemic, icteric, or haemolytic specimens may give inconsistent test result. Specimens, of containing precipitate, should be clarified prior to testing.
- Do not use heat-inactive specimens.

TEST PROCEDURE

- Bring the test to room temperature (15-30℃) before opening the pouch to avoid condensation of moisture on the membrane if stored in the refrigerator.
- Remove the test cassette from its protective pouch and mark the test.
- 2~3 drops into the sample well on the cassette.
- Wait 5 minutes and read results. Do not read results after 8 minutes.

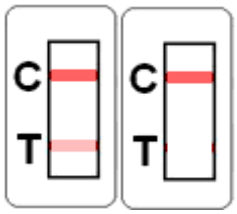


TERPRETATION OF RESULTS



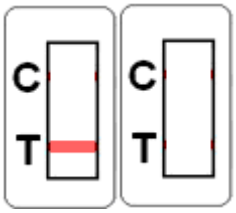
Positive

Two red lines are visible in the control ("C") and test ("T") regions of the test window. The intensity of the test line is as the same as or stronger than that of the control line; this means a PSA concentration is more than 4ng/ml.



Negative

The color intensity of the test line is weaker than that of the control line. This means a PSA concentration is less than 4ng/ml. (If a control line appears in the control region, with no visible second line in the test region, then this result also indicates that the PSA concentration is below the cutoff concentration of 4 ng/ml)



Invalid

The test is invalid if the control line is not visible at five minutes. The test failed, or the test procedure was not followed properly. Verify the test procedure and repeat the test with a new testing cassette.

LIMITATION OF PROCEDURE

1. The test is ONLY for in vitro diagnostic use.
2. Although the test is very accurate in detecting .Elevated PSA, a low incidence of false results can occur.
3. The test is a qualitative screening assay and is not suggested for use to determine the quantitative PSA level of serum.
4. Some hetemphile antibody may affect the results.

Disposal

Return test cartridges and droppers to original pouches.
Dispose of test materials according to local, state and federal regulations.

QUALITY CONTROL

A procedural control is included in the test. A colored band appearing on the control region (C) is considered an internal positive procedural control, indicating proper performance and reactive reagents.

PERFORMANCE CHARACTERISTICS

- **Sensitivity**
- The Chemtrue™ One-Step PSA Test detects Prostate specific antigen (PSA) in serum or plasma specimens with concentration of 4ng/ml or higher as indicated by the intensity of the test line is as the same as or stronger than that of the control line.
- **Interference:**

The following substances were added to PSA negative and 4.0ng/ml PSA spiked serum samples. No interference was found with any of the substances at the following concentrations:

Bilirubin	10 mg/dl
Triglycerides	500 mg/dl
Cholesterol	800 mg/dl
Hemoglobin	250 mg/dl

- **Accuracy**

The Chemtrue™ One-Step PSA Test was tested with ABON PSA test which is CE marked by using 201 clinical samples.

Chemtrue™		ELISA TEST		
		+	-	TOTAL
One-Step PSA Test	+	57	2	**59**
	-	0	142	**142**
Total		**57**	**144**	**201**

Relative Sentivity: 57/57=100%
Relative Specificity: 142/144=98.62%
Relative Accuracy: (57+142)/201=99.01%
The data demonstrate the excellent correlation between the Chemtrue™ One-Step PSA Test and ABON PSA Test. The clinical significance of the two tests is comparable.

- **Dose Hook Effect**

There is no dose hook effect at 10000ng/ml PSA.

REFERENCE

1. Greenlee RT,Murray T,Bolden S,et al.Cancerstatistics, 2000[J].CA Cancer JC lin,2000,50(1)：733.
2. Ito K, Kubota, Suzuki K, et al. Correlation of prostate specific antigen before prostate cancer detection and clinicopathologic features: Evaluation of mass screening populations [J]. Urology, 2000；55(5):705-709.
3. Oesterling JE, Kumamoto Y, Tsukamoto T; [M];Bri J Urology; 1995.
4. Mario BO, Manuel V, Renata M, et al; Oncology Hematology; 2003.

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CE **0123**

Index of symbols	
	Attention, see instruction for use
IVD	For in vitro diagnostic use only
	Store between 4-30°C
	Tests per kit
	Use by
LOT	Lot number
	Manufacturer
	Do not reuse
REF	Catalog#
EC REP	Authorized Representative
	Keep dry
	Caution

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