

3. **Invalid:** If there is no distinct rose-color band visible in the control window, then the test result is invalid. It is recommended that the specimen be retested.

**Important:** A positive result will not change once established at ten minutes. However, in order to prevent any incorrect results, do not interpret results after 15 minutes.

**LIMITATIONS OF THE PROCEDURE**

1. The test is limited to the detection PSA in serum, plasma, or recalcified plasma.
2. The test is for *in vitro* diagnostic use only.
3. Although the test is very accurate in detecting elevated PSA, a low incidence of false results can occur.
4. The test is a qualitative screening assay and is not suggested for use to determine the quantitative PSA level of serum.
5. As with all diagnostic tests, a definite clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

**PERFORMANCE CHARACTERISTICS**

1. Sensitivity: The analytical sensitivity of the One-Step PSA Test is 5 ng/ml.
2. Accuracy: A study was performed using 101 positive and negative serum specimens assayed with One-Step PSA Test and another commercially available ELISA test according to the respective package insert procedures.

Correlation Study  
(n=101)

One-Step PSA Test/ ELISA	
+/+	+/-
36	1
-/+	-/-
0	64

Relative Sensitivity: 100%  
Relative Specificity: 98.5%

The data demonstrates the excellent correlation between the One-Step PSA Test and the ELISA test. The clinical significance of the two tests is comparable.

3. Specificity: The specificity of the One-Step PSA Test was determined in two ways: first cross reactivity in PSA free serum was assessed; second interference was measured in normal serum containing PSA. Serum with triglyceride concentration up to 500 mg/100 ml, with Bilirubin concentration up to 10 mg/100 ml, hemolyzed specimens with hemoglobin concentration up to 10 mg/ml, and proteins such as PAP (prostatic acid phosphatase, 1000 ng/ml), albumin (20 mg/ml), chorionic gonadotropin (900,000 mIU/ml), transferrin (5 mg/ml) and prolactin (1 ug/ml) were analyzed and did not show interference or cross reactivity with the test.
4. Precision: The precision of the One-Step PSA Test was determined using replicate assays of samples from three different patients serum pools, with kits from three different production lots. Each specimen sample was run through ten parallel assays. The data demonstrated 100% precision for the duplicates of each sample and 100% precision using the test kits from different lots.

**REFERENCES**

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**P715: 11/01**

#### INTENDED USE

The One-Step PSA Test is a colloidal gold/antibody complex based immunoassay designed for the qualitative determination of human prostate specific antigen in serum. It is intended for professional use as an aid in the diagnosis and staging of prostate cancer, as well as to minor response to therapy.<sup>1</sup>

#### SUMMARY

Prostate specific antigen (PSA) is a single chain glycoprotein containing two hundred forty amino acid residues and four carbohydrate side chains.<sup>1</sup> The complete gene encoding PSA has been sequenced and localized to chromosome 19.<sup>1</sup> PSA functions as a kallikrein like serine protease and is produced exclusively by the epithelial cells lining the acini and ducts of the prostate gland.<sup>2-4</sup> It is secreted into the prostatic ducts, and at ejaculation it serves to liquefy the seminal coagulum.<sup>5</sup>

Qualitative PSA detection by enzyme linked immunosorbent assay (ELISA) indicates the range of normal human serum PSA concentration is between 0.1 and 2.6 ng/ml: and that the half life of serum PSA between 2.2 and 3.2 days.<sup>5,7,8,9</sup>

Many studies confirm that PSA is the most useful and meaningful tumor marker known for prostate cancer.<sup>9</sup>

The One-Step PSA Test is a chromatographic immunoassay which utilizes monoclonal antibodies to selectively detect PSA in serum with a high degree of sensitivity.

#### PRINCIPLES OF THE PROCEDURE

The One-Step PSA Test consists of a chromatographic absorbent device and a unique combination of monoclonal antibodies that selectively detect PSA in test samples with a high degree of sensitivity. In ten minutes, elevated levels of PSA as low as 5 ng/ml are detected.

Serum migrates through the absorbent area and along the test membrane, PSA present in the specimen is bound by antibody-dye conjugate forming antibody-antigen complex. The complex is captured by the anti-PSA antibody immobilized in the test zone (T) of the membrane forming a pink-rose band (in the absence of PSA, no line will form in the test zone). Dye conjugate is captured by the antibody immobilized in the control zone (C) of the membrane producing a pink-rose color band regardless of the test sample composition. The clearly visible control band serves for evaluation of the test band intensity, and as an indicator of the assay validity.

#### REAGENTS AND MATERIALS PROVIDED

1. Reaction Pack - An absorbent device with a lyophilized mouse monoclonal antibody coated membrane and a pad treated with mouse polyclonal IgG-dye conjugate in a protein matrix containing sodium azide.
2. Dropper - A serum transfer pipette is included in each test pouch.

#### MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection container
2. Centrifuge capable of 1000 x g (for centrifuging whole blood specimens)
3. Clock or timer

4. Positive & Negative controls

#### TEST STORAGE

Store the test below 28°C; do not freeze. Prior to use, bring test and components to room temperature.

#### WARNINGS AND PRECAUTIONS

1. Handling should preclude any pipetting by mouth.
2. Do not allow smoking or eating where specimen and reagents are being handled.
3. Wear disposable gloves while handling kit reagents or specimens. Wash hands thoroughly afterwards.
4. Avoid splashing or aerosol formation.
5. Clean up spills thoroughly using an appropriate intermediate-to-high level disinfectant.
6. Decontaminate and dispose of all specimens and potentially contaminated materials as if they were infectious.
7. Do not use reagents after the expiration date.
8. For *in vitro* diagnostic use only.

#### QUALITY CONTROL

The use of control is recommended to verify proper kit performance. Quality control samples should be tested according to quality control requirements established by the testing laboratory.

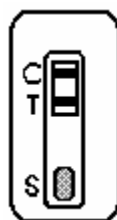
Use the control in the same manner as a specimen by following the test procedure. The expected results should be obtained when using the control. Positive and negative controls are included with the test kit.

#### TEST PROCEDURE

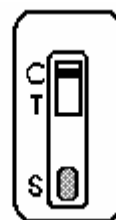
1. Bring test components including serum to room temperature. Remove test device from the pouch.
2. Holding the dropper vertically, transfer exactly four drops of sample specimen into the sample well (S) of the test device.
3. Read results at ten minutes.

#### INTERPRETATION OF RESULTS

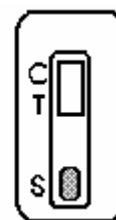
A positive or negative result is determined by comparing the color intensity of the two pink-rose color bands that appear at ten minutes. The control bands color intensity indicates a PSA reading of about 5 ng/ml.



POSITIVE



NEGATIVE



INVALID

1. **Positive:** A color band appears at both the control region and test region. The color intensity of the test line reflects the concentration level of PSA.
2. **Negative:** A color band appears at control region only. (Or non-existent indicating the PSA level is below the 5 ng/ml cutoff.)