Diagnostic Automation / Cortez Diagnostics, Inc.
IMMUNO DIAGNOSTICS

OneStep PSA Serum RapiCard™ InstaTest

Cat #13070-1

IVD See external Label 2 -30°C ∑= 1 Test

Specificity	**98 %**
Sensitivity	**4.0 ng/ml or greater**

INTENDED USE

The Cortez Diagnostics PSA test is an immunochromatography based one step in vitro test.

SUMMARY AND EXPLANATION

Prostate cancer is the one of the most common types of cancer found in man. The incidence of prostate cancer increases with age and accounts for a growing number of newly diagnosed patients. Prostate specific antigen (PSA) is produced primarily in the prostate gland and is secreted into the prostate ducts and at ejaculation serves to liquefy the seminal coagulum. Virtually all healthy males under 50 years of age have PSA concentration under 4.0 ng/ml. If PSA level is above 20 ng/ml, the patient most likely to have prostate cancer. Some studies indicated that elevated total PSA levels are found in serum from patients who have prostate cancer cells metastasized throughout their bodies. Other studies indicated that Free PSA, which can not foam a complex with serine protease tends to be more abundant in patients with benign prostatic hyperplasia. Cortez Diagnostics PSA test use antibodies which can equally recognize both free PSA and PSA-ACT complex.

Cortez Diagnostics PSA test is a sandwich immunoassay. When serum sample is added to sample pad, it moves through the conjugate pad and mobilizes gold anti-PSA conjugate that is coated on the conjugate pad. The mixture moves along the membrane by capillary action and reacts with anti-PSA antibody that is coated on the test region. If PSA is present, the result is the formation of a colored band in the test region. The color intensity is dependent on the concentration of PSA in the sample. On the other hand, a light color band will always appear at the control zone. This control band serves as a reference of 4.0 ng/ml of PSA.

TEST PRINCIPLE

It is designed for the rapid semi-quantitative determination of human prostate specific antigen (PSA) in serum specimens.

SPECIMEN COLLECTION AND PREPARATION

1. The serum specimen should be collected under standard laboratory conditions.
2. Patient samples performed best when tested immediately after collection. If the assay is not performed immediately, serum specimen may be refrigerated at 2-8oC or frozen up to 7 days. Frozen samples should be thawed and brought to room temperature before proceeding.
3. Sodium azide can be added as a preservative up to 0.1% without effecting the test results.

MATERIALS AND COMPONENTS

Materials provided witht the test kit

1. Instruction for use.
2. Cortez Diagnostics PSA Test device. The amount of each coated antigen and/or antibody on the strip is less than 1.0 mg for antigen conjugate and is less than 1.0 mg for goat anti-mouse IgG antibody.

Test zone: contains mice monoclonal anti-PSA antibody.
Control zone: contains goat anti-rabbit IgG antibody.
Conjugate Pad: contains gold-mice monoclonal anti-PSA antibody conjugate.

Materials required but not provided

1. Serum collection containers.
2. Timer or clock.

ASSAY PROCEDURE

For Test Card:

1. Bring all materials and specimens to room temperature.
2. Remove the test card from the sealed foil pouch.
3. Place the transfer pipette in the specimen and depress the bulb to withdraw a sample.
4. Hold the pipette in a vertical positon over the sample well of the test card and deliver 3 drops (120-150µl) of sample into the sample well.
5. Read the result at 8 minutes.
   Note: Results after 8 minutes may change and cause false interpretation.

RESULTS

- **Positive:** If the color of test band is equal or stronger than that of control band, it indicates the PSA level is equal or higher than the cut-off, 4.0 ng/ml.
- **Negative:** If only a colored control band appears or the color intensity of the test band is less than that of control band, it indicates the PSA level is less than cut-off, 4.0 ng/ml.
- **Invalid Result:** The test result is invalid if a colored band does not form in the control region. The sample must be re- tested, using a new test device

PERFORMANCE CHARACTERISTICS

Sensitivity:
Cortez Diagnostics PSA test can detect PSA in serum with concentration of 4.0 ng/ml or greater.

Specificity and Cross-Reactivity:

Copound	Concentration	Cross reactivity
PSA	4.0 ng/mL	100%

Accuracy
100 clinical specimens containing PSA at the concentration between 0.1 and 2012 ng/ml were tested. The sensitivity and the specificity were summarized as the table.

PSA (ng/ml)	0.1 – 3.9	4.0 or higher	Percent agreement with GC/MS
Number of samples	40	60	
Number of positive	0	59	100%
Number of negative	40	1	97.5%

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Interference testing:
The following substances were added to PSA negative and 4.0 ng/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

QUALITY CONTROL

Good Laboratory Practice recommends the daily use of control materials to validate the reliability of device. Control materials should be assayed as a clinical specimen and challenging to the assay cut-off concentration, e.g., 25% above and below cut-off concentration. If control values do not fall within the established range, assay results are invalid. Control materials, which are not provided with this test kit are commercially available.

The Cortez Diagnostics PSA test provide a built-in process control with a different antigen/antibody reaction at the control region (C). This control line should always appear regardless of the presence of drug or metabolite. If the control line does not appear, the test device should be discarded and the obtained result considered invalid. The presence of this control band in the control region serves as:

1. Verification that sufficient volume is added and that proper flow is obtained.
2. The build-in control also serves as reference line for color comparison. It represents the color intensity of 4ng/ml of PSA. ***You should always follow local, state and federal guidelines for running QC.***

LIMITATIONS OF PROCEDURE

1. The test is for in vitro diagnostic use only.
2. The test is limited to the semi-quantitative detection of PSA levels in serum specimen.
3. Although the test is very accurate in detecting elevated PSA, a low incidence of false positive results can occur.
4. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

EXPECTED VALUES

Cortez Diagnostics PSA Test is a semi-quantitative assay. It identifies if the PSA in human serum is higher than 4 ng/ml or not. The exact concentration of the PSA cannot be determined by this assay. The test is intended to distinguish a normal PSA level result from a presumptive positive result. All positive results must be confirmed using a quantitative PSA assay.

PRECAUTION

1. For in vitro diagnostic use only.
2. Do not use test kit beyond expiration date.
3. Do not use the product if the pouch is damaged or the seal is broken.
4. Handle all specimens as potentially infectious.
5. Store the test device at 2 to 30°C in the original sealed pouch. Do Not Freeze.
6. The expiration date given was established under these storage conditions. The test device should remain in its original sealed pouch until ready for us. The device is designed for single use. Once the pouch is opened, the device must be tested as soon as possible and cannot be reused.

ISO 13485
ISO 9001

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