



Asan Easy Test[®] PSA

Diagnostic Kit for Prostate Specific Antigen Detection in Serum or Plasma

IVD

Immunochromatography

EXPLANATION OF THE TEST

Asan Easy Test[®] PSA is a chromatographic immuno-assay for the rapid qualitative determination of prostate specific antigen (PSA) in human serum or plasma. For diagnosis of PSA, the specific antibodies to PSA were used as a capture materials of the immuno-chromatographic test. The Asan Easy Test[®] PSA contains the membrane pre-coated with a monoclonal antibody to PSA on the test band region. During test, the sample is allowed to react with the Rabbit anti-PSA-colloid gold conjugate, which has been pre-dried on the conjugate pad between membrane and sample pad. The mixture then moves upward on the membrane by capillary action. For positive result, a visible line with high sensitivity and specificity as forming antigen-antibody-gold complex appears in the test band region of the membrane. Regardless of the presence of PSA, the mixture continuously moves across the membrane to pre-dried control line. Therefore, the control line will always appear and verify proper performance of the test. The Asan Easy Test[®] PSA minimizes the possibility for the false positive and places high confidence in the test result using high quality of antibodies.

MATERIALS PROVIDED

- Asan Easy Test[®] PSA contains following items to perform the assay.
- 1. Test device in aluminium pouch with a desiccant.
- 2. Instruction manual for use.

PRECAUTIONS

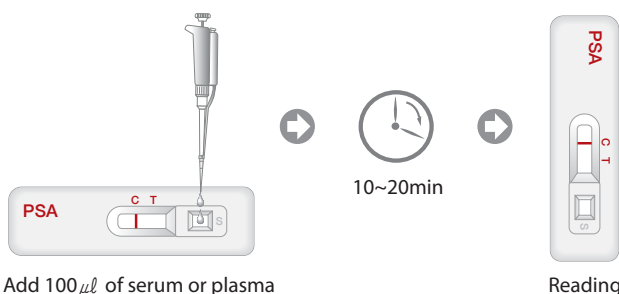
- 1. For *in vitro* diagnostic use only.
- 2. The test kit should remain in the sealed pouch until ready for use.
- 3. The test kit is sensitive to humidity and to heat.
- 4. Do not smoke, eat or drink in areas where specimens or kit component are handled.
- 5. All specimens and reagents should be considered potentially hazardous and handled in the same manner as an infection agent.
- 6. Wear protective gloves while handling samples and wash hands thoroughly after the assay is complete.
- 7. Avoid any contact with the eyes, broken skin or mucous membranes.
- 8. The test device and all materials should be discarded in a proper biohazard container after testing.

SPECIMEN COLLECTION AND STORAGE

- 1. The test should be performed using human serum or plasma.
- 2. If specimens are not immediately tested, they should be refrigerated at 2~8 °C . For storage periods more than three days, freezing is recommended.
- 3. Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assay.

TEST PROCEDURE

- 1. All materials should be equilibrated to room temperature before performing test.
- 2. Remove the device from its protective pouch.
- 3. Add 100 µl of serum or plasma into the sample well(S).
- 4. Interpret test results within 10~20 minutes. Do not interpret after 20 minutes.



(CAUTION : The above interpretation time is based on reading the test results at room temperature of 15 ~ 30°C . If your room temperature is significantly lower than 15 °C , then the interpretation time should be properly increased.)

INTERPRETATION OF THE TEST

- 1. A color band will appear in the upper section ("C" zone) of the window to show that the test is working properly. This band is a control band.
- 2. The down section ("T" zone) of the window indicates the test results, test band. If another color band appears in the down section of the window, this band is a test band.

A. NEGATIVE RESULTS:

The presence of only one purple color band("C" band) within the result window indicates a negative result.



B. POSITIVE RESULTS:

The presence of two color bands ("T" band and "C" band) within the result window regardless of which band appears first indicates a positive result .



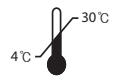
C. INVALID RESULTS:

If no band is visible within the window after performing the test, the result is considered invalid. Some causes of invalid results are: not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test kit.



STORAGE & EXPIRATION

- 1. Asan Easy Test[®] PSA should be stored at 4 ~ 30°C (39.2 ~ 86°F).
- 2. Expiration date of this kit is 24 months after its manufacture date.



PERFORMANCE CHARACTERISTICS

This clinical test was performed using a total of 300 specimens. Each specimen was tested with Asan Easy Test[®] PSA and Commercial PSA kit. The results are summarized in the following tables.

n= 300		Commercial PSA		Total
		Positive	Negative	
Asan Easy Test [®] PSA	Positive	100	1	101
	Negative	0	199	199
Total		100	200	300

※ Relative Sensitivity : >99%, Relative Specificity : 99.5%

※ Detection limit : 3 ng/ml

LIMITATIONS OF THE TEST

Other clinically available tests are required if questionable results are obtained. As all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but be made by the physician after all clinical and laboratory findings have been evaluated.



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