Code: 343 PSA 25t

CYPRESS DIAGNOSTICS

PSA

Intended use:
Cypress Diagnostics' PSA Quick Test is a rapid direct binding test for the qualitative detection of Prostate Specific Antigen (PSA) in serum or plasma as an aid in the diagnosis of prostate cancer.
The sensitivity of the test is adjusted to 4 ng/ml.
For *in vitro* diagnostic use. For professional use only.

Clinical significance:
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 whole blood or serum is 0.1-2.6 ng/ml. Reports have suggested that elevated level of whole blood or serum PSA is the most useful tumour markers in diagnosis of prostate cancers. Cypress Diagnostics' PSA Quick Test is designed to detect PSA concentration in serum or plasma as low as 4 ng/ml within 5 minutes.

Principle:
Cypress Diagnostics' PSA Quick Test has been designed to detect human Prostate specific antigen in serum or plasma samples through visual interpretation of color development in the test device. The test device contains a membrane strip, which is pre-coated with anti PSA antibody on the Test Line region (T) and goat anti-mouse antibody on the Control Line 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 areas of the test window. The intensity of the test line is the same as or stronger than that of the control line; this means that the PSA concentration is more than 4 ng/ml. For a negative result, the intensity of the test line is less than that of the control line; this means that the PSA concentration is less than 4 ng/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 device.

Content of the kit:
Each kit contains items to perform 25 tests:
- **test device and pipette in sealed pouch - 25**
- **Instruction leaflet - 1**

Additional material required: Timer.

Preparation:
All the kit components are ready for use.

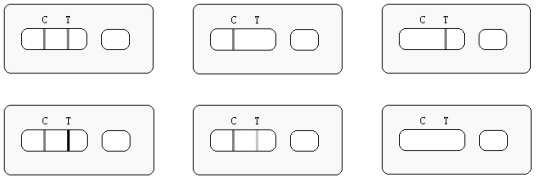
Storage and stability:
The test kit is to be stored at room temperature (4 to 30°C) in the sealed pouch for the duration of the shelf-life.

Precautions
- **Each test device is intended to be used once. Do not reuse.**
- **The test device should remain in the sealed pouch until use.**
- **Do not use it after the expiration date.**
- **All samples should be considered potentially hazardous and handled in the same manner as an infectious agent.**
- **The test device should be discarded in a proper biohazard container after testing according to applicable local regulations.**

Samples:
The PSA Quick Test is performed on human serum or plasma.
Remove the serum or plasma from the clot or red cells, respectively, as soon as possible to avoid hemolysis. Lipemic, icteric, or hemolyzed specimens may give inconsistent test result. Specimens containing precipitate should be clarified prior to testing.
PSA is thermo-labile. The samples should preferably be examined immediately after collection. If not possible, they can be stored at 2 to 8°C up to 5 days. If storage periods longer than 5 days are anticipated, the sample should be frozen. Do not use heat-inactivated specimens.

Test procedure:
1. **Allow test devices and samples to equilibrate to room temperature (15-30°C) before testing.**
2. **Do not open pouches until ready to perform the assay. Remove the required number of test devices from their pouches by tearing along the notched area and place on a flat surface area. By using the provided pipette, dispense 2-3 drops of sample into the sample well on the cassette.**
3. **Wait for 5 minutes and read the results. Do not read any results after 8 minutes.**

Interpretation of the results:



Positive **Negative** **Invalid**

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

Negative: The control line appears in the test window. If no test line appears or the intensity of the test line is less than that of the control line, this means that the PSA concentration is less than 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 device.

Quality control:
A procedural control is included in the test. A coloured line appearing on the Control region (C) of the membrane indicates proper performance of the test and the device.

Limitations of the procedure:
- **Despite the fact that the test is very accurate in detecting elevated PSA levels, a low incidence of false positive and negative results can occur.**
- **This qualitative assay is not appropriate for the quantitative measurement of PSA in serum or plasma.**
- **The presence of heterophile antibodies may affect the results.**
- **As in case of all diagnostic tests a definitive clinical diagnosis should not be based on the results of a single test but rather be made by a physician after all the clinical findings have been evaluated.**

Performance characteristics:
Sensitivity:
The Cypress Diagnostics' PSA Quick test detects Prostate specific antigen (PSA) in human serum or plasma specimens in a concentration of 4 ng/ml or higher, as indicated by the appearance of a test line whose intensity is equal to or higher than that of the control line.

Accuracy:
201 clinical samples were tested with the Cypress Diagnostics PSA quick test and a commercially available ELISA test. The results are summarized in the following table:

		ELISA		
		+	-	Total
Cypress Diagnostics PSA	+	57	2	59
	-	0	142	142
	Total	57	144	201

- **Relative sensitivity: 100%**
- **Relative specificity: 98.62%**
- **Relative accuracy: 99.01%**

Dose Hook Effect:
No dose hook effect was observed up to PSA concentrations of 10000 ng/ml.

Interferences:
The following substances were added to PSA-negative and 4.0 ng/ml PSA-spiked serum samples. No interferences were observed with any of the following substances at the indicated concentrations: bilirubin (10 mg/dl), triglycerides (500 mg/dl), cholesterol (800 mg/dl) and haemoglobin (250 mg/dl).

References:

- **Greenlee RT et al.CA Ancer JC; 2000; 50 (1): 733**
- **Ito K. et al; Urology; 2000 : 55(5) : 705**
- **Oesterling JE et al. Bri J. Urology 1995.**
- **Mario BO et al. Oncology; 2003**

02.2017, Rev. 8.1

Cypress Diagnostics: Nijverheidsstraat 8 • 2235 Hulshout • Belgium
www.diagnostics.be • Tel: ++ 32 15 67 67 68 • e-mail: cypress@diagnostics.be