The PSA Rapid Test Cassette (Whole Blood/ Serum/Plasma) is a rapid immunochromatographic immunoassay for the qualitative detection of Prostate Specific Antigen (PSA) in whole blood, serum or plasma.

**PROSTATE SPECIFIC ANTIGEN (PSA) DETECTION**

PSA is produced by prostate glandular and epithelial cells. It is a single chain glycoprotein with a molecular weight of approximately 34 kDa. PSA exists in three major forms in circulation: free PSA, PSA bound to Albumin (PSA:Alb) and PSA bound to Alpha-2-Human glycoprotein (PSA:AGP). PSA has also been detected in the male urogenital system but only prostate glandular and endothelial cells secrete it. The PSA level in serum of healthy men is between 0.1 ng/mL and 2.6 ng/mL. It can be elevated in malignant conditions as prostate cancer, and in benign conditions such as benign prostatic hyperplasia and prostatitis. A PSA level of 3 to 10 ng/mL is considered to be in the “gray-zone” and levels above 10 ng/mL are highly indicative of cancer. A PSA level below 3 ng/mL should undergo further analysis of the prostate by biopsy.

The PSA Rapid Test Cassette is the most valuable tool available for the diagnosis of early prostate cancer. Many studies have confirmed that the presence of PSA is the most useful and meaningful tumor marker known for prostate cancer and prostate infection of Benign Prostatic Hyperplasia (BPH). The PSA Rapid Test Cassette (Whole Blood/Serum/Plasma) utilizes a combination of conjugate and anti-PSA antibody to selectively detect total PSA in whole blood, serum or plasma. The test has a cut-off value of 0.1 ng/mL and a reference value of 10 ng/mL.

**PRACTICAL USE**

The PSA Rapid Test Cassette (Whole Blood/Serum/Plasma) is a semi-quantitative, membrane-based immunoassay for the detection of PSA in whole blood, serum or plasma. The test kit is provided in an easy-to-use cassette format. The PSA Rapid Test Cassette utilizes a combination of conjugate and anti-PSA antibody to selectively detect total PSA in whole blood, serum or plasma.

**STORAGE AND STABILITY**

The PSA Rapid Test Cassette (Whole Blood/Serum/Plasma) Cassette should be kept below 20°C. Do not freeze. PSA levels may be unreliable in patients who receive hormone therapy or prostate gland manipulation.

**INTERPRETATION OF RESULTS**

**POSITIVE:** Three distinct colored lines appear.

1. A test line (T) intensity weaker than the reference line (R) indicates that the PSA level is between 0.1 ng/mL and 10 ng/mL.
2. A test line (T) intensity equal or close to the reference line (R) indicates that the PSA level is approximately 10 ng/mL.
3. A test line (T) intensity stronger than the reference line (R) indicates that the PSA level is more than 10 ng/mL.

**NEGATIVE:** No colored lines appear.

**INVALID:** Control line (C) or reference line (R) fails to appear. Insufficient specimen volume or incorrect procedural techniques is the most likely reason for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

**QUALITATIVE CONTROL**

A procedural control is included in the test. The appearance of colored lines in the control line (C) and reference line (R) is a procedural control. It confirms sufficient specimen volume, adequate mixing of components and procedural technique.

**CUT-OFF LEVELS**

The PSA Rapid Test Cassette (Whole Blood/ Serum/Plasma) will only indicate the semi-quantitative level of PSA in the specimen and should not be used as the sole criteria for the diagnosis of PSA levels.

**LIMITATIONS**

1. The PSA Rapid Test Cassette (Whole Blood/ Serum/Plasma) is for in vitro diagnostic use only. This test is not designed for use in whole blood, serum or plasma specimen.
2. This PSA Rapid Test Cassette (Whole Blood/ Serum/Plasma) will only indicate the semi-quantitative level of PSA in the specimen and should not be used as the sole criteria for the diagnosis of PSA level.
3. A significant number of patients with BPH (more than 15%) and less than 1% of healthy individuals have elevated PSA. Even if the test results are positive, further clinical evaluation should be considered with additional clinical information available to the physician.
4. PSA levels may be unreliable in patients who receive hormone therapy or prostate gland manipulation.
5. High concentrations of PSA may produce a dose hook effect, resulting in false negative results. The hook effect has not been observed with this test up to 30,000 ng/mL PSA.

**EXPECTED VALUES**

The minimum indicative level of PSA for Prostate Cancer is generally agreed to be 3 ng/mL and the upper limit is considered to be 10 ng/mL. For PSA Rapid Test Cassette (Whole Blood/ Serum/Plasma) there has been a tested with a leading commercial PSA EIA test the correlation between two tests is more than 99.9%.

**PERFORMANCE CHARACTERISTICS**

PSA Rapid Test Cassette (Whole Blood/ Serum/Plasma) has been tested with a leading commercial PSA EIA test using clinical samples.