A rapid test for the qualitative detection of Prostate Specific Antigen (PSA) in whole blood, serum or plasma. For use in vitro diagnostic use only.

[INTENDED USE]

The PSA Prostatic Specific Antigen Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for semi-quantitative detection of Prostatic Specific Antigen in whole blood, serum or plasma.

[SUMMARY]

Prostatic specific antigen (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 circulating in the serum. These forms are free PSA, PSA bound to α2-macroglobulin (PSA-A2M) and PSA complexed with α2-macroglobulin (PSA-A2M).

PSA has been detected in various tissues of the male urogenital system but only prostatic glandular and endothelial cells produce detectable amounts of healthy serum. PSA is a useful serum marker for prostate cancer, hence, serum PSA levels are usually checked on patients with prostate symptoms or as a follow-up of prostate cancer treatments. PSA levels become elevated in prostate cancer, benign prostatic hypertrophy or prostatic inflammation. However, PSA levels are also increased in patients with prostate-related infections, prostate surgery or prostate biopsies. Therefore, PSA levels should be interpreted carefully in patients with prostate-related diseases.

PSA detection can be achieved through different techniques. In general, these methods can be divided into two groups: qualitative and quantitative tests. Qualitative tests only provide a positive or negative result, whereas quantitative tests provide a value indicating the PSA level. Qualitative methods are usually performed through immunoassay techniques, such as lateral flow assays. These tests are simple, rapid and inexpensive; however, they may lack sensitivity and specificity. Quantitative methods include enzyme immunoassay (EIA) and competitive immunoassay methods. These tests provide a more accurate quantification of PSA levels; however, they are more expensive and time-consuming. New qualitative assays may have been developed to replace these methods.

[INTERPRETATION OF RESULTS]

PSA Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. This test should be used for the detection of PSA in whole blood, serum or plasma specimen.