Prostate Specific Antigen (PSA) Rapid Quantitative Test（Fluorescence immunoassay)

User manual

【Product name】

Prostate Specific Antigen (PSA) Rapid Quantitative Test（Fluorescence immunoassay)

【Package specification】

25 Tests/kit

【Intended use】

This kit is used for quantitative determination of PSA in human whole blood, plasma and serum.

Human prostate-specific antigen (PSA) is a serine protease, a single chain glycoprotein with a molecular weight of approximately 34,000 daltons containing 7% carbohydrate by weight. In human serum, PSA exists in at least 3 different forms: free, alpha 1-antichymotrypsin (PSA-ACT) and alpha 2-macroglobulin (PSA-AMG). Only free PSA and PSA-ACT can be detected with available immunoassays. Elevated serum PSA concentrations have been reported in patients with prostate cancer, benign prostatic hypertrophy, prostatitis or inflammatory conditions of other adjacent genitourinary tissues. Also, increases in PSA to 4-10 ng/mL are not uncommon among men with benign prostatic hyperplasia (BPH) or prostatitis. The determination of PSA serum levels is not only important for the screening of patients for prostate cancer, but also for monitoring patients that have been treated for this disease.

【Inspection principle】

The PSA Rapid Test is a one-step chromatographic sandwich immunoassay designed for the quantitative measurement of PSA. The PSA antigen in the sample was first bound with the conjugated compound of fluorescent labeled PSA monoclonal antibody, then moved and combined with another PSA monoclonal antibody fixed on the nitrocellulose membrane, and the double antibody sandwich complex was formed at the detection line of the cellulose nitrate membrane. The quantitative detection results were obtained by NIR-1000 dry fluoroimmunoassay analyser.

【Components】

Name	Quantity	Component
Test cards	25	It is composed of fluorescent pad (coated with fluorescent labeled PSA monoclonal mouse antibody), nitrocellulose membrane (coated with PSA monoclonal mouse antibody and Goat anti mouse IgG antibody), absorbent paper and backing
Sample diluent	25（300μL/tube）	Phosphate buffer
ID card	1	With specific stand curve file

The components in different batches of kits cannot be used interchangeably.

【Storage conditions and validity】

The kit should be stored at 4℃~30℃, out of direct sunlight. It is valid for 18 months. The test card should be used within 15 minutes after unsealing under the environment of 15℃~30℃ and 20% ~ 90% relative humidity.

The production date, batch number and expiration date are shown in the outer package of the product.

【Applicable instruments】

NIR-1000 dry fluoroimmunoassay analyser produced by WWHS Biotech. Inc.

【Sample requirements】

1. Plasma, serum and whole blood can be used as samples. The whole blood should be collected in a tube containing heparin, citrate or EDTA as the anticoagulant. If the serum procedure is used, collect blood in a tube without anticoagulant and allow clotting. Hemolyzed samples should not be used.
2. Venous blood was collected according to routine laboratory methods to avoid hemolysis.
3. It is highly recommended to use fresh samples instead of keeping the samples at room temperature for a long time. After samples were collected, the detection should be completed within 4 hours at room temperature (15℃~30℃). The whole blood sample can be stored at 2℃ ~8℃ for 24 hours. Plasma and serum samples can be stored at 2℃~ 8℃ for 7 days, -20℃for 30 days.
4. Before testing, the sample should return to room temperature (15℃~30℃). The frozen samples should be completely thawed, rewarming and mixed evenly before use. Repeated freeze-thaw cycles should be avoided.

【Procedure】

1. Before the test, please read the instructions completely. If the test card and sample are stored in cold storage, they should be balanced at room temperature (15-30)℃ for not less than 30min before use.
2. Start NIR-1000 dry fluoroimmunoassay analyser according to the instruction manual of the instrument, and carry out quality control verification according to the instruction manual of the instrument （ Note: the reagent has been calibrated in advance, and the calibration curve parameters of each batch of reagent have been stored in the information card. The information card is inserted before use, so it is not necessary to calibrate again, and the test can be carried out only after the quality control is passed. Otherwise, the cause should be found out before testing.)
3. Remove the test card from the aluminum foil bag and use it within 15 minutes.
4. Place the test card on a clean horizontal table and mark it horizontally.
5. Mix 100 μL of patient sample with 300μL of sample diluent. Apply 100 μL of diluted samples to the well of the test card.
6. Insert the test card into NIR-1000 dry fluoroimmunoassay analyser, read and record the results at 10 minutes after addition of samples, then dispose of used test appropriately.

【Reference interval】

Healthy males are expected to have serum PSA values below 4ng/mL. However，as PSA levels

increase with age, the use of age-specific reference ranges has been suggested in order to increase the sensitivity in younger men and increase the specificity in older men. Each laboratory must establish its own normal ranges based on the representative local population.

【Interpretation of results】

1. This reagent is only used for auxiliary detection. If the test results are abnormal, it should be reviewed in time and judged in combination with clinical symptoms.
2. For samples with PSA concentration lower than 2ng/ml and higher than 100ng/ml, the detection results are reported as "< 2ng/ml" and "> 100ng /ml", respectively.

【Limitations of methods】

1. This kit is only used to detect human plasma/whole blood samples
2. Due to the limitations of immunoassay methods of antigen and antibody reaction, the results cannot be used as the only basis for clinical diagnosis, but should be evaluated with all the existing clinical and experimental data.
3. The content of triglyceride in the sample shall not exceed 15mg/ml, the content of hemoglobin shall not exceed 5mg/ml, and the content of bilirubin shall not exceed 0.5mg/ml, and the relative deviation of the test results shall not exceed ±15%。
4. When the concentration of PSA in the sample is less than 20000ng/ml, there is no hook effect.
5. HAMA effect was not produced when the concentration of human anti rat in the sample was less than 50ng/ml.
6. When RF concentration in the sample is less than 2000IU/ml, the relative deviation of the test results is within ±15%.

【Performance】

1. Limits of detection

No more than 0.5ng /ml.

2. Accuracy

The relative deviation from the target value is within ±15%.

3. Precision

The within and between assay coefficient of variations are within 15%.

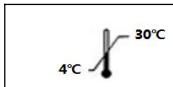
4. Linear range

Within the linear range (2 ~ 100ng/ml), the linear correlation coefficient R≥0.990.

【Note】

1. This kit is only used for in vitro diagnosis.
2. The test card and sample diluent are disposable and cannot be reused.
3. Please check the integrity and validity of the kit package before use, and then open the package. When it is stored at low temperature, it should be restored to room temperature (15℃ ~30℃) before opening the package for use. The reagents with damaged inner package and beyond the validity period cannot be used.
4. The requirements of specimen collection and storage should be strictly observed. If the specimen is turbid, it should be centrifuged and discarded before use.
5. The used kits should be treated as potential infectious substances, and all samples, reagents and potential pollutants should be disinfected and treated according to the relevant local regulations.

【Interpretation of signs】

	Storage temperature		Non reusable
	Avoid light	IVD	In vitro diagnostic reagents
	moisture-proof		See instruction manual

【Reference】

[1] Allard WJ, Zhou Z, and Yeung KK.Novel immunoassay for the measurement of complexed prostate-specific antigen in serum. Clinical Chemistry 44:6, 1216-1223 (1998).

[2] Väisänen V, Eriksson S, Ivaska KK, Lilja H, Nurmi M, and Pettersson K. Development of Sensitive Immunoassays for Free and Total Human Glandular Kallikrein 2. Clinical Chemistry50:9, 1607-1617 (2004).

[3] España F, Sánchez-Cuenca J, Estellés A, Gilabert J, Griffin JH, and Heeb MJ. Quantitative immunoassay for complexes of prostate-specific antigen with a2-macroglobulin. Clinical Chemistry 42:4, 545-550 (1996).

【Essential information】

Registered/manufacturer name: WWHS Biotech. Inc

Address: 505, building 1, Shenzhen Biomedical Innovation Industrial Park, 14 Jinhui Road, Kengzi street, Pingshan New District, Shenzhen

Contact: 0755-84235529

Name of after sales service unit: WWHS Biotech. Inc

Contact: 0755-84235529

Production address: 505, building 1, Shenzhen Biomedical Innovation Industrial Park, 14 Jinhui Road, Kengzi street, Pingshan New District, Shenzhen

[date of approval and revision] 2021-06-12