IVD

fPSA Fast Test Kit

(Immunofluorescence Assay)

User Manual

REF

IF1072 for Getein1100
IF3072 for Getein1180
IF2072 for Getein1600

INTENDED USE

fPSA Fast Test Kit (Immunofluorescence Assay) is intended for in vitro quantitative determination of free PSA in human serum and plasma samples. It is mainly used for dynamic monitoring of patients with malignant tumors to assist in judging the disease process or treatment effect. It cannot be used as a basis for early diagnosis of malignant tumors, and is not suitable for tumor screening in the general population.
This assay is intended to be used in conjunction with the Getein total PSA test as an aid in distinguishing prostate cancer from benign prostatic conditions in men age 50 years or older who have a digital rectal examination (DRE) that is not suspicious for prostate cancer and the Getein total PSA value between 4 ng/mL and 10 ng/mL.

SUMMARY

Prostate-specific antigen (PSA) is a single-chain glycoprotein with molecular weight of 34 kilodaltons. As a serine protease with chymotrypsin-like activity, PSA belongs to the kallikrein family. PSA exists as a free or complex form with protease inhibitors such as α-1-antichymotrypsin (ACT) in blood. PSA is produced mainly by the glandular epithelium of the prostate and is secreted into the seminal fluid in high concentrations. Low levels of PSA are found in the blood as a result of leakage of PSA from the prostate gland. The function of PSA is the proteolytic cleavage of gel forming proteins in the seminal fluid resulting in liquification of the seminal gel and increased sperm mobility.
PSA tests lack sufficient sensitivity and specificity to be considered ideal or absolutely diagnostic for screening or early detection because PSA is not specific for prostate cancer. PSA is organ specific, but has long been known to be elevated in non-malignant conditions such as benign prostatic hyperplasia (BPH). A number of studies have found that the percent of free PSA was significantly lower in patients having prostate cancer than those with benign disease or normal controls. The ratio fPSA/tPSA has subsequently been demonstrated to improve the sensitivity and specificity in patients with tPSA values in the "gray zone" of 4-10 ng/mL.
An equimolar tPSA determination is the prerequisite for reliable ratios. In patients receiving therapy, particularly hormone withdrawal therapy, the fPSA/tPSA ratio cannot be utilized to differentiate prostate hyperplasia from cancer of the prostate. Combining tests from different manufacturers to determine tPSA and fPSA can produce erroneous values, since total PSA tests may be standardized by differing methods or detect free PSA to differing degrees.

PRINCIPLE

The test uses an anti-human fPSA monoclonal antibody Ⅰ conjugated with fluorescence latex coated on the junction of nitrocellulose membrane and sample pad, and another fPSA monoclonal antibody Ⅱ coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human fPSA antibody Ⅰ binds with fPSA in sample and forms a marked antigen-antibody complex. This complex moves to the test detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by anti-human fPSA antibody Ⅱ. The fluorescence intensity of test line increases in proportion to the amount of fPSA in sample.
Then insert test card into Getein1100 /Getein1180 Immunofluorescence Quantitative Analyzer/Automatically inserted by Getein1600 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein1100 , Getein1180 and Getein1600), the concentration of fPSA in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1180/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100/Getein1180 contains:
Package specifications: 25 tests/box, 10 tests/box
1) Getein fPSA test card in a sealed pouch with desiccant
2) Disposable pipet
3) Sample diluent
4) User manual: 1 piece/box
5) SD card: 1 piece/box
2. A kit for Getein1600 contains:
Package specifications: 2×24 tests/kit, 2×48 tests/kit
Sealed cartridge with 24/48 Getein fPSA test cards
User manual: 1 piece/box
Materials required for Getein1600:
1) Sample diluent: 1 bottle/box
2) Box with pipette tips: 96 tips/box
3) Mixing plate: 1 piece/box
3. Sample diluent composition:
Phosphate buffered saline, protein stabilizer and surfactant.
4. A test card consists of:
A plastic shell and a reagent strip which is composed of a sample pad (the junction of sample pad and nitrocellulose membrane is coated with fluorescence latex-labeled anti-human fPSA monoclonal antibody Ⅰ), nitrocellulose membrane (the test line is coated with another anti-human fPSA monoclonal antibody Ⅱ and the control line is coated with goat anti-mouse IgG antibody), absorbent paper and liner.
Note: Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1180 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test card at 4~30°C with a valid period of 24 months. Use the test card for Getein1100/Getein1180 within 1 hour once the foil pouch is opened.
For test card of Getein1600: If the cartridge is opened, it could be stable within 24 hours once exposure to air. Please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.
Store the sample diluent at 0~30°C with a valid period of 24 months.

PRECAUTIONS

1. For in vitro diagnostic use only.
2. For professional use only.
3. Do not use the kit beyond the expiration date.
4. Do not use the test card if the foil pouch or the cartridge is damaged.
5. Do not open pouches or the cartridge until ready to perform the test.
6. Do not reuse the test card.
7. Do not reuse the pipet.
8. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
9. Carefully read and follow user manual to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***serum and plasma samples***, other bodily fluids may cause incorrect or inaccurate results.
2. **Heparin, sodium citrate and EDTA** can be used as the anticoagulant for plasma. Samples should be free of hemolysis.
3. The test should be performed within 4 hours after blood collection. If testing is delayed, serum and plasma samples may be stored up to 5 days at 2~8°C or stored at -20°C for 6 months before testing.
4. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
5. Do not use heat-inactivated or hemolysis samples.
6. SAMPLE VOLUME ***(for Getein1100/Getein1180): 100 μL***

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample and reagent should reach to room

temperature before test.

For Getein1100:

3. Confirm SD card lot No. in accordance with test kit lot No. Perform “SD card” calibration when necessary.
4. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
5. Put the test card on a clean table, horizontally placed.
6. Using sample transfer pipette, deliver ***100 μL*** of sample into one tube of sample diluent, mix gently and thoroughly. Then drop ***100 μL*** of sample mixture into the sample port on the test card.
7. ***Reaction time: 10 minutes.*** Insert the test card into Getein1100 and start test after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein 1180:

8. Confirm SD card lot No. in accordance with test kit lot No..Perform “SD card” calibration when necessary.
9. Enter testing interface of Getein 1180.
10. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
11. Put the test card on a clean table,horizontally placed.
12. Using sample transfer pipette, deliver ***100 μL*** of sample into one tube of sample diluent, mix gently and thoroughly. Then drop ***100 μL*** of sample mixture into the sample port on the test card.
13. ***Reaction time: 10minutes.*** Insert the test card into Getein 1180 immediately after sample loading. The analyzer will count down the reaction time and automatically test the card after reaction time is elapsed. The result will be shoe on the screen and printed automatically.

For Getein1600:

14. Each cartridge for Getein1600 contains a specific RFID card which can calibrate automatically.
15. Place the sample diluent at the correct position of Getein1600.
16. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1600 will do the testing and print the result automatically.

Notes:

1. It is required to perform “SD card” calibration when using a new batch of kits.
2. It is suggested to calibrate once for one batch of kits for Getein1100/Getein1180.
3. Make sure the test card and the sample insertion is correct and complete.

TEST RESULTS

Getein1100/Getein1180/Getein1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/Getein1180/ Getein1600.

Others: Measuring range of the fPSA test kit is 0.05-30.00 ng/mL. Dilute the sample which concentration is higher than the upper limit with negative samples, and the dilution ration should be less than 4 times.

EXPECTED VALUE

The expected normal value for free PSA was determined by testing samples from 250 apparently healthy individuals. The reference range of free PSA is 1.00 ng/mL calculated by using normal distribution methods (95th percentile).
It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	0.05-30.00 ng/mL
Lower Detection Limit	≤ 0.05 ng/mL
Within-Run Precision	≤ 10%
Between-Run Precision	≤ 15%

LIMITATIONS

1. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
2. Samples containing interferent may influence the results. The table below listed the maximum allowance of these potential interferent.

Interferent	Triglyceride	Bilirubin
Concentration (Max)	25 g/L	0.6 g/L

REFERENCES

1. Chen R, Huang Y, Cai X, et al. Age-Specific Cutoff Value for the Application of Percent Free Prostate-Specific Antigen (PSA) in Chinese Men with Serum PSA Levels of 4.0-10.0 ng/ml. PLoS One. 2015, 10 (6): e0130308.
2. Ezenwa EV, Tijani KH, Jeje EA, et al. The value of percentage free prostate specific antigen (PSA) in the detection of prostate cancer among patients with intermediate levels of total PSA (4.0–10.0 ng/mL) in Nigeria. Arab J Urol. 2012, 10(4): 394-400.
3. Jun Seok Kim, Je-Guk Ryu, Jin Woong Kim, et al. Prostate-Specific Antigen fluctuation: what does it mean in diagnosis of prostate cancer? Int Braz J Urol. 2015,41(2): 258-264.
4. Salman J W, Schoots I G , Carlsson S V , et al. Prostate Specific Antigen as a Tumor Marker in Prostate Cancer: Biochemical and Clinical Aspects. Advances in Experimental Medicine and Biology, 2015, 867:93-114.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on fPSA Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2016.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult instructions for use	LOT	Batch code
	Temperature limit	IVD	*In vitro* diagnostic medical device
	Contains sufficient for <n> tests		Do not use if package is damaged
REF	Catalogue number	EC REP	Authorized representative in the European Community

Thank you for purchasing fPSA Fast Test Kit (Immunofluorescence Assay).
Please read this user manual carefully before operating to ensure proper use.

Version: WIF74-S-03


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