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tPSA
Fast Test Kit
(Immunofluorescence Assay)

IF2053 for Getein1600
IF1053 for Getein1100
IF3053 for Getein1180
REF IF4053 for Getein1200
IF5053 for Getein1160

User Manual

INTENDED USE

tPSA (total Prostate Specific Antigen) Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of tPSA in human serum and plasma samples. It can be used as an aid in the diagnosis and management of patients with prostate cancer.

SUMMARY

Prostate-specific antigen (PSA) is a single-chain glycoprotein with molecular weight of 34 kilodaltons. As a serine prostate 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. Total PSA represents the sum of both free and complex forms. Elevated PSA in serum or plasma is found in patients with prostate cancer, benign prostatic hypertrophy, or inflammatory tissues. PSA is uniquely associated with prostate tissues from normal, inflamed or cancerous stages.

PSA has been found in normal, benign hyperplastic, malignant prostatic tissue, metastatic prostatic carcinoma and also in prostatic fluid as well as in seminal fluid. PSA is not found in any other tissues in men, and it is not produced by cancers originating in the lung, colon, rectum, stomach, pancreas or thyroid. PSA measurement is an essential tool in assessing the status of disease in patients with prostate cancer when serial samples are measured over time. The clinical value realized by monitoring tPSA concentration in patients with prostate cancer regardless of the treatment regimen is well known.

PRINCIPLE

The test uses an anti-human PSA monoclonal antibody conjugated with fluorescence latex coated on the junction of nitrocellulose membrane and sample pad and another anti-human PSA monoclonal antibody coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labelled antihuman PSA antibody binds with the PSA in sample and forms marked antigen-antibody complex. This complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by antihuman PSA antibody. The fluorescence intensity of test line increases in proportion to the amount of tPSA in sample.

Then insert test card into Getein1100/Getein1160/Getein1180 Immunofluorescence Quantitative Analyzer/automatically inserted by Getein1200/Getein1600 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein1100, Getein1160, Getein1180, Getein1200 and Getein1600), the concentration of tPSA in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1160/Getein1180/Getein1200/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

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1. A kit for Getein1100/Getein1160/Getein1180 contains:
Package specifications: 25 tests/box, 10 tests/box
1) Getein tPSA test card in a sealed pouch with desiccant
2) Disposable pipet
3) User manual: 1 piece/box
4) SD card: 1 piece/box

2. A kit for Getein1200/Getein1600 contains:
Package specifications: 2×24 tests/box, 2×48 tests/box
Sealed cartridge with 24/48 Getein tPSA test cards
User manual: 1 piece/box
Materials required for Getein1200/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, proteins, detergent, preservative, stabilizer.

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-labelled anti-human PSA monoclonal antibody), nitrocellulose membrane (test line is coated with another fluorescence latex-labelled anti-human PSA monoclonal antibody and the control line C is coated with rabbit 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
Getein1160 Immunofluorescence Quantitative Analyzer
Getein1200 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/Getein1160/Getein1180 within 1 hour once the foil pouch is opened.

For test card of Getein1200/Getein1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, 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. Do not use the kit beyond the expiration date.
3. Do not use the test card if the foil pouch is damaged.
4. Do not open pouches until ready to perform the test.
5. Do not reuse the test card.
6. Do not reuse the pipet.
7. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
8. 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***. Heparin, EDTA and sodium citrate can be used as the anticoagulant for plasma. Samples should be free of hemolysis.
2. The test should be performed within 4 hours after whole blood collection.
3. If testing is delayed, serum and plasma samples may be stored up to 7 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 samples or hemolysis samples.
6. SAMPLE VOLUME ***(for Getein1100/Getein1160/Getein1180): 100 µl***.

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample and reagent should be brought to room temperature before testing.

For Getein1100:
3. Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
4. Enter testing interface of Getein1100.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
6. Put the test card on a clean table, horizontally placed.
7. Using sample transfer pipette, deliver ***100 µL*** of sample into the sample port on the test card.
8. ***Reaction time: 15 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 Getein1160/Getein1180:
9. Confirm SD card lot No. in accordance with test kit lot No..Perform "SD card" calibration when necessary.
10. Enter testing interface of Getein1160/Getein1180.
11. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
12. Put the test card on a clean table,horizontally placed.
13. Using sample transfer pipette, deliver ***100 µL*** of sample into the sample port on the test card.
14. ***Reaction time: 15 minutes.*** Insert the test card into Getein1160/Getein1180 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 shown on the screen and printed automatically.

For Getein1200/Getein1600:
15. Each cartridge for Getein1200/Getein1600 contains a specific RFID card which can calibrate automatically.
16. Place the sample diluent at the correct position in Getein1200/Getein1600.
17. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1200/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/Getein1160/Getein1180.
3. Make sure the test card insertion is correct and complete.

TEST RESULTS

Getein1100/Getein1160/Getein1180/Getein1200/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/Getein1160/Getein1180/Getein1200/Getein1600.

Others:
Measuring range of the tPSA test kit is 0.50 ng/mL~100.00 ng/mL. Dilute the sample which concentration is higher than the upper limit with negative samples, and the dilution ratio should be less than 4 times.

EXPECTED VALUE

The expected normal value for tPSA was determined by testing samples from 1000 apparently healthy individuals. The reference range of tPSA is 4.00 ng/mL calculated by using normal distribution methods (95% confidence interval).

It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	0.50~100.00 ng/mL
Lower Detection Limit	≤ 0.50 ng/mL
Within-Run Precision	≤ 10%
Between-Run Precision	≤ 15%

With-run Precision: Test tPSA with same batch for 10 times using tPSA control 1 (3.20~4.80 ng/mL) and tPSA control 2 (24.00~36.00 ng/mL) respectively, then calculate within-run precision which should not greater than 10%.

Between-run Precision: Randomly select 3 consecutive batches of tPSA products, and take 10 strips for each batch to test the quality control (24.00~36.00 ng/mL), calculate between-run precision which should not greater than 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	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	5 g/L	25g/L	0.1 g/L

REFERENCES

1. Mc Jimpsey EL. Molecular Form Differences Between Prostate-Specific Antigen (PSA) Standards Create Quantitative Discordances in PSA ELISA Measurements. Scientific Reports. 2016, 6: 22050.
2. Jun Seok Kim, Je-Guk Ryu, Jin Woong Kim, et al. Prostate-Specific Antigen fluctuation: what does it mean in diagnosis of prostate cancer? Br J Cancer. Int Braz J Urol. 2015, 41(2): 258-264.
3. Yasuhide Kitagawa, Mikio Namiki. Prostate-specific antigen-based population screening for prostate cancer: current status in Japan and future perspective in Asia. Asian J Androl. 2015, 17(3): 475-480.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on tPSA 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 tPSA Fast Test Kit (Immunofluorescence Assay).

Please read this user manual carefully before operating to ensure proper use.

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