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tPSA
Fast Test Kit
(Immunofluorescence Assay)

IF1053 for Getein 1100
IF5053 for Getein 1160
IF3053 for Getein 1180
REF IF2053 for Getein 1600
IF4053 for Getein 1200

Instructions for Use

INTENDED USE

tPSA 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. For professional and laboratory use.

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

tPSA Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay with a sandwich design. After the sample is applied to the test strip, the fluorescence-labelled PSA monoclonal antibody binds to the PSA in the sample, forming a marked antigen-antibody complex. This complex then moves to the test zone on the test card by capillary action. In the test zone, the marked antigen-antibody complex is captured by another PSA monoclonal antibody. The fluorescence intensity of the test zone increases in proportion to the amount of tPSA in sample. Fluorescent signals intensity can be analyzed by applicable device thus the tPSA in sample be detected quantitatively.

CONTENTS

Materials provided	Getein 1100/Getein 1160/ Getein 1180		Getein 1200/ Getein 1600	
	10 T/kit	25 T/kit	2*24 T/kit	2*48 T/kit
tPSA test card*	10 pcs	25 pcs	24 test cards in 1 cartridge, and 2 cartridges in 1 box	48 test cards in 1 cartridge, and 2 cartridges in 1 box
Disposable pipet	10 pcs	25 pcs	/	/
Sample diluent**	/	/	1 box	1 box
Instructions for use	1 pc	1 pc	1 pc	1 pc
SD card	1 pc	1 pc	1 pc in each cartridge	1 pc in each cartridge

* tPSA test card

A test card consists of: Fluorescence labelled PSA monoclonal antibody, PSA monoclonal antibody.

** Sample diluent

Sample diluent for Getein 1200/Getein 1600 is an independent packing box main consists of:

- Phosphate buffer (20 mmol/L), NaN3 (＜0.1%) (25 mL/bottle for Getein 1200, 40 mL/bottle for Getein 1600),
- Box with pipette tips (96 tips/box),
- Mixing plate (1 piece/box).

Note:

1. The standard curve data can be written to RFID card in the kit. According to the function of RFID card, we define it as "Standard Curve Data Card", short for "SD Card".
2. Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1160 Immunofluorescence Quantitative Analyzer
Getein 1180 Immunofluorescence Quantitative Analyzer
Getein 1600 Immunofluorescence Quantitative Analyzer
Getein 1200 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Realtime stability:

Store the kit at 4~30°C with a valid period of 24 months. The test kits are stable until the expiry date printed on the labels.

In-use stability:

- For the test card of Getein 1100/Getein 1160/Getein 1180: Use the test card within 1 hour once the foil pouch is opened.
- For test card of Getein 1200/Getein 1600: 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.

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 the instructions for use to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***serum, plasma samples***. Heparin, EDTA and sodium citrate should be used as the anticoagulant for plasma. Samples should be free of hemolysis.
2. It is recommended to test the sample within 4 hours after collection. Stable in serum and plasma for 7 days when stored at 2~8°C and 6 months when stored at -20°C.
3. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
4. Do not use heat-inactivated samples or hemolysis samples.
5. SAMPLE VOLUME ***(for Getein 1100/Getein 1160/Getein 1180): 100 μL***.

TEST PROCEDURE

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

For Getein 1100:

1. Confirm SD card lot No. in accordance with test kit lot No.. Perform “SD card” calibration when necessary.
2. Select the corresponding “Sample” on the analyzer according to the sample type (see the user manual of analyzer for details).
3. Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
4. Use disposable pipet or pipette, deliver ***100 μL*** of sample into the sample well on the test card.

Note:

The disposable pipette has a marked line. Squeeze the bulb to draw the sample to the **marked line**. Incomplete filling may lead to inaccurate test results.

5. ***Reaction time: 15 minutes***. After reaction time is elapsed, insert the test card into Getein 1100 and press "ENT" button or click on “Start” icon. The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:

1. Confirm SD card lot No. in accordance with test kit lot No.. Perform “SD card” calibration when necessary.
2. Select the corresponding “Sample” on the analyzer according to the sample type (see the instructions of analyzer for details).
3. Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
4. Use disposable pipet or pipette, deliver ***100 μL*** of sample into the sample well on the test card.

Note:

The disposable pipette has a marked line. Squeeze the bulb to draw the sample to the marked line. Incomplete filling may lead to inaccurate test results.

5. Insert the test card into Getein 1160/Getein 1180 immediately after sample loading. The analyzer will count down the reaction time (**15 minutes**) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and displayed automatically.

For Getein 1200/Getein 1600:

1. Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card which can calibrate automatically.
2. Place the sample diluent at the correct position of Getein 1200/Getein 1600.
3. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein 1200/Getein 1600 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 Getein 1100/Getein 1160/Getein 1180.
3. Make sure the test card and the sample insertion are correct and complete.

TEST RESULTS

Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the instructions for use of Getein 1100/Getein 1160/Getein 1180/ Getein 1200/Getein 1600.

Others:

Measuring range of the tPSA test kit is 0.40 ng/mL~100.00 ng/mL. Dilute the sample which concentration is higher than the upper limit with female 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 4.0 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 0.40~100.00 ng/ml

Limit of Detection ≤0.40 ng/ml

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-Lot 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-lot precision which should not greater than 15%.

Method Comparison: Perform clinical comparison study on 231 clinical serum samples from 231 patients. Concordance between tPSA Fast Test Kit (Immunofluorescence Assay) and Elecsys® tPSA were evaluated. The following regression data were obtained: N=231; y=0997x+0.0471; r=0,9984.

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 ELSA 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 15223-1:2021.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult *instructions for use* or consult electronic *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 and consult *instructions for use*
REF	Catalogue number		Caution

Thank you for purchasing tPSA Fast Test Kit (Immunofluorescence Assay). Please read the instructions for use carefully before operating to ensure proper use.

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