



IVD

# fPSA Fast Test Kit

## (Immunofluorescence Assay)

IF1072 for Getein 1100  
 IF5072 for Getein 1160  
 IF3072 for Getein 1180  
 IF2072 for Getein 1600  
 IF4072 for Getein 1200

REF

Instructions for Use

### 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  $\alpha$ -1-anti-chymotrypsin (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 Getein 1100/Getein 1160/Getein 1180 Immunofluorescence Quantitative Analyzer/Automatically inserted by Getein 1200/Getein 1600 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein 1100, Getein 1160, Getein 1180, Getein 1200 and Getein 1600), the concentration of fPSA in sample will be measured and displayed on the screen. The value will be stored in Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

### CONTENTS

1. A kit for Getein 1100/Getein 1160/Getein 1180 contains:  
 Package specifications: 25 tests/kit, 10 tests/kit

- 1) Getein fPSA test card in a sealed pouch with desiccant
- 2) Disposable pipet
- 3) Sample diluent
- 4) Instructions for use: 1 piece/kit
- 5) SD card: 1 piece/kit

#### 2. A kit for Getein 1200/Getein 1600 contains:

Package specifications: 2x24 tests/kit, 2x48 tests/kit  
 Sealed cartridge with 24/48 Getein fPSA test cards  
 Instructions for use: 1 piece/kit

#### Materials required for Getein 1200/Getein 1600:

- 1) Sample diluent: 1 bottle/kit
  - 2) Box with pipette tips: 96 tips/kit
  - 3) Mixing plate: 1 piece/kit
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

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

### STORAGE AND STABILITY

Store the test kit at 4~30°C with a valid period of 24 months.

Use the test card for Getein 1100/Getein 1160/Getein 1180 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 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.

### 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 instructions for use 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 Getein 1100/Getein 1160/Getein 1180): 100  $\mu$ L**

### TEST PROCEDURE

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

#### For Getein 1100:

1. Confirm SD card lot No. in accordance with test kit lot No. Perform "SD card" calibration when necessary.
2. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
3. Put the test card on a clean table, horizontally placed.
4. Using sample transfer pipette, deliver **100  $\mu$ L** of sample

into one tube of sample diluent, mix gently and thoroughly. Then drop **100 µL** of sample mixture into the sample well on the test card.

- 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 1160/Getein 1180:**

- Confirm SD card lot No. in accordance with test kit lot No..Perform “SD card” calibration when necessary.
- Enter testing interface of Getein 1160/Getein 1180.
- Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
- Put the test card on a clean table,horizontally placed.
- 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 well on the test card.
- Insert the test card into Getein 1160/Getein 1180 immediately after sample loading. The analyzer will count down the reaction time (10 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

**For Getein 1200/Getein 1600:**

- Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card which can calibrate automatically.
- Place the sample diluent at the correct position of Getein 1200/Getein 1600.
- 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:**

- It is required to perform “SD card” calibration when using a new batch of kits.
- It is suggested to calibrate once for one batch of kits for Getein 1100/Getein 1160/Getein 1180.
- Make sure the test card and the sample insertion is 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 fPSA test kit is 0.03-30.00 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	0.03-30.00 ng/mL
Lower Detection Limit	≤ 0.03 ng/mL
Within-Run Precision	≤ 10%
Between-Run Precision	≤ 15%

**LIMITATIONS**

- 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.
- Interferents in samples 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












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**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 15223-1:2021.

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		Batch code
	Temperature limit		In vitro diagnostic medical device
	Contains sufficient for <n> tests		Do not use if package is damaged and consult instructions for use
	Catalogue number		

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

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