Prostate-Specific Antigen (PSA) Self-Test Kit (LFIA)

Self-testing
FOR IN VITRO DIAGNOSTICUSE ONLY.
FOR SELF-TESTING.
PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST.
Instructions For Use

Test Kit Contents

Test Cassette | Alcohol Pad | Buffer | Disposable Lancet | Dropper | Instructions For Use | Bio-Safety Bag

Note: 1. Additional required but not provided equipment: Timer;
2. Sample tube rack would be provided for 012103-20-142.

REF	Specification	Test Cassette	Alcohol Pads	Buffer	Disposable Lancet	Dropper	Instructions For Use	Bio-Safety Bag
012103-01-142	1 pc/Box	1	2	1	1	1	1	1
012103-02-142	2 pcs/Box	2	4	2	2	2	1	2
012103-05-142	5 pcs/Box	5	10	5	5	5	1	5
012103-20-142	20 pcs/Box	20	40	20	20	20	1	20

The PSA test strip contains a colloidal gold labeled anti-PSA antibody, and another anti-PSA antibody is fixed on the T-line. And it contains a colloidal gold labeled Chicken IgY antibody, and Goat anti-chicken IgY antibody is fixed on the C-line. The T line and control line (C line) are in the detection window on the nitrocellulose membrane.
Note: The strip components and buffer in different batches of Prostate-Specific Antigen (PSA) test kit (LFIA) are not interchangeable.
The buffer have 220uL per unit. Buffer is composited by NaCl, $Na_2HPO_4{\cdot}12H_2O$, $NaH_2PO_4{\cdot}2H_2O$, PEG6000, Tween 80, ProClin-300.

Summary

Prostate specific antigen (PSA) is synthesized and secreted by prostate epithelial cells into the semen, and is one of the main components of seminal plasma. In the late 1960s, during the study of immunocontraception, Hare et al. discovered that prostatic fluid and semen contained a semen-specific protein with a molecular weight of about 34 KDa. This protein was extracted and purified from prostate tissue in 1979. PSA is a specific marker for prostate cancer and is one of the few organ-specific tumor markers available. The detection rate of PSA in prostate cancer is 70%-90%. Besides being used for detection and early detection of prostate cancer, serum PSA can also be used for monitoring after treatment. After prostate surgery, PSA concentration can gradually decrease to normal, if the concentration does not decrease after surgery or increases again after decreasing, tumor metastasis or recurrence should be considered. Serum PSA levels can also be elevated in prostate enlargement, prostatitis, kidney and genitourinary diseases. Total Prostate-specific antigen (PSA) is a biomarker used to screen for prostate cancer. However, its specificity is limited because it is produced by the prostate gland in general, not just by cancerous cells. Consequently, elevated PSA levels can be caused by a variety of benign (non-cancerous) conditions, most notably benign prostatic hyperplasia (BPH) and prostatitis. Therefore, it is mainly used clinically for the auxiliary diagnosis and differential diagnosis of prostate diseases, etc.
The symptoms of prostate problems include:
• Frequent urge to urinate
• Urgency to get up many times during the night to urinate
• Blood in urine or semen
• Pain or burning urination
• Painful ejaculation
• Frequent pain or stiffness in lower back, hips, pelvic or rectal area, or upper thighs
• Dribbling of urine

Intended Use

The Prostate-Specific Antigen (PSA) Test Kit is a rapid test strip method (LFIA, lateral flow immunoassay) intended for the qualitative detection of total PSA in fingertip whole blood.Total PSA includes both free PSA and PSA in a complex form (such as PSA-ACT,PSA bound
to α1-antichymotrypsin). This kit is intended to aid to diagnosis of suspected benign prostatic hyperplasia (BPH) or prostate cancer in males aged 45 years and above who present with clinical symptoms such as frequent urination, urgency, and dysuria. This kit is not automated. It is intended for lay users without training, qualification or experience. The kit is designed for self-testing.

Test Principle

This reagent uses colloidal gold double antibody sandwich method to qualitatively detect the concentration of PSA in human whole blood samples. After the diluted sample is dropped into the sample well of the cassette, the PSA in the sample and the colloidal gold-labeled anti-PSA monoclonal antibody I combine to form an immune reaction complex, which moves forward along the nitrocellulose membrane, the anti-PSA monoclonal antibody II in the detection area of the plain membrane is captured to form a detection line. detection line, and the intensity of the detection line

The more analytes in the sample, the more complexes accumulated on the
reflects the contentof the analytecaptured. Thecolloidalgold-labeled antibody that is not captured in the detection area moves forward along the nitrocellulose membrane and combines with the quality control antibody in the quality control area to form a quality control signal.

Storage Condition and Shelf Life

The test kit should be stored away from direct sunlight at 2℃ - 30℃ or 35℉ – 86℉ with a shelf-life of 24 months. Do not freeze. The shelf life is 24 months. After opening the aluminum foil bag of the test cassette, please use it within 1 hour.

Sample Condition

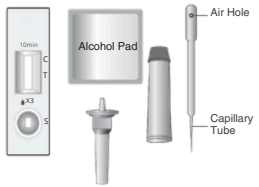
1. This product requires a fingertip blood sample as the test sample.
2. Samples should be tested immediately after collection.

Testing Procedure

Read the instruction for use completely before testing, and operate strictly in accordance with the instructions, otherwise reliable results cannot be guaranteed. Bring the kit contents to room temperature before testing.

Check the expiry date on the box.

Check that the Test kit contents have not been previously used (these disposable materials cannot be used twice). Do not open pouch until ready to use.



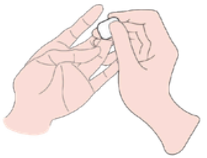
Read the Instruction of Use Carefully.

Wash your hands thoroughly, dry your hands before performing the test.

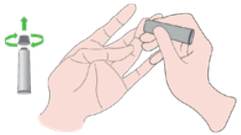
Open the foil pouch,take out the test cassette,Put it on a flat surface.

Massage the selected fingertip which to be tested.

Clean the fingertip with alcohol pad provided in the kit.

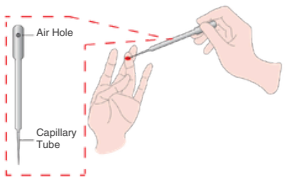


Remove the protective cap from the lancet, then place end of lancet on the test site and push the lancet down.



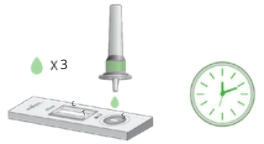
Massage and squeeze fingers to collect blood.

Dip the capillary of the dropper into the fingertip blood until the sample reaches the black line of the dropper.



Press the air hole of the dropper and add the fingertip blood from the dropper vertically into the sampling hole.

Add 3 drops of buffer,Read the results within 10-15 min. Result observed after 15 min is invalid

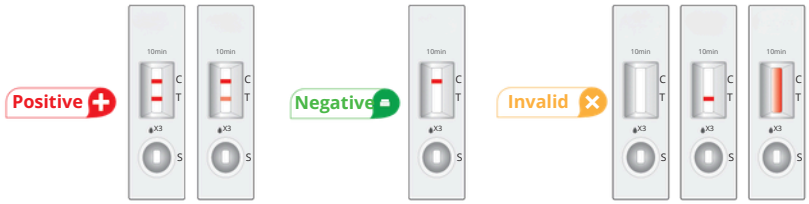


When the testing is completed. Affix biosafety signs, dispose all those used materials into the bag and seal well.

Remark: Additional required but not provided equipment: Timer

Interpretation of Test Results

Negative result: If only the control line (C line) shows red and the test line does not, it is negative which means that PSA concentrations is lower than 4ng/ml. PSA level might be normal but if you have symptoms of prostate problems, please looking for the help from professionals. It should be concerned that the result might be false negative because of medicine intake or prostate surgery.
Positive result: If both the control line (C line) and the detection line (T) show red, it is positive which means that PSA concentrations is equal or higher than 4ng/ml. PSA level might be higher than normal. Please see professionals to conduct further test to check it again. It should be concerned that the result might be false positive because of vigorous exercise or hormone therapy.
Invalid result: If the control line (C line) cannot be observed, it is invalid regardless of whether there is a detection line displayed. Samples with invalid test results should be treated as infectious contaminants, and samples should be collected again.



"C": Control Line "T": PSA Test Line "S": Sample Well

Product Performance Index

These product performance index is continuesly monitored for post-market surveillance.
1. Precision
The positive detection rate of three batches of reagents in different laboratories for positive samples is 100%, the positive detection rate of detection limit samples is 100%, and the negative detection rate of negative samples is 100%
2. Repeatability
When 10 kits in the same batch detect PSA precision control samples with concentrations of 95ng/mL, 50ng/mL and 20ng/mL, the results should be consistent, the color rendering should be consistent, and should be all positive.
3. The limit of detection
4ng/ml determined by Prostate specific antigen (human) (total: PSA-ACT + free PSA) from WHO International Standard. NIBSC code: 17/100
4. The interference and cross-reactivity substance are listed below:

Concentration	200 g/L	500 mg/mL	10 mg/mL	20 mmol/L	27 μmol/L	240 IU/mL	100 ng/mL	<1:50	20 mg/mL	10 mg/mL	
Effect on PSA Test Kit (LFIA)	Not effected	Not effected	Not effected	Not effected	Not effected	Not effected	Not effected	Not effected	Not effected	Not effected	
Concentration	20 mg/mL	20 μg/mL	20 ng/mL	5 μg/mL	500 μg/mL	1000 ng/mL	1200 ng/mL	1000 KU/L	1000 ng/mL	-	
Effect on PSA Test Kit (LFIA)	Not effected	Not effected	Not effected	Not effected	Not effected	Not effected	Not effected	Not effected	Not effected	Effected	

The table above shows the results of interference and cross-activity substances effect to the kit performance. There are no effect less than this concentrations. The substances below this concentration do not affect the test performance except finasteride tablets. Patients taking oral finasteride tablets should not use this kit for testing during the medication period. If they have taken finasteride tablets but have stopped taking them, they need to wait until the complete metabolism of finasteride tablets is completed (about 21 days) before testing, or go to a medical institution for a more comprehensive diagnosis.

5. Clinical results
In this clinical trial, the Prostate-Specific Antigen (PSA) Test Kit (LFIA) produced by Jiangsu Medomics Medical Technology Co.,Ltd. was compared with the immunofluorescence reagent on the market, and the consistency of the detection results was analyzed to evaluate the accuracy and effectiveness of the assessment reagent. The results are showed below:

The results of the comparison between serum sample for Prostate-Specific Antigen (PSA) Rapid Quantitative Test (fluorescent immunoassay) and fingertip blood sample for Prostate-Specific Antigen (PSA) Test Kit (LFIA):

Results analysis		Serum results of Immunofluorescence reagent		Total
		Positive	Negative	
Fingertip blood results of Prostate-Specific Antigen (PSA) Test Kit (LFIA)	Positive	52	1	53
	Negative	1	63	64
Total		53	64	117
Positive concordance rate: 98.11%; 95% confidence interval: 89.93%~99.95%				
Negative concordance rate: 98.44%; 95% confidence interval: 91.60%~99.96%				
Overall concordance rate: 98.29%; 95% confidence interval: 93.96%~99.79%				
Kappa value: 0.9655				

6. Hook effect
No hook effect was observed for samples containing PSA at concentration up to 500 ng/mL.

Warnings and Precautions

1. This test kit is used for self-testing (layman test).
2. This kit is only used to detect human fingertip blood. Other body fluids or samples may give inaccurate results.
3. This test kit is a single-use in vitro diagnostic reagent, please do not reuse it, and do not use expired products.
4. This test kit should be used within 1 hour after opening the foil pouch.
5. Do not use the test kit contents beyond the expiration date printed on the outside of the box.
6. Please check the package and expired date before use. DO NOT USE if the package is damaged or the kit is expired.
7. For reagents of different batch numbers, the test cassette and the buffer cannot be mixed.
8. The contents include desiccant in the aluminum foil bag, do not swallow.
9. Keep out of the reach of children and pets before and after use.
10. Avoid contact with skin and eyes;If the extraction buffer comes in contact with the skin or eyes, flush with plenty of water. If irritation persists, seek medical advice from a doctor or your local medical centre
11. After the test, put all used components back into your bio-safety bag. Follow the applicable regulations when disposing.
12. Do not move the test cassette around during the test.
13. The false positive result may have the following reasons: similar antibody cross-reaction in the blood; Some nonspecific components of blood have similar antigenic determinants to trap colloids gold-labeled antibody.
14. False negative results may have the following reasons: some unknown components shield the antigen so that it cannot bind to the antibody; The unstable PSA antigen degrades over time and is not recognized by the antibody at time or temperature.
15. Test results need to be combined with other clinical and laboratory data for clinical diagnosis. If the test results are inconsistent with the clinical evaluation, further examination is needed.
16. Other factors may also lead to errors in test results, including technical reasons, operational errors and other sample factors.
17. All test samples must be considered as potentially infectious, and appropriate protective measures should be taken during the collection, disposal, storage, and mixing of samples and testing. Therefore, please wear protective measures such as gloves and masks. All waste should be treated as potentially biologically hazardous items.
18. The blood test should be performed immediately after the sampling needle. High fat chylo-like, jaundice, or high rheumatoid factor samples are not recommended. If there are obvious hemolysis and blood clots in the blood, it will interfere with the test and cause false results. Do not use.
19. Like all the diagnostic tests, the final diagnosis should be made by the physician after comprehensively combining the various test indicators and clinical symptoms.
20. If you have any questions or suggestions during the use of this test, please contact the manufacturer.
21. The lancet is sterilised. Contamination of lancet might cause infection. The package of lancet is not allowed to open before use. The package of lancet should be checked before use. Use a new kit if the package is broken up.
22. The elevated PSA level can be caused by many factors, such as a urinary infection, an enlarged prostate, prostatitis, or prostate cancer. Therefore, please consult the professionals before making any medical decision.
23. Any serious incident that has occurred in relation to the device please report to the manufacturer and the competent authority of the Member State in which the user or the patient.
24. Safety data sheet (SDS) can be obtained by contacting the manufacturer or by email.
25. The usual influencing factors of test performance include increasing factors and decreasing factors. Increasing factors include prostate injury, such as digital rectal examination (DRE), indwelling catheterization, cystoscopy, etc; Prostate diseases such as acute and chronic prostatitis. The main reducing factors are oral administration of finasteride, etc.
26. Fingertip whole blood should be used as soon as possible after collection. High-fat chylous, jaundiced, or high rheumatoid factor samples are not recommended. If there is significant hemolysis or blood clots in the blood, it will interfere with the test and lead to incorrect results.

Test Method Limitations

1. The accuracy of the test is dependent on the quality of the sample. Improper sampling and handling of samples can affect test results.
2. Test results can also be affected by temperature and humidity.
3. Some medication (e.g. high concentration of Triglyceride) in the collected samples may interfere with the test result.
4. Please perform the test again if the result is in doubt.
5. This product is only for qualitative testing and the specific concentration of the indicator must be measured using other quantitative methodologies.
6. The PSA Test Kit is primary test so the final diagnosis should be combined with clinical symptoms and further test. Patients with positive results should undergo further analysis of the prostate by biopsy.
7. A false-positive result on a PSA test suggests that you might have prostate problems when you actually don't. A false-positive result might lead to unnecessary testing that is more invasive, such as repeated biopsies. It can also cause you and your family unnecessary anxiety and distress.
8. A false-negative result means that the test shows that the PSA level is normal even though prostate problems are present. Not all prostate problems cause a high PSA level. A false-negative result might cause the delay of treatment.

Reference

[1]Watt KWK, Lee P-J, Timkulu TM, Chan W-P, Loor R. Human prostate-specific antigen: structural and functional similarity with serine proteases. Proc Natl Acad SciUSA 1986;83:3166–70.
[2]Allard WJ, Zhou Z, Yueng KK. Novel immunoassay for the measurement of complexed prostate-specific antigen in serum. Clin. Chem.1998; 44(6); 1216-1223.
[3]Jahn JL,Giovannuccie EL,Stampfer MJ. The high prevalence of undiagnosed peostate cancer at autopsy:implications for epidemiology and treatment of prostate cancer in the Prostate-specific Antigen-era. Int J Cancer 2015; 137:2795-2802

Disposable Lancet
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Version	Change History	Effect Date
V1.0.08B	Initial CE marked version	2026-01-16
V1.0.09B	Updated EU REP Adress information,and Alcohol Pads Manufacturer information	2026-05-20

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CE 3018 CE Marked Davice with Normed Booy number
IVD Authonzed representative Medical Device
LOT Batch code
Contains Surticlem: for tests
STERILE
EUREP Authorized representatie In the European Community
Do Not Re- use
Do not use if Backage is damaged
Temperature limit
EUREP Authorized In the Eutooean Commumly
Date manutacture
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