

# Prostate Health Test

## Instructions for use

### Prostate and PSA

The prostate specific antigen (PSA) is a protein produced by the epithelial cells of the prostate gland. Its function is to fluidify the ejaculate and therefore increase sperm mobility. PSA also plays a role in dissolving cervical mucus, allowing sperm to enter the uterus. Small quantities of PSA are normally found in the blood of men with a healthy prostate. Prostate abnormalities (such as prostatitis, benign prostatic hyperplasia, prostate cancer) lead to an increase in the bloodlevels of PSA. PSA levels also increase naturally with age, after prostate surgery or after specific diagnostic tests (rectal examination, prostate biopsy, prostate ultrasound scan, etc.).

### Who is the prostate psa test for?

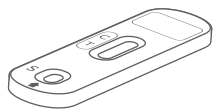
- For men who do not have symptoms, are aged over 45, who wish to check their prostate;
- For men with urinary tract symptoms (difficulty urinating, pain, increased frequency).

### References

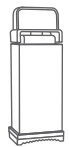
1. Catalona W.J., Southwick P.C., Slawin K.M., Partin A.W., Brawer M.K., Flanigan R.C., Patel A., Richie J.P., Walsh P.C., Scardino P.T., Lange P.H., Gasior G.H., Loveland K.G., Bray K.R.: Comparison of percent free PSA, PSA density, and age-specific PSA cutoffs for prostate cancer detection and staging. *Urology*. 2000 Aug 1;56(2):255-60.
2. Fritsche H.A., Babaian R.J.: Analytical performance goals for measuring prostate-specific antigen. *Clin Chem*. 1993 Jul;39(7):1525-29.
3. Catalona W.J. "Prostate Cancer Screening" *Med Clin North Am*. 2018 Mar;102(2):199-214.

### Content

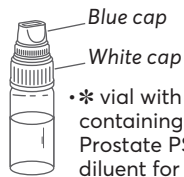
\* The number of the testing devices of the kit may vary. For the exact number of tests contained, please refer to the "content" section on the external box.



- \* hermetically sealed aluminium pouch containing:
  - x1 Prostate PSA Test
  - x1 Desiccant bag



- \* sterile lancets for self-drawing blood



- \* vial with dropper tip containing sufficient Prostate PSA Test diluent for 1 test

- \* transparent plastic bag containing a pipette for collecting blood



- \* antiseptic skin cleanser gauze
- x1 Instructions for use leaflet

- \* Material required but not supplied: cotton wool, a device to measure time (i.e. timer, watch).
- \* Do not open the sealed aluminium bag until just before performing the test. Take care to open it as marked.
- \* The desiccant packet must not be used. Dispose of it with household waste without opening it.

Self-test to measure PSA levels to screen for prostate abnormalities such as prostate cancer, prostate enlargement and prostatitis.

### Precautions

1. Read these instructions for use carefully before performing the test. The Test is reliable only if all the instructions are followed correctly.
2. Keep the Test out of the reach of children.
3. Do not use the Test after the expiry date or if the package has been damaged.
4. Follow the procedure exactly, using only the specified quantities of blood and diluent.
5. Store the Test components at a temperature between +4°C and +30°C. Do not freeze.
6. Use the test and lancing device once only.
7. The test is for external use only. DO NOT SWALLOW.
8. In vitro diagnostic device for individual use.
9. Not recommended for people who take anti-coagulant medications (blood thinners) or people suffering from haemophilia.
10. After using, please dispose of all components according to your local waste disposal laws. Ask your pharmacist for advice.

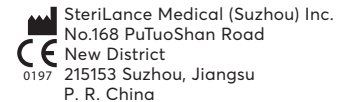
### Medical devices inside the kit:

Antiseptic cleanser gauze: 70% Alcohol

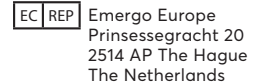
STERILE R Lancet



Vitrex Medical A/S  
Vasekaer 6-8  
DK-2730 Herlev  
Denmark



SteriLance Medical (Suzhou) Inc.  
No.168 PuTuoShan Road  
New District  
215153 Suzhou, Jiangsu  
P. R. China



EC REP Emergo Europe  
Prinsessegracht 20  
2514 AP The Hague  
The Netherlands

### Symbols

IVD In vitro diagnostic device

+4°C +30°C Temperature limits

REF List number

i Read the instructions before use

Do not reuse

LOT Lot number

STERILE R Sterilised using irradiation

Σ<sub>n</sub> Sufficient for <n> tests

CE CE marking

EC REP Authorised Representative in the European Community

Expiry date (last day of the month)

Legal manufacturer

Self-test for the determination of the Prostate-Specific Antigen (PSA) in whole blood samples.

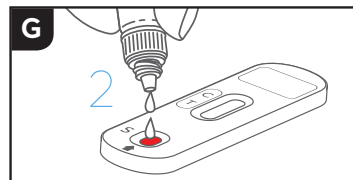
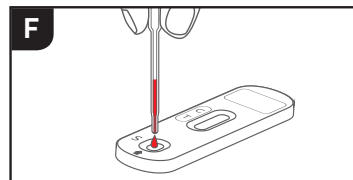
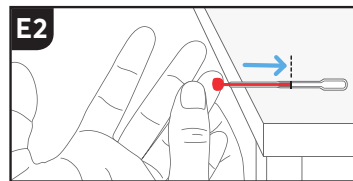
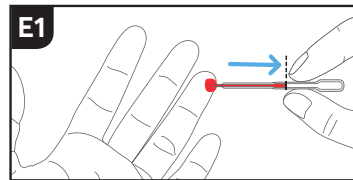
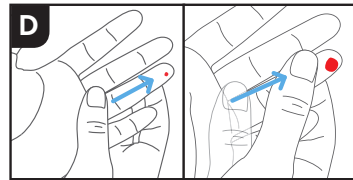
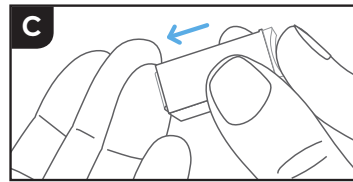
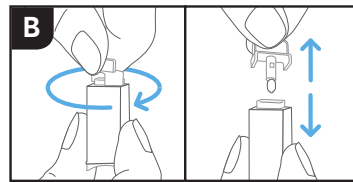
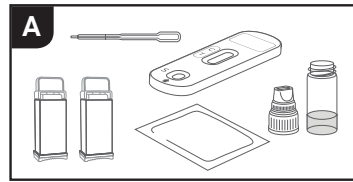


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EC REP Qarad EC-REP BV  
Pas 257  
2440 Geel  
Belgium

## Test procedure

- 1 Wash hands with soap and warm water, rinse with clean water and allow to dry. If this is not possible, use the provided gauze as an alternative.  
Note: The use of warm water facilitates capillary blood collection as it induces vasodilation.
- 2 Prepare the necessary material as follows: open the aluminium pouch, take out only the test cassette and throw away the desiccant bag. Open the plastic packet containing the pipette. – FIG. A
- 3 Carefully rotate the protective cap of the sterile lancet 360° without pulling it. Extract and discard the released cap. – FIG. B
- 4 Carefully massage the finger chosen for the puncture (the side of the ring finger is recommended). It is important that the massage is done from the palm of the hand to the phalanx, to improve blood flow. Press the open end of the lancet (the side the cap has been extracted from), against the fingertip – FIG. C The tip of the lancet automatically retracts after use. If the lancet does not work properly, discard it and use the second one supplied. If the second one is not required, it can be disposed of without special precautions.
- 5 Holding the hand down, massage the finger until a large drop of blood forms. It is important to massage from the palm of the hand to the phalanx to improve blood flow. – FIG. D
- 6 Take the pipette **without pressing the bulb**. Two sampling methods are suggested:  
– FIG. E1: hold the pipette horizontally **without pressing the bulb** place it in contact with the drop of blood, it will enter the pipette by capillarity. Move the pipette away when the black line is reached. If there is not enough blood, continue to massage the finger until the black line is reached.  
– FIG. E2: place the pipette on a clean, flat surface with the tip protruding from the shelf, then place the drop of blood in contact with the pipette, it will enter by capillarity. If blood is not sufficient, continue massaging the finger until the blood has reached the black line.  
Avoid, as far as possible, to continuously move the tip of the pipette away from the finger in order to prevent the formation of air bubbles.
- 7 Place the blood collected with the pipette into the well indicated on the cassette (S) by pressing the pipette bulb. – FIG. F
- 8 Unscrew the blue cap from the dropper vial (leave the white cap tightly screwed on). Deposit 2 DROPS into the well indicated on the cassette (S), wait for 5 seconds between the first and second drop. – FIG. G
- 9 **Wait 5 minutes** and read the results referring to the next section for result interpretation.



## Results Interpretation

Read the result after exactly 5 minutes.

The intensity of the line colours is not relevant for the purposes of interpretation of the Test's results.



**Positive result** • Two coloured bands appear in the reading window by the T (test) and C (control) signs. The T band may be less intense (lighter) than the C line. **This result means that the value of prostate specific antigen (PSA) in the blood is higher than normal, so you must consult a physician.**



**Negative results** • A coloured band appears only under the C (control) sign. **This means that the value of prostate specific antigen (PSA) in the blood is normal.** A negative result does not exclude the possibility of prostatic pathologies.



**Non valid result** • No bands appear or there is a line only under the T (test) sign and not under the C (control) sign. In this case it is not possible to interpret the result of the test, which must be considered not valid. Repeat the test with a new blood sample.



## F.A.Q • Questions and answers

**How does the prostate health test work?** • The prostate specific antigen is a protein secreted normally by the prostate and circulating in our body in small quantities. Values above normal may be a sign of the presence of pathological conditions in the prostate, which may be of infectious or inflammatory origin (prostatitis), benign (benign prostatic hyperplasia) or malignant (cancer). The Prostate Health Test is a rapid qualitative test for measuring the levels of total PSA in whole blood. The test uses a unique combination of specific antibodies that can selectively identify PSA. A positive result means PSA values are above 4 ng/ml. In some cases, samples with PSA concentrations between 3 ng/ml and 3.9 ng/ml can yield positive results.

**When can the test be used?** • Prostate Health Test can be performed at any time of the day, but in some cases it is advisable to wait for a specific period of time in order to avoid a false positive result. The blood concentration of PSA may increase in the cases listed below:

Activity	Waiting times	Activity	Waiting times
<i>prolonged periods of time spent on a bicycle/motorbike</i>	24 hours	<i>insertion of a urinary catheter</i>	2-3 days
<i>sexual intercourse/ejaculation</i>	24-48 hours	<i>transrectal ultrasound scans</i>	2-3 days
		<i>infections of the urinary tract</i>	1 week

**Can the result be incorrect?** • The result is correct if the instructions are followed carefully. However, the result may not be correct if: the device comes into contact with other liquids before being used, if part of the diluent is accidentally spilt, if the amount of blood is not enough or the number of drops dispensed in the well is more than 3.

**How do i interpret the test if the colour and intensity of the test and control bands are different?** • The colour and the intensity of the bands are not important for the interpretation of the result. The bands must be full and homogeneous. The test is positive regardless of the intensity of the colour of the test band.

**Is the result reliable if read after 10 minutes?** • No. The test must be read 5 minutes after the procedure is completed.

**What should i do if the result is positive?** • If the result is positive, the concentration of PSA in the blood is above normal levels and you must consult a physician, who will establish what to do next. **PSA IS A SPECIFIC PROSTATE MARKER BUT IT DOES NOT NECESSARILY IMPLY THE PRESENCE OF NEOPLASIA.**

**What should i do if the result is negative?** • If the result is negative, the concentration of PSA is normal. A negative result does not exclude the possibility of prostatic pathologies. If the result is negative but you have urinary tract symptoms (difficulty urinating, pain, increased frequency) you should talk to your physician.

**How accurate is the Prostate Health Test?** • The Test is very accurate. Assessment reports show a concordance rate of 92.34% (95% CI: 87.93-95.23%) with reference methods.