

Questions and Answers

What is PSA?

Prostate Specific Antigen (PSA) is a protein in your blood secreted by the prostate gland.

How does this test work?

The level of PSA is measured in the blood sample. Elevated levels (greater than 4 ng/ml) may be an important signal of possible prostate disease. This test is designed with a cut-off level of 4 ng/ml.

What do I do if the test indicates a raised test result?

This test is meant only as a screen, if you get a raised result, contact your doctor and discuss the result. Your doctor will decide how best to proceed.

How long do I have to wait to read the results?

The test result must be read 10 minutes after adding the buffer solution. The results are not valid if they are read after 10 minutes.

What if the lines in the Results Window are not the same colour or intensity?

The colour or intensity of the lines in the Results Window do not have any significance. If the lines are visible and unbroken then they can be interpreted as explained in Section 12.

What is the purpose of the line in the Control Area?

The line in the Control Area assures you that the test was run correctly.

If no line appears in the Control Area the test is invalid and a new test should be carried out.

What should I do if the levels are high?

Discuss the results with your doctor. It is likely that you will be invited for further testing to determine the cause of elevated PSA levels, which could also be BPH or prostatitis. Take these instructions with you to show to your doctor.

What should I do if the test is negative?

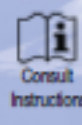
The negative result does not necessarily exclude a prostate condition. Re-test again in a few days. If you still have concerns or symptoms, contact your doctor for advice.

What other factors may influence PSA results?

Competitive sports, bicycle riding, horse riding, and sexual activity within 48 hours before using the test may influence PSA levels. Recent prostate biopsy and some blood thinning medications can also influence PSA levels.

What is the clinical performance of this test?

The test showed an accuracy of 96.2%, specificity of 95.3% and sensitivity of 97.3% when compared to 161 clinically confirmed samples.



Read instructions carefully before use!

Keep out of reach of children.

Do not use the test after expiry date.

(See bottom of box)

Store at 15° - 30°C (59° - 86°F).

Use test and safety lancet only once.

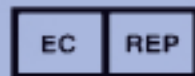
Do not take the test cassette apart.

Do not ingest buffer solution

For external use only.

In-vitro diagnostic device for self-testing.

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Lancet:

STERILE

CE

0197



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SC8220B v.2

Instructions for Use

- 1 Wash your hands with soap and warm water. Open foil package by tearing along the slice on the package and remove the Test Device and Dropper.
- 2 Use enclosed Alcohol Swab to wipe the finger you intend to prick with the lancet:
 - Remove plastic cover from the safety lancet.
 - Hold your finger tight; squeeze the blood towards the tip of your finger (Figure 1).
 - Place the red end of the Lancet against your finger and press firmly as shown in (Figure 2).
 - Squeeze your finger, making sure you get a large hanging drop of blood (Figure 3).



Figure 1



Figure 2



Figure 3

- 3 Hold the Dropper provided horizontally (flat) and touch the tip of the Dropper to the drop of blood (Figure 4).
Do not squeeze the bulb. Blood will flow into the Dropper. If you need to, squeeze your finger to get additional blood and fill the Dropper with blood up to the line.
- 4 Place the filled Dropper against the Sample Well (round hole) marked with an "S" on the Test Device (Figure 5).
- 5 Squeeze the top of the Dropper, squeezing the entire blood sample into the Test Device.
- 6 Wait 90 seconds after adding the blood to the Sample Well.
- 7 Twist open the cap of the buffer Solution vial.
Please note that the vial only contains 0.5 ml of clear buffer solution and therefore it can appear to be empty.
- 8 Slowly add five (5) drops of buffer Solution to the Diluent Well marked with a "D" (Figure 6).



Figure 4



Figure 5



Figure 6

Prostate Health Test

Instructions for use



Please read both sides of these instructions carefully before performing the test.

General information:

Prostate cancer occurs when the cells of the prostate begin to grow uncontrollably. When caught and treated early, prostate cancer has a cure rate of over 90%.

PSA is a protein produced by the prostate and released in very small amounts into the blood-stream. When there is a problem with the prostate, such as enlarged prostate, prostatitis or development of prostate cancer, more and more PSA is released until it reaches a level where it can be easily detected in the blood.

This test is sensitive and allows early detection of heightened levels of PSA in the blood, giving you the opportunity to take early action and request further tests from your doctor should the levels be elevated. Every man over the age of 50 should perform this test regularly.

Before Carrying out the Test

Store the test at room temperature (15 - 30°C or 59 - 86°F).

Do not use the test after the expiration date printed on the package.

Contents of Package

- Sealed Foil Pouch (contains: test cassette, dropper and desiccant)
- Buffer solution
- Single use lancet
- Instructions For Use leaflet
- Alcohol swab

Materials required but not provided:

- Clock with second hand or timer

Intended Use

This test can be used to identify elevated levels of Prostate Specific Antigen (PSA), which may be associated with enlarged prostate (benign hyperplasia of the prostate) or, in some cases, it may indicate the possible presence of prostate cancer.

If you have any questions regarding the instructions or your results, please refer to the Question and Answer section on reverse side or call our Customer Care Line on +44 (0) 1580 211358

SELFCheck

- 9 Carefully monitor the time and read the result at exactly 10 minutes.
- 10 **How to Read Your Result**
In the Results Window there is a Control Area marked with a "C" and a Test Area marked with a "T".
 - One line appears in the Control Area - test is negative (Figure 7).
 - Two lines appear: one in the Control Area and one in the Test Area - test indicates raised PSA (Figure 8).
 - No lines appear or one line appears in the Test Area - test is invalid and should be repeated (Figure 9).

NOTE: The colour and the intensity of the lines do not matter. One line may be darker than the other.
If the line is visible and unbroken, the result can be interpreted as described above.
- 11 Do not read the result after 10 minutes as they will not be valid.
- 12 Contact your doctor to discuss if you still have concerns or symptoms.



Negative Result
Figure 7



Positive Result
Figure 8



Invalid Result
Figure 9

Limitations of the Test

- Do not use the test within 48 hours of performing competitive sports, bicycle riding, horse riding, and sexual activity.
- The SELFCheck Prostate Health test is a screening test limited to the detection of PSA in whole blood.
- This test is intended for in-vitro (external) use only.
- Although the test is accurate in detecting PSA levels, a small number of false results may occur.
- As with all self-testing devices, a definitive diagnosis should not be made on the basis of a single test. The diagnosis should be made by a doctor after all clinical and laboratory findings have been evaluated.
Note: If the test result is raised, see your doctor to confirm the results.
If the test result is negative but you are not feeling well or if you are concerned about your prostate health, see your doctor for further testing and diagnosis.
- This test device can only be used once. Discard it after use.
- Do not use after the expiration date on the package.