fortel®

One-Step Whole Blood PSA Test

Contents of Package

- Foil Package (Contains: Test Device and Dropper)
- Vial of Test Solution
- Finger Stick Device (Lancet - CE0197, 93/42/EEC)
- Alcohol Swab

Self Test Device
FOR *IN-VITRO* DIAGNOSTIC USE
NOT FOR INTERNAL USE

Materials required but not provided:

- Clock with second hand or timer

PLEASE READ CAREFULLY BEFORE BEGINNING TEST

Before You Begin 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.

Do not use the test within 48 hours of performing competitive sports, bicycle riding, horse riding, and sexual activity.

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 Technical Service department at 800-854-3002.

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. This test is a highly sensitive immunochromatographic assay that utilizes monoclonal antibodies to detect PSA.

Instructions for Use

1. Wash your hands. Tear open foil package by tearing along the slice on the package and remove the Test Device and Dropper.
2. Wipe the finger you intend to stick with the Alcohol Swab; and using the Lancet provided, remove protective cap, and stick your finger as follows:
   -- Hold your finger tight; squeeze the blood toward 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).

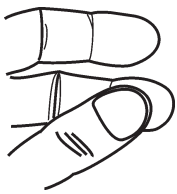


Figure 1

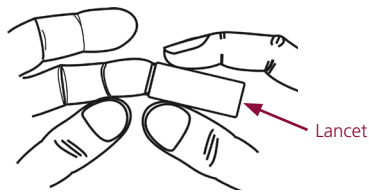


Figure 2

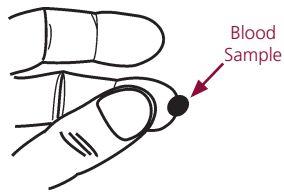


Figure 3

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. You will need to squeeze your finger to get additional blood. Fill blood to the line on the Dropper.
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 Test Solution vial.
8. Slowly add five (5) drops of Test Solution to the Diluent Well marked with a "D" (Figure 6).

Figure 4

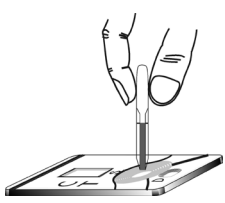


Figure 5

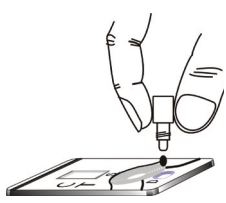


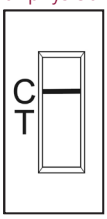
Figure 6

9. Start the timer and read results at exactly 10 minutes.

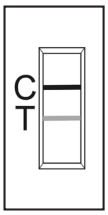
Continued on reverse side.

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 is positive (Figure 8).
    - **No lines appear or one line appears in the Test Area** - test is invalid and should be repeated (Figure 9).

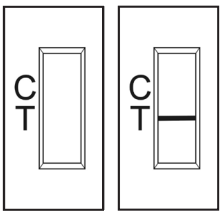
    NOTE: The color and the intensity of the lines do not matter. One line may be darker than the other. If the line is visible and unbroken, the result can be interpreted as described above.
11. Do not read the result before or after 10 minutes.
12. Contact your physician to discuss your test results.



Negative Result
Figure 7



Positive Result
Figure 8



Invalid Result
Figure 9

Limitations of the Test

- The FORTEL-PSA™ 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 physician after all clinical and laboratory findings have been evaluated.

  Note: If the test result is positive, see your physician to confirm the results and to possibly obtain treatment. If the test result is negative but you are not feeling well or if you are concerned about your prostate health, see your physician 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.
- Some materials in this product were derived from bovine origins. The product is manufactured, processed, and handled in such a manner as to prevent the transmission of communicable disease pathogens.

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 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 do I do if the test indicates a positive result?
This test is meant only as a screen. If you get a positive result, call your doctor and discuss the result. Your doctor may decide to run more tests.

How long do I have to wait to read the results?
The test results must be read at 10 minutes after adding the Test 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 color or intensity?
The color 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 above.

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 then the test is invalid and should be repeated.

What are the performance characteristics of the test?
The test showed an accuracy of 97.5%, specificity of 95.0%, and sensitivity of 100.0% when compared to 161 clinically confirmed samples.

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