DIAGOPSA TEST

One-Step Whole Blood PSA Test

FOR IN-VITRO DIAGNOSTIC USE. NOT FOR INTERNAL USE. SELF-TESTING DEVICE.

PLEASE READ THE INSTRUCTION MANUAL CAREFULLY BEFORE PERFORMING THE TEST.

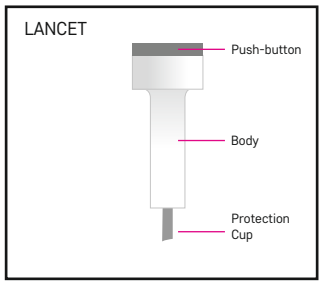
DO NOT TAKE ANY DECISION OF ANY MEDICAL RELEVANCE WITHOUT FIRST CONSULTING A MEDICAL PRACTITIONER AFTER PERFORMING THE TEST.

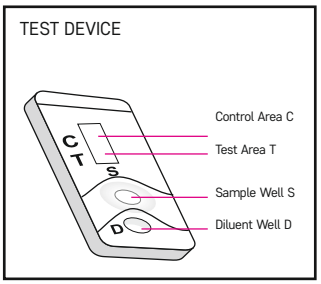
WARNING! DO NOT PRESS ORANGE PUSH-BUTTON BEFORE USING LANCET

THE TEST SHOULD BE CARRIED OUT WITHIN 15 MINUTES FROM OPENING A FOIL PACKAGING.

INSTRUCTIONS FOR USE

PSA is an acronym for Prostate Specific Antigen. This antigen is a useful tumour marker (these are substances whose increased concentration may be associated with the presence and development of cancer) for early detection of prostate cancer. In healthy men, it penetrates into the blood stream in trace amounts. The correct value of the PSA is in the range of 0-4 ng/ml. The increase in PSA to the levels higher than 4 ng/ml is caused by the damaged prostate cells and infiltration of the antigen into the blood. This may indicate a pending disease process in prostate. The most important diseases causing increase in PSA levels are: beginning prostate hyperplasia (enlarged prostate), prostate cancer, adenocarcinoma or prostate inflammation. PSA level should be determined in all men older than 50 years. Concentration limits, on which the test effect is based is 4 ng/ml. Determination of PSA levels is an initial stage of prevention and diagnosis of prostate diseases.





CONTENTS OF PACKAGE

Foil Package (Contains: Test Device and Dropper), Vial of Test Solution, Finger Stick Device (lancet), Alcohol Swab, Instruction for use.

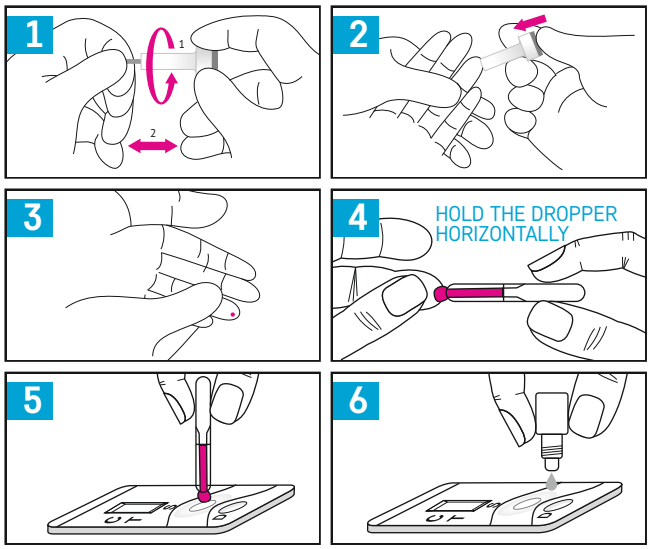
NOTE: The foil Package contains desiccant sachet for moisture protection which should be discarded.

HOW TO 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 (look at pictures aside):

- Twist and remove The Protection Cap (Figure 1).
- Place the Lancet against your finger and press firmly (Figure 2).
- Squeeze your finger, making sure you get a large hanging drop of blood (Figure 3).

3. Hold the Dropper provided horizontally (flat) and touch the tip of the Dropper to the drop of blood (Figure 4).



NOTE: 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 black 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).
9. Start the timer and read results at exactly 10 minutes.

BEFORE YOU BEGIN THE TEST:

Store the test at room temperature 15 - 30°C (59 - 86°F).
Do not use the test after the expiration date printed on the package.
If you have any questions regarding the instructions or your results, please refer to the Question and Answer section on reverse side or call Infoline 800 70 30 11

MATERIALS REQUIRED BUT NOT PROVIDED:

Clock with second hand or timer.

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".

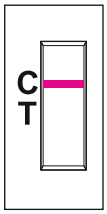


Figure 7

NEGATIVE RESULT

The result is negative if:

- One line appears in the Control Area C

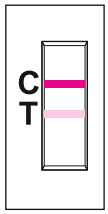


Figure 8

POSITIVE RESULT

The result is positive if:

- Two lines appear, one in the Control Area C and one in the Test Area T

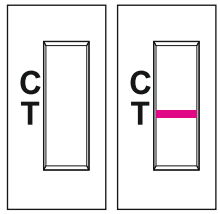


Figure 9

INVALID RESULT

The result is invalid if:

- No lines appear in the Control Area C and Test Area T
- One line appears in the Test Area T

Repeat the test using a new test kit.

CAUTION:

- If the test result is positive, then it means that PSA antigen level in the blood sample is higher than normal value of 4 ng/ml. Please note that Diago PSA test is intended merely for control. In the case of a positive result, you should contact your doctor and discuss the result. Your doctor may decide on the need for additional testing.
- If the test result is negative, then it means that PSA antigen level in the blood sample is normal, however in case of symptoms associated with urinary tract or in case of symptoms indicating a health deterioration, you should also consult your doctor for further tests and a final diagnosis.
- The colour and intensity of lines do not matter. One line may be darker than the other one. If the line is visible and continuous, the test can be interpreted as described above.
- Do not read the test result after 10 minutes as the test continues to be subject to chemical reactions that may impact the test result.

TEST LIMITATIONS:

- DIAGO PSA test is a control test intended solely for detection of prostate specific antigen concentration (PSA) in whole blood.
- The test is intended solely to be used in vitro (externally).
- The accuracy of DIAGO PSA test result depends on the proper conduct of the test.
- As with all tests intended for self-testing, the final diagnosis should not be based on a single test result. The diagnosis should be made by the doctor after evaluation of all clinical and laboratory tests results.
- The test plate can be used only once. After use, it should be disposed. All components of the test are in contact with blood, hence a care must be taken to avoid a potential infection.
- Do not use the test after the expiry date stated on the package. Keep away from children.

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 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 96.2%, specificity of 95.3%, and sensitivity of 97.3% when compared to 161 clinically confirmed samples.

ALL ELEMENTS OF THE USED TEST SHOULD BE INSERTED INTO THE ORIGINAL BOX AND TREATED AS A WASTE.
DO NOT RE-USE ANY PIECE OF THE TEST KIT.

For DiagoPSA test

DIAGNOSIS S.A.
ul. Gen. W. Andersa 38A
15-113 Białystok, POLAND

CE 0197 | 15 °C 59 °F – 30 °C 86 °F | Σ 1 | IVD

For MEDLANCE lancet

HTL STREFA S.A.
Adamówek 7
95-035 Ozorków, POLAND

CE 0344 | STERILE R | Σ 1 | REF 7004

1,5 mm blade
Penetration depth – 1,5 mm.

Store at 15-30°C (59-86°F).
See the package and the label for the Batch code and expiration date.

15 °C – 30 °C	Temperature limit		Consult instruction for use
LOT	Batch Code		Do not re-use
	Use-by date	IVD	In vitro diagnostic medical device
	Manufacturer	REF	Catalogue number
Σ 1	Contains sufficient for <n> tests	Rev.	Last updated
STERILE R	Sterilized using irradiation		Keep away from sunlight
	Do not use if package is damaged		Keep dry

Diagnosis S.A.
ul. Gen. W. Andersa 38A
15-113 Białystok, POLAND
www.diagnosis.pl

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