



"We're Bringing HealthCare Home™"

HEALTHCHECK MEN'S PROSTATE HEALTH TEST

INTENDED USE

The **HealthCheck Men's Prostate Health Test*** is a One-step immunoassay for the rapid, semi-qualitative determination of human Prostate Specific Antigen (PSA) in whole blood. The test is intended for OTC use as an aid in the diagnosis of prostate cancer

SUMMARY

Prostate cancer is the most common type of cancer found in men in the U.S. Approximately one out of ten men with cancer suffer from this disease. The incidence of prostate cancer increases with age and accounts for a growing number of newly diagnosed patients.

Nearly 32,000 cases of prostate cancer are diagnosed in the UK each year. In Ireland, prostate cancer is the leading type of cancer in men, with 80% diagnosed individuals begin over the age of 65.* (*source: Cancer Research UK*)

Prostate Specific Antigen (PSA) is produced primarily in the prostate gland and is secreted into the prostate ducts and at ejaculation serves to liquefy the seminal coagulum. Many studies have been done to quantify the PSA levels in normal males using different methodologies. Virtually all healthy men under 50 years or age have PSA concentrations under 4.0 ng/ml. But if PSA concentration is above 7 ng/ml, the patient should be checked for prostate cancer. The results from different methodologies should not be interchanged and normal as well as elevated values may vary.

Some studies indicate that elevated total PSA levels are found in serum from patients having prostate cancer cells metastasized throughout their body. Other studies indicate that Free PSA, which cannot form a complex with serine proteases, tends to be more abundant in patients with benign prostatic hyperplasia (BPH). It is important for a simple qualitative test to recognize

elevated PSA in whatever form it exists in the blood stream.

The Dual PSA uses a specific mix of antibodies to measure equally both forms of PSA, Free PSA as well as PSA-ACT complex form.

PRINCIPLES OF THE PROCEDURE

HealthCheck Men's Prostate Health Test utilizes a sandwich immunoassay system and the immunochromatographic detection assay, to be performed in one assay.

If PSA is present in the sample in concentrations above the detection level, a labeled specific antibody-dye conjugate binds to it, forming an antigen-antibody-dye complex. This complex is then captured by another specific antibody immobilized in the Test Zone ("T") of the membrane, producing a visible pink-rose color band on the membrane. The color intensity will depend on the concentration of PSA in the sample. On the other hand, two color bands will always appear at the Reference zone, one on the top and one on the bottom in the device ("C1 and C2"). The C1 band serves as a reference of 4 ng/ml of PSA and C2 serves as a reference to 7 ng/ml.

* A membrane-based test strip covered under US Patent 4,774,192. Other patents pending.

MATERIALS PROVIDED

1. Test Device (4ng/ml and 7ng/ml cut-off)
2. 20 µl pipette
3. Buffer

MATERIALS REQUIRED BUT NOT PROVIDED

1. Timing device

WARNINGS AND PRECAUTIONS

For in vitro diagnostic use: Do not use the kit beyond the expiration date printed on the outside of the kit box. Dispose of all used test devices properly.

STORAGE CONDITIONS

The device may be stored at room temperature (18°C - 30°C) for 18 months.

OBTAINING BLOOD

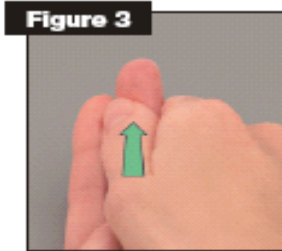


Figure 3

a. Place selected finger flat on the tabletop. With the thumb of your opposite hand, massage or “milk” the selected finger, five or six times, to push blood to the tip (Figure 3).

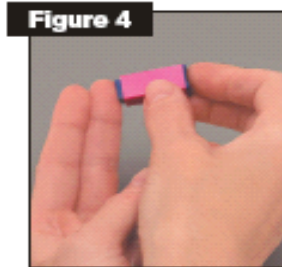


Figure 4

b. Place the raised end of the lancet firmly against the side of the selected finger.

Press the lancet against your finger until you hear a “click”. You may feel a slight sting. (Figure 4).

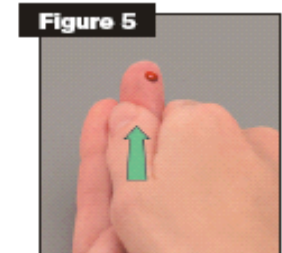


Figure 5

c. With the thumb of your opposite hand, massage or “milk” your finger until a large drop of blood forms. (Figure 5).

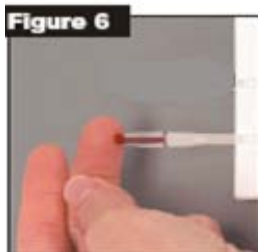


Figure 6

d. Gently touch the drop of blood to the tip of one dropper (Figure 6). Be sure to touch the drop of blood directly over the puncture site. The dropper will start to fill with blood.

e. Fill the dropper until the blood reaches the black line.

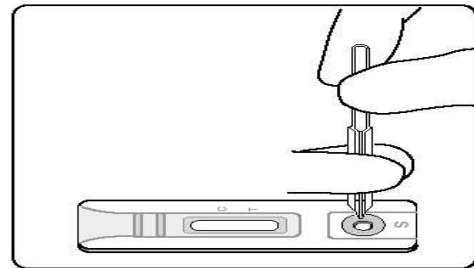
If necessary, massage your finger to get more blood.

NOTE: The dropper WILL NOT fill past the black line.

Test Procedure:

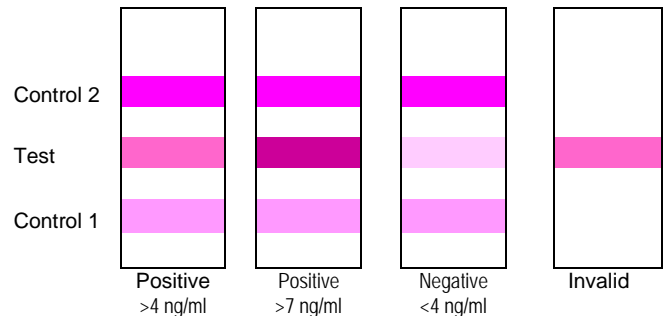
Prior to use, bring all test components and patient samples to room temperature.

1. Remove the device from the foil wrapper by tearing along the “splice”, and place it on a clean level surface.
2. Using the enclosed pipette, add 20 µl of whole blood from a finger stick into the Sample Well (S) of the device, as shown in picture; then add 2 drops of buffer immediately.
3. Read the results at 10 minutes.



INTERPRETATION OF RESULTS

To determine your result, compare the color intensity, i.e. shade of color, lightness or darkness of color, of the test band “T” to the control band “C”.



1. **Positive:** If the color intensity of the Test line is darker than the Control 1 line, the concentration of PSA is greater than 4 ng/ml.
2. If the color intensity of the Test line is darker than the Control 2 line, the concentration of PSA is greater than 7 ng/ml. See your doctor.
3. **Negative:** If the color density of the Test line is lighter than the Control 1 line, the concentration of PSA is less than 4 ng/ml.
4. **Invalid:** If a color band does not appear in the Control zone C1 or C2, the test results are invalid. The specimen may have been added to the wrong window, or the test device may have deteriorated. The specimen should be re-tested using a new test device.

ESTIMATION OF CONCENTRATION OF THE ONE-STEP DUAL PSA™ BY TEST

Color Intensity:	PSA ng/ml
T is lighter than C1	Less than 4
T is equal to C1	Equal to 4
T is darker than C1 but lighter than C2	4-7
T is equal to C2	Equal to 7
T is darker than C2	Greater than 7

LIMITATION OF THE TEST

1. The test is for in vitro diagnostic use only.
2. The test is limited to the detection of PSA levels in blood.
3. Although the test is very accurate in detecting elevated PSA, a low incidence of false positive results can occur. The test is a semi-quantitative screening assay.
4. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the results of a single test, but should only be made by a physician after all clinical and laboratory findings have been evaluated.

CUT-OFF LEVELS

The two cut-off levels of the Dual PSA One-Step Test are 4 ng/ml and 7 ng/ml of PSA. The concentration of PSA was determined by Hybritech Tandem-E PSA.

PRECISION

The precision of the Dual PSA One-Step Blood Test was determined using replicate assays of samples from three different patients' pools, with kits from three different production lots. Each specimen sample was run through ten parallel assays. The data demonstrated 100% precision for the duplicates of each sample and 100% precision using the test kits from different lots.

SPECIFICITY & INTERFERING SUBSTANCES

The following substances were tested for cross-reactivity in PSA free blood and in normal blood containing PSA. None of the substances showed interference or cross-reactivity with the test.

Substances Added	Concentration
Triglycerides	250 mg/100 ml
Bilirubin	10 mg/100 ml
PAP	1000 ng/ml
HCG	100 IU/ml
Transferrin	5 mg/ml
Prolactin	1µg/ml
Acetaminophen	20 mg/dl

Frequently Asked Questions:

Q: What is PSA?

A: PSA (Prostate Specific Antigen) is a protein produced by the prostate gland and released into the bloodstream in very small quantities. If there is a problem with the prostate, such as prostatitis, enlarged prostate or prostate cancer, the prostate will release larger amounts of PSA into the blood. The HealthCheck Men's Prostate Health Test tests positive when PSA levels are elevated above normal.

Q: Who should test for PSA and how often?

A: All men over the age of 40 should test regularly to detect potential signs of prostate problems early.

Q: Why is it important to test for prostate health?

A: Prostate cancer is the most common type of cancer found in men in the U.S. Approximately one out of ten men with cancer suffer from this disease. The incidence of prostate cancer increases with age and accounts for a growing number of newly diagnosed patients.

Nearly 32,000 cases of prostate cancer are diagnosed in the UK each year. In Ireland, prostate cancer is the leading type of cancer in men, with 80% diagnosed individuals begin over the age of 65.* (*source: Cancer Research UK)

Q: What should I do if my PSA levels are outside the norm?

A: Consult your doctor for further testing and diagnosis. Do not make any medical decisions without consulting a doctor first.

HEALTH-CHEM DIAGNOSTICS LLC

3341 S.W 15th Street - Pompano Beach, FL 33069 – USA

website: www.healthchemdiagnostics.com

CUSTOMER HOT-LINE 1-800-482-2907

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