

Hybritech®
PSA &
free PSA
Tests

*Aids To Detect
Prostate Cancer*



BECKMAN
COULTER®

Introduction

A blood test is available called the Prostate Specific Antigen (total PSA) test. Traditionally, this test has been used to help doctors decide how to manage patients with prostate cancer. Of the different PSA blood tests available, the Hybritech® PSA test, when used in combination with the digital rectal examination (DRE), has been shown to be safe and effective in detecting prostate cancer in men aged 50 years or older.

Depending on the results of your DRE and total PSA test, your physician may decide to order an additional blood test, called free PSA. This test is used to help the physician interpret the results when the total PSA test, combined with a non-suspicious DRE, are ambiguous.

What Is The Prostate Gland?

The prostate gland is part of the male reproductive system (Figure 1). It is about the size of a walnut and is located in front of the rectum and just below the bladder. The prostate gland produces the liquid part of semen, which transports sperm.

What Is Cancer?

Cancer is really a group of diseases. There are many different types of cancer. One type is cancer of the prostate. Normal human cells divide and grow in an orderly way, which helps to keep the

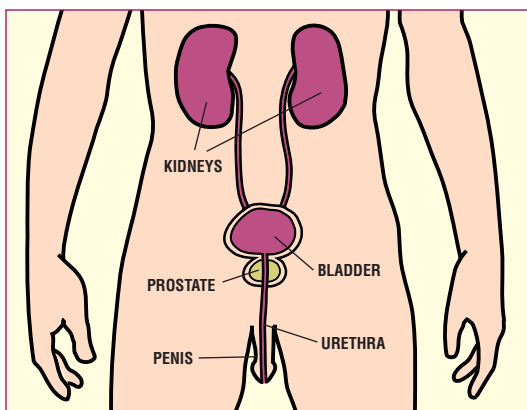


Figure 1 — Front View of Male Urinary System and Prostate

body in good repair. Sometimes, however, normal cells begin to divide too rapidly. This uncontrolled cell growth forms a mass, or tumor. Tumors may cause pain but usually do not when they are small. Some tumors are benign. Benign tumors are not cancerous. They do not spread to other parts of the body and usually are not life-threatening.

Cancerous tumors are called malignant tumors. They can metastasize, or spread to other parts of the body and form new tumors. This is why it is important to find a malignant tumor as early as possible when the cancer may be treatable.

What Is PSA?

Prostate Specific Antigen (PSA, which is also called the total PSA) is a substance that is produced only by the prostate gland. Small amounts of this substance may get into the bloodstream and can be measured by the PSA test. Certain abnormal

conditions of the prostate, however, may raise the level of PSA in the blood. High levels of PSA do not harm you; they are only important as a signal to your doctor of possible prostate disease.

PSA exists in several different forms in the blood. Some forms are bound to proteins, and others are unbound (or “free”). Total PSA, as measured by your first PSA test, actually measures all of the PSA in your blood, both the protein-bound form and the free form. Your physician may request additional blood tests depending on the results of the first total PSA test and your DRE.

What Is The PSA Blood Test?

The PSA blood test is a simple laboratory procedure. A small sample of blood is taken from a vein in your arm and sent to a laboratory. The laboratory tests it to see how much PSA is present and then sends the result to your doctor. You should be aware that the PSA test alone does not indicate the presence or absence of prostate cancer.

In addition to the PSA blood test, your doctor will perform an examination of the prostate gland by inserting a gloved finger into the rectum. Your doctor uses the finger to feel the prostate gland and search for areas of hardness or irregularity that may indicate prostate disease. This procedure is called a digital rectal examination, or DRE (Figure 2).

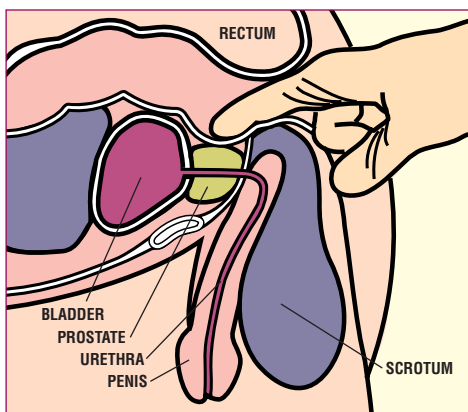


Figure 2 — Examination of the Prostate by Digital Rectal Exam

Why Should PSA and DRE Tests Be Done Together?

When the PSA test and digital rectal examination are used together, they are more effective in detecting prostate cancer than when either test is used alone.

It is still possible, however, that some prostate cancers may be missed. This is because some cancers are too small to raise the PSA blood level or to be felt during a digital rectal examination. There is also the chance that a healthy man may be identified as possibly having prostate cancer.

If the PSA test result is higher than normal or the digital rectal examination is suspicious, biopsy of the prostate is required before your doctor can make a definite diagnosis of cancer. Biopsy is the removal of a small amount of prostate tissue. This tissue is examined under a microscope to see if cancer is present.

When Should A Man Have The PSA Blood Test?

It is useful for men 50 years of age and older to have a PSA test and DRE periodically to help the doctor detect the possible presence of prostate cancer. These tests can be done during a yearly physical examination.

Men in higher risk groups, such as African Americans and those with blood relatives who have had prostate cancer, should consult with their doctor for advice on more frequent testing.

What Do The Hybritech® PSA Test Results Mean?

A result of 0 – 4 ng/mL is generally considered normal. However, many men with a PSA level greater than 4 ng/mL do not have prostate cancer. Likewise, a PSA value under 4 ng/mL does not rule out the possibility of cancer. If the result of the Hybritech® PSA test is higher than 4 ng/mL, other medical procedures, including the additional free PSA blood test, biopsy, or ultrasound, are required before your doctor can determine whether you have prostate cancer.

Your doctor will interpret the results of the PSA test and rectal examination to determine whether additional testing is required.

What Are The Chances Of Having Prostate Cancer?

Prostate cancer is the most common cancer found in men in the United States. It occurs in about 1 out of 10 men during their lifetime. Prostate cancer is more common in older men. It is more likely that a man with prostate cancer will die from some other cause than from the prostate cancer itself. It is, however, the second leading cause of cancer death in American men.

Remember that a normal PSA blood test and normal DRE do not rule out the possibility of having prostate cancer. And about 1 out of 2 men with a positive PSA test and a suspicious DRE do not have prostate cancer.

What Other Test(s) May Be Needed If The PSA Level Is Higher Than Normal?

- **The Hybritech free PSA blood test**

If your PSA level is above normal, but your DRE appears normal, your physician may suggest an additional test, called the free PSA test. This may require that an additional blood sample be taken. The results of this test are used with the results of the total PSA test, to determine how much of each of the different forms of PSA are in your blood. This is called the percent free PSA (or the percentage of free PSA in your blood). Your percent free PSA is the result of dividing the free

PSA result by the total PSA result, and multiplying by 100 (free PSA/total PSA x 100). It is also sometimes referred to as the “free PSA ratio.”

Total PSA, as measured by your first PSA test, actually measures both the bound form of PSA and the free form of PSA. Reports have shown that measuring the different forms of PSA can help the physician in distinguishing prostate cancer from benign prostatic conditions. In patients with moderately elevated PSA concentrations, men with prostate cancer tend to have lower percent free PSA values than men with benign disease.

The difference in the free PSA ratio can help you and your physician to determine the most appropriate course of action. Additional information is available to the physician in the Hybritech free PSA Assay – Information for Physicians brochure.

The table below shows that a higher percent free PSA result indicates a lower risk of cancer.

Table 3. Probability of Prostate Cancer Based on PSA and Percent Free PSA Results (for Men with Nonsuspicious DRE Results, Regardless of Patient Age)

PSA	Probability of Cancer	Percent free PSA	Probability of Cancer
0-2 ng/mL	1%	0-10%	56%
2-4 ng/mL	15%	10-15%	28%
4-10 ng/mL	25%	15-20%	20%
>10 ng/mL	>50%	20-25%	16%
		>25%	8%

- **Other tests and procedures**

If your PSA level is above normal, and/or if your rectal examination reveals an area of hardness in the prostate, your doctor may recommend that you have an ultrasound scan of the prostate and a biopsy. No evidence to date suggests that ultrasound scanning causes bodily harm.

In an ultrasound scan, sound waves are sent into the body and are used to take “pictures” of the prostate gland. These “pictures” help your doctor to locate suspicious areas of the prostate. These areas may contain cancer and should be biopsied.

Biopsy involves the removal of a small amount of tissue from the prostate. Examination of the biopsied tissue under a microscope is the only way to be certain of the presence of prostate cancer.

What Other Conditions May Cause A High PSA Level?

There are several conditions other than prostate cancer that can cause the level of PSA in the bloodstream to rise. The most common condition leading to a higher than normal PSA level is enlargement of the prostate gland, called benign prostatic hyperplasia (BPH).

BPH is very common in men over 50 years of age, and may cause difficulty with urination. About 4 out of 5 men eventually develop enlarged prostates. BPH is not cancer, nor is there evidence that it leads to cancer.

Infection or inflammation of the prostate gland is called prostatitis. This condition may also cause higher than normal PSA levels.

Counseling

You should ask your doctor about these tests, how much they cost, where they are given, and other questions that you may have. Your doctor can provide you with more information.

Precautions

These blood tests (PSA and free PSA) cannot tell you absolutely if you have prostate cancer or not. In addition, there are many PSA tests available from manufacturers other than Hybritech. The amount of free PSA and total PSA in a blood sample measured with tests from manufacturers' other than Hybritech cannot be used interchangeably with Hybritech tests as they may not provide the same results.



*This brochure about the Hybritech tests
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*To order additional copies, or to obtain additional
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for your physician is also available.*



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