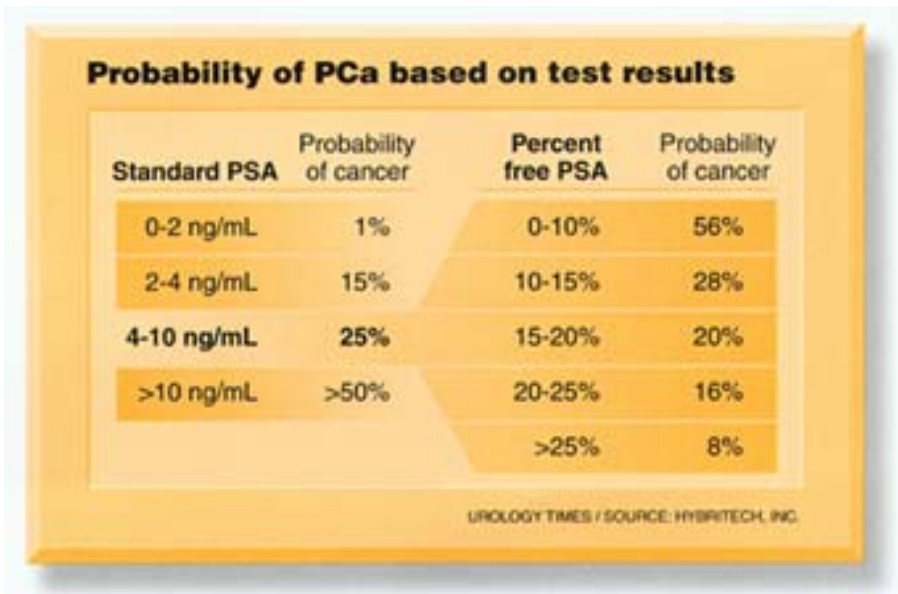


JAMA Article Says New Blood Test Enhances Accuracy of Prostate Cancer Screening

CHICAGO – A new blood test eliminates many unnecessary biopsies for prostate cancer, according to an article in the May 20 1998 issue of The Journal of the American Medical Association.



Above: Chart Depiction of Prostate Cancer Probability based on PSA and free PSA test results

The new test for "free" prostate-specific antigen (PSA) will reduce health care costs and eliminate many of the false alarms that have characterized previous PSA testing, said William J. Catalona, M.D., lead author and head of the Division of Urologic Surgery at Washington University School of Medicine, in St. Louis.

Use of the new assay is expected to resolve a lingering controversy over PSA testing. Higher PSA can indicate cancer, but may also be due to benign conditions. The JAMA article concluded that when PSA levels are moderately elevated, the Hybritech Free PSA test helps physicians more precisely determine the likely cause. The study addressed in the article found an association between a high percentage of free PSA and a low risk of cancer.

"The biggest criticism of earlier PSA tests has been that they were not specific enough," Dr. Catalona said. "Previously, many suspicious readings had nothing to do with cancer, which meant too many cancer-free men had to undergo uncomfortable and expensive biopsies."

The JAMA article details a large, prospective, multi-center study conducted at seven U.S. medical centers, involving 773 men between ages 50 and 75, with total PSA values between 4 and 10 ng/mL and digital rectal exams that were non-suspicious for cancer – men in the so-called "diagnostic gray zone."

Measuring the percentage of free PSA for men in that group can eliminate 20 percent of biopsies and detect 95 percent of cancers, the JAMA article said. The 5 percent of prostate cancers the test misses are "the less aggressive ones in older men, and they can be caught with follow-up PSA tests," said Dr. Catalona.

Dr. Catalona estimated the average total cost of a prostate biopsy to be \$1,200. The anticipated average cost of having both the total and free PSA tests is

For more information on prostate cancer, also check out these websites:

[National Cancer Institute](#)
[American Cancer Society](#)
[American Institute for Cancer Research](#)
[American Medical Association](#)
[CaP CURE](#)
[U. of Michigan Prostate Cancer Home Page](#)

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\$130. Both tests are required to determine the percentage of free PSA. There were an estimated 600,000 prostate biopsies performed in the United States in 1997.

The article also outlines two other important findings. First, the study found that among men with moderately elevated PSA levels, an individual's percentage of free PSA can be used by his physician to determine that man's cancer risk.

"You can give patients individual risk assessments of the likelihood that a biopsy would reveal cancer," said Dr. Catalona. "The tests provide patients and physicians with the power to make more informed decisions about care."

Second, the study indicated that the new free PSA test may be useful in determining the most appropriate therapy for prostate cancer patients. Among those patients who had cancer, higher free PSA values were associated with less widespread and less aggressive cancers.

PSA exists in several forms in blood, with some forms bound to protein and others unbound ("free"). As with cholesterol testing, scientists have found it useful to measure these various forms for better risk predictions. The free PSA test is used with the standard, total PSA test to determine the percentage of free PSA.

The free PSA test is used as a follow-up test for men who have moderately elevated levels of total PSA (4 to 10 ng/mL). These men have a 25 percent risk of having prostate cancer, compared to a 4 percent risk for the general population of men over 50. But 75 percent of men with these moderately elevated levels are found not to have cancer when biopsied. The new test for free PSA better identifies these men so they do not have to undergo an unnecessary biopsy.

The test used in the JAMA study is the Hybritech Free PSA test, developed by Beckman Coulter, Inc., of Fullerton, Calif. The study on which the JAMA article was based was funded by a research grant from Beckman Coulter. The FDA in March approved the Hybritech Free PSA test for clinical use in prostate cancer detection. Beckman Coulter also developed the first FDA-approved test for total PSA, which has been widely used for prostate cancer screening since the early 1990's.

Other centers that participated in the clinical trial of the free PSA test were The Johns Hopkins Hospital, in Baltimore; Baylor College of Medicine, in Houston; the Harvard Program in Urology at Brigham & Women's Hospital, in Boston; Loyola University, in Chicago; University of California-Los Angeles; and the University of Washington, in Seattle.

Prostate cancer is the most commonly diagnosed cancer in American men. An estimated 184,500 American men will learn they have prostate cancer this year, and the disease will kill more than 39,000 American men in 1998, according to the American Cancer Society.

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If you want more information on the Hybritech free PSA test can call toll-free to (888) 880-0518.