U.S. Food and Drug Administration - Center for Devices and Radiological Health

Medical Device Approvals

Bayer Immuno 1™ Complexed Prostate-Specific Antigen (PSA) Assay-P990055

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.
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Product Name: Bayer Immuno 1™ Complexed Prostate-Specific Antigen (PSA) Assay
Manufacturer: Bayer Corporation, Business Group Diagnostics
Address: 511 Benedict Avenue, Tarrytown, NY 10591-5097
Approval Date: September 8, 2000
Approval Letter: http://www.fda.gov/cdrh/pdf/p990055a.pdf

What is it? A new laboratory test, used in conjunction with a digital rectal examination (DRE), to measure complexed prostate-specific antigen (cPSA) in the blood of men 50 years or older as an aid in detecting prostate cancer. Other laboratory tests for prostate cancer measure total PSA. PSA is an enzyme produced by cells of the prostate gland. Concentrations of complexed PSA are higher in men with prostate cancer than men without cancer.

How does it work? A sample of blood is tested in a laboratory (using the Bayer Immuno 1™ system) to test for elevated concentrations of cPSA. Concentrations of cPSA above 3.6 ng/mL (nanograms per milliliter) are considered abnormally high, which indicates the possibility of prostate cancer.

When is it used? This blood test may be prescribed by physicians for men 50 years and older as an aid in detecting prostate cancer. The test is used in addition to a digital rectal examination (DRE).

What will it accomplish? This test helps to detect prostate cancer. The presence of the cancer is confirmed by biopsy (surgical removal and examination of tissue). A study evaluated the use of the Bayer cPSA assay in conjunction with digital rectal examination (DRE) in 3268 men aged 50 years or older at six locations in the U.S. The study showed that cPSA in combination with DRE detects significantly more cancer cases than DRE alone. The study also showed that the cPSA test and the total PSA test are comparable in their ability to detect prostate cancer when they are used in combination with DRE.

What risks are associated with its use? Because elevated levels of total PSA may occur in benign (non-cancerous) prostate diseases, an elevated level of cPSA does not necessarily indicate the presence of prostate cancer. This means that if a man with benign prostate disease shows a high level of cPSA (or total PSA with the other test), he could be subjected to an unnecessary biopsy. Conversely, a low level of serum cPSA does not necessarily indicate the absence of prostate cancer. This means that if a man with prostate cancer shows a low level of cPSA (or total PSA with the other test), he might not receive a needed biopsy. Because of these drawbacks, the diagnosis of prostate cancer should not depend solely on this test.

Additional information: Summary of Safety and Effectiveness and labeling is available at: http://www.fda.gov/cdrh/pdf/p990055.html

(Updated 5/18/2001)