Diagnostic Products Corporation's Total Prostate Specific Antgen (PSA) Assays on the Immulite and Immulite 2000 Analyzers - P930027/S4

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.

Product Name:	Total Prostate-Specific Antigen (PSA) Assays - Immulite PSA and Immulite 3rd Generation PSA on the Immulite Analyzer and Immulite 2000 PSA, Immulite 2000 3rd Generation PSA on the Immulite 2000 Analyzer
Manufacturer:	Diagnostic Products Corporation
Address:	5700 West 96th Street, Los Angeles, California 90045
Approval Date:	June 19, 2001
Approval Letter:	http://www.fda.gov/cdrh/pdf/p930027s004a.pdf

What is it? A laboratory test that measures total prostate-specific antigen (PSA) in human blood. PSA is an enzyme produced by cells of the prostate gland. Healthy men have low concentrations of PSA in their blood, whereas men with certain prostate conditions, including prostate cancer and benign prostate enlargement, have higher concentrations. This test is used to detect prostate cancer in men aged 50 years and older, along with digital rectal examination (DRE), an examination of the size and texture of the prostate. Several total PSA tests are available.

How does it work? A blood sample is tested by a professional clinical laboratory for elevated amounts of PSA. The presence of amounts above 4.0 ng/mL (nanograms per milliliter) indicates an abnormally high concentration of PSA, and the possibility of prostate cancer. However, a prostate biopsy (surgical removal and microscopic examination of tissue) is required to confirm the diagnosis 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 DRE.

What will it accomplish? This test helps detect prostate cancer. A study of 3,810 blood samples from men aged 50 or older showed that the combination of the PSA test and DRE detected significantly more cancer cases than DRE alone.

What are the risks associated with its use? Because elevated levels of total PSA may occur in benign (non-cancerous) prostate diseases, an elevated level of PSA does not necessarily indicate the presence of prostate cancer. This means that if a man with benign prostate disease shows a high level of PSA, he could be subjected to an unnecessary biopsy. Conversely, a low level of PSA does not necessarily indicate the absence of prostate cancer. This means that if a man with prostate cancer shows a low level of PSA 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: The SSED and Labeling will be available at: http://www.fda.gov/cdrh/pdf/p930027s004.html

Other:

- **Tuesday, March 25, 1997, National Institutes of Health, NCI New Release on Prostate Cancer at: http://www.hhs.gov/news/press/1997pres/970325b.html
- **CDC general information at: http://www.cdc.gov/cancer/prostate/prostate.htm
- **HHS Topics -- Men's Health at: http://www.dhhs.gov/topics/men.html
- **healthfinder® - your guide to reliable health information at: http://www.healthfinder.gov/HTMLGen/TxtSrch.cfm?NewText=prostate&ShowPg=0
- **http://www.aoa.dhhs.gov/aoa/pages/agepages/prostate.html

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