Roche Elecsys Total Prostate-Specific Antigen (PSA) Assay on the 1010 and 2010

Revised 2/28/2001

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:	Roche Elecsys Total Prostate-Specific Antigen (PSA) Assay on the 1010 and 2010 immunoassay analyzers
Manufacturer:	Roche Diagnostics Corporation
Address:	9115 Hague Road, Indianapolis, IN 46250
Approval Date:	November 22, 2000
Approval Letter:	http://www.fda.gov/cdrh/pdf/p990056a.pdf

What is it? An in vitro diagnostic laboratory test that measures total prostate-specific antigen (PSA) in human serum, the straw colored fluid portion of the blood. PSA is an enzyme produced by cells in the prostate gland. Healthy men have low concentrations of PSA in their serum. This test, when used with digital rectal examination (DRE), an examination of the size and texture of the prostate, is useful in the detection of prostate cancer in men aged 50 years and older. This test also aids in the management of cancer patients by measuring total PSA at regular intervals. Several total PSA tests are available.

How does it work? A serum sample is tested by a professional clinical laboratory for elevated amounts of PSA. The presence of amounts above 4.0 ng/mL indicates elevated levels of PSA, and the possibility of prostate cancer. However, a prostate biopsy (surgical removal of tissue) is required to confirm the diagnosis of prostate cancer.

When is it used? During a physical examination of men aged 50 years or older, a digital rectal exam (DRE) is performed. This test may be prescribed by physicians at this time, to help in the diagnosis of prostate cancer, or to aid in the management of cancer patients.

What will it accomplish? Aid the physician and patient in the detection of prostate cancer. Confirmation of prostate cancer is determined by biopsy. A study evaluated the use of the Roche Elecsys 1010 and 2010 PSA assays when used with digital rectal examination (DRE) in 1121 men aged 50 years or older at 36 community urological clinical practice or university related practice sites throughout the U.S. The study showed that total PSA in combination with DRE detects significantly more cancer cases than DRE alone.

What risks are associated with its use? A PSA test result should not be used as the only tool to assess prostatic diseases. Because elevated levels of total PSA may occur in benign prostatic diseases, an elevated PSA level may not necessarily indicate the presence of prostate cancer. The presence of elevated

PSA may subject men to unnecessary biopsy. A low PSA level does not necessarily indicate the absence of prostate cancer and may prevent a necessary biopsy. Therefore, assessment of patient status should not be based exclusively on a PSA test.

Additional information: Summary of Safety and Effectiveness is available at: http://www.fda.gov/cdrh/pdf/p990056.html

Other: Roche Elecsys free Prostte-Specific Antigen (fPSA) Assay on the Elecsys 1010 and 2010 immunoassay analyzers: P000027

FDA Oncology Tools: http://www.fda.gov/cder/cancer/