Roche Elecsys free Prostate-Specific Antigen (fPSA) Assay on the Elecsys 1010 and 2010 immunoassay analyzers

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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 free Prostate-Specific Antigen (fPSA) Assay on the Elecsys 1010 and 2010 immunoassay analyzers
Manufacturer:	Roche Diagnostics Corporation
Address:	9115 Hague Road, Indianapolis, IN 46250
Approval Date:	December 12, 2000
Approval Letter:	http://www.fda.gov/cdrh/pdf/p000027a.pdf

What is it? An in vitro diagnostic laboratory test to specifically measure free prostate-specific antigen (fPSA) in human serum, the straw colored fluid portion of blood. PSA is an enzyme produced by cells in the prostate gland. Healthy men have low concentrations of PSA in their serum. A small proportion of total PSA is unbound (free). Free and bound PSA make up total PSA. A ratio of free to total PSA (%fPSA) is useful in the differentiation of prostate cancer from benign disease. These tests should be accompanied by a digital rectal examination (DRE), an examination of the size and texture of the prostate. The free PSA test should be used when the DRE examination is not suspicious for cancer and the total PSA value is in the range 4 ng/ml to 10 ng/ml.

How does it work? A serum sample is tested by a professional clinical laboratory for a concentration of fPSA. Lowered ratios of free to total PSA (usually less than 0.25) indicate a positive test 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 the same time or after a total PSA test.

What will it accomplish? This test aids in differentiating prostate cancer from benign conditions and deciding on further testing procedures. Confirmation of prostate cancer is determined by biopsy. Clinical studies evaluated 1602 men aged 50 years and older with no history of a prostate cancer evaluation or treatment for benign prostatic disease in 39 community clinical practices or university related practices throughout the United States. These men had been referred to a urologist for determination of prostate cancer. Biopsied patients with total PSA between 4 and 10 ng/mL and a DRE result not suspicious for cancer were identified and selected. The studies indicate that the probability of finding prostate cancer on needle biopsy increases with progressively lower ratios of %fPSA.

What risks are associated with its use? Because low ratios of %fPSA may occur in benign prostatic

diseases, a low ratio may not necessarily indicate the presence of prostate cancer. The presence of low %fPSA may subject men to unnecessary biopsy. A high ratio of %fPSA 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 free or total PSA test result.

Additional information: Summary of Safety and Effectiveness is available at: http://www.fda.gov/cdrh/pdf/p000027.html

Other: Roche Elecsys total Prostate-Specific Antigen (PSA) Assay on the 1010 and 2010 immunoassay analyzers: P990056

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