Dimension RxL PSA Flex Reagent Cartridge - P000021

Product Name: Dimension RxL Flex PSA Reagent Cartridge (a Prostate-Specific Antigen or PSA assay)
Manufacturer: Dade-Behring, Inc
Address: P.O. Box 6101, Newark, Delaware 19714
Approval Date: July 5, 2001
Approval Letter: http://www.fda.gov/cdrh/pdf/p000021a.pdf

What is it? An *in vitro* diagnostic 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. 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 699 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 risks are 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:

- Summary of Safety and Effectiveness and labeling will be available at: http://www.fda.gov/cdrh/pdf/p000021.html

(Updated 7/23/01)