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CLL FEATURE

Ultrasensitive Test for PSA Developed

The presence of prostate specific antigen (PSA) in prostatic tissue, seminal plasma, and serum has been shown to be a valuable marker for cancer management. In 1991, PSA was recommended as a first-line screening test for prostate cancer (see *Clinical Lab Letter*™, Special Supplement No. 22, February 15, 1995). Although PSA testing enables clinicians to identify previously undiagnosed cancers, the test is prone to both false-negative and false-positive results. Furthermore, nearly 20% of prostate cancers develop in an area that can be felt on rectal examination, before the PSA blood levels become elevated. Experts suggest that recurrent or metastatic cancer following radical prostatectomy may be indicated by elevated PSA levels. Some doubt remains, however, regarding the efficacy of postoperative PSA monitoring. Although commercially available tests can detect approximately 0.1 µg/L of PSA in serum, in most postoperative patients PSA levels decrease significantly below this value, particularly when

PSA TEST
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limit of about 0.1 µg/L," **Eleftherios Diamandis**, Ph.D., head of clinical biochemistry at Mt. Sinai's *Department of Pathology and Laboratory Medicine*, told this newsletter. "The ultrasensitive assay has a sensitivity of 0.01 µg/L which is 10 times more sensitive than standard screening PSA assays." The researchers claimed that they were able to "detect relapse by an average of 14 to 29 months earlier" than with conventional assays. In addition, the PSA changes were useful for calculating tumor-doubling time, an indicator of the proliferative potential of a tumor, they stated.

"The ultrasensitive assay can detect smaller amounts of PSA in serum much earlier than conventional PSA assays," Diamandis claimed. "At the same time, the doubling time can be determined." The ultrasensitive PSA test enables physicians to make informed decisions about when, and how aggressively, to treat the tumor by providing the clinician with a method for detecting relapse and calculating tumor-doubling rates as much as two years earlier than conventional PSA tests.

"The ultrasensitive assay can detect smaller amounts of PSA in serum much earlier than conventional PSA assays." — Diamandis

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The scientists also suggested that the ultrasensitive test can be used to monitor patients receiving hormonal or radiation therapy following radical prostatectomy. They explained that, by accurately monitoring PSA in the range of 0.001-0.02 µg/L, it may be possible to detect relapse earlier. Since small tumors respond better than large tumors, and require lower doses of adjuvant therapy, the information provided by ultrasensitive assays could potentially improve patient morbidity and mortality following radical prostatectomy.

Because present adjuvant therapy is not very effective for treating recurrent prostate cancer, the assay's full capabilities cannot be assessed until more powerful chemotherapeutic regimens are developed, the researchers emphasized. A third-generation assay, presently under development, is expected to have additional applications for detecting PSA in women's sera for breast cancer diagnosis and monitoring. Index: Prostate specific antigen, cancer, increased detection limits; Prostate cancer, ultrasensitive PSA assay, long-term monitoring. CLL