



November 2009; 23 : 14-16



Prostate cancer biomarkers

Discovery and validation of new prostate cancer biomarkers is always a subject of considerable interest. In the informative report by William Check, PhD, in the June 2009 issue, a few novel candidate prostate cancer biomarkers are described ("New prostate markers waiting in the wings," page 1). I would like to comment on the prostate cancer biomarker EPCA-2 discovered by Robert Getzenberg, PhD, and his colleagues. Their original paper was published in *Urology* (2007;69:714–720). Close examination of this paper reveals methodological and interpretative shortcomings, which were described in my letter to the editor of *Urology* soon after the paper was published. The editor, Alan Partin, MD, who was a co-author of this paper, withheld my letter for many months and, after repeated requests for a decision, informed me that he will publish my letter with a response from the authors. To date, he has not published my letter or a response. I then chose to publish a "Point" in *Clinical Biochemistry on EPCA-2* (2007;40:1437–1439). Dr. Getzenberg's group was invited to write a "Counter-point" but declined.

Dr. Getzenberg continues to advocate that EPCA-2 is a promising biomarker for prostate cancer. But how would the reader know if this test is really effective, as described in your report?

Highly promising biomarkers for cancer can now be validated effectively, and in a blinded fashion, through the Early Detection Research Network, or EDRN, of the [National Cancer Institute](#). This organization is keen to validate promising cancer biomarkers, like EPCA-2, and provides all the necessary resources for such validation, including high-quality samples, blinded testing, and expert data interpretation. In fact, recently, a validation study of many candidate prostate cancer biomarkers has been conducted by the EDRN under the leadership of Daniel W. Chan, PhD (also from Johns Hopkins University and a co-author of Dr. Getzenberg's paper), but EPCA-2 was not included, giving the impression that Dr. Getzenberg wishes to avoid a blinded and independent validation of his prostate cancer biomarker.

The scientific community needs better ways to establish if certain technologies that promise to revolutionize the practice of medicine really work. In therapeutics we have randomized controlled trials. For diagnostics, on many occasions, investigators appear to be more interested in getting publicity in newspapers and other informative publications such as CAP TODAY and less keen to subject their discoveries to rigorous validation by independent bodies to find out their actual performance. Others recently questioned the effectiveness of EPCA-2

I conclude that EPCA-2 needs independent validation before it is considered a prostate cancer biomarker.

*Eleftherios P. Diamandis, MD, PhD
Head of Clinical Biochemistry
Mount Sinai Hospital and University Health Network
Professor and Head
Division of Clinical Biochemistry
Department of Laboratory Medicine and Pathobiology
University of Toronto*