



## TECHNOLOGY

# Method and Assay for Early Diagnosis of Prostate Cancer

## OVERVIEW

For well over 20 years, digital rectal examination (DRE) combined with the measurement of prostate specific antigens (PSA) have remained the most recommended screening tests for the detection of prostate cancer for men over 40. However, both exams remain highly unreliable due to the high prevalence of false positive and negative results. To improve the screening of potential prostate cancer, UMB researchers have developed a non-invasive method to detect and evaluate the general state of prostate cancer progression through the quantification of changes that occur in the genetic material of two biomarkers (galectin isoforms and Glutathione S-transferase P (GSTP1)), both of which have a significant correlation with poor patient prognosis in prostate cancer patients. Epigenetic alterations including hypermethylation of gene promoters are believed to be the early events in cancer progression and it is these methylated genes that can serve as indicators to detect cancer from clinical specimens. This invention relates to a method for determining and comparing the level of modification of genetic material through methylation between normal and prostate cancer samples taken from tissue biopsies, serum and urine. An accurate means of early prostate cancer testing is much needed as approximately 90% of patients with advanced prostate cancer develop osseous metastases making eradication difficult and reducing the mean survival time to less than one year. This invention provides a reliable means in which prostate cancer can be detected during the early stages when treatment is the most effective and chances of survival are the highest.

## APPLICATIONS

For men with elevated PSA levels, only one in six prostatic biopsies will detect the presence of prostate cancer. This culminates into 1.3 to 1.6 million men biopsied to detect approximately 200,000 cases of prostate cancers. Prostatic biopsies additionally carry the significant risk of impotency, incontinence, and even death, missing 10% to 30% of prostate cancers. Due to the controversial nature of PSA testing, as of May 2012, PSA screening received a Grade D from the U.S. Preventative Service Task Force (USPSTF) which recommends against the service due to moderate to high certainty that the service has no net benefit or that the harms outweigh the benefits. However, no other prostate cancer screening test is currently available to provide an accurate means of early detection, leaving a multi-million dollar market open for the next means of early prostate cancer detection. This invention provides a cost-effective, minimally invasive, and accurate method to screen men for prostate cancer that is improved over current PSA testing method that remains ineffective and with limited improvements on survival outcome.

## ADVANTAGES

- Simple and non-invasive test to accurately detect prostate cancer and the state of advancement.
- Cost-effective method that can be applied as a recommended preventative test for all men.
- Improved detection of prostate cancer when combined with other genes whose promoter methylation is specific to prostate cancer e.g GSTP1.

## STAGE OF DEVELOPMENT

Accurate measurements have been confirmed in studies conducted in normal, BPH, Stage I, II, III and IV cancer prostate tissues.

(MB- As of 6/15/2017)

## R&D REQUIRED

Further validation required with incorporation into a kit.

## LICENSING POTENTIAL

UMB seeks to develop and commercialize by an exclusive or non-exclusive license agreement and/or sponsored research with a company active in the area.

## CONTACT INFO

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## Additional Information

### INSTITUTION

University of Maryland, Baltimore

### PATENT STATUS

-U.S. Patent 7,632,634 B2, issued 12/15/2009 -CIP Patent 8,268,549 issued 09/18/2012

### LICENSE STATUS

Available for non-exclusive license

### CATEGORIES

- Diagnostics

### INVESTIGATOR(S)

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### ATTACHMENTS

-  [Download HA-2010-082 -final.pdf](#)

### EXTERNAL RESOURCES

- [Promoter Methylation in Prostate Cancer and its Application for the Early Detection of Prostate Cancer...](#)
- [Evidence of heavy methylation in the galectin 3 promoter in early stages of prostate adenocarcinoma...](#)
- [Differential expression of galectins in normal, benign and malignant prostate epithelial cells...](#)

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