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Method and Assay for Early Diagnosis of Prostate Cancer

Summary

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 by quantifying methylation levels of the promoter region of the galectin (gal) isoform, gal3. Galectins, a family of β-galactoside-binding proteins, are involved in growth development as well as cancer progression and metastasis.

Key Investigator
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Field
Oncology

Technology
Diagnostic
Prostate Cancer

Status
Available for licensing
Available for sponsored research

Patent Status
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CIP Patent 8,268,549
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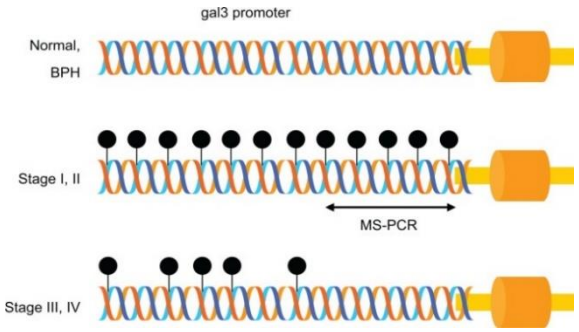
UMB Docket Reference
HA-2010-082

External Reference
Biochem Biophys Res Commun. 2007 Jun 22;358(1):241-6.
Transl Oncol. 2009 Aug 18;2(3):146-56.
Biomark Cancer. 2010 Feb

Market

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.



Schematic representation of MS-PCR. In normal and BPH (benign prostatic hyperplasia) prostate tissues, the gal3 promoter is unmethylated, whereas in stage I and II, it is methylated heavily. However, gal3 promoter is lightly methylated in stage III and IV. Stage-specific cytosine methylation of the gal3 promoter enabled the development of MS-PCR for the detection of stage I and II PCa.

Technology

This invention is a methylation-specific PCR (MS-PCR) assay for the early detection of prostate cancer. UMB inventors have shown that the gal3 gene promoter is highly methylated in stage I and II prostate cancer tissue but not in normal tissue. This method can be used with samples taken from **tissue biopsies, serum and urine**. Epigenetic alterations, including hypermethylation of gene promoters, are believed to be the early events in cancer progression and these methylated genes that can serve as biomarkers for early detection of cancer. 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 for detecting the early stages of prostate cancer when treatment is the most effective and chances of survival are the highest.

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.

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