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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

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(54) Title: AMACR CANCER MARKERS

(57) Abstract: The present invention relates to compositions and methods for cancer diagnostics, including but not limited to, cancer markers. In particular, the present invention provides gene expression profiles associated with prostate cancers. The present invention also provides novel markers useful for the diagnosis, characterization, and treatment of prostrate cancers. In particular, the present invention provides methods and compositions for the use of α-methylacyl-CoA racemase (AMACR) as a marker for prostrate cancer detection and prognosis.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US05/27223

A. CLASSIFICATION OF SUBJECT MATTER
IPC: **G01N 33/53**(2006.01);**G01N 33/48**(2006.01)

USPC: 435/7.1;436/63
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 435/7.1; 436/63

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	Zhou et al, Expression and Diagnostic Utility of Alpha-Methylacyl-CoA-Racemase (P504S) in Foamy Gland and Pseudohyperplastic; Am. J. Syrg. Pathol., 2003, Vol. 27, No. 6, pages	1-9
Y	Jiang et al, Expression of α-Methylacyl-CoA Racemase (P504S) in various Malignant Neoplasms and Normal Tissues: Hum. Pathol., 2003, Vol. 34, No. 8, pages 792-796.	1-9
Y	Sreekumar et al : Humoral Immune Response to α-Methylacyl-CoA Racemase and Prostate Cancer;	1-9
Y	Kuefer et al. α-Methyacyl-CoA Racemase: Expression Levels of this Novel Cacncer Biomarker Depend on Tumor ;, Am. J. Pathol., 2002, Vol. 161, No. 3, pages 841-848.	1-9
Y	Rubin et al, Quantitative Determination of Expression of the Prostate Cancer Protein α-Methylacyl CoA Racemase; Am. J. Pathol., 3 March 2004, Vol. 164, No. 3, pages 831-840.	1-9
X, P	Zielie et al. A Novel Diagnostic Test For Prostate Cancer Emerges From The Determination Of α-Methylacyl-Coenzyme A Racemase;, J. Urol., September 2004, Vol. 172, pages 1130-	1-9
Y	Fox Chase Cancer Center, publication On Line, 20 April 2000, 2 pages, at http//:www.sciencedaily.com/releases/2000/04/000406090853.htm, retrieved 10/10/2006	1-9

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
10 October 2006 (10.10.2006)	22 NOV 2006
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Marjorie Moran Telephone No. (571)272-1600

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US05/27223

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
Please See Continuation Sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of any additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 1-9

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US05/27223

C. (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	Cohly et al. Pilot-Study : A Non-Invasive Urine Test for Potential Prostate Abnormalities ; Int. J. Mol. Sci.. 2002, Vol. 3, pages 1039-1047.	1-9
Y	Rubin et al, α-Methylacyl Coenzyme A Racemase as a Tissue Biomarker for Prostate Cancer; JAMA,03 April .2002, Vol. 287. No. 13, pages 1662-1670.	1-9

BOX III. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claim(s) 1-9, drawn to a method of detecting -methylacyl-CoA racemase in urine.

Group II, claim(s) 10-14, drawn to a kit for detecting prostate cancer in a subject.

Group III, claim(s) 15-24, drawn to a method for determining risk of prostate cancer progression in a subject.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: a method of detecting α-methylacyl-CoA rasemate in urine and a method of determining risk of prostate cancer recited in claim 15 are known in the art. SeeCarter, JNCI, 96(11):813-815 (2 June, 2004); Luo. Cancer Res., 62:2220-2226 (1 April, 2002); Leav, Hum. Pathology, 34(3): 228-233 (3 March, 2003); Rubin, Am. J. Pathology, 164(3):831-840 (March 2004).

Continuation of B. FIELDS SEARCHED Item 3:

East, STN, Google, Biosis, Compuscience, Biotechno, Biotechds, Medline, Embase, WPI covering search terms: cancer, prostate cancer, marker, alpha-methylacyl-CoA, PSA, urine, antibody.