(54) Title: CIRCULATING TUMOR CELLS (CTC's): EARLY ASSESSMENT OF TIME TO PROGRESSION SURVIVAL AND RESPONSE TO THERAPY IN METASTATIC CANCER PATIENTS

(57) Abstract: A cancer test having prognostic utility in predicting time to disease progression, overall survival, and response to therapy in patients with MBC based upon the presence and number of CTCs. The Cell Spotter® System is used to enumerate CTCs in blood. The system immunomagnetically concentrates epithelial cells, fluorescently labels the cells and identifies and quantifies CTCs. The absolute number of CTCs detected in the peripheral blood tumor load is, in part, a factor in prediction of survival, time to progression, and response to therapy. The mean time to survival of patients depended upon a threshold number of 5 CTCs per 7.5 ml of blood. Detection of CTCs in metastatic cancer represents a novel prognostic factor in patients with metastatic cancers, suggests a biological role for the presence of tumor cells in the blood, and indicates that the detection of CTCs could be considered an appropriate surrogate marker for prospective therapeutic clinical trials.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
IPC: C12Q 1/00 (2006.01);G01N 33/48 (2006.01),33/53(2006.01),33/574(2006.01)
USPC: 435/4,435/7.1,435/7.23;436/64
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.: 435/4,435/7.1,435/7.23; 436/64

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)
Medline Biosis Lifesci Biotechs Scirearch Hcuplus

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
</table>

Further documents are listed in the continuation of Box C.

See patent family annex.

Date of the actual completion of the international search
07 August 2006 (07.08.2006)

Date of mailing of the international search report
02 OCT 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
Karen A. Canella
Telephone No. 703-305-0196

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