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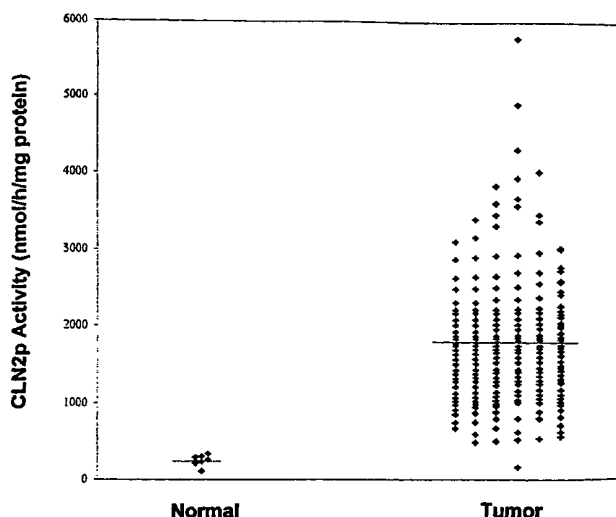
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(54) Title: A LYSOSOMAL PEPSTATIN-INSENSITIVE PROTEINASE AS A NOVEL BIOMARKER FOR DETECTING AND DIAGNOSING BREAST CANCER



(57) Abstract: The present invention describes diagnostic and prognostic assays to detect in vascular and tissue samples the presence and activity of the lysosomal pepstatin-insensitive proteinase, CLN2p, which has been newly found to be associated with breast cancer and serves as a novel biomarker for breast cancer, including primary, non-primary, or metastatic breast tumors, neoplasms and carcinomas. The activity of CLN2p was discovered to be significantly elevated when measured in breast tissue samples from patients with primary breast carcinoma, compared with CLN2p levels in normal sample controls, thereby demonstrating an approximately two- to seventeen-fold higher CLN2p activity in breast tumors. These higher levels of CLN2p activity in breast tumors were positively correlated with several known breast cancer biomarkers, such as cathepsin D, estrogen receptor and progesterone receptor. The present invention thus provides CLN2p as new biomarker for use in the detection, diagnosis and prognosis of breast cancer.



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INTERNATIONAL SEARCH REPORT

International Application No

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A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 G01N33/574 G01N33/58 G01N33/577 G01N33/543 G01N33/573
C12Q1/37

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)

IPC 7 G01N C12Q

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 practical, search terms used)

EPO-Internal, WPI Data, PAJ, CHEM ABS Data, BIOSIS, MEDLINE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 96 24065 A (ONCOGENE SCIENCE INC) 8 August 1996 (1996-08-08) the whole document ---	1,8,14, 21,25,34
A	WO 98 55872 A (AMDL INC ; CRESS MICHAEL C (US); MOORE RONALD J (US); NGO THAT T (U) 10 December 1998 (1998-12-10) the whole document ---	1,8,14, 21,25,34
P,X	JUNAID M A ET AL: "A lysosomal pepstatin-insensitive proteinase as a novel biomarker for breast carcinoma" THE INTERNATIONAL JOURNAL OF BIOLOGICAL MARKERS, vol. 15, no. 2, 2000, pages 129-134, XP008001480 the whole document -----	1-34

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Patent family members are listed in annex.

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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.

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INTERNATIONAL SEARCH REPORT

Information on patent family members

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			EP 1019727 A1	19-07-2000
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