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(54) **METHOD AND KIT FOR DISCRIMINATING BETWEEN BREAST CANCER AND BENIGN BREAST DISEASE**

(75) Inventors: **Xun Ye**, Shanghai (CN); **Fei Wu**, Shanghai (CN); **Qinghua Xu**, Hangzhou (CN); **Xia Meng**, Shanghai (CN); **Bruno Mougin**, Lyons (FR)

(73) Assignee: **BIOMERIEUX**, Marcy l'Etoile (FR)

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(58) **Field of Classification Search**
None
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

7,171,311	B2 *	1/2007	Dai et al.	702/19
7,842,467	B1 *	11/2010	Heidbrink et al.	435/7.1
2007/0015148	A1	1/2007	Orr et al.	
2007/0224201	A1	9/2007	Wu et al.	
2009/0123924	A1 *	5/2009	Krause et al.	435/6
2010/0003189	A1	1/2010	Tlsty et al.	
2010/0209928	A1 *	8/2010	Mirza et al.	435/6
2011/0217297	A1 *	9/2011	Kao et al.	424/133.1

FOREIGN PATENT DOCUMENTS

CN	101354393	A	1/2009
WO	2007067813	A2	6/2007
WO	2009039023	A2	3/2009

OTHER PUBLICATIONS

Tamimi et al., Cancer, Nov. 1, 2010, pp. 4944-4953.*
Hartmann et al., New England Journal of Medicine, Jul. 21, 2005, 353(3), pp. 229-237.*
Brenton et al., Journal of Clinical Oncology, Oct. 10, 2005, 23(29), pp. 7350-7360.*
André et al., Lancet Oncol, 2009, 10, pp. 381-390.*
GeneChip Human Genome U133 Arrays Data Sheet (Affymetrix, 2003-2007, pp. 1-8.*
Arce et al., "Molecular and Genomic Characterization of Human DLEC, a Novel Member of the C-type Lectin Receptor Gene Family Preferentially Expressed on Monocyte-Derived Dendritic Cells," Eur. J. Immunol., vol. 31, pp. 2733-2740, 2001.
Bourgon, "Diagnostic Plots for Independent Filtering," pp. 1-5, Oct. 25, 2009.
Drucker et al., "Support Vector Regression Machines," Advances in Neural Information Processing Systems, pp. 155-161, 1996.
Haram et al., "Gene Expression Profile of Mouse Prostate Tumors Reveals Dysregulations in Major Biological Processes and Identifies Potential Murine Targets for Preclinical Development of Human Prostate Cancer Therapy," The Prostate, vol. 68, pp. 1517-1530, 2008.
Qin et al., "Increased Expression of the Inflammatory Protein YK:-40 in Precancers of the Breast," Int. J. Cancer, vol. 121, pp. 1536-1542, 2007.
Roslind et al., "YKL-40 Expression in Benign and Malignant Lesions of the Breast: A Methodologic Study," Appl Immunohistochem Mol Morphol, vol. 15, No. 4, pp. 371-381, Dec. 2007.
Whitney et al., "Individuality and Variation in Gene Expression Patterns in Human Blood," PNAS, vol. 100, No. 4, pp. 1896-1901, Feb. 18, 2003.
Wisniewski et al., "Distribution of LILRA3 (ILT6/LIR4) Deletion in Psoriatic Patients and Healthy Controls," Human Immunology, vol. 64, pp. 458-461, 2003.
Yang et al., "Using Peripheral Blood mRNA Signature to Distinguish Between Breast Cancer and Benign Breast Disease in Non-Conclusive Mamaography Patients," Cancer Biology & Therapy, vol. 10, No. 12, pp. 1235-1239, Dec. 15, 2010.
Mar. 10, 2011 International Search Report issued in International Application No. PCT/CN2010/073342.
Mar. 10, 2011 Written Opinion issued in International Application No. PCT/CN2010/073342.
Wilson et al., "QC and Affymetrix Data," Paterson Institute for Cancer Research, pp. 1-14, 2009.

* cited by examiner

Primary Examiner — Juliet Switzer
(74) *Attorney, Agent, or Firm* — Oliff PLC

(57) **ABSTRACT**

A method and kit are related to discriminating between breast cancer and benign breast disease by the determination of the expression level of at least one target gene including a nucleic acid sequence selected from the nucleic acid sequences set forth in SEQ ID NOs: 1, 2 or 3, 4 and 5 or 6 to obtain an expression profile for the patient, and the comparison of the expression profile of the patient with expression profiles of target genes from patients previously clinically classified as breast cancer and expression profiles of target genes from patients previously clinically classified as benign breast disease.

13 Claims, No Drawings