(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
10 February 2005 (10.02.2005)

PCT

(10) International Publication Number
WO 2005/011474 A2

(51) International Patent Classification[7]: A61B

(21) International Application Number: PCT/US2004/024413

(22) International Filing Date: 30 July 2004 (30.07.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/491,524 1 August 2003 (01.08.2003) US
10/902,427 30 July 2004 (30.07.2004) US

(71) Applicants *(for all designated States except US)*: **CORRELOGIC SYSTEMS, INC.** [US/US]; 6701 Democracy Boulevard, Suite 300, Bethesda, MD 20817 (US). **THE UNITED STATES OF AMERICA as represented by the secretary of THE DEPARTMENT OF HEALTH AND HUMAN SERVICES** [US/US]; c/o National Institute of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **HITT, Ben, A.** [US/US]; 929 Clopper Road, #B2, Gaithersburg, MD 20878 (US). **LEVINE, Peter, A.** [US/US]; 9608 Sotweed Dr., Potomac, MD 20854 (US). **LIOTTA, Lance, A.** [US/US]; 8601 Bradley Blvd., Bethesda, MD 20817 (US). **PETRICOIN, Emanuel, F.** [US/US]; 2805 Feather Ridge Ct., Dunkirk, MD 20754 (US).

(74) Agent: **FORD, Timothy, D.**; c/o Cooley Godward, LLC, One Freedom Square, Reston Town Center, 11951 Freedom Drive, Reston, VA 20190-5656 (US).

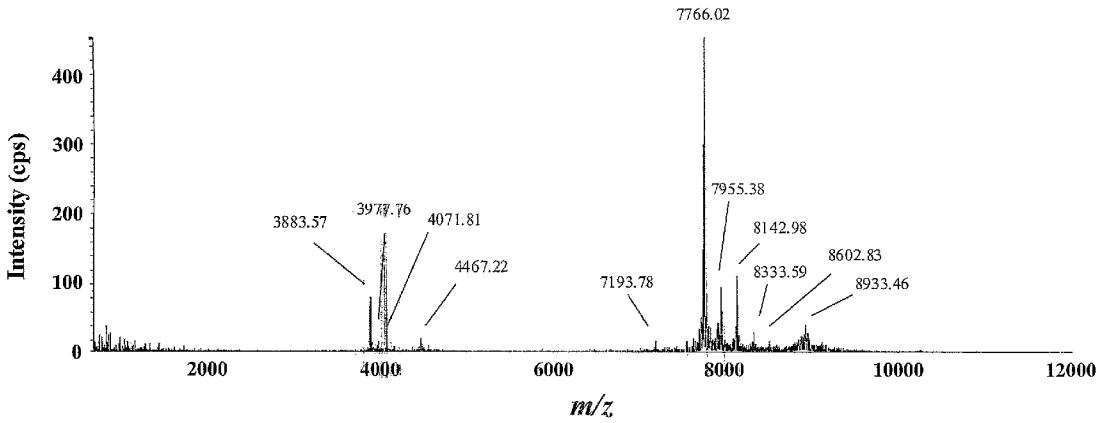
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *without international search report and to be republished upon receipt of that report*

[Continued on next page]

(54) Title: MULTIPLE HIGH-RESOLUTION SERUM PROTEOMIC FEATURES FOR OVARIAN CANCER DETECTION



(57) Abstract: A well-controlled serum study set (n = 248) from women being followed and evaluated for the presence of ovarian cancer was used to extend serum proteomic pattern analysis to a higher resolution mass spectrometer instrument platform to explore the existence of multiple distinct highly accurate diagnostic sets of features present in the same mass spectrum. Multiple highly accurate diagnostic proteomic feature sets exist within human sera mass spectra. Using high-resolution mass spectral data, at least 56 different patterns were discovered that achieve greater than 85 % sensitivity and specificity in testing and validation. Four of those feature sets exhibited 100 % sensitivity and specificity in blinded validation. The sensitivity and specificity of diagnostic models generated from high-resolution mass spectral data were superior ($P < 0.00001$) than those generated from low-resolution mass spectral data using the same input sample.

WO 2005/011474 A2

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.