

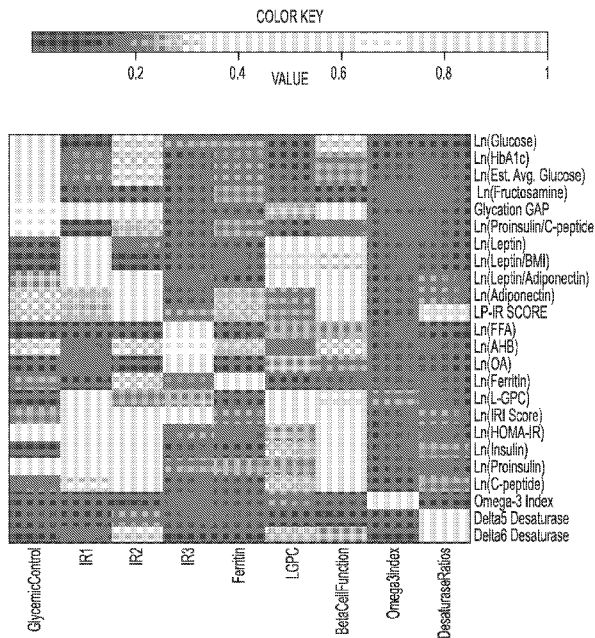


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- (71) Applicant: HEALTH DIAGNOSTIC LABORATORY, INC. [US/US]; 737 N. 5th Street, Suite 103, Richmond, VA 23219 (US).
- (72) Inventors: CAFFREY, Rebecca; 737 N. 5th Street, Suite 103, Richmond, VA 23219 (US). VARVEL, Steve; 737 N. 5th Street, Suite 103, Richmond, VA 23219 (US). POTALA, James, V.; 737 N. 5th Street, Suite 103, Richmond, VA 23219 (US). VOROS, Szilard; 21 White Pine Lane, East Setauket, NY 11733 (US).

- (74) Agent: TOWNES, Jeffrey, N.; LeClairRyan, 2318 Mill Road, Suite 1100, Alexandria, VA 22314 (US).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM,

[Continued on next page]

(54) Title: METHOD OF DETERMINING AND MANAGING TOTAL CARDIODIABETES RISK



(57) Abstract: A method for generating a report presenting a patient-specific information relevant to assessing a patient's cardiometabolic risk to guide and allow a physician or health-care provider in the choice of therapy or therapies that will be maximally effective for a specific patient, to monitor the response to the chosen therapy and reduce the patient's risk of developing cardiometabolic and/or its complications.

FIG. 8



TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))

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15 January 2015

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2013/069257

A. CLASSIFICATION OF SUBJECT MATTER
 INV. G01N33/68 G06F19/00
 ADD.

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)
 G01N

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)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2010/007526 A1 (PFUETZNER ANDREAS [DE]) 21 January 2010 (2010-01-21) whole document; in particular [0007] and claim 1, p. 31, first paragraph ----- -/--	1-34

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 but 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

17 July 2014

Date of mailing of the international search report

17/11/2014

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
 NL - 2280 HV Rijswijk
 Tel. (+31-70) 340-2040,
 Fax: (+31-70) 340-3016

Authorized officer

Lüdemann, Susanna

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2013/069257

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>T. SCHONDORF ET AL: "Increased prevalence of cardiovascular disease and risk biomarkers in patients with unknown type 2 diabetes visiting cardiology specialists: results from the DIASPORA study", DIABETES & VASCULAR DISEASE RESEARCH : OFFICIAL JOURNAL OF THE INTERNATIONAL SOCIETY OF DIABETES AND VASCULAR DISEASE, vol. 7, no. 2, 18 February 2010 (2010-02-18), pages 145-150, XP055128772, ISSN: 1479-1641, DOI: 10.1177/1479164109358241 whole document; in particular abstract and table 2</p> <p style="text-align: center;">-----</p>	1-34
A	<p>C HERDER ET AL: "Biomarkers for the Prediction of Type 2 Diabetes and Cardiovascular Disease", CLINICAL PHARMACOLOGY & THERAPEUTICS, vol. 90, no. 1, 8 June 2011 (2011-06-08), pages 52-66, XP055129444, ISSN: 0009-9236, DOI: 10.1038/clpt.2011.93 whole document, in particular table 5 and 6</p> <p style="text-align: center;">-----</p>	1-34
A,P	<p>ALESSANDRA SALDANHA DE MATTOS MATHEUS ET AL: "Impact of Diabetes on Cardiovascular Disease: An Update", INTERNATIONAL JOURNAL OF HYPERTENSION, vol. 47, no. 6, 1 January 2013 (2013-01-01), pages 1239-15, XP055129445, ISSN: 2090-0384, DOI: 10.1155/2012/485812 the whole document</p> <p style="text-align: center;">-----</p>	1-34
A,P	<p>Anonymous: "Benefits of IR2Dx Multi-marker Panels IR2Dx", 14 July 2014 (2014-07-14), XP055129646, Retrieved from the Internet: URL:http://ir2diagnostics.com/products/benefits-of-ir2dx-multi-marker-panels/ [retrieved on 2014-07-17] the whole document</p> <p style="text-align: center;">-----</p>	1-34

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/069257

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.: **1-34(partially)**
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:
see FURTHER INFORMATION sheet PCT/ISA/210

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:

see additional 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 an additional fees, this Authority did not invite payment of 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.:
1-34(partially)

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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-34(partially)

A method of assessing a patient's cardiometabolic risk based on the markers glucose (first mentioned marker of the total glycemic control panel), serum amylase (first mentioned marker of the beta cell function panel) and D-mannose (first mentioned marker of the insulin resistance panel)

2-99. claims: 1-34(partially)

Methods of assessing a patient's cardiometabolic risk based on a combination of at least one biomarker from at least three panels, combining all markers from claims 2 with claims 3-6, but also two or three or more biomarkers from each panel combined with any other two or three biomarkers from each panel according to claims 7-16 and so on.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 1-34(partially)

Present claims 1-34 relate to an extremely large number of possible methods.

In particular the following terms are unclear: " biomarker from at least three of the following panels: (1) a total glycemic control panel; (2) a beta cell function panel; (3) an insulin resistance panel; (4) an inflammation panel; and (5) a dyslipidemia panel".

Support and disclosure in the sense of Article 6 and 5 PCT is to be found however for only a very small proportion of the methods claimed, see the marker panels in the examples.

The non-compliance with the substantive provisions is to such an extent, that the search was performed taking into consideration the non-compliance in determining the extent of the search of claim 1 (PCT Guidelines 9.19 and 9.23).

The search of claim 1 was restricted to the methods according to the marker panels of invention 1 as defined in the item discussing non-unity

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guidelines C-IV, 7.2), should the problems which led to the Article 17(2) declaration be overcome.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2013/069257

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2010007526	A1	21-01-2010	
		AU 2009272369 A1	21-01-2010
		EP 2338051 A1	29-06-2011
		ES 2437610 T3	13-01-2014
		US 2010130404 A1	27-05-2010
		US 2013210718 A1	15-08-2013
		WO 2010007526 A1	21-01-2010
