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Declarations under Rule 4.17:

- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))
- of inventorship (Rule 4.17(iv))

Published:

- with international search report (Art. 21(3))

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21 October 2010

(54) Title: DNA INTEGRITY ASSAY (DIA) FOR CANCER DIAGNOSTICS, USING CONFOCAL FLUORESCENCE SPECTROSCOPY

(57) Abstract: The present invention relates, e.g., to a method for determining the size distribution of DNA molecules in a sample comprising cell-free nucleic acid, comprising labeling the DNA with a fluorescent dye in a stoichiometric manner, subjecting the DNA to molecular spectroscopy (e.g., cylindrical illumination confocal spectroscopy), analyzing suitable fluorescent burst parameters of the labeled DNA, and conducting single molecule DNA integrity analysis of the labeled DNA molecules in the sample. In one embodiment of the invention, the method is used as a diagnostic method for detecting cancer.



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A. CLASSIFICATION OF SUBJECT MATTER*C12Q 1/68(2006.01)i, G01N 33/52(2006.01)i*

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)

C12Q 1/68; G06F 19/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Korean utility models and applications for utility models

Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

eKOMPASS(KIPO internal) & Keywords: DNA integrity, cell-free nucleic acids, fluorescent spectroscopy, cylindrical illumination, single molecule spectroscopy, cancer

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	Clinical Chemistry 52:6 1062-1069 (Umetani et al.) 30 December 2006 See whole document	1-21,23-30
A	Biophysical Journal 95 2964-2975 (Liu et al.) 30 September 2008 See whole document	1-21,23-30
A	US 2007-0122823 A1 (DIANA BIANCHI et al.) 31 May 2007 See abstract, claims	1-21,23-30



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 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

12 JULY 2010 (12.07.2010)

Date of mailing of the international search report

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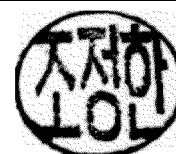
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INTERNATIONAL SEARCH REPORTInternational application No.
PCT/US2009/063262**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

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.: 22
because they relate to subject matter not required to be searched by this Authority, namely:
Claim 22 pertains a method for diagnostic test of human body whether or not having cancer, and thus relates to a subject matter which this ISA is not required to search under PCT Art. 17(2)(a)(i) and Rule 39.1(iv) of the Regulations under the PCT.
2. ☐ Claims Nos.:
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:
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:

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 fee, this Authority did not invite payment of any additional fee.
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.:

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.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2009/063262Patent document
cited in search reportPublication
datePatent family
member(s)Publication
date

US 2007-0122823 A1

31.05.2007

None