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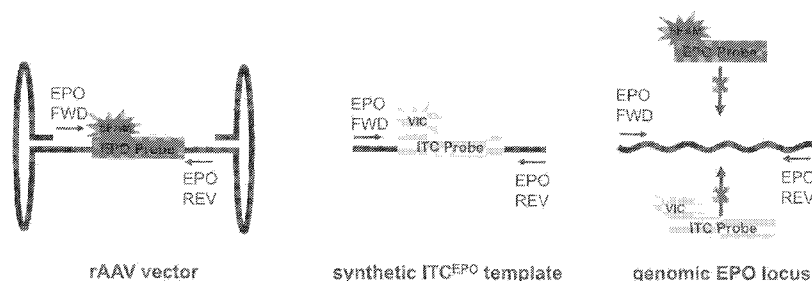
(88) **Date of publication of the international search report:**
7 March 2013

(54) Title: DETECTION METHODS FOR TARGET DNA

Figure 1A

ITC Testing for Gene Transfer Vectors

(across transgene cDNA exon-exon junction or on heterologous sequences)



(57) **Abstract:** The invention pertains to a safe, quick and reliable method of detecting the presence of a target DNA sequence in a sample. The invention also pertains to a system for detecting presence of a target DNA sequence in a biological sample. The system includes an ITC template that includes a probe binding sequence that binds to a corresponding ITC probe and a first and second flanking primer recognizing sequence that binds to a first and second primer, respectively. The system also includes an ITC probe that binds to the ITC template probe binding sequence. The ITC probe includes a first marker molecule. The system also includes a first primer that binds to the first flanking primer sequence and a second primer that binds to said second primer sequence. The system further includes a target DNA sequence probe, wherein the target DNA sequence probe comprises a second marker molecule.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/023485**A. CLASSIFICATION OF SUBJECT MATTER***C12Q 1/68(2006.01)i, C12N 15/11(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

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:Internal Threshold Control, foreign DNA detection, real-time PCR, disease diagnosis

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	LEFEVRE, J. et al., 'Real-time PCR assays using internal controls for quantitation of HPV-16 and -globin DNA in cervicovaginal lavages', Journal of Virological Methods, December 2003, vol.114, no.2, pp.135-144. See Abstract; pp.136-137.	17-23
A	STOCHER, M. et al., 'A simple approach to the generation of heterologous competitive internal controls for real-time PCR assays on the LightCycler', Journal of Clinical Virology, 2002, vol.25, pp.S47-S53. See Abstract.	17-23
A	TEMPLETON, KE. et al., 'Development and clinical evaluation of an internally controlled, single-tube multiplex real-time PCR assay for detection of Legionella pneumophila and other Legionella species', Journal of Clinical Microbiology, September 2003, vol.41, no.9, pp.4016-4021. See Page 4017.	17-23
A	DAMEN, M. et al., 'Real-Time PCR with an internal control for detection of all known human adenovirus serotypes', Journal of Clinical Microbiology, December 2008, vol.46, no.12, pp.3997-4003. See Abstract; Page 3998.	17-23

☒ 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

28 DECEMBER 2012 (28.12.2012)

Date of mailing of the international search report

02 JANUARY 2013 (02.01.2013)

Name and mailing address of the ISA/KR

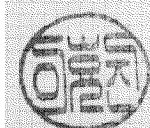
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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2012/023485

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
T	Ni, W. et al., 'Development and utility of an internal threshold control (I TC) real-time PCR assay for exogenous DNA detection' , PLoS ONE, 3 May 2012 , vol.7, issue.5, e36461, pp.1-12. See the Whole Document.	17-23

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2012/023485**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.: 1-16,24-27
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 1-16,24-27 pertain to methods for treatment of the human body by therapy, as well as diagnostic methods, and thus relate to a subject matter which this International Searching Authority is not required, under Article 17(2)(a)(i) of the PCT and Rule 39.1(iv) of the Regulations under the PCT, to search.
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/US2012/023485Patent document
cited in search reportPublication
datePatent family
member(s)Publication
date

None