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(54) Title: A GENETIC MARKER FOR DETECTION OF HUMAN PAPILLOMAVIRUS

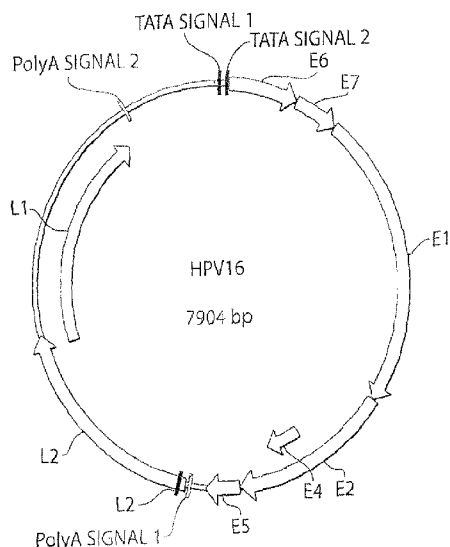


Fig. 1

(57) Abstract: The invention provides compositions and methods for the differential detection of high risk forms of HPV from a urine sample provided by a patient. Specifically, the invention provides primers and probes that specifically recognize and bind sequences within the E1 gene of HPV. Detection of high risk forms of HPV identify individuals at risk of developing or in the early stages of cervical carcinoma.

WO 2010/051261 A3



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**INTERNATIONAL SEARCH REPORT**

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<b>A. CLASSIFICATION OF SUBJECT MATTER</b> INV. C12Q1/70 ADD.		
According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b>		
Minimum documentation searched (classification system followed by classification symbols) C12Q		
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 practical, search terms used) EPO-Internal, BIOSIS, CHEM ABS Data, EMBASE, WPI Data, Sequence Search		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 97/05164 A1 (CSL LTD [AU]; UNIV QUEENSLAND [AU]; WEBB ELIZABETH ANN [AU]; MARGETTS) 13 February 1997 (1997-02-13) page 8, paragraph 4 page 15, paragraph 3 page 16, paragraph 5	1-3,6-10
X	WO 2006/066353 A1 (HUMAN GENETIC SIGNATURES PTY [AU]; MILLAR DOUGLAS SPENCER [AU]; MIKLOS) 29 June 2006 (2006-06-29) sequences 625,631,637,655,667 ----- -/--	1-3,6-10
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> 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 document 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  <p align="center"><b>8 October 2010</b></p>		Date of mailing of the international search report  <p align="center"><b>27/10/2010</b></p>
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  <p align="center"><b>Knudsen, Henrik</b></p>

## INTERNATIONAL SEARCH REPORT

 International application No  
 PCT/US2009/062114

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Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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International application No

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E	<p>WO 2010/052317 A1 (DKFZ            KREBSFORSCHUNGSZENTRUM [DE]; SCHMITT            MARKUS [DE]; GISSMANN LUTZ [ ]            14 May 2010 (2010-05-14)            sequence 23</p>	1,3,6-10
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Y A	<p>page 619, right-hand column, last paragraph</p>	22-28 17
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Y	<p>US 2002/119478 A1 (UMANSKY SAMUIL R [US] ET AL) 29 August 2002 (2002-08-29)            paragraphs [0144], [0189]; claims 22-26</p>	22-28
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## INTERNATIONAL SEARCH REPORT

International application No

PCT/US2009/062114

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DAPONTE A ET AL: "Evaluation of high-risk human papillomavirus types PCR detection in paired urine and cervical samples of women with abnormal cytology" JOURNAL OF CLINICAL VIROLOGY, ELSEVIER, AMSTERDAM, NL LNKD- DOI:10.1016/J.JCV.2006.03.009, vol. 36, no. 3, 1 July 2006 (2006-07-01), pages 189-193, XP025178621 ISSN: 1386-6532 [retrieved on 2006-07-01] page 190, right-hand column, paragraph 3	11-29
A	ANTONISHYN NICK A ET AL: "The impact of the distribution of human papillomavirus types and associated high-risk lesions in a colposcopy population for monitoring vaccine efficacy." ARCHIVES OF PATHOLOGY & LABORATORY MEDICINE JAN 2008 LNKD- PUBMED:18181674, vol. 132, no. 1, January 2008 (2008-01), pages 54-60, XP9139515 ISSN: 1543-2165 page 59, left-hand column, lines 8-16	11-29
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Y,P	* abstract	22-28

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US2009/062114

## 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.:  
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:

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.:

### 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: 1-10

Invention concerns isolated genetic marker for HPV containing a sequence encoded by one of SEQ ID NOs: 69-97 or their complementary sequence, an oligonucleotide encoded by one of SEQ ID NOs: 1-15, a composition comprising the complementary sequence of one of SEQ ID NOs: 1-15 and a composition comprising a sequence at least 70% homologous to the E1 gene.

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2. claims: 11-29

Method of diagnosing HPV infection by detecting a sequence of the E1 gene in a urine sample from a patient

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# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2009/062114

Patent document cited in search report	Publication date	Patent family member(s)	Publication date	
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