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Published:

— *with international search report (Art. 21(3))*

— *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))*

(88) Date of publication of the international search report:
7 June 2012

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(54) Title: COMPOSITIONS AND ASSAYS TO DETECT SWINE H1N1 INFLUENZA A VIRUS, SEASONAL H1 INFLUENZA A VIRUS AND SEASONAL H3 INFLUENZA A VIRUS NUCLEIC ACIDS

(57) Abstract: Methods for detecting the presence or absence of the swine H1N1 influenza A virus, seasonal H1 influenza A virus and/or seasonal H3 influenza A virus nucleic acids in biological samples are disclosed. Compositions that are target-specific nucleic acid sequences and kits comprising target-specific nucleic acid oligomers for amplifying in vitro the swine H1N1 influenza A virus, seasonal H1 influenza A virus and/or seasonal H3 influenza A virus nucleic acid and detecting amplified nucleic acid sequences are disclosed.

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A. CLASSIFICATION OF SUBJECT MATTER
INV. C12Q1/70
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)
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, Sequence Search, EMBASE, FSTA, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	CHIUAN-CHIAN CHIOU ET AL: "Detection of pandemic (H1N1) 2009 influenza virus by allele discrimination", CLINICA CHIMICA ACTA, vol. 411, no. 15-16, 9 April 2010 (2010-04-09), pages 1080-1083, XP55013404, ISSN: 0009-8981, DOI: 10.1016/j.cca.2010.04.002 abstract table 1 page 1081, paragraph bridging - page 1082 ----- -/--	1-11, 22-28, 35-62, 68-70, 76-82

[X] Further documents are listed in the continuation of Box C.

[X] 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	Date of mailing of the international search report
10 April 2012	20/04/2012

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Ripaud, Leslie

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Form PCT/ISA/210 (second sheet) (April 2005)

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Box No. I Nucleotide and/or amino acid sequence(s) (Continuation of item 1.c of the first sheet)

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, the international search was carried out on the basis of:

   a. (means)

   [ ] on paper

   [X] in electronic form

   b. (time)

   [ ] in the international application as filed

   [ ] together with the international application in electronic form

   [X] subsequently to this Authority for the purpose of search

2. [X] In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

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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: 1-11, 24-28, 54-58(completely); 22, 23, 35-53, 59-62, 68-70, 76-82(partially)

   concerns a composition comprising two primers and optionally a detection probe, wherein said primers and probe are specific for the NP or the H1 nucleic acid of the swine H1N1 influenza A virus, a kit comprising at least said primers, and a method for detecting an H1N1 influenza A virus using at least said primers. In particular, said primers and probes are selected among SEQ ID N° 1-62.

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2. claims: 12-16, 29-31, 63-67(completely); 22, 23, 35-53, 59-62, 68-70, 76-82(partially)

   concerns a composition comprising two primers and optionally a detection probe, wherein said primers and probe are specific for the H1 nucleic acid of the seasonal H1 influenza A virus, a kit comprising at least said primers, and a method for detecting a seasonal H1 influenza A virus using at least said primers. In particular, said primers and probes are selected among SEQ ID N° 63-76.

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3. claims: 17-21, 32-34, 71-75(completely); 22, 23, 35-53, 59-62, 68-70, 76-82(partially)

   concerns a composition comprising two primers and optionally a detection probe, wherein said primers and probe are specific for the H3 nucleic acid of the seasonal H3 influenza A virus, a kit comprising at least said primers, and a method for detecting a seasonal H3 influenza A virus using at least said primers. In particular, said primers and probes are selected among SEQ ID N° 77-102.

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2009/151407 A2 (VEREDUS LAB PTE LTD [SG]; ONG KIAN LEONG [SG]; TAN SOK PIN [SG]) 17 December 2009 (2009-12-17) tables D1, D2 sequences 1, 2, 5,6,17-24,31,32 claim 1 page 1, lines 17-21 page 9, lines 3-9 page 12, lines 17-22 page 14, lines 3-4 page 22, lines 1-10 page 32, line 25 - page 33, line 13 pages 35-36 page 42 page 45, lines 6-10 page 44, lines 16-19 page 48, line 5 - page 52, line 23	1-82

X	WAI-YIP LAM ET AL: "Development and comparison of molecular assays for the rapid detection of the pandemic influenza A (H1N1) 2009 virus", JOURNAL OF MEDICAL VIROLOGY, vol. 82, no. 4, 1 April 2010 (2010-04-01), pages 675-683, XP55013410, ISSN: 0146-6615, DOI: 10.1002/jmv.21725 table 1 figure 1 page 679, right-hand column, paragraph 1st full	1-82

X	QIN M ET AL: "Detection of pandemic influenza A H1N1 virus by multiplex reverse transcription-PCR with a GeXP analyzer", JOURNAL OF VIROLOGICAL METHODS, ELSEVIER BV, NL, vol. 168, no. 1-2, 7 May 2010 (2010-05-07), pages 255-258, XP027168687, ISSN: 0166-0934 [retrieved on 2010-07-22] table 1 page 256, left-hand column page 256, paragraph bridging - page 258 figure 1	1-82

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	YANG Y ET AL: "Simultaneous typing and HA/NA subtyping of influenza A and B viruses including the pandemic influenza A/H1N1 2009 by multiplex real-time RT-PCR", JOURNAL OF VIROLOGICAL METHODS, ELSEVIER BV, NL, vol. 167, no. 1, 1 July 2010 (2010-07-01), pages 37-44, XP027058495, ISSN: 0166-0934 [retrieved on 2010-03-19] table 1 page 39, paragraph 2.5	1-82
X	KR 100 796 007 B1 (KOREA CENT DISEASE CONTROL) 21 January 2008 (2008-01-21) sequences 1-4	12-23, 29-53, 59-82
X	US 2007/172835 A1 (MCBRIDE MARY T [US] ET AL) 26 July 2007 (2007-07-26) table 1 claim 1 paragraphs [0064], [0160] - [0162]	12-23, 29-53, 59-82
X	US 2009/111089 A1 (LINDSTROM STEPHEN [US] ET AL) 30 April 2009 (2009-04-30) table 1 paragraphs [0179] - [0189]	12-23, 29-53, 59-82
X,P	WO 2011/008171 A1 (AGENCY SCIENCE TECH & RES [SG]; INOUE MASAFUMI [SG]) 20 January 2011 (2011-01-20) page 10, lines 1-6 table 1 example 1	1-82
A	QIN MENG ET AL: "[Development of single-tube multiplex real-time PCR for simultaneous detection of novel influenza A H1N1 and human seasonal influenza A H1N1 and H3N2 virus].", BING DU XUE BAO = CHINESE JOURNAL OF VIROLOGY / [BIAN JI, BING DU XUE BAO BIAN JI WEI YUAN HUI] MAR 2010 LNKD-PUBMED:20480637, vol. 26, no. 2, March 2010 (2010-03), pages 97-102, XP55013421, ISSN: 1000-8721 abstract	1-82

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2011/043736

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2009151407 A2	17-12-2009	EP 2291545 A2	09-03-2011
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