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C12Q 1/37 (2006.01)

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(71) Applicant (for all designated States except US): **ECI BIOTECH, INC.** [US/US]; 85 Prescott Street, Worcester, MA 01605 (US).

(72) Inventor; and

(71) Applicant : **MACY, Dale** [US/US]; 24 Maplewood Ave., West Boylston, MA 01583 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **SANDERS, Mitchell, C.** [US/US]; 88 Ball Street, Northborough, MA 01532 (US). **RAKITIN, Andrei** [CA/US]; 264 Morse Road, Sudbury, MA 01776 (US). **MANKUS, Courtney** [US/US]; 5 Sabina Circle, Rochdale, MA 01542 (US).

(74) Agents: **SANDERS, Deirdre, E.** et al.; Hamilton, Brook, Smith & Reynolds, P.C., 530 Virginia Rd., P.O. Box 9133, Concord, MA 01742-9133 (US).

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AO, AT, AU, AZ, BA, BB, BG, BH, 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, IS, JP, KE, KG, KM, 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, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, 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.

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Declarations under Rule 4.17:

— of inventorship (Rule 4.17(iv))

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))

— with sequence listing part of description (Rule 5.2(a))

(88) Date of publication of the international search report:

16 August 2012



WO 2012/040434 A3

(54) Title: ULTRASENSITIVE DETECTION OF BETA HEMOLYTIC *STREPTOCOCCUS*

(57) Abstract: The present invention is directed to a method for the ultrasensitive detection of beta hemolytic *Streptococcus*, a bacterium implicated in strep throat, using a specific protease marker. Also disclosed is a device as well as a biosensor, both of which are useful for the detection of beta hemolytic *Streptococcus*. The biosensor and the device can be used in conjunction with other reagents as part of a kit for detecting strep throat.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2011/052716

A. CLASSIFICATION OF SUBJECT MATTER
INV. C12Q1/04 C12Q1/37 G01N33/558
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 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, COMPENDEX, EMBASE, FSTA, INSPEC, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|---|-----------------------|
| Y | WO 2005/042770 A2 (ETHICON INC [US]; EXPRESSIVE CONSTRUCTS INC [US]; SEBASTIAN SHITE [US]) 12 May 2005 (2005-05-12) | 35-42 |
| A | claims 1, 13 | 1-34 |
| A | WO 03/063693 A2 (EXPRESSIVE CONSTRUCTS INC [US]; SANDERS MITCHELL C [US]; LOWE ADRIAN M) 7 August 2003 (2003-08-07) claim 55 | 1-42 |
| | ----- -/-- | |

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents :

| | |
|---|---|
| <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent but published on or after the international filing date</p> <p>"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)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> | <p>"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</p> <p>"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</p> <p>"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</p> <p>"&" document member of the same patent family</p> |
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| Date of the actual completion of the international search 31 January 2012 | Date of mailing of the international search report 05/06/2012 |
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| 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 Jacques, Patrice |
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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2011/052716

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
 - in electronic form
 - b. (time)
 - in the international application as filed
 - together with the international application in electronic form
 - subsequently to this Authority for the purpose of search
2. 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:

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2011/052716

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.:

1-21, 35-42(completely); 30(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.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2011/052716

| C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT | | |
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| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
| X | WO 2008/075214 A1 (KIMBERLY CLARK CO [US]; SONG XUEDONG [US]) 26 June 2008 (2008-06-26) | 1-21,30 |
| Y | page 4, line 19 - line 21; figure 2 page 14, line 31 - page 15, line 29 page 15, line 26 - page 16, line 2 page 16, line 2 - line 29 page 17, line 16 - page 18, line 29 page 17, line 28 - line 31 page 21, line 13 - page 22, line 18 page 22, line 6 - line 10 ----- | 35-42 |
| A | R. E. O'LOUGHLIN ET AL: "The Epidemiology of Invasive Group A Streptococcal Infection and Potential Vaccine Implications: United States, 2000-2004", CLINICAL INFECTIOUS DISEASES, vol. 45, no. 7, 1 October 2007 (2007-10-01), pages 853-862, XP055017943, ISSN: 1058-4838, DOI: 10.1086/521264 the whole document ----- | 1-22,30, 35-42 |
| A | FR 2 886 312 A1 (ABAG SA [FR]) 1 December 2006 (2006-12-01) the whole document ----- | 1-42 |

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2011/052716

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
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| WO 2008075214 | A1 | 26-06-2008 | CA 2670519 A1 26-06-2008 |
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| FR 2886312 | A1 | 01-12-2006 | EP 1885745 A2 13-02-2008 |
| | | | FR 2886312 A1 01-12-2006 |
| | | | WO 2006125914 A2 30-11-2006 |
| ----- | | | |

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

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

1. claims: 1-21, 35-42(completely); 30(partially)

A device for detecting the presence or absence of a bacterium in a sample comprising a first and a second amplifier.

A similar device further comprising a lateral flow cassette.

A kit comprising said devices.

Methods using said devices.

2. claims: 22-29, 31-34(completely); 30(partially)

A biosensor for detecting the presence or absence of a bacterium in a sample comprising a solid support and a first amplifier.

An isolated peptide comprising an amino acid sequence selected from the group consisting of SEQ. ID.: 1, SEQ. ID.: 2, SEQ. ID.: 3.
