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[Continued on next page]

(54) Title: DEVICE AND METHOD FOR SAMPLING BODILY FLUID FOR MEDICAL ANALYTES IN ULTRA LOW CONCENTRATIONS

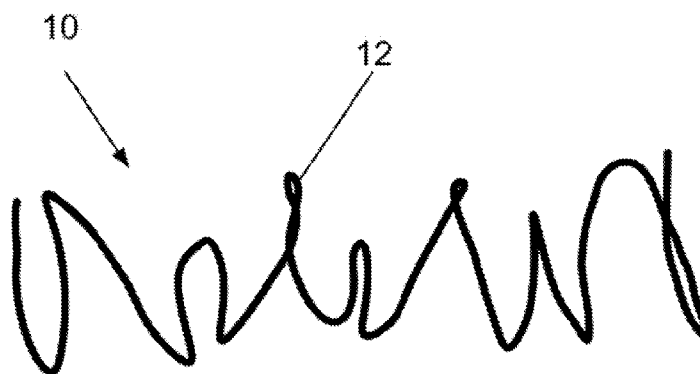


FIG. 1A

(57) Abstract: Trapping devices and methods are provided for capturing a medical analyte, in blood or another biological fluid. The device may include a structural substrate and a binding agent, such as an antibody, affixed to the structural substrate, wherein the binding agent is capable of binding or attaching with a medical analyte, such as a viral particle, and the device is configured for placement in a biological cavity or vessel (containing a biological fluid) in a patient. The trapping device, which may be in a twisted coil shape, is configured to trap at least some of the medical analyte, such a viral particle, present in the biological fluid. The method may include deploying a trapping device into the patient's blood vessel; after a period following the deployment, removing the trapping device from the biological cavity or blood vessel; and then analyzing the trapping device for the presence of the medical analyte.



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- *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))*

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2011/068165

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61F2/01 G01N33/53 G01N33/543
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)

A61F 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)

EP0-Internal, BIOSIS, EMBASE, 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	<p>Gregory J. Ekchian: "Design and evaluation of a device for trapping hepatitis C viral particles at ultra low concentrations",</p> <p>1 January 2010 (2010-01-01), pages 1-58, XP055023816, Boston</p> <p>Retrieved from the Internet: URL: http://dspace.mit.edu/bitstream/handle/1721.1/62675/714257917.pdf?sequence=1 [retrieved on 2012-04-04] page 18, paragraph 2 - page 25, paragraph 3; figure 6</p> <p style="text-align: center;">----- -/--</p>	1-14, 35, 36

☒ 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 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

5 April 2012

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02/07/2012

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INTERNATIONAL SEARCH REPORT

International application No

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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	US 2008/241847 A1 (HOON DAVID [US] ET AL) 2 October 2008 (2008-10-02) paragraph [0009]; figures 4-8 paragraph [0033] - paragraph [0034] paragraph [0040] paragraph [0094] paragraph [0103] -----	1-11
X	WO 2006/133392 A1 (UNIV VANDERBILT [US]; CAPRIOLI RICHARD [US]) 14 December 2006 (2006-12-14) page 5, paragraph 3; claims 69,72,73 page 6, paragraph 1 - paragraph 3 -----	1-4,9,10
A	JOONG SHIN ET AL: "Non-invasive Testing for Rupture of the Fetal Membranes", US OBSTETRICS AND GYNECOLOGY, vol. 1, 1 January 2007 (2007-01-01), pages 13-16, XP055024018, figure 1 -----	1-14,35, 36

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2011/068165

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.:

1-14, 35, 36

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: 1-14, 35, 36

A trapping device for capturing a medical analyte, comprising: a structural substrate; and at least one binding agent affixed to the structural substrate, capable of binding or attaching with the medical analyte, wherein the trapping device is dimensioned and adapted for placement in a biological cavity or vessel in a patient, which cavity or vessel contains a biological fluid, the trapping device being configured to trap at least a portion of the medical analyte present in the biological fluid.

2. claims: 15-32

A method of sampling bodily fluid for analyzing for the presence of a medical analyte in a patient, the method comprising: deploying a trapping device into a biological cavity or blood vessel of a patient; after a period of time following the deployment, removing the trapping device from the biological cavity or blood vessel; and then analyzing the trapping device for the presence of the medical analyte.

3. claims: 33, 34

A method for selectively obtaining and analyzing a constituent of a patient's bodily fluid, the method comprising: providing a device for collecting the constituent from the bodily fluid, the device comprising a material that has an affinity to the constituent; deploying the device into a location to contact the bodily fluid for a predetermined period, wherein a quantity of the constituent adheres to the material; and thereafter removing the device from the location.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2011/068165

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2008241847 A1	02-10-2008	US 2005153309 A1	14-07-2005
		US 2008241847 A1	02-10-2008

WO 2006133392 A1	14-12-2006	US 2008195062 A1	14-08-2008
		WO 2006133392 A1	14-12-2006
