

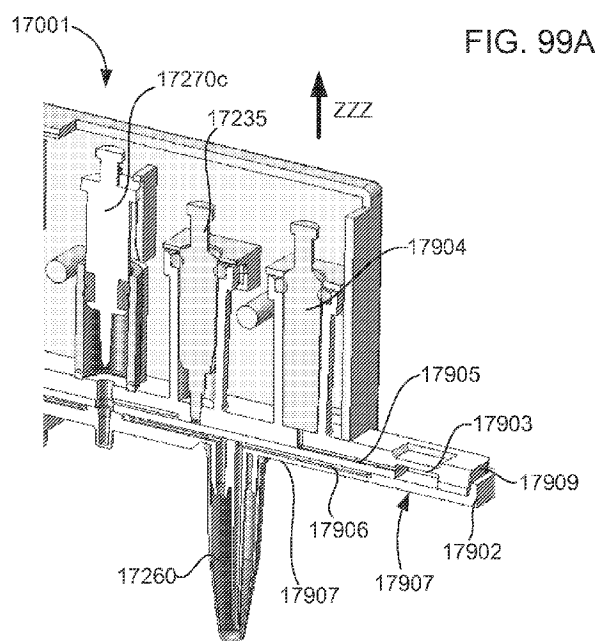


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- (81) **Designated States (unless otherwise indicated, for every kind of national protection available):** AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, 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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[Continued on next page]

(54) **Title:** APPARATUS AND METHODS FOR INTEGRATED SAMPLE PREPARATION, REACTION AND DETECTION

(57) **Abstract:** An apparatus includes a housing, a reaction vial and a transfer mechanism. The housing defines a first flow path and a second flow path. The housing has transfer port defining an opening in fluid communication with the second flow path and a volume outside of the housing. The transfer port includes a flow control member to limit flow through the opening. The reaction vial is coupled to the housing and defines a reaction volume, which is in fluid communication with the transfer port via the second flow path. The transfer mechanism is configured to transfer a sample from an isolation chamber of an isolation module to the reaction volume via at least the first flow path when the transfer mechanism is actuated. The transfer mechanism configured to produce a vacuum in the reaction vial to produce a flow of a sample from the isolation chamber to the reaction volume.



(88) Date of publication of the international search report:
13 March 2014

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 12/36491

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - B01F 5/06 (2012.01)

USPC - 250/341.3; 250/343; 422/947

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)

IPC (8) - B01F 5/06 (2012.01)

USPC - 250/341.3; 250/343; 422/947

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

IPC (8) - B01F 5/06 (2012.01)

USPC - 250/341.3; 250/343; 422/947 (keyword delimited)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PubWEST (PGPB,USPT,USOC,EPAB,JPAB) Terms - cartridge cassette disposable reactor isolating isolation port PCR DNA syringe plunger vacuum puncture GENTURADX

Google - PCR Cassette (plunger OR syringe) aspiration vacuum pierce layer; PCR Cassette (plunger OR syringe)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 7,910,062 B2 (YU, ET AL.) 22 March 2011 (22.03.2011), col 3, ln 25-40; col 5, ln 14-17; col 6, ln 44-46	1-7
Y	WO 2010/132834 A1 (BERTRAND, ET AL.) 18 November 2010 (18.11.2010), para [0023]	1, 2, 6, 7
Y	US 5,511,558 A (SHEPARD, ET AL.) 30 April 1996 (30.04.1996), fir 2, 6, 7; col 3-4	3-7
A	US 2010/0303687 A1 (BLAGA, ET AL.) 02 December 2010 (02.12.2010), entire document	1-7

☐ Further documents are listed in the continuation of Box C.


* 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

21 September 2012 (21.09.2012)

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Name and mailing address of the ISA/US

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 12/36491

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:

The following claim groups were found:

Group I: Claims 1-7

Group II: Claims 8-14

Group III: Claims 15-21

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

-- see extra 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 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.:
1-7

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.

Continuation of Box No. III -- Observations where unity of invention is lacking

Group I: is drawn to an apparatus, comprising: a housing defining a first flow path and a second flow path, the housing having a transfer port, the transfer port defining an opening in fluid communication with the second flow path and a volume outside of the housing, the transfer port including a flow control member configured to limit flow through the opening; a reaction vial coupled to the housing, the reaction vial defining a reaction volume, the reaction volume in fluid communication with the transfer port via the second flow path; and a transfer mechanism configured to transfer a sample from an isolation chamber of an isolation module to the reaction chamber via at least the first flow path when the transfer mechanism is actuated, the transfer mechanism configured to produce a vacuum in the reaction vial to produce a flow of a sample from the isolation chamber to the reaction volume.

Group II: is drawn to an apparatus, comprising: a housing defining a first flow path and a second flow path, the housing having a flow cell portion defining a detection volume; a reaction vial coupled to the housing, the reaction vial defining a reaction volume, the reaction volume in fluid communication with the detection volume via the first flow path; and a transfer mechanism in fluid communication with the detection volume via the second flow path, the transfer mechanism configured to transfer a sample from the reaction volume to the detection volume when the transfer mechanism is actuated.

Group III: is drawn to an apparatus, comprising: a housing defining a flow path; a reaction vial coupled to the housing, the reaction vial defining a reaction volume, the reaction volume in fluid communication with the flow path; a transfer mechanism configured to transfer a sample from the reaction chamber into the flow path when the transfer mechanism is actuated; and a plurality of movable members movably coupled to the housing, the plurality of movable members configured to separate the flow path into a plurality of PCR volumes, each PCR volume from the plurality of PCR volumes being fluidically isolated from an adjacent PCR volume from the plurality of PCR volumes.

The inventions listed in the above-mentioned groups do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups I-III lack unity of invention, because even though the inventions of these groups require the technical features of a housing defining a first flow path and a second flow path, a reaction vial coupled to the housing, the reaction vial defining a reaction volume, a transfer mechanism configured to transfer a sample, these technical features are not special technical features as they do not make a contribution over the prior art in view of US 5,164,598 A to Hillman et al., which discloses a housing (col 22, ln 20-22) defining a first flow path and a second flow path (col 27, ln 19-24), a reaction vial coupled to the housing, the reaction vial defining a reaction volume (col 16, ln 18-19), a transfer mechanism configured to transfer a sample (col 5, ln 50-52).

Further,

Group I includes the technical feature of an isolation chamber, not found in the other groups.

Group II includes the technical feature of a flow cell portion defining a detection volume, not found in the other groups.

Group III includes the technical feature of a plurality of PCR volumes, not found in the other groups.

Groups I-III therefore lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.