



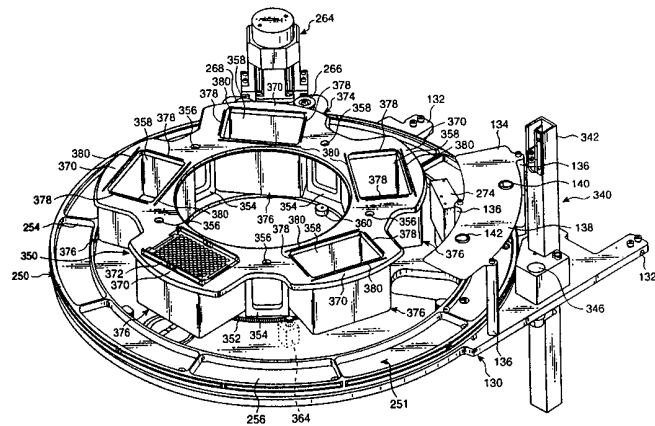
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : B01L 7/00, G01N 35/00	A3	(11) International Publication Number: WO 99/57561 (43) International Publication Date: 11 November 1999 (11.11.99)
(21) International Application Number: PCT/US99/09343 (22) International Filing Date: 30 April 1999 (30.04.99) (30) Priority Data: 60/083,927 1 May 1998 (01.05.98) US (71)(72) Applicant and Inventor: AMMANN, Kelly, G. [US/US]; 656 Wade Road, Longmont, CO 80503 (US). (72) Inventors; and (75) Inventors/Applicants (for US only): BURNS, Ralph, E. [US/US]; 302 27th Street, Boulder, CO 80303 (US). HANSBERRY, Ernest, V. [US/US]; 29435 Roon Drive, Evergreen, CO 80439 (US). HORNER, Glenn, A. [US/US]; 715 Zamia Court, Boulder, CO 80304 (US). JAKUB, Cheryl, A. [US/US]; 10792 Emanuel Way, Golden, CO 80403 (US). KLING, John, E. [US/US]; 4507 Mulberry Court, Boulder, CO 80301 (US). NIEGLOS, Donald, J. [US/US]; 1474 East Weldona Way, Superior, CO 80027 (US). SCHNEIDER, Robert, E. [US/US]; 145 South Tanner Court, Louisville, CO 80027 (US). SMITH, Robert, J. [US/US]; 889 Larkspur Court, Louisville, CO 80027 (US).	(74) Agents: LIPPITT, Raymond, A. et al.; Pillsbury Madison & Sutro, LLP, 1100 New York Avenue, N.W., Washington, DC 20005 (US). (81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i> (88) Date of publication of the international search report: 6 January 2000 (06.01.00)	

(54) Title: AUTOMATED DIAGNOSTIC ANALYZER AND METHOD

(57) Abstract

An automated analyzer for performing multiple diagnostic assays simultaneously includes multiple stations, or modules, in which discrete aspects of the assay are performed on fluid samples contained in reaction receptacles. The analyzer includes stations for automatically preparing a specimen sample, incubating the sample at prescribed temperatures for prescribed periods, performing an analyte isolation procedure, and ascertaining the presence of a target analyte. An automated receptacle transporting system moves the reaction receptacles from one station to the next. The analyzer further includes devices for carrying a plurality of specimen tubes and disposable pipette tips in a machine-accessible manner, a device for agitating containers of target capture reagents comprising suspensions of solid support material and for presenting the containers for machine access thereto, and a device for holding containers of reagents in a temperature controlled environment and presenting the containers for machine access thereto. A method for performing an automated diagnostic assay includes an automated process for isolating and amplifying a target analyte. The process is performed by automatically moving each of a plurality of reaction receptacles containing a solid support material and a fluid sample between stations for incubating the contents of the reaction receptacle and for separating the target analyte bound to the solid support from the fluid sample. An amplification reagent is added to the separated analyte after the analyte separation step and before a final incubation step.



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INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/09343

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 B01L7/00 G01N35/00

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 6 B01L 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 practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 93 25912 A (MEDICAL RES COUNCIL; HAWKINS TREVOR LEONARD (US); SULSTON JOHN EDW) 23 December 1993 (1993-12-23) page 7, paragraph 6 -page 10, paragraph 6; figure 1; example	1,2
A	---	
A	EP 0 171 140 A (UNIV TOKYO) 12 February 1986 (1986-02-12) page 25, line 16 -page 31, line 1; figures 7-10	1,2
X	---	
X	EP 0 628 824 A (ORTHO DIAGNOSTIC SYSTEMS INC) 14 December 1994 (1994-12-14)	3
Y	column 5, line 37 -column 6, line 36; figures 1-4	6

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Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

° Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
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- "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

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- "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

2 November 1999

Date of mailing of the international search report

10. 11. 1999

Name and mailing address of the ISA

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/09343

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 5 470 744 A (ASTLE THOMAS W) 28 November 1995 (1995-11-28)	4,5
Y	column 3, line 24 -column 4, line 55; figures 1,2,6	6

X	WO 93 03383 A (DU PONT) 18 February 1993 (1993-02-18) page 15, line 30 -page 16, line 22; figure 6 page 20, line 1 - line 20; figure 7	7

X	DE 94 05 224 U (KODAK AG) 26 May 1994 (1994-05-26) page 4, last paragraph -page 5, last paragraph page 7, line 19 - line 22 page 9, line 13 - line 17; figures 2,3	8,9

A	US 5 389 339 A (PETSCHER HARRY E ET AL) 14 February 1995 (1995-02-14) column 4, line 46 - line 64 column 5, line 35 - line 41; figure 1B	8,9

X	EP 0 502 638 A (CIBA CORNING DIAGNOSTICS CORP) 9 September 1992 (1992-09-09) column 15, line 21 -column 16, line 18; figures 43-49	10
A	figures 34,35	7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 99/09343

Box I Observations where certain claims were found unsearchable (Continuation of item 1 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 II Observations where unity of invention is lacking (Continuation of item 2 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 fee, this Authority did not invite payment of any additional fee.
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.
- No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US 99/09343

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

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

1. Claims: 1,2

Automated process for isolating and amplifying target sample

2. Claim : 3

Transport mechanism for analyser

3. Claims: 4-6

Incubator

4. Claim : 7

Magnetic separation device

5. Claims: 8,9

Carousel assembly

6. Claim : 10

Agitator device

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 99/09343

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