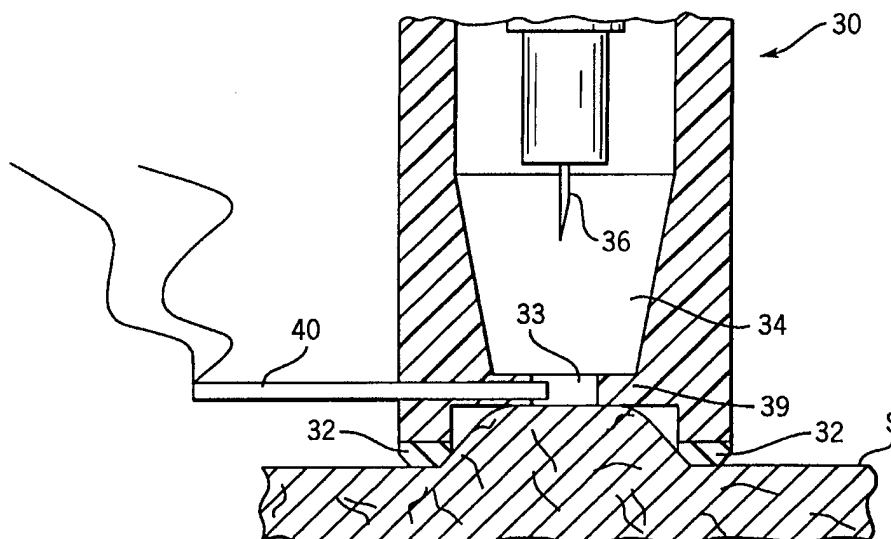




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61B 5/14, G01N 33/52	A3	(11) International Publication Number: WO 98/24366 (43) International Publication Date: 11 June 1998 (11.06.98)
(21) International Application Number: PCT/US97/22618 (22) International Filing Date: 4 December 1997 (04.12.97) (30) Priority Data: 08/759,698 6 December 1996 (06.12.96) US 60/036,395 24 January 1997 (24.01.97) US (71) Applicant (for all designated States except US): ABBOTT LABORATORIES [US/US]; CHAD 0377/AP6D-2, 100 Abbott Park Road, Abbott Park, IL 60064-3500 (US). (72) Inventors; and (75) Inventors/Applicants (for US only): CUNNINGHAM, David, D. [-/US]; 40097 North Highway 45, Lake Villa, IL 60046 (US). HENNING, Timothy, P. [-/US]; 189 Sheffield Lane, Vernon Hills, IL 60061 (US). SHAIN, Eric, B. [-/US]; 459 Grove Street, Glencoe, IL 60022 (US). YOUNG, Douglas, F. [-/US]; 212 Bonnie Brae Avenue, Graylake, IL 60030 (US). LOWERY, Michael, G. [-/US]; Apartment 201, 33720 Royal Oak Lane, Wildwood, IL 60030 (US). SCHAPIRA, Thomas, G. [-/US]; 21616-107th Street, Bristol, WI 53104 (US). GRAHAM, Hugh, W. [-/US]; 3408 Cheyenne, Gurnee, IL 60031 (US). MUETTERTIES, Andrew, J. [-/US]; 27321 N. Oakleaf Court, Mundelein, IL 60060 (US). CHAMBERS, Geoffrey, R. [-/GB]; 32 Elgood Avenue, Northwood, Middlesex HA6 3QS (GB). HUGHES, Graham, J. [-/GB]; 101 Old Road, Headington, Oxford OX3 8SX (GB). WATKIN, Jared, L. [-/GB]; 11 Kysbie		Place, Abingdon, Oxon OX14 1XZ (GB). PROKOP, Gary, F. [-/US]; 830 Pick Street, Wheaton, IL 60187 (US). GOLD-FARB, Joshua, P. [-/US]; Apartment 3C, 37 East Division, Chicago, IL 60610 (US). (74) Agents: WEINSTEIN, David, L. et al.; Abbott Laboratories, CHAD 0377/AP6D-2, 100 Abbott Park Road, Abbott Park, IL 60064-3500 (US). (81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, 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, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, 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: 29 October 1998 (29.10.98)

(54) Title: METHOD AND APPARATUS FOR OBTAINING BLOOD FOR DIAGNOSTIC TESTS



(57) Abstract

Method and apparatus for obtaining a sample of blood from a patient for subsequent diagnostic tests, e.g., glucose monitoring. In one aspect of the invention, the method comprises the steps of: (a) forming an unobstructed opening in the area of the skin from which the sample of blood is to be extracted; and (b) extracting the sample of blood from the unobstructed opening in the skin, with the aid of a vacuum and a stretching of the skin. In another aspect of the invention, an apparatus for carrying out the method described previously is provided. The apparatus comprises: (a) a device for forming an unobstructed opening in an area of skin from which said sample is to be extracted, preferably a lancing assembly; and (b) a vacuum pump. Preferably, the apparatus also includes a housing. In a further aspect of the invention, a pneumatic lancing assembly is provided. The pneumatic lancing assembly uses differential gas pressure to thrust a lancet into skin tissue. In another aspect of this invention, an article is provided for an article capable of both collecting blood and detecting an analyte in that blood. The article, which contains an appropriate detection element for determining the amount of analyte in the blood, can be used in conjunction with a meter that measures the signal generated by the detection element of the article.

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 97/22618

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B5/14 G01N33/52

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 A61B A61M 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.
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A	---	108, 126-130, 132-134
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

7 September 1998

Date of mailing of the international search report

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INTERNATIONAL SEARCH REPORT

 Internati Application No
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 97/22618

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.: 1-18 52 87-95 138-143
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
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 97/22618

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

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

1. Claims: 19-30

Apparatus for obtaining a body fluid comprising means for opening a skin area under influence of a skin lifting suction force.

2. Claims: 31-51

pneumatically actuated lancet

3. Claims: 53-86

multiple-layer article

4. Claims: 96-107

nosepiece

5. Claims: 108-137

blood sampling apparatus comprising a fluid collector positioned in a sealable chamber

INTERNATIONAL SEARCH REPORT

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