

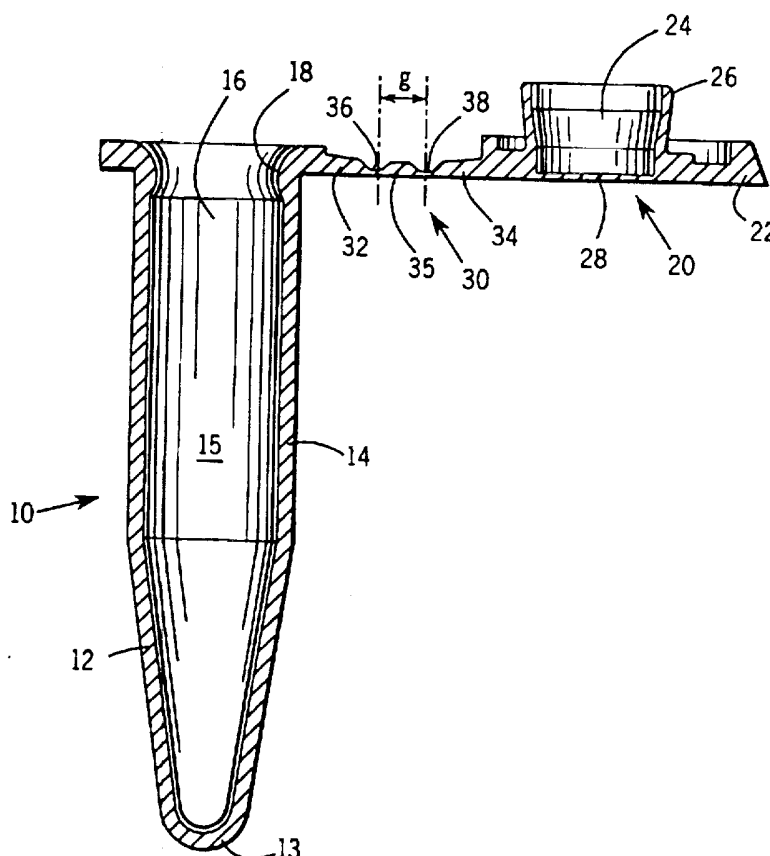


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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| (51) International Patent Classification ⁶ : B01L 7/00, 3/14, C12Q 1/68 | A3 | (11) International Publication Number: WO 95/11083 (43) International Publication Date: 27 April 1995 (27.04.95) |
| (21) International Application Number: PCT/US94/12125 (22) International Filing Date: 21 October 1994 (21.10.94) (30) Priority Data: 08/140,632 22 October 1993 (22.10.93) US (71) Applicant: ABBOTT LABORATORIES [US/US]; CHAD-0377/AP6D-2, 100 Abbott Park Road, Abbott Park, IL 60064-3500 (US). (72) Inventors: HANLEY, Kathleen, A.; 758 Greenview Street, Gurnee, IL 60031 (US). HOFFERBERT, A., David; 1710 Pleasant Valley Road, Grafton, WI 53024 (US). LEE, Helen, H.; 825 Morningside Drive, Lake Forest, IL 60045 (US). PEPE, Curtis, J.; 3609 Cornell Court, McHenry, IL 60050 (US). PERKO, Timothy, J.; 7017 Westmoreland Drive, St. Louis, MO 63130 (US). ZUREK, Thomas, F.; 752 Ashland, River Forest, IL 60305 (US). (74) Agents: BRAINARD, Thomas, D. et al.; Abbott Laboratories, CHAD 0377/AP6D-2, 100 Abbott Park Road, Abbott Park, IL 60064-3500 (US). | (81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). 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: 31 August 1995 (31.08.95) | |

(54) **Title:** REACTION TUBE AND METHOD OF USE TO MINIMIZE CONTAMINATION(57) **Abstract**

A disposable reaction vessel for performing nucleic acid amplification assay. The disposable reaction vessel has a penetrable cap that can be penetrated by an automated pipettor to aspirate a portion of an amplified reaction product. The disposable reaction vessel contains the reagents necessary to perform a nucleic acid amplification assay. A patient specimen is added to the unit dose reagents in the disposable reaction vessel and the penetrable cap is closed. The disposable reaction vessel containing the reaction mixture and the specimen undergoes amplification, typically by placing it in a thermal cycler. After amplification the intact disposable reaction vessel is transferred to an automated analyzer where an automated pipettor penetrates the closure membrane and aspirates a portion of the amplified sample for further processing, without removal of the reaction vessel cap. This avoids the generation of potentially contaminating aerosols or droplets.



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INTERNATIONAL SEARCH REPORT

Inter nal Application No
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| A. CLASSIFICATION OF SUBJECT MATTER IPC 6 B01L7/00 B01L3/14 C12Q1/68 | | |
| 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 C12Q B65D | | |
| 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) | | |
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| Y | --- | 25 |
| Y | see column 7, line 10 - line 36 --- | 29 |
| -/-- | | |
| <div style="display: flex; justify-content: space-between;"> <input checked="" type="checkbox"/> Further documents are listed in the continuation of box C. <input checked="" type="checkbox"/> Patent family members are listed in annex. </div> | | |
| <div style="display: flex;"> <div style="flex: 1;"> <p>* Special categories of cited documents :</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document 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> </div> <div style="flex: 1;"> <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> </div> </div> | | |
| Date of the actual completion of the international search <div style="text-align: center; font-weight: bold;">29 June 1995</div> | | Date of mailing of the international search report <div style="text-align: center; font-weight: bold;">07.08.95</div> |
| Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016 | | Authorized officer <div style="text-align: center; font-weight: bold;">Osborne, H</div> |

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INTERNATIONAL SEARCH REPORT

In .ational application No.

PCT/US 94/ 12125

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:

1. CLAIMS 1-12, 25-28
2. CLAIMS 13-24
3. CLAIMS 29-35

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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/210

LACK OF UNITY OF INVENTION

1. Claims: 1-12, 25-28

method for performing a nucleic acid amplification assay, wherein the transfer of amplified target nucleic acid is effected by piercing the cap membrane of an amplification vessel with a pipettor probe, and reaction vessel suitable for such a method, comprising a puncturable membrane of no more than 0.015 inches.

2. Claims: 13-24

Kits for performing a nucleic acid amplification assay comprising an amplification composition with a low concentration of Mg^{2+} in one container, and a sample treatment composition including a higher concentration of Mg^{2+} in a second container.

3. Claims: 29-35

Reaction vessel suitable for performing a nucleic acid amplification assay, whose sealing cap includes a puncturable membrane, wherein a bi-fold hinge holds the cap to the tube.

Nucleic acid amplification assays are known. The piercing of a membrane during such an assay appears to be the special technical feature claimed by claim 1. This feature also appears in claims 25-28, and the sets of claims 1-12 and 25-28 consequently satisfy the requirement of Rule 13.1 PCT.

The claims 13-17 and 18-24 do not refer to the piercing of a membrane, nor do they relate to any other special technical feature (in the sense of Rule 13.2 PCT) of claims 1-12. Therefore claims 13-17 and 18-24 do not relate to the same general inventive concept as claims 1-12 and consequently do not satisfy the requirement of Rule 13.1 PCT.

Claim 25 refers to a reaction vessel suitable for performing a nucleic acid amplification assay according to the method of claims 1-12. Claims 29-35 refer to a second kind of device suitable for performing a nucleic acid amplification assay according to the method of claims 1-12. Reaction vessels with a hinged sealing cap suitable for performing a nucleic acid amplification assay are known (see EP488769, fig 50). EP341342 describes such a small capped centrifuge container, withstanding boiling temperatures, and thus suitable for thermal cycling. The cap of this container is held to the tube by an hinge, and includes a puncturable membrane. EP341342 describes all the technical features common to claims 25 and 29. There is therefore no special technical feature in the sense of Rule 13.2 PCT which is common to claims 25 and 29: compared with the reaction vessel of EP341342, the special technical features of claims 25-28 would be the thickness of the puncturable membrane, whereas the special technical feature of claim 29 would be the bifold hinge. Therefore claims 29-35 do not relate to the same general inventive concept as claims 25-28 and consequently do not satisfy the requirement of Rule 13.1 PCT.

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