(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
17 November 2005 (17.11.2005)

PCT

(10) International Publication Number
WO 2005/108976 A1

(51) International Patent Classification[7]: G01N 31/22

(21) International Application Number:
PCT/US2005/015875

(22) International Filing Date: 6 May 2005 (06.05.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
10/842,000 6 May 2004 (06.05.2004) US

(71) Applicant *(for all designated States except US)*: **AKERS BIOSCIENCES, INC.** [US/US]; 201 Grove Road, Thorofare, NJ 08086 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **ANDRELCZYK, Susan** [US/US]; 1103 Barnesdale Road, West Deptford, NJ 08096 (US). **SCHLUTER, Leonard, L.** [US/US]; 603 Good Intent Road, Blackwood, NJ 08012 (US).

(74) Agents: **BRIVANLOU, Margaret** et al.; Jones Day, 222 East 41st Street, New York, NY 10017-6702 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: TEST STRIP CARD

(57) Abstract: The present invention relates to a test strip for determining and/or quantifying a property of a sample, such as the concentration of an analyte, the pH, the viscosity, or the specific gravity of a fluid specimen. More particularly, the present invention relates to an improved test strip and scale for determining and/or quantifying a property of a sample, such as the concentration of an analyte, the pH, the viscosity, or the specific gravity of a fluid specimen.

WO 2005/108976 A1

TEST STRIP CARD

[001] FIELD OF THE INVENTION

[002] The present invention relates to a test strip for determining and/or quantifying a property of a sample, such as the concentration of an analyte, the pH, the viscosity, or the specific gravity of a fluid specimen. More particularly, the present invention relates to an improved test strip and scale for determining and/or quantifying a property of a sample, such as the concentration of an analyte, the pH, the viscosity, or the specific gravity of a fluid specimen.

[003] BACKGROUND OF THE INVENTION

[004] Test strips on which a fluid specimen is dropped, or which are dipped into a fluid specimen, are known in the art. The test strip has a sample pad, on which the sample or specimen is received, and a reagent pad with a reaction zone carrying a reagent. The sample is received on the sample pad and migrates from there to the reaction pad. On the reaction pad, the sample and a reagent on the reaction pad undergo a reaction. Such a reaction can be, *e.g.*, a colorimetric reaction or a reaction that changes the light reflection properties of the reaction pad. The reagent pad may be coextensive with the sample pad, or spaced from the sample pad so that the specimen migrates from the sample pad to the reagent pad. The sample may also be placed directly onto the reaction pad. Once the fluid specimen reacts with the reagent in the strip, the reagent pad (in a reaction zone of the reagent pad) changes its light reflection and/or absorption pattern, which may be perceived as a change of color and/or brightness. The test strip is then carried to a comparison scale where the reagent pad is compared with the scale. Typically, the comparison scale is a color scale, and the color of the reagent pad is aligned with the substantially identical color on the comparison scale to determine the quantity of the component in question in the fluid sample, or the presence of a particular component in the fluid sample, or another characteristic or property of the fluid sample. Such components and characteristics include for example, the pH of a liquid, the concentration of certain ions, the presence of certain microorganisms in the sample, temperature, the concentration of certain biomolecules (such

as sugars, DNA, RNA, lipids, proteins, peptides and amino acids) and/or the concentration of small organic or inorganic molecules or other analytes.

[005] Because the test strip has to be carried to a color scale, the doctor, nurse, technician, or tester must handle the strip not only to apply the fluid specimen thereto, but also to manipulate the test strip with respect to the color scale. Such additional handling is generally undesirable for efficiency as well as hygienic reasons, yet has been heretofore essentially unavoidable. Moreover, the test strip is generally a rather thin, flimsy piece of paper or the like and can easily be blown over or otherwise inadvertently moved to an undesired location by, for example, a breeze of air.

[006] Therefore, it would be desirable to reduce the amount of handling required to utilize a test strip for measuring the presence or amount of a component in question. Moreover, it would be desirable to modify the test strip so that it is not easily displaced.

[007] SUMMARY OF THE INVENTION

[008] In accordance with the principles of the present invention, a test strip is coupled to a test scale card on which a test scale is provided. The test scale comprises a comparison scale. Optionally, the test scale further comprises a reading scale. The test strip has a reagent pad with a reaction zone. The reaction zone is the area of the reagent pad where the reaction between the sample that is to be tested and a reagent takes place. The reaction zone can be coextensive with the reaction pad, or, alternatively, the reaction zone can be a part of the reaction pad. The reaction results in a visual signal in the reaction zone. The reaction zone of the test strip is positioned adjacent the comparison scale so that the test strip may be moved or slid along the comparison scale to align the reaction zone with the matching visual value or zone (hereinafter "level" for the sake of convenience) on the comparison scale of the test scale. The user thus can readily determine a property, such as the concentration of an analyte, the pH, the viscosity or the specific gravity, of the specimen dropped on the test strip (or in which the test strip was dipped) upon comparison of the reagent pad with the comparison scale and reading the corresponding value on the reading scale.

[009] In one embodiment, the test strip is slidable in a pocket in the test scale card with the reaction zone of the test strip visible through a window (*e.g.*, a slot) in the test scale card. The comparison scale is provided along the window so that movement of the test strip

moves the reaction zone into alignment with the matching level along the comparison scale so that a match and thus an appropriate reading may be achieved with ease.

[010] The test strip preferably is readily accessible to the user so the user may readily move the test strip with respect to the test scale card. For instance, the test strip may extend slightly beyond the edge of the test scale card. Alternatively, a portion of the test strip may be accessible through the test scale card. For instance, a notch may be provided at an end of the test scale card to expose a pull end, such as a pull tab section, of the test strip.

[011] BRIEF DESCRIPTION OF THE DRAWINGS

[012] The present invention can be better understood by reference to the following drawings, wherein like references numerals represent like elements. The drawings are merely exemplary and the present invention is not limited to the embodiments shown.

[013] **FIG. 1** is a top perspective view of an exemplary sliding test strip in accordance with the principles of the present application;

[014] **FIG. 2** is a top perspective view of another exemplary sliding test strip in accordance with the principles of the present application; and

[015] **FIG. 3** is a bottom perspective view of an exemplary sliding test strip in accordance with the principles of the present application.

[016] DETAILED DESCRIPTION OF THE INVENTION

[017] As illustrated in **FIG. 1**, exemplary test strip card **10,** formed in accordance with the principles of the present invention, has test scale card **20** on which comparison scale **22** and reading scale **24** are provided and to which a test strip **30** is movably coupled. Test strip **30** has a reagent pad **32** with reaction zone **34** that reacts with a specimen, such as a fluid specimen, applied to test strip **30**, as described in further detail below. Reaction zone **34** is the area of reagent pad **30** where the reaction between the sample that is to be tested and a reagent takes place, as described in further detail below. The reaction results in a visual signal in reaction zone **34**. Test strip **30** is movably coupled to test scale card **20** to move reagent pad **32** or at least reaction zone **34** along comparison scale **22** to align reaction zone **34** with a matching level along comparison scale **22.**

[018] Thus, test strip card **10** permits a specimen to be applied to a test strip and for the test strip to be "read" with a single, combined testing device. Individual exemplary

components of test strip card **10** and their exemplary functions will now be described in greater detail.

[019] Test scale card **20** preferably is formed from a sufficiently rigid or stiff enough material so that test scale card **20** has structural stability and remains relatively stiff and flat without external support (an element with such structural stability is described hereinafter as "self-supporting" for the sake of convenience). For instance, test scale card **20** may be formed from heavy-weight paper, paperboard, lightweight cardboard, or plastic. For the sake of economy, the thickness of such material is selected to be as thin as possible while still permitting test scale card **20** to be self-supporting. Thus, material use is minimized, and more test strip cards can fit in the same amount of space (thus facilitating sale and storage of large quantities). Alternatively, a relatively flimsy material may be used to form test scale card **20** (such that test scale card **20** is not self-supporting) and an additional support may be provided so that test strip card **10** is self-supporting.

[020] Test strip **30** may be movably coupled to test scale card **20** in any of a number of manners. For instance, test scale card **20** may be in the form of a sleeve or double-walled element with a pocket therebetween in which test strip **30** is movably or slidably positioned. Reagent pad **32**, or at least reaction zone **34**, is visible through window **40** in test scale card **20** along which comparison scale **22** is provided. Window **40** may be an open window for the sake of simplicity. However, if it is desired to protect reaction zone **34** from contaminants (such as dust), a transparent material (*e.g.,* plastic) may be fitted in window **40**.

[021] As illustrated in **FIG. 1**, test scale card **20** may be formed with a front wall **50** and a back wall **52** coupled together to form a pocket **54** therebetween in which test strip **30** is movably or slidably positioned. A pull end **56** of test strip **30** may extend beyond the borders of test scale card **20** so that a user may access and move test strip **30** with respect to test scale card **20**. If desired, a notch **58** may be formed in one or both of walls **50**, **52** to access pull end **56** of test strip **30** so that pull end **56** need not extend beyond the borders of test scale card **20**. Thus, test strip **30** is readily accessible by a user to move reaction zone **34** into alignment with the matching level along comparison scale **22**.

[022] Front wall **50** and back wall **52** may be formed separately and coupled together in any desired manner to form a single-piece test scale card **20**. Alternatively, front wall **50** and back wall **52** may be formed from a single piece of material folded (*e.g.*, in half) to form a double-walled test scale card. If desired, front wall **50** and back wall **52** may

have different dimensions. For example, back wall **52** may be larger than front wall **50** and comparison scale **22** may be provided along the portion of back wall **52** visible when front wall **50** is coupled to back wall **52** (such as by aligning two adjacent edges or borders of front wall **50** with two adjacent edges or borders of back wall **52**), as illustrated in **FIG. 2.**

[023] Comparison scale **22** and reading scale **24** may be printed directly on front wall **50**, or may be formed on a separate piece of material affixed (*e.g.*, adhered) to front wall **50** of test strip card **10**. Comparison scale **22** may be a "color" chart having a variety of different colors or varying shades or hues or tints (herein, these terms are understood as interchangeable) of a single color. In certain embodiments, the scale is a scale of different degrees of brightness or different grey values. Any other type of scale may be used instead.

[024] In certain embodiments, the comparison scale comprises a continuous scale of levels on the comparison scale, such as a continuous scale of colors, or a series of fields, each field encompassing different visual information, *i.e.*, different levels, such as a different color. In certain embodiments, a reading scale of the comparison scale consists of a series of numerical values that are printed next to the continuous scale of levels or the different fields of the comparison scale. The numerical values and the levels are matched such that a level or a range of levels corresponds to a numerical value. In more specific embodiments, the numerical value is the quantified property in the sample being tested. The property to be tested can be the concentration of an analyte, the pH, the viscosity, or the specific gravity of the sample. The test strip and the comparison scale are calibrated such that if the level on the test strip matches with a level in the comparison scale, the concentration of the component being tested is the numerical value on the reading scale that corresponds to the matching level on the comparison scale.

[025] The sample can be applied to the test strip, *i.e.*, to the sample pad or directly on the reaction pad, by any method known to the skilled artisan. In certain embodiments, the sample is dropped on the sample pad or directly on the reaction pad. In certain, more specific embodiments, the sample is placed onto the test strip using a pipette. In certain embodiments, the test strip is placed directly into the sample. In certain embodiments, the sample pad is made from an absorbent material. If the material is not directly applied to the reaction pad, the sample can migrate from the sample pad to the reaction pad. In certain embodiments, the sample pad, the reagent pad, and the reaction zone are attached to a solid support, wherein the solid support is less absorbent than the sample pad and the reagent pad. The reagent pad is impregnated with a reagent that can react with and/or bind to the

component of which the presence or the concentration is to be determined. The reaction and/or binding takes place at the reaction zone. The reaction or binding between the component and the reagent results in a change of the optical properties of the reagent and the light absorption/reflection spectrum of the reagent pad changes at the reaction zone.

[026] Any test strip known to those of ordinary skill in the art for performing the desired tests and produce accurate easily detectable results may be used. A variety of different test strips for determining or detecting various properties or characteristics are known, as described below, and may be used in test strip card **10** of the present invention.

[027] In certain embodiments, the test strip of the present invention can be used to measure total and high-density lipoprotein (HDL) cholesterol concentration. Blood cholesterol levels are directly related to the risk of cardiovascular disease. The HDL and Total Cholesterol rapid assays provide semi-quantitative determinations of high-density lipoprotein (HDL) cholesterol and total cholesterol levels in whole blood obtained from a finger stick. The tests have been designed in a strip format; and an enzymatic color reaction from a single drop of blood can produce results in approximately three minutes. The strip may contain a sandwich of membranes that perform the following functions: separation of blood cells from serum, collection of serum, reaction of serum with cholesterol oxidase and substrate, and substrate color formation. The membrane sandwich may be assembled in such a way that the whole blood sample is applied to the surface of the separator membrane, and the serum produced moves vertically through the sandwich contacting the reagents in successive layers. The substrate color is formed on the bottom layer of the sandwich.

[028] In certain embodiments, the test strip of the present invention can be used to determine the concentration of glucose in a sample. Determination of blood glucose levels are important in the diagnosis and management of diabetes. The glucose rapid assay provides semi-quantitative determinations of glucose levels in whole blood obtained from a finger stick. The test may be designed in a strip format; and an enzymatic color reaction from one or more drops of blood can produce a result in approximately three minutes. The strip may contain a sandwich of membranes that perform the following functions: separation of blood cells from serum, collection of serum, reaction of serum with glucose oxidase and substrate, and substrate color formation. The membrane sandwich may be assembled in such a way that the whole blood sample is applied to the surface of the separator membrane, and the serum produced moves vertically through the sandwich

contacting the reagents in successive layers. The substrate color is formed on the bottom layer of the sandwich.

[029] In certain embodiments, the test strip can be used to determine the pH in a sample. For instance, urinary pH levels are important in the diagnosis of disease states and nutritional deficiencies. The urine pH rapid assay provides semi-quantitative determinations of pH directly from a drop of urine. The test may be designed in a strip format; and a color reaction from a single drop of urine can produce results immediately. The strip may contain a sandwich of membranes that perform the following functions: separation of urinary precipitates or debris, and reaction of the urine with a test strip producing color formation. The membrane sandwich may be assembled in such a way that the urine sample is applied to the surface of the separator membrane, and the filtered urine produced moves vertically through the sandwich contacting the test strip. The color is formed on the bottom layer of the sandwich.

[030] In certain specific embodiments, a test strip in accordance with U.S. Patent 4,774,192, issued September 27, 1988 to Terminiello et al., and U.S. Patent 4,877,580, issued October 31, 1989 to Aronowitz et al., both of which are incorporated herein by reference in their entirety, may be used.

[031] Certain other exemplary tests for the quantification of glucose or protein or determining the pH that may be used in the present invention are described in U.S. Patent 5,178,831, issued January 12, 1993 to Sakota et al. (see, *e.g.*, section entitled "Test Reagent Layer"), which is incorporated herein by reference in its entirety.

[032] In one embodiment, the fluid specimen is dropped onto a sample pad **69** on the back surface of test strip **22**, as illustrated in **FIG. 3**. Preferably, for the sake of convenience, sample pad **69** is accessible through an application window **62** through back wall **52** of test scale card **20**. Alternatively, test strip **30** may be withdrawn from test scale card **20** so that the specimen may be applied to sample pad **69**. In one embodiment, the sample pad separates those components in the sample that interfere with the reaction and retains them. For instance, the sample pad may retain blood cells so that only serum passes to the reagent pad, and red blood cells will not alter a color change that occurs upon reaction of the sample with the reagent. The specimen then migrates to reaction zone **34** on the reagent pad **32** and the reaction zone **34** changes its optical properties. In certain embodiments, reaction zone **34** and reagent pad **32** are coextensive with each other such that the entire reagent pad changes its optical properties.

[033] In certain embodiments, reagent pad **32** has a plurality of layers, wherein one of the layers is reaction zone **34**. While the sample migrates through the different layers of reagent pad **32**, the sample or a component of the sample can undergo one or more reactions. However, the visual signal that is being compared with comparison scale **22** results from the contact between the sample and reaction zone **34**.

[034] The test strip cards are packaged in kits containing finger stick devices and all other necessary accessories, making them ideal for office or home use.

[035] It will be appreciated that the scope of the invention is not limited to the embodiment illustrated in the figures and that the principles of the present invention are broader than such embodiment. For instance, the present invention encompasses a test strip card having more than one test strip and more than one comparison scale. In one embodiment, a test strip card formed in accordance with the principles of the present invention may be formed to test cholesterol levels in a patient's blood sample. Thus, a first test strip and comparison scale may be provided to measure HDL cholesterol levels in the blood sample, and a second test strip and comparison scale may be provided to measure total cholesterol level in the blood sample.

[036] Additionally, it will be appreciated that the positions of any of the comparison scale, test strip, and window may be modified from the locations illustrated. For instance, the test strip may be along a side edge and the comparison scale provided on the side edge of the test scale card.

[037] Accordingly, while the foregoing description and drawings represent embodiments of the present invention, it will be understood that various additions, modifications and substitutions may be made therein without departing from the spirit and scope of the present invention as defined in the accompanying claims. In particular, it will be clear to those skilled in the art that the present invention may be embodied in other specific forms, structures, arrangements, proportions, and with other elements, materials, and components, without departing from the spirit or essential characteristics thereof. One skilled in the art will appreciate that the invention may be used with many modifications of structure, arrangement, proportions, materials, and components and otherwise, used in the practice of the invention, which are particularly adapted to specific environments and operative requirements without departing from the principles of the present invention. The presently disclosed embodiments are therefore to be considered in all respects as illustrative

and not restrictive, the scope of the invention being indicated by the appended claims, and not limited to the foregoing description.

WHAT IS CLAIMED:

[001.] A test strip card for testing a property of a fluid specimen, said test strip card comprising:

a test scale card bearing a comparison scale; and

a test strip having a reaction zone movably coupled to said test scale card adjacent said comparison scale;

wherein said test strip is movable with respect to said comparison scale to align said reaction zone with a matching region in said comparison scale indicating the property of the specimen.

[002.] A test strip card as in claim 1, wherein:

said test scale card further comprises a front wall, a back wall, and a pocket between said front wall and said back wall; and

said test strip is movably located within said pocket in said test scale card.

[003.] A test strip card as in claim 2, wherein:

a window is formed in said front wall along said comparison scale; and part of said reaction zone on said test strip is visible through said window along said comparison scale.

[004.] A test strip card as in claim 3, further comprising transparent material in said window through which said reaction zone is visible.

[005.] A test strip card as in claim 2, wherein said test strip has a pull end extending beyond the borders of said front wall and said back wall.

[006.] A test strip card as in claim 2, wherein:

a notch is defined at an end of at least one of said front wall and said back wall; and said test strip has a pull end accessible through said notch.

[007.] A test strip card as in claim 2, wherein said test strip has a front side adjacent said front wall of said test scale card and on which said reaction zone is positioned, and a back side adjacent said back wall of said test scale card and carrying a sample pad, wherein the sample is administered to said sample pad.

[008.] A test strip card as in claim 7, wherein:

a window is formed in said front wall along said comparison scale and part of said reaction zone on said test strip is visible through said window along said comparison scale; and

an access window is formed in said back wall of said test scale card through which a specimen may be applied to said sample pad on said test strip.

[009.] A test strip card as in claim 1, wherein said comparison scale comprises a spectrum or series of visual levels selected from the group consisting of colors, hues, shades, and tints.

[0010.] The test strip card of claim 9, further comprising a reading scale aligned with said comparison scale and including a series of numerical values that are matched with the different visual levels of said comparison scale.

[0011.] The test strip of claim 1, wherein said property is the concentration of an analyte.

[0012.] The test strip of claim 11, wherein the analyte reacts with or binds to a reagent in the reaction zone, and wherein the binding or reaction between the analyte and the reagent results in a change of the optical properties of said reaction zone.

[0013.] The test strip of claim 1, wherein the property is the viscosity, the pH, or the specific gravity of the liquid specimen.

[0014.] A method of testing a property of a fluid specimen, said method comprising:

applying a fluid specimen to a test strip movably coupled to a test scale card bearing a comparison scale, wherein the test strip includes a reaction zone that is altered upon contact with the fluid sample; and

moving the test strip with respect to the comparison scale to align the reaction zone with a matching region in the comparison scale indicating information about the fluid specimen characteristic being tested;

wherein the test strip remains coupled to the test scale card during applying of the fluid specimen.

[0015.] The method of claim 14, wherein:

said test scale card further comprises a front wall, a back wall, and a pocket between said front wall and said back wall; and

said test strip is movably located within said pocket in said test scale card.

[0016.] The method of claim 15, wherein:

a window is formed in said front wall along said comparison scale; and part of said reaction zone on said test strip is visible through said window along said comparison scale.

[0017.] The method of claim 16, said test scale card further comprising transparent material in said window through which said reaction zone is visible.

[0018.] The method of claim 15, wherein said test strip has a pull end extending beyond the borders of said front wall and said back wall.

[0019.] The method of claim 15, wherein:

a notch is defined at an end of at least one of said front wall and said back wall; and said test strip has a pull end accessible through said notch.

[0020.] The method of claim 15, wherein said test strip has a front side adjacent said front wall of said test scale card and on which said reaction zone is positioned, and a back side adjacent said back wall of said test scale card and carrying a sample pad, wherein the sample is administered to said sample pad.

[0021.] The method of claim 20, wherein:

a window is formed in said front wall along said comparison scale and part of said reaction zone on said test strip is visible through said window along said comparison scale; and

an access window is formed in said back wall of said test scale card through which a specimen may be applied to said sample pad on said test strip.

[0022.] The method of claim 14, wherein said comparison scale comprises a spectrum or series of visual levels selected from the group consisting of colors, hues, shades, and tints.

[0023.] The method of claim 22, further comprising a reading scale aligned with said comparison scale and including a series of numerical values that are matched with the different visual levels of said comparison scale.

[0024.] The method of claim 14, wherein said property is the concentration of an analyte.

[0025.] The method of claim 24, wherein the analyte reacts with or binds to a reagent in the reaction zone, and wherein the binding or reaction between the analyte and the reagent results in a change of the optical properties of said reaction zone.

[0026.] The method of claim 14, wherein the property is the viscosity, the pH, or the specific gravity of the liquid specimen.

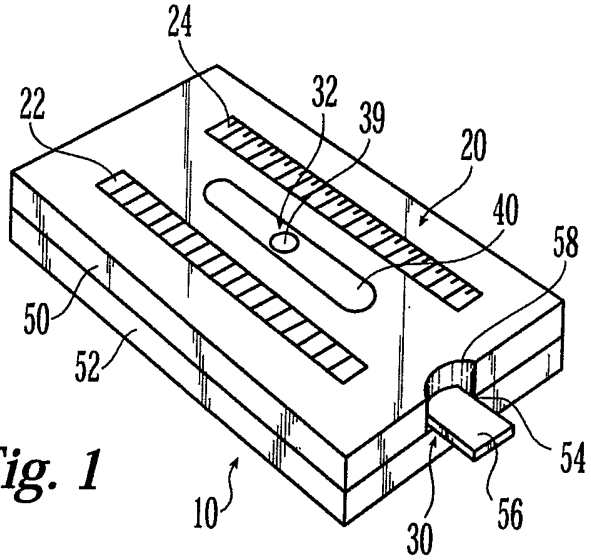

Fig. 1

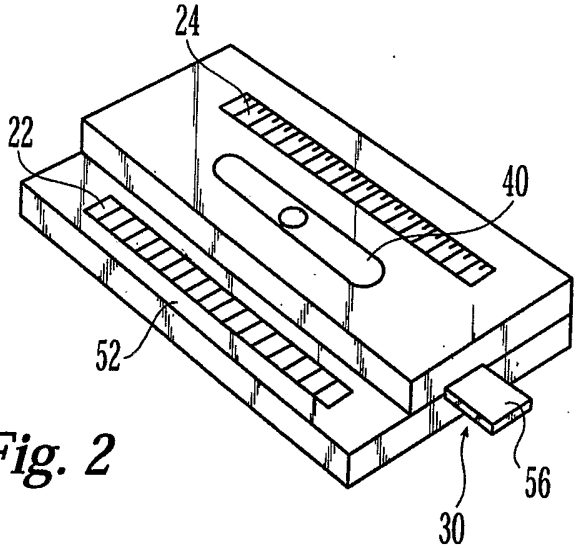

Fig. 2

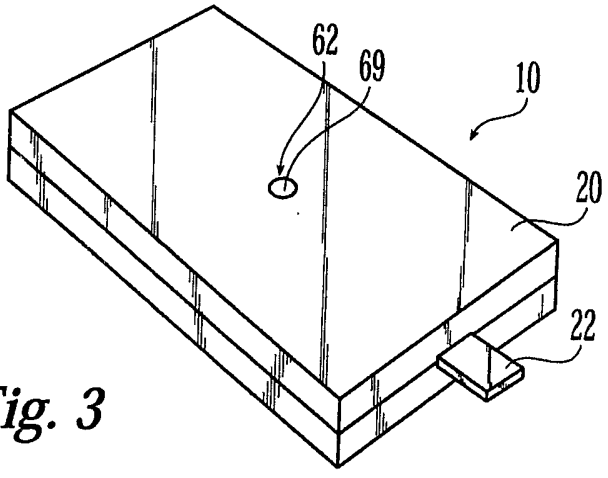

Fig. 3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US05/15875

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : G01N 31/22
US CL : 422/58,68.1
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)
U.S. : 422/55,58,68.1,82.05

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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 4,877,580 A (ARONOWITA et al.) 31 October 1989 (31.10.1989), column 2, lines 22-31, lines 45-56, column 3, lines 35-38, claim 10, Figures. (1, 1A, 1B, 4, 5).	1-3,5,7,9-12 --- 4,6,8,13-26
Y	US 5,595,187 A (DAVIS) 21 January 1997 (21.01.1997), column 3, line 50 -column 4, line 5, column 4, lines 42-48, Figure 1.	4,13,17,26
Y	US 6,184,040 B1 (POLIZZOTTO et al.) 06 February 2001 (06.02.2001), column 4, lines 18-20.	8,21
Y	US 6377894 B1 (DEWEESE et al.) 23 April 2002 (23.04.2002), Figure 1A.	6,19

☐ 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 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	Date of mailing of the international search report
12 September 2005 (12.09.2005)	04 OCT 2005
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Paul S. Hyun Telephone No. 571-272-1700

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US05/15875

BOX III. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

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.

Group I, claim(s) 1-13, drawn to a test strip card.

Group II, claim(s) 14-26, drawn to a method of testing a property of a fluid specimen.

The inventions listed as Groups I and II 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 and II share a common technological feature, which is a test strip card bearing a comparison scale, a test strip comprising a reaction zone that is altered upon contact with the fluid sample, wherein the test strip is movably coupled to the test scale card adjacent the comparison scale.

However, the technological feature shared by Groups I and II is disclosed by Aronowitz et al. (US 4,877,580). Because the technological feature does not contribute over prior art, Groups I and II do not relate to a single general inventive concept.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US05/15875

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:
Please See Continuation 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 any 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.:

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.