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(54) **Diagnostic test strip for collecting and detecting an analyte in a fluid sample and method for using same**

Diagnostischer Teststreifen zum Sammeln und Bestimmen eines Analyts in einer fluiden Probe und Verfahren zur Verwendung desselben

Bande de test diagnostique pour recueillir et déterminer une analyte d'un échantillon fluide et méthode d'utilisation

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Description

FIELD OF THE INVENTION

[0001] The present invention relates generally to diagnostic instruments and, more particularly, to a diagnostic test strip for use in determining the concentration of an analyte in a liquid sample.

BACKGROUND OF THE INVENTION

[0002] Test strips *(e.g.,* biosensors) containing reagents are often used in assays for determining the concentration of an analyte in a fluid sample. Testing and self-testing for the concentration of glucose in blood is a common use for test strips. One method of obtaining a blood sample and analyzing the sample for determining the glucose level is with a lancing device and a separate blood collection device. In obtaining a blood sample, a drop of blood is obtained from the fingertip using the lancing device, and the blood is harvested using a test strip, which is then analyzed by a test unit that determines the concentration of glucose in the blood. Test strips are also used for determining the concentration or presence of various other analytes (*e.g.*, fructosamine, hemoglobin, cholesterol, glucose, alcohol, drugs including illegal drugs, *etc.*) in a variety of body fluids (*e.g.*, blood, interstitial fluid, saliva, urine, *etc.*).

[0003] A drawback associated with the use of physically separate lancing and collection devices is that a patient/user must manipulate two different instruments requiring the user/patient to bring the collection device (*e.g.*, the test strip) to the area of skin that has been lanced to collect the sample. Because the user must align the collection device with the sample to be collected, a larger than necessary amount of sample often is produced and collected to ensure an accurate analysis. In other situations, not enough sample is collected for accurate analysis because the collection device is not properly positioned. This problem can be further compounded if the user has impaired vision or poor dexterity. Because test systems are requiring smaller volumes of blood for analysis, it is difficult to position a collection instrument for proper collection.

[0004] The surface condition of the skin affects the formation of a blood droplet at the lancet site on skin. Many individuals use hand lotions, have oily or sweaty skin, or do not dry their hands completely after washing which also affects droplet formation. Often users do not always cleanse the area of skin to be lanced with alcohol. These variations increase the wettability of the skin's surface causing the droplet to spread in an uncontrolled and unpredictable manner making it difficult to harvest the sample.

[0005] Further, the collection of blood samples on alternative sites such as the forearm is complicated by the presence of body hair because the sample (e.g., blood) has a tendency to "wick up" the hairs found on these parts of the body. Cleaning the lance site with alcohol does not alleviate this wicking problem. Thus, there exists a need for a lancing and collection device that co-locates the lancet and the collection point to accurately collect a blood sample for analysis.

[0006] US 6, 206,841 B1 discloses a method and apparatus for obtaining a sample of blood from a patient for subsequent diagnostic tests, e.g., glucose monitoring. 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. The apparatus may also include a housing. In another aspect of this invention, an article is provided 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. In one embodiment, the article is a multiple-layer element comprising: (a) a layer capable of receiving blood and transporting the blood received by means of chemically aided wicking; (b) a layer capable of detecting the presence of analyte or measuring the amount of analyte in blood; and (c) a layer that can be placed in contact with a meter, the meter-contactable layer overlying the blood-transporting layer, said layer (a) capable of transporting blood to said layer (b).

[0007] WO 02/100278 A1 discloses systems and methods for the sampling of bodily fluid from an incision in the skin, including test strips which are positioned adjacent to the skin and which include features to inhibit the passage of the bodily fluid between the skin and the underside of the test strip. One system utilizes a sealing member located on the bottom surface of the test strip and positioned to provide a fluid tight seal with the skin. A second system includes a recessed surface aligned with the inlet opening of the test strip to preclude contact of the bodily fluid directly with the bottom surface of the test strip. A third system involves the use of a hydrophobic surface on the underside of the test strip to inhibit wicking of the bodily fluid along the test strip. WO 02/100278 A1 further encompasses the combination of the foregoing sampling systems with each other, and with incising, expressing and/or testing systems and methods, particularly in a single, integrated device.

SUMMARY OF THE INVENTION

[0008] A test strip for use of the determination of an analyte in a fluid sample according to one embodiment of the present invention is disclosed. The test strip comprises a base having a top and a bottom, a collection chamber that extends between the top and the bottom of the base, a containing ring that is disposed on the bottom of the base and surrounds the collection chamber, and a capillary channel formed either in top of the base, or formed on top of the base, the top of the base forming

the bottom of the capillary channel and a spacer layer forming the side walls of the capillary channel. The capillary channel has an inlet fluidly coupled to the collection chamber, a test element disposed within the capillary channel. The test strip further comprises a test area in fluid communication with the capillary channel, a test element being disposed within the test area. The capillary channel extends beyond the test area to form a vent. A lid is attached to at least a portion of the top of the base and covers at least a portion of the collection chamber, the test area, and the capillary channel.

[0009] The above summary of the present invention is not intended to represent each embodiment, or every aspect, of the present invention. Additional features and benefits of the present invention will become apparent from the detailed description, figures, and claims set forth below.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010]

FIG. 1 is an upper perspective view of a portion of a test strip according to one embodiment of the present invention.

FIG. 2 is a lower perspective view of the test strip of FIG. 1.

FIG. 3 is a perspective view of a test strip integrated into a lancing and harvesting device according to one embodiment of the present invention.

FIG. 4 is a side view of a lancing and harvesting device and end cap according to another embodiment of the present invention.

FIG. 5a-5f are oversized perspective and side views of a forward end of a lancing and harvesting device illustrating various points during the lacing of a test subject's skin and the subsequent sample harvesting according to one embodiment of the present invention.

FIG. 6 is a top perspective view of a test strip according to one embodiment of the present invention.

[0011] While the invention is susceptible to various modifications and alternative forms, specific embodiments are shown by way of example in the drawings and are described in detail herein. It should be understood, however, that the invention is not intended to be limited to the particular forms disclosed. Rather, the invention is to cover all modifications, equivalents and alternatives falling within the scope of the invention as defined by the appended claims.

DESCRIPTION OF ILLUSTRATED EMBODIMENTS

[0012] Turning now to the drawings and initially to FIGS. 1 and 2, a test strip 10 is shown according to one embodiment of the present invention. The test strip 10 includes a base 12 and a lid 14. The base 12 has a lower surface 13 and an upper surface 15. The base 12 includes a collection chamber 16, a capillary channel 18 that includes a test area 19, and a containing ring 24. The capillary channel 18 is extended beyond the test area 19 to form an optional vent 22. The lid 14 covers the collection chamber 16 and the capillary channel 18 including the test area 19. The lid 14 is adhered to the base 12 according to one embodiment of the present invention. A test element 20, which includes a regent for use in an assay, is disposed in the test area of the capillary channel 18. The test strip 10 may be incorporated into a lancing and harvesting device 26 (FIG. 4) according to one embodiment of the present invention as will be described in detail in connection with FIGS. 4-5f.

[0013] The collection chamber 16 and the capillary channel 18, which includes the test area and the vent 22 (if any), may be embossed upon the upper surface 15 of the base 12, but may also be formed in the molding of the base 12, by machining, or through another suitable manufacturing method. In the illustrated embodiment, the collection chamber 16 is a cylindrical aperture extending through the base 12. The inlet of the capillary channel 18 is formed in the side wall of the collection chamber 16. The capillary channel 18 fluidly couples the collection chamber 16 and the test area 19 containing the test element 20. The collection chamber 16, the capillary channel 18 including the test area 19, or a combination thereof may be coated with a hydrophilic material to promote movement of the fluid sample. Additionally, according to one embodiment of the present invention, the capillary channel 18 is appropriately sized to provide under-fill protection.

[0014] In one embodiment of the present invention, a test element 20 is attached to the lid 14 with an adhesive, which is substantially clear in embodiments wherein the test element 20 is optically read through the lid 14. In embodiments where the test element 20 is adhered to the lid 14, the test area 19 of the capillary channel 18 is dimensioned to provide a slight clearance between the bottom of the test area 19 and the bottom of the test element 20 so that the fluid sample is exposed to more surface area of the test element 20. Similarly, the test area 19 of the capillary channel 18 may be dimensioned to provide for clearance around the edge of the test element 20 as is shown in FIG. 1, for example. In alternative embodiments of the present invention, the test element can be attached to the base 12.

[0015] In the collection of a body fluid sample, such as blood, from a test subject, the lower surface 13 of the base 12 is placed on the test subject's skin. A containing ring 24, which surrounds the collection chamber 16 and downwardly extends from the lower surface 13 of the base 12, contacts the test subject's skin. As will be described in detail below, the test subject's skin is punctured within the periphery of the collection chamber 16. The containing ring 24 inhibits the spreading of the sample across the skin and maintains the sample within the periphery of the collection chamber 16. The containing ring

24 is formed during the molding of the base 12, is embossed upon the lower surface 13, or is otherwise attached to the lower surface 13 of the base 12 during manufacturing.

[0016] The base 12 can be composed of any suitable material such as, for example, polycarbonate, polypropylene, polystyrene, etc. The lid 14 is constructed of any suitable material as required by the nature of the analysis to be performed. For example, if an optical analysis is desired, the lid 14 may be constructed of a substantially optically clear material such as polyethylene terephthalate (PET) or polycarbonate, for example. Alternatively, for applications where the opacity of the lid 14 is not relevant, the lid 14 may be constructed of polycarbonate, polypropylene, polystyrene, and polyethylene terephthalate (PET). The lid material is substantially nonporous so that the lid does not absorb the sample; rather, the lid directs the sample to the inlet of the capillary channel 18 as described below.

[0017] The test strip 10 may be implemented into a variety of lancing devices according to alternative embodiments of the present invention. Examples of lancing devices that may be used with various embodiments of the present invention include those described in U.S. Patents Nos. 5,152,942 ("Vacuum Assisted Lancing Device"); 5,350,392 ("Lancing Device with Automatic Cocking"); and 6,364,889 ("Electronic Lancing Device"); each of which is incorporated herein by reference in its entirety. The implementation of a test strip 10 with a lancing device 26 enable the lancing device 26 to lance the skin of a test subject and to harvest the body fluid sample from the lancet site.

[0018] Referring now to FIG. 3, the forward end of a lancing and harvesting device 26 that implements a test strip 10 is shown according to one embodiment of the present invention. The test strip 10 can take on a variety of shapes and configurations to conform with numerous instrument concepts, while operating as described above. For example, while FIG. 3 shows the test strip 10 being dimensioned substantially the same as the cross-section of the end cap 30, the test strip 10 can be generally rectangular-shaped as shown in FIGS. 1-2. The test strip 10 may be attached to an end cap 30, which is removably attached to the lancing device 26. The lancing and harvesting device 26 contains a lancet 28 for puncturing both the lid 14 and the skin of the subject as is described below.

[0019] Referring now to FIG. 4, the lancing and harvesting device 26 that implements a test strip 10 is shown according to one embodiment of the present invention. The lancing assembly includes a body 32 that houses a lancing assembly 31 having a plunger 34 for driving the lancet 28. A top end 36 of the plunger 34 extends beyond the housing 32. In using the lancet 28 to puncture a test subject's skin, a user grasps the device 26 by the body 32 and depresses the top end 36 of the plunger 34—moving the plunger 34 into the body 32 of the device 26—to downwardly advance the lancet 28 into a test subject's skin. A lancet holder (not shown) is disposed within the body 32. The lancet 28 is removably attached to the lancet holder so that the lancet 28 may be detached and discarded after use. Within the housing 32, an opposite end of the lancet holder is coupled to the plunger 34. Thus, the plunger 34 moves the lancet holder which, in turn, drives the lancet 28.

[0020] The end cap 30 attaches to a forward end 40 of the device 26 opposite the plunger 34. A rim 42 of the end cap 30 removably attaches to the forward end 40 of the plunger 34. (The forward end 40 includes an O-ring according to vacuum-assisted embodiments of the lacing device 26 for forming an airtight seal between the end cap 30 and the forward end 40.) An open end 44 of the end cap 30 includes an aperture 46 through which the lancet 28 passes to puncture a test subject's skin. In one embodiment of the invention, the end cap 30 contains an aperture 45 in its sidewall for inserting and removing a test strip 10. In another embodiment of the present invention, the test strip 10 is fixedly attached to the end cap 30, which is disposable such that removing the end cap 30 also removes the used test strip 10.

[0021] During the lancing of a test subject's skin, the open end 44 of the end cap 30 is placed on an area of the test subject's skin (*e.g.,* a forearm, a finger, *etc.*). The plunger 34 is depressed to advance the lancet 28 from a retracted position wherein the lancet 28 is completely contained within the end cap 30, to a lancing position wherein the lancet 28 extends through the aperture 46 in the end cap 30. Movement of the plunger 34 by the user triggers a spring (not shown) within the body 32 of the lancing assembly 31 that rapidly advances the lancet 28 into a test subject's skin. The lancing assembly 31 includes a second spring (not shown) for moving the lancet 28 back toward the retracted position.

[0022] In the embodiment shown in FIG. 4, the lancing assembly 31 further includes an instrument 48 for reading the test strip 10 (not shown) and determining the analyte concentration in the sample. The instrument 48 includes a display 50 for communicating the results of the assay to the user. In embodiments of the present invention that do not include the instrument, a separate device is used for reading the test strip 10.

[0023] According to one embodiment of the present invention, the lancing device 26 is vacuum assisted as described in U.S. Patent No. 5,152,942 (incorporated by reference above) to facilitate the production of a blood sample at the puncture site on the test subject's skin. In such an embodiment, the rim 42 of the end cap 30 forms an airtight seal with the use of an O-ring as is described above. And an airtight seal is created between the open end 44 of the end cap 30 and the test subject's skin by pressing the end cap against the skin. The lancing assembly 31 includes a vacuum member (not shown) such as a diaphragm or bellows that displaces air within the lancing assembly and end cap 30 to form a vacuum within the end cap 30. During the lancing operation, release of the plunger 36 by the user triggers the vacuum member

which evacuates air from the end cap 30.

[0024] As discussed above, the test element 20 contains a reagent for use in determining the concentration of the analyte of interest in a sample. The reagent is designed to react with the analyte in the sample. That reaction is indicative of the analyte concentration in the sample and can be measured by an appropriate sensor. The specific reagent incorporated into the test element 20 is a function of the analyte, and the type of assay to be used for determining the concentration of the analyte.

[0025] According to one embodiment of the present invention, the reagent applied to the test element 20 is designed to produce a colorimetric reaction indicative of the analyte concentration as is known in the art. An optical readhead or detector is used to measure the degree of the color change for determining the concentration of the analyte. According to one embodiment of the present invention, a light detector is disposed within the end cap 30 of the device 26 for reading the test strip. Colorimetric testing is described in detail in U.S. Patents Nos. 6,181,417 B1 (entitled "Photometric Readhead with Light Shaping Plate"); 5,518,689 (entitled "Diffuse Light Reflectance Readhead"); and 5,611,999 (entitled "Diffuse Light Reflectance Readhead"); each of which is incorporated herein by reference in its entirety.

[0026] Alternatively, the reagent applied to the test element 20 is designed to produced an electrochemical reaction indicative of the analyte concentration in the sample as is known in the art. In an electrochemical assay, the regent is designed to react with the analyte to create an oxidation current at electrodes disposed within the test area 19 which is directly proportional to the concentration of glucose in the user's blood. The resulting current can be measured by a meter, such as a meter incorporated in to the instrument 48. Electrochemical testing is described in U.S. Patents Nos. 5,120,420 (entitled "Biosensor and a Process for Preparation Thereof'); 5,660,791 ("Fluid Testing Sensor for Use in Dispensing Instrument"); 5,759,364 (entitled "Electrochemical Biosensor"); and 5,798,031 (entitled "Electrochemical Biosensor"); each of which is incorporated herein in its entirety.

[0027] Turning now FIG. 5a, the operation of the lancing and harvesting device 26 will be described according to one embodiment of the present invention. The lancing and harvesting device 26 is placed against the test subject's skin S. The containing ring 24 contacts the skin S of the test subject. In an embodiment of the present invention wherein the lancing and harvesting device 26 is vacuum assisted, the vacuum is used to draw the skin S of the test subject into contact with the containing ring 24.

[0028] In FIG. 5 a, the lancet 28 is shown just prior to lancing the skin of the test subject. In operation, the lancet 28 passes through (*i.e.*, punctures) the lid 14 on its way the skin S of the test subject. When the skin S of the test subject is in contact with the containing ring 24, the user depresses the plunger 36 which triggers the lancing assembly 31 (FIG. 4). Upon actuation, the lancet 28 pierces the lid 14 then proceeds through the collection chamber 16 and pierces the skin S of test subject. The lance site on the test subject's skin is bounded by the collection chamber 16 (*i.e.,* within the outer periphery of the collection chamber 16).

[0029] Referring now to FIG. 5b, the device 26 is shown after piercing the lid 14 and while puncturing the test subject's skin S. After the skin S of the test subject is pierced, the lancet 28 withdraws from the subject's skin S as shown in FIG. 5c. After the withdraw of the lancet 28 from the skin S, blood B begins to fill the collection chamber 16. Upon entering the collection chamber 16, some of the blood B begins to enter the capillary channel 18. As the blood B continues to fill the capillary channel 18, the blood B contacts the lid 14 as can be seen in FIG. 5d which directs the blood B toward the inlet of the capillary channel 18. The collection chamber 16, bounded by the containing ring 24 and the lid 14, collect and contain the blood sample B. Thus, according to one embodiment of the present invention, the harvesting of the blood sample is not dependant on any particular blood droplet formation.

[0030] Referring now to FIG. 5e, upon further filling of the collection chamber 16, the blood B continues to move along the capillary channel 18 from the collection chamber 16 towards the test element 20. The blood B contacts the test element once it moves into the test area 19. According to the illustrated embodiment of the test strip 10, a vent 22 facilitates the movement of the blood B through the capillary channel 18, which allows air within the capillary channel 18 to exhaust from the channel as the blood B fills the channel 18.

[0031] As shown in FIG. 5f, after reaching the end of the capillary channel 18 the blood B enters the test area 19 and contacts the test element 20, where the blood B is absorbed. The spacing along side of the test element 20 increases the exposure of the test element 20 to the blood in the reaction area, which allows for quicker absorption of the blood B by the test element 20. Further, if desired, spacing may be provided under or above the test element 20 to further facilitate rapid absorption of the blood B as is discussed above. Once the blood B is absorbed by the test element, the blood mixes with the reagent applied to the test element 20, which produces a reaction indicative of the concentration of the analyte (e.g., glucose) in the blood. If the assay is colorimetric in nature, a light sensor disposed within the end cap 30 measures the colorimetric reaction. If the assay is electrochemical in nature, a meter measures the amount of current produced by the electrochemical reaction. After use, in one embodiment, the end cap 30 and the test strip 10 may be removed from the lancing and harvesting device 26 and discarded.

[0032] Referring now to FIG. 6, a test strip 50 according to an alternative embodiment of the present invention is shown. The test strip 50 includes a partially enclosed collection chamber 56 that is formed at one end of a base 52 of the test strip 50. The partially enclosed collection

chamber 56 may have varying degrees of closure according to alternative embodiments of the present invention. The test strip 50 includes a lid 54 having a lip 57 that extends a distanced from the lid 54. As the blood collects in the partially enclosed collection chamber 56, the blood contacts the lid 54 and lip 57 which directs the blood sample toward the inlet of the capillary channel 19.

[0033] While the test strip has been described thus far as having a two piece construction (i.e., a base 12 and a lid 14) with a capillary channel 18 formed in the base 12, the test strip 10 can have a three piece construction. In such an embodiment, a U-shaped spacer layer is disposed between the base 12 and the lid 14 and may be attached to each with an adhesive. The interior of the U-shaped spacer layer forms the side walls of a capillary channel while the lid and base form the top and bottom, respectively.

[0034] While the invention is susceptible to various modifications and alternative forms, specific embodiments thereof have been shown by way of example in the drawings and are described in detail herein. It should be understood, however, that it is not intended to limit the invention to the particular forms disclosed, but, to the contrary, the intention is to cover all modifications, equivalents and alternatives falling within the scope of the invention as defined by the appended claims.

Claims

1. A test strip (10) for use in the determination of an analyte in a fluid sample, the test strip (10) comprising:

a base (12) having a top (15) and a bottom (13);
a collection chamber (16) extending from the bottom (13) of the base (12);
a capillary channel (18)

(i) formed in top (15) of the base (12), or
(ii) formed on top (15) of base (12), the top (15) of base (12) forming the bottom of the capillary channel (18) and a spacer layer forming the side walls of the capillary channel,

the capillary channel (18) having an inlet fluidly coupled to the collection chamber (16);
a test area (19) in fluid communication with the capillary channel (18); and
a test element (20) being disposed within the test area (19);
characterized
in that the capillary channel (18) extends beyond the test area (19) to form a vent (22); and
in that the test strip (10) further comprises
a containing ring (24) disposed on the bottom (13) of the base (12), the containing ring (24) surrounding the collection chamber (16); and
a lid (14) attached to at least a portion of the top (15) of the base (12), the lid (14) covering at least a portion of the collection chamber (16), the test area (19), and the capillary channel (18).

2. The test strip (10) of claim 1 wherein the lid (14) is constructed of a substantially nonporous material.

3. The test strip (10) of claim 1 or 2 wherein the test element (20) include a reagent for producing a reaction indicative of the concentration of the analyte in the fluid sample.

4. The test strip (10) of claim one of the claims 1 to 3 in combination with a lancing device (26).

5. The test strip (10) of one of the claims 1 to 4 comprising a hydrophilic coating disposed on at least a portion of the capillary channel (18).

6. The test strip (10) of one of the claims 1 to 5 wherein the test element (20) is attached to the lid (14).

7. The test strip (10) of one of the claims 1 to 6, wherein a transverse dimension of the test area (19) is greater than a transverse dimension of the test element (20).

8. The test strip (10) of one of the claims 1 to 7, wherein a depth of the test area (19) is greater than a thickness of the test element (20).

9. The test strip (10) of one of the claims 1 to 8 wherein the containing ring (24) outwardly extends from the bottom (13) of the base (12).

10. The test strip (10) of claim 1 wherein the test area (19) includes a top (15) and a bottom (13), the test element (20) including a raised portion extending from one of the top and bottom of the test area (19), the raised portion including reagent thereon.

11. A device (26) for use in the determination of an analyte in a body fluid, the device (26) including a lancing assembly (31) having a lancet (28) for puncturing the skin of a test subject, the lancet (28) being adapted to move between a retracted position and an extended position for puncturing the skin of a test subject, the device comprising:

an end cap (30) removably attached to the lancing device (26), the end cap (30) having a rim for contacting the skin of the test subject, the lancet (28) extending beyond the rim of the end cap (30) when in the extended position; and
a test strip (10) disposed within the end cap (30), the test strip (10) including a collection chamber (16) and a capillary channel (18) fluidly coupled

to the collection chamber (16) and formed

(i) in top (15) of the base (12), or
(ii) formed on top (15) of base (12), the top (15) of base (12) forming the bottom of the capillary channel (18) and a spacer layer forming the side walls of the capillary channel,

the test strip (10) including a test area (19) in fluid communication with the capillary channel (18), a test element (20) being disposed within the test area (19), the lancet (28) puncturing the lid (14) and extending through the collection chamber (16) when moving between the retracted position and the extended position;
characterized in that
the capillary channel (18) extends beyond the test area (19) to form a vent (22); and
the test strip (10) includes a lid (14) disposed over at least a portion of the collection chamber (16) and the capillary channel (18).

12. The device (26) of claim 11 wherein the test strip (10) includes a containing ring (24) outwardly extending from a bottom (13) of the test strip (10) for contacting a test subject's skin.

13. The device (26) of claim 11 or 12 wherein the lancing assembly (31) is vacuum assisted.

14. The device (26) of one of the claims 11 to 13 wherein the lid (14) is constructed of a substantially nonporous material.

15. The device (26) of one of the claims 11 to 14 wherein the test element (19) of the test strip (10) includes a reagent for producing a reaction indicative of the concentration of the analyte in the fluid sample.

16. The device (26) of claim 15 wherein the reagent produces a colorimetric reaction, the device (26) comprising an optical device for reading the reaction.

17. The device (26) of claim 15 wherein the reagent produces an electrochemical reaction, the device (26) comprising a meter for measuring the reaction.

18. The device (26) of one of the claims 11 to 17 comprising a hydrophilic coating disposed on at least a portion of the capillary channel (18) of the test strip (10).

19. The device (26) of one of the claims 11 to 18 wherein the test element (20) is attached to the lid (14) of the test strip (10).

20. The device of one of the claims 11 to 19 wherein a transverse dimension of the test area (19) is greater than a transverse dimension of the test element (20).

21. The device (26) of one of the claims 11 to 19 wherein a depth of the test area (19) is greater than a thickness of the test element (20).

22. The device (26) of claim 11 wherein the test area (19) includes a top and a bottom, the test element (20) including a raised portion extending from one of the top and bottom of the test area (19), the raised portion including reagent thereon.

23. A method for lancing the skin of a test subject and harvesting a body fluid sample with a lancing and harvesting device (26), the lancing and harvesting device (26) having a test strip (10) including a collection chamber (16), a containing ring (24) surrounding the collection chamber (16), a capillary channel (18)

(i) formed in top (15) of the base (12), or
(ii) formed on top (15) of base (12), the top (15) of base (12) forming the bottom of the capillary channel (18) and a spacer layer forming the side walls of the capillary channel,

the capillary channel (18) having an inlet fluidly coupled to the collection chamber (16), and a lid (14) disposed over the collection chamber (16) and a least a portion of the capillary channel (18), the lancing and harvesting device (26) having a lancet (28) adapted to puncturing the lid (14) and to extend through the collection chamber (16) when moving between the retracted position and the extended position, the method comprising:

placing the containing ring (24) of the test strip (10) on the skin of the test subject;
lancing an area of the skin of the test subject bounded by the periphery of the containing ring (24);
maintaining a body fluid sample produced at the lance site within the periphery of the containing ring (24);
collecting the body fluid sample produced at the lance site with the test strip (10);
directing, with the lid (14), at least a portion of the body fluid sample from the collection chamber (16) toward an inlet of the capillary channel (18); and
directing at least a portion of the body fluid sample from the capillary channel (18) to a test area (19) in fluid communication with the capillary channel (18), the capillary channel (18) extending beyond the test area (19) to form a vent (22).

24. The method of claim 23 comprising measuring the

concentration of an analyte in the collected body fluid sample, wherein measuring further comprises reacting the analyte in the collected body fluid sample with a reagent, the reagent being disposed on a test element (20) received in the capillary channel (18) of the test strip (10).

Patentansprüche

1. Teststreifen (10) zur Verwendung bei der Bestimmung eines Analyts in einer Fluidprobe, wobei der Teststreifen (10) Folgendes umfasst:

eine Basis (12) mit einer Oberseite (15) und einer Unterseite (13);
eine Sammelkammer (16), die sich von Unterseite (13) der Basis (12) aus erstreckt;
einen Kapillarkanal (18), der

(i) in der Oberseite (15) der Basis (12) ausgebildet ist oder
(ii) auf der Oberseite (15) der Basis (12) ausgebildet ist, wobei die Oberseite (15) der Basis (12) die Unterseite des Kapillarkanals (18) bildet und eine Abstandsschicht die Seitenwände des Kapillarkanals bildet,

wobei der Kapillarkanal (18) einen Einlass aufweist, der in Fluidverbindung mit der Sammelkammer (16) steht;
einen Testbereich (19) in Fluidkommunikation mit dem Kapillarkanal (18); und
ein Testelement (20), das innerhalb des Testbereichs (19) angeordnet ist;
dadurch gekennzeichnet, dass
der Kapillarkanal (18) sich über den Testbereich (19) hinaus erstreckt, um eine Entlüftungsöffnung (22) zu bilden;
und
der Teststreifen (10) weiters Folgendes umfasst:

einen Einschlussring (24), der an der Unterseite (13) der Basis (12) angeordnet ist, wobei der Einschlussring (24) die Sammelkammer (16) umgibt; und
einen Deckel (14), der an zumindest einem Teil der Oberseite (15) der Basis (12) befestigt ist, wobei der Deckel (14) zumindest einen Abschnitt der Sammelkammer (16), des Testbereichs (19) und des Kapillarkanals (18) abdeckt.

2. Teststreifen (10) nach Anspruch 1, wobei der Deckel (14) aus einem im Wesentlichen nichtporösen Material besteht.

3. Teststreifen (10) nach Anspruch 1 oder 2, wobei das Testelement (20) ein Reagens zur Erzeugung einer Reaktion umfasst, welche die Konzentration des Analyts in der Fluidprobe anzeigt.

4. Teststreifen (10) nach einem der Ansprüche 1 bis 3 in Kombination mit einer Stechvorrichtung (26).

5. Teststreifen (10) nach einem der Ansprüche 1 bis 4, der eine hydrophile Beschichtung umfasst, die auf zumindest einem Abschnitt des Kapillarkanals (18) aufgebracht ist.

6. Teststreifen (10) nach einem der Ansprüche 1 bis 5, wobei das Testelement (20) am Deckel (14) befestigt ist.

7. Teststreifen (10) nach einem der Ansprüche 1 bis 6, wobei die Querabmessung des Testbereichs (19) größer ist als die Querabmessung des Testelements (20).

8. Teststreifen (10) nach einem der Ansprüche 1 bis 7, wobei die Tiefe des Testbereichs (19) größer ist als die Dicke des Testelements (20).

9. Teststreifen (10) nach einem der Ansprüche 1 bis 8, wobei sich der Einschlussring (24) von der Unterseite (13) der Basis (12) aus nach außen hin erstreckt.

10. Teststreifen (10) nach Anspruch 1, wobei der Testbereich (19) eine Oberseite (15) und eine Unterseite (13) aufweist, wobei das Testelement (20) einen erhöhten Abschnitt umfasst, der sich von der Oberseite oder Unterseite des Testbereichs (19) aus erstreckt, wobei auf dem erhöhten Abschnitt ein Reagens vorhanden ist.

11. Vorrichtung (26) zur Verwendung bei der Bestimmung eines Analyts in einer Körperflüssigkeit, wobei die Vorrichtung (26) eine Stechanordnung (31) mit einer Lanzette (28) zur Punktion der Haut eines Testindividuums umfasst, wobei die Lanzette (28) zur Bewegung zwischen einer eingefahrenen Position und einer ausgefahrenen Position zum Punktieren der Haut eines Testindividuums ausgebildet ist, wobei die Vorrichtung Folgendes umfasst:

eine Endkappe (30), die abnehmbar an der Stechvorrichtung (26) angebracht ist, wobei die Endkappe (30) einen Rand aufweist, der mit der Haut des Testindividuums in Kontakt gebracht wird, wobei sich die Lanzette (28) in der ausgefahrenen Position über den Rand der Endkappe (30) hinaus erstreckt; und
einen Teststreifen (10), der innerhalb der Endkappe (30) angeordnet ist, wobei der Teststreifen (10) eine Sammelkammer (16) und einen

Kapillarkanal (18), der in Fluidverbindung mit der Sammelkammer (16) steht und

(i) in der Oberseite (15) der Basis (12) ausgebildet ist oder
(ii) auf der Oberseite (15) der Basis (12) ausgebildet ist, wobei die Oberseite (15) der Basis (12) die Unterseite des Kapillarkanals (18) bildet und eine Abstandsschicht die Seitenwände des Kapillarkanals bildet, umfasst,

wobei der Teststreifen (10) einen Testbereich (19) in Fluidkommunikation mit dem Kapillarkanal (18) umfasst, wobei ein Testelement (20) innerhalb des Testbereichs (19) angeordnet ist, wobei die Lanzette (28) den Deckel (14) durchsticht und sich durch die Sammelkammer (16) hindurch erstreckt, wenn sie sich zwischen der eingefahrenen Position und der ausgefahrenen Position bewegt;
dadurch gekennzeichnet, dass
der Kapillarkanal (18) sich über den Testbereich (19) hinaus erstreckt, um eine Entlüftungsöffnung (22) zu bilden; und
der Teststreifen (10) einen Deckel (14) umfasst, der zumindest einen Abschnitt der Sammelkammer (16) und des Kapillarkanals (18) abdeckt.

12. Vorrichtung (26) nach Anspruch 11, wobei der Teststreifen (10) einen Einschlussring (24) umfasst, der sich von der Unterseite (13) des Teststreifens (10) aus nach außen hin erstreckt, um mit der Haut eines Testindividuums in Kontakt gebracht zu werden.

13. Vorrichtung (26) nach Anspruch 11 oder 12, wobei die Stechvorrichtung (31) vakuumgestützt ist.

14. Vorrichtung (26) nach einem der Ansprüche 11 bis 13, wobei der Deckel (14) aus einem im Wesentlichen nichtporösen Material besteht.

15. Vorrichtung (26) nach einem der Ansprüche 11 bis 14, wobei das Testelement (19) des Teststreifens (10) ein Reagens zur Erzeugung einer Reaktion umfasst, welche die Konzentration des Analyts in der Fluidprobe anzeigt.

16. Vorrichtung (26) nach Anspruch 15, wobei das Reagens eine kolorimetrische Reaktion erzeugt, wobei die Vorrichtung (26) eine optische Vorrichtung zum Ablesen der Reaktion umfasst.

17. Vorrichtung (26) nach Anspruch 15, wobei das Reagens eine elektrochemische Reaktion erzeugt, wobei die Vorrichtung (26) ein Messgerät zur Messung der Reaktion umfasst.

18. Vorrichtung (26) nach einem der Ansprüche 11 bis 17, die eine hydrophile Beschichtung umfasst, die auf zumindest einem Abschnitt des Kapillarkanals (18) des Teststreifens (10) aufgebracht ist.

19. Vorrichtung (26) nach einem der Ansprüche 11 bis 18, wobei das Testelement (20) am Deckel (14) des Teststreifens (10) befestigt ist.

20. Vorrichtung (26) nach einem der Ansprüche 11 bis 19, wobei die Querabmessung des Testbereichs (19) größer ist als die Querabmessung des Testelements (20).

21. Vorrichtung (26) nach einem der Ansprüche 11 bis 19, wobei die Tiefe des Testbereichs (19) größer ist als die Dicke des Testelements (20).

22. Vorrichtung (26) nach Anspruch 11, wobei der Testbereich (19) eine Oberseite und eine Unterseite aufweist, wobei das Testelement (20) einen erhöhten Abschnitt umfasst, der sich von der Oberseite oder Unterseite des Testbereichs (19) aus erstreckt, wobei auf dem erhöhten Abschnitt ein Reagens vorhanden ist.

23. Verfahren zum Durchstechen der Haut eines Testindividuums und Entnehmen einer Körperflüssigkeitsprobe mit einer Stech- und Entnahmevorrichtung (26), wobei die Stech- und Entnahmevorrichtung (26) einen Teststreifen (10) mit einer Sammelkammer (16), einem Einschlussring (24), der die Sammelkammer (16) umgibt, einem Kapillarkanal (18), der

(i) in der Oberseite (15) der Basis (12) ausgebildet ist oder
(ii) auf der Oberseite (15) der Basis (12) ausgebildet ist, aufweist, wobei die Oberseite (15) der Basis (12) die Unterseite des Kapillarkanals (18) bildet und eine Abstandsschicht die Seitenwände des Kapillarkanals bildet,

wobei der Kapillarkanal (18) einen Einlass, der in Fluidverbindung mit der Sammelkammer (16) steht, und einen Deckel (14) aufweist, der über der Sammelkammer (16) und zumindest einem Abschnitt des Kapillarkanals (18) angeordnet ist, aufweist, wobei die Stech- und Entnahmevorrichtung (26) eine Lanzette (28) aufweist, die ausgebildet ist, um den Deckel (14) zu durchstechen und sich durch die Sammelkammer (16) hindurch zu erstrekken, wenn sie sich zwischen der eingefahrenen Position und der ausgefahrenen Position bewegt, wobei das Verfahren Folgendes umfasst:

das Platzieren des Einschlussrings (24) des Teststreifens (10) auf der Haut des Testindivi-

duums;
das Punktieren eines Bereichs der Haut des Testindividuums, der vom Umfang des Einschlussrings (24) begrenzt wird;
das Halten einer Körperflüssigkeitsprobe, die an der Punktierstelle gewonnen wird, innerhalb des Umfangs des Einschlussrings (24);
das Entnehmen der an der Punktierstelle gewonnenen Körperflüssigkeitsprobe mit dem Teststreifen (10);
das Leiten, mithilfe des Deckels (14), zumindest eines Teils der Körperflüssigkeitsprobe von der Sammelkammer (16) zu einem Einlass des Kapillarkanals (18); und
das Leiten zumindest eines Teils der Körperflüssigkeitsprobe vom Kapillarkanal (18) zu einem Testbereich (19), der in Fluidkommunikation mit dem Kapillarkanal (18) ist, wobei sich der Kapillarkanal (18) zwischen über Testbereich hinaus erstreckt, um eine Entlüftungsöffnung (22) zu bilden.

24. Verfahren nach Anspruch 23, welches das Messen der Konzentration eines Analyts in der entnommenen Körperflüssigkeitsprobe umfasst, wobei das Messen weiters das Umsetzen des Analyts in der entnommenen Körperflüssigkeitsprobe mit einem Reagens umfasst, wobei das Reagens auf einem Testelement (20) angeordnet ist, das im Kapillarkanal (18) des Teststreifens (10) aufgenommen ist.

Revendications

1. Bande de test (10) destinée à être utilisée pour déterminer un analyte dans un échantillon de fluide, la bande de test (10) comprenant :

une base (12) ayant une partie supérieure (15) et une partie inférieure (13) ;
une chambre de collecte (16) s'étendant depuis la partie inférieure (13) de la base (12) ;
un canal capillaire (18)

(i) formé dans la partie supérieure (15) de la base (12), ou bien
(ii) formé sur la partie supérieure (15) de la base (12), la partie supérieure (15) de la base (12) formant la partie inférieure du canal capillaire (18) et une couche d'espacement formant les parois latérales du canal capillaire,

le canal capillaire (18) ayant une entrée couplée de manière fluide à la chambre de collecte (16) ;
une zone de test (19) en communication de fluide avec le canal capillaire (18) ; et
un élément de test (20) étant disposé dans la zone de test (19) ;
caractérisée en ce que le canal capillaire (18) s'étend au-delà de la zone de test (19) afin de former un évent (22) ; et
en ce que la bande de test (10) comprend en outre :

une bague de confinement (24) disposée sur la partie inférieure (13) de la base (12), la bague de confinement (24) entourant la chambre de collecte (16) ; et
un couvercle (14) fixé au moins sur une partie de la partie supérieure (15) de la base (12), le couvercle (14) recouvrant au moins une partie de la chambre de collecte (16), de la zone de test (19) et du canal capillaire (18).

2. Bande de test (10) selon la revendication 1, dans laquelle le couvercle (14) est construit à partir d'un matériau sensiblement non poreux.

3. Bande de test (10) selon la revendication 1 ou 2, dans lequel l'élément de test (20) comprend un produit réactif pour produire une réaction indiquant la concentration de l'analyte dans l'échantillon de fluide.

4. Bande de test (10) selon l'une quelconque des revendications 1 à 3, en combinaison avec un autopiqueur (26).

5. Bande de test (10) selon l'une quelconque des revendications 1 à 4, comprenant un revêtement hydrophile disposé sur au moins une partie du canal capillaire (18).

6. Bande de test (10) selon l'une quelconque des revendications 1 à 5, dans laquelle l'élément de test (20) est fixé sur le couvercle (14).

7. Bande de test (10) selon l'une quelconque des revendications 1 à 6, dans laquelle une dimension transversale de la zone de test (19) est supérieure à une dimension transversale de l'élément de test (20).

8. Bande de test (10) selon l'une quelconque des revendications 1 à 7, dans laquelle une profondeur de la zone de test (19) est supérieure à une épaisseur de l'élément de test (20).

9. Bande de test (10) selon l'une quelconque des revendications 1 à 8, dans laquelle la bague de confinement (24) s'étend vers l'extérieur à partir de la partie inférieure (13) de la base (12).

10. Bande de test (10) selon la revendication 1, dans

laquelle la zone de test (19) comprend une partie supérieure (15) et une partie inférieure (13), l'élément de test (20) comprenant une partie relevée s'étendant à partir de l'une parmi la partie supérieure et la partie inférieure de la zone de test (19), la partie relevée comprenant un produit réactif sur celle-ci.

11. Dispositif (26) destiné à être utilisé pour déterminer un analyte dans un fluide corporel, le dispositif (26) comprenant un autopiqueur (31) ayant une lancette (28) pour piquer la peau d'un sujet de test, la lancette (28) étant adaptée pour se déplacer entre une position rétractée et une position étendue afin de piquer la peau d'un sujet de test, le dispositif comprenant :

un capuchon d'extrémité (30) fixé de manière amovible sur l'autopiqueur (26), le capuchon d'extrémité (30) ayant un bord pour entrer en contact avec la peau du sujet de test, la lancette (28) s'étendant au-delà du bord du capuchon d'extrémité (30) lorsqu'elle est dans la position étendue ; et
une bande de test (10) disposée à l'intérieur du capuchon d'extrémité (30), la bande de test (10) comprenant une chambre de collecte (16) et un canal capillaire (18) couplé de manière fluide à la chambre de collecte (16) et formé :

(i) dans la partie supérieure (15) de la base (12), ou bien
(ii) formé sur la partie supérieure (15) de la base (12), la partie supérieure (15) de la base (12) formant la partie inférieure du canal capillaire (18) et une couche d'espacement formant les parois latérales du canal capillaire,

la bande de test (10) comprenant une zone de test (19) en communication de fluide avec le canal capillaire (18), un élément de test (20) étant disposé à l'intérieur de la zone de test (19), la lancette (28) perforant le couvercle (14) et s'étendant à travers la chambre de collecte (16) lorsqu'elle passe de la position rétractée à la position étendue ;
caractérisé en ce que :
le canal capillaire (18) s'étend au-delà de la zone de test (19) afin de former un évent (22) ; et
la bande de test (10) comprend un couvercle (14) disposé sur au moins une partie de la chambre de collecte (16) et le canal capillaire (18).

12. Dispositif (26) selon la revendication 11, dans lequel la bande de test (10) comprend une bague de confinement (24) s'étendant vers l'extérieur à partir d'une partie inférieure (13) de la bande de test (10) pour entrer en contact avec la peau d'un sujet de test.

13. Dispositif (26) selon la revendication 11 ou 12, dans lequel l'autopiqueur (31) est assisté par vide.

14. Dispositif (26) selon l'une quelconque des revendications 11 à 13, dans lequel le couvercle (14) est construit avec un matériau sensiblement non poreux.

15. Dispositif (26) selon l'une quelconque des revendications 11 à 14, dans lequel l'élément de test (19) de la bande de test (10) comprend un produit réactif pour produire une réaction indiquant la concentration de l'analyte dans l'échantillon de fluide.

16. Dispositif (26) selon la revendication 15, dans lequel le produit réactif comprend une réaction colorimétrique, le dispositif (26) comprenant un dispositif optique pour lire la réaction.

17. Dispositif (26) selon la revendication 15, dans lequel le produit réactif produit une réaction électrochimique, le dispositif (26) comprenant un dispositif de mesure pour mesurer la réaction.

18. Dispositif (26) selon l'une quelconque des revendications 11 à 17, comprenant un revêtement hydrophile disposé sur au moins une partie du canal capillaire (18) de la bande de test (10).

19. Dispositif (26) selon l'une quelconque des revendications 11 à 18, dans lequel l'élément de test (20) est fixé sur le couvercle (14) de la bande de test (10).

20. Dispositif selon l'une quelconque des revendications 11 à 19, dans lequel une dimension transversale de la zone de test (19) est supérieure à une dimension transversale de l'élément de test (20).

21. Dispositif (26) selon l'une quelconque des revendications 11 à 19, dans lequel une profondeur de la zone de test (19) est supérieure à une épaisseur de l'élément de test (20).

22. Dispositif (26) selon la revendication 11, dans lequel la zone de test (19) comprend une partie supérieure et une partie inférieure, l'élément de test (20) comprenant une partie relevée s'étendant à partir de l'une parmi la partie supérieure et la partie inférieure de la zone de test (19), la partie relevée comprenant un produit réactif sur celle-ci.

23. Procédé pour piquer la peau d'un sujet de test et collecter un échantillon de fluide corporel avec un autopiqueur et un dispositif de collecte (26), l'autopiqueur et le dispositif de collecte (26) ayant une bande de test (10) comprenant une chambre de collecte (16), une bague de confinement (24) entourant la chambre de collecte (16), un canal capillaire (18)

(i) formé dans la partie supérieure (15) de la base (12), ou bien
(ii) formé sur la partie supérieure (15) de la base (12), la partie supérieure (15) de la base (12) formant la partie inférieure du canal capillaire (18) et une couche d'espacement formant les parois latérales du canal capillaire,

le canal capillaire (18) ayant une entrée couplée de manière fluide à la chambre de collecte (16) et un couvercle (14) disposé sur la chambre de collecte (16) et au moins une partie du canal capillaire (18), l'autopiqueur et le dispositif de collecte (26) ayant une lancette (28) adaptée pour perforer le couvercle (14) et s'étendre à travers la chambre de collecte (16) lorsqu'elle passe de la position rétractée à la position étendue, le procédé comprenant les étapes consistant à :

placer la bague de confinement (24) de la bande de test (10) sur la peau du sujet de test ;
piquer une surface de la peau du sujet de test reliée par la périphérie de la bague de confinement (24) ;
maintenir un échantillon de fluide corporel produit au niveau du site de perforation à l'intérieur de la périphérie de la bague de confinement (24) ;
collecter l'échantillon de fluide corporel produit au niveau du site de perforation avec la bande de test (10) ;
diriger, avec le couvercle (14), au moins une partie de l'échantillon de fluide corporel de la chambre de collecte (16) vers une entrée du canal capillaire (18) ; et
diriger au moins une partie de l'échantillon de fluide corporel du canal capillaire (18) jusqu'à une zone de test (19) en communication de fluide avec le canal capillaire (18), le canal capillaire (18) s'étendant au-delà de la zone de test (19) afin de former un évent (22).

24. Procédé selon la revendication 23, comprenant l'étape consistant à mesurer la concentration d'un analyte dans l'échantillon de fluide corporel collecté, dans lequel l'étape de mesure comprend en outre l'étape consistant à faire réagir l'analyte dans l'échantillon de fluide corporel collecté avec un produit réactif, le produit réactif étant disposé sur un élément de test (20) reçu dans le canal capillaire (18) de la bande de test (10).

Fig. 1

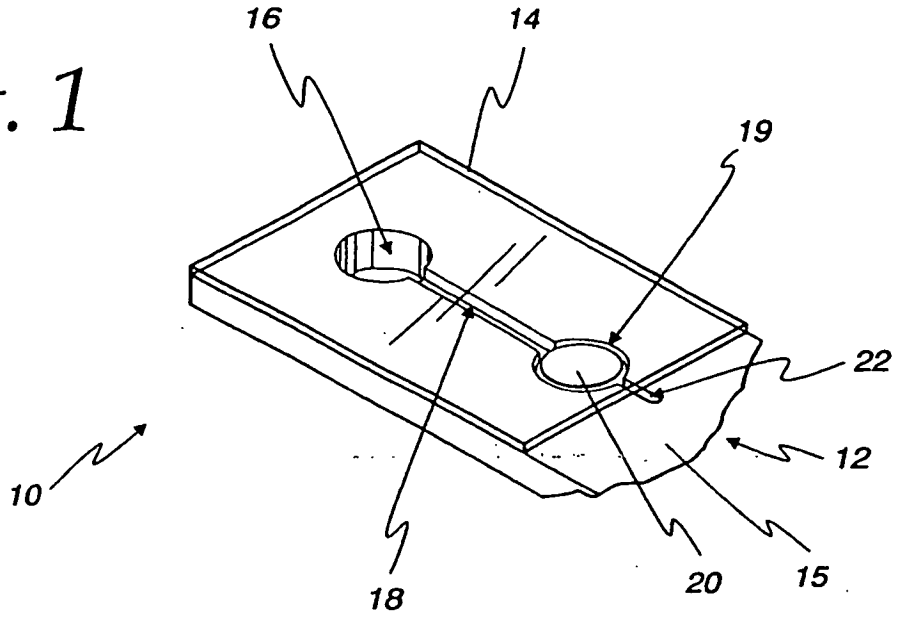


Fig. 2

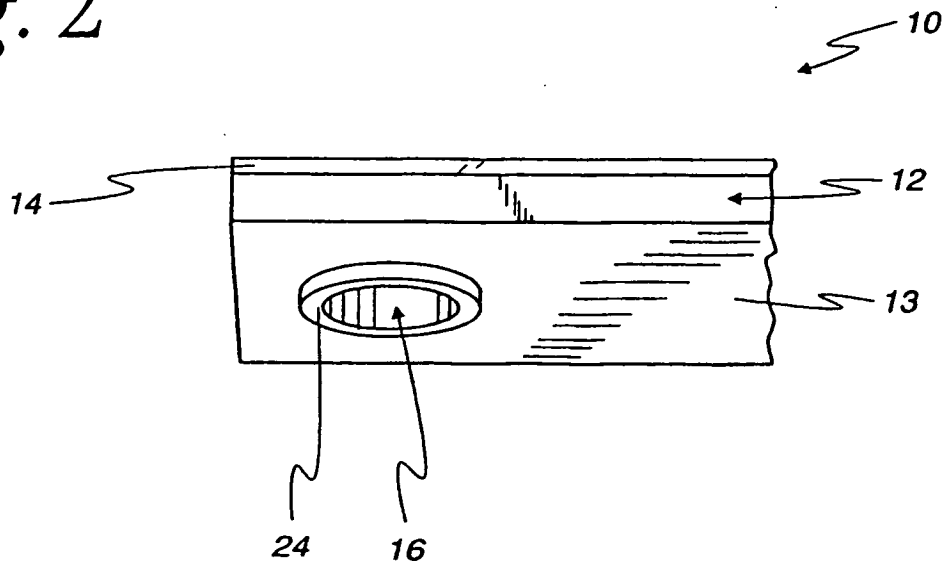


Fig. 3

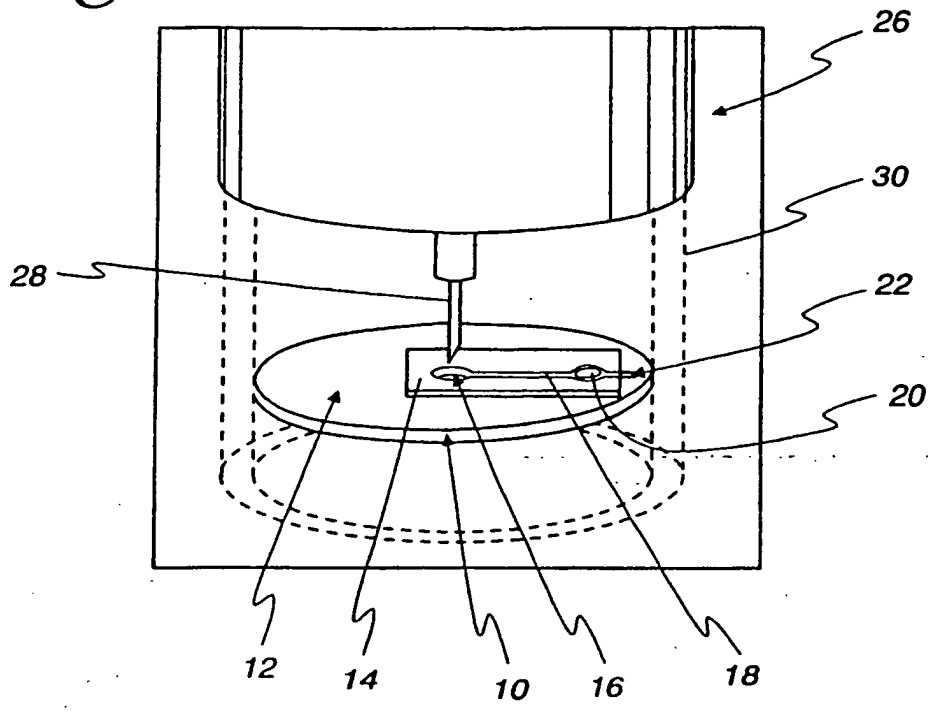


Fig. 6

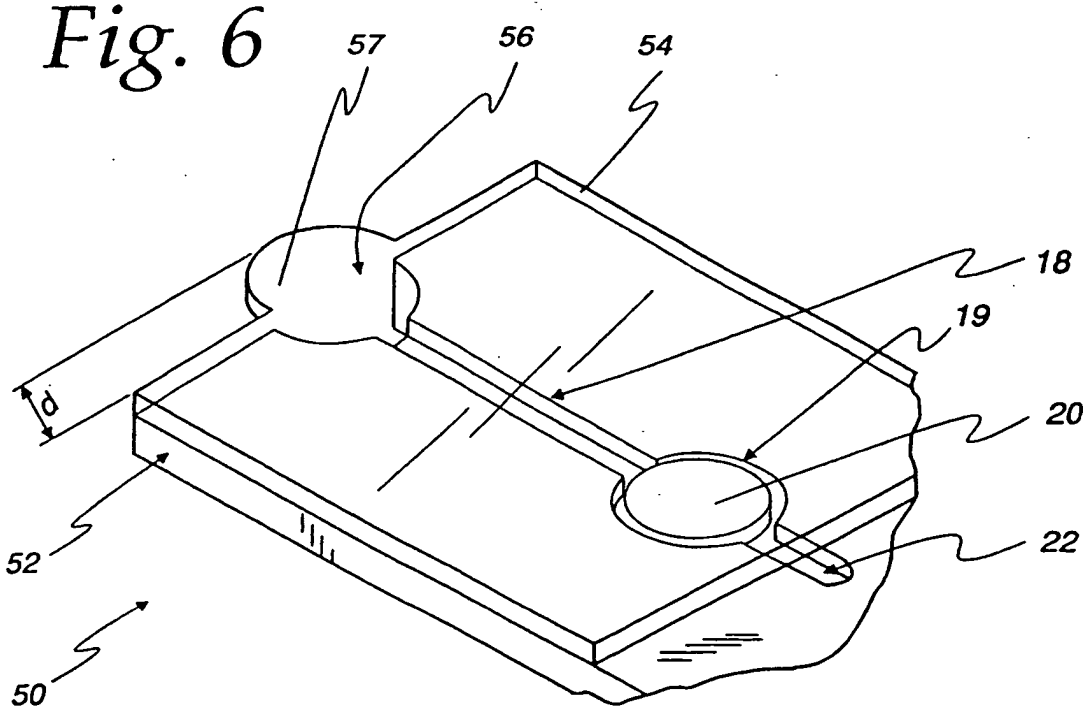


Fig. 4

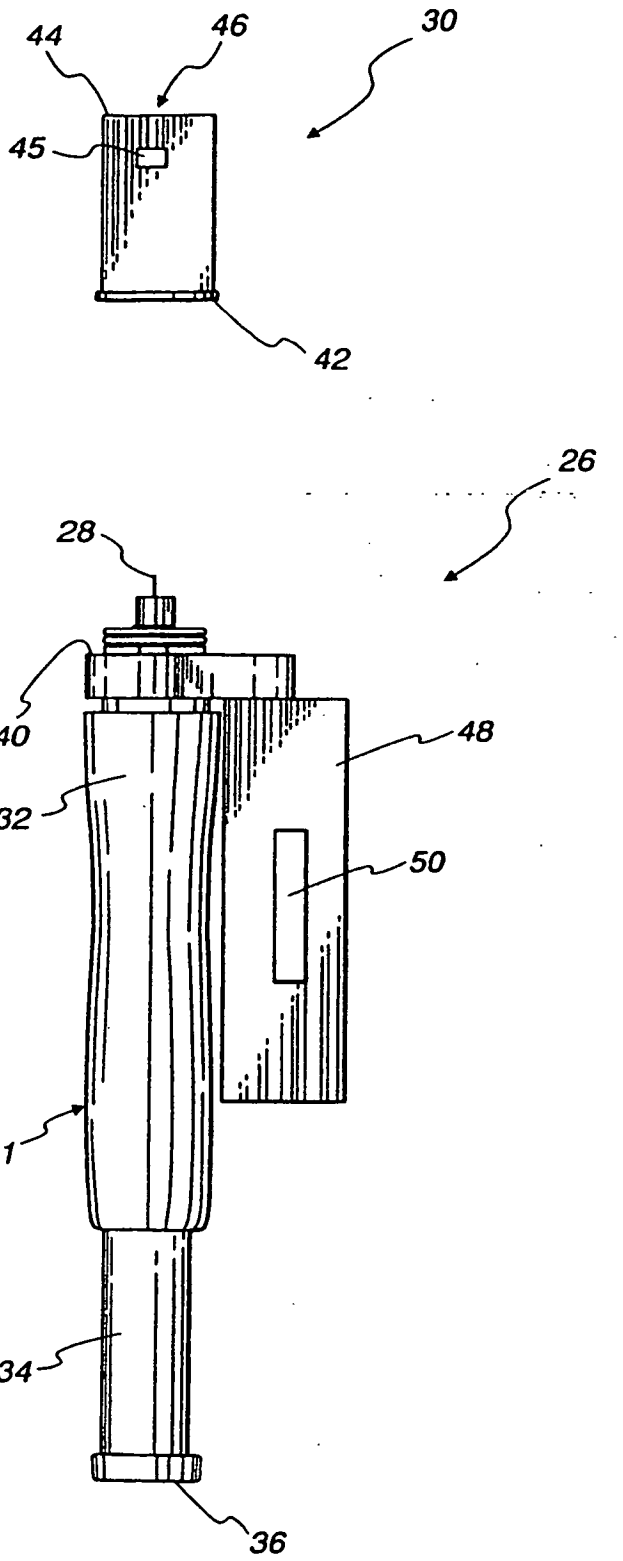


Fig. 5a

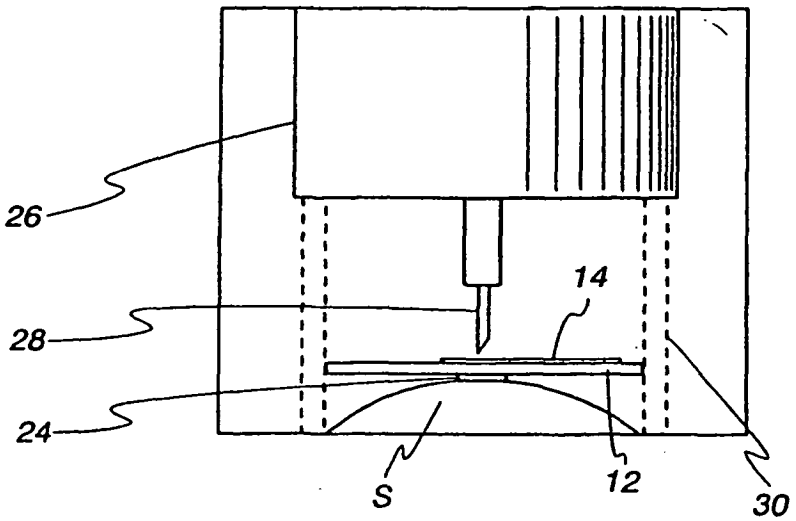


Fig. 5b

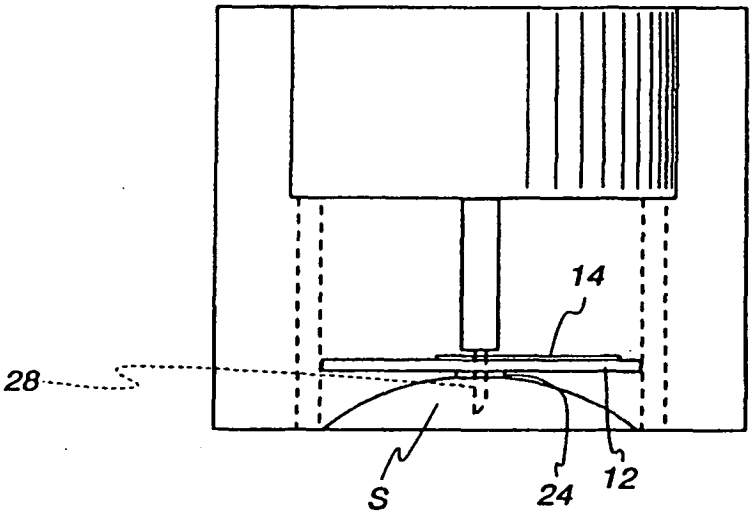


Fig. 5c

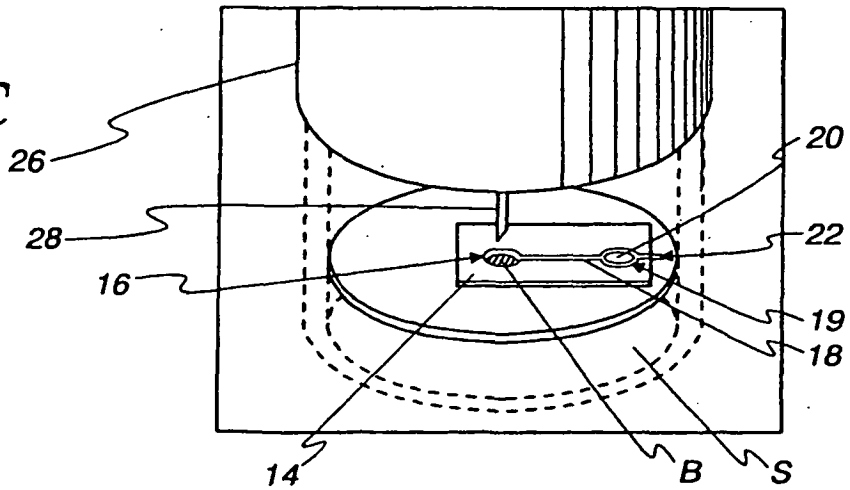


Fig. 5d

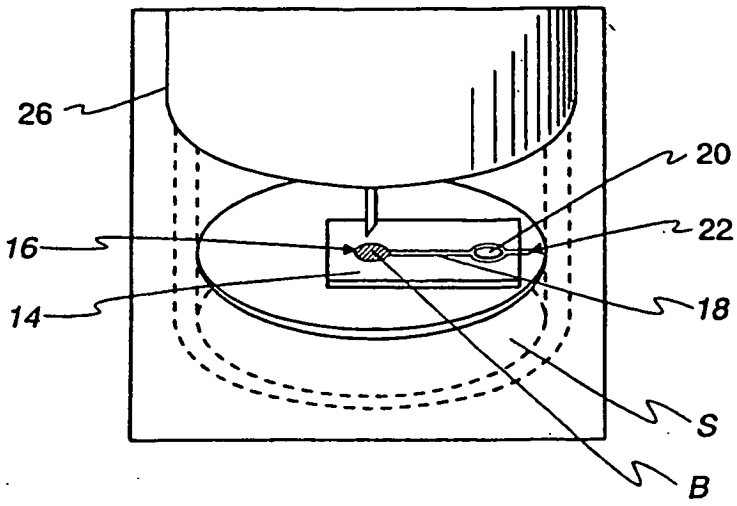


Fig. 5e

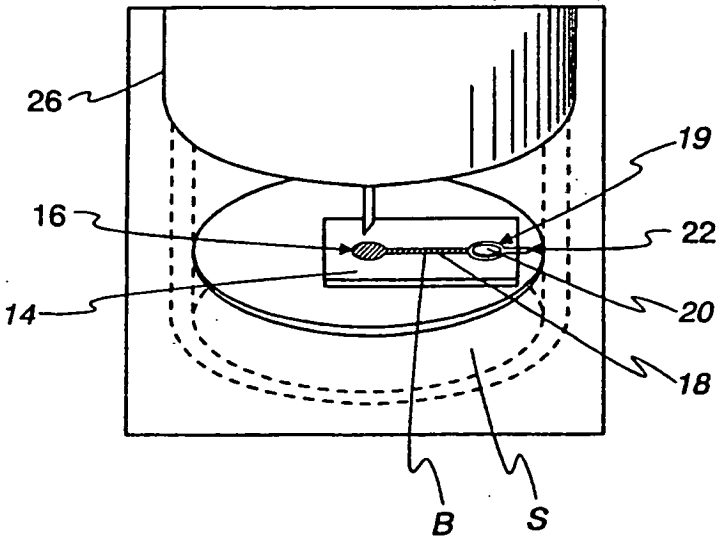
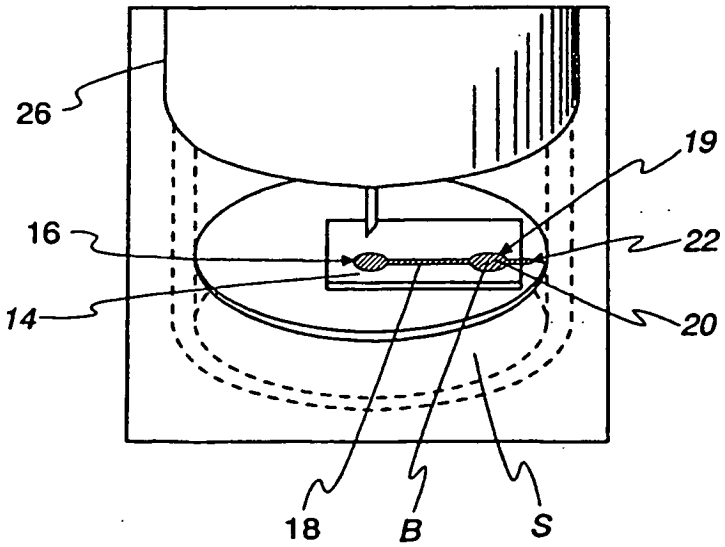


Fig. 5f



REFERENCES CITED IN THE DESCRIPTION

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- US 5759364 A **[0026]**
- US 5798031 A **[0026]**

专利名称(译)	用于收集和检测流体样品中的分析物的诊断测试条及其使用方法		
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摘要(译)

公开了一种用于根据本发明的一个实施方案测定流体样品中的分析物的测试条。测试条包括具有顶部和底部的基部，在基部的顶部和底部之间延伸的收集室，设置在基部的底部并围绕收集室的容纳环，以及毛细管通道形成在基座顶部的，其具有流体连接到收集室的入口，测试元件设置在毛细管通道内。盖子连接到基座的顶部并覆盖收集室，测试膜和毛细管通道的至少一部分。

Fig. 1

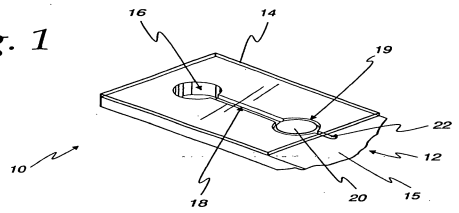

Fig. 2