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(54) **Containers for reading and handling diagnostic reagents and methods of using the same**

Behälter zum Auslesen und zur Verarbeitung diagnostischer Reagenzien und Verfahren zu dessen Verwendung

Boîtier de lecture et de traitement de réactifs de diagnostiques et procédé d'utilisation

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(73) Proprietor: **Bayer HealthCare LLC**
Tarrytown, NY 10591 (US)

(72) Inventor: **Charlton, Steven C.**
Osceola
46561 Indiana (US)

(74) Representative: **Linhart, Angela et al**
Bayer HealthCare AG
CAO Law & Patents
Patents & Licensing
51368 Leverkusen (DE)

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Description

FIELD OF THE INVENTION

[0001] The present invention relates to containers for reading and handling diagnostic reagents and methods of using the same. More specifically, the present invention relates to containers that use tape that includes diagnostic reagents, and methods of using the same.

BACKGROUND OF THE INVENTION

[0002] The quantitative determination of analytes in body fluids is of great importance in the diagnoses and maintenance of certain physiological abnormalities. For example, lactate, fructosamine, cholesterol; bilirubin, alcohol, and drugs may be monitored or tested in certain individuals. The monitored or tested body fluids may include blood, interstitial fluid, saliva, or urine. In particular, determining glucose in body fluids is important to diabetic individuals who must frequently check the glucose level in their body fluids to regulate the glucose intake in their diets.

There have been existing containers that have included reagents in tape form. These containers, however, have one or more disadvantages. For example, one disadvantage of existing containers is that the test sensors must be delivered from the container. In such containers, the used sensors are not stored in the container and, thus, may not allow for a convenient and/or safe disposal. Other disadvantages of existing containers include not (a) adequately providing protection against environmental moisture that degrades the reagent and/or (b) keeping the reagent-sensing device adequately clean and protecting it from wear and tear of normal usage.

[0003] WO02/100274 A1 discloses a bodily fluid sampling device and test media cassette to be used with such a device. The cassette includes a test media tape, which has a contaminated section that is contaminated with past samples of the bodily fluid and an uncontaminated section. The cassette includes a housing that has a supply portion in which the uncontaminated section of the test media tape is enclosed. The housing further includes a storage portion in which the contaminated section of the test media tape is enclosed. The housing defines an exposure opening along the test media tape at which the test media tape is exposed to the bodily fluid. A supply reel is disposed in the supply portion of the housing around which the uncontaminated section of the test media tape is wrapped. A storage reel is disposed in the storage portion of the housing around which the contaminated section of the test media tape is wrapped.

[0004] DE 198 49 539 A1 discloses a portable blood glucose measuring device. The blood glucose measuring device comprises a cassette with a continuoes tape which is wrapped around a dispensing reel and a disposal reel within the cassette. A drop of blood of a test person can be provided onto the tape and the blood glucose in the blood is measured without removing the cassette from the measuring device.

[0005] It would be desirable to provide a container that detects an analyte concentration such as glucose that overcomes the above-noted shortcomings.

SUMMARY OF THE INVENTION

[0006] According to the invention a container with a rotatable lid for reading and handling diagnostic reagents in tape form comprises a body portion, a lid portion, a continuous tape, a reagent-sensing device, and a storage device. The body portion includes an inner and outer surface. The lid portion is attached to the body portion and is adapted to rotate from a closed position to an open position. The continuous tape includes a diagnostic reagent. The reagent-sensing device is attached to either the body portion or the lid portion and adapted to read the diagnostic reagent. The storage device is attached to the body portion that is adapted to hold and dispense an unused portion of the continuous tape. During the rotation of the lid portion, the continuous tape is advanced from the first storage device and is extended over the reagent-sensing device.

[0007] According to a preferred embodiment, a container with a rotatable lid for reading and handling diagnostic reagents in tape form comprises a body portion, a lid portion, a continuous tape, a reagent-sensing device, a first storage device, and a s econd s torage device. The body portion includes an inner and outer surface. The lid portion is attached to the body portion and is adapted to rotate from a closed position to an open position. The continuous tape includes a diagnostic reagent. The reagent-sensing device is attached to either the body portion or the lid portion and adapted to read the diagnostic reagent. The first storage device is attached to the body portion that is adapted to hold and dispense an unused portion of the continuous tape. The second storage device is attached to the lid portion that is adapted to receive a used portion of the continuous tape. During the rotation of the lid portion, the continuous tape is advanced from the first storage device and is extended over the reagent-sensing device and received by the second storage device.

[0008] According to a preferred embodiment, a container with a rotatable lid for reading and handling diagnostic reagents adapted to determine glucose concentration in tape form comprises a body portion, a lid portion, a continuous tape, a reagent-sensing device, and a first storage device. The body portion includes an inner and outer surface. The lid portion is attached to the body portion and is adapted to rotate from a closed position to an open position. The continuous tape includes a diagnostic reagent to determine glucose concentration. The reagent-sensing device is attached to either the body portion or the lid portion and adapted to read the diagnostic reagent. The first storage device is attached to the body portion that is adapted to hold and dispense an unused

portion of the continuous tape. During the rotation of the lid portion, the continuous tape is advanced from the first storage device and is extended over the reagent-sensing device..

[0009] According to the method of the invention, a container with a rotatable lid for reading and handling diagnostic reagents in tape form comprises providing a rotatable container. The rotatable container comprises a body portion, a lid portion, a continuous tape, a reagent-sensing device and a first storage device. The body portion includes an inner and outer surface. The lid portion is attached to the body portion. The continuous tape includes a diagnostic reagent. The reagent-sensing device is attached to either the body portion or the lid portion and adapted to read the diagnostic reagent. The first storage device is attached to the body portion and is adapted to hold and dispense an unused portion of the continuous tape. The lid is rotated from a closed position to an open position. The continuous tape is advanced from the first storage device to extend over the reagent-sensing device during the rotation of the lid portion.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] Other advantages of the invention will become apparent upon reading the following detailed description and upon reference to the drawings in which:

FIG. 1 is a rotatable container shown in a closed position according to one embodiment of the present invention;
FIG. 2 is the rotatable container of FIG. 1 shown in an open position;
FIG. 3 is a rotatable container shown in a closed position according to another embodiment of the present invention; and
FIG. 4 is the rotatable container of FIG. 3 shown in an open position.

[0011] 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 will herein be described in detail. It should be understood, however, that it is not intended to limit the invention to the particular forms disclosed but, on the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the appended claims.

DETAILED DESCRIPTION OF THE ILLUSTRATED EMBODIMENT

[0012] The present invention is directed to containers for reading and handling diagnostic reagents in tape form and methods of using the same. The diagnostic reagents may be independently selected to test one or more analytes such as glucose, lactate, fructosamine, cholesterol, bilirubin, alcohol and/or drugs. It is contemplated that other analytes may be tested using the containers of the present invention. The body fluids to be tested may include blood, interstitial fluid, saliva, or urine. It is contemplated that other fluids may be tested using the containers of the present invention. One commonly tested analyte is glucose in a whole blood sample.

[0013] The containers of the present invention comprise a body portion, a lid portion, a continuous tape, a reagent-sensing device, and a first storage device that is adapted to hold and dispense an unused portion of the continuous tape. The rotatable container provides protection against environmental moisture that degrades the reagent and keeps the reagent-sensing device clean and protects it from wear and tear of normal usage. The lid portion is adapted to rotate from a closed position to an open position where the rotation advances the continuous tape.

[0014] Referring to FIGs. 1 and 2, a rotatable container 10 is depicted in a closed position (FIG. 1) and an open position (FIG. 2). The rotatable container 10 is adapted to read and handle diagnostic reagents in tape form. The rotatable container 10 comprises a body portion 12, a lid portion 14, a continuous tape 16, and a reagent-sensing device 18. The lid portion 14 is adapted to rotate from a closed position to an open position as shown in FIGs. 1 and 2. The rotatable container may be rotated from the open position to the closed position via hinge 30. The hinge may be made of metal or may be a living hinge. Living hinges are typically made of polymeric materials that are flexible such as polypropylenes or polyethylenes. It is contemplated that the rotatable container may be moved from the open position to the closed position using other methods.

Continuous Tape

[0015] The continuous tape 16 includes a diagnostic reagent and is stored on a first storage device 20 in FIGs. 1 and 2. The first storage device 20 may be a spool or reel that is generally circular such as shown in FIGs. 1 and 2. Alternatively, the first storage device may be a polygonal shape such as a rectangle or a non-polygonal shape that is adapted to hold and dispense the continuous tape 16. It would be desirable to have a first storage device that is adapted to hold and dispense a Z-folded continuous tape. The first storage device 20 is shown attached to the body portion 12 and is adapted to hold and dispense an unused portion of the continuous tape 16. As shown in FIG. 2, the continuous tape 16 includes an unused portion 16a and a used or spent portion 16b. During the rotation of the lid portion 14 from the body portion 12, the continuous tape 16 is advanced from the first storage device 20. The continuous tape 16 is extended or pulled over the reagent-sensing device 18. The advancing of the continuous tape 16 places the unused reagent in the correct position against the reagent-sensing device 18. Thus, the opening of the lid portion 14 from

the body portion 12 accomplishes (a) exposing the reagent-sensing device 18, (b) advancing the continuous tape 16 to a fresh or unused reagent area, and (c) stretching the continuous tape 16 with the reagent over the reagent-sensing device 18. When the lid portion 14 is placed in a closed position, the continuous tape 16 moves away from the reagent-sensing device 18 as shown in, for example, FIG. 1.

[0016] The continuous tape 16 may include one or more reagents to assist in determining the concentration of the amount of a fluid sample. The diagnostic reagent may be disposed in or on the continuous tape. For example, in one embodiment, the diagnostic reagent is disposed on membranes adhered to the continuous tape. The diagnostic reagent may be humidity sensitive. To determine glucose in a whole blood sample, for example, t he r eagent may be an enzyme such as glucose oxidase. One example of a reagent may be found in the Glucometer ENCORE® made by Bayer Corporation. Another glucose indicator reagent that may be used is glucose dehydrogenase, NAD, diaphorase, tetrazolium indicator (WST-4), and polymers. Other non-limiting examples of reagents may be used in the continuous tape. The continuous tape 16 may be made of polymeric materials, including polyethylene terephthalate (PET), polycarbonate or polystyrene. An example of a reagent on tape is one used in the CLINITEK ATLAS® automated urine chemistry analyzer made by Bayer Corporation.

[0017] According to one embodiment, the reagent is a part of the continuous tape and, thus, remains attached to the continuous tape throughout the process. According to another embodiment, the reagent may be laminated to the continuous tape such that the reagent is adapted to separate from the continuous tape. In such an embodiment, the continuous tape may be referred to as a carrier.

[0018] According to one embodiment, the rotatable container 10 further comprises a second storage device 22. The second storage device 22 may be, for example, a spool or other type of storage device adapted to receive the used or spent continuous tape. As shown in FIGs. 1 and 2, the second storage device 22 is attached to the lid portion 14. The second storage device 22 may be desirable because it provides a convenient and safe disposal for the used or spent portion of the continuous tape 16. In such an embodiment, it is desirable for the used reagent to remain on the continuous tape 16. For example, when the lid portion 14 is placed in a closed position, the used portion of the continuous tape (i.e., the portion with used or spent reagent) is placed in or on the second storage device 22.

Reagent-Sensing Device

[0019] The reagent-sensing device of the present invention is adapted to read the diagnostic reagent. The reagent-sensing device also transmits the information (e.g., glucose concentration) to the test subject.

[0020] Referring to FIGs. 1 and 2, the reagent-sensing device 18 is attached to the body portion 12. The reagent-sensing device 18 is shown as being attached to an inner surface of the body portion 12, but it is contemplated that the reagent-sensing device may be attached to an outer surface of the body portion. For example, the reagent-sensing device may be attached near or at a top outer surface edge of the body portion (i.e., the edge of the body portion closest to the lid when the lid is in a closed position). It is often desirable to locate the reagent-sensing device within the body portion 12 because it assists in keeping the reagent-sensing device clean a well as preventing or inhibiting additional wear and tear through normal usage. The reagent-sensing device 18 is protected from such conditions when the lid portion 14 is in a closed position.

[0021] According to one embodiment of the present invention, the reagent-sensing device comprises a test sensor such as an electrochemical biosensor or an optical biosensor as are known in the art. An electrochemical biosensor uses the reagent from the continuous tape that is designed to react with an analyte in the test fluid to create an oxidation current at electrodes disposed within the electrochemical biosensor. That current is directly proportional to the concentration of the analyte in the test fluid.

[0022] Examples of an electrochemical biosensor that can be used to measure glucose concentrations are those used in Bayer Corporation's Glucometer DEX® and ELITE® systems. The reagent-sensing device of these electrochemical sensors may be integrated into the body portion and the lid portion of the containers of the present invention. Electrochemical biosensors that may be used in connection with the containers of the present invention are described in U.S. Patent Nos. 5,120,420, 5,660,791, 5,759,364, and 5,798,031, each of which is incorporated herein in its entirety. Another example of an electrochemical sensor is described in U.S. Patent Application Publication No. 2001/0042683, published on November 22, 2001, which is-incorporated by reference in its entirety. One or more of the electrochemical sensors may be purchased from Matsushita Electric Industrial Company. A further example of an electrochemical sensor that may be used is disclosed in U.S. Patent No 5,429,735, which is incorporated by reference in its entirety. It is contemplated that other electrochemical biosensors may be used in the present invention.

[0023] An optical biosensor uses a reagent from the continuous tape and is designed to produce a colorimetric reaction indicative of the concentration of the analyte in the test fluid. The colorimetric reaction is then read by a spectrophotometer incorporated into a testing instrument. An optical biosensor that may be used in connection is described in U.S. Patent No. 5,194,393, which is incorporated herein by reference in its entirety. Another example of an optical detection device is described in U.S. Patent No. 6,096,269, which is incorporated herein by reference in its entirety.

[0024] It is contemplated that a lancet for drawing test fluid such as blood may be integrated or coordinated with the biosensor. In one embodiment, the lancet is located on the interior of the body portion. It is contemplated that the lancet may be placed in other locations. Alternatively, a physically separated lancing device may be used.

[0025] The containers of the present invention may include a standard that calibrates and checks on the performance of the optical biosensor in the reagent-sensing device. The standard, if used in the rotatable container 10, may be mounted on the inside of the lid such that it is properly positioned in front of the reagent-sensing device 18 and protected from the environment. For example, in FIG. 2, a calibration standard 24 is shown as being attached to the lid portion. One example of a calibration standard material, is available from Edmund Industrial Optics of Barrington, New Jersey and is referred to as "white reflectance standard."

[0026] It is contemplated that additional items or devices may be located within the body portion 12. For example, to assist in maintaining a low humidity, a desiccant may be added within the body portion 12. A low humidity environment is desirable to protect at least the continuous tape with reagent. Non-limiting examples of suitable desiccants that may be used are a molecular sieve and silica gel. One type of desiccant material that may be used is 13X synthetic molecular sieves from Multisorb Technologies Inc. of Buffalo, New York, available in powder, pellet, and bead forms. Another desiccant that may be used is type 4A synthetic molecular sieves available from Multisorb Technologies Inc. of Buffalo, New York or Texas Technologies Inc. of Leander, Texas. It is contemplated that other desiccants known in the art may be used in the present invention.

[0027] To assist in preventing or inhibiting moisture vapor ingress, at least one seal may be attached to either body portion 12 or the lid portion 14 such that the seal is located between the body portion 12 and the lid portion 14 when the lid portion is in a closed position. The seal may be attached by, for example, an adhesive or thermal welding or it may be a part of the body portion or the lid portion. The seal may be deformed when the lid portion 14 is in a closed position. The seal geometry may be optimized to minimize water vapor transmission by extending the length of the diffusion path. It is desirable for the seal to avoid accommodating a continuous tape sliding therethrough because of the potential for leaks to occur a such a location. Seals may be made from a variety of materials including, but not limited to, polymeric materials. Some desirable attributes of a material for forming the seal are high barrier properties (e.g., those with low moisture vapor transmission rates), lubricity for easy opening and closing, and elasticity for allowing the mating surfaces to conform. One non-limiting example of a polymeric material is a polyolefin such as polypropylene. The seal may be made from other materials such as elastomeric materials. Some materials for forming the seal may include cellular rubber, styrene elastomers, polyolefin elastomers, polyamide elastomers, polyester elastomers, polyurethane elastomers, and combinations thereof.

[0028] According to another embodiment, a rotatable container 110 is depicted in a closed position (FIG. 3) and an open position (FIG. 4). The rotatable container 110 is adapted to read and handle diagnostic reagents in tape form. The rotatable container 110 comprises a body portion 112, a lid portion 114, a continuous tape 116, and a reagent-sensing device 118. The continuous tape 116 may be the same as described above with respect to the continuous tape 16. Similarly, the reagent-sensing device 118 may be the same as described above with the reagent-sensing device 18 except with its location on the rotatable container. In this embodiment, the reagent-sensing device 118 is moveably attached between the lid portion 114 and the body portion 112. In the closed position, the reagent-sensing device 118 is adjacent to an inner surface of the lid portion such that the reagent-sensing device 118 remains clean and protected from conditions such as dust and dirt. It is contemplated that the reagent-sensing device may be attached at other locations.

[0029] The rotatable container 110 further comprises a first storage device 120 and a second storage device 122. The lid portion 114 is adapted to rotate from a closed position to an open position as shown in FIGs. 3 and 4. The rotatable container may be rotated from the open position to the closed position via hinge 130 or a living hinge. The hinge 130 according to one embodiment is attached to the body portion 112 via a hinge support bracket 132. It is contemplated that the rotatable container may be moved from the open position to the closed position using other methods.

[0030] Referring still to FIGs. 3 and 4, the reagent-sensing device 118 is located external to the body portion 112 and is attached to the lid portion 114. One advantage of the rotatable container 110 is that the location of the reagent-sensing device 118 allows additional space to integrate the lancet, if used, with the reagent-sensing device 118. The reagent-sensing device 118 may be moved forward (*i.e.,* upwardly in FIGs. 3 and 4) by a mechanism such a rack and pinion drive 128 or a cam mechanism that, for example, is operated by a hinge. The first position of the reagent-sensing device 118 (see FIG. 3) is at approximately the same height as the top edge 112a of the body portion 112. The second position of the reagent-sensing device 11.8 (see FIG.4) is above the top edge of the body portion 112 by a height H1. The height H1 may vary but is generally from about 0.2 to about 0.4 inches. It is desirable to have the reagent-sensing device extend at least about 0.2 inches above the top edge 112a so as to assist the test subject in placing the test fluid on the continuous tape 116. Additionally, such a height may also assist placing the continuous tape against the reagent-sensing device such that the continuous tape is flat against the reagent-sensing device.

[0031] As discussed above, the rotatable container

110 may further include a standard to calibrate and check on the performance of the optical biosensor if used of the reagent-sensing device. The rotatable container 110 may also include a desiccant and seals.

[0032] The base portion and the lid portion of the rotatable containers may be made of materials having very low water vapor transmission rates. Some examples of such materials are polymeric materials including, but not limited to, polyethylene, polypropylene or metals such as aluminum. Additionally, it is contemplated that the individual properties of the base portion, the lid portion and seal are desirably optimized and do not have to be made of the same materials. It is desirable that the base portion and the lid portion in the closed position form a sealed container adapted to store humidity-sensitive diagnostic reagents.

Methods of the Present Invention

[0033] The methods for determining the analyte concentrations (*e.g.*, glucose concentrations) may be performed by the test subjects, especially those who are diabetic. It is also contemplated that the methods may be performed by hospital or clinic personnel.

[0034] According to one method, the lid portion is rotated with respect to the body portion to an open position by the test subject. During the rotation of the lid portion from the body portion, (a) the reagent-sensing device is exposed, (b) the continuous tape is advanced to a fresh or unused reagent area, and (c) the continuous tape is positioned with the fresh or unused reagent over the reagent-sensing device. The fluid sample (*e.g.*, a whole blood sample) is placed in contact with the unused portion continuous tape that includes a reagent and is located over the reagent-sensing device. The whole blood sample may be generated by a lancing device such as Bayer's MICROLET® adjustable lancing device. The lancing device may obtain blood by, e.g., pricking a person's finger. It is desirable to use a low volume of blood such as less than 1 μl. The reagent-sensing device determines the concentration of the analyte in the fluid sample (*e.g.*, glucose concentration) and returns this information to the test subject. It is desirable to return this information to the test subject in a short time frame such as from about 5 to about 15 seconds.

[0035] To protect the reagent of the unused portion of the continuous tape and the reagent-sensing device, the lid portion of the container is closed by the test subject upon completion of the testing. During the closing of the lid portion, (a) the continuous tape is moved away from the reagent-sensing device and (b) the reagent-sensing device is protected. Additionally, during the closing of the lid portion, the body portion is desirably sealed to prevent or inhibit moisture vapor transmission from entering thereto. It is also contemplated that if a second storage device is included in the rotatable container, then the closing of the lid portion may advance or wind the used portion of the continuous tape onto or in the second storage device.

[0036] In another method, the rotation of the lid portion from the body portion to the open position may move the reagent-sensing device forward to a location above the top edge of the body portion. Such a movement assists the test subject in placing the test fluid on the unused portion of the continuous tape over the reagent-sensing device.

[0037] While particular embodiments and applications of the present invention have been illustrated and described, it is to be understood that various modifications, changes and variations may be apparent from the foregoing descriptions without departing from the scope of the invention as defined in the appended claims.

Claims

1. A container (10) with a rotatable lid (14) for reading and handling diagnostic reagents in tape form, comprising:

   a body portion (12) including an inner and outer surface;
   a lid portion (14) being attached to the body portion (12);
   a continuous tape (16) including a diagnostic reagent;
   a reagent-sensing device (18) being attached to either the body portion (12) or the lid portion (14) and adapted to read the diagnostic reagent; and
   a storage device (20) being attached to the body portion (12) that is adapted to hold and dispense an unused portion of the continuous tape (16);
   characterized in that
   the lid portion (14) is adapted to rotate from a closed position to an open position,
   wherein during the rotation of the lid portion (14), the continuous tape (16) is advanced from the storage device (20) and is extended over the reagent-sensing device (18).

2. The container (10) of claim 1, wherein the reagent-sensing device (18) is attached to the inner surface of the body portion (12), to the outer surface of the body portion (12) or to the lid portion (14).

3. The container (10) of claim 1 or 2, further including a hinge (30) to rotate the body portion (12) and the lid portion (14) from each other.

4. The container (10) of one of the claims 1 to 3, wherein the diagnostic reagent remains with the continuous tape (16) during the advancing of the continuous tape (16).

5. The container (10) of one of the claims 1 to 3, wherein the diagnostic reagent is adapted to separate from

the remainder of the continuous tape (16) during the advancing of the continuous tape (16).

6. The container (10) of one of the claims 1 to 5 further comprising a lancet.

7. The container (10) of one of the claims 1 to 6 further comprising a calibration standard (24).

8. The container (10) of claim 7, wherein the calibration standard (24) is attached to the lid portion (14).

9. The container (10) of one of the claims 1 to 8, wherein the reagent-sensing device (18) includes an electrochemical sensor or an optical sensor.

10. The container (10) of one of the claims 1 to 9 further including means (128) for moving the reagent-sensing device (18).

11. The container (10) of claim 10, wherein means for moving the reagent-sensing device (18) is a rack and pinion drive, or a cam mechanism.

12. The container (10) of one of the claims 1 to 11 further comprising at least one seal that is located between the body portion (12) and the lid portion (14) when the lid portion (14) is in a closed position.

13. The container (10) of one of the claims 1 to 12 further comprising a desiccant.

14. The container (10) of one of the claims 1 to 13, further comprising
a second storage device (22) being attached to the lid portion (14) that is adapted to receive a used portion of the continuous tape (16),
wherein during the rotation of the lid portion (14), the continuous tape (16) is received by the second storage device (22).

15. A method of using a container (10) with a rotatable lid (14) for reading and handling diagnostic reagents in tape form, comprising:

providing a rotatable container (10) comprising a body portion (12), a lid portion (14), a continuous tape (16), a reagent-sensing device (18) and a first storage device (20), the body portion (12) including an inner and outer surface, the lid portion (14) being attached to the body portion (12), the continuous tape (16) including a diagnostic reagent, the reagent-sensing device (18) being attached to either the body portion (12) or the lid portion (14) and adapted to read the diagnostic reagent, the first storage device (20) being attached to the body portion (12) and being adapted to hold and dispense an unused portion of the continuous tape (16);
rotating the lid portion (14) from a closed position to an open position; and
advancing the continuous tape (16) from the first storage device (20) to extend over the reagent-sensing device (18) during the rotation of the lid portion (14).

16. The method of claim 15, wherein the container (10) further includes a second storage device (22) that is attached to the lid portion (14) and wherein during the advancing of the continuous tape (16), the second storage (22) device receives the used portion of the continuous tape (16).

17. The method of claim 15 or 16 further comprising rotating the lid portion (14) from the open position to the closed position and wherein during the rotation of the lid portion (14) to the closed position, moving the continuous tape (16) from the reagent-sensing device (18).

18. The method of one of the claims 15 to 17 further including placing a body fluid on the unused portion (16a) of the continuous tapem(16) over the reagent-sensing device (18) and determining the concentration of an analyte of the body fluid (14) from the reagent-sensing devicem (18).

19. The method of claim 18, wherein the analyte is glucose and the body fluid is a whole blood sample.

Patentansprüche

1. Behälter (10) mit einem schwenkbaren Deckel (14) zum Auslesen und zur Handhabung von diagnostischen Reagenzien in Bandform, umfassend:

einen Körper-Teil (12) mit einer inneren und einer äußeren Oberfläche;
einen Deckel-Teil (14), der an dem Körper-Teil (12) angebracht ist;
ein kontinuierliches Band (16) mit einem diagnostischen Reagens;
Reagens-Abfühlvorrichtung (18), die entweder an dem Körper-Teil (12) oder dem Deckel-Teil (14) angebracht und ausgebildet ist, um das diagnostische Reagens auszulesen; und
eine Speichervorrichtung (20), die an dem Körper-Teil (12) angebracht ist, der ausgebildet ist, um einen ungebrauchten Abschnitt des kontinuierlichen Bands (16) zu halten und auszugeben;
dadurch gekennzeichnet, dass
der Deckel-Teil (14) ausgebildet ist, um sich aus einer geschlossenen Position in eine geöffnete Position zu drehen,
worin während der Drehung des Deckel-Teils

(14) das kontinuierliche Band (16) aus der Speichervorrichtung (20) heraus befördert und über die Reagens-Abfühlvorrichtung (18) gezogen wird.

2. Behälter (10) nach Anspruch 1, worin die Reagens-Abfühlvorrichtung (18) an der inneren Oberfläche des Körper-Teils (12), an der äußeren Oberfläche des Körper-Teils (12) oder an dem Deckel-Teils (14) angebracht ist.

3. Behälter (10) nach Anspruch 1 oder 2, weiters umfassend ein Gelenk (30), um den Körper-Teil (12) und den Deckel-Teil (14) gegenüber dem jeweils anderen zu drehen.

4. Behälter (10) nach einem der Ansprüche 1 bis 3, worin das diagnostische Reagens während des Beförderns des kontinuierlichen Bands (16) im kontinuierlichen Band (16) bleibt.

5. Behälter (10) nach einem der Ansprüche 1 bis 3, worin das diagnostische Reagens ausgebildet ist, um sich während des Beförderns des kontinuierlichen Bands (16) von dem übrigen Teil des kontinuierlichen Bands zu lösen.

6. Behälter (10) nach einem der Ansprüche 1 bis 5, weiters umfassend eine Lanzette.

7. Behälter (10) nach einem der Ansprüche 1 bis 6, weiters umfassend einen Kalibrierungsstandard (24).

8. Behälter (10) nach Anspruch 7, worin der Kalibrierungsstandard (24) an den Deckel-Teil (14) angebracht ist.

9. Behälter (10) nach einem der Ansprüche 1 bis 8, worin die Reagens-Abfühlvorrichtung (18) einen elektrochemischen Sensor oder einen optischen Sensor umfasst.

10. Behälter (10) nach einem der Ansprüche 1 bis 9, weiters umfassend ein Mittel (128) zum Bewegen der Reagens-Abfühlvorrichtung (18).

11. Behälter (10) nach Anspruch 10, worin ein Mittel zum Bewegen der Reagens-Abfühlvorrichtung (18) ein Zahnstangen- und ein Kegelradantrieb oder ein Kurvengetriebe ist.

12. Behälter (10) nach einem der Ansprüche 1 bis 11, weiters umfassend zumindest eine Abdichtung, die zwischen dem Körper-Teil (12) und dem Deckel-Teil (14) liegt, wenn sich der Deckel-Teil in der geschlossenen Position befindet.

13. Behälter (10) nach einem der Ansprüche 1 bis 12, weiters umfassend ein Trocknungsmittel.

14. Behälter (10) nach einem der Ansprüche 1 bis 13, weiters umfassend eine zweite Speichervorrichtung (22), die an den Deckel-Teil (14) angebracht ist, welcher ausgebildet ist, um einen gebrauchten Abschnitt des kontinuierlichen Bands (16) aufzunehmen,
worin das kontinuierliche Band (16) während der Drehung des Deckel-Teils (14) von der zweiten Speichervorrichtung (22) aufgenommen wird.

15. Verfahren zur Verwendung eines Behälters (10) mit einem schwenkbaren Deckel (14) zum Auslesen und zur Handhabung von diagnostischen Reagenzien in Bandform, umfassend:

die Bereitstellung eines schwenkbaren Behälters (10), umfassend einen Körper-Teil (12), einen Deckel-Teil (14), ein kontinuierliches Band (16), eine Reagens-Abfühlvorrichtung (18) und eine erste Speichervorrichtung (20), wobei der Körper-Teil (12) eine innere und äußere Oberfläche umfasst, der Deckel-Teil (14) an dem Körper-Teil (12) angebracht ist, das kontinuierliche Band (16) ein diagnostisches Reagens umfasst, die Reagens-Abfühlvorrichtung (18) an entweder den Körper-Teil (12) oder den Dekkel-Teil (14) angebracht und ausgebildet ist, um das diagnostische Reagens auszulesen, wobei die erste Speichervorrichtung (20) an dem Körper-Teil (12) angebracht und ausgebildet ist, um einen ungebrauchten Abschnitt des kontinuierlichen Bands (16) zu halten und auszugeben;
das Drehen des Deckel-Teils (14) aus einer geschlossenen Position in eine geöffnete Position; und
das Befördern des kontinuierlichen Bands (16) aus der ersten Speichervorrichtung (20) heraus, damit dasselbe während der Drehung des Dekkel-Teils (14) über die Reagens-Abfühlvorrichtung (18) gezogen wird.

16. Verfahren nach Anspruch 15, worin der Behälter (10) weiters eine zweite Speichervorrichtung (22) umfasst, die an dem Deckel-Teil (14) angebracht ist und worin die zweite Speichervorrichtung (22) während des Beförderns des kontinuierlichen Bands (16) den gebrauchten Abschnitt des kontinuierlichen Bands (16) aufnimmt.

17. Verfahren nach Anspruch 15 oder 16, weiters umfassend das Drehen des Deckel-Teils (14) um von der geöffneten Position zu der geschlossenen Position und worin während der Drehung des Deckel-Teils (14) zur geschlossenen Position, das kontinuierliche Band (16) aus der Reagens-Abfühlvorrich-

tung (18) bewegt wird.

18. Verfahren nach einem der Ansprüche 15 bis 17, weiters umfassend das Platzieren eines Körperfluids auf den ungebrauchten Abschnitt (16a) des kontinuierlichen Bands (16) über der Reagens-Abfühlvorrichtung (18) sowie die Bestimmung der Konzentration eines Analyts des Körperfluids (14) aus der Reagens-Abfühlvorrichtung (18).

19. Verfahren nach Anspruch 18, worin der Analyt Glucose und das Körperfluid eine Vollblutprobe ist.

Revendications

1. Récipient (10) à couvercle tournant (14) pour la lecture et le traitement de réactifs de diagnostic en forme de bandes, comportant :

une partie de corps (12) présentant des surfaces intérieure et extérieure ;
une partie de couvercle (14) qui est attachée à la partie de corps (12) ;
une bande continue (16) comprenant un réactif de diagnostic ;
un dispositif (18) sensible au réactif qui est attaché soit à la partie de corps (12), soit à la partie de couvercle (14) et qui est conçu pour lire le réactif de diagnostic ; et
un dispositif de stockage (20) qui est attaché à la partie de corps (12) et qui est conçu pour contenir et distribuer une partie inutilisée de la bande continue (16) ;
caractérisé en ce que
la partie de couvercle (14) est conçue pour tourner d'une position fermée à une position ouverte,
dans lequel, pendant la rotation de la partie de couvercle (14), la bande continue (16) est avancée depuis le dispositif de stockage (20) et est étendue au-dessus du dispositif (18) sensible au réactif.

2. Récipient (10) selon la revendication 1, dans lequel le dispositif (18) sensible au réactif est attaché à la surface intérieure de la partie de corps (12), à la surface extérieure de la partie de corps (12) ou à la partie de couvercle (14).

3. Récipient (10) selon la revendication 1 ou 2, comprenant en outre une charnière (30) pour faire tourner la partie de corps (12) et la partie de couvercle (14) l'un par rapport à l'autre.

4. Récipient (10) selon l'une des revendications 1 à 3, dans lequel le réactif de diagnostic reste dans la bande continue (16) pendant l'avance de la bande continue (16).

5. Récipient (10) selon l'une des revendications 1 à 3, dans lequel le réactif de diagnostic conçu pour se séparer de la partie restante de la bande continue (16) pendant l'avance de la bande continue (16).

6. Récipient (10) selon l'une des revendications 1 à 5, comportant en outre une lancette.

7. Récipient (10) selon l'une des revendications 1 à 6, comportant en outre un témoin d'étalonnage (24).

8. Récipient (10) selon la revendication 7, dans lequel le témoin d'étalonnage (24) est attaché à la partie de couvercle (14).

9. Récipient (10) selon l'une des revendications 1 à 8, dans lequel le dispositif (18) sensible au réactif comprend un capteur électrochimique ou un capteur optique.

10. Récipient (10) selon l'une des revendications 1 à 9, comprenant en outre un moyen (128) destiné à déplacer le dispositif (18) sensible au réactif.

11. Récipient (10) selon la revendication 10, dans lequel le moyen destiné à déplacer le dispositif (18) sensible au réactif est un mécanisme d'entraînement à crémaillère et pignon, ou un mécanisme à came.

12. Récipient (10) selon l'une des revendications 1 à 11, comportant en outre au moins un joint d'étanchéité qui est placé entre la partie de corps (12) et la partie de couvercle (14) lorsque la partie de couvercle (14) est dans une position fermée.

13. Récipient (10) selon l'une des revendications 1 à 12, comportant en outre un desiccant.

14. Récipient (10) selon l'une des revendications 1 à 13, comportant en outre
un second dispositif de stockage (22) attaché à la partie de couvercle (14) qui est conçu pour recevoir une partie utilisée de la bande continue (16),
dans lequel, pendant la rotation de la partie de couvercle (14), la bande continue (16) est reçue par le second dispositif de stockage (22).

15. Procédé d'utilisation d'un récipient (10) ayant un couvercle tournant (14) pour la lecture et le traitement de réactifs de diagnostic en forme de bande, comprenant :

l'utilisation d'un récipient tournant (10) comprenant une partie de corps (12), une partie de couvercle (14), une bande continue (16), un dispositif (18) sensible à un réactif et un premier dis-

positif de stockage (20), la partie de corps (12) présentant des surfaces intérieure et extérieure, la partie de couvercle (14) étant attachée à la partie de corps (12), la bande continue (16) comprenant un réactif de diagnostic, le dispositif (18) sensible au réactif étant attaché soit à la partie de corps (12), soit à la partie de couvercle (14) et étant conçu pour lire le réactif de diagnostic, le premier dispositif de stockage (20) étant attaché à la partie de corps (12) et étant conçu pour contenir et distribuer une partie inutilisée de la bande continue (16) ;
le fait de faire tourner la partie de couvercle (14) d'une position fermée à une position ouverte ; et
l'avance de la bande continue (16) à partir du premier dispositif de stockage (20) pour qu'elle s'étende au-dessus du dispositif (18) sensible au réactif pendant la rotation de la partie de couvercle (14).

16. Procédé selon la revendication 15, dans lequel le récipient (10) comprend en outre un second dispositif de stockage (22) qui est attaché à la partie de couvercle (14) et dans lequel, pendant l'avance de la bande continue (16), le second dispositif de stockage (22) reçoit la partie usagée de la bande continue (16).

17. Procédé selon la revendication 15 ou 16, comprenant en outre la rotation de la partie de couvercle (14) de la position ouverte à la position fermée et dans lequel, pendant la rotation de la partie du couvercle (14) vers la position fermée, la bande continue (16) est déplacée à partir du dispositif (18) sensible au réactif.

18. Procédé selon l'une des revendications 15 à 17, comprenant en outre la mise en place d'un fluide corporel sur la partie inutilisée (16a) de la bande continue (16) au-dessus du dispositif (18) sensible au réactif et la détermination de la concentration d'un analyte du fluide corporel (14) à partir du dispositif (18) sensible à un réactif.

19. Procédé selon la revendication 18, dans lequel l'analyte est du glucose et le fluide corporel est un échantillon de sang entier.

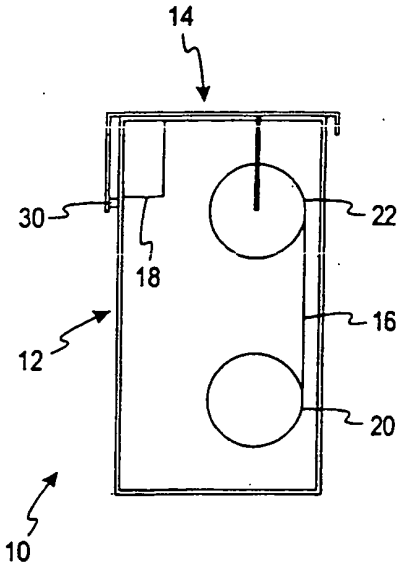

Fig. 1

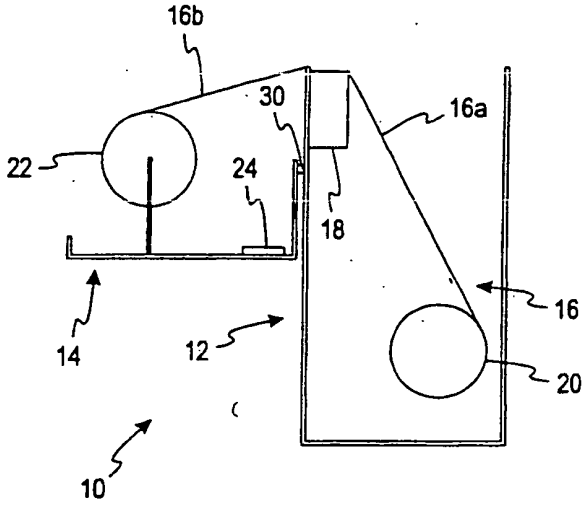

Fig. 2

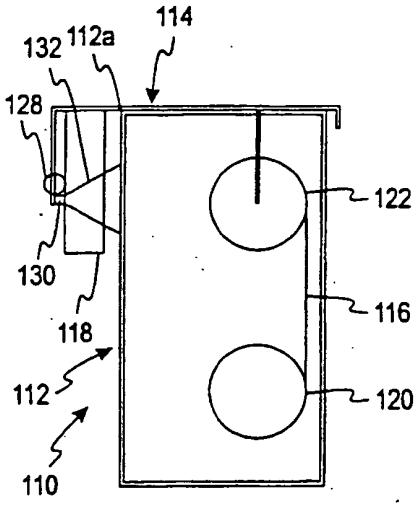

Fig. 3

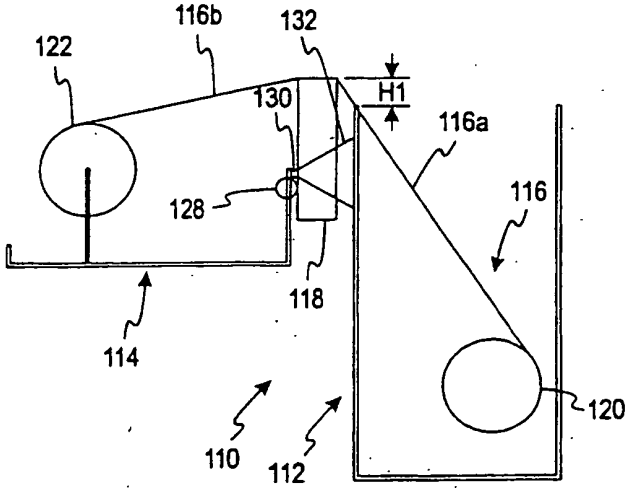

Fig. 4

REFERENCES CITED IN THE DESCRIPTION

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专利名称(译)	用于读取和处理诊断试剂的容器及其使用方法		
公开(公告)号	EP1488736B1	公开(公告)日	2009-04-22
申请号	EP2004013401	申请日	2004-06-07
[标]申请(专利权)人(译)	拜尔健康护理有限责任公司		
申请(专利权)人(译)	拜耳医药保健，LLC		
当前申请(专利权)人(译)	拜耳医药保健有限责任公司		
[标]发明人	CHARLTON STEVEN C		
发明人	CHARLTON, STEVEN C.		
IPC分类号	A61B5/00 G01N33/48 G01N31/22 G01N33/487 G01N33/52 G01N33/66 G01N35/00 G01N35/02 G01N35/04 G01N35/10		
CPC分类号	G01N33/48764 A61B5/14532 A61B5/1455 A61B5/1486 A61B2562/0295 G01N31/22 G01N35/00009 G01N35/1002 G01N2035/00019 Y10T436/104998 Y10T436/11 Y10T436/110833 Y10T436/113332		
优先权	60/479170 2003-06-18 US		
其他公开文献	EP1488736A1		
外部链接	Espacenet		

摘要(译)

一种具有可旋转盖的容器，用于读取和处理带形式的诊断试剂，包括主体部分，盖部分，连续带，试剂传感装置和存储装置。主体部分包括内表面和外表面。盖部分附接到主体部分并适于从关闭位置旋转到打开位置。连续胶带包括诊断试剂。试剂传感装置连接到主体部分或盖子部分，并适于读取诊断试剂。存储装置附接到主体部分，该主体部分适于保持和分配连续带的未使用部分。在盖部分旋转期间，连续带从第一存储装置前进并在试剂传感装置上延伸。