## Description

This invention relates to the construction of containers used to contain reagents for an assay, for example, to extract antigens for an immunoassay.

Immunoassays have been used in recent years to detect the presence of infectious diseases. In order for the assay to be useful, it must detect a particular organism with a high degree of reliability. In most cases, this requires the isolation and reaction of antigens peculiar to the organism with corresponding antibodies, using an extraction procedure. For the test to be commercially successful, the extraction also needs to be relatively inexpensive, simple to use and rapid.

Examples of organisms which can be detected by immunoassay are, (1) Chlamydia trachomatis - (herein C. trachomatis) which is one of two micro- al species of the two microbial species of the genus Chlamydiaceae, order Chlamydiales. (2) Herpes simplex virus (HSV) which remains a serious problem. (3) Gonorrhea, which is a disease usually transmitted by sexual contact caused by a bacterium of the Neisseria genus, especially N. gonorrhea. (4) N. meningitidis and N. lactamica, which are also species of considerable medical and diagnostic interest.

In certain cases, it is necessary for reagents used in an extraction to be deposited in measured quantities and/or stored in an extraction container prior to its use resulting in more accurate and more rapid tests. An example of such an extraction container is more specifically discussed in US -A-4,639,419 entitled "Immunological Color Change Test Involving Two Differently Colored Reagent Spots" issued on January 27, 1987, disclosing a closed-ended tube where two reagents spots are aced into a well of the tube located in the closed end. Other patents disclosing deposits of reagents within an extraction device are US -A-4,808,524 entitled "Test Kit and Method For The Determination of Streptococcus A Antigen" issued on February 28, 1989, US -A-4,673,639 entitled "Dry Form Micronitray Acid Streptococci Extraction-Agglutination Test" issued on June 16, 1987 and US -A-4,746,614 entitled "Extraction Device" issued on May 24, 1988.

However, standard extraction containers have not been adequate in keeping extraction reagents separated during the depositing and drying process or storage while allowing for adequate mixing upon reconstitution and for proper orientation of the container. As a result, extraction reagents have been allowed to interact before drying causing neutralization and inaccurate test results. Also, standard extraction containers have not aided the retention of dried extraction reagents within the closed end.

Such inadequacies in extraction containers have greatly reduced the accuracy of existing immunoassays employing the use of extraction containers. Furthermore, the extraction container is limited as to structural features that can be included, since the side walls adjacent the closed end need to be flexible enough to allow the container to be squeezed, to aid in dissolving the extraction reagent.

Therefore, prior to this invention, there has been a need for an extraction container which assists in more rapid and more accurate detection of antigens in an immunoassay through the use of effective depositing, drying and storage of extraction reagents in the extraction container.

An additional need has been to have predetermined measured quantities of reagents deposited, dried and stored in the extraction container in a manner producing in a more precise analytical determination.

The problems noted above are overcome with an extraction container that is effective in solving the above-noted problems by separation of extraction reagents during drying and storage of reagents.

More specifically, in accordance with one aspect of the invention, the problems noted above are overcome with a container useful for extracting antigens, having wall means defining open and closed opposite ends,

characterized in that the container further comprises dividing means located in the closed end of the container for dividing the volume of the closed end into at least two separate regions,

and in that a portion of the wall means adjacent to the closed end is shaped and sized to cooperate with depositing means to ensure separated deposit of reagents on opposite sides of the dividing means, the wall means adjacent the closed end and the dividing means being flexible to allow the container to be squeezed for proper mixing of the reagents.

In accord with another aspect of the invention, the problems noted above are overcome with a container for storing reagents on a wall of the container. The container is characterized in that the wall includes at least one raised rib over which the reagents are separately deposited, to anchor the reagents in place, the rib having a height less than the height of the separate deposits.

In accord with still another aspect of the invention, the problems noted above are overcome with a kit for extracting an antigen from body fluids, the kit including an extraction device in which two or more reagents are added, and a swab for insertion of body fluid specimen into the container and for mixing of the specimen and reagents, wherein the extraction container used to extract the antigens for

the immunoassay comprises a container as described above.

In accord with a further aspect of the invention, the problems noted above are overcome with a method of depositing two different reagents in a closed end of a container so as to be divided from one another, the method comprising the steps of:

A. while placing a container having a dividing means on the bottom surface dividing the volume of the bottom into at least two separate regions in a holder, automatically forcing the container to have a fixed orientation by reason of means on the container for orienting the container relative to the holder,

B. thereafter inserting a depositing means into the container, the depositing means having a predetermined orientation relative to the holder, and

C. ejecting separate reagents onto said bottom surface on opposite sides of said dividing means from at least two different parts of the depositing means, so that the separate reagents are separately deposited in said separate regions.

Accordingly, it is an advantageous feature of the invention that the container is oriented automatically with respect to a depositing means to insure that separate reagents are deposited on opposite sides of a dividing means, thereby preventing premature interaction and neutralization.

Another advantageous feature is that such a container can be provided with means for aiding in the retention of deposited reagent.

The present invention will now be described by way of example with reference to the accompanying drawings in which,

Fig. 1 is an elevational view, partly sectioned, of an extraction container constructed in accordance with the invention,

Fig. 2 is a section view taken generally along lines II-II of figure 1,

Fig. 3 is a section view of Fig. 1, taken generally along the line III-III,

Fig. 4 is a view similar to Fig. 2 but illustrating an alternate embodiment,

Fig. 5 is an elevational view similar to Fig. 1, but illustrating a separate embodiment and a depositing means for the reagents,

Fig. 6 is a section view of the embodiment illustrated in Fig. 5, taken along the line V-V,

Fig. 7 is a view similar to the elevational view of Fig. 1, but illustrating an alternated embodiment, taken along the line VII-VII of Figure 8,

Fig. 8 is a section view of Fig. 7, taken along the line VIII-VIII of Figure 7,

Fig. 9 is a section view similar to Fig. 7 but illustrating a separate embodiment,

Fig. 10 is a section view similar to Fig. 7 and 9, but illustrating a separate embodiment,

Fig. 11 is a bottom plan view of a device constructed in accordance with the invention, but illustrating an alternate embodiment,

Fig. 12 is a fragmentary section view taken generally along the lines XII-XII of Fig. 11,

Fig. 13 is a plan view of the open end of a container holder constructed for engaging a container as illustrated in Figs. 11 and 12, and

Fig. 14 is a fragmentary section view, taken along the line XIV-XIV of Fig. 13.

The invention is described hereinafter in connection with certain preferred embodiments wherein the extracted container is particularly suited for extracting antigens for immunoassays, requiring separation of deposited extraction reagents. It is also useful for deposited reagents used for other purposes.

The preferred extraction container, Figure 1, has wall means 14 defining open and closed opposite ends 12 and 18, wherein a portion of wall means 14 is shaped so that it has at least one generally flat surface 22, and preferably also an opposite generally flat surface 20, Figure 3, to automatically orient the container in a holder. Also included are dividing ridge 16 at closed end 18 of the container to ensure that separate reagents 15 and 17 are directed into at least two separate regions on the inside surface 19 of wall means 14. Flat surfaces 20 and 22 can have any predetermined angular orientation relative to dividing ridge 16. Two preferred orientations are as follows, one in which they extend generally perpendicular to the dividing ridge 16, Figure 2, and one in which the flat surfaces 20A, 22A are generally parallel to the dividing ridge 16A as seen in Figure 4. The flat surfaces 20, 22 or 20A, 22A primarily serve the purpose of orienting the container so that the dividing means 16 is in the correct position for a twin-channel depositing means. That is, when end 18 of the container is inserted into a holder (not shown), flat surfaces 20 and 22 or 20A, 22A automatically force the container to be properly oriented relative to the holder. The container will not insert into the holder until the flat surfaces 20, 22 are properly aligned with a flat surface in the holder. Because the twin-channel depositing means is already properly oriented relative to the holder, this in turn serves to orient the depositing means relative to the container, and specifically to the dividing ridge 16 or 16A. As a result, when the twin channels of the depositing means are activated, they deposit separate reagents on opposite, rather than the same, sides of dividing ridge 16 or 16A.

The preferred reagents used with this invention are dithiothreitol, a reducing agent, with polyacralamide, a stabilizer and TRISMA (tris-

hydroxyaminomethane) which are used in the extraction of the chlamydial antigen.

Also useful, as described in US -A-4,255,928, commonly owned and filed on October 7, 1988 by Pronovost, et al and entitled "High pH Extraction Composition And Its Use To Determine A Chlamydial Gonococcal or Herpes Antigen", is a reagent composition for extracting antigen from chlamydial, gonococcal or herpes organisms having a pH of at least about 8 and comprising a strong base and an alcoholamine. Other addenda preferably included in the extraction composition include a cationic surfactant, one or more reducing agents, preservatives to prevent hydrogen peroxide activity and chelating agents. It is conceivable that either the strong base, the alcoholamine, the cationic surfactant or the reducing agent could be used for depositing and drying in this invention.

Examples of other reagents which could be deposited, dried, stored and used for other purposes in this invention are enzymes, enzyme substrates, antibodies, antigens, haptens, inorganic and organic reagents, buffers, salts and the like, as well as radioactively tagged or fluorescent reagents of the foregoing types including nonisotopic tags such as enzymes, cofactors, luminescent agents and the like.

An alternative embodiment of this invention is shown in Figure 5 and Figure 6. Parts similar to those previously described bear the same reference numeral to which the distinguishing suffix "B" is appended. Here, the dividing ridge, 16B, and wall means 14B, adjacent to the closed end 18B of the container are both shaped into an arc. The arc of dividing ridge 16B, is generally parallel to the arc of the wall means 14B, Fig. 6. Flats, as illustrated at 20, Figure 1, would not be necessary in this embodiment for the purpose of orienting the container and the dividing means. The reason is as follows, a depositing means 30, Figure 5, having turrets 32, 34 and 34' is constructed to deposit or eject reagent centrally, and on one or both sides. Since depositing means 30 has a snug fit within open end 12B, and ridge 16B is spaced to fit in between turrets 32 and 34, 34', the orientation is achieved automatically.

Dividing ridge 16, Figure 1, and 16B, Figure 5, are each sufficiently flexible for allowing it to be collapsed, in order to allow a swab to push against the dried reagents for proper mixing of the reagents during reconstitution. Some materials tested in the construction of the container cracked or showed signs of stress crack. The reagents used in the immunoassay in those cases would leak out of their region. It has been found that polyethylene or ethylene vinyl acetate are the preferred materials with which to construct the container. Preferably, dividing ridge 16 or 16A or 16B is no thicker than about 0.23 mm, to aid in flexibility.

The preferred embodiment, Figure 1, has been found to be surprisingly effective in providing accurate, rapid results. Most importantly, it has been found to effectively store extraction reagents in a separated condition.

The embodiments as illustrated in Figure 1 and Figure 5 may also be constructed with a cross-rib, Figure 7. The device of Figure 7 is similar to the embodiment illustrated in Figure 1. Parts similar to those previously described bear the same reference numeral to which the distinguishing suffix "C" is appended. Thus, the container has a closed end 18C, a dividing ridge 16C, and at least one flat surface 22C. However, in addition two raised ribs 28 are provided which have a height less than the height of each separate reagent deposit, Fig. 7. Preferably they extend generally perpendicular to dividing ridge 16C, Fig. 8. Extraction reagents are separately deposited over the raised ribs. The cross-ribs 28 serve the purpose of retention of deposits 15C, 17C, Figure 8, of reagents in the closed end 18C of the container. The cross-ribs are preferred over cross-grooves or roughened surfaces as an anchoring means.

The container can also be constructed with a reinforcing means mounted on the closed end of the container for absorbing shock to prevent subsequent dislodging of dried reagents located in their separate regions, Figures 9 and 10. Parts similar to those previously described bear the same reference numeral to which the distinguishing suffix "D" is appended. Thus, the container has a dividing ridge 16D in closed end 18D. However, shock absorber means are added, that extend from end 18D. Preferably the shock absorber comprises a flange 52 or a skirt 52' as shown in Figures 9 and 10, respectively. Other projections that would be apparent to one skilled in the art, can also be used. The shock absorber needs to attach at or below the tangent point of wall 14D, to keep that wall flexible for squeezing. As used herein, the "tangent point" is that point where the curved bottom end 18D attaches to a straight wall portion, e.g., point T, Fig. 10.

Preferably, the shock absorber means will resist the dislodging of a 0.016 g amount of dried reagent deposited in closed end 18D when the container, weighing 1.716 g in all, is dropped a distance of 76.2 cm onto a hard surface. A length of 0.254 cm and a thickness of about 1 mm for plastic flange 52 is a representative example of an embodiment that achieves such results.

An alternate embodiment is illustrated in Figs. 11-12 wherein a skirt for shock absorbance is also useful to orient the container. Parts similar to those previously described bear the same reference numeral to which the suffix "E" is appended. Thus,

the container has wall means 14E defining open and closed opposite ends and dividing ridge 16E located in the closed end 18E of the container which divides the volume of the closed end 18E into at least two separate regions. In this embodiment, the container has orienting means 100 orienting dividing ridge 16E with respect to a reagent-depositing means. Preferably the orienting means 100 comprise two skirts 102 and 104 shaped and sized in two separate arcs generally opposite to each other on opposite sides of end 18E. The skirts are an extension of wall means 14E, and do not meet in a circle. These skirts cooperate with mating slots 202 and 204, in a hole 200 formed in a container holder 210, Figures 13 and 14. That is, skirts 102 and 104, Fig. 11, are shaped and sized to fit into the recessed mating slots 202 and 204, Fig. 13, of the container holder.

The extraction container of this embodiment is thus forced into proper orientation with holder 210, which is already oriented with a depositing means which is to be inserted into the open end of the container. The result is to force dividing ridge 16E to locate as shown in phantom, Figure 14, so the depositing means can deposit reagent on opposite sides thereof.

The shock absorbing means is described and claimed per se in commonly-owned application U.S. Serial No. 380,843 co-filed herewith by Dennis Zander, entitled "Device for Absorbing Shock to a Container".

Most preferably, the extraction container of this invention is packaged in a kit form. Although the extraction containers disclosed herein may be prepared at the time of their use, it is contemplated that they will find their greatest utility as pre-prepared and pre-packaged test kits to be used in clinics, hospitals, physicians' offices or in the home. Such a kit comprises the extraction container of this invention, a swab for insertion of body fluid specimen into the container and for mixing of the specimen and extraction reagents. Conveniently, all of this is packaged into a package.

## Claims

1. A container useful for extracting antigens, having wall means (14, 19; 14A; 14B; 14C; 14D; 14E) defining open (12; 12B) and closed (18; 18B; 18C; 18D; 18E) opposite ends,

   characterized in that the container further comprises dividing means (16; 16A; 16B; 16C; 16D; 16E) located in the closed end (18; 18A; 18B; 18C; 18D; 18E) of the container for dividing the volume of the closed end (18; 18A; 18B; 18C; 18D; 18E) into at least two separate regions,

   and in that a portion of the wall means (14, 19; 14A; 14B; 14C; 14D; 14E) adjacent to the closed end (18; 18A; 18B; 18C; 18D; 18E) is shaped and sized to cooperate with depositing means (30, 32, 34, 34') to ensure separated deposit on reagents (15, 17; 15A, 17A; 15B, 17B; 15C, 17C) of opposite sides of the dividing means (16; 16A; 16B; 16C; 16D; 16E), the wall means (14, 19; 14A; 14B; 14C; 14D; 14E) adjacent the closed end (18; 18A; 18B; 18C; 18D; 18E) and the dividing means (16; 16A; 16B; 16C; 16D; 16E) being flexible to allow the container to be squeezed for proper mixing of the reagents.

2. A container according to claim 1 wherein the portion of the wall means (14, 19; 14A; 14B; 14C; 14D; 14E) adjacent to the closed end (18; 18A; 18B; 18C; 18D; 18E) is shaped so that it has at least one flat surface (20, 22; 20A, 22A; 22C) to orient the container and the dividing means (16; 16A; 16B; 16C; 16D) at the closed end (18; 18A; 18B; 18C; 18D) to ensure that separate reagents are directed into separate regions.

3. A container according to claim 1 or 2 wherein the at least one flat surface (20A, 22A) extends generally parallel to the dividing means (16A).

4. A container according to claim 1 or 2 wherein the flat surface (20, 22; 22C) extends generally perpendicular to the dividing means (16; 16C; 16D; 16E).

5. A container according to claim 1 wherein the portion of the wall means (14B) adjacent to the closed end (18B) and the dividing means (16B) are both shaped in an arc, the dividing means (16B) being generally parallel to the arc of the wall means (14B).

6. A container according to any one of claims 1 to 4 further characterized in that the container comprises anchoring means (28) for anchoring deposits of reagents (15C, 17C) within the closed end (18C) of the container.

7. A container according to claim 6 wherein the anchoring means comprises a raised rib (28) over which the reagents (15C, 17C) are separately deposited, to anchor the reagents (15C, 17C) in place, the rib (28) having a height less than the height of the separate deposits (15C, 17C).

8. A method of depositing two different reagents in a closed end of a container so as to be divided from one another, the method compris-

the container has wall means 14E defining open and closed opposite ends and dividing ridge 16E located in the closed end 18E of the container which divides the volume of the closed end 18E into at least two separate regions. In this embodiment, the container has orienting means 100 orienting dividing ridge 16E with respect to a reagent-depositing means. Preferably the orienting means 100 comprise two skirts 102 and 104 shaped and sized in two separate arcs generally opposite to each other on opposite sides of end 18E. The skirts are an extension of wall means 14E, and do not meet in a circle. These skirts cooperate with mating slots 202 and 204, in a hole 200 formed in a container holder 210, Figures 13 and 14. That is, skirts 102 and 104, Fig. 11, are shaped and sized to fit into the recessed mating slots 202 and 204, Fig. 13, of the container holder.

The extraction container of this embodiment is thus forced into proper orientation with holder 210, which is already oriented with a depositing means which is to be inserted into the open end of the container. The result is to force dividing ridge 16E to locate as shown in phantom, Figure 14, so the depositing means can deposit reagent on opposite sides thereof.

The shock absorbing means is described and claimed per se in commonly-owned application U.S. Serial No. 380,843 co-filed herewith by Dennis Zander, entitled "Device for Absorbing Shock to a Container".

Most preferably, the extraction container of this invention is packaged in a kit form. Although the extraction containers disclosed herein may be prepared at the time of their use, it is contemplated that they will find their greatest utility as pre-prepared and pre-packaged test kits to be used in clinics, hospitals, physicians' offices or in the home. Such a kit comprises the extraction container of this invention, a swab for insertion of body fluid specimen into the container and for mixing of the specimen and extraction reagents. Conveniently, all of this is packaged into a package.

## Claims

1. A container useful for extracting antigens, having wall means (14, 19; 14A; 14B; 14C; 14D; 14E) defining open (12; 12B) and closed (18; 18B; 18C; 18D; 18E) opposite ends,

   characterized in that the container further comprises dividing means (16; 16A; 16B; 16C; 16D; 16E) located in the closed end (18; 18A; 18B; 18C; 18D; 18E) of the container for dividing the volume of the closed end (18; 18A; 18B; 18C; 18D; 18E) into at least two separate regions,

   and in that a portion of the wall means (14, 19; 14A; 14B; 14C; 14D; 14E) adjacent to the closed end (18; 18A; 18B; 18C; 18D; 18E) is shaped and sized to cooperate with depositing means (30, 32, 34, 34') to ensure separated deposit on reagents (15, 17; 15A, 17A; 15B, 17B; 15C, 17C) of opposite sides of the dividing means (16; 16A; 16B; 16C; 16D; 16E), the wall means (14, 19; 14A; 14B; 14C; 14D; 14E) adjacent the closed end (18; 18A; 18B; 18C; 18D; 18E) and the dividing means (16; 16A; 16B; 16C; 16D; 16E) being flexible to allow the container to be squeezed for proper mixing of the reagents.

2. A container according to claim 1 wherein the portion of the wall means (14, 19; 14A; 14B; 14C; 14D; 14E) adjacent to the closed end (18; 18A; 18B; 18C; 18D; 18E) is shaped so that it has at least one flat surface (20, 22; 20A, 22A; 22C) to orient the container and the dividing means (16; 16A; 16B; 16C; 16D) at the closed end (18; 18A; 18B; 18C; 18D) to ensure that separate reagents are directed into separate regions.

3. A container according to claim 1 or 2 wherein the at least one flat surface (20A, 22A) extends generally parallel to the dividing means (16A).

4. A container according to claim 1 or 2 wherein the flat surface (20, 22; 22C) extends generally perpendicular to the dividing means (16; 16C; 16D; 16E).

5. A container according to claim 1 wherein the portion of the wall means (14B) adjacent to the closed end (18B) and the dividing means (16B) are both shaped in an arc, the dividing means (16B) being generally parallel to the arc of the wall means (14B).

6. A container according to any one of claims 1 to 4 further characterized in that the container comprises anchoring means (28) for anchoring deposits of reagents (15C, 17C) within the closed end (18C) of the container.

7. A container according to claim 6 wherein the anchoring means comprises a raised rib (28) over which the reagents (15C, 17C) are separately deposited, to anchor the reagents (15C, 17C) in place, the rib (28) having a height less than the height of the separate deposits (15C, 17C).

8. A method of depositing two different reagents in a closed end of a container so as to be divided from one another, the method compris-

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ing the steps of:

A. while placing a container having a dividing means on the bottom surface dividing the volume of the bottom into at least two separate regions in a holder, automatically forcing the container to have a fixed orientation by reason of means (20, 22; 20A, 22A; 22C; 100) on the container for orienting the container relative to the holder,

B. thereafter inserting a depositing means (30, 32, 34, 34') into the container, the depositing means (30, 32, 34, 34') having a predetermined orientation relative to the holder, and

C. ejecting separate reagents onto said bottom surface on opposite sides of said dividing means from at least two different parts of the depositing means (30, 32, 34, 34'), so that the separate reagents are separately deposited in said separate regions.

9. A kit for extracting an antigen from body fluids, the kit including an extraction device in which two or more reagents are added, and a swab for insertion of body fluid specimen into the container and for mixing of the specimen and reagents, wherein the extraction container used to extract the antigens for the immunoassay comprises a container according to any one of claims 1 to 6.

**Patentansprüche**

1. Behälter für die Extraktion von Antigenen, mit Wandungsmitteln (14, 19; 14A; 14B; 14C; 14D; 14E), die einander gegenüberliegende offene (12; 12B) und geschlossene (18; 18B; 18C; 18D; 18E) Endabschnitte aufweisen,

   **dadurch gekennzeichnet, daß** der Behälter in seinem geschlossenen Endabschnitt (18; 18A; 18B; 18C; 18D; 18E) Trennmittel (16; 16A; 16B; 16C; 16D; 16E) umfaßt, die das Fassungsvolumen des geschlossenen Endabschnitts (18; 18A; 18B; 18C; 18D; 18E) in mindestens zwei voneinander getrennte Bereiche unterteilen, und daß

   ein dem geschlossenen Endabschnitt (18; 18A; 18B; 18C; 18D; 18E) benachbarter Abschnitt der Wandungsmittel (14, 19; 14A; 14B; 14C; 14D; 14E) so ausgebildet und geformt ist, daß er mit Einbringmitteln (30, 32, 34, 34') zusammenwirkt und so ein getrenntes Einbringen der Reagenzien (15, 17; 15A, 17A; 15B, 17B; 15C, 17C) an einander gegenüberliegenden Seiten der Trennmittel (16; 16A; 16B; 16C; 16D; 16E) gewährleistet, wobei die dem geschlossenen Endabschnitt (18; 18A; 18B; 18C; 18D; 18E) benachbarten Wandungsmittel (14, 19; 14A; 14B; 14C; 14D; 14E) sowie die Trennmittel (16; 16A; 16B; 16C; 16D; 16E) so biegbar sind, daß der Behälter zum Zwecke des sorgfältigen Mischens der Reagenzien zusammendrückbar ist.

2. Behälter nach Anspruch 1, dadurch gekennzeichnet, daß der dem geschlossenen Endabschnitt (18; 18A; 18B; 18C; 18D; 18E) benachbarte Abschnitt der Wandungsmittel (14, 19; 14A; 14B; 14C; 14D; 14E) so ausgebildet ist, daß er mindestens eine plane Fläche (20, 22; 20A, 22A; 22C) aufweist, um den Behälter und die Trennmittel (16; 16A; 16B; 16C; 16D; 16E) am geschlossenen Endabschnitt (18; 18A; 18B; 18C; 18D; 18E) so auszurichten, daß getrennte Reagenzien in voneinander getrennte Bereiche einbringbar sind.

3. Behälter nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß sich die mindestens eine plane Fläche (20A, 22A) im wesentlichen parallel zu den Trennmitteln (16A) erstreckt.

4. Behälter nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß sich die plane Fläche (20, 22; 22C) im wesentlichen senkrecht zu den Trennmitteln (16; 16C; 16D; 16E) erstreckt.

5. Behälter nach Anspruch 1, dadurch gekennzeichnet, daß der dem geschlossenen Endabschnitt (18B) benachbarte Abschnitt der Wandungsmittel (14B) sowie die Trennmittel (16B) bogenförmig ausgebildet sind und daß sich die Trennmittel (16B) im wesentlichen parallel zum Bogen der Wandungsmittel (14B) erstrecken.

6. Behälter nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, daß der Behälter Haltemittel (28) zum Anlagern eingebrachter Reagenzien (15C, 17C) innerhalb seines geschlossenen Endabschnitts (18C) aufweist.

7. Behälter nach Anspruch 6, dadurch gekennzeichnet, daß die Haltemittel eine Rippe (28) aufweisen, auf deren Oberfläche die Reagenzien (15C, 17C) getrennt eingebracht und angelagert werden, wobei die Rippe (28) eine Höhe hat, die geringer ist als die Höhe der getrennt eingebrachten Reagenzien (15C, 17C).

8. Verfahren zum getrennten Einbringen von zwei verschiedenen Reagenzien in einen geschlossenen Endabschnitt eines Behälters, **dadurch gekennzeichnet, daß**

   a) ein Behälter, der auf seiner Bodenfläche das Fassungsvolumen in mindestens zwei

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separate Bereiche unterteilende Trennmittel umfaßt, in einen Halter eingesetzt und selbsttätig von behälterseitigen Mitteln (20, 22; 20A, 22A; 22C; 100) so positioniert wird, daß er eine vorbestimmte Ausrichtung relativ zum Halter hat,

b) Einbringmittel (30, 32, 34, 34') in den Behälter eingesetzt werden, die eine vorbestimmte Ausrichtung relativ zum Halter haben, und daß

c) getrennte Reagenzien von mindestens zwei verschiedenen Teilen der Einbringmittel (30, 32, 34, 34') aus auf die auf einander gegenüberliegenden Seiten der Trennmittel vorgesehene Bodenfläche ausgestoßen werden, so daß die Reagenzien getrennt in die getrennten Bereiche eingebracht werden.

9. Anordnung zum Extrahieren eines Antigens aus Körperflüssigkeiten, wobei die Anordnung eine Extraktionsvorrichtung umfaßt, in der zwei oder mehr Reagenzien zusammengefügt werden, und Auftragmittel aufweist, die Proben der Körperflüssigkeiten in den Behälter einführen und die Proben und die Reagenzien mischen, dadurch gekennzeichnet, daß der zum Extrahieren der Antigene für das Immunoassay verwendete Behälter dem Behälter gemäß einem der Ansprüche 1 bis 6 entspricht.

**Revendications**

1. Récipient utilisable pour extraire des antigènes, comportant un dispositif formant paroi (14, 19 ; 14A ; 14B ; 14C ; 14D ; 14E) définissant des extrémités opposées ouverte (12; 12B) et fermée (18; 18B; 18C; 18D; 18E),

caractérisé en ce que le récipient comprend en outre un dispositif diviseur (16 ; 16A ; 16B ; 16C ; 16D ; 16E) situé dans l'extrémité fermée (18 ; 18A ; 18B ; 18C ; 18D ; 18E) du récipient pour diviser le volume de l'extrémité fermée (18 ; 18A ; 18B ; 18C ; 18D ; 18E) en au moins deux régions séparées,

et en ce qu'une partie du dispositif formant paroi (14, 19 ; 14A ; 14B ; 14C ; 14D; 14E) adjacente à l'extrémité fermée (18 ; 18A ; 18B ; 18C ; 18D ; 18 E) a une forme et une dimension lui permettant de coopérer avec un dispositif de dépôt (30, 32, 34, 34') pour assurer le dépôt séparé de réactifs (15, 17 ; 15A, 17A; 15B, 17B ; 15C, 17C) sur les côtés opposés du dispositif diviseur (16 ; 16A ; 16B ; 16C ; 16D ; 16E), le dispositif formant paroi (14, 19 ; 14A ; 14B ; 14C ; 14D ; 14E) adjacent à l'extrémité fermée (18 ; 18A ; 18B ; 18C ; 18D ; 18E) et le dispositif diviseur (16 ; 16A ; 16B ; 16C ; 16D ; 16E) étant flexibles pour permettre au récipient d'être pressé pour le mélange approprié des réactifs.

2. Récipient selon la revendication 1, dans lequel la partie du dispositif formant paroi (14, 19 ; 14A ; 14B ; 14C ; 14D ; 14E) adjacente à l'extrémité fermée (18 ; 18A ; 18B ; 18C ; 18D ; 18E) a une forme telle qu'elle comporte au moins une surface plate (20, 22 ; 20A, 22A ; 22C) pour orienter le récipient et le dispositif diviseur (16 ; 16A ; 16B; 16C ; 16D) à l'extrémité fermée (18 ; 18A ; 18B ; 18C ; 18D) pour garantir que des réactifs séparés soient dirigés dans des régions séparées.

3. Récipient selon la revendication 1 ou 2, dans lequel la ou les surfaces plates (20A, 22A) s'étendent sensiblement parallèlement au dispositif diviseur (16A).

4. Récipient selon la revendication 1 ou 2, dans lequel la surface plate (20, 22 ; 22C) s'étend sensiblement perpendiculairement au dispositif diviseur (16 ; 16C ; 16D ; 16E).

5. Récipient selon la revendication 1, dans lequel la partie du dispositif formant paroi (14B) adjacente à l'extrémité fermée (18B) et le dispositif diviseur (16B) sont l'un et l'autre sous forme d'un arc, le dispositif diviseur (16B) étant sensiblement parallèle à l'arc du dispositif formant paroi (14B).

6. Récipient selon l'une quelconque des revendications 1 à 4, caractérisé en outre en ce que le récipient comprend un dispositif d'ancrage (28) pour ancrer les dépôts de réactifs (15C, 17C) dans l'extrémité fermée (18C) du récipient.

7. Récipient selon la revendication 6, dans lequel le dispositif d'ancrage comprend une nervure relevée (28) sur laquelle les réactifs (15C, 17C) sont déposés séparément pour ancrer les réactifs (15C, 17C) en place, la nervure (28) ayant une hauteur inférieure à la hauteur des dépôts séparés (15C, 17C).

8. Procédé de dépôt de deux réactifs différents dans une extrémité fermée d'un récipient de manière qu'ils soient séparés l'un de l'autre, le procédé comprend les étapes consistant à :

A. forcer automatiquement un récipient comportant sur la surface inférieure un dispositif diviseur divisant le volume du fond en au moins deux régions séparées à avoir une orientation fixée, tandis qu'on le place dans un support, grâce à des dispositifs

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(20, 22 ; 20A, 22A ; 22C ; 100) sur le récipient pour orienter le récipient par rapport au support,

B. insérer ensuite un dispositif de dépôt (30, 32, 34, 34') dans le récipient, le dispositif de dépôt (30, 32, 34, 34') ayant une orientation prédéterminée par rapport au support, et

C. éjecter depuis au moins deux parties différentes du dispositif de dépôt (30, 32, 34, 34') des réactifs séparés sur ladite surface inférieure sur les côtés opposés dudit dispositif diviseur de manière que les réactifs séparés soient déposés séparément dans lesdites régions séparées.

9. Trousse pour extraire un antigène de fluides corporels, la trousse comprenant un dispositif d'extraction dans lequel sont ajoutés deux réactifs ou plus, et un écouvillon pour insérer un échantillon de fluide corporel dans le récipient et pour mélanger l'échantillon et les réactifs, dans laquelle le récipient d'extraction utilisé pour extraire les antigènes pour l'immunoanalyse comprend un récipient selon l'une quelconque des revendications 1 à 6.