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(54) **METHOD AND APPARATUS FOR COLLECTING AND PREPARING BIOLOGICAL SAMPLES FOR TESTING**

division of application No. 13/055,536, filed on Mar. 31, 2011, now abandoned, filed as application No. PCT/US09/51335 on Jul. 22, 2009, which is a continuation-in-part of application No. 12/179,248, filed on Jul. 24, 2008, now abandoned.

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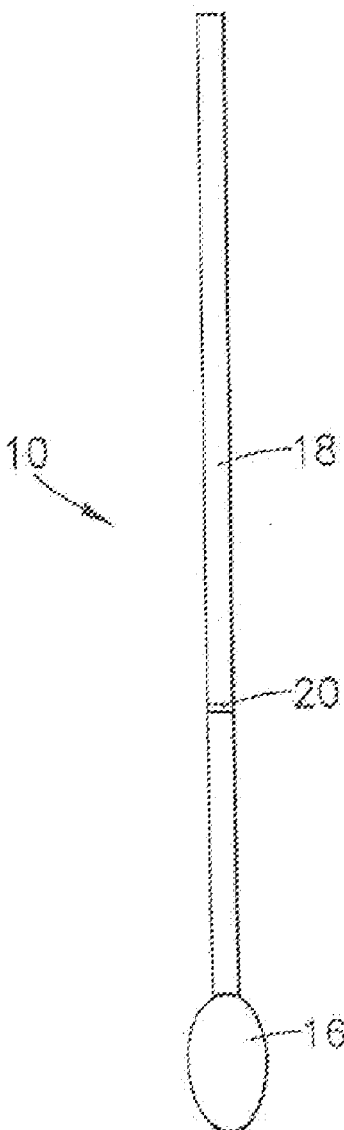
(52) **U.S. Cl.**  
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(57) **ABSTRACT**

**Related U.S. Application Data**

(60) Continuation of application No. 16/373,445, filed on Apr. 2, 2019, now Pat. No. 11,350,913, which is a

A kit and a method are disclosed for collecting and preparing a biological sample for testing where the sample is to be mixed with a buffer prior to being tested.



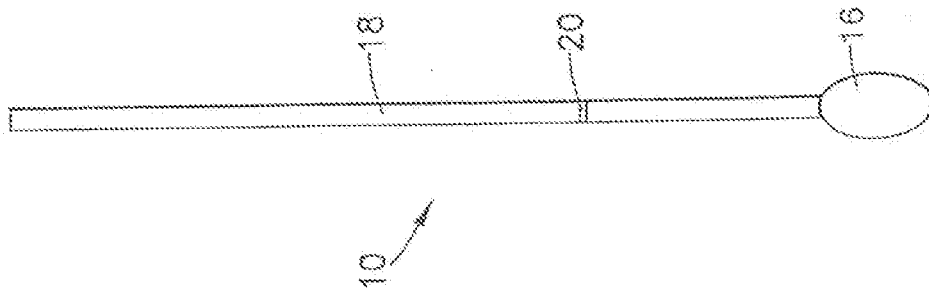


FIG. 2

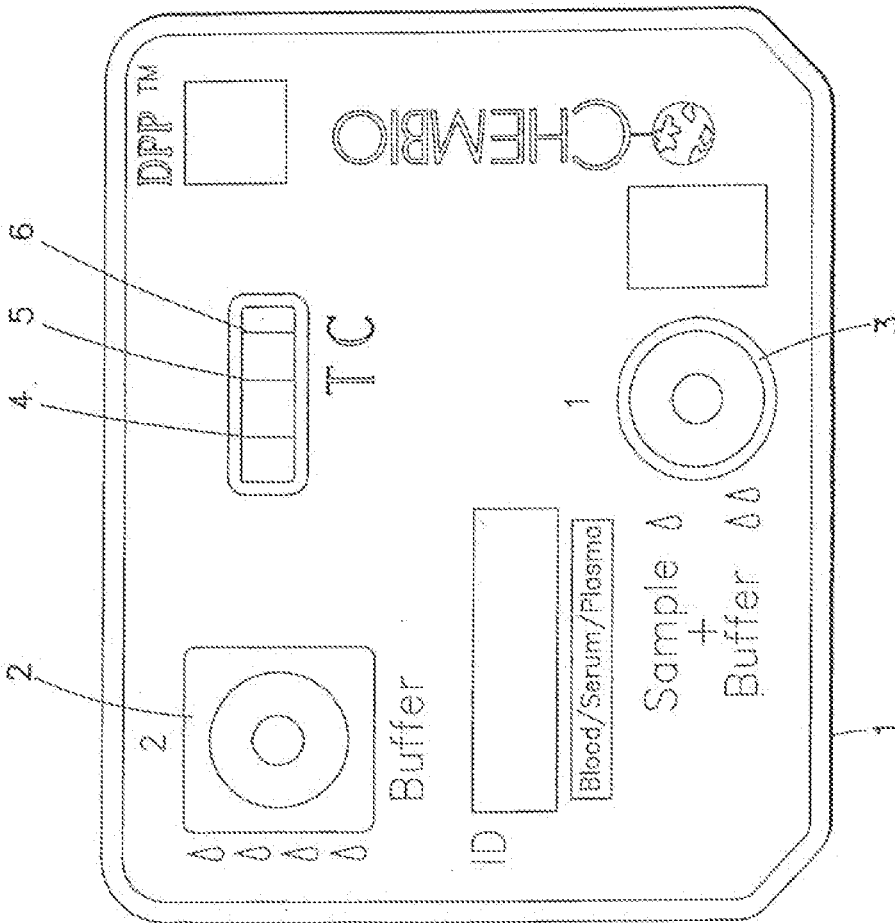


FIG. 1  
PRIOR ART

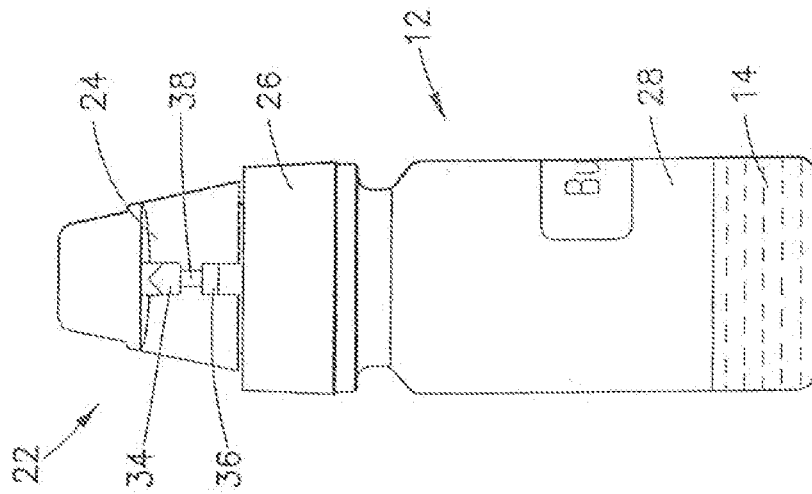


FIG. 3

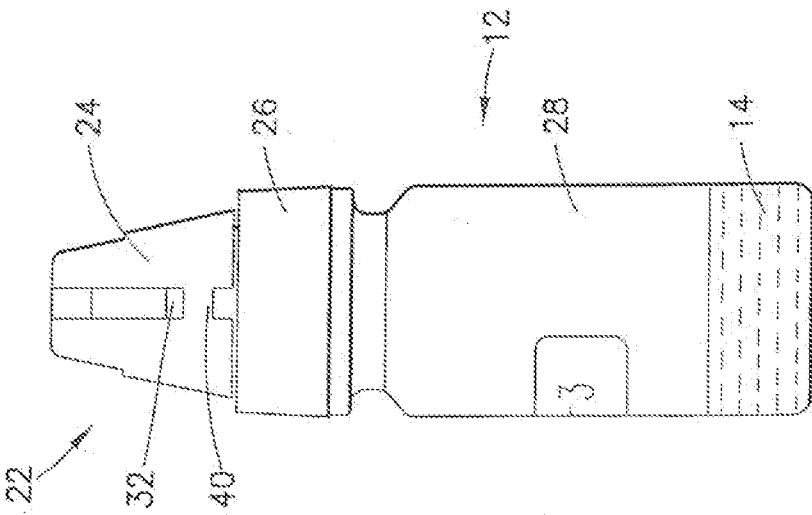


FIG. 4

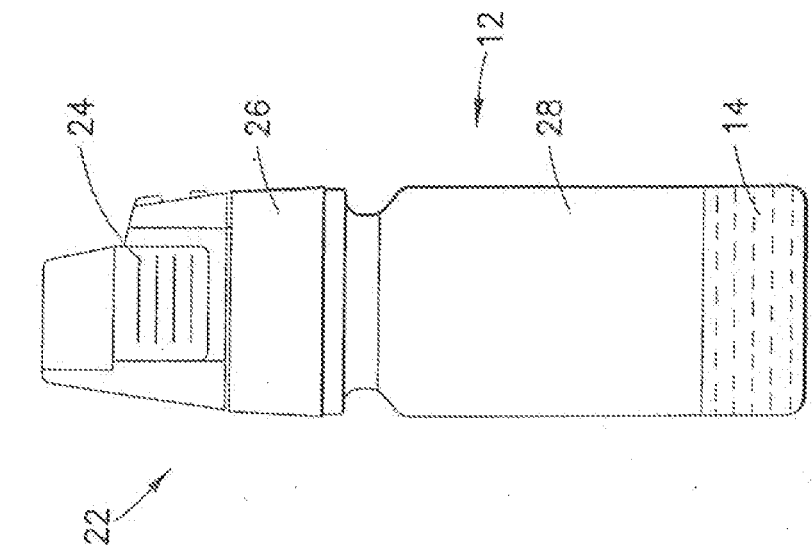


FIG. 5

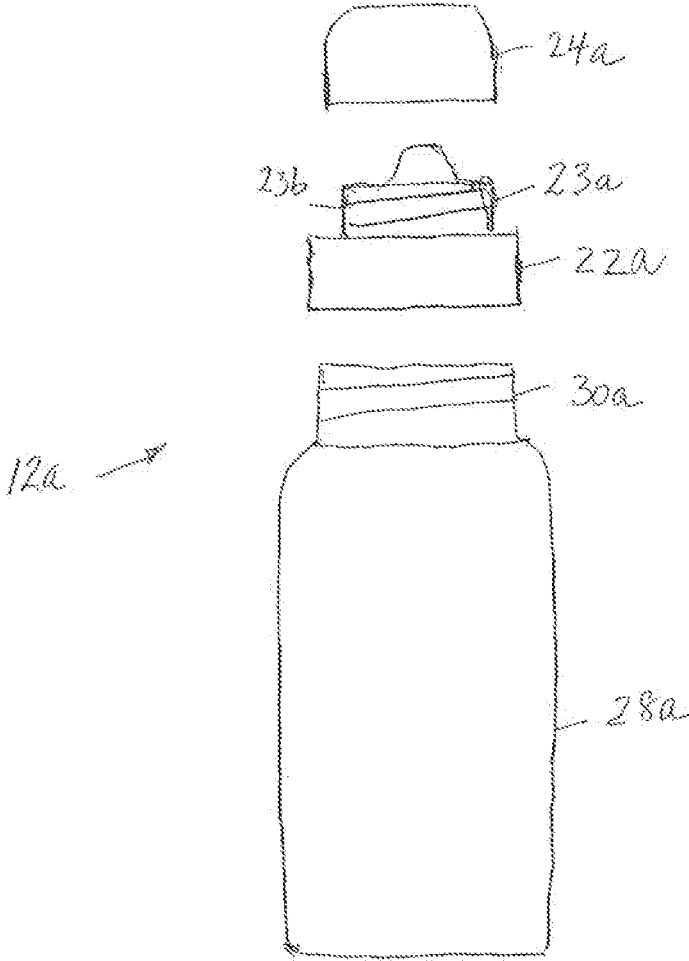
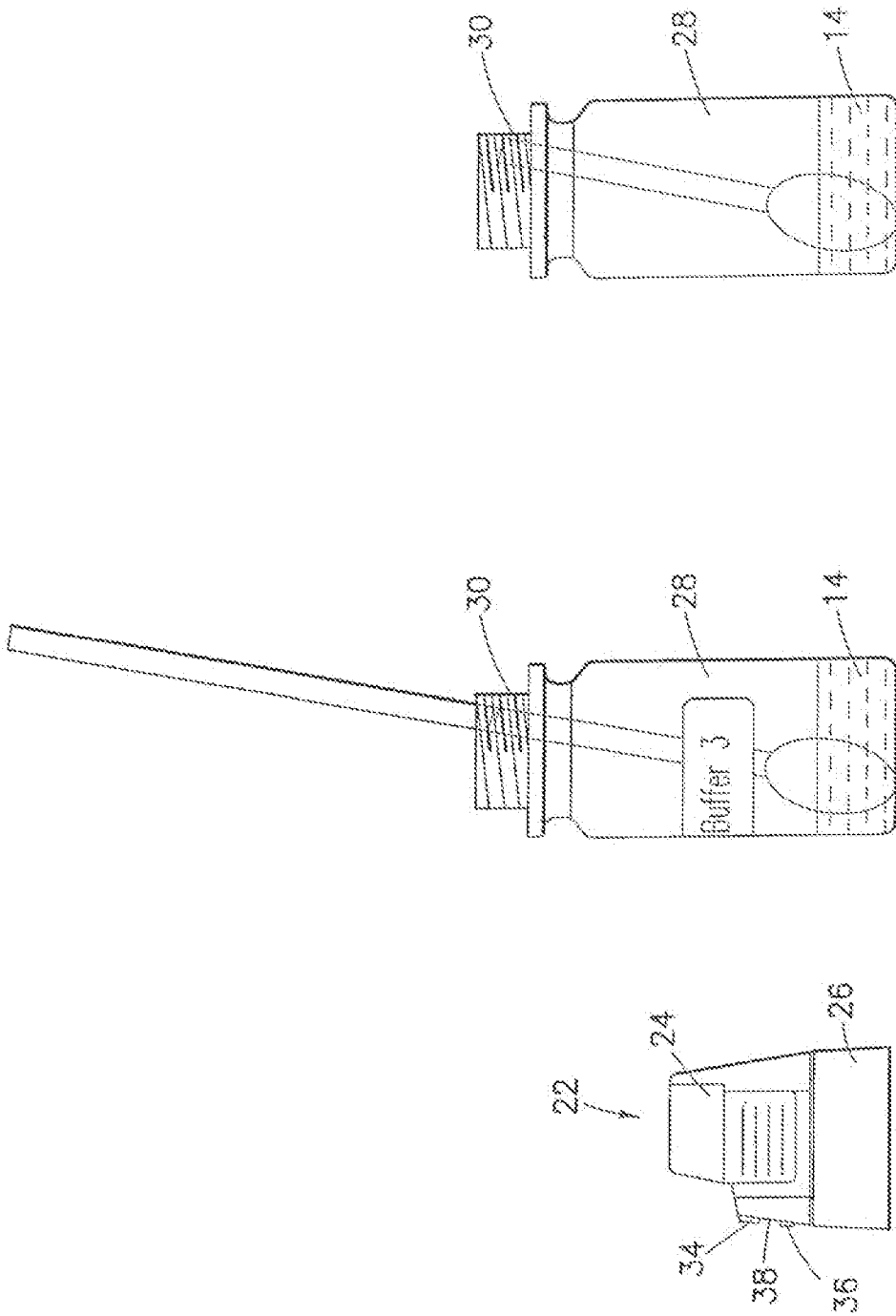


FIG 5a



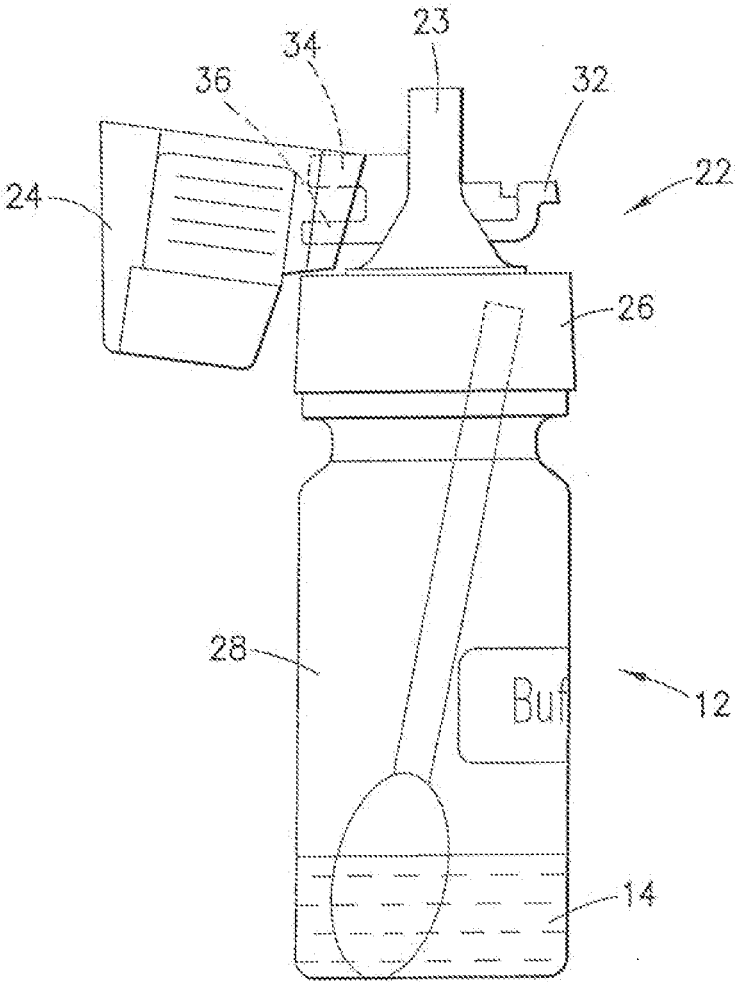


FIG.8

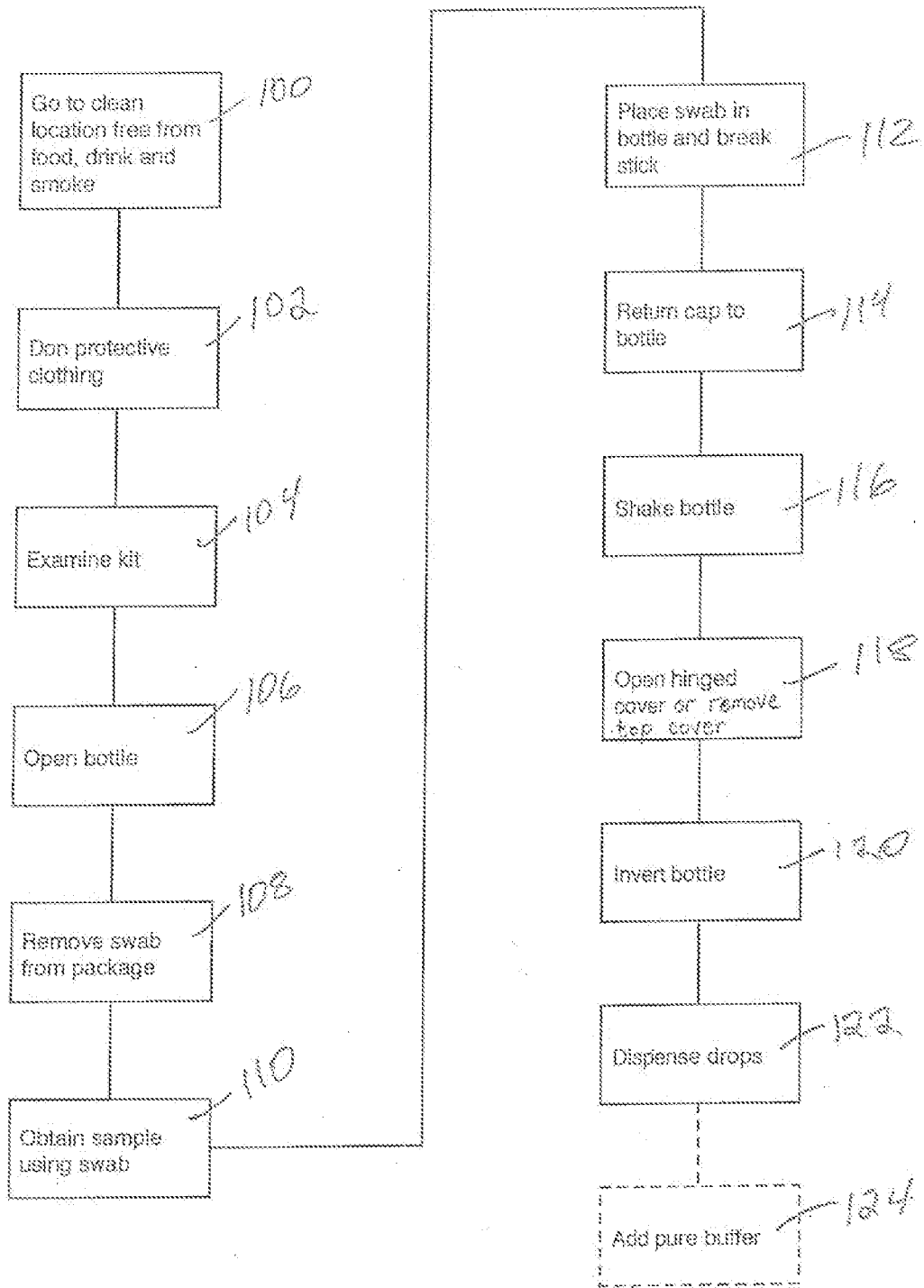


Fig. 9

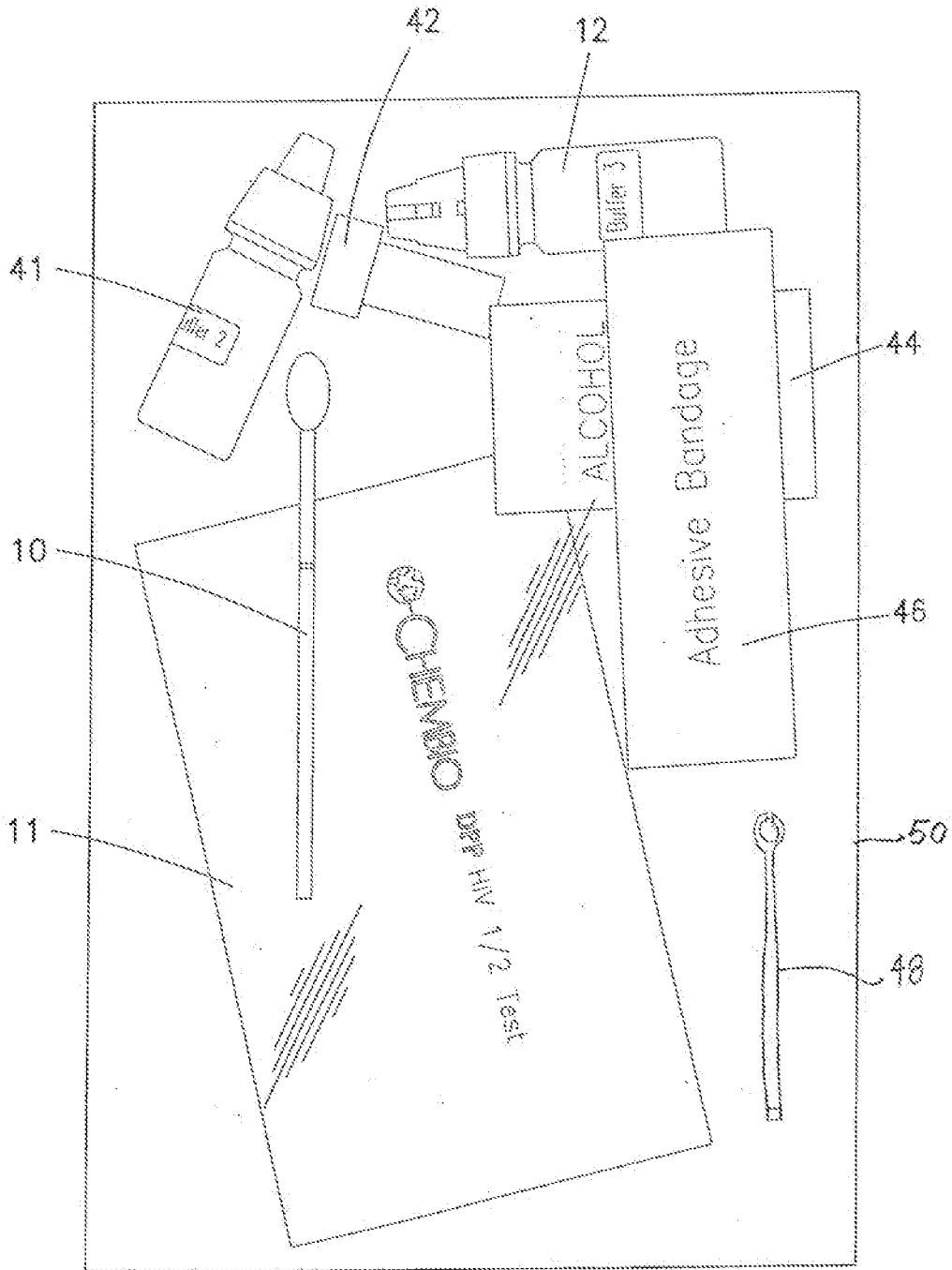


FIG. 10



## METHOD AND APPARATUS FOR COLLECTING AND PREPARING BIOLOGICAL SAMPLES FOR TESTING

### CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is related to co-owned U.S. Pat. No. 7,189,522, entitled "Dual Path Immunoassay Device," the complete disclosure of which is hereby incorporated by reference herein.

### BACKGROUND OF THE INVENTION

#### 1. Field of the Invention

[0002] This invention relates broadly to the testing of biological samples such as blood, oral fluids, epithelia, urine, stool, etc. More particularly, this invention relates to methods and apparatus for collecting and preparing such samples prior to testing.

#### 2. State of the Art

[0003] Many types of ligand-receptor assays have been used to detect the presence of various substances, often generally called ligands, in body fluids such as blood, urine, or saliva. These assays involve antigen antibody reactions, synthetic conjugates comprising radioactive, enzymatic, fluorescent, or visually observable polystyrene or metal sol tags, and specially designed reactor chambers. In all these assays, there is a receptor, e.g., an antibody, which is specific for the selected ligand or antigen, and a means for detecting the presence, and in some cases the amount, of the ligand-receptor reaction product. Some tests are designed to make a quantitative determination, but in many circumstances all that is required is a positive/negative qualitative indication. Examples of such qualitative assays include blood typing, most types of urinalysis, pregnancy tests, and AIDS tests. For these tests, a visually observable indicator such as the presence of agglutination or a color change is preferred.

[0004] U.S. Pat. No. 6,485,982 discloses what may be called a single path immunoassay device. The device has an elongate outer casing which houses an interior permeable material, e.g., glass fiber, capable of transporting an aqueous solution by capillary action, wicking, or simple wetting. The casing defines a sample inlet, and interior regions which, for ease of description, can be designated as a test volume and a reservoir volume. The reservoir volume is disposed in a section of the test cell spaced apart from the inlet, and preferably is filled with sorbent material. The reservoir acts to receive liquid transported along a flow path defined by the permeable material and extending from the inlet and through the test volume. In the test volume is a test site comprising a first protein having a binding site specific to a first epitope of the ligand immobilized in fluid communication with the flow path, e.g., bound to the permeable material or to latex particles entrapped in or bonded to the permeable material. A window such as a hole or transparent section of the casing permits observations of the test site through the casing wall. The method requires that the test sample be mixed with a conjugate or buffer before it is dispensed into the inlet.

[0005] Previously incorporated U.S. Pat. No. 7,189,522 discloses both dry and liquid conjugate immunoassay device systems. The systems include test cells with a first sorbent having a first location for receiving a buffer solution (in the

case of a dry conjugate system) or a conjugate solution (in the case of a liquid conjugate system) with the first sorbent defining a first horizontal flow path, a second sorbent having a second location for receiving a sample with the second sorbent defining a second horizontal flow path distinct from the first flow path, and a test line or test site with immobilized antigens or antibodies or other ligand binding molecules such as aptamers, nucleic acids, etc. located in a test zone at a junction of the first and second sorbents.

[0006] Where the test cell is provided in a housing, such as the housing 1 show in prior art FIG. 1, the housing is provided with a first opening 2 adjacent the first location and a second opening 3 adjacent the second location. A viewing window 4 is provided in the housing above the test line 5.

[0007] In the preferred embodiment, the first sorbent and second sorbent are separate pieces which overlie one another and the test line is printed on one or both of the sorbent materials at the junction. Alternatively, although not preferred, the first and second sorbents can be integral with each other. The systems preferably also include a control line 6 or site which may be seen from the viewing window 4.

[0008] According to one set of embodiments, the sorbents (and the housing in which the sorbents are provided) are laid out in a T shape, where the first location 2 for receiving the buffer or buffer-conjugate solution is located near one end of the top bar of the T, the second location 3 for receiving the sample is located near the end of the stem of the T, and the sorbents overlie each other at the intersection.

[0009] According to one disclosed method, a sample of interest is provided to the second opening or location 3. After a desired amount of time, a liquid such as a buffer solution is added to the first opening or location 2. If the sorbent is supporting a conjugate (i.e., in a dry conjugate system), the liquid is preferably simply a buffer solution. If the sorbent is not supporting a conjugate (i.e., in a liquid conjugate system), the liquid is preferably a buffer-conjugate liquid subsystem. In any event, after sufficient time to permit the conjugate to migrate to the test site 5 (and control site 6 if provided), the test site (and control site if provided) is inspected in order to determine whether the sample is "positive" or not.

[0010] The disclosed system can be used in conjunction with different types of samples such as blood, urine, saliva, and feces, and can be used to test for the presence of any ligand. Where blood, saliva or feces is to be provided, the blood, saliva or feces may be diluted or mixed with buffer prior to being added through the second hole 3. Alternatively, in some cases, the sample may be added through the hole and then a diluent may be added through the same hole 3.

### SUMMARY OF THE INVENTION

[0011] The present invention provides a kit and a method for collecting and preparing a biological sample for use with an immunoassay device where the sample is to be mixed with a buffer prior to being added to the device. The kit includes a sterile swab and a dropper bottle assembly containing the buffer solution to which the sample is added. In one embodiment, the dropper bottle assembly includes a dropper cap having a hinged cover and a threaded base and a bottle having a threaded neck. When the kit is delivered for use, the dropper cap is threadably connected to the threaded neck of the bottle and the hinged cover is closed. The sterile swab includes a sorbent mounted on the end of a stick. The

stick is preferably long enough so that a sample can be obtained without the person taking the sample contaminating it. The stick is provided with a weakened portion where the stick can be readily broken.

[0012] A method according to one embodiment of the invention includes opening the dropper bottle assembly by unscrewing the cap, inserting the swab into the bottle, snapping the swab stick to break it, and screwing the cap back on the bottle. The bottle containing the sorbent end of the swab is then agitated by shaking it. Now the mixed sample and buffer are ready to dispense into the testing device. This is done by opening the hinged cover of the dropper cap, inverting the bottle and dispensing the appropriate number of drops onto the device by gently squeezing the bottle.

[0013] From the foregoing, it will be appreciated that the location of the weakened portion of the swab stick is such that when the swab is placed into the bottle and touching the bottom of the bottle, the weakened portion of the stick is directly adjacent to the upper lip of the bottle neck. In this manner, the stick can be broken simply by bending it against the bottle neck with the sorbent end in the bottle.

[0014] According to a presently preferred embodiment, the hinged cover on the dripper cap has a lock which prevents it from being inadvertently opened. This prevents contamination and loss of buffer solution. The kit according to the invention preferably also contains a second bottle of buffer solution for use with a test device employing a dual path immunoassay system. Optionally, the kit includes an alcohol swab, a safety lancet, and a bandage. The kit may, and preferably does contain an immunoassay device, preferably a dual path immunoassay device. A blood collection loop is also optionally provided.

[0015] A method of testing a blood sample according to one embodiment of the invention includes using the alcohol swab to clean the area of the skin from which the sample will be taken, pricking the skin with the safety lancet, and collecting blood using the collection swab. The method then proceeds as described above.

[0016] Additional objects and advantages of the invention will become apparent to those skilled in the art upon reference to the detailed description taken in conjunction with the provided figures.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0017] FIG. 1 is a plan view of a prior art immunoassay test device;

[0018] FIG. 2 is a side elevation view of a swab according to the invention;

[0019] FIG. 3 is a side elevation view of a dropper bottle assembly according to the invention;

[0020] FIG. 4 is a front elevation view of the dropper bottle assembly;

[0021] FIG. 5 is a rear elevation view of the dropper bottle assembly;

[0022] FIG. 5a is a front elevation view of an alternative dropper bottle assembly;

[0023] FIG. 6 is a side elevation view of the dropper bottle assembly with the cap removed and the swab inserted into the bottle;

[0024] FIG. 7 is a side elevation view of the dropper bottle with the sorbent end of the swab and the stick broken;

[0025] FIG. 8 is a side elevation view of the dropper bottle assembly with the sorbent end of the swab contained therein and the hinged cover opened;

[0026] FIG. 9 is a flow chart illustrating the method steps of the invention; and

[0027] FIG. 10 is a plan diagram of an expanded kit containing a dual path test device and related sampling items.

#### DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENTS

[0028] Turning now to FIGS. 2-5, a kit according to the invention includes a sterile swab 10 and a dropper bottle assembly 12 containing the buffer solution 14 to which the sample is to be added. The sterile swab 10 includes a sorbent 16 mounted on the end of a stick 18. The stick 18 is preferably long enough (e.g., six inches long) so that a sample can be obtained without contaminating it. The stick is provided with a weakened portion 20 where the stick 18 can be readily broken. The dropper bottle assembly 12 includes a dropper cap 22 having a dropper spout 23, a hinged cover 24 and a threaded base 26 and a bottle 28 having a threaded neck 30 (FIGS. 6 and 7). When the kit is delivered for use, the dropper cap is threadably connected to the threaded neck of the bottle and the hinged cover is closed as shown in FIGS. 3-5.

[0029] Referring now to FIGS. 3-5 and 8, the dropper cap 22 includes a forward projecting finger 32 and two rearward projecting fingers 34, 36. The cover 24 has a rear slot which is bifurcated by a cross member 38 and a front slot which is either bifurcated or terminated by a cross member 40. As seen best in FIGS. 5, 6, and 8, the rearward projecting fingers extend into the rear slot and embrace the cross member 38 thereby forming a hinge. As seen best in FIG. 4, when the cover is closed, the forward projecting finger 32 engages the front slot above the cross member 40 and thereby prevents the cover from accidentally opening. The cover 24 is made of resilient material which can be deformed by squeezing the sides of the cover. Squeezing the sides of the cover deforms it in a manner that causes the cross member 40 to move forward and out from under the finger 32 thereby unlocking the cover and allowing it to be hingedly rotated about cross member 40 thereby opening the cover to the position shown in FIG. 8 with the spout 23 exposed. A dropper bottle assembly of the type described above is also described in U.S. Pat. No. 5,328,058, the complete disclosure of which is incorporated by reference herein.

[0030] An alternative dropper bottle assembly 12a useful in lieu of bottle assembly 12 is seen in FIG. 5a. Dropper bottle assembly 12a includes a bottle 28a having a threaded neck 30, a dropper cap 22 having internal threads (not shown) for mating with threaded neck 30 and a spout 23a having a neck 23b with external threads, and a cover 24a with internal threads (not shown) for mating with the threads of neck 23b. As will be appreciated, cap 22a and cover 24a can be removed together from bottle 28a, and cover 24a can be removed separately from cap 22a.

[0031] A method according to the invention is illustrated in FIG. 9. The method is preferably performed in a clean room which is free from food, drink, and smoke as illustrated at 100. Optimally, the person performing the method may don protective clothing such as a face mask and rubber gloves as indicated at 102. Before beginning the method, the

kit should be examined at **104** to determine whether it has expired or been contaminated through a broken package. The method then proceeds by opening up the kit and then opening the dropper bottle assembly at **106** by unscrewing the cap **22** (or cap **22a** plus cover **24a**) and preferably placing the bottle and the cap (or cap plus cover) on a sterile surface. The swab is then removed from its sterile package (not shown) at **108** and is used to obtain a sample at **110** which may be oral fluid (e.g., saliva or sputum), blood, urine, stool (feces), epithelia, etc. The sorbent end of the swab is then placed into the open bottle (FIG. 6) and the stick is broken at **112** (FIG. 7) typically by leveraging the stick against the edge of the threaded neck **30** of the bottle **12** so that the weakened portion **20** of the stick is near the leveraged point and snaps. Thus, the weakened portion of the stick is preferably selected to be located at a distance from the end of the sterile swab which is approximately (i.e., plus or minus 10%) the same height as the dropper bottle assembly without its cap. The cap (or cap plus cover) is then screwed back onto the bottle at **114** with the broken-stick-swab therein and the bottle is agitated at **116**, preferably by shaking it a number of times, e.g. ten. The hinged cover is then opened (FIG. 8) at **118** (or the cover **24a** is removed from the cap **22a**) and the bottle inverted at **120** so that the buffer reaches the spout (the bottle may be held at an angle). The bottle is positioned over the test apparatus which has been removed from its sterile package (see **11** in FIG. 10) and an appropriate number of drops are dispensed at **122** through the dropper spout **23** (or **23a**) by gently squeezing the bottle. When a dual path immunoassay device is used, at **124**, pure buffer from a separate bottle (discussed below) is added to another location of the test apparatus.

**[0032]** The apparatus of the invention was tested on one hundred patients known to be infected with HIV. The tests involved collecting oral fluid and performing the procedure described above. Ninety-seven positive test results were obtained and one indeterminate result. This compared favorably with a currently (at the time of the tests) FDA approved test which obtained ninety-eight positive test results from the one hundred patients. The apparatus of the invention was tested on twenty-five patients known to be not infected with HIV. The tests involved collecting oral fluid and performing the procedure described above. All twenty-five patients tested negative for HIV. The FDA approved test achieved the same results.

**[0033]** The above described kit (with bottle **12** or bottle **12a**) and method can be used with a single path assay device or with a dual path assay device. FIG. 10 shows a kit which is specifically intended for use with a dual path assay device (**1** in FIG. 1) which is shown in a sterile package **11**. The kit includes the swab **10** which is preferably contained in a sealed sterile package (not shown) and bottle assembly **12** (which can be replaced with bottle assembly **12a**). The kit may also include the assay device **1** and a second dropper bottle **41** containing the buffer solution to be added to hole **2** in FIG. 1 and as shown in phantom at **124** in FIG. 9. The kit preferably further includes a safety lancet **42**, a packaged alcohol swab **44** and a bandage **46**. Thus, the kit contains all that is needed to test several different kinds of samples, including blood. If desired, the kit may also include a blood collection loop **48**. All elements of the kit may be provided in a container or bag **50**.

**[0034]** A method of testing a blood sample includes using the alcohol swab **44** to clean the area of the skin from which

the sample will be taken, pricking the skin with the safety lancet **42**, collecting blood using the collection swab **10**, and bandaging the collection site with the bandage **46**. The method then proceeds as described above with reference to FIG. 9. While the presently preferred embodiment of the kit and method are designed for use with a dual path immunoassay device, a kit and method for use with a single path device are also contemplated by the invention. When applied to a single path device, the kit need not contain the second dropper bottle **41**.

**[0035]** As previously mentioned, if desired the kit of FIG. 10 may also include a blood collection loop **48**. If a blood collection loop is used to collect a blood sample, the blood sample in the loop may be transferred to the assay device by touching the loop with blood collected therein to the sample pad at the sample opening. One or more drops of buffer may then be added. If the assay device is a dual path assay device, the blood sample is applied at the sample opening **3**. Buffer from the second dropper bottle **41** (i.e., the pure or “running” buffer) is then added to the sample pad at the sample opening **3**. After a period of time, a desired number of drops of buffer from bottle **41** are then added to opening **2** of the assay device **1**.

**[0036]** There have been described and illustrated herein methods and apparatus for the collection and preparation of biological samples for testing. While particular embodiments of the invention have been described, it is not intended that the invention be limited thereto, as it is intended that the invention be as broad in scope as the art will allow and that the specification be read likewise. Thus, depending upon the assay device which is included in the kit, or with which the kit is to be used, different numbers of bottles of buffer, and different types of buffers or different types of solutions might be utilized, and the methods of use might vary. Also, depending upon the technique of the technician using the kit, it will be appreciated that different steps can be performed in different order. It will therefore be appreciated by those skilled in the art that yet other modifications could be made to the provided invention without deviating from its spirit and scope as claimed.

1.-15. (canceled)

**16.** A kit for collecting and preparing a biological sample for testing, the kit comprising:

a sterile swab separate and distinct from a dropper bottle assembly;

wherein the sterile swab has a stick with a sorbent fixed to the stick at one end of the stick, the stick having a weakened portion at a pre-selected location to facilitate breaking the stick; and

wherein the dropper bottle assembly comprises a dropper cap having a spout and a base, a squeezable bottle with a neck, and a cover that is manually removable from the dropper cap to expose the spout of the dropper cap, the bottle containing a liquid buffer, the base of the dropper cap being coupled to the neck of the bottle, and the dropper cap configured to dispense at least one drop from contents of the bottle when the bottle is squeezed, wherein length of the sterile swab is greater than height of the bottle without the dropper cap, and wherein the weakened portion of the stick is located a distance from the end of the sorbent, the distance being 90% to 100% of the height of the bottle without the dropper cap.

- 17.** A kit according to claim **16**, further comprising: an alcohol swab, a safety lancet, and a bandage.
- 18.** A kit according to claim **16**, further comprising: a blood collection loop.
- 19.** A kit according to claim **16**, wherein: the cover is connected to the dropper cap by a hinge that permits the cover to rotate about the hinge relative to the dropper cap
- 20.** A kit according to claim **16**, wherein: the cover is connected to the dropper cap by a thread interface.
- 21.** A kit according to claim **16**, wherein: the base of the dropper cap is connected to the neck of the bottle by a thread interface.
- 22.** A kit according to claim **16**, wherein: the biological sample is a blood sample.
- 23.** A kit according to claim **16**, wherein: the biological sample is one of oral fluid, blood, urine, stool, and epithelia.
- 24.** A kit for collecting and testing a biological sample, the kit comprising:  
 an immunoassay device;  
 a sterile swab separate and distinct from a dropper bottle assembly;  
 wherein the sterile swab has a stick with a sorbent fixed to the stick at one end of the stick, the stick having a weakened portion at a pre-selected location to facilitate breaking the stick;

- wherein the dropper bottle assembly comprises a dropper cap having a spout and a base, a squeezable bottle with a neck, and a cover that is manually removable from the dropper cap to expose the spout of the dropper cap, the bottle containing a liquid buffer, the base of the dropper cap being coupled to the neck of the bottle, and the dropper cap configured to dispense at least one drop from contents of the bottle when the bottle is squeezed, wherein length of the sterile swab is greater than height of the bottle without the dropper cap, and wherein the weakened portion of the stick is located a distance from the end of the sorbent, the distance being 90% to 100% of the height of the bottle without the dropper cap; and wherein the immunoassay device has a first opening identified for receiving drops dispensed from the bottle.
- 25.** A kit according to claim **24**, further comprising: an additional dropper bottle containing a liquid buffer; wherein the immunoassay device has a second opening identified for receiving drops dispensed from the additional bottle.
- 26.** A kit according to claim **24**, wherein: the biological sample is a blood sample.
- 27.** A kit according to claim **24**, wherein: the biological sample is one of oral fluid, blood, urine, stool, and epithelia.

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