



Europäisches Patentamt
European Patent Office
Office européen des brevets



(11) **EP 0 901 822 A2**

(12) **EUROPEAN PATENT APPLICATION**

(43) Date of publication:
17.03.1999 Bulletin 1999/11

(51) Int. Cl.⁶: **B01L 3/14**, A61B 5/14

(21) Application number: **98115775.3**

(22) Date of filing: **21.08.1998**

(84) Designated Contracting States:
**AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU
MC NL PT SE**
Designated Extension States:
AL LT LV MK RO SI

(30) Priority: **12.09.1997 US 928249**

(71) Applicant:
Becton, Dickinson and Company
Franklin Lakes, New Jersey 07417-1880 (US)

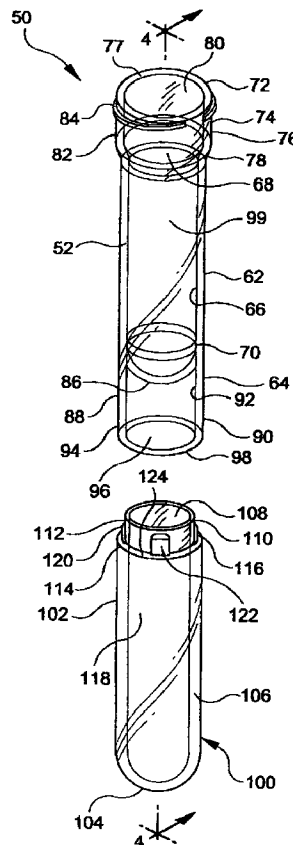
(72) Inventor: **Kelly, Karin E.**
Scotch Plains, New Jersey 07076 (US)

(74) Representative:
Selting, Günther, Dipl.-Ing. et al
Patentanwälte
von Kreisler, Selting, Werner
Postfach 10 22 41
50462 Köln (DE)

(54) **Collection container assembly**

(57) The present invention is a collection container assembly (50) comprising a first container (52) with a second container (100) removably secured to the bottom of the first container (52) wherein the external dimensions of the assembly (50) are substantially the same as a standard-sized blood collection tube but with a reduced internal volume.

FIG-3



EP 0 901 822 A2

Description

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0001] This invention relates to a specimen collection container assembly and more particularly to a collection container for collecting biological fluid specimens where a small quantity of fluid may be collected and retained in the container while maintaining a container size sufficient to be easily accommodated and/or compatible with standard clinical equipment and instrumentation.

2. Description of Related Art

[0002] Blood samples and other biological fluid specimens are routinely taken and analyzed in hospital and clinical situations for various medical purposes. Collection, handling and testing of these samples typically requires the use of various medical testing instruments. As the blood and fluid specimens are usually collected in a standard sized collection tube, the medical instruments used to test the samples are designed to accommodate these standard sized collection tubes.

[0003] Conventional blood collection tubes used in most clinical situations are elongated cylindrical containers having one end closed by a semi-spherical or rounded portion and an opposed open end. The open end may be sealed by a resilient cap or stopper. The tube defines a collection interior which collects and holds the blood sample. The most common size of these blood collection tubes are designed to accommodate approximately 10 ml of blood or other biological fluid samples. Illustrative of such blood collection tubes is the VACUTAINER® brand blood collection tube sold by Becton, Dickinson and Company, 1 Becton Drive, Franklin Lakes, NJ (registered trademark of Becton, Dickinson and Company).

[0004] A phlebotomist or other medical technician typically obtains a specimen of the patient's blood in the tube by techniques well known in the art. The tube is then appropriately labeled and transferred from the site of collection to a laboratory or other location where the contents of the tube are analyzed. During collection and analysis the tube may be supported by various medical instruments. The plasma or serum derived therefrom is processed and analyzed either manually, semiautomatically or automatically. In some cases, the specimen must first be dispensed from the collection tube to a sample test tube or cuvette.

[0005] In certain situations it is only necessary to obtain a small quantity of blood or other biological fluid specimens. These situations may include pediatric, or geriatric patients and other instances where large blood samples are not required. Small quantities of blood cannot be easily collected in standard collection tubes as described above because the sample level in such con-

tainers would not be adequate for retrieval prior to analysis. Such small quantities of fluids also have a tendency to significantly evaporate when stored in larger containers, thus concentrating the chemical and enzymatic constituents therein. This may result in erroneous analytical results and could possibly affect the diagnosis and treatment given the patient. Therefore, it is desirable to employ small-volume containers which substantially inhibit evaporation for the storage and delivery of minute fluid samples in the laboratory.

[0006] Various specimen containers such as those incorporating a "false bottom" have been proposed to achieve decreased volume capacity in conjunction with standard external dimensions. However, these various specimen containers are not compatible with standard clinical equipment and instrumentation due to their design. In particular, these specimen containers have false bottoms with a generally fiat, planar bottom end and a circular shaped opening.

[0007] Other specimen containers include partial-draw tubes which have standard external dimensions with partial evacuation so that blood fills only a portion of the internal volume. However, partial-draw tubes exhibit a reduction in the draw rate of a sample which reduces the collection efficiency of such tubes. In addition, partial-draw tubes may result in an inconsistent fill volume which may alter test results. Furthermore, it is difficult to determine the accurate sample quantities with such partial-draw tubes because the slow rate of sample draw is not consistently measurable.

[0008] In clinical use, it is desirable for such specimen collection containers to have rounded bottom configurations that closely simulate a standard-sized blood collection tube configuration instead of planar bottoms. Rounded bottom configurations facilitate compatibility with clinical equipment and instrumentation.

[0009] Therefore there is a need to provide a specimen collection container assembly for collecting blood samples and other biological fluid specimens of relatively small volumes where the assembly may be accommodated and/or compatible with standard clinical equipment and/or instrumentation and where the integrity of the sample and specimens are maintained during draw, storage and transport.

SUMMARY OF THE INVENTION

[0010] The present invention is a collection assembly comprising a first container and a second container. The first container preferably comprises an open top portion, a bottom portion and a sidewall extending from the open top portion to the bottom portion. The bottom portion comprises a closed bottom end or true bottom and an annular skirt extending from the closed bottom end to a stop end at a lower bottom portion. The assembly further comprises a second container that may be secured and unsecured to the lower bottom portion of the container.

[0011] Most preferably, the second container comprises a top portion, a bottom portion, a sidewall extending from the top portion to the bottom portion and an open end associated with the top portion having an integral connector. Most preferably, the integral connector has an inner surface, an outer surface, and ribs associated with the outer surface of the connector. Most preferably, the bottom portion is fully rounded or substantially spherical in shape. Most preferably, the integral connector fits or mates with the lower bottom portion of the annular skirt of the first container.

[0012] The second container is removably secured to the first container whereby the integral connector is inserted into the annular skirt of the first container by force or friction fit. Thereby, the second container provides the assembly with a false bottom end that is rounded. The second container may be the same or different material than the first container. The second container is removably unsecured from the first container whereby the user slightly twists the first container and the second container in opposite rotating directions thereby releasing the integral connector from the annular skirt and removing the second container from the first container.

[0013] The annular skirt of the container provides a false bottom effect to the assembly and the second container provides a means for allowing the first container to be modified so as to be compatible with standard clinical equipment and instrumentation.

[0014] The true bottom may be the same or different material than the first container and may be integral with the container or may be a discrete member. Additionally, the true bottom may be arcuate in shape to provide an internal volume for specimen collection having at least a partially rounded true bottom portion, or may be conical in shape.

[0015] In addition, the assembly may further comprise a closure such as a cap or a stopper at the open end of the first container.

[0016] Preferably, the external dimensions of the assembly which includes the first container and the second container are substantially the same as a standard-sized or full draw blood collection container assembly.

[0017] Most preferably, the assembly of the present invention can be either evacuated or non-evacuated. Desirably, the assembly is made from polyethylene terephthalate, polypropylene, polyethylene, polyethylene naphthalate polyvinyl chloride or copolymers thereof.

[0018] An advantage of the assembly of the present invention is that it provides a full-draw blood collection container assembly having a reduced internal volume but with external dimensions about the same as a standard-sized blood collection container assembly.

[0019] A further advantage of the assembly of the present invention is that it provides a specimen collection container which is universally compatible with various clinical equipment and instrumentation.

[0020] The assembly of the present invention may be

easily handled by equipment configured to handle standard-sized blood collection tubes having standard external dimensions.

[0021] Most notably, is that the assembly of the present invention provides a blood collection container having full draw external dimensions but with a reduced internal volume as compared to standard-sized full draw blood collection.

[0022] Standard-sized full draw blood collection containers have an outer diameter of about 13 to about 16 millimetres, a length of about 75 to about 100 millimeters and an internal volume of about 6 to about 10 milliliters.

[0023] The assembly of the present invention therefore addresses the need for a full-draw low-volume blood collection container assembly that presents the external dimensions of a standard-sized blood collection tube.

[0024] The assembly of the present invention may be used to reliably collect small samples of blood or biological fluids and to maintain the integrity of the samples during storage and transport as compared to using standard-sized blood collection tubes. In addition, the assembly of the present invention can also be accommodated by standard-sized blood collection, transportation, storage, and diagnostic equipment.

[0025] Most notably, is that the assembly of the present invention provides a rounded bottom configuration that is substantially the same as a standard-sized blood collection tube with a fully rounded bottom. This particular feature in conjunction with all of the features of the container, distinguishes it from the specimen containers that have flat planar bottoms.

[0026] The assembly of the present invention is also compatible with existing instrumentation, labels, and bar code readers and obviates the need for new instrumentation and handling devices or procedures that would be required for smaller or varying sized tubes or tubes with flat planar bottoms.

DESCRIPTION OF THE DRAWINGS

[0027]

FIG. 1 is a perspective view of a false bottom specimen tube of the prior art.

FIG. 2 is a longitudinal sectional view of the tube of FIG. 1 taken along line 2-2 thereof.

FIG. 3 is a perspective view of the assembly of the present invention with the second container unsecured from the first container.

FIG. 4 is a longitudinal sectional view of the assembly of FIG. 3 taken along line 4-4 thereof with the second container removably secured to the first container.

FIG. 5 illustrates the removal of the second container from the first container.

FIG. 6 is a perspective view of an alternate embod-

iment of the present invention.

DETAILED DESCRIPTION

[0028] The present invention may be embodied in other specific forms and is not limited to any specific embodiment described in detail which is merely exemplary. Various other modifications will be apparent to and readily made by those skilled in the art without departing from the scope and spirit of the invention. The scope of the invention will be measured by the appended claims and their equivalents.

[0029] Referring to the drawings in which like reference characters refer to like parts throughout the several views thereof, FIGS. 1 and 2 show a false bottom specimen container 10 of the prior art, having a sidewall 12 having an outer surface 14 and an inner surface 16. Cylindrical sidewall 12 extends from an upper portion 18 to a lower portion 20. Upper portion 18 includes an open end 22 and a rim 24. Lower portion 20 comprises a closed bottom end 26. An annular skirt 28 extends from lower portion 20 and outer surface 14 to a flat planar bottom end 30 to define an open false bottom area 36. Interior volume 34 extends between rim 24 and closed bottom end 26.

[0030] Referring to the drawings in which like reference characters refer to like parts throughout the several views thereof, FIGS. 3 and 4 show the preferred embodiment of the present invention, assembly 50. Assembly 50 comprises a first specimen container 52, having a cylindrical sidewall 62 having an outer surface 64 and an inner surface 66. Sidewall 62 extends from an upper portion 68 to a lower portion 70. Upper portion 68 includes an open end 72 and an integral neck 74.

[0031] Integral neck 74 has a first cylindrical sidewall 76 that extends from a rim 77 to a second cylindrical sidewall 78. Second cylindrical sidewall 78 has an external diameter less than the external diameter of first cylindrical sidewall 76. Second cylindrical sidewall 78 tapers inwardly towards cylindrical sidewall 62, wherein the external diameter of sidewall 62 is less than the external diameter of second cylindrical sidewall 78. First cylindrical sidewall 76 includes an inner surface 80 an outer surface 82 and threads 84 located on outer surface 82 for cooperating with threads on a closure.

[0032] Lower portion 70 of assembly 50 comprises a closed bottom end or true bottom 86. An annular skirt 88 having an outer surface 90 and an inner surface 92, extends from lower portion 70 and outer surface 64 to a bottom end or false bottom end 94 to define an open false bottom area 96 and planar rim surface 98. An interior volume 99 extends between rim 77 and closed bottom end 76.

[0033] Closed bottom end 76 may be positioned at any point below rim 77 thus providing a variable interior volume 99. Closed bottom end 76 may be generally fiat or planar in shape to provide a flat bottom surface for interior volume 99. Alternatively, closed bottom end 76

may be arcuate in shape to provide at least a partially rounded bottom surface for interior volume 99. Most preferably, closed bottom end is generally conical in shape to provide a conical, pointed bottom surface for interior volume 99. Additionally, closed bottom end 76 may be integral with sidewall 62 or may be a discrete member. Preferably closed bottom end 76 is integrally formed with sidewall 62.

[0034] As shown in FIGS. 3 and 4, second container 100 includes a top portion 102, a bottom portion 104, a cylindrical sidewall 106 extending from the top portion to the bottom portion, an open end 108 associated with top portion 102 and an integral connector 110 extending from top portion 102. Integral connector 110 extends between a top portion 112 and a bottom portion 114 having a cylindrical sidewall 116 that includes an inner surface 118 and an outer surface 120. A plurality of ribs 122 are associated on outer surface 120. Cylindrical sidewall 116 has an external diameter less than the external diameter of cylindrical sidewall 106. The bottom portion of the integral connector is connected to top portion 102 by a flat shoulder surface 124. Bottom portion 104 is fully rounded or substantially semi-spherical in shape.

[0035] As shown in FIG. 4, assembly 50 has an outer diameter A of about 16 millimeters, a length B of about 75 millimeters, as measured from rim 74 to bottom portion 104 of second container 100, and an interior volume 94 of about 1 to 3 milliliters. It is within the purview of this invention that assembly 50 may have an outer diameter of about 13 to about 16 millimeters, a length of about 75 to about 100 millimeters and an interior volume of about 1 to about 3 millilitres.

[0036] Annular skirt 88 provides a means for allowing the container to be placed upright on a flat surface, as well as providing a means for converting the assembly with the second container to substantially the same external dimensions as a standard-sized blood collection tube.

[0037] As shown in FIGS. 4 and 5, second container 100 is readily compatible with open false bottom area 96. Open false bottom area 96 receives integral connector 110 of second container 100 whereby inner surface 92 of annular skirt 88 and ribs 122 of integral connector 110 provide an interference fit and flat shoulder surface 124 meets with planar rim surface 98.

[0038] As shown in FIG. 5, the second container may be removed from the first container whereby the user slightly twists the first container and the second container in opposite directions thereby removing the second container from the first container.

[0039] The invention, as shown in FIG. 6 includes many components which are substantially identical to the components of FIGS. 3-4. Accordingly, similar components performing similar functions will be numbered identically to those components of FIGS. 3-4, except that a suffix "a" will be used to identify the similar components in FIG. 6.

[0040] As illustrated in FIG. 6, a further embodiment of the invention is assembly 150 which includes a closure 160.

[0041] The embodiment of FIG. 6 may be evacuated or non-evacuated. When assembly 150 is evacuated, interior volume 99a is typically maintained at a lower-than-atmospheric internal pressure so that when a blood collection probe penetrates through the closure placing interior volume 99a in communication with the circulatory system of a patient, the lower-than-atmospheric pressure of interior volume 99a will draw blood from the patient into the tube. Assembly 150 may be described as a full-draw blood collection tube because the internal pressure of interior volume 99a is low enough to draw a volume of blood substantially equal to the volume of interior volume 99a.

Claims

1. A collection assembly comprising:
 - a first container comprising a top portion, a bottom portion, a sidewall extending from said open top portion to said bottom portion, an annular skirt extending from said bottom portion to a lower bottom portion; and a second container comprising a top portion, a bottom portion, an open end associated with said top portion and an integral connector associated with said top portion having an inner surface, an outer surface and ribs associated with said outer surface.
2. The assembly of Claim 1, wherein said bottom portion of said first container is a closed bottom end or true bottom
3. The assembly of Claim 1, wherein said bottom portion of said first container is arcuate in shape.
4. The assembly of Claim 1, wherein said bottom portion of said first container is conical in shape.
5. The assembly of Claim 1, wherein said lower bottom portion of said first container comprises an open false bottom area and a planar rim surface.
6. The assembly of Claim 1, further comprising a closure.
7. The assembly of Claim 1, wherein said first container is made from polyethylene terephthalate, polypropylene, polyethylene, polyethylene naphthalate, polyvinyl chloride, or copolymers thereof.
8. The assembly of Claim 1, wherein said second container is made from polyethylene terephthalate, polypropylene, polyethylene, polyethylene naphthalate, polyvinyl chloride, or copolymers thereof.

late, polyvinyl chloride, or copolymers thereof.

9. The assembly of Claim 1, wherein said assembly comprises an outer diameter, a length and an internal volume, wherein said outer diameter is about 13 to about 16 millimeters, said length is about 75 to about 100 millimeters and said interior volume is about 1 to 3 milliliters.

FIG-1 PRIOR ART

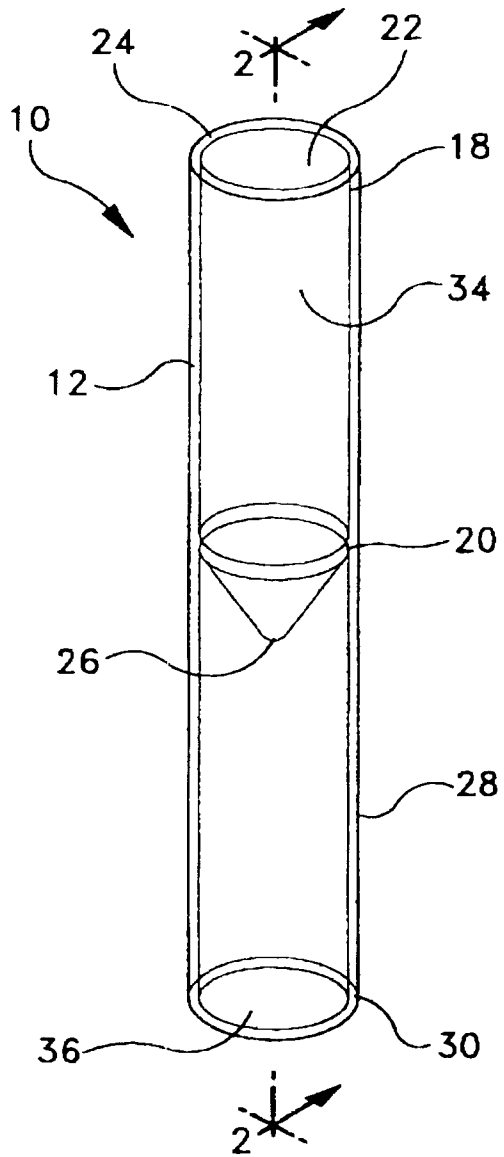


FIG-2 PRIOR ART

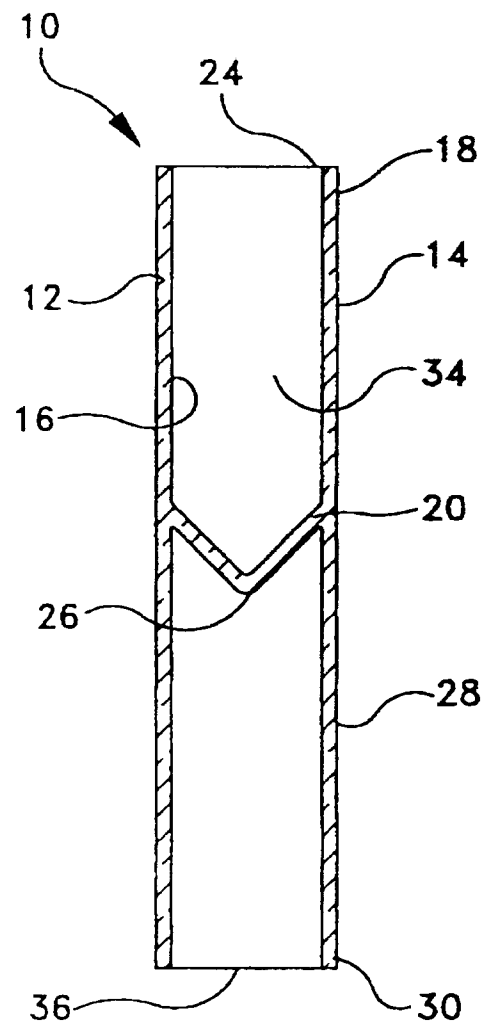


FIG-3

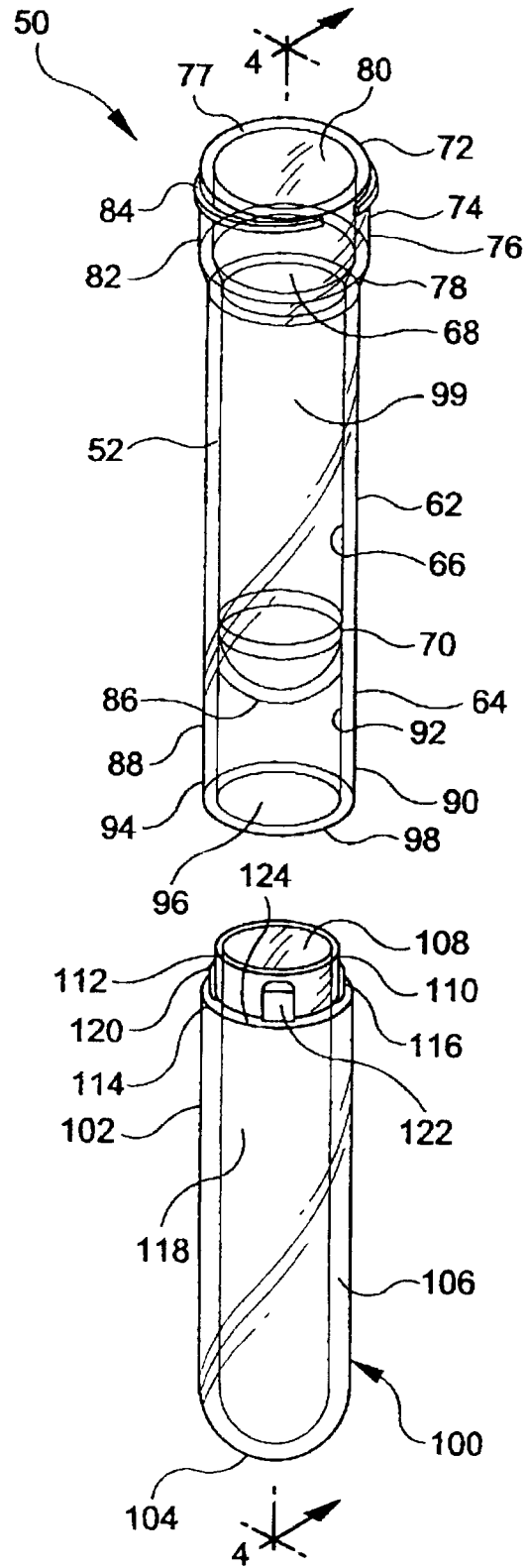


FIG-4

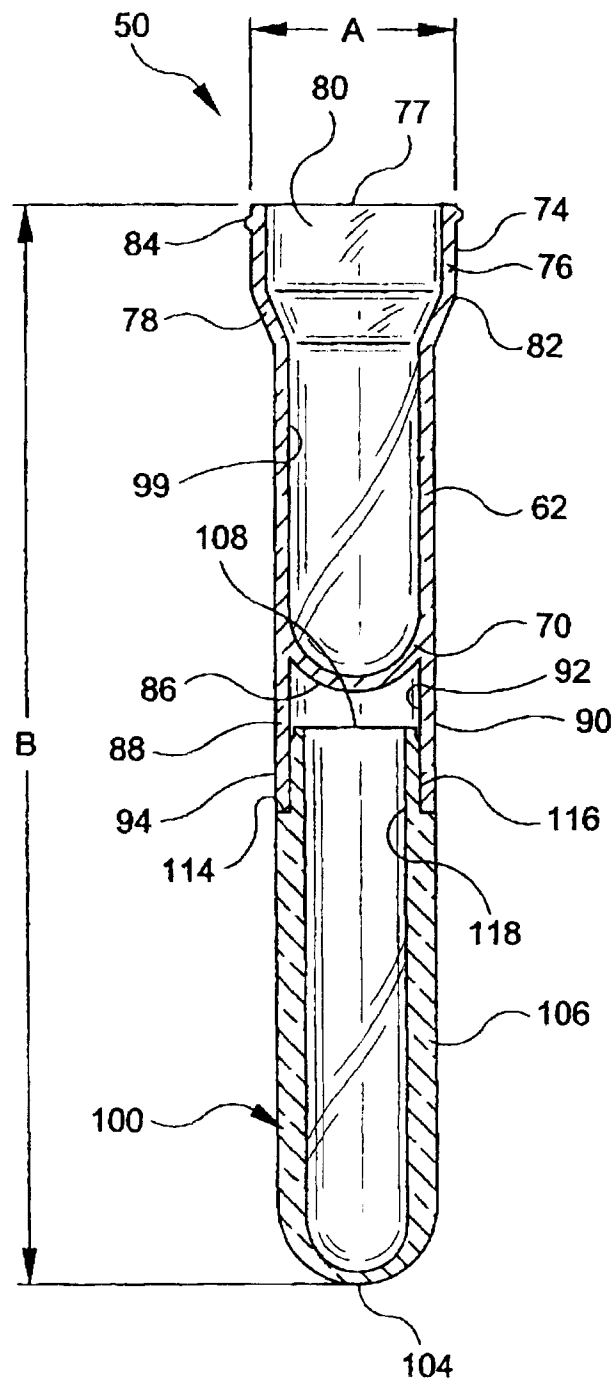


FIG-5

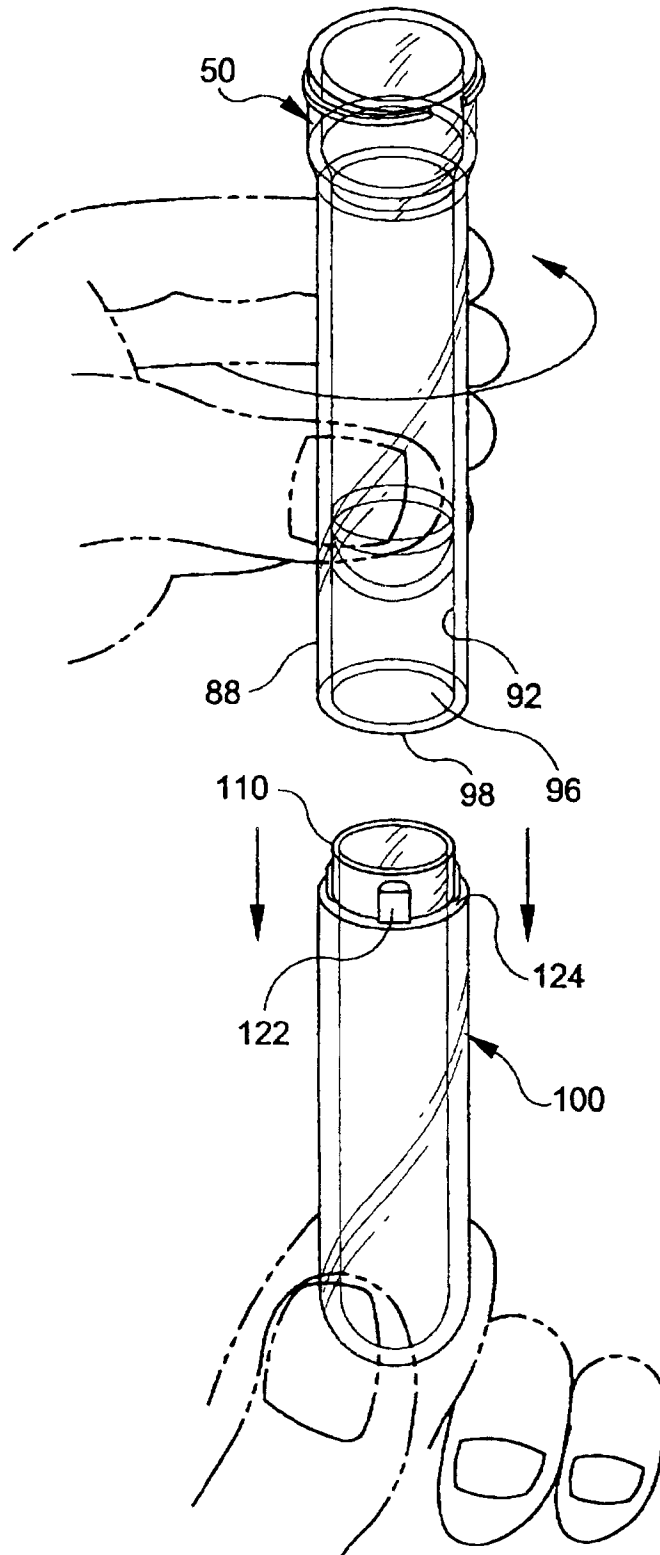


FIG-6

