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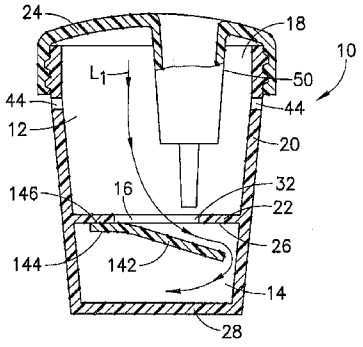

FIG.2A

(57) Abstract: A specimen collection container having a separation chamber includes a first chamber, a second chamber, and a valve located between the first chamber and the second chamber. In an open position, the valve permits fluid communication between the first chamber and the second chamber. In a closed position, the valve maintains fluid isolation between the first chamber and the second chamber. A fluid stream passes from the first chamber to the second chamber through the valve permitting a predetermined volume of fluid to pass from the first chamber to the second chamber. When the predetermined volume of fluid passes to the second chamber, the valve transitions from the open position to the closed position so that additional fluid of the fluid stream received by the first chamber is maintained in the first chamber in fluid isolation from the predetermined volume of fluid contained in the second chamber.

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SPECIMEN COLLECTION CONTAINER HAVING A FLUID SEPARATION CHAMBER

BACKGROUND OF THE INVENTION

Field of the Invention

[0001] The present invention is directed to a specimen collection container and, more particularly, a specimen collection container having two chambers separated by a valve for separating a patient's initially voided urine from the mid-stream portion of the urine sample.

Description of Related Art

[0002] When obtaining a urine sample for an ambulatory patient, it is generally preferable to collect the sample from the midstream portion of the urine stream. It is important to reject the "first-burst" urine from samples because the first volumes of voided urine carry a disproportionately higher level of bacteria. Bacteria is often picked up from external skin/tissue and also possibly from the urethral volume. The elevated bacteria level of the first stream or first-burst urine can lead to false-positive results for presence of bacteria, and could falsely suggest urinary tract infection, leading to unnecessary treatment or medication and inappropriate patient management. Since surface bacteria are always present, the chance for contamination of a urine sample is universal. As a result, urine samples are typically requested as "clean catch" or "mid-stream". Such requests require the patient or a care provider to use antiseptic wipes to disinfect external tissue. Additionally, patients are instructed to allow the first urine to fall into the toilet before filling a sample collection cup. It is believed that the first-burst urine not only contains elevated bacteria from the tissue surface, but in fact "washes" the external surfaces, such that there is little or no errant surface bacteria captured in later midstream urine volumes.

[0003] The state-of-the-art for midstream urine collection is essentially a manual process which relies entirely on the user or patient to perform the collection correctly. Typical instructions for midstream urine collection may require a user to void into the toilet, then stop urine flow, move the collection cup into position, void into the cup until it is full, stop the urine flow and move the filled cup away, and finish voiding into the toilet. Generally a user will be instructed to clean the surrounding external tissue/skin with an antiseptic wipe before voiding. The process is messy, with a user's hands being near the urine stream and often exposing the user's skin to urine.

[0004] Messiness and discomfort are not the only drawbacks from having a manual user-dependent process. In addition, patients need to be given adequate instructions placing an

additional requirement and burden on both patient and caregiver. Often, such as in situations where privacy is impossible (e.g., in the midst of a busy emergency room setting), caregivers do not provide any instructions at all. In addition, patients may not understand or choose not to follow the instructions even when they are given, particularly if the patient is already nervous, scared, or agitated. For example, there is significant anecdotal evidence of people not using the antiseptic wipes, either because they burn or are uncomfortable or because patients mistake the antiseptic wipes for hand wipes to be used after providing the sample. Indeed, there is no way to know, short of actually watching the patient provide the urine sample, whether any of the instructions are actually followed.

[0005] There are also physiological complications that may contribute to elevated bacterial contamination. Some evidence indicates that intentionally interrupting the urine flow can lead to the reintroduction of bacteria, essentially creating a new "first-burst" of urine from the reinitiated urine flow. The reinitiated urine may not flow over the same skin/tissue as the first flow, and, as a result, may pick up bacteria from previously un-wetted skin. Another possibility is that the ceased urine flow may actually dislodge bacteria, dead cells, or other potential contaminants that would not have been available to contaminate urine during an otherwise normal voiding event. Thus, the manual start-stop-start again process for collecting midstream urine may itself contribute to some bacterial contamination.

[0006] The frequency of bacterial contamination of urine samples ranges from 10-40%, depending on the nature of the tests and the institution where the studies are performed. Such statistics indicate that the problem is widespread and quite common. It likely contributes to significant waste, both in increased cost and time associated with handling poor samples or running tests that give ambiguous or potentially useless data. Retesting may be appropriate in some circumstances; however, especially in outpatient settings, the patient may not be available to provide a second sample. Consequently, a re-test is either never performed or simply never requested.

[0007] Therefore, in view of the difficulties in obtaining a correct urine sample using currently available methods, there is a need for a collection apparatus which makes the collection process easier and reduces the risk of exposing the patient to the urine flow. The apparatus should be intuitive to use and should be designed to promote proper use and handling of the collected sample at all points before, during, and after voiding of urine. Further, the device should increase patient comfort and convenience by effectively selecting the midstream urine, so the user does not need to consciously force stop-then-start voiding. Not requiring the patient to start-stop-start voiding urine flow reduces the risk of natural

physiologic contamination from stream interruption. Similarly, the device should require only minimal manipulation by a patient in order to collect the urine. Furthermore, the apparatus should eliminate the need for patients to be directly exposed to the urine stream. Finally, to ensure safe and easy transfer of the urine sample from the collection container to a specimen collection tube for testing, the device should include one or more access ports permitting direct flow of the collected sample from the container to a test tube.

SUMMARY OF THE INVENTION

[0008] Provided herein is a specimen collection container having a fluid separation chamber for receiving a fluid stream and for separating an initial volume of the fluid stream from a midstream portion of the fluid stream. The specimen collection container further includes a port for accessing and removing the midstream portion of the fluid from the container and for transferring the midstream portion to a sample collection tube. A method for collecting a fluid sample using a specimen collection container having a fluid separation chamber is also disclosed.

[0009] In accordance with one embodiment of the present invention, a specimen collection container includes a first chamber having an open top portion, a sidewall, and a bottom portion; a second chamber having a top, a closed bottom, and a sidewall; and a valve disposed between the first chamber and the second chamber. The valve is transitionable from an open position which permits fluid communication between the first chamber and the second chamber to a closed position which maintains fluid isolation between the first chamber and the second chamber. In the open position, a predetermined volume of fluid, received in the first chamber, may pass from the first chamber to the second chamber. When the predetermined volume of fluid passes to the second chamber, the valve transitions from the open position to the closed position such that additional fluid received within the first chamber is maintained in the first chamber in fluid isolation from the predetermined volume of fluid contained in the second chamber.

[0010] In certain configurations, the valve of the specimen collection container includes a channel extending between the first chamber and the second chamber and an absorbent expandable material. The absorbent expandable material absorbs the predetermined volume of fluid and expands to engage with the channel thereby transitioning the valve to the closed position. In certain alternative configurations, the container further comprises a gasket such that expansion of the absorbent expandable material positions the gasket to transition the valve. The absorbent expandable material may be a sponge.

[0011] In certain alternative configurations, the valve includes a channel, extending between the first chamber and the second chamber, and a buoyant float. When the second chamber receives the predetermined volume of fluid, the buoyant float engages the channel by a buoyancy force exerted on the float by the predetermined volume of fluid to transition the float from the open to the closed position. Optionally, a portion of the buoyant float initially seals the channel. Fluid passing from the first chamber to the second chamber disengages the float from the channel placing the valve in the temporarily open position.

[0012] In certain configurations, the specimen collection container further includes a port for accessing and removing a fluid sample from the first chamber. The port may include a nozzle defining a channel between the first chamber and an exterior of the specimen collection container; and a septum covering the channel which transitions from a closed position to an open position to allow removal of the fluid sample therefrom. The port may be disposed within the sidewall of the first chamber. The port may also include a needle having an external tip, an internal tip adjacent the first chamber, and a needle cannula extending therebetween, wherein fluid access to the first container is established through the needle cannula. Optionally, the external tip of the needle is recessed with respect to an external surface of the collection container for safe handling of the device.

[0013] In accordance with a further embodiment of the present invention, a specimen collection container includes an interior chamber having a bottom portion, a sidewall, and an open top; and an absorber disposed within the interior chamber which absorbs a predetermined volume of fluid. When a fluid stream enters the chamber through the open top, the absorber absorbs the predetermined volume. Additional fluid from the fluid stream is maintained in the internal chamber in fluid isolation from the fluid absorbed by the absorber. Optionally, the absorber includes bentonite, diatomaceous earth, pelites, zeolites, chitosan, alginates, starch-based powders, and/or sodium polyacrylate. The absorber may include a powder. Alternatively, the absorber may include a pouch enclosing an absorbent material.

[0014] In certain configurations, the interior chamber includes a screen separating the interior chamber into a first chamber and a second chamber with the absorber maintained therein. The screen permits fluid to pass from the first chamber to the second chamber but prevents the absorber from passing from the second chamber to the first chamber.

[0015] In accordance with a further embodiment of the present invention, a specimen collection container includes a first chamber having an open top portion, a sidewall, and a bottom portion; a second chamber having a top, a closed bottom, and a sidewall; and a valve disposed between the first chamber and the second chamber. The valve is transitionable from

a first closed position in which the first chamber and the second chamber are in fluid isolation, to an open position which permits fluid communication between the first chamber and the second chamber, to a second closed position in which fluid isolation between the first chamber and the second chamber is restored. The valve may include a spring action flapper valve.

[0016] In certain configurations, a fluid entering the first chamber transitions the valve from the first closed position to the open position and the presence of a predetermined volume of fluid within the second chamber transitions the valve from the open position to the second closed position. Optionally, the valve includes a flapper valve transitionable from the first closed position to the open position when fluid contacts the surface of the flapper adjacent the first chamber. The valve is also subsequently transitionable from the open position to the second closed position when a predetermined volume of fluid received within the second chamber contacts the surface of the flapper adjacent the second chamber.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] The following description is provided to enable those skilled in the art to make and use the described embodiments contemplated for carrying out the invention. Various modifications, equivalents, variations, and alternatives, however, will remain readily apparent to those skilled in the art. Any and all such modifications, variations, equivalents, and alternatives are intended to fall within the spirit and scope of the present invention.

[0018] **FIG. 1A** is a cross-sectional front view of a specimen collection container with a valve in the open position in accordance with an embodiment of the present invention.

[0019] **FIG. 1B** is a cross-sectional front view of the container of **FIG. 1A** with the valve in the closed position in accordance with an embodiment of the present invention.

[0020] **FIG. 2A** is a cross-sectional front view of a specimen collection container with a valve in the open position in accordance with an embodiment of the present invention.

[0021] **FIG. 2B** is a cross-sectional front view of the container of **FIG. 2A** with the valve in the closed position in accordance with an embodiment of the present invention.

[0022] **FIG. 3A** is a cross-sectional front view of a specimen collection container with a valve in the open position in accordance with an embodiment of the present invention.

[0023] **FIG. 3B** is a cross-sectional front view of the container of **FIG. 3A** with the valve in the closed position in accordance with an embodiment of the present invention.

[0024] **FIG. 4** is a perspective view of a specimen collection container having an absorbent pouch in accordance with an embodiment of the present invention.

[0025] **FIG. 5** is a perspective view of the absorbent pouch of **FIG. 4**, in accordance with an embodiment of the present invention, with a partial cut-away portion to reveal the interior of the pouch.

[0026] **FIG. 6** is a perspective view of a specimen collection container having an absorbent material in accordance with an embodiment of the present invention.

[0027] **FIG. 7** is a cross-sectional front view of a specimen collection container, having an outflow port, in accordance with an embodiment of the present invention.

[0028] **FIG. 8** is a cross-sectional front view of a specimen collection container, in accordance with an embodiment of the present invention, having a sharps-free elastomeric port.

[0029] **FIG. 9** is a cross-sectional front view of the specimen collection container of **FIG. 8** engaged with a sample collection tube for removing a sample from the container, in accordance with an embodiment of the present invention.

[0030] **FIG. 10** is a cross-sectional front view of a sample collection tube, in accordance with an embodiment of the present invention.

[0031] **FIG. 11A** is a top view of an absorbent material for use in a specimen collection container, in accordance with an embodiment of the present invention.

[0032] **FIG. 11B** is a top view of an absorbent material for use in a specimen collection container, in accordance with an embodiment of the present invention.

[0033] **FIG. 11C** is a top view of an absorbent material for use in a specimen collection container, in accordance with an embodiment of the present invention.

[0034] **FIG. 11D** is a top view of an absorbent material for use in a specimen collection container, in accordance with an embodiment of the present invention.

[0035] **FIG. 11E** is a perspective view of an absorbent material for use in a specimen collection container, in accordance with an embodiment of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0036] For the purpose of facilitating understanding of the invention, the accompanying drawings and description illustrate preferred embodiments thereof, from which the invention, various embodiments of its structures, construction and method of operation, and many advantages may be understood and appreciated.

[0037] For purposes of the description hereinafter, the terms "upper", "lower", "right", "left", "vertical", "horizontal", "top", "bottom", "lateral", "longitudinal", and derivatives thereof shall relate to the invention as it is oriented in the drawing figures. However, it is to

be understood that the invention may assume alternative variations and step sequences, except where expressly specified to the contrary. It is also to be understood that the specific devices and processes illustrated in the attached drawings, and described in the following specification, are simply exemplary embodiments of the invention. Hence, specific dimensions and other physical characteristics related to the embodiments disclosed herein are not to be considered as limiting.

[0038] With reference to **FIGS. 1A-3B**, a specimen collection container **10** includes a first chamber **12** in fluid communication with a second chamber **14** through a valve **16**. The specimen collection container **10** is adapted to receive and separate a fluid stream into an initial or void volume and a midstream or sample volume. The midstream or sample volume can be removed from the specimen collection container **10** for biological testing. The container **10** is formed from any relatively inert medical grade polymer such as high density polyethylene or polystyrene. Alternatively, the container **10** may be formed from glass, paper or cellulose-based products.

[0039] The specimen collection container **10** includes a first chamber **12** having an open top portion **18**, a sidewall **20**, and a closed bottom portion **22**. As shown in FIGS. **3A-3B**, the sidewall **20** may be sloped toward the bottom portion **22** of the first chamber **12** giving the first chamber **12** a funnel shape such that the diameter **A** of the open top portion **18** is larger than the diameter **B** of the closed bottom portion **22**. In this configuration, fluid introduced to the funnel shaped chamber more easily slides downward towards the bottom of the container.

[0040] The first chamber **12** may include a fluid volume indicator **44** to show the amount of fluid contained therein. The first chamber **12** may be covered by a removable lid **24** which can be placed over the open top **18** of the first chamber **12** after the fluid sample is introduced to the chamber **12**. The lid **24** prevents the fluid sample from leaking from the container **10** and prevents the sample from being contaminated.

[0041] The first chamber **12** is in fluid communication with the second chamber **14**. The second chamber **14** includes a closed top **26**, sidewall **20**, and closed bottom **28.** In one non-limiting embodiment, the second chamber **14** is positioned below the first chamber **12** such that the bottom portion **22** of the first chamber **12** also forms the closed top **26** of the second chamber **14**. In one embodiment, the second chamber **14** has a volume of about 12 mL to 15 mL which may be smaller than the volume of the first chamber **12**.

[0042] Fluid communication between the first chamber **12** and the second chamber **14** is established through the valve **16**. The valve **16** transitions from a first position in which fluid communication between the first chamber **12** and second chamber **14** is established to a

second position in which the first chamber **12** and the second chamber **14** are held in fluid isolation. In one embodiment, valve **16** includes a channel **32** that connects the first chamber **12** with the second chamber **14**. When valve **16** is in the closed position, the channel **32** is blocked to prevent fluid in the first chamber **12** from flowing to the second chamber **14**. Similarly, the valve **16** prevents fluid contained in the second chamber **14** from passing back to the first chamber **12**. When the valve **16** is in the closed position, fluid follows fluid flow path $\mathbf{L_2}$. In the open position, fluid flow $\mathbf{L_1}$ is permitted between the first chamber **12** and the second chamber **14** through the channel **32**.

[0043] With reference to **FIGS. 1A** and **1B**, in one non-limiting embodiment of the present invention, the valve **16** includes an expandable absorbent material **34**, such as a compressed sponge, contained within the second chamber **14**. The absorbent material **34** may be glued to the closed bottom **28** of the second chamber **14**. In one exemplary embodiment, the absorbent material **34** has a diameter of 1.7 inches and an expanded height of about 5/8 inch. In comparison, the height of the second chamber **14** is about ½ inch. Consequently, when expanded, the absorbent material **34** takes up an entire volume of the second chamber **14**. When wetted, the absorbent material **34** expands upward toward the closed top **26** to engage the channel **32**. The absorbent material **34** may be formed in any configuration which allows for rapid fluid absorption and expansion in size. Some configurations increase the absorption rate by increasing the surface area of the absorbent material **34**. With reference to **FIGS. 11A-11E**, possible shapes of the absorbent material **34** include, but are not limited to, a cylinder, a cylindrical shaped object with perforated holes, a cylindrical shape with wedges removed, a donut shape, and a plurality of separate thinner cylinders.

[0044] With reference again to **FIGS. 3A** and **3B**, according to one non-limiting embodiment, the second chamber **14** includes a ribbed base **36**. The absorbent material **34** is placed on the ribbed base **36** or similar support structure. The support structure elevates the absorbent material **34** permitting fluid to collect in the space **38** beneath the absorbent material **34** and allowing the fluid to be absorbed by a bottom surface of the absorbent material **34**. Exposing an additional surface of the absorbent material **34** to fluid increases the absorption rate.

[0045] According to a further non-limiting embodiment, the valve **16** further includes a gasket **40** for creating a water-tight seal in the channel **32**, as shown in **FIGS. 1A-1B**. The gasket **40** is attached to a top portion of the absorbent material **34**. The gasket **40** can be, for example, a polymeric foam disk. It is noted that the gasket **40** effectively blocks a portion of the absorbent material **34** from absorbing liquid. Accordingly, it is important that other

surfaces of the absorbent material **34** are accessible to fluid flow L_1 so that the absorbent material **34** expands as quickly as possible. As the wetted absorbent material **34** expands and rises in an upward direction, the gasket **40** engages the channel **32**, thereby sealing the channel **32** and, effectively, transitioning the valve **16** to the closed position. Once the gasket **40** is in place and engaged with the channel **32**, the first chamber **12** and the second chamber **14** are in fluid isolation from one another. Accordingly, any additional fluid that enters the first chamber **12** through the open top **18** is maintained in the first chamber **12**. This fluid maintained in the first chamber **12** is the midstream urine sample.

[0046] In a further non-limiting embodiment, the valve **16** consists of a buoyant float **142** which is forced in an upward direction toward the channel **32** as the fluid level of the second chamber **14** rises. In one embodiment, the buoyant float **142** includes gasket **40** for forming a seal between the float **142** and channel **32**.

[0047] With reference to **FIGS. 2A** and **2B**, in a further embodiment of the invention, the valve **16** is a "flapper valve". In the flapper valve, a portion **144** of the float **142** is attached to the closed top **26** of the second chamber **14** forming a hinge **146**. In one embodiment, the hinge **146** is a living hinge. In another embodiment, the flapper valve includes a mechanical spring. The float **142** is held in close proximity to the channel **32** such that, initially, the float **142** covers the channel **32**. Force exerted on the float **142** from fluid flow L_1 entering the first chamber **12** pushes the float **142** away from the channel **32** allowing fluid to pass directly through the channel **32** from the first chamber **12** to the second chamber **14**. As the fluid level of the second chamber **14** increases, the range of movement for the float **142** is reduced, until, ultimately, the float **142** is held in place against the top **26** of the second chamber **14** and the channel **32**. Once the float **142** is in place against the channel **32**, fluid flow L_2 from the first chamber **12** to the second chamber **14** is blocked. Therefore, additional fluid introduced to the first chamber **12** is collected and maintained in the first chamber **12**. The fluid collected within the first chamber **12** is the midstream portion of the urine stream.

[0048] With reference again to **FIGS. 3A** and **3B**, the valve **16** of the specimen collection container **10** may also include both a float **142** and expandable absorbent material **34**. When wetted, the absorbent material **34** increases in size eventually contacting the float **142** of the flapper valve **16** and forcing the float **142** toward the channel **32** to form a seal. When expanded, the absorbent material **34** maintains the float **142** in the closed position, thereby ensuring that the first chamber **12** and the second chamber **14** remain in fluid isolation even when the specimen container is jostled or moved.

[0049] With reference to **FIGS. 4** and **5**, according to a further embodiment of the present invention, an absorbent pouch **234** is included within the sample collection container **10**. The pouch **234** may be a non-woven filter paper bag **236** enclosing a micro-absorbent powder **238**. Fluid enters the container according to fluid flow **L**. The pouch **234** absorbs a first predetermined volume of the fluid. The absorbed portion corresponds with the initial burst or voided urine which is held in isolation in the second chamber in the embodiments of the invention described above. In the present embodiment, once the pouch **234** reaches a saturation point, indicating that it has absorbed the predetermined amount of fluid, any additional fluid introduced to the container **10** is maintained in the container **10** in liquid form.

[0050] In one embodiment, the container **10** includes a screen **240** separating the first chamber **12** from the second chamber **14**. The screen **240** effectively holds the pouch **234** within the second chamber **14** and prevents the pouch from floating toward the top of the container as the fluid level increases. The screen **240** could be formed from a wire mesh or from a disk having a plurality of perforated holes.

[0051] With reference to **FIG. 6**, according to a further embodiment of the present invention, the first chamber **12** and the second chamber **14** are separated by a piece of filter paper **340**. The second chamber **14** contains an absorbent powder **334**. The absorbent powder **334** may be a mineral based compound or a synthetic compound. Examples of mineral based absorbent compounds include bentonite and diatomaceous earth. Bentonite is an absorbent aluminum phyllosilicate formed from impure clay. Diatomaceous earth is a compound composed of absorbent silica particles. Other natural absorbent materials include: pelites, zeolites, and chitosan. Organic absorbent powders are commercially available from a number of sources including: Sigma-Aldrich, LLC, MedTrade Products Ltd., and Haliburton. Absorbent alginates or starch based powders can also be used within the scope of the invention. Most synthetic absorbent powders are formed from sodium polyacrylate. One commercially available sodium polyacrylate powder is "Insta-Snow" produced by Steve Spangler, Inc. of Englewood, Colorado.

[0052] When wetted, the absorbent powder forms a solid structure which will not pass through the filter paper **340**, thereby separating the first chamber **12** from the second chamber **14**. The powder **334** holds a predetermined initial volume of fluid. Once the powder **334** is saturated, any additional fluid introduced to the container **10** is maintained in the container **10** in liquid form. As with previous embodiments described above, the unabsorbed liquid portion constitutes the midstream urine sample. Alternatively, fiber papers are known in the

art which are impregnated with sodium polyacrylate particles. Absorbent paper of this type is made by Safetec of America, Inc. located in Buffalo, NY. One or more pieces of the absorbent paper are placed in the second chamber **14** of the container **10**. The absorbent paper is used to absorb a first-burst of fluid in much the same way as the absorbent powder.

[0053] With reference to **FIG. 7**, according to one non-limiting embodiment, the invention further includes an outflow port **50** for removing the sample (e.g., the midstream urine) from the sample container **10**. In one embodiment, the outflow port **50** comprises a needle **52** having a needle cannula **59** for accessing the sample contained in the first chamber **12**. The needle **52** may be located in a cut-away portion **56** of the sidewall **20** or lid **24** such that a proximal end **83** of the needle **52** is recessed from the surfaces of the container **10**. The needle **52** is in contact with an access tube **58** that extends into the first chamber **12** of the container **10**. Fluid passes through access tube **58** before entering the needle cannula **54** for removal from the container **10**.

[0054] With reference to **FIGS. 7** and **10**, to extract a sample from the container **10**, a user places a sample collection tube **510** (e.g., a test tube) over the needle **52**. Generally, the tube **510** includes an open end **512** covered by a stopper **514** having a pierceable septum **516**. The needle **52** pierces the septum **516** accessing an interior portion **518** of the tube **510** and creating a fluid connection between the first chamber **12** and the tube **510** through the needle cannula **54**. In one configuration, the sample collection tube **510** may be evacuated such that upon engagement with the container **10**, fluid is drawn from the container interior into the sample collection tube **510** by vacuum draw. In another configuration, the entire container assembly may be inverted allowing fluid (e.g., the midstream urine sample) to flow from the collection container **10** to the specimen collection tube **510**.

[0055] With reference to **FIG. 8**, according to an alternative embodiment, a sharps free port **70** extends from either the sidewall **20** or lid **24** of the first chamber **12**. The sharps free port **70** includes a nozzle **72** extending from the container **10** or lid **24**. A channel **74** is defined through the nozzle **72** allowing access to the first chamber **12**. An elastomeric seal **76** covers the channel **74** preventing fluid from leaking from the port **70** until a user is prepared to collect the fluid in a specimen collection tube **410**, as shown in **FIG. 9**. With reference to **FIG. 9**, the specimen collection tube **410** has an open top **412** covered by a stopper or flip-cap closure **414**. The flip-cap closure **414** includes an access tube **418**. The access tube **418** fits within the channel **74** of the nozzle **72** and pushes the elastomeric seal **76** out of the way to establish a fluid connection between the first chamber **12** and the sample collection tube **410**. Once the fluid connection is established, the container **10** is inverted

allowing the fluid sample to flow, along flow path L_3, from the first chamber **12** to the collection tube **410** by gravity. The flip-cap closure **414** may further include a vent **420** allowing air displaced by the fluid sample to escape from the enclosed tube **410**.

[0056] The presently claimed sample collection container **10** is used to collect a sample of midstream urine for testing. In use, a patient directs a urine stream to the container **10** through the open top **18** of the first chamber **12**. The urine stream flows down the sidewall **20** toward the channel **32** and valve **16**. In one embodiment, the first chamber **12** is funnel shaped having a sloped sidewall **20**. The sloped sidewall **20** allows fluid to more easily flow downward toward the bottom **22** of the first chamber **12**. The funnel shaped first chamber **12** also ensures that all of the first-burst or first urine stream will pass through the first chamber **12** and enter the second chamber **14**. For containers having straight sides and right angled corners, a portion of the first-burst may pool in the first chamber **12**, potentially contaminating the fluid sample.

[0057] The fluid stream passes through the channel **32** and valve **16** and collects in the second chamber **14**. As the fluid level in the second chamber **14** increases to a pre-determined level, the valve **16** transitions from an open to a closed position. The pre-determined volume for the second chamber **14** may be between about 12 mL and 15 mL. The valve **16** should not transition to the closed position until the pre-determined volume of fluid passes to the second chamber **14**. If the valve **16** closes too soon, a portion of the initial burst of urine will be trapped in the first chamber **12** contaminating the midstream urine sample. If the valve **16** closes too slowly, some of the first-burst urine, which initially passed to the second chamber **14**, will flow back to the first chamber **12** contaminating the urine sample contained in the first chamber **12**.

[0058] Once the required amount of midstream urine is collected in the first chamber **12**, the specimen collection container **10** is removed from the urine stream. Alternatively, the patient may consciously stop urine flow to prevent overflowing the container **10**. The container **10** may include a fluid level indicator line **44** to inform the patient when the necessary amount of fluid has been collected. The lid **24** is then placed over the open top **18** of the first chamber **12** to prevent fluid from leaking from the container **10** or from being contaminated. The midstream urine sample is then removed from the first chamber **12** through the outflow port **50** or from the sharps free port **70** using any of the extraction procedures described above.

WHAT IS CLAIMED IS:

1. A specimen collection container comprising:

a first chamber having an open top portion, a sidewall, and a bottom portion;

a second chamber having a top, a closed bottom, and a sidewall; and

a valve disposed between the first chamber and the second chamber and transitionable from an open position which permits fluid communication between the first chamber and the second chamber to a closed position which maintains fluid isolation between the first chamber and the second chamber,

wherein, in the open position, a predetermined volume of fluid received in the first chamber may pass from the first chamber to the second chamber and, wherein when the predetermined volume of fluid passes to the second chamber, the valve transitions from the open position to the closed position such that additional fluid received within the first chamber is maintained in the first chamber in fluid isolation from the predetermined volume of fluid contained in the second chamber.

2. The specimen collection container of claim 1, wherein the valve comprises:

a channel extending between the first chamber and the second chamber; and

an absorbent expandable material, wherein the absorbent expandable material absorbs the predetermined volume of fluid and expands to engage with the channel thereby transitioning the valve to the closed position.

3. The specimen collection container of claim 2, further comprising a gasket such that expansion of the absorbent expandable material positions the gasket to transition the valve.

4. The specimen collection container of claim 2, wherein the absorbent expandable material is a sponge.

5. The specimen collection container of claim 1, wherein the valve comprises:

a channel extending between the first chamber and the second chamber; and

a buoyant float which, when the second chamber receives the predetermined volume of fluid, engages the channel by a buoyancy force exerted on the float by the predetermined volume of fluid to transition the float from an open position to a closed position.

6. The specimen collection container of claim 5, wherein a portion of the buoyant float initially seals the channel, and wherein fluid passing from the first chamber to the second chamber disengages the float from the channel placing the valve in the open position.

7. The specimen collection container of claim 1, further comprising a port for accessing and removing a fluid sample from the first chamber.

8. The specimen collection container of claim 7, wherein the port comprises:

a nozzle defining a channel between the first chamber and an exterior of the specimen collection container; and

a septum covering the channel which transitions from a closed position to an open position to allow removal of the fluid sample therefrom.

9. The specimen collection container of claim 7, wherein the port is disposed within the sidewall of the first chamber.

10. The specimen collection container of claim 7, wherein the port is disposed within a removable lid adapted to cover the open top portion of the first chamber.

11. The specimen collection container of claim 7, wherein the port comprises a needle having an external tip, an internal tip adjacent the first chamber, and a needle cannula extending therebetween, wherein fluid access to the first chamber is established through the needle cannula.

12. The specimen collection container of claim 11, wherein the external tip of the needle is recessed with respect an external surface of the collection container.

13. A specimen collection container comprising:

an interior chamber having a bottom portion, a sidewall, and an open top; and

an absorber disposed within the interior chamber which absorbs a predetermined volume of fluid, wherein when a fluid stream enters the chamber through the open top, the absorber absorbs the predetermined volume, and additional fluid from the fluid stream is maintained in the interior chamber in fluid isolation from the fluid absorbed by the absorber.

14. The specimen collection container of claim 13, wherein the absorber comprises bentonite, diatomaceous earth, pelites, zeolites, chitosan, alginates, starch-based powders, and/or sodium polyacrylate.

15. The specimen collection container of claim 13, wherein the interior chamber comprises a screen separating the interior chamber into a first chamber and a second chamber with the absorber maintained therein, and wherein the screen permits fluid to pass from the first chamber to the second chamber but prevents the absorber from passing from the second chamber to the first chamber.

16. The specimen collection container of claim 13, wherein the absorber comprises a powder.

17. The specimen collection container of claim 13, wherein the absorber comprises a pouch enclosing an absorbent material.

18. A specimen collection container, comprising:

a first chamber having an open top portion, a sidewall, and a bottom portion;

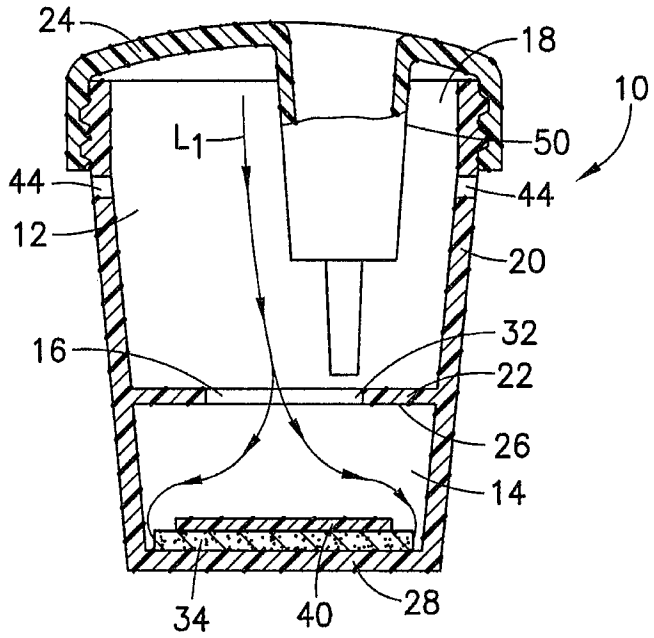
a second chamber having a top, a closed bottom, and a sidewall; and

a valve disposed between the first chamber and the second chamber and transitionable from a first closed position in which the first chamber and the second chamber are in fluid isolation, to an open position which permits fluid communication between the first chamber and the second chamber, to a second closed position in which fluid isolation between the first chamber and the second chamber is restored.

19. The specimen collection container of claim 18, wherein the valve comprises a spring action flapper valve.

20. The specimen collection container of claim 18, wherein a fluid entering the first chamber transitions the valve from the first closed position to the open position, and wherein the presence of a predetermined volume of fluid within the second chamber transitions the valve from the open position to the second closed position.

21. The specimen collection container of claim 18, wherein the valve comprises a flapper valve transitionable from the first closed position to the open position where fluid contacts a surface of the flapper valve adjacent the first chamber, and subsequently transitionable from the open position to the second closed position when a predetermined volume of fluid received within the second chamber contacts the surface of the flapper valve adjacent the second chamber.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18
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L1
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12
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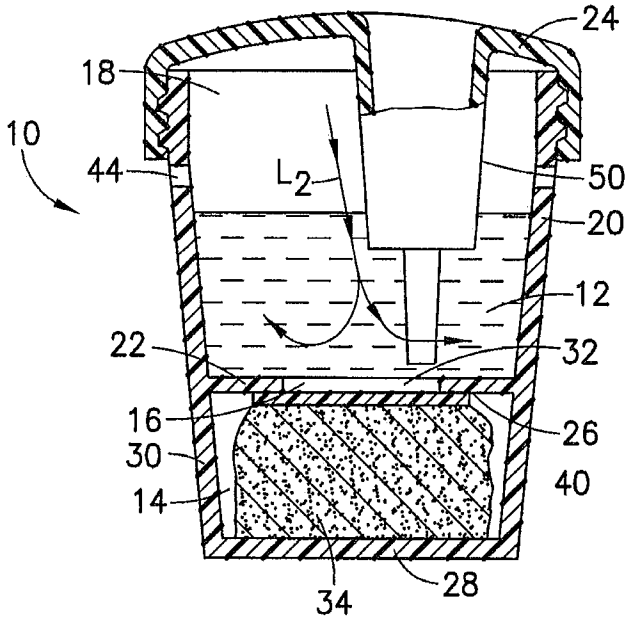
28

FIG.1A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L2
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FIG.1B

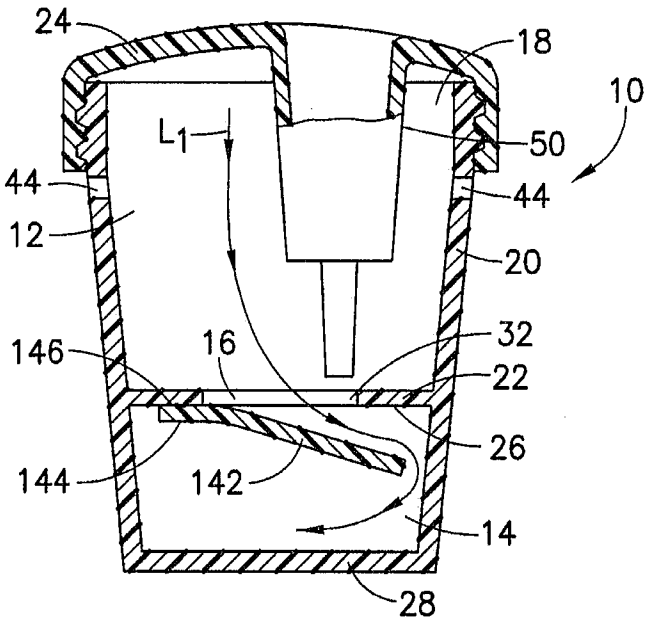
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FIG.2A

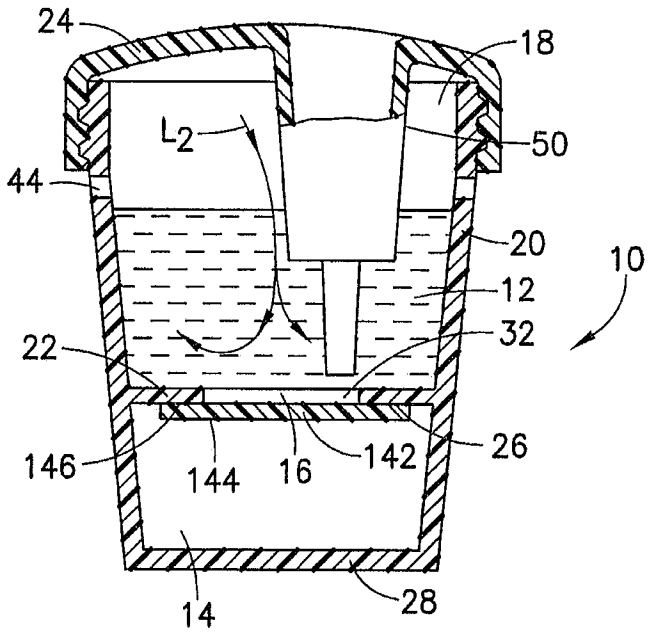
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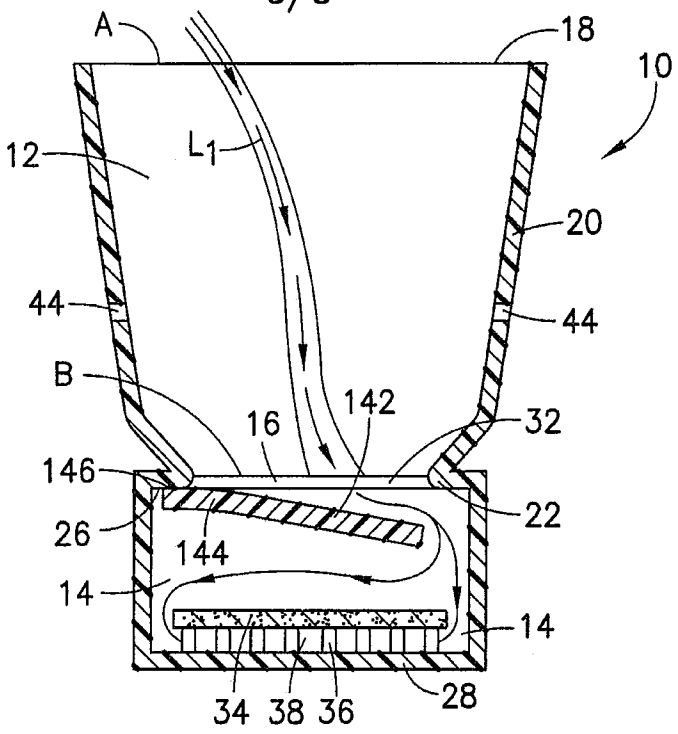
FIG.2B


A
18
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12
L_1
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B
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FIG.3A

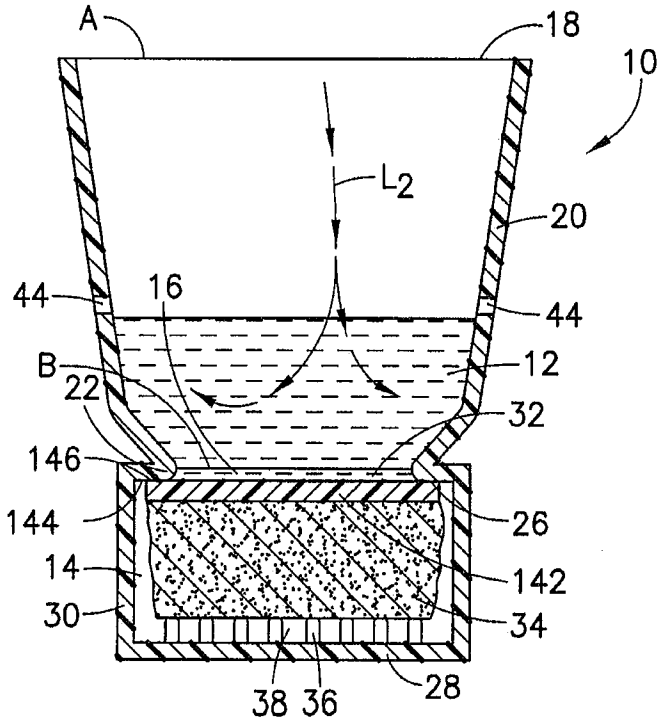
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FIG.3B

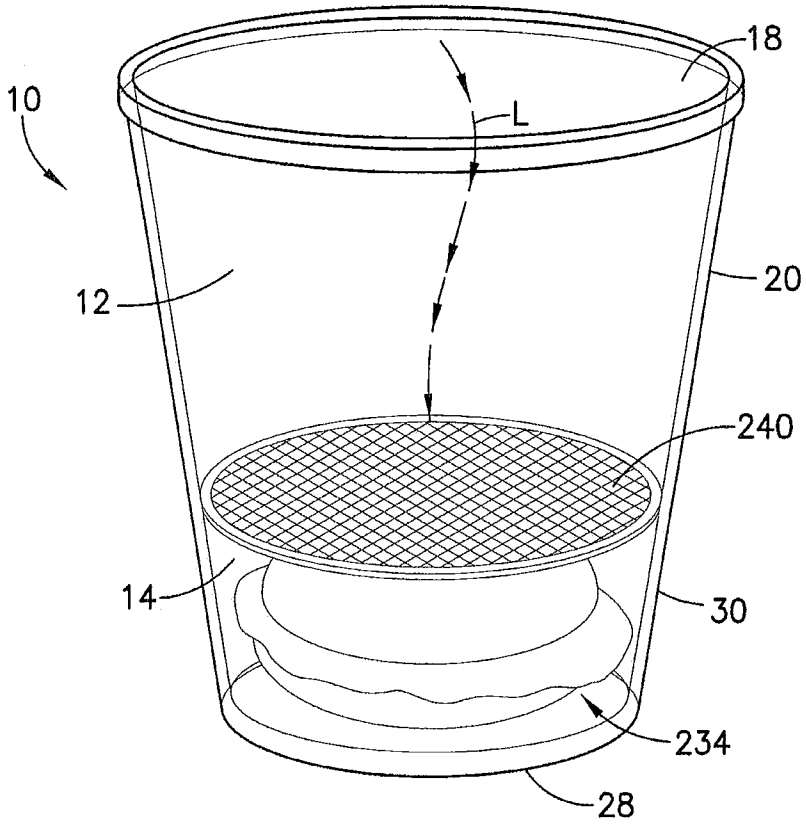

FIG.4

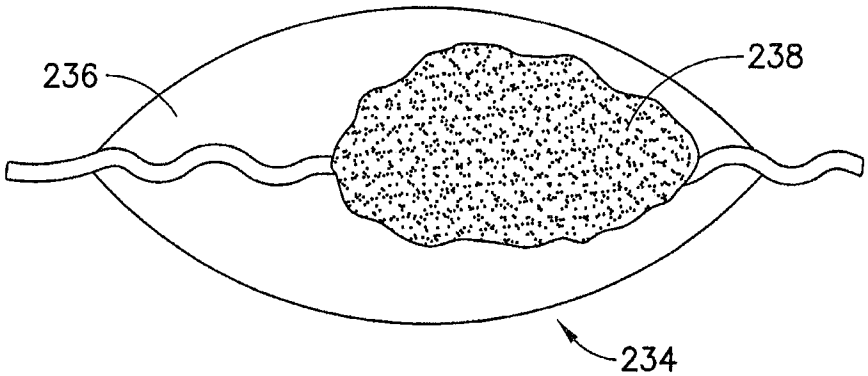

FIG.5

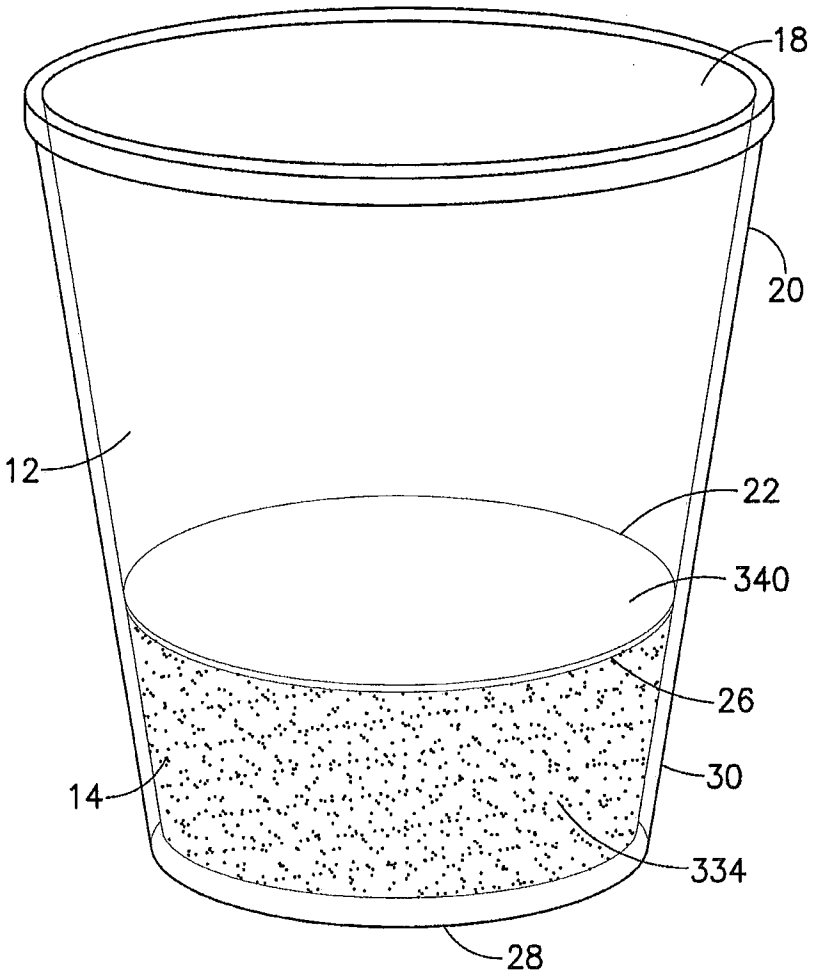

FIG.6

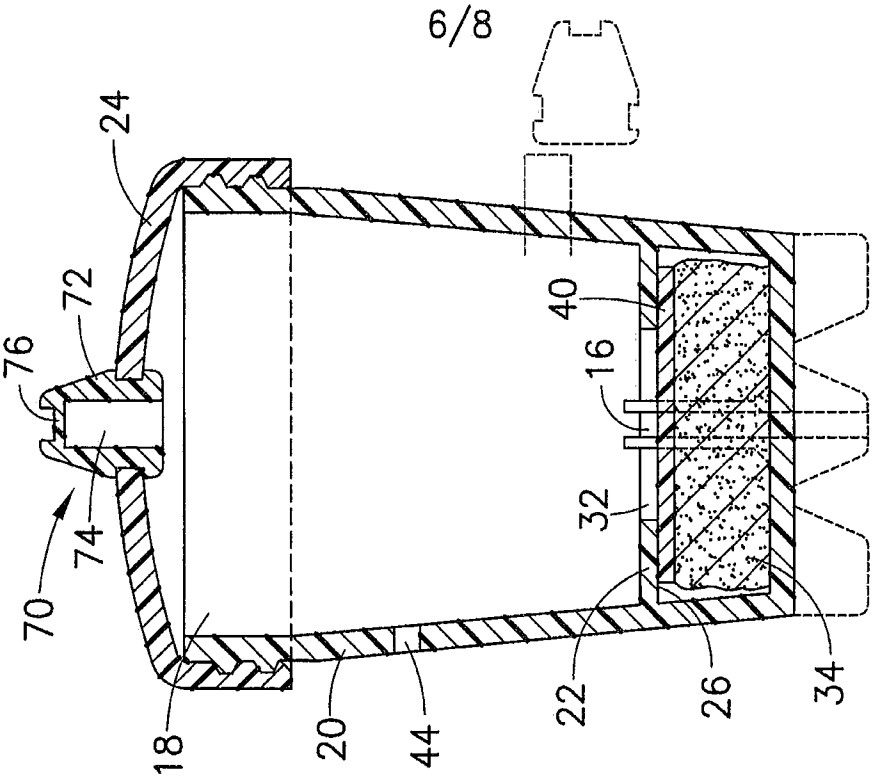
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FIG.8

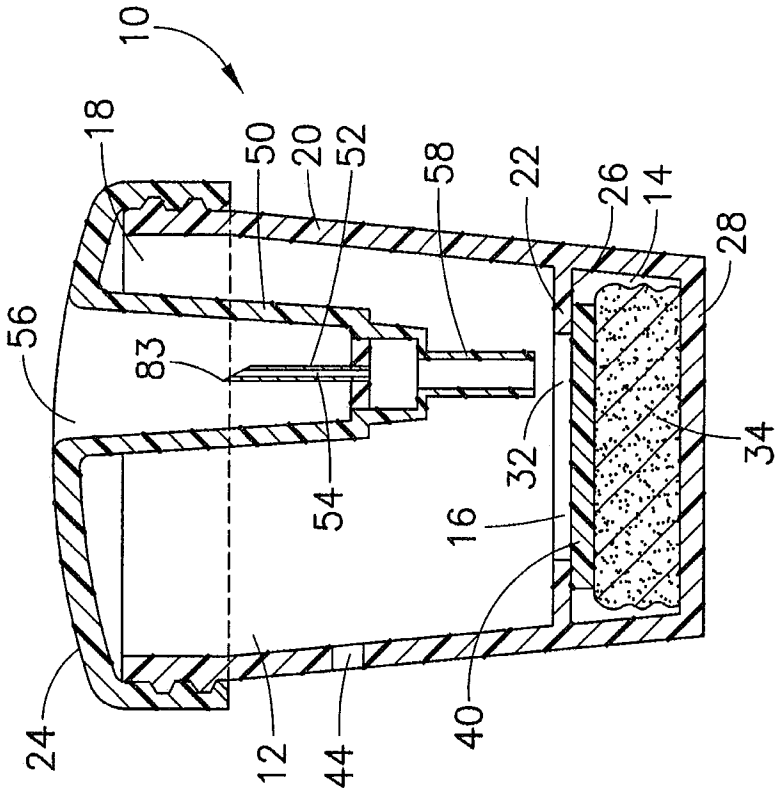
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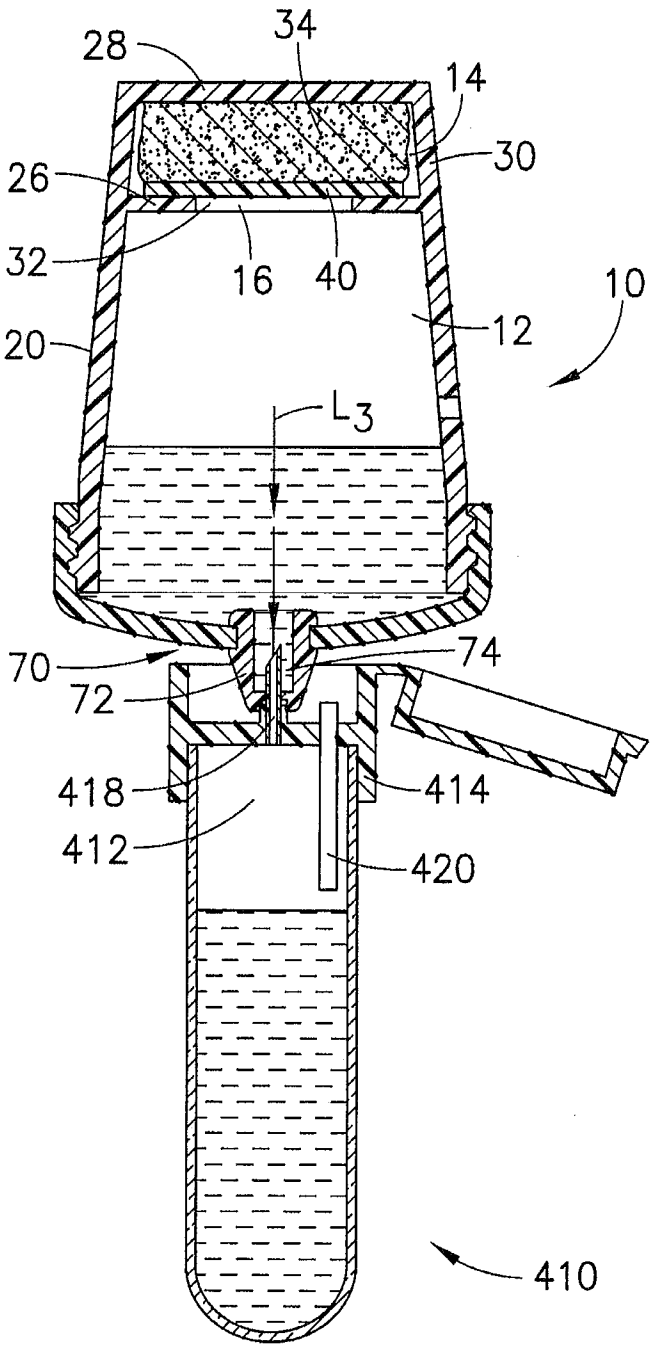
FIG.7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L_3
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72
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414
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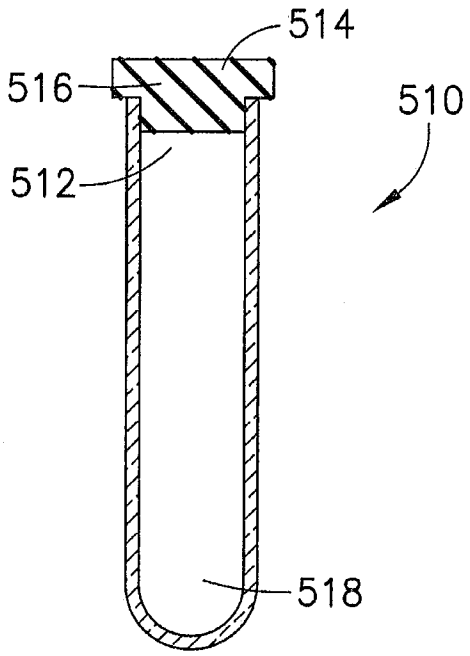
410

FIG.9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518

FIG.10

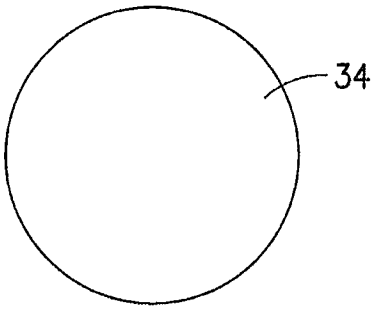

FIG.11A

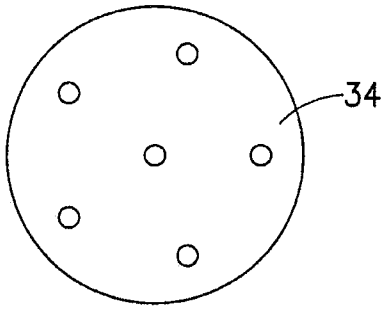

FIG.11B

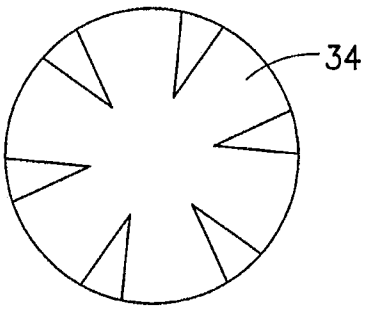

FIG.11C

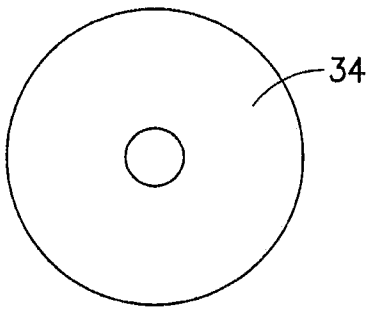

FIG.11D

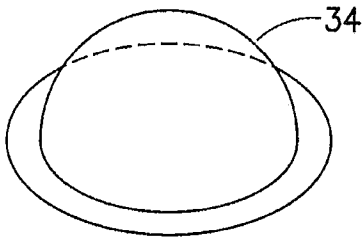

FIG.11E

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2013/023707

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B10/00
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3 928 875 A (PERSSON STURE IVAN) 30 December 1975 (1975-12-30)	1,5
A	Column 1, lines 41-63 and Fig. 1	2-4,6

X	US 4 769 215 A (EHRENKRANZ JOEL R L [US]) 6 September 1988 (1988-09-06)	1,5
A	Figs. 3a and 3b; column 4, line 39 - column 5, line 18	2-4,6

A	WO 2004/026166 A2 (ARCUS MEDICAL LLC [US]; MISKIE MARK [US]) 1 April 2004 (2004-04-01) Figs. 2, 4, 7, 8	1-6

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
22 August 2013	28/08/2013

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Foged, Søren

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/023707

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

2-6(completely); 1(partially)

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 2-6(completely); 1(partially)

A specimen container comprising a valve arranged between a first and a second chamber, the valve comprising a channel and an absorbent expandable material which when fluid flows through the channel expands (STF1a) and thereby causes the absorbent expandable material to expand to close the valve, or
A specimen container comprising a valve arranged between a first and a second chamber, the valve comprising a channel and a buoyant float which when the second chamber receives a predetermined volume of fluid engages the channel (STF1b) such that the channel is closed
Both (STF1a and STF1b) solving the of closing the valve when a predetermined amount of liquid has entered the second chamber

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2. claims: 7-12(completely); 1(partially)

A specimen container comprising a valve arranged between a first and a second chamber, wherein the first chamber comprises a port for accessing and removing a fluid sample (STF2) from the container, solving the problem of allowing the liquid sample to be retrieved from the first chamber

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3. claims: 13-17

A specimen container comprising an interior chamber in which an absorber is provided which absorbs a predetermined volume of fluid which is separated from additional fluid entering the interior chamber (STF3), solving the problem of separating a first liquid sample from a second liquid sample when contained in the same chamber

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4. claims: 18-21

A specimen container comprising a valve separating a first and a second chamber, the valve being transformable from a first closed position to an open position and to a second closed position (STF4), solving the problem of preventing a second chamber from being contaminated prior to receiving a liquid sample

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2013/023707

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 3928875 A	30-12-1975	AT 341658 B	27-02-1978
		AU 6574274 A	21-08-1975
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		SE 378356 B	01-09-1975
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