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STERILE DEVICE FOR EXTRACTING URINE SAMPLES AND
THE LIKE AND PACKAGE FOR SAME
Filed June 30, 1965

3,460,529

FIG. 1.

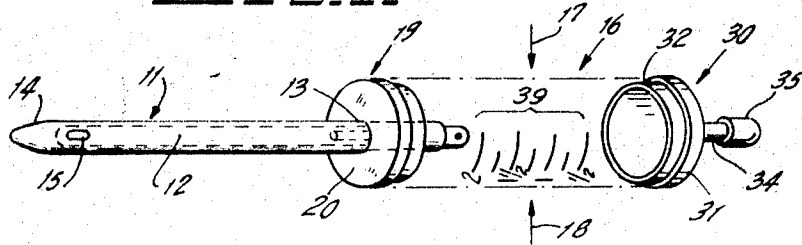


FIG. 2a.

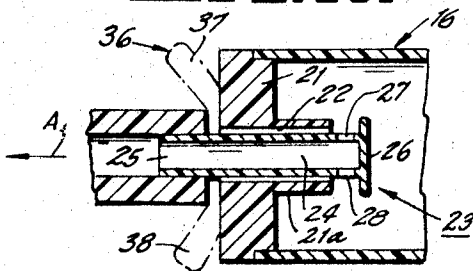


FIG. 2b.

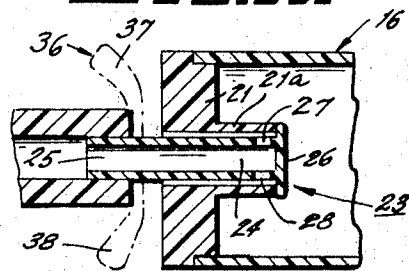


FIG. 4a.

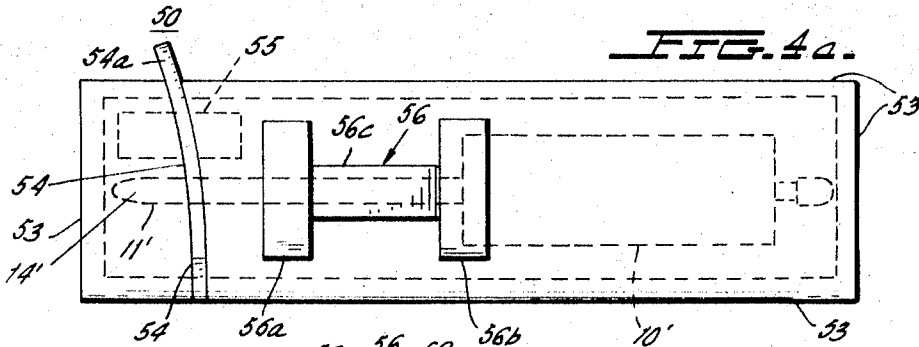


FIG. 4b.

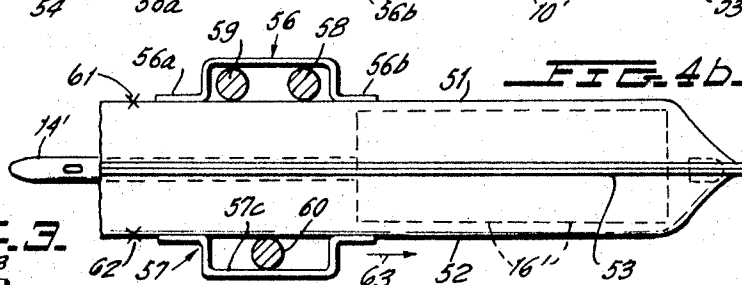


FIG. 3.

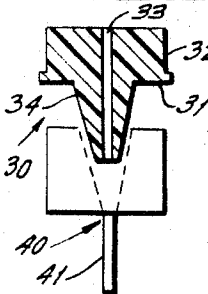
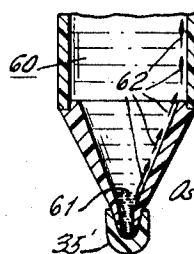
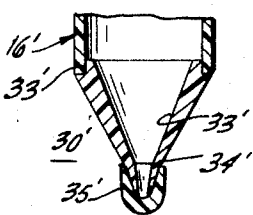


FIG. 5.



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1

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**STERILE DEVICE FOR EXTRACTING URINE
SAMPLES AND THE LIKE AND PACKAGE
FOR SAME****Gino Leucci, Philadelphia, Pa., assignor of thirty percent
to Richard Mailman****Filed June 30, 1965, Ser. No. 468,417****Int. Cl. A61m 25/00, 1/00; G01n 1/14****U.S. Cl. 128—2****5 Claims****ABSTRACT OF THE DISCLOSURE**

An assembly including a flexible container and an integrally mounted catheter for extracting urine samples. After the sample is extracted, an adjustable valve means may be closed and the catheter may be removed to facilitate handling of the container. A dispensing nozzle is provided for dispensing single drops and for coupling to a hypodermic needle for injection of the specimen, when desired. One cap structure may be provided with a tapered interior to collect sediment when the container is vigorously shaken by a centrifuge to permit dispensing of one drop of sediment which will not be diluted during the dispensing operation due to the fact that the sediment is collected at the tapered end of the cap. The entire assembly is kept sterile and housed within a package which may easily be torn open. Handles may be provided on the exterior of the package to permit insertion of the catheter without handling the assembly. The package may include a lubricating jelly to facilitate insertion of the catheter.

The instant invention relates to clinical apparatus and more particularly to a device for taking sterile urine samples and a package for housing such a device to retain its sterile condition until use.

Urine samples are often taken quite frequently as part of a clinical procedure for the purpose of detecting infections and other ailments of the body, as well as for a variety of other medical reasons. Conventional apparatus for taking urine samples is comprised of a catheter in a sterile container, typically a glass bottle or test tube having a cover or lid. The catheter is inserted into the urinary bladder. Insertion is facilitated by a sterile lubricating jelly which may, for example, be applied to the top of the catheter. The container lid is removed and the free end of the catheter is placed in the container so as to receive the sample. The container cover is then replaced and the closed container is sent to a lab for preparation of cultures as well as any other test procedures.

Microscopic examinations are normally performed by placing a small drop of the sample upon a glass slide for the purpose of viewing under a microscope. The preparation of such a procedure is cumbersome when using conventional devices in that no adequate means, which forms part of the device for taking the sample, exists for the simple straightforward preparation of such an examination. Cultures are normally prepared by placing a small drop of the sample upon a culture plate and smearing it with a special loop. The preparation of such a procedure requires completely non-contaminated urine. It is not possible to have completely non-contaminated urine when the conventional apparatus for collection of urine samples is used because the container is exposed to the atmosphere and anything which may be present in the atmosphere during the time in which the urine sample is transmitted from the bladder through the catheter into the container.

The instant invention contemplates an apparatus for taking urine samples which is a completely closed system so that the urine sample is not in any way exposed to the

2

atmosphere from the time at which the urine sample is taken until the time in which cultures or other tests are performed through the use of the extracted sample.

When microscopic examination of the urine sediment is performed, with the present conventional apparatus, the urine from the container has to be transferred to another glass tube which is inserted into the centrifuge. Centrifugation is performed for a few minutes in order to obtain the sediment, a drop of which must be examined. Therefore, after centrifugation, the supernatant fluid is poured out until only one drop of urine sediment remains in the bottom of the tube. This drop of sediment is then transferred from the bottom of the tube to the slide. In performing this procedure therefore, the drop of sediment has to move from the bottom to the edge of the tube. Since the inside wall of the conventional tube will always be wet with the discarded urine, due to the adhesion force, the drop of sediment going from the bottom to the top of the glass, crossing in other words the entire length of the glass tube, will no longer be pure sediment but will be partly diluted.

The instant invention is comprised of a substantially hollow cylindrical shaped housing which is preferably formed of a transparent resilient plastic material and is closed at both ends thereof by means of first and second caps. A first cap is provided with a short tapered nozzle which communicates with the interior of the housing through a suitable opening in the first cap. The short tapered nozzle is sealed by means of a substantially cone-shaped cap which may threadably engage or be force-fitted upon the short tapered nozzle.

The second cap of the container is provided with a short hollow projection communicating with the interior of the housing by means of a suitable aperture. One end of a catheter is snugly fitted over the projection. The second cap is further provided with a manually adjustable valve means which is initially positioned so as to allow the housing interior to directly communicate with the opening of the catheter. The manually adjustable valve means may be manipulated from the exterior of the cylindrical housing.

The catheter is inserted in the typical manner with insertion being facilitated by a sterile lubricating jelly. In order to suitably initiate removal of the urine sample, and once the catheter is suitably in place, the resilient housing may be squeezed and released by the fingers in order to create a vacuum or suction condition so as to initiate flow of the urine sample into the container. The transparent housing is preferably provided with graduated markings which may be readily observed from the exterior thereof so as to easily and readily determine the amount of the sample within the container.

Once a suitable liquid amount of sample has been extracted, the manually operable valve means is manipulated so as to completely seal the contents of the container from the catheter. The catheter may then be removed from the projection of the second cap and be discarded. Since the container is completely sealed, no additional lid or cover means, as is the case with prior art devices, need be provided.

The container can now be transmitted to a lab for preparation of the desired cultures or for any other tests.

A culture may be simply and readily prepared by removing the substantially cone-shaped cover from the tapered nozzle member and holding the nozzle immediately above a culture plate. By squeezing the cylindrical housing by a slight amount, a single small drop of the sample is simply and readily deposited upon the glass slide. Additional cultures may be prepared in exactly the same manner.

When microscopic examination of the sediment is desired, and this is a regular routine, the sterile device of the

instant invention can directly be inserted in the centrifuge for a few minutes. Then, removing the cone-shaped cover member and holding the nozzle immediately above the glass slide, by squeezing the cylindrical housing by a slight amount, a single small drop of the pure sediment is simply and readily deposited upon the glass slide. The sediment is 100% pure because it leaves the container immediately at the dispensing end and does not have to travel through the length of the container thereby avoiding in such a way the cumbersome and unorthodox procedure which has to be performed at present with the conventional apparatus.

In many cases it is desirable to inject an extracted urine sample into a guinea pig, rabbit or other animal for the performance of other tests. Such an injection may be simply and readily made by securing a sterile hypodermic needle to the short tapered nozzle which is specifically designed to receive said needle and by squeezing the cylindrical container the sample may then be injected into the animal.

It can be seen that the device of the instant invention keeps the urine sample substantially free from any exposure to the surrounding environment from initial extraction through to the preparation of cultures and/or injection of the sample. The nozzle, valve and dispensing means provided as an integral part of the container, permit the entire device to be pre-assembled as an entire unit which is substantially completely sealed from the atmosphere throughout its use.

The device, once assembled, is preferably housed within a polyplastic package to preserve its sterile condition. The package is preferably provided with a suitable tear strip or other means to facilitate the opening thereof with the tear strip being positioned in close proximity to the tip of the catheter. It is also preferable to position the sterile lubricating jelly adjacent the catheter tip so that it may be quickly and readily applied to the catheter tip for insertion into the patient with substantially no hesitation. The package is also provided with a pair of "handles" or grips which may be used to guide the fingers of one hand while the other hand is used to guide the insertion of the catheter into the urinary bladder so that the package may be moved only by an amount substantially equal to that in which the catheter has been inserted into the urethra so as to shield the catheter from the atmosphere.

It is therefore one object of the instant invention to provide a novel device for taking sterile urine samples.

Another object of the instant invention is to provide a novel device for taking sterile urine samples comprised of a flexible container integrally coupled to a catheter through adjustable valve means.

Still another object of the instant invention is to provide a novel device for taking sterile urine samples comprised of a flexible container integrally coupled to a catheter through adjustable valve means and wherein dispensing means are provided as an integral part of the container means to simplify the preparation of microscopic examination of cultures and injection procedures.

Another object of the instant invention is to provide a novel device for taking sterile urine samples comprised of a flexible container integrally coupled to a catheter through adjustable valve means wherein said container is comprised of a flexible housing for the purpose of facilitating initiation of the extraction process as well as facilitating dispensing of the extracted sample.

Another object of the instant invention is to provide a novel device for taking sterile urine samples wherein said device is housed within a container so as to maintain the device in a sterile condition until it is used.

Still another object of the instant invention is to provide a novel device for taking sterile urine samples wherein said device is housed within a package having means for guiding one hand of the operator to facilitate removal of the package leaving the other hand of the

operator free to insert the catheter into the urinary bladder.

Still another object of the instant invention is to provide a novel device for taking sterile urine samples wherein the device housing is uniquely adapted for insertion into a centrifuge and permits the simple dispensing of a single drop of pure urine sediment for a very critical examination procedure.

These and other objects of the instant invention will become apparent when reading the accompanying description and drawing in which:

FIGURE 1 is a perspective view showing the device of the instant invention.

FIGURES 2a and 2b show sectional views of the valve means in the device of FIGURE 1 in the open and closed positions, respectively.

FIGURE 3 shows a sectional view of the dispensing tip of the device of FIGURE 1 and the manner in which it may be used with a hypodermic needle.

FIGURES 4a and 4b are top and side views, respectively, of the package for the device of FIGURE 1.

FIGURES 5 and 5a show a sectional view of a unique embodiment for the end cap of FIGURE 3. FIGURE 5a shows the manner in which sediment is formed in dispenser.

Referring now to the drawings, FIGURE 1 shows the device 10 for taking a sterile urine sample from the urinary bladder of a patient and is comprised of a catheter 11 having a hollow interior 12, a first open end 13 and a tapered and closed tip 14. The catheter 11 is further provided with a pair of openings 15 (only one of which is shown) on opposite surfaces of the catheter communicating with the hollow opening 12.

The device 10 is further comprised of a hollow cylindrical body 16 which is formed of a transparent resilient preferably plastic material which is capable of being flexed or squeezed by the fingers (not shown) when a slight force is applied to the cylinder by the fingers in the direction shown by arrows 17 and 18. The cylindrical shaped housing 16 is open at both ends. A first end thereof is closed off by means of a first cap 19 having a cap surface 20 and a side wall 21 (see FIGURES 2a and 2b) which has a diameter slightly less than the diameter of cap surface 20 so as to make a force-fit with the interior surface of cylindrical housing 16. The cap 19 is provided with a central opening 22 for receiving a slidably mounted cylindrical member 23 which is force-fitted into the opening 22. The left-hand end of cylindrical member 23 makes a force-fit with the open end 13 of catheter 11. Cylindrical member 23 has a hollow interior 24 communicating with its open left-hand end 25 while its right-hand end 26 is sealed. Two or more openings 27 and 28 are provided along the surface of member 23 near its closed end 26 so as to enable the hollow interior 12 of catheter 11 to communicate with the interior of housing 16 through the opening 25, hollow interior 24 and openings 27 and 28 of member 23.

The device 10 of FIGURE 1, when first assembled and hence when removed from its package (to be more fully described) for use in extracting a urine sample, is in the position shown in FIGURES 1 and 2a. In this position, and when the catheter 11 is inserted into the urinary bladder of the patient, the urine sample may flow through openings 15 and hollow interior 12 of catheter 11 through the hollow interior 24 and openings 27 and 28 of cylindrical member 23 so as to be collected within the cylindrical housing 16.

The opposite open end of cylindrical member 16 is provided with a cap 30 having a cap surface 31 and a side wall 32 which has a diameter just slightly less than cap surface 31 so as to be force-fitted into the right-hand end of cylindrical housing 16. Cap 30 is provided with a central opening 33 which extends through a tapered projection or nozzle 34. The dispensing nozzle 34 is normally sealed by a cone-shaped cap member 35 which

may either be force-fitted upon nozzle 34 or may be threadedly engaged therewith. The transparent cylindrical housing 16 is provided with a plurality of visually observable graduations 39 which provide easily readable indication of the amount (for example, in ounces) of the sample collected within housing 16. While the graduations may be shown in ounces it should be understood that any other unit of measurement may be employed.

The manner in which the device 10 of FIGURE 1 is used in extracting a urine sample is as follows:

The region of tip 14 of catheter 11 is preferably facilitated for insertion into the urinary bladder through the application of a sterile lubricating jelly (not shown). The catheter 11 is then inserted into the urinary bladder. It should be understood that the length of the catheter 11, as shown in FIGURE 1, is not intended to be the preferred length of the catheter, but any desired length of catheter may be employed. After the catheter is suitably inserted into the urinary bladder the housing 16 is preferably held at a level which is at least slightly lower than the level occupied by the tip 14 of catheter 11. In order to facilitate flow of the urine sample, the flexible cylindrical housing 16 may be squeezed and released a few times by applying pressure by use of the fingers in positions substantially as shown by the arrows 17 and 18. Squeezing and releasing a few times in this manner creates a vacuum or suction effect thereby facilitating flow of the urine sample through the catheter 11 and hollow cylindrical member 23 into the cylindrical container 16. It can be seen that this flow will be substantially unimpeded while at the same time none of the sample may flow out of the container 16 due to the nozzle 34 being sealed by cap 35. After a suitable amount of sample has been collected within container 16, which can easily be ascertained through observation of the graduations 39, the catheter 11 may be gripped near its end 13 by the fingers of one hand in order to pull end 13 of catheter 11 as well as cylindrical member 23 from the position shown in FIGURE 2a in the direction shown by arrow A toward the position shown in FIGURE 2b.

With the hollow cylindrical member 23 occupying the position shown in FIGURE 2b it can be seen that its sealed end 26 abuts the cylindrical projection 21a of cap member 19 such that the end 26 completely seals the interior end of opening 22 in cap member 19, while the cylindrical shaped projection 21a further acts to seal the openings 27 and 28 in hollow cylindrical member 23. The end 13 of catheter 11 may then be removed from hollow cylindrical member 23 without any concern about the fluid contained within housing 16 since both cap structures 19 and 30 act to completely seal the urine sample within the container. The end 13 of catheter 11 may now be removed from hollow cylindrical member 23 and discarded.

The completely sealed container may now be forwarded to a lab or any other suitable place for the purpose of preparing cultures or any other functions which have to be performed. Since the cylindrical housing 16 is formed of a plastic material no handling problems whatsoever are encountered. For example, if the sealed container is accidentally dropped, there is no danger of any breakage nor is there any danger that any liquid will escape the container. Since there is an adequate force-fit provided between hollow cylindrical member 23 and the opening 22 in cap 19 there is no danger that hollow cylindrical member 23 will be dislodged from its position shown in FIGURE 2b.

Once the sealed container has arrived at the laboratory and it is now desired to prepare one or more glass slides, this function may be very easily performed by removing the cap 35 from the tapered dispensing nozzle 34 and holding the nozzle above a glass slide (not shown). By squeezing the sealed container at the points generally indicated by arrows 17 and 18, and due to the narrow opening 33 in cap member 30, it is very simple to dispense one

single drop of the sample upon the glass slide. Further glass slides may be prepared in a substantially identical manner.

In many cases the sterile sample may be employed for the purpose of injection into an animal for any one of a variety of tests. FIGURE 3 shows the manner in which a hypodermic needle structure 40 having a hollow tubular-shaped needle 41 and a base portion 42, is force fitted upon the tapered projecting portion 34 of end cap 30. Either a force fit or a threaded engagement may be used for coupling the hypodermic needle structure 40 to the projection 34. The urine may then be simply and readily dispensed (after having inserted the needle into the body of the animal) simply by squeezing the flexible walls of transparent cylinder member 16 which is shown in FIGURES 1 and 2.

In cases where it is desirable to examine the urine sample sediment, the sampling device 10 is designed so that its container 16 has dimensions which are suitable for being inserted by a conventional centrifuge (not shown). The sample is thereby vigorously agitated for a few minutes so as to form a sediment at the dispensing end of the structure. FIGURE 5 shows an alternative end cap structure 30' which is substantially similar in shape to the end cap structure 30 of FIGURES 1 and 3 except that its interior opening 33' is tapered in substantially the same manner as the exterior portion 34'. The diameter of transparent cylinder portion 16' is such as to permit it to be fitted into a conventional centrifuge. After having been agitated in the centrifuge the sample 60 within the structure as shown in FIGURE 5a forms a sediment shown by the darkened area 61 in the nozzle portion of the structure which is then to be used for examination purposes. This sediment may be dispensed simply by removal of the end cap 35' and by squeezing the flexible cylindrical housing 16', insuring dispensing of just the sediment 61 without any of the remaining liquid being dispensed therewith. This provides the unique advantage over conventional devices in that, after the sediment is formed at the base of the container the liquid portion 60 is poured out of the container. The container is then tipped for removal of the sediment which moves along one wall of the container as shown by the arrow 62 of FIGURE 5a. The urine sample although having been poured out of the container, nevertheless leaves a thin coating of liquid along the interior surface of the container. The sediment 61 in moving from the base of the container to the top thereof passes over this thin film and becomes significantly diluted due to this inter-action, thus destroying the previous quality of the sediment. The container of the instant invention completely avoids the necessity of dispensing in the conventional manner and further dispenses pure sediment to provide for reliable examination thereof.

The valve means shown in FIGURES 2a and 2b, as well as FIGURE 1, may be modified in the following manner:

Instead of providing a force fitting between the central opening 22 in cap 19 and hollow cylindrical member 23 the central opening 22 may be threaded so as to threadedly engage a cooperative threading on the exterior surface of hollow cylindrical member 23. The forward end or left-hand end of hollow cylindrical member 23 may be provided with a wing nut structure 36 having wings or ears 37 and 38 and being rigidly secured to hollow cylindrical member 23. By twisting or rotating the wing nut structure 36 with the thumb and finger, the hollow cylindrical member 23 may be moved in a direction shown by arrow A from the position of FIGURE 2a to the position of FIGURE 2b. It should be understood that either of the two alternatives will provide suitable valve action and the choice is dependent only upon the needs of the user. Either of the two structures may be formed of metal or plastic, or a combination of both, but an all plastic valve structure would be preferred from the viewpoint of manufacturing costs.

FIGURES 4a and 4b show the manner in which the

device of FIGURE 1 may be packaged. The arrangement 50 of FIGURES 4a and 4b is comprised of a suitable plastic housing, preferably transparent or nearly so which may, for example, be formed of first and second plastic sheets 51 and 52 which are heat-sealed along their marginal edges 53 so as to completely and sterily seal the sampling device 10' until it is used. The package 50 is preferably provided with a tear strip 54 having a free end 54a, which tear strip is positioned adjacent the tip 14' of catheter 11' so as to expose only a small portion of the catheter. Also positioned at this end of the package is a small tube or packet 55 of a sterile lubricating jelly which may be applied to the tip 14' of catheter 11' in order to facilitate insertion of the catheter into the urinary bladder. Positioned immediately behind the tear strip 54 are a pair of "handles" 56 and 57 which are substantially identical in configuration and function. Each of the handles, for example handle 56, is arranged so as to be a spaced distance from the surface of sheet 51 in order to permit the insertion of one or two fingers, represented by the shaded circles 58 and 59, between main handle portion 56 and the surface of sheet 51. The remaining handle 57 is arranged in a like manner so as to facilitate the insertion of the thumb represented by the shaded circle 60.

It can therefore be seen that the instant invention provides a novel device and package for extracting sterile urine samples from the body of a patient which may very simply be employed in a highly sterile manner without the use of sterile gloves especially in male patients and the like and which is further designed so as to simplify the extraction of the urine sample as well as providing a totally sealed container for shipment to a lab and for providing a simple dispensing arrangement for use in either preparing cultures or injecting the urine sample into the body of an animal.

Although there has been described a preferred embodiment of this novel invention, many variations and modifications will now be apparent to those skilled in the art. Therefore, this invention is to be limited, not by the specific disclosure herein, but only by the appending 40 claims.

What is claimed is:

1. Apparatus for extracting sterile fluid samples from a body comprising:

- a catheter;
- a hollow container having first and second end cap structures sealing said container;
- at least one of said cap structures having an opening communicating with the interior of said container;
- manually operable valve means movable between an open and closed position mounted within the opening of said one end cap structure;
- a portion of said manually operable valve means positioned on the exterior of said one end cap for manually operating said valve means between said open and closed positions;
- one end of said catheter being removably coupled to

said valve means whereby the interior of said container communicates with the interior of the catheter through said open valve means; said hollow container being comprised of a transparent substantially cylindrical housing formed of a flexible material to facilitate squeezing of said container for both collection and dispensing purposes.

2. The device of claim 1 wherein said second cap structure is provided with a tapered dispensing nozzle having a hollow interior communicating with the interior of said container;

third cap means removably mounted upon said nozzle for sealing said container.

3. The device of Claim 1 wherein said hollow container is comprised of a transparent substantially cylindrical housing formed of a flexible material to facilitate squeezing of said container for both collection and dispensing purposes; the surface of said container being provided with visually observable graduations for measuring the amount of sample collected.

4. The device of claim 1 wherein said valve means is comprised of a hollow substantially cylindrical member force-fitted into an opening in said first cap structure; a first end of said cylindrical member being open and the opposite end being sealed; said cylindrical member having at least one aperture intermediate the ends thereof; said aperture being sealed by the opening in said first cap structure when said valve means is moved to said closed position.

5. The device of claim 4 wherein said opening is tapped;

the surface of said hollow cylindrical member being threaded to threadedly engage said tapped opening; wing-shaped handle means rigidly secured near the open end of said hollow cylindrical member for rotating said hollow cylindrical member being in said open and closed positions.

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73—425; 128—278