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Logiadis

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[54] **URINE SAMPLING DEVICE AND METHOD**

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[52] **U.S. Cl.** ..... **128/2 F;** 4/110; 128/295

[51] **Int. Cl.** **A61b 10/00**

[58] **Field of Search** ..... 128/2 F, 295; 4/110

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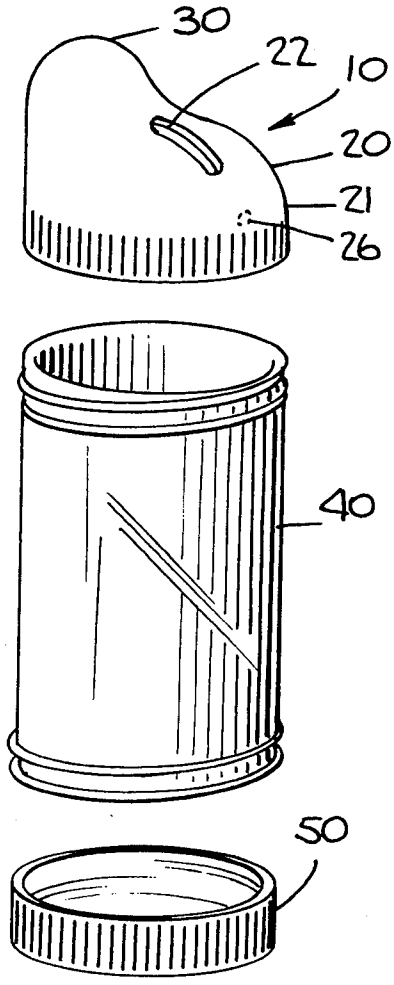
[57] **ABSTRACT**

A one piece, hollow, molded plastic cap is formed with two structural portions and is secured to a container. The first portion is a blunt, bulbous protuberance extending above the major surface of the second portion. The second portion is generally dome-shaped, blending smoothly into the first portion, and has a slit communicating with the container and extending radially from the base of the bulbous protuberance toward the side wall of the cap. The bulbous protuberance is placed in the opening of the vagina in contact with all the surrounding vaginal walls covering and blocking the vaginal introitus while simultaneously positioning the cap so that the urethal meatus is surrounded by the slit. The base of the container is lifted vertically slightly thereby sealingly contacting the surrounding tissue with dome-shaped portion. Means are also provided to vent the container during the taking of the urine sample. The base of the container is fitted with a standard closure for substitution with the urine sampling cap to seal the container.

14 Claims, 4 Drawing Figures



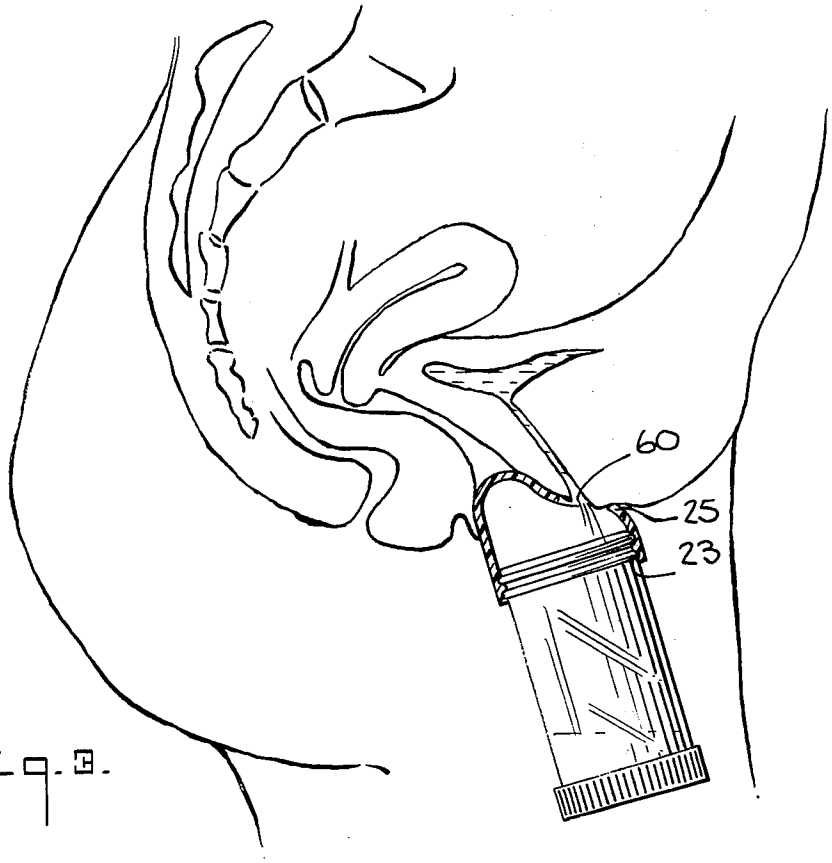


Fig. 3.

Fig. 1.

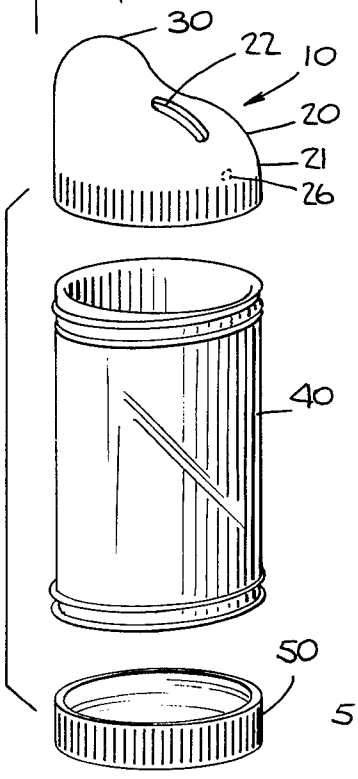


Fig. 4.

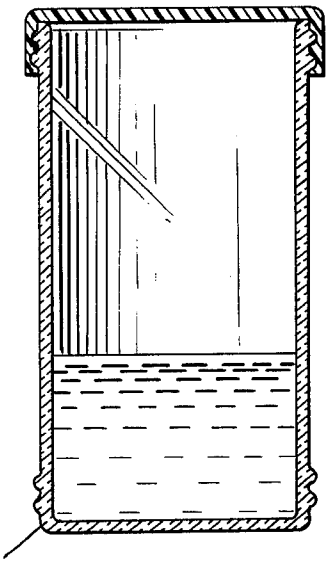
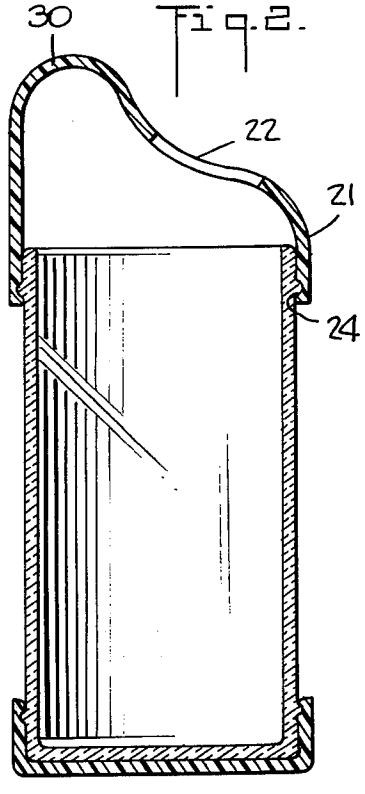


Fig. 2.



URINE SAMPLING DEVICE AND METHOD

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention relates to a portable device for taking urine samples of the type which is utilized by being momentarily pressed against the female genitalia while the urine sample is being taken and to an improved process of taking urine samples. More specifically the invention relates to an improved molded plastic cap of a unique shape mounted to a container and its manner of use so that the cap is easily positioned with respect to the urethral meatus and the urine sample is simply and readily taken.

2. Description of the Prior Art

A variety of female intravaginal urinals are known which are designed to be worn by the female for long periods of time and are particularly suited for bedfast, incontinent or incapacitated persons. These devices usually have a member which is inserted into the vagina and presses against the anterior vaginal wall. Such devices are strapped to the female and attempt to prevent leakage or seepage in all positions, sitting, lying or standing. Some such devices surround the entire genital area forward of the vagina. None of the aforesaid devices are adapted for momentary use for taking urine samples, as is applicant's device, but are more or less permanent body fixtures. One such prior art device is inserted into the vaginal cavity and is held in place by an absorbent pad strapped to the wearer. Another prior art device uses a suction head attached to a vacuum source, the suction head shaped as a modified cast of the entire female genitalia with ducts leading to the suction line. None provide a one piece molded plastic cap for a urine sampling device having applicant's unique structure.

The problem of providing a simple, disposable device usable for taking a urine sample without the annoying and unpleasant prospect of urinating on one's hands and clothing and on the device itself and with the hope of providing a urine specimen free of extraurethral contamination thereby reflecting the condition of the urine in the bladder was tackled by other numerous persons in the past besides applicant. One prior art device includes a foldable thermoplastic coated paper blank which unfolds into a funnel. Similarly, another device includes a molded or foldable plastic form with an exit hole that can be capped off. Both devices are wide-mouthed type devices covering the entire genital area and are discarded after use by flushing or otherwise. Neither is a cap for a container as is applicant's device and neither discloses applicant's unique structure. Another apparatus is designed to surround the urethral meatus with a compressible resilient pad which has a central opening and is connected to a tube and container. The pad is positioned by moving the flask so that a surface portion of the pad presses against the distal end of the anterior vaginal wall and through prolapse of the meatus and surrounding tissue a protrusion is formed which extends into the central opening. A separate vent pipe is also provided because the pad compresses and distorts sealing the central opening and preventing air from escaping as the sample is taken. This device, although similar to applicant's device, does not disclose a one piece molded plastic cap for a container having applicant's unique structure for providing a simple device for taking urine samples. Also, the last mentioned device does not position the apparatus by placing in the vaginal opening a blunt, bulbous protuberance which contacts all the surrounding vaginal walls to position a slit around the urethral meatus.

SUMMARY OF THE INVENTION

The invention is in a specially configured cap for a container and its method of use in taking female urine samples. The cap has two portions, a generally dome-like shaped portion constituting the major surface portion of the cap and a bulbous protuberance portion extending therefrom. The dome-shaped portion is provided with a radial slit extending from the base of the bulbous portion almost to the side wall of the dome portion. The slit communicates with the container which is secured through coupling means to the base of the cap. The container also carries a standard closure secured to the base of the container. The bulbous portion is placed in the vaginal opening in snug contact with the surrounding vaginal walls spreading the labia majora and minora while positioning the slit around the urethral opening. Pressing the dome-like portion against the body holds back the labia and seals the area surrounding the slit. The angle at which the container is pressed against the body is adjusted so that a small portion of the slit near the side wall of the dome remains open to the atmosphere and acts as a vent as the urine sample is taken. Alternatively, a separate vent hole is located in the side wall adjacent the slit.

It is an object of this invention to provide a one piece molded plastic cap which provides a simple effective external device for taking female urine samples without the risk of urinating on one's hands or clothes or on the device itself and without the risk of extraurethral contamination.

It is a further object to provide a container for use in combination with the cap and a standard closure carried by the container to provide a small, complete, inexpensive urine sample-taking package.

It is an object to provide an improved process for the taking of female urine samples.

It is a further object to provide a disposable device for taking urine samples which can be kept sterile in sealed sterile bags until ready for use, and which, if desired, can be recycled and sterilized for reuse.

It is an object to provide a urine sampling device which provides a means for venting the device during taking of the sample.

Additional objects will be evident from the description of the drawings and preferred embodiments described below.

DESCRIPTION OF THE DRAWINGS

FIG. 1 is an exploded elevation view showing the cap, the container and the standard closure.

FIG. 2 is a sectional side view showing the cap, the container and the standard closure ready for use.

FIG. 3 is a partial sectional view showing the invention in position during use.

FIG. 4 is a sectional side view showing the standard closure secured to the top of the container.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The cap is generally designated **10** in FIG. **1.** It is a one piece hollow cap molded of thermosetting plastic or the like.

The cap is formed with two general portions designated **20, 30** in FIG. **1.** The portion **20** is the major surface portion of the cap and is generally a contoured, dome-like, shaped portion formed about a longitudinal axis. It is generally round but may be elliptical as well, with the long dimension aligned with the slit. Side wall portion **21** is nearly straight and blends gradually and smoothly into the portion **20** which blends smoothly into portion **30.** The dome portion **20** is formed with slit **22** therethrough which is in communication with a container secured to the base of the cap and described below. The slit **22** extends radially of the cap from adjacent the base of the portion **30** nearly to the side wall **21.** The slit **22** is centrally located in portion **20.**

The portion **30** is a smooth, blunt, bulbous protuberance extending a short distance above the major surface portion **20** and generally along a line parallel to the longitudinal axis of the portion **20.** The portion **30** is preferably round but also may be elliptical with the long dimension aligned with the slit. The protuberance **30** at its widest diameter is about 1½ inches and extends approximately three-quarters inch beyond the dome portion **20.**

The base of the cap **21** is provided with means **23** for coupling the cap to a container **40.** Preferably this is accomplished by internal screw threads **23** which cooperate with external threads on the top of the container. An internal annular bead **24** instead of threads could also be used to snap the cap over a cooperating lip on the container.

The container **40** is conventional and can be either glass or plastic or the like.

One additional optional feature of the container is the provision of a standard screw-on or snap-on closure **50** conveniently carried at the base **51** of the container so that after the urine sample is taken, the slitted female urine sampling cap is removed and replaced by the standard closure **50** to seal the container from the atmosphere providing a complete urine sampling package which can be conveniently left at a doctor's office or lab or the like.

The coupling means at the base of the slitted cap and the coupling means at the base of the container are compatible, i.e., both screw threads or snap-on, so that the urine cap **10** and closure **50** can be interchanged.

The bulbous protuberance **30** is not intended as an internal structure. Rather, the primary purpose of the bulbous protuberance **30** is as a positioning device for locating the slit **22** around the urethral meatus **60** and is best shown in FIG. **3.** The positioning is accomplished by first placing the bulbous protuberance **30** in the opening of the vagina to cover and block the vaginal introitus and to spread the labia majora and minora thereby exposing the urethral meatus. Thus once placed in position, the protuberance **30** snugly contacts all of the surrounding vaginal walls and automatically positions the slit, once the slit is vertically aligned with the person's body, to surround the urethral meatus. The next movement is simply to raise the lower end of the container slightly and press the dome-like portion **20** against the body tissue between the labia majora and minora permitting the slit to surround the urethral meatus. A slight pressing action at this point will not only hold back the labia majora and minora so that there is no interference with taking the sample, but also prevents inadvertent movement of the slit out of its position surrounding the urethral opening. Additionally, the pressing seals the contact between the tissue and the cap so that no leakage occurs in taking the urine samples which is the final step. The urine passes directly from the urethral meatus into the container and is not contaminated by any extraurethral bacteria. Thus, an external device is provided for taking a sterile urine sample.

Since in most cases the container is not completely filled with urine during the taking of a sample, a vent is not necessary. However, applicant's device inherently provides for a vent should the vent be desired. It is noted that it is not necessary that the entire area of contact around the slit be sealed. The length of the slit is preferably 1 inch to 1¼ inch, and since the portion **20** is dome-like and contoured, there is a small portion **25** of the slit next to the side wall **21** which may remain open to the atmosphere for venting air from the container while the urine sample is being taken. This is accomplished by adjusting the angle at which the container is pressed against the body. See FIG. **3.** It is only necessary to lower the bottom end of the container slightly to expose the uppermost portion **25** of the slit to atmosphere. An alternative means of venting is to provide a small hole **26** in the side wall **21** adjacent the end of the slit **22.**

The aforesaid process can be accomplished with one hand, freeing the other hand to keep clothing from interfering with the process.

Following the taking of the urine sample, the slitted cap **10** is removed, the closure cap **50** is removed from the base of the container and is secured to the top of the container to seal it from the atmosphere.

Preferably the entire package including the slitted cap **10,** the container **40** and the standard closure **50** is shipped in a single sterile sealed wrapping in which it is retained until it is used. Optionally the three elements can be separately sealed and shipped, being assembled at the time of use. In this manner a completely sterile package is provided for obtaining a completely uncontaminated urine sample. Following use, the entire package is preferably disposed of since it is relatively inexpensive. However, if desired, it can be sterilized again and reused, particularly if glass containers are used.

I claim:

1. A one-piece cap of smooth, impermeable, heat sterilizable material for use with a collection container for taking a human female urine specimen comprising:

a dome-like major surface in the form of an oblate hemispheroid terminating in a cylindrical skirt sized to fit the top of a specimen container;

an eccentric generally hemispherical protrusion having a diameter about half the skirt diameter and located to one side of and extending above the apex of the major surface;

an intermediate surface smoothly blending the base of the protrusion into the major surface; and

an elongated slot through the major surface communicating with the interior of the cap and extending from about the center of the major surface radially away from the eccentric protrusion, the protrusion

being adapted to occlude the vaginal opening of a female person when pressed thereagainst to prevent vaginal secretions from contaminating the specimen, the width of the slot being adapted to encompass the urethral meatus, and the length of the slot being at least equal to the perineal distance from the vaginal opening to the urethral meatus for the normal range of human female anatomy.

2. The cap of claim **1** wherein the slot is of a length adapted to extend beyond the maximum normal perineal spacing between vaginal opening and urethral meatus of the normal human female into the region of increasing curvature of the oblate major surface near the skirt to provide a vent from the interior of the container when the flattened portion of the oblate spheroid is pressed into sealing contact with the perineal tissue adjacent to the slot when taking a specimen.

3. The cap of claim **1** further comprising a vent hole in the skirt adjacent to the end of the slot for venting the container.

4. The cap of claim **1** wherein the diameter of the protrusion is about 1½ inches at its widest dimension and the protrusion extends about three-quarters of an inch beyond the apex of the major surface.

5. The cap of claim **1** wherein the slot is about one-quarter inch wide and 1¼ inch long.

6. The cap of claim **1** composed of a plastic material capable of retaining its shape at temperatures high enough to insure sterilization.

7. The cap of claim **6** further comprising an annular bead on the inside of the skirt sized to snap over a corresponding lip on a container.

8. The cap of claim **1** further comprising internal threads formed in the cylindrical skirt for mating engagement with a threaded container.

9. The cap of claim **1** in combination with an open-mouth container for collecting a urine specimen through the slot in the cap, the combination comprising mounting means on the inside of the cap skirt and cooperative mounting means on the outside of the container mouth for removably fixing the cap on the container.

10. The combination of claim **9** further comprising:

a base on the container having the same diameter as the container mouth,

external mounting means on the side of the base identical to the cooperative mounting means on the outside of the container mouth, and

a sealing closure for the container removably mounted on the base with the interior of the closure facing the base, the combination of the container, collector cap and closure being sterilized so that when a urine sample has been taken, the closure can be removed from the base mounting means and substituted for the slotted collector cap with the sterile interior of the closure exposed to the interior of the container for sealing the container and protecting its contents against contamination.

11. The method of obtaining a self-collected uncontaminated urine specimen from a human female by means of a sterile container equipped with a removable one-piece sterile domed cap having a generally oblate hemispheroidal major surface, an eccentric generally hemispherical protrusion approximately half the diameter of the cap located to one side of and extending above the apex of the major surface, and an elongated slot through the major surface extending from near the apex radially away from the eccentric protrusion comprising the steps of:

holding the container in one hand with the slot in the cap facing forwardly from the eccentric protrusion;

placing the eccentric protrusion against the vaginal opening to spread the inner and outer labia and to block the vaginal opening for preventing vaginal secretions from entering the container through the slot;

raising the lower end of the container slightly to press the region of the major surface surrounding the slot into sealing contact with the perineal tissue with the slot enclosing the urethral meatus; and

passing a specimen of urine from the urethral meatus through the slot in the container.

12. The method of claim **11** further comprising the step of venting the container while passing the urine specimen through the slot into the container.

13. The method of claim **12** wherein the elongated slot in the cap of the container extends beyond the flattened region of the major surface, and the step of venting the container comprises leaving the outer portion of the slot open to the atmosphere while passing the urine specimen into the container.

14. The method of claim **11** wherein the container is further equipped with a sterile closure cap removably mounted on the base of the container, and further comprising the steps of:

removing the slotted cap from the top of the container after collecting the urine specimen,

removing the closure cap from the base of the container, and

securing the closure cap to the top of the container so that the sterile surface of the closure cap that previously faced the base of the container is exposed to the interior of the container for sealing the container and preventing contamination of the specimen.

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