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APPARATUS FOR OBTAINING URINE SAMPLES

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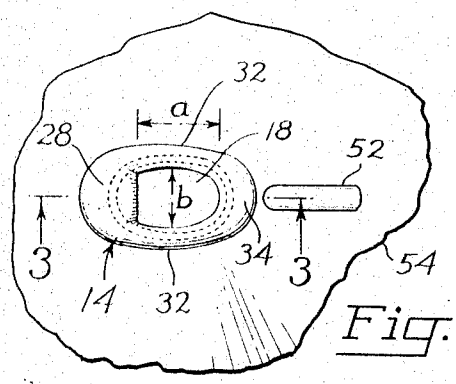


Fig. 2.

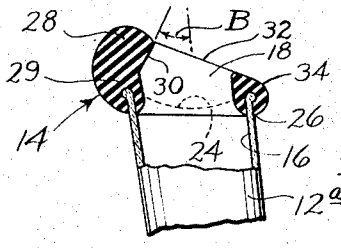


Fig. 3.

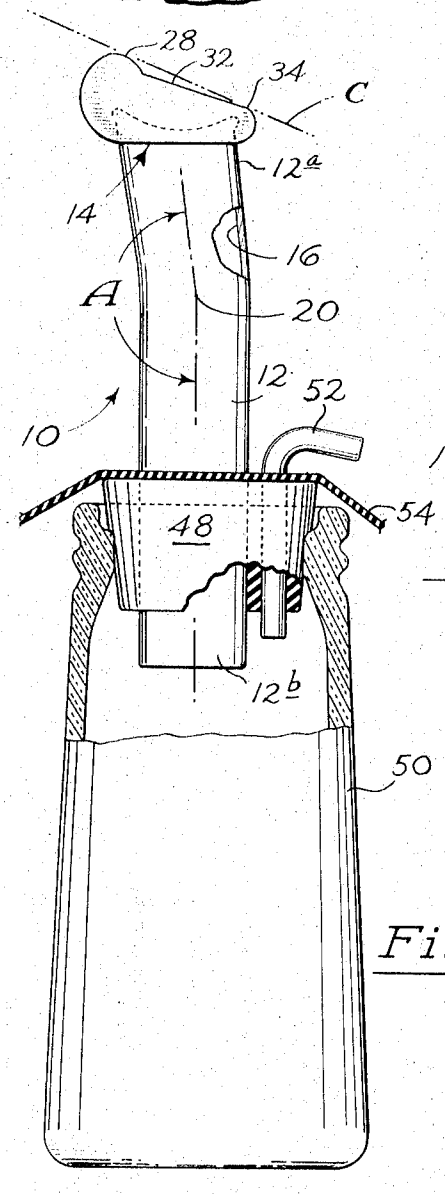


Fig. 1.

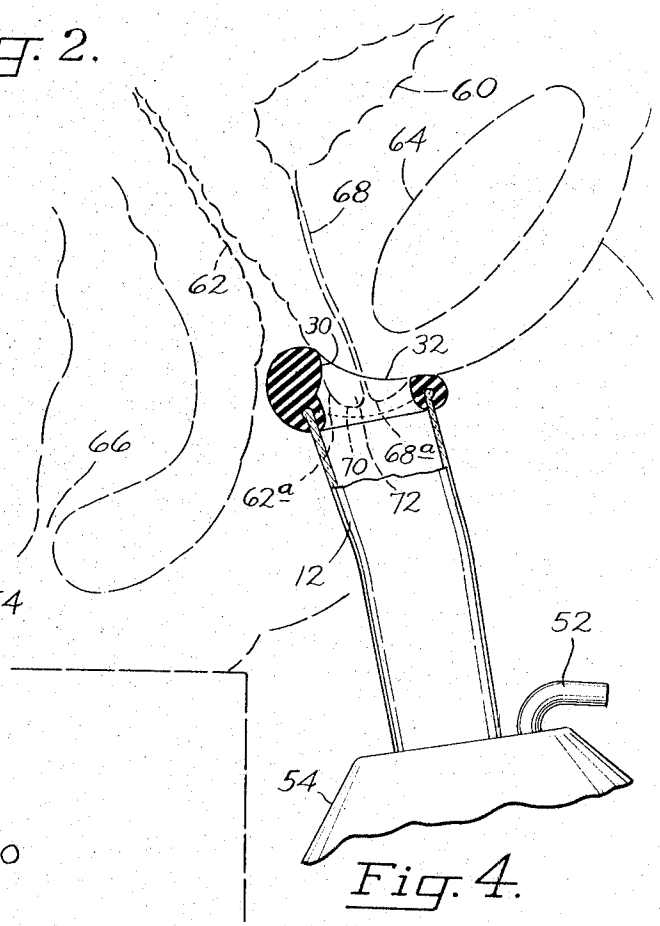


Fig. 4.

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APPARATUS FOR OBTAINING URINE SAMPLES

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This invention relates to collecting urine samples from female patients, where special problems are introduced in obtaining urine samples free from extraurethral contamination.

Medical science has become increasingly aware of the importance of obtaining urine samples in performing a thorough examination of a patient. It has been discovered, for instance, that in the vast majority of cases, urine samples collected from patients either show very few bacteria, or a bacteria count which is many times what is usual. A low bacteria count is indicative of a normal condition, while a high bacteria count often indicates an unhealthy condition which suitable diagnosis may correct. A bacteria count falling between these low and high ranges is a relatively rare event. Thus, in order that urine analysis be a useful diagnostic tool for the physician, it is important that a means be devised that makes possible the taking of urine samples where the bacteria therein is an accurate reflection of the condition of the urine as it exists in the bladder.

In the female, because of the position of the urethra, difficulties have been encountered in obtaining truly representative urine samples. Commonly, such samples are obtained by inserting a catheter into the urethra, with urine then flowing directly from the bladder. This, however, has the potential danger of introducing bacteria into what previously was a sterile bladder, a particularly disadvantageous feature with patients susceptible to urinary tract infections. With other techniques, urine samples frequently are contaminated with bacteria derived from extraurethral sources, such as the vagina, so that the samples do not show the condition of the urine as it exists in the bladder.

Generally, an object of this invention is to provide a device for obtaining urine samples from the urethra, where such samples are collected without penetration of the urethra and are relatively free of extraurethral contamination.

More specifically, an object is to produce such a device which includes means that forms a relatively tight seal about the meatus of the urethra, such seal defining a zone which excludes regions outside the urethra from where extraurethral contamination might be derived.

Yet a further object is to provide a device for taking urine samples which may be placed simply and rapidly in operative, urine-collecting position. The device features means which senses the anterior vaginal wall and with reference to this wall properly positions the sealing means described. The device is particularly well adapted to be used with the patient in a sitting position.

Yet another object is to provide a novel method for obtaining urine samples from females, which relies upon establishing a sealed zone about the meatus of the urethra, with such zone being properly positioned by reference to the anterior vaginal wall but excluding the vagina proper and adjoining areas.

These and other objects and advantages are obtained by the invention, and the same is described in connection with the accompanying drawings, wherein:

FIG. 1 illustrates apparatus as contemplated herein,

with portions broken away, such including a tubular body and a container for collecting urine mounted on one end of the tubular body;

FIG. 2 is a top view of the apparatus in FIG. 1;

FIG. 3 is a cross sectional view, taken along the line 3—3 in FIG. 2; and

FIG. 4 illustrates in dashed outline a representative female pelvis in median section, and shows how the device is used to obtain urine samples.

Referring now to the drawings, it will be noted that the apparatus illustrated comprises an elongated tubular body **10**, comprising tube **12**, and mounted on an end **12***a* of this tube, an annular pad indicated at **14**.

Tube **12** preferably is made of a rigid or semirigid material, such as "Pyrex," to enable suitable positioning of end **12***a* thereof by manipulation of end **12***b*. Pad **14** may be of compressible and resilient relatively soft material, whereby a cushion is formed at one end of the tubular body, and by way of example may be made of foamed rubber or other elastomer.

Extending along through the tube is a channel **16**. Pad **14** has a center opening extending therethrough, shown at **18**, and opening **18** and channel **16** together form a passage extending the length of the tubular body with an entrance end adjacent end **12***a* of tube **12**.

It will be noted that tube **12** is bent at **20** between the ends thereof, so that tubular body **10** has a concavo-convex outline viewing a side profile thereof. Thus, two reaches of tube are present which extend out to opposite ends of the tube and which define an obtuse angle, shown at A. This angle in a typical case may be in the range of 165°, plus or minus 5°.

The upper end of the tubular body in FIG. 1, i.e., end **12***a* of the tube and pad **14**, is placed between the labia of a female when taking a urine sample, and to facilitate such positioning, end **12***a* of tube **12** may be flattened slightly, as best shown in FIG. 2, whereby a somewhat eliptical outline is given to the cross section thereof. This outline is shared by cushion or pad **14**.

At end **12***a* of tube **12**, opposite lateral sides of the tube are shown bounded by concave edges such as the one indicated at **24**. Pad **14** is grooved at **26** on the underside thereof and this groove receives the edges bounding the end of the tube including edges **24**.

As best shown in FIGS. 2 and 3, pad **14** includes a shoulder **28** located beyond end **12***a* of the tube and supported by a wall **29** adjacent one side of tube **12**. A surface **30** bounds shoulder **28** on the inside of the shoulder, and, as best illustrated in FIG. 3 by the angle B, the surface slopes away from the axis of passage **12** progressing axially inwardly from the end of the tubular body. Integral with opposite ends of shoulder **28** are lip portions **32**, and these smoothly meet with a heel portion **34**, the heel and lip portions also being beyond end **12***a* of the tube. Wall **29** is flexible, and thus permits shoulder **28** to flex outwardly (or to the left in FIG. 3) when the device is used. Lip portions **32** joining with the shoulder are stretchable and elongate when shoulder **28** is bent outwardly. With the pad of compressible, resilient material, they are also compressible to a degree, in an axially inward direction at the end of the tubular body.

As best shown in FIG. 1, the outer end of shoulder **28**, the lip portions, and the outer part of portion **34** generally define a plane C which is inclined from perpendicularity to the axis of the tube adjacent end **12***a*. Describing the relationship in another way, the heel portion is disposed inwardly toward end **12***a* of the tube from

a plane passing through the outermost extremity of the shoulder and normal to the axis of end **12***a* of the tube.

Further describing the device, lower end **12***b* of the tube extends through a stopper **48** which is employed to mount the tube in the top of a flask or container **50**, with the passage within tube **12** communicating with the interior of the flask. At **52** is indicated a vent conduit which communicates with the interior of the flask through the stopper. A diaphragm **54** forms a dam between the top of the flask and upper portions of tube **20**. Thus, the crevice around the stopper where the stopper meets the neck of the flask is covered.

Referring to FIG. 4, where a female pelvis is illustrated in median section with such female in a sitting position, bodily portions shown include a bladder **60**, the vagina **62**, the symphysis pubis **64**, and rectum **66**. The urethra which connects with the bladder is shown at **68** and the urethral meatus at **68***a*. The distal end of the anterior wall of the vagina is indicated at **62***a*, and it will be noted that the anterior wall of the vagina and tissue adjacent the urethral meatus form what is referred to herein as a vaginal vestibule angle designated at **70**.

When using the device of the invention, as an initial step, the device is thoroughly sterilized so as to be free of contamination. The patient whose urine is to be analyzed may then be placed in a seated position with her legs spread slightly apart. To obtain a sample, the upper end of the tube with pad **14** thereon is inserted between the labia and the pad brought to bear on tissue surrounding the urethral meatus with the pad thus forming a sealed zone about the meatus. Positioning of the pad is accomplished by proper manipulation of the flask and lower portion of tube **12**. In positioning the pad, shoulder **28** is utilized as a positioning aid by moving surface **30** of the shoulder against the distal end of the anterior vaginal wall. With the pad positioned so as to encircle the urethral meatus and vestibule angle, the pad is pressed firmly against the tissue surrounding the meatus so that through prolapse of the meatus and adjacent tissue a protrusion is formed (shown in FIG. 4 at **72**) extending into the space bounded by the pad. The pad itself deforms somewhat, with shoulder **28** bending outwardly or to the left. In FIG. 4 it will be noted that surface **30** more nearly parallels the side wall of the tube than it does in FIG. 3. With outward bending of the shoulder, there is stretching and elongation of lips **32**. Since the lips are bearing against tissue, they also tend to be compressed inwardly somewhat, and thus in FIG. 4 a concave curvature is illustrated for the edges of the lips which is not shown in FIG. 3.

Ultimately a snug fit is produced about tissue protrusion **72**. Surface **30** forms a seal with the anterior wall of the vagina, and the pad lips and portion **34** likewise form a seal with the tissue around the meatus. Because of the angularity described in connection with plane C defined by the top of the pad, tube **12** extends out from the labia at the slight incline illustrated in FIG. 4, thus to clear any means used to support the patient in her seated position. With the bend described in the tube, proper drainage into the flask occurs.

It will be noted that there is no penetration of the urethra. A relatively small sealed region is produced by the pad which includes only a small portion of the anterior vaginal wall. Urine flowing into the flask in this manner is kept free from extraurethral contamination and this is done without incurring the danger of introducing bacteria into the urethra.

Upon completing the taking of a urine sample, it is an easy matter to remove the device from the patient, and afterwards separate the stopper from the flask to accommodate the removal of urine from the flask.

The device of the invention may be utilized as described in taking urine samples from female patients of widely different ages and physical descriptions. Results have indicated that reliable bacteria counts are obtainable using the method.

While there has been described an embodiment of the invention, variations and modifications are possible without departing therefrom. It is desired to cover all such modifications and variations as would be apparent to one skilled in the art, and that come within the scope of the appended claims.

It is claimed and desired to secure by Letters Patent:

1. A device for obtaining urine samples from the urethra, with such samples free of extraurethral contamination, comprising

an elongated tube of stiff material having a passage extending therethrough with an entering end of the passage at one end of the tube,

said tube between the ends thereof containing a bend whereby two reaches are present which define an obtuse angle, one of such reaches extending out to said one end of the tube,

an annular pad of stretchable and more pliable material than the tube mounted on said one end of the tube and extending around said entering end of said passage,

said pad including a shoulder on one side of the tube at said one end, which is disposed outwardly beyond said one end of the tube and bounded by an inner surface that slopes away from the axis of said tube progressing axially inwardly from said one end,

said pad further including opposed lip means and a heel portion on the side of said tube opposite the tube's said one side which are outwardly beyond said one end of the tube and cooperate with said shoulder to bound said entering end and to produce encirclement of a urethral meatus and to form a seal therethereabout with the device in operative position,

said heel portion being disposed inwardly toward said one end of the tube from a plane passing through the outermost extremity of said shoulder and normal to the axis of said one end of the tube.

2. A device for obtaining urine samples from the urethra, with such samples free of extraurethral contamination, comprising

an elongated tube having a passage extending therethrough with an entrance to said passage at one end of the tube,

said tube being of stiff material to enable positioning of said one end by manipulation of the opposite end of the tube,

an annular pad of compressible and resilient material mounted on said one end of the tube and extending around said entrance of said passage,

said pad including a shoulder on one side of the tube disposed beyond said one end of the tube and supported by a flexible wall in said pad permitting said shoulder to deflect laterally of the tube,

said pad further including oppositely disposed lip portions joining with opposite ends of said shoulder, which are disposed outwardly beyond said one end of the tube and are stretchable to permit elongation, and deflecting of said shoulder,

said pad further including a heel portion disposed beyond said one end of the tube and on the side of the tube opposite the tube's said one side with opposite ends of the heel portion joining with said lip portions,

said lip portions, heel portions, and shoulder cooperating to produce encirclement of a urethral meatus and to form a seal thereabout with the device in operative position,

said heel portion being disposed inwardly toward said one end of the tube from a plane passing through the outermost extremity of said shoulder and normal to the axis of said one end of the tube.

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