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3,175,553

URINE TEST KIT

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FIG. 2.

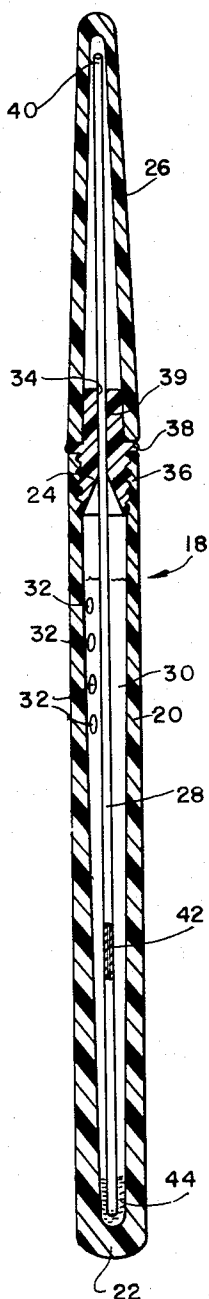


FIG. 1.

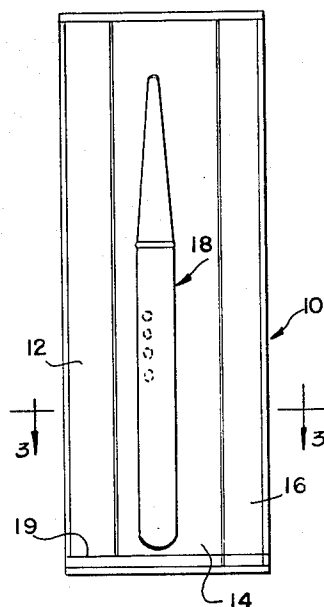
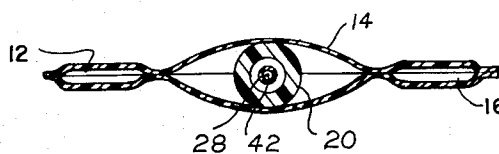


FIG. 3.



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URINE TEST KIT

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5 Claims. (Cl. 128—2)

The present invention relates to the acquisition, transport and analysis of urine specimens, and more particularly to a novel urine test kit for performing these operations.

Although the invention is suited to use with both male and female patients it has particular utility with respect to the acquisition, transport and analysis of urine specimens from female patients because of the many problems which now exist when practicing present methods. For a reliable analysis of the urine of female patients of all ages, it is generally conceded that a urine specimen obtained by catheterization should be studied, so as to minimize the likelihood of any contamination of the specimen.

By way of review, the presently practiced method for so obtaining a specimen, which method is almost universal in application, is as follows. The operation is performed by a nurse using a sterile catheterization tray, containing towels, basins, sponges, rubber gloves, long flexible rubber catheters, and other miscellaneous items which enable the nurse to wash the vulva or entire perineum, and then insert the catheter directly into the urethral meatus to obtain the urine specimen. The urine specimen thus collected in this manner is then usually transferred to a specimen bottle from the urine collecting pan, and this bottle then identified with the patient's name and other pertinent information, the specimen bottle then being transported to the laboratory. If the specimen is to be taken from a male patient, the specimen bottle is used directly, and then identified and transported to the laboratory in the same manner.

In a routine study of a urine specimen in most laboratories, the specimen must be transferred from the specimen bottle to a centrifuge tube, or frequently from the specimen bottle to a culture plate. In any case, the specimen itself is transferred in and to many different types of containers in order that the various conventional analytical tests may be made thereon. In other words, in the normal course of laboratory analysis the specimen itself is manipulated and handled frequently and in many different ways.

It is therefore a primary object of the present invention to provide means wherein urine specimens may be taken, transported, and analyzed without requiring the use of much of the presently required sterile equipment, such as the catheterization tray, various paper and plastic specimen bottles, sterile culture bottles, centrifuge tubes, common glass test tubes and other related apparatus.

It is a further object of the present invention to provide means for obtaining, transporting, and analyzing urine specimens which is of light-weight construction and of minimum size so as to render it very portable. The present invention is of such a portable nature that it may be easily carried either in the pocket or medical bag of a physician when he makes a house call, or in a conventional pneumatic tube system, to be conveniently transported throughout a hospital.

It is yet another object of the present invention to provide an extremely useful and practical urine test kit which is of such economical construction that it may be thrown away after use, hence eliminating the necessity for resterilization prior to subsequent use.

It is a further object of the present invention to provide a portable, disposable urine test kit comprising a container means whereby the urine specimen obtained

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may be transported and centrifuged without removing it from said container means, and wherein means are provided for discharging the specimen from said container means drop by drop in a controlled manner for purposes of laboratory analysis. It is a related object to provide additional disposable container means adapted to receive larger portions of the urine specimen for analysis thereof.

These and other objects of the present invention will become apparent from consideration of the present specification taken in connection with the accompanying drawings in which there is shown a single embodiment of the invention by way of example, and wherein:

FIGURE 1 is a top plan view of a urine test kit embodying the principles of the present invention;

FIGURE 2 is an enlarged longitudinal sectional view of a single embodiment of the catheterization device which forms a part of the present invention; and

FIGURE 3 is an enlarged transverse sectional view taken along line 3—3 of FIGURE 1.

Generally speaking, there is disclosed herein a single embodiment of a urine test kit embodying the principles of the present invention. The test kit basically comprises two elements, namely a compartmented plastic film bag, and a catheterization device comprising a semi-rigid catheter and container means for holding said catheter and receiving the specimen obtained thereby.

Thus, referring more particularly to the drawings, there is illustrated in FIGURE 1 an elongated compartmented bag 10 having defined therein three elongated compartments 12, 14 and 16. The bag 10 may be formed of any suitable plastic film material, such as polyethylene or the like, and is preferably at least semi-transparent, for reasons as will hereinafter be discussed. The structure of the bag 10 is very simple, comprising only two sheets of the suitable plastic film material cut to the proper rectangular shape and then heat sealed to define compartments 12, 14 and 16, and close the ends of the bag, as can be seen. In FIGURE 1, there is shown sealed within the bag 10 the catheterization device, designated generally at 18, and more clearly illustrated in FIGURE 2. In order to open the bag 10, to thereby remove the catheterization device 18, there is provided tear tape 19 across the bottom thereof.

The catheterization device 18 comprises tube member 20 having one end thereof, as at 22, closed, and provided at its other open end with a plug member 24 rigidly secured thereto. Tightly but releasably affixed to the upper end of plug 24 is a cap member 26. Disposed within the tube member 20 and cap member 26, rigidly held in place by plug member 24, is catheter 28.

As can be seen, the tube member 20 is of cylindrical external shape, and is provided with a central chamber 30 diminishing in diameter towards a point of minimum cross-sectional area at the closed end 22 of the tube. The tube member 20 is formed of any suitable flexible plastic material, such as, for example, vinyl or polyethylene. It is important that a flexible material be used because it is intended that the tube 20 serve as a "squeeze-bottle" type tube, or a squeeze-tube as it will be called. Disposed within central chamber 30 are a plurality of color-coded balls 32 of different specific gravity, to be used to determine the specific gravity of a specimen contained within the squeeze-tube 20, as will be apparent.

Rigidly secured to the upper open end of squeeze-tube 20 is plug member 24 having central aperture 34 extending longitudinally therethrough. The plug member 24 may be secured to the open end of squeeze-tube 20 in any suitable manner, as by means of threads 36. If desired the plug may be actually fused or welded to the tube 20 or it may be formed integrally therewith, as in most applications it is not necessary that it ever be removed from

the tube. Disposed about the external periphery of plug member 24 is peripheral flange 38 which serves to properly locate the plug member with respect to the squeeze-tube 20. On the upper end of plug 24 there is provided boss 39 which is adapted to receive, in a releasable connection, cap member 26. The plug member 24 may be formed of any suitable material having sufficient rigidity to hold the catheter 28, the tube 20, and cap 26 in a fluid-tight relationship.

Rigidly held in place by central aperture 34 of plug member 24 is catheter 28, which extends downwardly into chamber 30 of the squeeze-tube 20 to a position wherein it terminates adjacent the closed end 22 thereof. In the other direction, the catheter 28 extends to a point approximately three and one-half inches beyond the plug member 24, terminating at free end 40. Catheter 28 may be held in place simply by the frictional engagement thereof with aperture 34, as long as a fluid-tight connection is obtained. The catheter 28 is formed from an appropriate semi-rigid material, as for example rubber or plastic. As can be seen, the catheter 28 is provided with a central longitudinally disposed passageway 42 running the full length thereof, and open at each end.

In order to protect the outwardly extending portion of the catheter 28 from contamination and structural damage there is provided semi-rigid cap member 26 which is releasably secured, as by frictional engagement, to the boss 39 of plug member 24.

The completely assembled urine test kit, as it would appear when purchased, or otherwise acquired, is illustrated in FIGURE 1. The entire kit, including the compartmented bag 10, and the catheterization device 18 disposed within compartment 14 of the bag, would be sterilized, as by gas, ultraviolet light, or any other suitable sterilization means. To facilitate easy removal of the catheterization device 18 from the bag and to provide access to the compartments 12 and 16 there is provided tear tape 19, which, if pulled, will open the entire end of the bag.

In actual use the urine test kit would replace, among other things, the entire, almost universally used, catheterization tray with all of its associated equipment. When it is desired to obtain a urine specimen from a female patient the only necessary equipment required will be the present kit and a cotton sponge moistened with Zephiran, or other antiseptic agent. With the patient in the proper position for catheterization, the nurse need cleanse only the urethral meatus rather than the entire perineum. She then will open the sterile bag 10, as by means of tear tape 19, and remove therefrom the catheterization device 18. The cap member 26 protecting the outwardly extending end of the catheter 28 will then be manually removed. To then obtain the urine specimen the nurse will insert the small diameter catheter tube 28 directly into the urinary bladder, and the urine specimen will be aspirated directly from the bladder, whereupon it will pass through passageway 42 into the sterile chamber 30 of squeeze-tube 20. It will be understood that catheter tube 28 is sterile when it is used and that the specimen is sterile. The catheter tube is contaminated only with the flora of the patient and there is no external contamination. Upon withdrawal of the catheter 28, the sterile cap member 26 will once again be firmly secured upon the boss 39 of plug member 24, in order to preserve sterility of the interior of catheterization device 18 and the urine specimen now contained within chamber 30 of squeeze-tube 20.

The present invention may also be used to obtain a urine specimen from a male patient, although it is particularly suited to the rapid catheterization of females. However, in the case of a male, the patient would first void into a paper cup, or other suitable container, and the specimen thus obtained would be transferred into the squeeze-tube 20, by either removing plug member 24 and pouring it in, or by compressing the sides of squeeze-tube

20 and then inserting the end 40 of the catheter 28 into the cup of specimen and drawing the specimen into chamber 30 by suction.

Once the squeeze-tube 20 has received a sufficient amount of specimen, it will then be returned to compartment 14 in bag 10, and the bag will be identified with the patient's name. Because of the material and construction of the compartmented bag the patient's name and other pertinent information may be conveniently imprinted upon the bag by means of Addressograph plates. These plates are conventionally used in many hospitals and serve to eliminate having to write information upon the container or bag in long hand. There is also eliminated the use of identification tags, which are easy to lose. Properly labeled, the bag 10 will then be transported, as by means of a conventional pneumatic tube system, to the laboratory. Of course, any means of transporting the bag and catheterization device may be utilized, as will be apparent. For example, when a doctor is on a house call he can conveniently carry the test kit in his pocket.

Once the specimen has arrived in the laboratory, a urine culture can be inoculated directly from the squeeze-tube 20 simply by removing the cap member 26 and then squeezing squeeze-tube 20 to eject a few drops of the specimen onto a culture plate. This removal of the specimen, of course, does not require the use of any intermediate transfer container, nor is there any possibility of contamination, as will be appreciated. The plastic balls 32 contained within chamber 30 will indicate the specific gravity of the urine specimen. Since each of the balls 32 is of a different color, each color representing the specific gravity of that ball, by observing which of the balls are floating and which are not, it is possible to determine the range of the specific gravity of the specimen. In this regard, it is important that the material of which the squeeze-tube 20 is formed, be, at least, semi-transparent, in order that the balls 32 may be observed.

To prepare the specimen for further laboratory analysis it is conventional to centrifuge the specimen to precipitate out the urinary sediment therein. To facilitate this operation without the use of the conventional centrifuge tube, the external shape of the squeeze-tube 20 is so designed that it will accurately mate with the internal surface of the metal carrier of a centrifuge, sometimes called the head of the centrifuge. It is important that the squeeze-tube 20 be of a mated or complementary shape for otherwise it would have insufficient strength to withstand, by itself, the physical forces encountered during centrifuging, and would therefore become significantly distorted. Thus, by providing the tube with an external shape substantially the same as that of a conventional centrifuge tube, it is thereby possible to eliminate the use of such a centrifuge tube by centrifuging the specimen directly in the squeeze-tube 20.

As a result of the centrifuge action upon the specimen there is precipitated into the narrow diameter lower closed end portion 22 of the tube 20 the urinary sediment which is in the specimen, as shown at 44. The narrowness of the chamber 30 at its lower end serves the very useful purpose of locating the sediment immediately adjacent the open lower end of the catheter 28. Thus, when it is desired to obtain a drop or so of the sediment, for purposes of qualitative analysis, it is only necessary to squeeze the tube 20 to thereby force the sediment upwardly through passageway 42, so that it can be dispensed drop by drop upon a microscopic slide or other item of analytic equipment for purpose of study. Since the shape of chamber 30 positions the centrifuged sediment adjacent the inner end of the catheter 28, it will be the first portion of the specimen to be ejected. There are many analytic tests which require but a single drop of the sediment, hence the present squeeze-tube device is excellent for this purpose.

When it is desired to perform a more accurate analysis

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of the urine specimen, as for the presence of sugar or protein, it is necessary to test larger samples of the specimen. For this purpose, there are provided the two chambers 12 and 16 in the film bag 10. Accordingly, when such a test is performed, the specimen contained within the squeeze-tube 20 is dispensed into the two compartments or chambers 12 and 16, whereupon reagents may be added to the specimen to accurately analyze its composition. The use of the sterilized bag 10 is ideal for those tests which require a sample in the order of several cubic centimeters to make an accurate test. One of the primary advantages thus obtained is that the film bag 10 is disposable and may be discarded after use. Therefore there is eliminated the use of conventional test tube equipment which cannot be discarded after use and which must be resterilized prior to reuse. In order to observe the results of any test reaction taking place in the specimen within one of the compartments 12 or 16, the film material of which the bag is formed should be at least semi-transparent.

There has thus been described and illustrated means for acquiring, transporting, and analyzing a urine specimen, which means is ideally suited for the dispensing of the specimen in any amount that is desired, including the dispensing drop by drop of only the urinary sediment contained within the specimen. In actual use, at least with female patients, it should never be necessary to remove the plug member 24 from the upper end of the squeeze-tube 20, nor should it ever, in any case, be necessary to insert instruments into the chamber 30. Generally, only 5 to 7 cubic centimeters of specimen are required in order to enable the laboratory to carry out all of the routine tests customarily performed upon a urine specimen; thus, the chamber 30 need only be of sufficient volume to contain this amount.

The urine test kit described, which exemplifies the principles of the present invention, comprises both the plastic film bag and the device removably disposed therein for obtaining urine samples, both of which elements are completely disposable. As will be appreciated, both elements of the kit complement each other towards achieving a mutual result, namely the acquisition, transporting and testing of urine specimens. Thus, the bag provides sterile means for containing the catheterization device free from contamination, both before it is used and after it is used, and, in addition, provides container means to be used in conjunction with the squeeze-tube for the analysis of relatively large samples of specimen. Furthermore, the bag provides means for having imprinted thereon the information necessary to identify the specimen contained within the squeeze-tube when carried within the bag.

Thus, there is disclosed in the above description, and in the drawings, an exemplary embodiment of my invention which fully and effectively accomplishes the objects of the invention. However, it will be understood by

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those skilled in the art that the specific details of construction and arrangement of parts, as described, are by way of example only and are not to be construed as limiting the scope of the invention. I, therefore, do not wish to be limited to the precise details set forth, and intend that the invention embody all such features and modifications as are within the scope of the appended claims.

Having thus described my invention, what I claim as new and desire to secure by Letters Patent is:

1. Apparatus for acquiring, transporting and analyzing urine specimens, comprising: hollow container means of elongated substantially cylindrical external configuration having flexible side walls, an open end and a closed end; and hollow tube means rigidly secured to the open end of said container means in a fluid tight connection for obtaining a urine specimen and delivering it into said container means, said tube means having one end extending into said container means and terminating adjacent the closed end thereof, the opposite end of said tube extending away from said container means whereby urine contained in said container means may be dispensed drop by drop through said tube means by compressing the flexible sides of said container means.

2. Apparatus as claimed in claim 1, wherein said tube means is a catheter, and the hollow portion within said container means tapers to a point of minimum cross-section, the inwardly extending end of said catheter terminating adjacent said point of minimum cross-section.

3. Apparatus as claimed in claim 1, wherein the hollow portion of said container means is an interior chamber of elongated, tapered configuration, the first mentioned end of said tube means being disposed in the narrowest portion of said tapering chamber.

4. Apparatus as claimed in claim 1, further comprising means disposed within said container means for determining the specific gravity of a specimen contained therein.

5. Apparatus as claimed in claim 4, wherein said last named means comprises a plurality of color-coded balls of different specific gravity.

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