

DEVICE AND PROCESS FOR AUTOMATIC COLLECTION OF FIRST-VOID, MIDSTREAM AND LATE STREAM URINE SPECIMENS

FIELD OF THE PRESENT DISCLOSURE

[0001] The present disclosure generally relates to a urine collecting device, and specifically relates to an automatic urine collecting device and process for collecting first-void, midstream, and late stream urine specimens separately.

BACKGROUND

[0002] One of the most popular tests ordered from the microbiology laboratory is urine culture, primarily requiring clean-voided midstream urine (MSU) specimens. The right specimen collection and its timely arrival at the laboratory determines the accuracy and, consequently, utility of the culture results. However, all the UTI suspected women do not receive or understand proper instructions to collect the MSU specimen and not all instructions are followed while collecting the MSU specimen which leads to contamination from First-void urine (FVU) in upto ~30% of the total cases.

[0003] To minimize the risk of genital bacterial contamination, patients must receive clear and precise instructions during urine collection. Laboratories should ensure that specimens are delivered within two hours of collection. If this is not possible, refrigeration should be provided until pickup, or preservative-containing urine transport tubes should be supplied.

[0004] Suprapubic aspirates must be clearly labeled to ensure all bacterial growth is identified and reported accurately. These procedures are typically performed on infants or individuals suspected of having a urinary tract infection (UTI) when obtaining clean-voided urine samples is challenging. This guidance also applies to specimens collected during invasive procedures, such as cystoscopy. Anaerobic cultures should be performed on suprapubically aspirated urine, but only when specifically requested.

[0005] Rapid screening techniques for urinary tract infections (UTIs) include direct Gram staining and various commercially available methods such as dipstick tests, bioluminescence, and filtration devices. To create a Gram stain, a drop of well-mixed,

uncentrifuged urine is placed on a slide, air-dried, and then stained. The slide is examined under an oil immersion lens, where observing one or more organisms per field correlates to a bacterial count of 10^5 or more colony-forming units per milliliter. For colony counts of 10^5 or higher, the correlation between the stain and culture results should be fairly excellent if the Gram stain is read by a skilled microscopist.

[0006] Typically, contamination with normal gastrointestinal flora is indicated by the presence of mixed bacterial species or a moderate proportion of smooth epithelial cells. Furthermore, circumstances in which 10^4 colony-forming units per milliliter or less would be regarded as significant but cannot be detected by direct Gram staining. If alternative quick screening techniques are employed to weed out specimens that would be culture negative and have a strong negative predictive value. However, caution should be exercised to make sure that specimens with lower colony counts (10^4 to 10^5) are not removed during the screening process. Furthermore, it is important to assess the screening system's dependability, especially for individuals who are neutropenic.

[0007] Contemporary methods to detect UTI involve Urine Culture test of the clean voided midstream urine collected by following the given verbal instructions. The diagnostic laboratory staff members or nurses are required to guide the UTI suspected women, but the issue is that all the UTI suspected women do not receive proper instructions to collect the MSU specimen and not all instructions are followed while the MSU specimen is collected.

[0008] According to literature many interventions were tested across the globe to reduce contamination like, in Kathmandu, Nepal, three groups of equal number of 200 individuals of both the genders combined were tested for three parameters. The first group was given a sterile container and instructed to collect MSU after urogenital cleaning with a provided piece of paper soap. The second group was given sterile containers and SVI (Strict Verbal Instructions) to collect the MSU specimen after urogenital cleansing by tap water only. The third group was given the sterile container and instructed to collect MSU. The contamination rate in the three groups were 6.0%, 13.0%, and 27.5%, respectively, (P value < 0.05), which was statistically significant.

[0009] In Australia, a study was conducted with instructions and without instructions with a group of 120 females each; the contamination rate was reduced from 40% to 25% by the intervention. In another study, in Istanbul, 1,609 individuals in the experimental group used

Genital Region Cleansing Wipe (GRCW) before sampling, while 1,046 in the control group did not use any wipes (GRCW). The contamination rate in the experimental group patients was 7.7%, while it was 15.8% in the control group. In another study, in Kolkata, SVI in native language were given to 196 Females that are called group 1, and no instructions were provided in group 2 of 200 Females. The culture contamination rate reduced, 6.1% in instructed group (that is, group 1) and 19.5% in non-instructed group (that is, group 2).

[0010] According to the study, in ~30% of cases, doctors do not receive clinically useful results from the urine culture because these specimens are contaminated. The contamination error rate was 16% for midstream urine compared to 23% for First-void urine with Urine culture test, 27% for midstream urine compared to 40% for First-void urine with microscopic analysis, and 25% for midstream urine compared to 33% for First-void urine with dipstick testing.

[0011] According to the other study, 300 individuals were tested on midstream vs first-voided urine collection by using automated analysers for particle examination. Counts of epithelial cells (EC), erythrocytes (ERY) and leukocytes (LEU) but not for cylinders (CAS) were significantly higher in the first-voided samples. This indicates how FVU contamination can lead to false positives for UTIs.

[0012] In this crossover design, 40 menstrual-age female emergency department staff without UTI symptoms collected urine two ways: directly in a cup ("non-clean") and midstream clean catch ("ideal"). Samples underwent standard automated urinalysis and culture. Urinalysis indices and culture contamination were compared. The study results showed 77.5% bacteria in FVU and 62.5% bacteria MSU (difference -7 to 37%), which clearly indicates false positive UTI diagnosis for many.

[0013] In the other study, 2 different urine collection methods and 2 different antimicrobial wipes were compared. And there was no difference observed in midstream clean-catch urine culture contamination among the 4 groups, after the intervention of devices and wipes. Group A, n = 67 (29.9% contaminated); Group B, n = 69 (34.8% contaminated); Group C, n = 51 (23.5% contaminated); Group D, n = 36 (22.2% contaminated). The use of a funnel urine-collection system and silver-impregnated wipe did not reduce urine-culture contamination in adult midstream clean-catch urine cultures in the emergency department, hence there is need for Midstream Urine collecting device.

[0014] Midstream Urine sampling implies that the first and last part of urine is avoided. This reduces the risk of the sample being contaminated with bacteria from; your hands, the skin around the urethra, and the urethral opening (urethra is the tube that carries urine out of the body). There are some known solutions in the art for example, universal urine collector is widely used to collect urine specimens, but these are not compatible with the female body and are susceptible to manual error.

[0015] Usually, babies and small children cannot wee 'on demand', which makes it difficult to get a sample. There are four possible ways for collecting a urine sample from younger children, that is, Clean-catch; Bag specimen; Catheter; and Suprapubic aspirate (SPA). It is found that these solutions are inefficient for the younger children or pediatric population.

[0016] In the narratives of patients with recurrent urinary tract infections and their experiences of diagnostic urine specimen collection, 4 themes were compared; Theme 1: uncomplicated urine specimen collection, Theme 2: painful catheter urine specimen, Theme 3: the superior catheter urine specimen, Theme 4: naturally voided urine as standard clinical practice. It was concluded that MSU collections using the collecting device were challenging procedures for patients providing a urine specimen for diagnostic testing, which again indicates the unmet need for an efficient device.

[0017] There is an existing device, Peezy UCD, that automatically discards the first flow part of the urine specimen, capturing the MSU (without interrupting the urine flow) in a sterile bottle attached to the device. Another existing device, Whiz Midstream UCD, uses a pressure valve system to allow the early urine stream to flow into the toilet and the midstream sample then flows into a sample bottle.

[0018] In the existing midstream urine collecting devices, such as Peezy UCD and Whiz Midstream UCD, were compared along with SVI with reference to gold standard methods. Study results show ~ 25% of the samples are contaminated which indicates a non-significant reduction in contamination, 26.5% with the Peezy UCD, 28.2% with the Whiz Midstream UCD, and 29.0% with SVI. And 100 (25.3%) device failures with the Peezy UCD and 35 (8.8%) with the Whiz Midstream UCD. However, neither the Peezy UCD nor the Whiz Midstream UCD reduced urine sample contamination. Additionally, there are also few more existing midstream urine collecting kits in the field that are not very comfortable for UTI suspected females and female

UTI patients.

[0019] Although using UCDs can be difficult for women experiencing UTI symptoms, they may be appropriate for asymptomatic sampling in other clinical populations. In pregnant women, the contamination rate of midstream samples is comparable with the contamination rates of morning and clean-catch samples. The quantity of contaminants varied among the three samples collected by one woman. These results show that more complex, unpractical, and time-consuming morning and clean-catch samples are not superior. Therefore, midstream sampling to assess bacteriuria in pregnant women is equally effective for UTI detection.

[0020] However, first-void and midstream urine samples collection could be standardized with the use of a urine collecting device to increase the specificity of urine culture test and in order to avoid manual errors. The existing alternatives or the existing solutions to the Universal Urine collector are not efficient. Accordingly, there is a need for an efficient urine collecting device and process to facilitate error-free diagnostic testing. This can enhance the specificity of urine culture tests and help avoid manual errors. Also, this reduces the chances of contaminating urine samples from the FVU, LSU, host's feces, skin, and/or vaginal secretions, thus minimizing the likelihood of false positive results in urine culture.

SUMMARY

[0021] To achieve the foregoing and other objects and needs, the present disclosure provides a midstream urine collecting device and a process for collecting urine specimens to facilitate error-free diagnostic testing. The midstream urine collecting device enhances the specificity of urine culture tests and helps avoid manual errors, thereby reducing the chances of contaminating urine samples.

[0022] In an aspect, a urine collecting device for collecting first-void, midstream, and late stream urine specimens is disclosed. Herein, the term "urine specimen" or "urine sample" or "sample" are being used interchangeably, without any limitation. The urine collecting device comprises a funnel for automatically part the labia majora from the vulvar region and allow urine to pass therethrough. The device further comprises a compartment disposed below the funnel. The

compartment comprises a plurality of chambers arranged vertically side by side, the plurality of chambers including a first chamber, a second chamber, a third chamber, and a fourth chamber, wherein each chamber is configured to collect a urine specimen. The compartment further comprises a spherical floater disposed within each of the first chamber, the second chamber, the third chamber, and the fourth chamber. The spherical floater is configured to securely retain the urine specimen upon the respective chamber being filled. The device further comprises a locking ring operatively coupling the funnel to the compartment.

[0023] The device further comprises a urine flow segregating pathway unit detachably disposed between the funnel and the compartment, wherein the urine flow segregating pathway unit is configured to sequentially divert urine received from the funnel into the first chamber, the second chamber, the third chamber, and the fourth chamber, such that: when the first chamber is filled with urine, the floater in the first chamber moves from a bottom position to a top position to securely retain the urine therein, and subsequently, the urine is diverted to and retained in the second chamber, the third chamber, and the fourth chamber in a similar manner, wherein the first chamber is configured to collect a first-void urine (FVU), and the second chamber and the third chamber are configured to collect a first midstream urine (MSU1) and a second midstream urine (MSU2), respectively.

[0024] In one or more embodiments, the fourth chamber is configured to collect a late stream urine (LSU).

[0025] In one or more embodiments, the funnel comprises an upper portion including an inlet and a lower portion including an outlet. The lower portion further comprises L-shaped locking slots configured to engage with locking pins of the locking ring, wherein the locking pins is aligned with the L-shaped locking slots.

[0026] In one or more embodiments, the inlet of the upper portion is configured to part the labia majora from the vulvar region, thereby allowing urine to pass therethrough to the outlet of the lower portion, and the urine is directed into the chambers in subsequent manners for the collection of urine specimen, thereby preventing contamination and ensuring a sterile urine specimen is supplied to the second chamber and the third chamber.

[0027] In one or more embodiments, the urine flow segregating pathway unit comprises a first hole, a second hole, a third hole, and a fourth hole, said holes being disposed in

a sequential and/or a clockwise direction within the urine flow segregating pathway unit. The first hole is opposite to the fourth hole, and the second hole is opposite to the third hole. The urine flow segregating pathway unit further comprises a boundary disposed and extended between the first hole, the second hole and the third hole, the fourth hole, wherein the first hole and the second hole are located on one side of the boundary, and the third hole and the fourth hole are located on the opposite side of the boundary, thereby forming passages on either side of the boundary. The first hole corresponds to the first chamber, the second hole corresponds to the second chamber, the third hole corresponds to the third chamber, and the fourth hole corresponds to the fourth chamber. Upon receiving the urine from the outlet of the funnel, the urine flow segregating pathway unit sequentially diverts the urine into the first chamber, the second chamber, the third chamber, and the fourth chamber through the first hole, the second hole, the third hole, and the fourth hole, respectively.

[0028] In one or more embodiments, the device further comprising a lid configured to seal the compartment upon detachment of the funnel, wherein the lid comprises L-shaped locking slots configured to engage with corresponding locking pins of the locking ring, the locking pins being alignable with the L-shaped locking slots of the lid to securely cover the compartment.

[0029] In one or more embodiments, each of the first chamber, the second chamber, the third chamber, and the fourth chamber, comprises: a body defining an elongated hollow cavity configured to collect and contain the urine specimen; an open end configured to provide access to the hollow cavity of the body; and a closed end opposite the open end, said closed end providing a sealed base to retain the collected urine specimen. The first chamber, the second chamber, the third chamber, and the fourth chamber are adapted to function as collection chambers resembling test tubes.

[0030] In one or more embodiments, the body of the fourth chamber comprises a curved-shaped hollow cavity, the curved-shaped hollow cavity having an open end at one side, the open end being configured to facilitate controlled flow of excess urine into the curved-shaped hollow cavity of the fourth chamber.

[0031] In another aspect, a process for collecting a first void and a midstream urine specimen separately is disclosed. The process comprises positioning a funnel to automatically part labia majora from a vulvar region, allowing urine to pass therethrough. The process further

comprises directing the urine into a compartment through a urine flow segregating pathway unit that sequentially diverts the urine into a first chamber, a second chamber, a third chamber, and a fourth chamber of the compartment, wherein the compartment is disposed below the funnel. The process further comprises filling the first chamber with urine, wherein a spherical floater in the first chamber moves from a bottom position to a top position to securely retain the urine therein. The process further comprises subsequently diverting the urine into the second chamber, the third chamber, and the fourth chamber, such that the spherical floater in each chamber moves from a bottom position to a top position upon being filled, securely retaining the urine in each respective chamber. The process further comprises collecting a first-void urine (FVU) in the first chamber, and a first midstream urine (MSU1) and a second midstream urine (MSU2) in the second chamber and the third chamber, respectively, and a late stream urine (LSU) in the fourth chamber.

[0032] In one or more embodiments, positioning the funnel automatically fits into the space adjacent to the labia majora, allowing urine to pass through for a spill-proof process.

[0033] In one or more embodiments, the process further comprising detaching the funnel from the compartment; and sealing the compartment with a lid configured to seal the compartment upon detachment of the funnel, wherein the lid comprises L-shaped locking slots configured to engage with corresponding locking pins of a locking ring, the locking pins being alignable with the L-shaped locking slots of the lid to securely cover the compartment.

[0034] The foregoing summary is illustrative only and is not intended to be in any way limiting. In addition to the illustrative aspects, embodiments, and features described above, further aspects, embodiments, and features will become apparent by reference to the drawings and the following detailed description.

BRIEF DESCRIPTION OF THE FIGURE

[0035] For a more complete understanding of example embodiments of the present disclosure, reference is now made to the following descriptions taken in connection with the accompanying drawings in which:

[0036] FIG. 1A illustrates a front view of a urine collecting device, in accordance with one or more exemplary embodiments of the present disclosure.

[0037] FIG. 1B illustrates a back view of the urine collecting device, in accordance with one or more exemplary embodiments of the present disclosure.

[0038] FIG. 1C illustrates a top view of the urine collecting device, in accordance with one or more exemplary embodiments of the present disclosure.

[0039] FIG. 1D illustrates a bottom view of the urine collecting device, in accordance with one or more exemplary embodiments of the present disclosure.

[0040] FIG. 1E illustrates a side view of the urine collecting device, in accordance with one or more exemplary embodiments of the present disclosure.

[0041] FIG. 1F illustrates another side view of the urine collecting device, in accordance with one or more exemplary embodiments of the present disclosure.

[0042] FIG. 2 illustrates an exploded view of the urine collecting device, in accordance with one or more exemplary embodiments of the present disclosure.

[0043] FIG. 3 illustrates a perspective view of a locking ring of the urine collecting device, in accordance with one or more exemplary embodiments of the present disclosure.

[0044] FIG. 4 illustrates a perspective view of a urine flow segregating pathway of the urine collecting device, in accordance with one or more exemplary embodiments of the present disclosure.

[0045] FIG. 5 illustrates a perspective view of a compartment of the urine collecting device, according to an embodiment of the present disclosure.

[0046] FIG. 6 illustrates flow of urine through a funnel to the compartment, in accordance with one or more exemplary embodiments of the present disclosure.

[0047] FIG. 7 illustrates flow of the urine through the urine flow segregating pathway, in accordance with one or more exemplary embodiments of the present disclosure.

[0048] FIG. 8A-8C illustrate movement of a floater from a bottom position to a top position flow in the chambers, in accordance with one or more exemplary embodiments of the present disclosure.

[0049] FIG. 9 illustrates the urine collecting device, sealed with a lid after collecting a first-void, a midstream and a late stream urine specimen, in accordance with one or more

exemplary embodiments of the present disclosure.

[0050] FIG. 10 illustrates an exploded view of the urine collecting device, sealed with the lid after collecting the first-void, the midstream, and the late stream urine specimen, in accordance with one or more exemplary embodiments of the present disclosure.

[0051] FIG. 11A illustrates a front view of a bathroom-dependent urine collecting device, in accordance with one or more exemplary embodiments of the present disclosure.

[0052] FIG. 11B illustrates a back view of the bathroom-dependent urine collecting device, in accordance with one or more exemplary embodiments of the present disclosure.

[0053] FIG. 11C illustrates a top view of the bathroom-dependent urine collecting device, in accordance with one or more exemplary embodiments of the present disclosure.

[0054] FIG. 11D illustrates a bottom view of the bathroom-dependent urine collecting device, in accordance with one or more exemplary embodiments of the present disclosure.

[0055] FIG. 11E illustrates a side view of the bathroom-dependent urine collecting device, in accordance with one or more exemplary embodiments of the present disclosure.

[0056] FIG. 11F illustrates another side view of the bathroom-dependent urine collecting device, in accordance with one or more exemplary embodiments of the present disclosure.

[0057] FIG. 12 illustrates an exploded view of the bathroom-dependent urine collecting device, in accordance with one or more exemplary embodiments of the present disclosure.

[0058] FIG. 13 illustrates a cross-sectional view of the bathroom-dependent urine collecting device, in accordance with one or more exemplary embodiments of the present disclosure.

[0059] FIG. 14 illustrates a flow chart of a process for collecting first-void, midstream, and late stream urine specimens, according to an embodiment of the present disclosure.

[0060] FIG. 15A illustrates an exemplary test result of incubated petri plates, in accordance with one or more exemplary embodiments of the present disclosure.

[0061] FIG. 15B illustrates exemplary colonies picked for cPCR, in accordance with one or more exemplary embodiments of the present disclosure.

[0062] FIG. 15C illustrates an exemplary agarose gel electrophoresis showing the positive results for bacteria, in accordance with one or more exemplary embodiments of the present disclosure.

DETAILED DESCRIPTION

[0063] In the following description, for purposes of explanation, numerous specific details are set forth in order to provide a thorough understanding of the present disclosure. It will be apparent, however, to one skilled in the art that the present disclosure can be practiced without these specific details. In other instances, apparatuses and methods are shown in block diagram form only in order to avoid obscuring the present disclosure.

[0064] Reference in this specification to “one embodiment” or “an embodiment” or “another embodiment” or “one or more embodiments” means that a particular feature, structure, or characteristic described in connection with the embodiment is included in at least one embodiment of the present disclosure. The appearance of the phrase “in one embodiment” in various places in the specification are not necessarily all referring to the same embodiment, nor are separate or alternative embodiments mutually exclusive of other embodiments. Moreover, various features are described which may be exhibited by some embodiments and not by others. Similarly, various requirements are described which may be requirements for some embodiments but not for other embodiments.

[0065] Although the following description contains many specifics for the purposes of illustration, anyone skilled in the art will appreciate that many variations and/or alterations to said details are within the scope of the present disclosure. Similarly, although many of the features of the present disclosure are described in terms of each other, or in conjunction with each other, one skilled in the art will appreciate that many of these features can be provided independently of other features. Accordingly, this description of the present disclosure is set forth without any loss of generality to, and without imposing limitations upon, the present disclosure.

[0066] Referring to FIG. 1A, 1B, 1C, 1D, 1E and 1F, different views of the urine

collecting device (represented by reference numeral 100) is illustrated. Herein, the urine collecting device is also referred to as “automatic first-void, midstream, and late stream urine collecting device”, “collecting device” or “urine collecting device” or “urine collector device” or “collector device”, or “automatic first-void, midstream, and late stream collection device”, “automatic collecting device” and the said terms have been interchangeably used hereinafter without any limitations.

[0067] Referring to FIG. 2, an exploded view of the urine collecting device is illustrated. Specifically, the assembly and positioning of each part, including the funnel, the compartment, and the locking mechanism is illustrated. Now referring to FIGS. 1A-1F and FIG. 2, in combination, the device 100 comprises a funnel 200. The funnel looks like a teacup. The funnel 200 is provided with a labia-separating funnel 202. The labia-separating funnel 202 is a critical component and designed to accommodate the anatomical variations of women for a comfortable and effective urine collection process. Herein, the labia-separating funnel 202 is made from medical-grade silicone making the funnel flexible and soft, ensuring minimal discomfort while maintaining a secure fit to the body. Herein, anatomical adaptability reduces the risk of contamination from the vulvar region, promoting cleaner, more accurate urine specimens for diagnostic purposes. Further, the funnel is available in multiple sizes—small, medium, and large—tailored to the common anatomical dimensions of women, specifically targeting the diverse population of women in India. The silicone funnel measures 14.5 cm in length, 8 cm in diameter, and 3.2 cm in height – medium size, it will also be available in different sizes to align with the anatomical variations, 12.5 cm in length, 7 cm in diameter and 3 cm in height - small size, 15.5 cm in length, 9 cm in diameter, and 3.5 cm in height – large size, without any limitations.

[0068] As illustrated in FIG. 2, the funnel 200 is provided with a holder 204. Herein, the holder 204 serves as a supporting structure that secures the labia-separating funnel in place during urine collection. Herein, the term “urine” and “urine specimen” are being interchangeably used, without any limitation. During urine collection, the user can hold the holder 204 securely. Hereinafter, the holder 204 will be referred to as the “funnel holder.” Additionally, the funnel holder is made from durable polyethylene (PE), providing stability and comfort while ensuring that the funnel's ergonomic design aligns with the user's anatomy. The labia-separating funnel 202 is molded into the funnel holder 204 in such a way that it fits perfectly, forming the funnel 200, wherein an upper portion 206 of the funnel 200 comprises an inlet and a lower portion 208 of the

funnel 200 comprises an outlet. The funnel 200 and 202 designs are aimed at restroom-independent urine collection without spill. The funnel holder 204 has a length of 13 cm, a diameter of approximately 6.7 cm, and a height of 3.3 cm. Furthermore, the funnel holder includes an outlet that allows the urine specimen to pass through. The funnel holder also features locking slots (which will be described later). When the inlet of the upper portion 206 is engaged with the labia majora of the vulvar region, the inlet provides a path for the urine to be supplied to the compartment. Referring to FIGS. 1A-1F and FIG. 2, the device 100 comprises a compartment 300, wherein the compartment 300 comprises a plurality of chambers arranged vertically side by side in the compartment (we will describe it later). The device 100 comprises a locking ring 400. Referring to FIG. 3, the locking ring of the urine collecting device is illustrated. The locking ring 400 is operatively coupling the funnel 200 to the compartment 300, wherein the locking ring 400 is placed just between the funnel 200 and the compartment 300 (which we will describe later). The locking ring 400 is a hollow structured ring. The locking ring 400 has a diameter of about 5.8 cm and a height of about 2.2 cm, without any limitations. The locking ring 400 has four projections on its four sides which helps the funnel 200 to lock with the compartment 300. The four projections may be in the form of locking pins 402. Specifically, the locking ring 400 comprises four locking pins 402 provided on outer periphery of the locking ring 400.

[0069] Referring to FIGS. 1A-1F and 2 in combination, the compartment 300 is disposed below the funnel 200 or the funnel 200 is disposed above the compartment 300 or the funnel 200 is detachably engaged with the compartment 300, wherein the locking ring 400 is configured to operatively coupling the funnel 200 to the compartment 300. As illustrated in FIG. 2, the bottom portion 208 of the funnel 200 has L-shaped locking slots 210 that are configured to engage with the locking pins 402 of the locking ring 400. The locking pins 402 align with the L-shaped locking slots 210. Before coupling the funnel to the compartment, the locking ring 400 is being fixed to the compartment 300 using a press fit or snap fit arrangement. Once the locking ring 400 is tightly fixed or secured to the compartment 300, the funnel 200 can be connected to the locking ring 400, wherein the L-shaped locking slots 210 of the funnel 200 are engaged with the locking pins 402 of the locking ring 400. Specifically, the L-shaped locking slots 210 are aligned with the locking pins 402, after which the funnel 200 is rotated in an anticlockwise direction to engage the L-shaped locking slots 210 with the locking pins 402. This way, the funnel 200 is securely attached to the compartment.

[0070] Referring to FIGS. 1A-1F and FIG. 2, the plurality of chambers includes a first chamber 304, a second chamber 306, a third chamber 308, and a fourth chamber 310. Herein, each chamber is configured to collect a urine specimen. The first chamber 304 collects a first void urine (FVU), the initial urine flow of the urine hence, also known as a first void urine (FVU) chamber. The first void urine often contains contaminants from the urethra, skin microflora, hence urine path is designed as such ensuring midstream samples remain uncontaminated. The second chamber 306 and the third chamber 308 are sequentially filled with a first midstream urine (MSU1) and a second midstream urine (MSU2). Hence, the second chamber 306 and the third chamber 308 also known as a midstream urine (MSU1 and MSU2) chamber. The midstream urine is very crucial for diagnostic accuracy (to analyse the pathogen growing in the urinary bladder and causing the UTI symptoms). Ideally, the urine samples (MSU2) collected in the third chamber 308 are used for the diagnostic purposes, but in case of low-urine-output patients who are suffering from severe UTI, samples from the second chamber 306 will be considered for the urine culture test.

[0071] The fourth chamber 310 collects the terminal urine flow, a late stream urine (LSU). The fourth chamber 310, also known as a late stream urine (LSU) chamber prevents the midstream urine sample contamination from the urethra and/ perineal region present in the terminal urine flow.

[0072] The first chamber 304, the second chamber 306, the third chamber 308, and the fourth chamber 310 are adapted to function as collection chambers resembling test tubes. The test tube-like collection chamber ensures hygienic and spillage-free handling of urine samples during dipstick analysis, making it ideal for performing urine culture and antimicrobial susceptibility testing (AST), significantly improving efficiency and accuracy compared to conventional containers. The test tube-like collection chamber facilitates the easy transfer of urine into diagnostic test tubes or culture media, minimizing the risk of contamination or sample loss. The compartment's precise chamber ensures that the sample remains intact and uncontaminated, significantly improving both the efficiency and accuracy of diagnostic procedures. This feature streamlines the diagnostic process, enhancing the reliability of test results and reducing potential errors.

[0073] Referring to FIG. 5, a perspective view of the compartment of the urine

collecting device is illustrated. In the illustration of FIG. 5, each of the first chamber 304, the second chamber 306, the third chamber 308, and the fourth chamber 310, comprises: a body 314 defining an elongated hollow cavity configured to collect and contain the urine specimen. In one or more embodiments, the body 314 of the first chamber 304, the second chamber 306, and the third chamber 308 are cylindrical, while the body 314 of the fourth chamber 310 has a curved shape. Due to the curve shape 316 of the body 314, the fourth chamber 310 has the hollow cavity that provides more space. Therefore, the fourth chamber 310 can store a greater volume of urine specimens. The fourth chamber 310 may accommodate more urine because its storage capacity is greater than that of the first chamber 304, the second chamber 306, and the third chamber 308. Specifically, the first chamber 304, the second chamber 306, and the third chamber 308 are particularly sized to accommodate up to 10 ml of urine specimens, having a diameter of 5 cm and a height of 11 cm, (plus these are Boric Acid coated, as per standard requirement for Urine collection containers/test tubes/ urine collecting vacutainers), without any limitation. On the other hand, the fourth chamber 310 is designed in a way that its physical capacity to store the urine specimen is up to 61 ml. Moreover, the capacity of the fourth chamber 310 may increase upto 250 ml with the addition of water absorbing 2.5 g of sodium polyacrylate, widely used in diapers and other products.

[0074] Referring to FIG. 5, the chambers 304, 306, 308, 310 further comprise an open end 312 configured to provide access to the hollow cavity of the body 314. In one or more embodiments, the open end 312 of the first chamber 304, the second chamber 306, and the third chamber 308 has circular opening configured to facilitate controlled flow of urine specimen therethrough into the hollow cavity in the first chamber 304, the second chamber 306, and the third chamber 308. On the other hand, the open end 312 of the fourth chamber 310 is configured to facilitate controlled flow of excess urine therethrough into the hollow cavity 316 in the fourth chamber 310.

[0075] Referring to FIG. 5, the chambers 304, 306, 308, 310 further comprise a closed end opposite the open end. The closed end is providing a sealed base to retain the collected urine specimen.

[0076] The compartment 300 utilizes a ball float valve system to control filling. Referring to FIG. 8A-8C, the floater movement from a bottom position to a top position in the

chambers is illustrated. The compartment 300 comprises a floater 302 or a spherical floater 302 disposed within each of the first chamber 304, the second chamber 306, the third chamber 308, and the fourth chamber 310. Herein, the term “spherical floater” or “floating ball” or “floater” is being used interchangeably, without any limitation. The floater 302 is configured to securely retain the urine specimen upon the respective chamber being filled. The floating ball 302 has a diameter and height of 1 cm each. The floater 302 moves inside the chambers. Specifically, upon receiving the urine specimen in the chambers, the floater 302 is configured to move from the bottom position to the top position in each of the chambers. Once the chambers reach their capacity, the floater locks the respective chamber, preventing overflow or backflow.

[0077] Referring to FIG. 4, a perspective view of a urine flow segregating pathway of the urine collecting device is illustrated. The device 100 further includes a urine flow segregating pathway unit 500, which is detachably disposed between the funnel 200 and the compartment 300. Referring to FIG. 7, the flow of the urine through the urine flow segregating pathway is illustrated. As shown in FIGS. 2, 4, 5, and 6, the urine flow segregating pathway unit 500 is positioned between the funnel 200 and the compartment 300. Specifically, as illustrated in FIG. 7, the urine flow segregating pathway unit 500 is disposed at an upper portion of the compartment 300.

[0078] Referring to FIGS. 4 and 7 in combination, the urine flow segregating pathway unit 500 comprises a first hole 502, a second hole 504, a third hole 506, and a fourth hole 508. The holes are disposed in a clockwise direction within the urine flow segregating pathway unit 500, such that the first hole 502 is followed by the second hole 504, the third hole 506, and then the fourth hole 508. The first hole 502 is opposite the fourth hole 508, and the second hole 504 is opposite the third hole 506. The urine flow segregating pathway unit 500 has a diameter of about 4.5 cm and height of about 2.2 cm, without any limitation.

[0079] Referring FIGS. 4, 5, and 7 in combination, the urine flow segregating pathway unit 500 is disposed in the upper portion of the compartment 300 such that the first hole 502 corresponds to the first chamber 304, the second hole 504 corresponds to the second chamber 306, the third hole 506 corresponds to the third chamber 308, and the fourth hole 508 corresponds to the fourth chamber 310. Upon receiving the urine from the outlet of the funnel 200, the urine flow segregating pathway unit 500 sequentially diverts the urine into the first chamber 304, the

second chamber 306, the third chamber 308, and the fourth chamber 310 through the first hole 502, the second hole 504, the third hole 506, and the fourth hole 508, respectively (which we will describe later).

[0080] Further referring to FIGS. 4 and 6, the urine flow segregating pathway unit 500 includes a boundary 510 extending between the first hole 502 and the second hole 504 and the third hole 506 and the fourth hole 508. In other words, the boundary 510 separates the first hole 502 and the second hole 504 from the third hole 506 and the fourth hole 508. On one side of the boundary 510, the first hole 502 and the second hole 504 are located, while on the other side, the third hole 506 and the fourth hole 508 are located, thereby forming passages on either side of the boundary 510. These passages direct urine flow in predetermined directions. The boundary 510 within the urine flow segregating pathway unit 500 is configured to ensure that the flow of urine is sequentially directed into the chambers.

[0081] Referring to FIG. 7, the urine flow segregating pathway unit 500 is configured to sequentially divert the urine received from the funnel 200 into the first chamber 304, the second chamber 306, the third chamber 308, and the fourth chamber 310, such that: when the first chamber 304 is filled with urine, the floater 302 in the first chamber 304 moves from a bottom position to a top position to securely retain the urine therein, and subsequently, the urine is diverted to and retained in the second chamber 306, the third chamber 308, and the fourth chamber 310 in a similar manner, wherein the first chamber 304 is configured to collect a first-void urine (FVU), and the second chamber 306 and the third chamber 308 are configured to collect a first midstream urine (MSU1) and a second midstream urine (MSU2), respectively.

[0082] Referring to FIG. 9, the urine collecting device is sealed with a lid after collecting the first-void, the midstream urine specimen (MSU1 and MSU2), and the late stream is illustrated. The device 100 further comprises a lid 600 configured to seal the compartment 300 upon detachment of the funnel 200. Herein, the lid may be a cap or cover used for sealing. The lid 600 comprises L-shaped locking slots 602 configured to engage with corresponding locking pins 402 of the locking ring 400, the locking pins 402 being alignable with the L-shaped locking slots 602 of the lid 600 to securely cover the compartment 300. In one or more embodiments, once the urine specimen is collected, the lid 600 is screwed onto the compartment 300 after removing the funnel 200. The lid 600 helps in protecting the urine specimen from contamination from the

surroundings or environment. The lid 600 helps in safe storage of urine specimens for further examination.

[0083] Referring to FIG. 10, an exploded view of the urine collecting device 100 sealed with the lid 600 after collecting the midstream urine specimen is illustrated.

[0084] Referring to FIG. 6, the flow of urine through the funnel to the compartment is illustrated. In an example, the device is used to collect urine from a user. The user may be a woman, girl, or female, without limitation. Herein, the user receives the entire device 300 with proper assembly, wherein the user need not to attach the funnel to the compartment while collecting the urine specimen. The user attaches the funnel 200 to the vulvar region, wherein the funnel 200 is configured to automatically part the labia majora from the vulvar region. In an alternative embodiment, the funnel 200 may be replaced with an appropriate design suitable for users who are men, boys, or males, without limitation.

[0085] As shown in FIG. 6, urine passes through the funnel 200 into the urine flow segregating pathway unit 500. The first hole 502 of the urine flow segregating pathway unit 500 corresponds to the first chamber 304 of the compartment 300 and directs urine into the first chamber 304. As illustrated in FIG. 8A, when the first chamber 304 begins to fill with urine, the floater 302 within the first chamber 304 moves from a bottom position towards a top position. As depicted in FIG. 8B, when the first chamber 304 is approximately half-filled, the floater 302 is reached to the midpoint of the first chamber 304. Further, as shown in FIG. 8C, when the first chamber 304 is completely filled, the floater 302 reaches the top position of the first chamber 304. At this stage, the open end 312 of the first chamber 304 is automatically locked with the floater 302 to securely retain the urine therein which prevents the specimen from spilling out. After locking, the first chamber 304 prevents any additional urine from entering. Herein, a first-void urine (FVU) sample is collected in the first chamber 304, wherein the FVU may be required for metabolite and protein testing for example in case of cervical cancer screening.

[0086] Subsequently, the urine flow segregating pathway unit 500 directs the urine to the second chamber 306 via a passage 512. Specifically, the urine flow segregating pathway unit 500 diverts the flow of the urine from the first chamber 304 to the second chamber 306. Similar to the first chamber 304, the second chamber 306 and the third chamber 308 filled with urine and are locked by their respective floaters 302. A midstream urine (MSU) sample or a

midstream urine specimen is collected in the second chamber 306 and the third chamber 308. Specifically, the MSU1 (Midstream Urine 1, urine sample for diagnosis of UTI for patients with less urine output) is collected in the second chamber 306 and the MSU2 (Midstream Urine 2, ideal urine sample for diagnosis of UTI for all users) is collected in the third chamber 308.

[0087] Once the third chamber 308 is filled, the urine is diverted to the fourth chamber 310. The fourth chamber 310, having a larger capacity, collects the excess urine. Herein, the fourth chamber 310 collects a late-stream urine (LSU). Hence, this is a bathroom independent UCD, which collects complete Urine void volume, automatically (i.e., without manual input from the user) segregates the stream as per diagnostic requirement. After urination is complete, the funnel 200 is to be detached from the compartment 300 by rotating the funnel 200 in a clockwise direction. Herein, the funnel 200 used for collecting samples or specimens is discarded, as the funnel is intended for single-use only.

[0088] Referring to FIG. 9 and FIG. 10, the compartment 300 is then sealed with the lid 600, wherein the user aligns the L-shaped slots 602 of the lid 600 with corresponding locking pins 402 of the locking ring 400 and rotate the lid 600 in an anticlockwise direction to engage the lid with the compartment. After engaging the lid 600 with the compartment 300, the closed compartment is then sent to laboratories for further diagnosis.

[0089] In an embodiment, the urine collecting device 100 (that is, a bathroom-independent urine collecting device 100) is provided with the chambers 304, 306, 308, 310 for the collection of first-void, midstream urine (MSU1 and MSU2), and late stream urine specimens, as illustrated in FIGS. 1A-1F. In another embodiment, as illustrated in FIGS. 11A-11F, the urine collecting device 1100 is referred to as “bathroom-dependent urine collecting device”. The bathroom dependent urine collecting device 1100 is provided with falcon tubes 1104, 1106, 1108, 1110 attached below the funnel 1102. The falcon tubes are bathroom-dependent for the collection of first-void, midstream, and late stream urine specimens. Herein, the falcon tubes are generally known in the art and thus not been explained herein for the brevity of the present disclosure.

[0090] Referring to FIG. 12, an exploded view of the urine collecting device, which is a bathroom dependent device (that is, bathroom-dependent urine collecting), is illustrated. As illustrated in FIG 12, the bathroom-dependent urine collecting device 1100 comprises a funnel 1102 and falcon tubes of 15 ml volume capacity each, customized 5/8/10 ml tubes can be used for

different age groups of population, without any limitation. The bathroom-dependent urine collecting device 1100 is provided with a plurality of falcon tubes, the plurality of falcon tubes comprises: a first tube 1104, a second tube 1106, a third tube 1108, and a fourth tube 1110. Each falcon tube used herein is configured to collect a urine specimen for the collection of midstream urine specimens. The first tube 1104 is configured to collect a first-void urine (FVU), and the second tube 1106 and the third tube 1108 are configured to collect a first midstream urine (MSU1) and a second midstream urine (MSU2). The fourth tube 1110 is configured to collect a late stream urine (LSU).

[0091] Referring to FIG. 13, a cross-sectional view of the bathroom-dependent urine collecting device is illustrated. In the bathroom-dependent urine collecting device 1100, right side falcon tube (that is, the first tube 1104) is locked while left side falcon tube (that is, the second tube 1106) is open which allows to pass the urine into the left side falcon tube 1104. As illustrated in FIGS. 12 and 13, the spherical floaters 1112 are disposed of within each of the first tube 1104, the second tube 1106, and the third tube 1108. The spherical floater 1112 is configured to securely retain the urine specimen upon the respective tubes. The lower end of the fourth tube 1110 is open to pass the excess urine in the commode directly. The first tube 1104, the second tube 1106, and the third tube 1108 are provided with a ball's grip. The ball's grip helps to hold the balls back into the tubes minimizing the leakage and further contamination risks, which ensures balls remain in the defined cavity, and when the third falcon tube – filled with MSU2 is unscrewed from the device, it comes out without the balls (that's the unique feature) and it is capped/sealed with the cap provided, then sent to lab for testing.

[0092] The bathroom-dependent collecting device 1100 is used similarly to the bathroom-independent device 100. The segregation process of the midstream urine is also the same as the bathroom independent device 100. After completing the collection of urine specimens, the female user can unscrew the MSU tubes (the second and third falcon tubes) containing the midstream urine specimens from the device and cover it with the cap by screwing. The falcon tubes (the second tube 1106 and the third tube 1108) containing midstream urine specimens can be sent directly to the lab for diagnostic testing. The bathroom-dependent urine collecting device 1100 is useful while using in bathrooms where the diagnostic centers are available. The bathroom-dependent urine collecting device 1100 is compact and portable.

[0093] In one or more embodiments, the device 100 features a modular lower compartment that can be interchangeably adapted to accommodate varying urine volume capacities, specifically designed to meet the needs of pediatric and elderly populations. The lower compartment's volume can be reduced for pediatric use – FVU, MSU1, MSU2 and LSU of 5-8ml each for Urine culture test and other biochemical testing, since urine output is typically lower, ensuring efficient and accurate midstream urine (MSU) collection without loss of sample integrity.

[0094] In one or more embodiments, the device 100 features the compartment can be customized to handle larger volumes – FVU, MSU1, MSU2 and LSU of 12-15ml volume capacity each for the elderly population, addressing potential issues of reduced voluntary control during urination. This adaptability allows for precise sample segregation while maintaining the device's core functionality of minimizing contamination from FVU, LSU, and external contaminants. Such modifications ensure the device's usability across diverse patient groups, improving diagnostic outcomes for populations with specific clinical needs.

[0095] The present disclosure further provides a method for automatically collecting the midstream urine specimen of a female user. Various embodiments and variants disclosed above, with respect to the aforementioned device 100, apply *mutatis mutandis* to the present method. FIG. 14 is a flowchart 1400 of a method for automatically collecting the first-void urine specimen, the midstream urine specimen, and the late stream urine specimen of a female user. The various steps involved in the present method have been depicted as blocks in the flowchart 1400 of FIG. 14, and the details for the same have been provided hereinafter.

[0096] At step 1402, the method includes positioning a funnel 200 to automatically part the labia majora from the vulvar region, thereby allowing urine to pass therethrough without contamination from skin microflora. To collect a midstream urine sample directly from a human without manual intervention, the funnel 200 is positioned between the labia and the perineal area of the external genitalia. Referring to FIG. 6, the upper part of the funnel 200, referred to as the labia-separating funnel 202, is placed beneath the urethral opening after cleaning. The labia-separating funnel 202 automatically parts the labia, facilitating the flow of urine through the inlet of the funnel 200. The urine enters the funnel 200 directly from the female urethra via the inlet, and the outlet of the funnel 200 directs the urine flow toward the urine flow segregating pathway unit 500, which subsequently channels the urine into a compartment 300, wherein the

compartment 300 is disposed below the funnel 200.

[0097] At step 1404, the method includes directing urine into the compartment 300 through a urine flow segregating pathway unit 500 that sequentially diverts the urine into a first chamber 304, a second chamber 306, a third chamber 308, and a fourth chamber 310 of the compartment 300. As illustrated in FIG. 7, the urine specimen exiting the outlet of the funnel 200 passes through the urine flow segregating pathway unit 500. The first hole 502 in the urine flow segregating pathway unit 500 is positioned directly above the open end 312 of the first chamber 304, enabling the urine specimen to flow directly into the first chamber 304 of the compartment 300.

[0098] The urine flow segregating pathway unit 500 includes a passage 512 defined by the boundary 510. The boundary 510 is disposed and extends between the first hole 502, the second hole 504 and the third hole 506, the fourth hole 508. The boundary 510 within the urine flow segregating pathway unit 500 is configured to sequentially direct the flow of urine into the respective chambers through the passage 512. Once the first chamber 304 is completely filled, the flow of urine is directed to pass through the passage 512 of the urine flow segregating pathway unit 500, wherein the boundary 510 within the urine flow segregating pathway unit 500 subsequently directs the urine to the second chamber 306, followed by the third chamber 308, and finally to the fourth chamber 310.

[0099] At step 1406, the method includes filling the first chamber 304 with urine, wherein a spherical floater 302 in the first chamber 304 moves from a bottom position to a top position to securely retain the first-void urine therein. The compartment 300 employs a ball float valve system to control the filling process. As illustrated in FIGS. 8A and 8B, the compartment 300 comprises a spherical floater 302 disposed within each of the first chamber 304, the second chamber 306, third chamber 308, and the fourth chamber 310. Urine entering the first chamber 304 causes the floater 302 to move in parallel with the rising urine level. When the first chamber 304 reaches its full capacity, the floater 302 moves to the top position, locking the first chamber 304 to securely retain the urine. This automatic locking system prevents overflow or backflow of the urine specimen, thereby avoiding cross-contamination between chambers.

[00100] At step 1408, the method includes subsequently diverting the urine into the second chamber 306, the third chamber 308, and the fourth chamber 310. In each chamber, the

spherical floater 302 moves from a bottom position to a top position as the chamber fills, securely retaining the urine within the respective chamber. After the first chamber 304 is securely locked, the subsequent urine-stream flows through the passage of the urine flow segregating pathway unit 500. This unit directs the urine flow into the second chamber. Once the second chamber is filled to capacity, the floater locks the urine specimen by sealing the opening of the second chamber. Similarly, the third and fourth chambers are locked upon filling.

[00101] At step 1410, the method includes collecting a first-void urine (FVU) sample in the first chamber 304 and a first midstream urine (MSU1) and a second midstream urine (MSU2) samples in the second chamber 306 and the third chamber 308, respectively. The automatic locking of the first chamber 304, the second chamber 306, the third chamber 308, and the fourth chamber 310 after sequential filling ensures the segregation of distinct urine streams. The urine sample in the first chamber 304 is referred to as the first-void urine (FVU). The samples in the second chamber 306 and the third chamber 308 are referred to as midstream urine (MSU1 and MSU2). The fourth chamber 310 collects the late-stream urine (LSU) specimen. Sequential filling and locking prevent cross-contamination of samples, ensuring a clean and reliable midstream urine sample for accurate diagnosis and antimicrobial susceptibility testing (AST).

[00102] As illustrated in FIGS. 9 and 10, upon completing the urine sample collection process, the funnel 200 can be manually discarded. The compartment 300 can then be covered with a lid 600, which protects the urine samples from environmental contamination. This ensures safe storage of the urine samples for further examination. Additionally, the closed compartment 300 can be easily transported to nearby laboratories or clinics for culture tests of clean midstream urine samples.

[00103] The first void urine (FVU) collected using the proposed UCD has significant clinical applications beyond UTI diagnosis, particularly for cervical cancer screening. FVU contains exfoliated cells, mucus, and debris from the female genital tract, including the cervix. These components often harbor high-risk Human Papillomavirus (HPV) DNA and oncoproteins, which are critical biomarkers for cervical cancer detection. Meta-analyses have shown that the sensitivity for detecting high-risk HPV in FVU ranges between 78% and 87%, with specificity reaching 89% to 91%. This makes FVU a promising non-invasive alternative to traditional cervical swabs for HPV-based cervical cancer screening, particularly for HPV types 16 and 18, which

cause approximately 70% of cervical cancers. The clean and controlled collection facilitated by the UCD also opens avenues for self-sampling, providing a patient-friendly solution for cervical cancer screening in regions with low participation in screening programs, ultimately improving early detection rates.

[00104] Beyond cervical cancer, FVU has numerous diagnostic applications due to its rich concentration of epithelial cells, metabolites, and urethral contaminants. It is particularly useful for the detection of sexually transmitted infections (STIs) such as *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Mycoplasma genitalium* through PCR-based molecular assays, as pathogens are highly concentrated in the initial urine flow. Additionally, FVU serves as a valuable source for early cancer biomarker detection, aiding in the diagnosis of bladder and prostate cancers through the presence of exfoliated tumor cells, DNA, and RNA fragments. Metabolite analysis of FVU can also identify systemic diseases such as diabetes, kidney disorders, and liver dysfunction, offering insights via urine metabolomics. Furthermore, FVU can detect kidney stone precursors like calcium, oxalates, and uric acid, as well as serve in drug and substance abuse testing due to its higher concentration of recently excreted drug metabolites.

[00105] The late stream urine (LSU) collected in the UCD, originating from residual bladder contents, has its own diagnostic significance. The LSU is particularly useful for post-infection or residual pathogen detection, as it helps identify bacteria that may persist in the bladder after UTI treatment, offering insights into recurrent infections and treatment efficacy. It can also be analyzed for urinary biomarkers linked to chronic kidney disease (CKD), including specific proteins and enzymes indicative of kidney damage or disease progression. The LSU's composition enables hormonal assays for monitoring endocrine disorders such as cortisol, estradiol, or progesterone imbalances, providing a valuable tool for diagnosing hormonal issues in women. Moreover, the LSU is ideal for urinary sediment analysis, facilitating microscopic examination of casts, crystals, and red or white blood cells for conditions such as glomerulonephritis and nephrotic syndrome. The LSU also presents opportunities for research into the urinary microbiome, which is increasingly associated with immune function, urological health, and disease susceptibility, positioning the LSU as a versatile diagnostic resource.

EXAMPLE

[00106] In the example below, an experiment protocol is described. Particularly, in-

vitro Analysis with spiked samples is used to validate the design and sequential filling of the urine specimen into the device.

[00107] Further, the materials required for this experiment are Sterile 1X PBS buffer, MS media and agar plates, TSB media and agar plates and secondary culture of both the bacteria (incubated for 12-18 hrs.). The experiment is initiated by spiking the PBS buffer from known bacteria in 1000 cells per ml ratio. For this experiment, *Pseudomonas aeruginosa* is selected as the bacterium of the First Void Urine (FVU), and *Acinetobacter baumannii* is chosen as the bacterium for midstream urine (MSU). The bacteria are cultured for 12-18 hours, and the spiking of artificial urine samples is done based on known bacterial concentrations, with the goal of simulating natural urine contamination scenarios.

[00108] For preparation of spiked urine samples, first, an artificial urine solution is prepared and filtered. Then, spiked samples are prepared with 15 ml volumes of first void urine (FVU) and midstream urine (MSU). The FVU sample is spiked with *Pseudomonas aeruginosa*, while two different MSU samples (MSU1 and MSU2) are spiked with *Acinetobacter baumannii*. The spiking volume is calculated based on the optical density (OD) of each bacterial culture at 360 nm.

[00109] For plating of positive controls first ensure the bacteria's viability and proper spiking. In order to do so 50 µl from each spiked urine sample (FVU, MSU1, and MSU2) is plated onto the respective agar plates as a positive control. This step verifies the bacterial presence in the samples before proceeding with the experiment.

[00110] The experimental procedure involves using a sterile 15 ml Falcon tube, cleverCUP 1100, and the spiked urine samples. First, take 10 ml of FVU and poured it into the cleverCUP 1100, followed by MSU1 and MSU2. 50 µl of the flow through from the FVU compartment 1108 is then plated onto an MS agar plate. This procedure is repeated for the MSU1 1110 and MSU2 1104 samples, and 50 µl of the flow through is plated onto TSB agar plates. Hereinafter, the terms “bathroom dependent urine collecting device 1100” and “cleverCUP 1100” are being used interchangeably, without any limitation.

[00111] After the above procedure, the plates are incubated at 37°C for 12-18 hours, and bacterial growth is observed. As illustrated in FIG. 15A, the image showing the results of incubated petri plates at 37 degrees for 12-18 hrs, in accordance with one or more exemplary

embodiments of the present disclosure. The purpose of this incubation is to assess whether there is any cross-contamination between the different bacteria (FVU and MSU) when the urine samples are collected using the device cleverCUP.

[00112] As shown in the FIG. 15B, the observation reveals that only 3 colonies of *Pseudomonas aeruginosa* are present on the MSU1 plate, which contains the *Acinetobacter baumannii*-spiked MSU sample. However, no *Pseudomonas aeruginosa* growth is observed on the MSU2 plate, which also contains *Acinetobacter baumannii*-spiked MSU sample. These results suggest that the device design is effective in preventing the contamination of MSU samples with bacteria from the FVU. The 10 ml of solution-2 (used to wash the funnel) is sufficient to remove any traces of the FVU bacteria, preventing cross-contamination. Running a PCR confirms these bacteria with appropriate positive and negative controls. The PCR product reviewed on the 1.5% Agarose gel.

[00113] As shown in the FIG. 15C, the results are further corroborated by Colony PCR analysis, which confirms that no mixed bacterial growth occurs on the MSU2 plate, validating that the device is successful in isolating and preventing bacterial contamination between FVU and MSU samples.

[00114] According to the present disclosure, the collecting device has specifically designed compartments that are sequentially filled while passing the urine. The FVU is filled in the first compartment, the MSU is filled in the second compartment and the third compartment, and the LSU is collected in the fourth compartment. This sequential filling process ensures that the initial (containing contaminants like urethral microflora, vaginal secretions etc.) and final (containing contaminants like perineal microflora, feces etc.) portions of urine are excluded from the samples. The compartments are specifically designed to prevent cross-contamination, and their unique configuration ensures clear segregation between the FVU and LSU. This design minimizes the risk of contaminating urine samples with feces, skin, and/or vaginal secretions, thereby reducing the likelihood of obtaining false positive results in urine culture. Additionally, the collecting device 100 collects complete urine void volume, facilitates for urine specimen collection independent of restroom facilities. This device is a user-friendly urine collector for women ensuring minimal error and contamination.

[00115] The urine collecting device is specifically designed to address issues

associated with existing products in the market. The device is configured to segregate distinct urine streams first void, midstream, and late stream into separate compartments, thereby ensuring the collection of an uncontaminated midstream sample. Unlike conventional collection methods, the device includes an automatic labia-separating funnel constructed from medical-grade silicone and designed to accommodate anatomical variations. It will be available in small, medium, and large sizes. The funnel is configured to enhance user comfort and minimize contamination risks, effectively mitigating challenges in sample collection, such as improper technique and cross-contamination.

[00116] The present disclosure provides an efficient urine collector device to facilitate error-free diagnostic testing. This can enhance the specificity of urine culture tests and help avoid manual errors. The automatic urine collection device (UCD) is configured to automatically segregate different urine streams first void urine (FVU), midstream urine (MSU), and late stream urine (LSU) into separate compartments, thereby minimizing contamination. The device includes an automatic labia-separating funnel to ensure precise urine flow without contamination from skin microflora from vulvar region. The initial FVU, which may contain urethral contaminants, is directed to a dedicated compartment. Subsequently, the uncontaminated MSU is collected in two sequential chambers to enhance sample accuracy and accommodate UTI suspected women with low urine output. The LSU, which may include residual contaminants from perineal region, is similarly isolated in a separate compartment. This design prevents cross-contamination from skin microflora, vaginal secretions, and fecal matter, thereby ensuring a clean and reliable sample for accurate diagnosis and antimicrobial susceptibility testing (AST).

WE CLAIM: -

1. A urine collecting device for collecting first-void, midstream, and late stream urine specimens separately, the device comprising:
 - a funnel configured to automatically part labia majora from the vulvar region and allow urine to pass therethrough;
 - a compartment disposed below the funnel, the compartment comprising:
 - a plurality of chambers arranged vertically side by side, the plurality of chambers including a first chamber, a second chamber, a third chamber, and a fourth chamber, each chamber configured to collect a urine specimen, and
 - a spherical floater disposed within each of the first chamber, the second chamber, the third chamber, and the fourth chamber, the spherical floater configured to securely retain the urine specimen upon the respective chamber being filled;
 - a locking ring operatively coupling the funnel to the compartment; and
 - a urine flow segregating pathway unit detachably disposed between the funnel and the compartment, the urine flow segregating pathway unit is configured to:
 - sequentially divert urine received from the funnel into the first chamber, the second chamber, the third chamber, and the fourth chamber, such that:
 - when the first chamber is filled with urine, the floater in the first chamber moves from a bottom position to a top position to securely retain the urine therein, and
 - subsequently, urine is diverted to and retained in the second chamber, the third chamber, and the fourth chamber in a similar manner,
 - wherein the first chamber is configured to collect a first-void urine (FVU), and the second chamber and the third chamber are configured to collect a first midstream urine (MSU1) and a second midstream urine (MSU2), respectively.
2. The device as claimed in claim 1, wherein the fourth chamber is configured to collect a late stream urine (LSU).
3. The device as claimed in claim 1, wherein the funnel comprising:

an upper portion including an inlet; and

a lower portion including an outlet, the lower portion further comprising L-shaped locking slots configured to engage with locking pins of the locking ring, the locking pins aligning with the L-shaped locking slots.

4. The device as claimed in claim 3, wherein the inlet of the upper portion is configured to part the labia majora from the vulvar region, thereby allowing urine to pass therethrough to the outlet of the lower portion, and wherein the urine is sequentially directed into the chamber for the collection of urine specimen, thereby preventing contamination and ensuring a sterile urine specimen is collected into the second and third chambers.
5. The device as claimed in claim 4, wherein the urine flow segregating pathway unit comprises:
 - a first hole, a second hole, a third hole, and a fourth hole, said holes being disposed in a sequential and/or clockwise direction within the urine flow segregating pathway unit, wherein the first hole is opposite to the fourth hole, and the second hole is opposite to the third hole; and
 - a boundary disposed and extended between the first, second, third, and fourth holes, wherein the first and second holes are located on one side of the boundary, and the third and fourth holes are located on the opposite side of the boundary, thereby forming passages on either side of the boundary,
 - wherein the first hole corresponds to the first chamber, the second hole corresponds to the second chamber, the third hole corresponds to the third chamber, and the fourth hole corresponds to the fourth chamber, and wherein, upon receiving the urine from the outlet of the funnel, the urine flow segregating pathway unit sequentially diverts the urine into the first chamber, the second chamber, the third chamber, and the fourth chamber through the first hole, the second hole, the third hole, and the fourth hole, respectively.
6. The device as claimed in claim 1 further comprising a lid configured to seal the compartment upon detachment of the funnel, wherein the lid comprises L-shaped locking slots configured to engage with corresponding locking pins of the locking ring, the locking

pins being alignable with the L-shaped locking slots of the lid to securely cover the compartment.

7. The device as claimed in claim 1, wherein each of the first chamber, the second chamber, the third chamber, and the fourth chamber, comprises:

a body defining an elongated hollow cavity configured to collect and contain the urine specimen;

an open end configured to provide access to the hollow cavity of the body; and

a closed end opposite the open end, said closed end providing a sealed base to retain the collected urine specimen,

wherein the first chamber, the second chamber, the third chamber, and the fourth chamber are adapted to function as collection chambers resembling test tubes.

8. The device as claimed in claim 7, wherein the body of the fourth chamber comprises a curved-shaped hollow cavity, the curved-shaped hollow cavity having an open end at one side, the open end being configured to facilitate controlled flow of excess urine into the curved-shaped hollow cavity of the fourth chamber.

9. A process for collecting first void, midstream, and late stream urine specimens, the process comprising:

positioning a funnel to automatically part a labia majora from a vulvar region, allowing urine to pass therethrough;

directing the urine into a compartment through a urine flow segregating pathway unit that sequentially diverts the urine into a first chamber, a second chamber, a third chamber, and a fourth chamber of the compartment, wherein the compartment is disposed below the funnel;

filling the first chamber with urine, wherein a spherical floater in the first chamber moves from a bottom position to a top position to securely retain the urine therein;

subsequently diverting the urine into the second chamber, the third chamber, and the fourth chamber, such that the spherical floater in each chamber moves from a bottom

position to a top position upon being filled, securely retaining the urine in each respective chamber; and

collecting a first-void urine (FVU) in the first chamber, and a first midstream urine (MSU1) and a second midstream urine (MSU2) in the second chamber and the third chamber, respectively, and a late stream urine (LSU) in the fourth chamber.

10. The process as claimed in claim 9, wherein positioning the funnel

automatically fits into the space adjacent to the labia majora, allowing urine to pass through for a spill-proof process.

11. The process as claimed in claim 9, further comprising:

detaching the funnel from the compartment; and

sealing the compartment with a lid configured to seal the compartment upon detachment of the funnel, wherein the lid comprises L-shaped locking slots configured to engage with corresponding locking pins of a locking ring, the locking pins being alignable with the L-shaped locking slots of the lid to securely cover the compartment.