

[54] **METHOD AND APPARATUS FOR DISEASE DIAGNOSIS**

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[63] Continuation of Ser. No. 199,373, June 1, 1962, abandoned.

[30] **Foreign Application Priority Data**

June 5, 1961 Great Britain 20197/61

[52] U.S. Cl. 128/2 B, 128/232

[51] Int. Cl. A61b 10/00

[58] Field of Search..... 128/2, 232, 233, 128/240

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[57] **ABSTRACT**

A process and apparatus for procuring and processing cellular material, particularly for use in disease detection from body cavities in which a self-contained pipette structure is used for irrigating the body cavity with a solution, re-aspirating the solution with the samples to be collected; shipping the thus-obtained samples of cellular material to a laboratory and recovering at the laboratory by means of the pipette structure specimens of cellular material for purposes of analysis.

34 Claims, 9 Drawing Figures

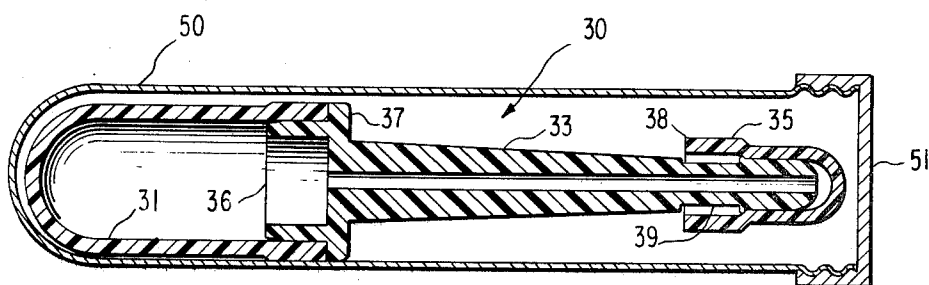


FIG. 1

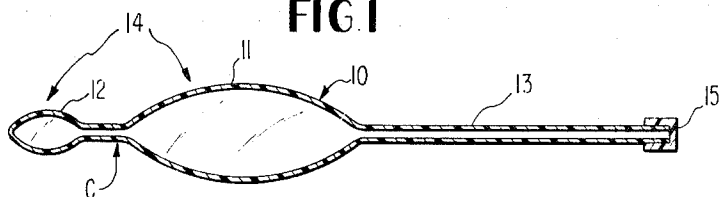


FIG. 2

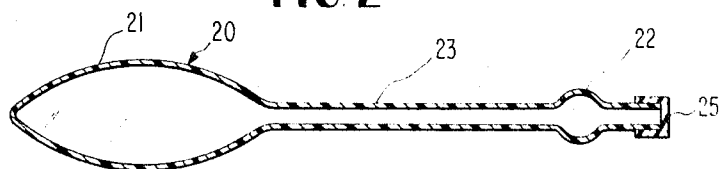


FIG. 3

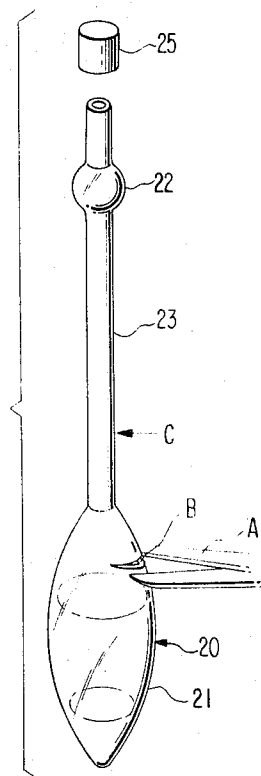
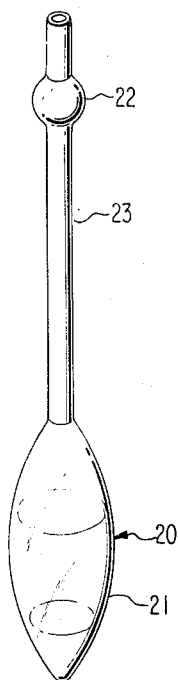
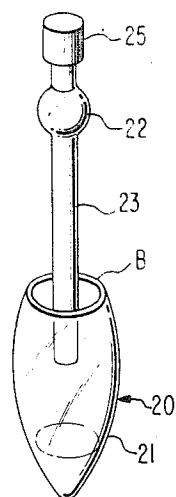


FIG. 4

FIG. 5



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FIG. 6

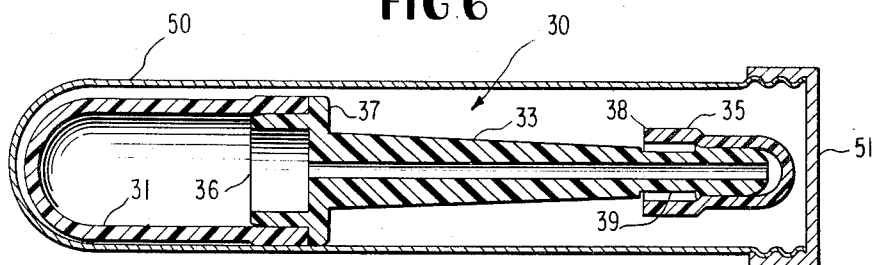


FIG. 7

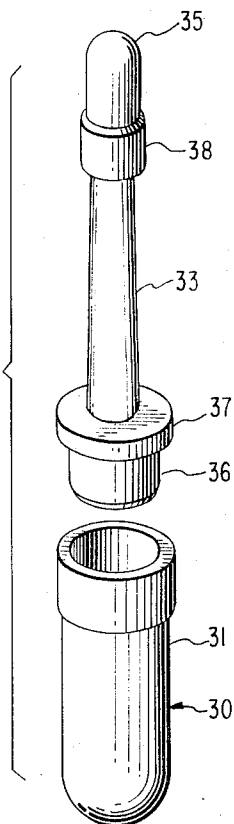


FIG. 8

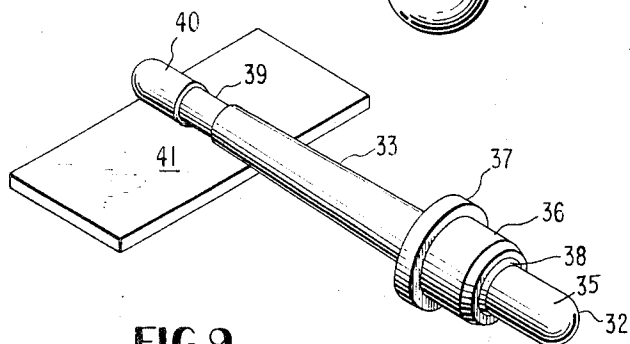
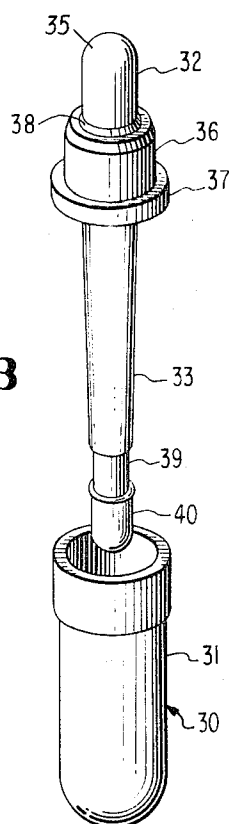


FIG. 9

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METHOD AND APPARATUS FOR DISEASE DIAGNOSIS

The present application is a continuation application of my application Ser. No. 199,373, entitled "Method and Apparatus for Disease Diagnosis," filed in the United States Patent Office on June 1, 1962, now abandoned.

The present invention relates to processing of samples of cellular material from body cavities for microscopic examination.

It is a purpose of the invention to provide a method which enables individual cell specimens to be processed safely without the danger of cross-contamination.

It is a further purpose of the invention to provide a method which enables the use of the same apparatus for the entire processing whereby the danger of cross-contamination is avoided.

It is a further purpose of the invention to provide a method which enables all the necessary steps to be accomplished by means of one single apparatus, thereby obviating the necessity of multiple pipettes, aspirating syringes, collection bottles, etc.

It is a further purpose of the invention to provide a method which eliminates the need for using and washing multiple items of laboratory equipment.

It is a further purpose of the invention to provide a method which expedites the processing and cuts down the time required in the laboratory.

It is a further purpose of the invention to provide a method which enables the procurement of cell samples to be taken by untrained personnel.

Still a further purpose of the invention is to provide the method which enables improvement of the quality of the microscopic preparations and thereby renders the microscopic examination more rapid and accurate.

It is a further purpose of the invention to provide an apparatus for carrying out the method.

Among other purposes of the invention one purpose is to provide an apparatus which enables the utilization of a single container structure as an aspirator as well as shipping and processing container.

Still a further purpose of the invention is to provide apparatus for procuring and processing samples of cellular material which provides a container for an irrigation and preservative solution, and simultaneously provides a pipette operable to aspirate the solution into said container and to enable said container to be used as a centrifugal container.

Still a further purpose of the invention is to provide apparatus for the purpose specified, a part of which can be used as a centrifugal container for processing the sample material and another part of which can be used as a pipette for aspirate material from said centrifugal container and distributing the material directly on a microscopic slide.

Further purposes of the invention will appear from the following specification in connection with the accompanying drawing, in which

FIG. 1 is a schematic longitudinal section through a pipette according to the invention in one embodiment;

FIG. 2 is a schematic longitudinal section through a pipette according to the invention in a modified embodiment;

FIG. 3 is a schematic perspective view of the pipette shown in FIG. 2 illustrating one step of the method;

FIG. 4 is a schematic perspective view in similarity with FIG. 3 showing another step of the method;

FIG. 5 is a further schematic perspective view illustrating a further step of the method;

FIG. 6 is a longitudinal section through a further modification of the apparatus according to the invention enclosed in a protective casing to be used for transportation;

FIG. 7 is a perspective view of the pipette structure shown in FIG. 6 illustrating one stage of the process;

FIG. 8 is a perspective view of the pipette structure shown in FIG. 6 with the parts differently assembled to illustrate another stage of the process;

FIG. 9 is a perspective view of a part of the pipette assembly shown in FIG. 8, illustrating its use for distributing material on a microscopic slide.

Basically, the invention provides a method for procuring and processing samples of cellular material by utilizing a single container structure, which comprises the steps of effectively aspirating cellular material into said container structure, shipping said container structure to a laboratory for processing said cellular material exclusively within said container structure to condition said cellular material for microscopic examination, and eventually distributing said cellular material on a microscopic slide directly from said container structure.

More specifically, the invention provides a method for procuring and conditioning samples of cellular material for microscopic inspection by means of a single container structure, which includes pipette means comprising the steps of aspirating cellular material such as from a body cavity of a human being into said container by means of said pipette means using an irrigating solution, shipping said container and pipette structure with the irrigating solution contained therein to a laboratory, processing said irrigating solution by centrifuging within said container structure to effectively condition the cellular material contained in said irrigating solution for microscopic examination, and eventually distributing said cellular material directly from said container by means of said pipette means on a microscopic slide.

Basically, with respect to the apparatus, the invention provides apparatus for procuring and processing samples of cellular material by means of a fluid which comprises first means effectively providing a container for the fluid, second means effectively providing a pipette structure having a bulb and a tubular portion, and being operable to deliver the fluid from said container and aspirate the fluid into said container again. Said container and said pipette structure are connected in a manner to effectively provide easy separation so as to render the container operable as a centrifugal container for processing the cellular material and condition the same for microscopic inspection. Furthermore, the structure includes means operable to render said tubular pipette portion effective as a pipette to withdraw fluid from said centrifugal container.

More specifically, with reference to the accompanying drawing, the container structure may be in the form of pipette structures 10, 20 and 30 as illustrated by the various embodiments of FIGS. 1-9 having main bulbs 11, 21 and 31 which in addition to providing the main pipette bulbs, effectively provide centrifugal first containers. The pipettes of FIGS. 1-5 may be in the form of unitary structures of suitable synthetic resinous material, which provide for separation of the first means

constituted by the main bulbs 11 and 21 from the remaining parts of the pipette structure by cutting such as indicated at B in FIG. 4, for example, by means of scissors A.

Alternately, said first bulb or container means 31, as shown in FIG. 6, may be detachable from the remaining part of the pipette structure.

The pipette structures 10, 20 and 30 of the different embodiments illustrated in FIGS. 1-9, in addition to the main bulbs 11, 21 and 31, include auxiliary bulb means 12, 22 and 32, respectively, operable in connection with the remaining parts of the pipette structures, as auxiliary pipette to aspirate the conditioned cellular material from the first container means 11, 21 and 31 to distribute the cellular material on a microscopic slide 41 as shown in FIG. 9.

More specifically, the pipette structure shown in FIG. 1 comprises a tubular portion 13 and a reservoir or container structure generally referred to by reference numeral 14. In the embodiment shown in FIG. 1, the reservoir structure 14 comprises a first container or main bulb 11 and auxiliary bulb means 12, both of which includes a flexible wall structure effectively providing bulb means operable to aspirate cellular sample material into the structure 10. The end of the tubular portion 13 is closed by means of a removable cap 15, which may be of natural or synthetic rubber, or of a synthetic resinous material enabling the cap to fit fluid-tight on the end of the tubular portion 13 and to remain in position during transportation.

The reservoir structure 14 is preferably transparent or at least sufficiently translucent to enable observation of the contents. Furthermore, the flexible wall portion of the reservoir structure 14 has preferably sufficient physical or mechanical strength to enable it to stand centrifuging of a solution contained in the reservoir structure. The entire pipette structure 10 is preferably made from a suitable soft or semi-soft synthetic resinous material.

The method of processing cellular material may comprise the following steps carried out within and with the use of the pipette structure 10 shown in FIG. 1.

Cellular material such as from a body cavity is aspirated by means of the pipette structure 10 by manipulating the flexible wall structure of the reservoir structure 14. Preferably, preservative solution is aspirated into the pipette together with the samples of cellular material. The cells are thereafter concentrated in one end of the reservoir structure 14, preferably by centrifuging, whereafter the supernatant solution is removed or discarded. A fixing solution is thereafter delivered into the pipette structure, and the cellular concentrate is mixed with said fixing solution within the pipette structure. After the mixing of the cellular material with the fixing solution, the cellular material can be further processed by:

a. separation from the supernatant fixing solution, preferably by centrifugation, and distribution on a microscopic slide for examination or further processing, or

b. by the addition of staining agents directly to the pipette structure; further processing may be carried out directly prior to examination of the material.

As will be appreciated, an important feature of the structure is that it comprises a container or receptacle structure adapted to be used as an aspirator for cellular

material as well as a centrifugal container, by means of which individual specimens can be further processed without the danger of cross-contamination.

The pipette structure 10 is delivered to the patient prefilled with an irrigation and preservative solution. Cellular material from the vagina can be obtained with or without medical assistance by removing the cap 15 of the pipette, inserting the tubular portion 13 into the vagina until only the main bulb 11 is outside, squeezing the main bulb 11 to eject the irrigating and preservative solution, releasing the pressure on the main bulb 11 to reaspirate the irrigating solution together with a cellular sample suspended in the solution. After procurement of the cellular specimen, the pipette structure 10 is shipped directly from the patient to the laboratory or the hospital, or other laboratory-like facility, for further processing and microscopic examination.

The preservative solution, with which the pipette structure is prefilled, is capable of being used as an irrigating solution without injuring the body tissues, but simultaneously being capable of inhibiting decomposition of the cellular sample material by bacterial, fungal or enzymatic action while maintaining a standard osmotic equilibrium with the cellular material.

Basically, the preservative solution comprises a mixture of alcohol and physiological salts with addition of a small amount of fungicide or antibiotic. The saline concentration should be sufficient to prevent the cells from swelling or shrinking. The alcohol concentration should be strong enough to inhibit bacterial growth and/or decomposition of the cellular material, but low enough not to injure the patient or alter the cells in such a manner as to make further processing difficult. Eventually, the solution contains a suitable agent within a variety of agents operative as a fungicide or antibiotic in a concentration, which is sufficient to ensure against the decomposition of the irrigating and preservative solution on prolonged storage.

Preferably, the solution also comprises a suitable pH indicator so that pH may be standardized by the simple addition of acid or base in small quantities. By way of example, a dyestuff may be used that changes its color from red to yellow, if for some reason acid is produced in the solution due to bacterial growth or other circumstances.

It will be understood, however, that the composition of this solution may be varied within certain limits and that different compounds can be used in the solution for the purposes here specified.

I have found that cellular material aspirated in a solution having the merits here described can be preserved for later processing in the laboratory for a substantial time, such as 4 or 5 weeks, which allows the procurement and transport of specimens from widely separated points for processing in a central laboratory-like facility. A laboratory-like facility is used herein to refer to an establishment manned by trained personnel, who will proceed with clinical analysis in a skillful, organized manner.

After the sample has been received in the laboratory, the processing comprises the steps of placing the pipette structure 10 in a standard centrifuge whereby the cells are concentrated in the closed end of the pipette structure 10, i.e., in the auxiliary bulb means 12. The supernatant solution is thereafter discarded, for example, by manipulating the flexible wall structure of the main bulb means 11. A fixing solution such as 90 per-

cent absolute alcohol in 10 percent ether is thereafter delivered into the pipette structure 10, for example, by aspiration, and by manipulating the auxiliary bulb means 12 and shaking the pipette structure 10, the cellular concentrate is mixed with the fixing solution within the pipette structure 10. The mixture is again centrifuged to concentrate the cells in the auxiliary bulb means 12. If desired, excess of supernatant fixing solution can be removed and eventually the cellular material is distributed on a microscopic slide directly from the pipette structure 10. To this purpose, the auxiliary bulb means 12 may be separated from the remaining part of the pipette structure 10 by cutting at C (FIG. 1) with scissors, or any other suitable instrument.

The pipette structure 20, illustrated in FIGS. 2-5, also includes a tubular portion 23, main bulb means 21 with a flexible wall portion operable as a bulb as well as a receptacle, a removable cap 25, and auxiliary bulb means 22. In contradistinction to the embodiment shown in FIG. 1, the auxiliary bulb means 22 is located near the cap end of the tubular portion 23.

Also, the pipette as shown in FIG. 2 may be delivered to the patient with a content of an irrigating preservative solution.

By centrifuging, the cellular material is concentrated at the closed end of the pipette structure 20, separated from the supernatant preservative solution. Before or after the first centrifugation, a partial cut is made as indicated at B, in FIG. 4, through the wall of the main bulb means 21 adjacent the top thereof; thus, an aperture B is provided through which the supernatant solution can be discarded. The fixing solution is then delivered into the main bulb means 21, and after mixing of the cellular concentrate with the fixing solution, the centrifugation is repeated.

The cut shown at B may then be completed and preferably the tubular portion 23 is cut at C, in FIG. 4, so as to enable the use of the tubular portion 23, with the auxiliary bulb means, as an auxiliary pipette for aspiration of the cellular concentrate in the main bulb means 21 and distribution thereof on a microscopic slide, in the same manner as the auxiliary bulb means 12 was used as an auxiliary pipette for this purpose according to the embodiment of FIG. 1.

Instead of having a flexible auxiliary bulb means 22 associated with the tubular portion 23 and a rigid cap 25 to close the end of the tubular portion 23, the cap 25 itself may be in the form of a flexible member operable to be used as an auxiliary pipette bulb, when the tubular portion 23 is cut off at C.

In FIG. 6, the pipette structure 30 is shown in a tubular container 50 having a screw cap 51. This container structure, which is used for shipping the pipette from the patient directly to the hospital laboratory, may be of aluminum or other lightweight material.

The pipette structure 30 shown in FIGS. 6-9 comprises a tubular portion 33 to which is detachably connected a flexible main bulb means or first container 31. The end of the tubular portion 33 remote from the main bulb means 31 is closed by means of a flexible cap 35 and the structure includes means operable to assemble said flexible cap 35 with the other end of the tubular portion 33 when the latter is separated from the main bulb means 31 to use said assembly as an auxiliary pipette.

The tubular portion 33 of the pipette structure 30 has at the end, which is assembled with the flexible main

bulb 31, a tubular extension 36 which fits into the open end of the main bulb means 31. In order to secure a sufficiently tight fit, the tubular extension 36 may have a slightly larger external diameter than the diameter of the main bulb means 31 and a radial flange or collar 37 to engage the edge of the open side of the main bulb means 31, when the parts are assembled. Preferably, the diameter of the flange 37 corresponds substantially to the exterior diameter of the main bulb means 31 at its open end.

In order to provide sufficiently fluid-tight connection between the main bulb means 31 and the tubular extension 36, the two parts may be slightly heat-sealed but not to any greater extent than it is possible to separate the parts manually.

In order to assemble the flexible cap 35 with the tubular portion 33 the flexible cap 35 has, adjacent its open end, a portion 38 of an exterior diameter that fits into the interior of the tubular extension 36 with a sufficiently tight fit to enable the cap 35 to be held in position as an auxiliary pipette bulb means 32. The nozzle end of the tubular portion 33 has a slightly reduced diameter portion 39, and adjacent its end, it is provided with a tiny annular rib 40. The cap 35 has slightly smaller interior diameter adjacent its closed end so as to enable its wall to frictionally engage the tiny rib 40. The portion 39 of reduced diameter effectively provides spacing means operable to distribute the fluid from the pipette structure 30 on a microscopic slide 41 in an even layer, as governed by the difference of diameter between the portion 39 and the remaining diameter of the tubular portion 33. It will be obvious that equivalent means would be in the form of an annular rib of slightly larger diameter instead of the portion 39.

The pipette structure shown in FIGS. 6-9 is used for carrying out the method of collecting and processing cellular material in the following manner.

After removal of the cap 36 cellular material such as from a body cavity is aspirated into the pipette by manipulating the main bulb means 31, whereafter the cap 35 is replaced.

In the laboratory, the pipette is placed in a standard centrifuge and the cells are concentrated in the closed end of the main bulb means or first container means 31 by centrifuging.

Thereafter, the pipette structure is disassembled, as shown in FIG. 7 which enables the supernatant solution to be poured out of the first container means 31. A fixing solution is thereafter delivered into the first container means 31 and the pipette structure 30 is reassembled and shaken to mix the cellular material with the fixing solution, whereafter the pipette is re-centrifuged to concentrate the cellular material in the bottom of the main bulb means or first container means 31.

The pipette structure 30 is thereafter again disassembled and the superfluous fixing solution is poured out.

After this disassembling of the pipette structure 30 the flexible cap 35 is inserted into the tubular extension 36 to act as auxiliary bulb means 32 and to form with the tubular portion 33 an auxiliary pipette by means of which, as shown in FIG. 8, the cellular material from the first container means 31 is sucked out, to be distributed on a microscopic slide 41, as shown in FIG. 9.

The portion 39 of the tubular portion 33 which has reduced diameter, may be of a length so adapted to the interior diameter of the tubular portion 33 that, by fill-

ing the auxiliary pipette structure (FIG. 8) only up to the end of the portion 39 which has reduced diameter, the amount of fluid in the auxiliary pipette corresponds to the amount to be distributed on the microscopic slide.

By pressing the auxiliary bulb means 32 of the auxiliary pipette structure, the content is thereafter applied to a microscopic slide 41. By moving the tubular portion 33 over the surface of the microscopic slide 41, in the manner illustrated in FIG. 9, the distribution of the cellular material on the microscopic slide surface is secured in the form of an even layer, because the tiny rib 40 will retain the exterior surface of the portion 39 spaced from the surface of the microscopic slide 41 a distance which corresponds substantially to the desired thickness of the layer on the microscopic slide 41.

As will be obvious from the foregoing, the apparatus of FIGS. 1-9 are in the form of pipette structures including one portion effectively providing a pipette having a main bulb and a tubular portion operable to deliver a fluid to a body cavity and suck the fluid back again. In addition, the structure includes means effectively providing a container which can be separated from the structure and thereby be operable as a centrifugal container. Eventually, the structure includes means operable to render the tubular pipette portion effective as an auxiliary to withdraw fluid from the centrifugal container.

Instead of using a part of the pipette structure as the centrifugal container, it is possible, however, within the scope of the invention to provide a pipette structure which is used as a pipette only and provide the container means by another part of the structure.

The plastic used for the pipette structure may be any suitable plastic. As an example, polyvinyl chloride is mentioned, though it will be understood that any other suitable plastic can be used. The same plastic may be used for the tubular structure as well as for the container and the cap, in which event a suitable soft material is used, which enables the container and the cap to be manipulated as pipette bulb. If desired, the tubular structure may be of a more rigid plastic.

Preferably, the material used for the main bulbs 11, 21 and 31 is transparent or translucent so as to enable visual inspection of the container through the wall.

It will be appreciated that the same pipette structure is used for the entire processing in such a manner that only parts of the pipette, which have been used for collecting the cellular material, are used throughout the method steps, whereby the danger of contaminating cellular material from one patient with cellular material from another patient is completely avoided.

It is also apparent from the foregoing that all necessary steps are accomplished by means of a single pipette structure, this obviating the necessity for multiple pipettes, aspirating syringes, collection bottles, centrifuge tubes, etc. as normally used in the processing of cellular sample material.

Furthermore, the utilization of a single pipette, which has a chamber structure operable as aspirator as well as centrifugal container up to the point of the delivery of the cell samples unto a labelled microscopic slide, not only eliminates the need for using and washing multiple items of laboratory equipment, but also expedites the processing and may cut down the time required in the laboratory to about one fourth of the time required with the use of traditional laboratory equipment.

Also, the utilization of the pipette structure, described for collecting, preserving and transporting the cellular sample, simplifies the procurement of cell samples to such an extent that it permits untrained personnel, including the patient herself, to procure vagina cell samples of diagnostic quality. Furthermore, because the proper distribution of cellular samples can be made in the laboratory, the quality of the microscopic preparations is greatly improved and the microscopic examination is more rapid and accurate.

It is an important feature of the invention that a unitary pipette structure is used for the entire processing of cellular aspirate up to the point of the delivery unto the microscopic slide. It is also an important feature of the invention that the pipette structure has a reservoir or receptacle structure adapted to be operated as a centrifugal container in which the cellular concentrate is separated from a supernatant solution, and that the structure further enables the supernatant solution to be discarded and to be replaced by a fixing solution.

It will be understood that the invention is not limited to the embodiment of the pipette structure shown and described with reference to the accompanying drawing. By way of example, the auxiliary bulb means 12 and 22 according to the embodiments shown in FIGS. 2-5, may be omitted. The flexibility of the tubular portions 13 and 23 as auxiliary pipette means.

It will be appreciated that the pipette structure described with reference to FIGS. 1-5 may be manufactured by blow-molding or by a combination of injection-molding and blow-molding, while the pipette structure described with reference to FIGS. 6-9 is rather constructed from separate parts, which can be manufactured by injection-molding.

The plug-in type connection means, described and illustrated enabling detachable connection between the elongated tubular portion 33 of the pipette structure 30 and the two end members 31-35, one of which is used as an auxiliary pipette bulb when plugged in, also may be modified in various respects within the scope of the invention.

Also, other synthetic resinous materials than polyvinyl chloride may be used for making the pipette, such as low-density polyethylene or styrene, though it will be understood that any other convenient synthetic resinous material can be used.

While I have shown and described only several embodiments in accordance with the present invention, it is understood that the same is not limited thereto but is susceptible of numerous changes and modifications as known to a person skilled in the art. For example, the recovery of the cell material could be realized by other conventional means. Hence I do not wish to be limited to the details shown and described herein but intend to cover all such changes and modifications as are within the scope of those skilled in the art.

I claim:

1. A method for procuring and preserving samples of cellular material from a body cavity and processing said cellular material to be conditioned for analysis by utilizing a single container structure including pipette means in such a manner as to enable the preparation of a specimen substantially completely under the control of a laboratory-like facility, comprising the steps of at least partly filling said container structure with a cell-preservative solution, delivering said container struc-

ture to the patient, aspirating cellular sample material into said container structure from the patient's body cavity by first irrigating the cavity with the solution and thereafter re-aspirating the solution by using said pipette means, delivering said container structure with said solution contained therein to a laboratory-like facility, and recovering the cellular material in the laboratory-like facility to effectively condition the cellular material contained in said solution for analysis whereby the danger of cross-contamination is substantially eliminated.

2. A method according to claim 1, wherein the step of recovering the cellular material includes the step of processing said solution within said container structure.

3. A method according to claim 2, wherein the analysis includes microscopic examination, and further comprising the step of eventually distributing the cellular material on a microscopic slide directly from said container structure by said pipette means whereby uniformly good slides are assured.

4. A method according to claim 1, wherein the analysis includes microscopic examination, and further comprising the step of eventually distributing the cellular material on a microscopic slide directly from said container structure by said pipette means whereby uniformly good slides are assured.

5. A method for procuring and preserving samples of cellular material from vagina and processing said cellular material to be conditioned for microscopic examination by utilizing a single container structure including pipette means in such a manner as to enable the preparation of a microscopic slide with the cellular material thereon substantially completely under the control of a laboratory-like facility, comprising the steps of at least partly filling said container structure with a solution containing alcohol in an alcohol concentration strong enough to inhibit bacterial growth and low enough neither to injure the body nor to substantially alter the cells and physiological salts in a concentration sufficient to prevent swelling and shrinking of the cells, delivering said container structure to the patient, aspirating cellular sample material into said container structure from the patient's vagina by first irrigating the vagina with the solution and thereafter re-aspirating the solution by using said pipette means, delivering said container structure with said solution contained therein to a laboratory-like facility, processing said solution by centrifuging within said container structure in the laboratory-like facility to effectively condition the cellular material contained in said solution for microscopic examination, and eventually distributing said cellular material on a microscopic slide directly from said container structure by said pipette means whereby the danger of cross-contamination is substantially eliminated and uniformly good slides are assured.

6. A method utilizing a single pipette structure for procuring samples of cellular material from a body cavity forming part of a female reproductive tract and processing said cellular material to be conditioned for analysis in disease detection in such a manner as to enable the preparation of a specimen containing the cellular material substantially completely under the control of a laboratory-like facility, comprising the steps of filling the pipette structure with a cell-preserving solution, transferring cellular sample material into said pipette structure from the tissue surfaces of said body

cavity, delivering said pipette structure containing the preservative solution to a laboratory-like facility, and recovering the cellular material from the solution containing the samples of cellular material in the laboratory-like facility to utilize said cellular material for the disease detection analysis.

7. A method for processing samples of cellular material from a body cavity forming part of a female reproductive tract by utilizing a single pipette structure having a first portion adapted to be used as a container and a second portion adapted to be used as an auxiliary pipette, in such a manner as to enable the preparation of a specimen of the cellular material substantially completely under the control of a laboratory-like facility, comprising the steps of transferring cellular material from tissue surfaces of said cavity into said first portion, closing said pipette structure, with the cellular material contained in a solution within said first portion, delivering the closed pipette structure with said cellular material enclosed therein to a laboratory-like facility, processing the cellular material in said pipette structure at the laboratory-like facility to separate said cellular material from the solution, and recovering the cellular material from said auxiliary pipette structure whereby the danger of cross-contamination is substantially eliminated.

8. A method for processing samples of cellular material from a cavity forming part of a female reproductive tract by means of a container structure including means forming a pipette, and conditioning the samples for microscopic inspection in a laboratory-like facility in such a manner as to enable the preparation of a microscopic slide with the cellular material thereon substantially completely under the control of the laboratory-like facility, comprising the steps of aspirating by the use of the pipette of said structure the cellular material from tissue surfaces of said cavity into the container structure, delivering the samples of cellular material to the laboratory-like facility in said container structure, processing the samples of cellular material at the laboratory-like facility by centrifuging the samples within said container structure, and eventually distributing the thus processed cellular material on a microscopic slide directly from said container structure, whereby the danger of cross-contamination is substantially eliminated.

9. A method of processing samples of cellular material from a living body by means of a single container structure including means forming a pipette and containing a solution which includes agents operative as preservatives for the cellular material and conditioning the samples for microscopic inspection in a laboratory-like facility in such a manner as to enable the preparation of a microscopic slide with the cellular material thereon completely under the control of laboratory-like facility, comprising the steps of: irrigating the part of the living body containing cellular material with the solution from the container structure, aspirating the irrigation solution containing samples of cellular material into the container structure, delivering the aspired solution containing the samples of cellular material to the laboratory-like facility in said container structure, processing by centrifuging the irrigation solution containing the said samples of cellular material within said container structure at the laboratory-like facility including, within said container structure, centrifuging the said solution to concentrate the cellular material

container in the irrigation solution within said container structure to form a supernatant solution, removing the supernatant solution from said container structure, supplying to the thus-concentrated cellular material a fixing solution and mixing the fixing solution to the thus-concentrated cellular material within said container structure, centrifuging within said container structure the mixture of concentrated cellular material and fixing solution to condition the cellular material for microscopic examination, and eventually distributing the thus processed cellular material on a microscopic slide directly from said container structure, whereby the danger of cross-contamination is substantially eliminated.

10. A method for processing by means of a single pipette structure adapted to contain an irrigation solution, samples of cellular material from a living body cavity and conditioning the samples for analysis in a laboratory-like facility in such a manner as to enable the preparation of a specimen of the cellular material completely under the control of laboratory-like facility, comprising the steps of: providing a pipette structure with a content of an irrigation solution having agents effective as preservative for the cellular material, irrigating the cavity of the living body containing cellular material with the irrigation solution from the pipette structure, re-aspirating the irrigation solution containing samples of cellular material into the pipette structure, delivering the samples of cellular material to the laboratory-like facility in said pipette structure, processing the contents of the pipette structure to recover specimens of cellular material from the solution at the laboratory-like facility and conditioning the specimens for said analysis, whereby the danger of cross-contamination is substantially eliminated.

11. A method according to claim 10, wherein the step of processing is carried out at least in part in said pipette structure.

12. A method according to claim 10, wherein the analysis includes microscopic examination, and wherein the conditioning step includes eventually distributing the thus processed cellular material on a microscopic slide.

13. A method according to claim 10, wherein the step of processing the contents of said pipette structure at the laboratory-like facility includes the steps of centrifuging in said pipette structure the said irrigation solution to concentrate the cellular material contained therein to form a supernatant solution, removing from the pipette structure the supernatant solution, supplying and mixing with the thus concentrated cellular material a fixing solution within said pipette structure, and centrifuging within said pipette structure the mixture of concentrate cellular material and fixing solution to condition the cellular material for analysis.

14. A method according to claim 13, further comprising the step of eventually distributing the thus processed cellular material on a microscopic slide directly from said pipette structure.

15. A method of utilizing a single pipette structure for procuring samples of cellular material from a body cavity of a human being and processing said cellular material to be conditioned for analysis in disease detection in such a manner as to enable the preparation of a specimen containing the cellular material substantially completely under the control of a laboratory-like facility, comprising the steps of filling the pipette struc-

ture with a cell-preserving solution, transferring cellular sample material into said pipette structure from said body cavity, delivering said pipette structure containing the preservative solution to a laboratory-like facility, and recovering the cellular material from the solution containing the samples of cellular material in the laboratory-like facility to utilize said cellular material for the disease detection analysis, the step of recovering the cellular material including processing said solution containing the samples of cellular material by centrifuging said pipette structure in the laboratory-like facility to concentrate the cellular material contained in said solution within said pipette structure to form a supernatant solution, discarding said supernatant solution, supplying fixing solution into said pipette structure, mixing said concentrated cellular material with said fixing solution within said pipette structure, re-centrifuging said pipette structure containing the mixture of concentrated cellular material and fixing solution to effectively condition said cellular material for microscopic examination.

16. A method for processing samples of cellular material by utilizing a single pipette structure having a first portion adapted to be used as a container and a second portion adapted to be used as an auxiliary pipette, in such a manner as to enable the preparation of a specimen of the cellular material substantially completely under the control of a laboratory-like facility, comprising the steps of transferring cellular material into said first portion, closing said pipette structure, with the cellular material contained in a solution within said first portion, delivering the closed pipette structure with said cellular material enclosed therein to a laboratory-like facility, processing the cellular material in said pipette structure at the laboratory-like facility to separate said cellular material from the solution, and recovering the cellular material from said auxiliary pipette structure whereby the danger of cross-contamination is substantially eliminated, the step of processing including centrifuging said pipette structure in the laboratory-like facility to concentrate said cellular material in said first portion thereof, separating at least partly said first portion of said pipette structure from the other portion thereof, discarding the supernatant solution from said pipette structure, supplying a fixing solution into said separated portion of said pipette structure, re-centrifuging said cellular material with said fixing solution, discarding from said cellular material supernatant solution, sucking up cellular material by means of said auxiliary pipette defined by said second portion thereof, and distributing said material on a microscopic slide directly from said auxiliary pipette structure.

17. A method for processing samples of cellular material aspirated in a solution into a container structure having means to enable aspiration of one's own cellular material and operable to be used as an aspirator, comprising the steps of processing said solution within said container structure to separate said cellular material from the solution, and recovering the cellular material including the step of conditioning the same for diagnostic detection analysis whereby the danger of cross-contamination is greatly minimized, including the steps of centrifuging said container structure to concentrate said cellular material therein, discarding the supernatant solution from said concentrated cellular material, supplying a fixing solution to said container structure, mixing said concentrated cellular material and said fix-

ing solution, re-centrifuging said container structure to condition said cellular material for microscopic examination, and distributing said cellular material on a microscopic slide directly from said container structure.

18. Apparatus for procuring and processing samples of cellular material from a living body by means of a fluid within the apparatus so as to minimize cross-contamination comprising in combination: a first hollow member, a tubular portion and a second hollow member having a flexible wall portion constituting a flexible bulb, connector means operatively associated with said members and said tubular portion to enable various assemblies of said first and second hollow members and of said tubular portion including means connecting said first and said second hollow members with said tubular portion into a unitary structure with said second hollow member connected with one end of said tubular portion and with said first hollow member closing the other end of said tubular portion, means by disassembly of at least some of said members to provide a separate pipette formed by said tubular portion and said second hollow member to aspirate said fluid, and means to disassemble said members from each other to constitute said first hollow member a centrifugal container.

19. A pipette structure comprising: an elongated tubular portion of a first diametric dimension having two ends, a first end member of relatively larger external dimension than said first diametric dimension, detachable connecting means provided at one end of said elongated tubular portion and at said first end member to enable connection between and separation of said one end of the tubular portion from said first end member, a second end member of relatively larger external dimension than said first diametric dimension having connecting means to enable connection between said second end member and said one end of said tubular portion, said second end member having at least in part an internal dimension of substantially the same dimension as said first diametric dimension to enable said second end member to be used as a closing cap over the other end of said tubular portion, said first end member and said second end member having flexible wall portions operable to use either of said end members as a pipette bulb when connected with said tubular portion.

20. A pipette structure comprising: an elongated tubular portion having a mouth end and an end provided with a first part of complementary connector means, a first flexible member having a closed end and an open end provided with a second part of complementary connector means detachably connecting said flexible member to said tubular portion to constitute said connected parts a first pipette as well as to enable separation of said tubular portion from said end member to constitute said flexible member an open container, a second member having an open end and a closed end and forming a cap member detachably closing said mouth end of said pipette structure, said second member and said tubular portion having further complementary connector means at said end provided with said first part of complementary connector means to allow alternative connection of said second member with said tubular portion to constitute said second member and said tubular portion a second pipette.

21. Apparatus for procuring and processing samples of cellular material by means of a fluid comprising in combination a first hollow flexible member having an

open end, a second hollow flexible member having an open end and a tubular portion open at both ends, first connector means detachably assembling said first hollow member with said tubular portion to provide a first pipette structure with said first hollow member constituting a pipette bulb and said tubular portion constituting an aspirating channel of substantial length, second connector means detachably assembling said second hollow member with said first pipette structure to effectively provide a closure member therefor, and third connector means on said second hollow member and said tubular portion to allow alternative connection of said second hollow member with said tubular portion when disassembled from said first hollow member to effectively provide a second pipette structure.

22. Apparatus for procuring and processing samples of cellular material by means of a fluid according to claim 21, wherein the first hollow flexible member is of a first interior volume and a physical strength sufficient to enable it to be used as a centrifugal container, the second hollow flexible member being of a relatively smaller interior volume, the first connector means detachably assembling said first hollow member with said tubular portion to provide the first pipette structure with said first hollow member constituting a pipette bulb as well as a reservoir for fluid aspirated into said first pipette structure, said second connector means assembling said second hollow member with said first pipette structure to effectively provide a closure member therefor and thus to enable said closed pipette structure to be shipped with a content of fluid aspirated therein, and said third connector means which assembles said second hollow member with said tubular portion, effectively providing a second pipette structure to be used for aspirating fluid from said reservoir upon disengagement of said first connector means.

23. A structure for procuring and processing, by the use of a fluid, samples of cellular material derived from a living body which minimizes the danger of cross-contamination, comprising: a first hollow member forming a container open at one end, a second hollow member open at one end thereof, a tubular portion open at both ends thereof, one end of said tubular portion being provided with means forming a fluid-tight detachable sealing connection with said first hollow member detachably connecting said one end with said first hollow member, and the diametric dimensions of said second hollow member and of the other end of said tubular portion being so correlated that said second hollow member sealingly fits over one of the two ends and into the other of the two ends of said tubular portion.

24. A structure according to claim 23, wherein said first and second hollow members are each provided with flexible wall means constituting a bulb

25. A structure according to claim 37, wherein the other end of said tubular portion is provided with means producing a uniform smear of cellular material on a microscopic slide.

26. A structure according to claim 25, wherein the means at the one end of said tubular portion is provided with means in the form of an abutment collar for the open end of said first hollow member and an axial extension of such diametric dimension enabling coaxial assembly with the open end of said first hollow member to provide said fluid-tight detachable sealing connection with said first hollow member.

27. A structure according to claim 23, wherein the means at the one end of said tubular portion is provided with means in the form of an abutment collar for the open end of said first hollow member and an axial extension of such diametric dimension enabling coaxial assembly with the open end of said first hollow member to provide said fluid-tight detachable sealing connection with said first hollow member.

28. A pipette structure comprising: an elongated tubular portion having two open ends, a first flexible end member having an open end and a closed end, said tubular portion being of at least the same order of length as said first end member, first connecting means provided at one end of said elongated tubular portion and said first end member to enable connection between said tubular portion and said first end member to constitute the connected parts a first pipette operable to discharge and reaspirate fluid into said first end member, a second flexible end member adapted to close the other end of said tubular portion, and second connecting means at said second end member to enable connection between said second end member and said tubular portion in such a manner as to constitute a second pipette structure capable of withdrawing fluid from the closed end of said first end member by insertion of said tubular portion over a substantial length thereof into said first end member.

29. A structure for procuring and processing, by the use of a fluid, samples of cellular material derived from a living body which minimizes the danger of cross-contamination, comprising: first means constituting a container for said fluid, second means including a relatively long tubular portion and constituting together with said first means a pipette structure for discharging the fluid from said container and re-aspirating said fluid back into said container, means to provide between said first and second means a separable connection so as to enable use of said container as a centrifuging container upon separation of said first means from said second means, and further means in said structure associated with the tubular portion of said second means to effectively constitute said tubular portion a further pipette structure for withdrawing fluid from said container by immersion of said tubular portion into said container, said further means being operable to close said structure in a fluid-tight manner with said first and second means connected, and a cell preservative fluid in said first means.

30. A device for procuring and processing samples of cellular material from a living body which minimizes cross-contamination, comprising a tubular portion forming an aspirating channel, said tubular portion being open at both ends, main bulb means connected to one end of said tubular portion, said main bulb means being of flexible material to permit use of said

tubular portion and said main bulb means as pipette and being of sufficient strength and dimensions to enable use thereof as centrifuging container upon separation from said tubular portion, a closure member for the other end of said tubular portion, and means in said device forming an auxiliary bulb means having a flexible wall structure, and the length of said tubular portion being at least of the same order of length as said main bulb means and forming directly an aspirating channel for the cellular material when inserted into a body cavity.

31. A device according to claim 30, wherein said auxiliary bulb means is connected to said main bulb means at the end opposite the connection of said tubular portion.

32. A device according to claim 31, wherein said auxiliary bulb means is formed within said tubular portion intermediate its two open ends.

33. A device according to claim 31, wherein said auxiliary bulb means is formed by said closure member.

34. A pipette structure for use in obtaining and processing cellular samples from the vagina, which minimizes the danger of cross-contamination, comprising an elongated tubular portion of relatively small diametric dimension and open at both ends, a first end member having flexible walls and of a diametric dimension larger than the diametric dimension of the tubular portion, said first end member being open at one end and closed at the other end, first complementary means at the open end of said first end member and at one open end of said tubular portion readily detachably connecting said first end member to said one end of said tubular portion to constitute the thus-connected first end member and tubular portion an aspirator to aspirate from the vagina a solution containing cellular samples and rendering said first end member usable directly as centrifuging container upon disconnection from said one end of said tubular portion, a second end member having a closed end and an open end, second complementary means at the open end of said second end member and at the other end of said tubular member detachably connecting said second end member to the other end of said tubular portion to provide a hermetic seal for the aspirated fluid in said structure and sufficiently tight to permit transportation of the pipette structure with the solution including the cellular samples contained therein, and said tubular portion being of sufficient length to extend into the vagina to obtain the solution with the cellular samples by aspiration while the first end member is operated as aspirator bulb with its flexible walls disposed substantially externally of the person from whom the cellular samples are to be obtained, and a cell-preservative solution contained in said structure.

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