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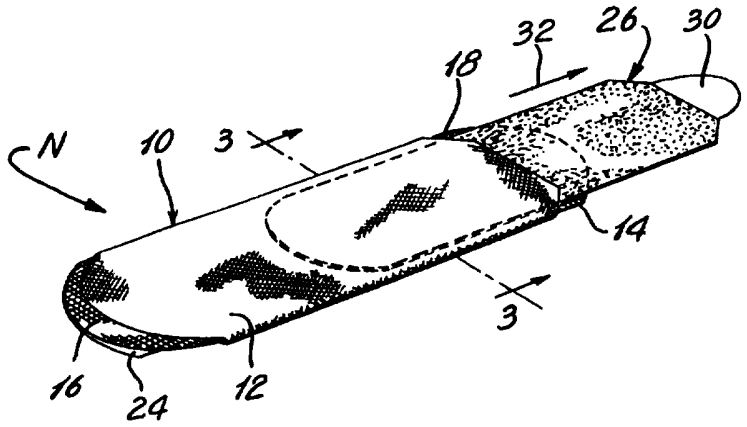

(57) Abstract

A collection device (N, D) and a method for enabling the patient to self-collect substances from the body, such as fluids, secretions, cells, and infectious and non-infectious agents, takes the form in the case of substances from the genital, anal or urinary regions of a sanitary napkin (N) used in a conventional manner in an undergarment and which comprises a porous outer sleeve (10) open ended at one longitudinal end (18) thereof and including upper and lower sheets (12, 14). An outer surface of the lower sheet (14) is provided with an impermeable sheet (22) coated with an adhesive covered, before use of the sanitary napkin (N), with a removable protective peel-off strip (24). The sanitary napkin (N) also comprises between its upper and lower sheets (12, 14) an absorbent layer (20) and a removable sampling strip or filter (26), the latter being slidably received in the outer sleeve (10) and extending between the upper sheet (12) and the absorbent layer (20) and protruding from the open end (18) of the sleeve (10) for removal from the sanitary napkin (N) once bodily substances have collected thereon. The sampling strip (26) is then typically sealingly packaged and stored until its analysis. The sampling strip can also be made more or less integral with the sanitary napkin such that the complete napkin is forwarded to the laboratory. Alternatively, the sampling strip (50) may be affixed, e.g. with an adhesive (52), on the outside of a sanitary napkin.

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SANITARY NAPKIN AND METHOD FOR COLLECTING SAMPLES OF BODILY SUBSTANCES

TECHNICAL FIELD

The present invention relates to collection devices for recovering samples of bodily fluids or cells for subsequent laboratory analysis and, more particularly, to a collection device and method for allowing the patient to recover samples of bodily fluids, secretions, cells, and infectious and non-infectious agents, in whole all hereinafter referred to as bodily substances, and, for instance, to a sampling strip for use with a sanitary napkin for collecting such substances from the genital, anal or urinary regions, and to a method associated with the use thereof.

BACKGROUND ART

United States Patent No. 5,231,992 issued on August 3, 1993 to Leon discloses a low-impact cervical cell and fluid collector which includes a substantially disc-shaped main body 12 which defines a generally concave recess 14 into which a porous collection membrane 16 is mounted. Therefore, when the collector 10 is in place adjacent to the patient's cervix, cells and fluids adhere to the outer surface of the membrane 16. Underneath the membrane 16, there is provided a layer 24 of a cell-moistening material or agent, such as a polymer gel adapted to release water during cell collection for moistening collected cells through the pores of the membrane 16 when the cells are adhered to the outer surface thereof. The main body 12 can be provided with a string 18 to facilitate the removal of the collector 10 from the body.

French Patent Application which was published as FR-2 599 500 on December 4, 1987 in the name of Chieusse discloses a transparent adhesive strip for

taking a sample directly from the skin's surface for microscopic examination or analysis, the adhesive strip comprising a rigid transparent resin or glass plate 1 covered successively with a transparent layer 2 which is self-adhesive on both of its sides, an isolating film or coating 4 of shorter length, and a semi-rigid cover layer 3 made, for instance, of strong paper or cardboard. The limited length of the film 4 defines a section 5 where the cover layer 3 adheres directly to the adhesive 2 and forms a joint line 6 which allows for the cover layer 3 to be pivotally lifted about the hinge 6, wherein in a closed position 7, the sample-taking surface 9 is protected for its transport or storage, whereas in its open position 8, the adhesive surface 2 can be brought into direct contact with the skin's surface such as to enable the adhesive strip 2 to remove and collect desired samples from the skin and other surfaces for subsequent analysis thereof.

United States Re-Issue Patent No. RE 24,666 issued on July 7, 1959 to Draghi discloses a tampon for the detection of cancer of the pelvic region. More particularly, the tampon of this U.S. Patent constitutes a preliminary diagnosis method which determines if there are present any indicia of cancer by taking a sample of cells which are present in the cervical canal and in the vagina and by the subsequent microscopic analysis of these cells. The tampon includes a tampon body 10 partly covered by a jacket 12 terminating with an enlarged cap 13 and, at the other end of the tampon body 10, there is provided a string 22. The assembly of the body 10 and jacket 12 forms a detection tampon 14. The enlarged cap 13 which closes one end of the tampon 14 is adapted to extend farthest into the vaginal canal and to collect and retain in moist form cells thereof. The jacket 12 also collects cells and retains them in a relatively moist condition thereby ensuring a more accurate clinical evaluation.

United States Patent No. 3,850,160 issued on November 26, 1974 to Denson discloses a diagnostic tampon 10 having a supporting body 13 covered by an outer film 12 and provided at one end thereof with a removal string 11. The tampon is particularly adapted for collecting cellular material from body cavities, in particular from the vaginal cavity, for subsequent examination.

United States Patent No. 5,432,097 issued on July 11, 1995 to Yourno teaches a method for the recovery of blood cells from dried blood spots on a filter paper.

United States Patent No. 5,119,828 issued on June 9, 1992 to Miller discloses a device 10 for collecting sebum which is secreted by the sebaceous glands of a patient, the device 10 including a microporous film 12 which is opaque to light when the pores are filled with gaseous material and which is substantially translucent when the film pores are filled with sebum. The film 12 is mounted to a substrate 14 which defines a light absorbing area 16 for enhancing visualization of the pores of the film 12 when filled with sebum. In use, the device is pressed against the patient's skin surface such that the film 12 contacts the skin and absorbs its sebum, whereby a sebum spot pattern is developed in the film 12 and is visually enhanced by way of the light absorbing area 16.

United States Patent No. 5,088,502 issued on February 18, 1992 to Miller discloses a device 10 for sampling the surface of the skin which includes a substrate 12 having a light absorbing area 14 disposed thereon with an adhesive layer 16 being disposed on the substrate 12 such as to overlie the light absorbing area 14. The adhesive layer 16 is optically clear and under pressure conforms to the surface of the skin to be sampled. A removable protective film 18 provided

with a tab 20 is disposed on the adhesive layer 16 for protecting the same prior to use of the device. The device and, more particularly, the adhesive layer 16 is placed against the skin surface such that, when removed, skin cells adhere to the adhesive layer 16. The sampled cells can then be visualized in view of the light absorbing area 14.

United States Patent No. 4,789,629 issued on December 6, 1988 to Baker et al teaches a device for collecting and testing fecal occult blood which includes a pocket-like member 16 and an absorbent insert 24 disposed in the pocket member 16. The pocket member 16 is disposed on the inside front cover of the device such that when the cover is in a closed position thereof, the pocket 16 overlies the fecal smear on the specimen receiving sheet 36, whereby with one single collection, two separate membranes, that is the specimen receiving sheet 36 and the absorbent insert 24, receive the components of the fecal sample and can be individually and independently tested.

United States Patent No. 4,808,379 issued on February 28, 1989 to Wardlaw et al discloses a device for obtaining stool samples and detecting occult blood and which is used in a way similar to toilet tissue to obtain a stool sample on a receptor sheet 26 provided in the device. Therefore, to obtain the stool sample, the patient, after defecation, draws the cover sheet 32 and its holes 34 across the rectum in the same manner as toilet tissue such that stool is thus wiped onto the cover sheet and passes through the openings 34 and deposits in spots on the receptor sheet 26. The cover sheet 32 is then peeled off and discarded, thereby exposing the stool spots S of the receptor sheet 26, after which the stool spots S can be effectively sealed in the device by folding the impermeable sheet 2.

DISCLOSURE OF INVENTION

It is therefore an aim of the present invention to provide an improved device for allowing a patient to collect externally from the body samples of bodily substances, such as fluids, cells, tissues, microorganisms, etc.

It is also an aim of the present invention to provide an improved method for allowing a patient to collect externally from the body samples of bodily substances, such as fluids, cells, tissues, microorganisms, etc.

It is a further aim of the present invention to provide a modified sanitary napkin for collecting samples of bodily substances from the genital, anal or urinary regions and, for instance, vaginal secretions.

It is a still further aim of the present invention to provide a modified sanitary napkin provided with an absorbent layer for collecting the samples of bodily substances from the genital, anal or urinary regions.

It is a still further aim of the present invention to provide a collection device, such as a modified sanitary napkin, having a removable collection strip, membrane or filter, in particular in the form of an absorbent strip, slidably received in a pocket defined in the collection device or sanitary napkin.

It is a still further aim of the present invention to provide a collection device, for instance in the form of an absorbent strip, which is used externally on a sanitary napkin for collecting bodily substances.

Therefore, in accordance with the present invention, there is provided a collection device for collecting bodily substances from the genital, anal or urinary regions, comprising a substantially flexible and comfortable member adapted to be positioned such that a receiving surface of said member is located

substantially opposite a location from which a sample of bodily substance is to be taken, collecting means being provided in communication with said receiving surface, wherein at least a bodily substance is collected at least partly by said collecting means for subsequent analysis thereof.

Also in accordance with the present invention, there is provided a collection device for allowing a user to collect bodily substances, comprising a member adapted to be externally worn by the user such that a receiving surface of said member is located substantially opposite a location of the user at which a sample of bodily substance is to be taken, collecting means in said member and in communication with said receiving surface, said collecting means being removable from said member by the user, whereby once sufficient bodily substance having contacted said receiving surface has been at least partly collected by said collecting means, said collecting means is removed from said member for subsequent analysis thereof.

Further in accordance with the present invention, there is provided a method of self-collection of bodily substances, comprising the steps of:

(a) self-positioning collector means externally on a user and at a location of the user at which a sample of bodily substance is to be taken; and

(b) collecting on said collector means at least one bodily substance from the user.

Still further in accordance with the present invention, there is provided a collection device for collecting bodily substances from the genital, anal or urinary regions, comprising absorbent sampling strip means adapted to be positioned with a sanitary napkin such that a receiving surface of said strip means is located substantially opposite a location from which a

sample of bodily substance is to be taken, wherein once at least a bodily substance has been collected by said strip means, at least said strip means can be retained for subsequent analysis of the bodily substance collected by said strip means.

Still further in accordance with the present invention, there is provided a collection device for collecting bodily substances from the genital, anal or urinary regions, comprising absorbent sampling strip means in combination with a sanitary napkin, said strip means being positioned relative to said sanitary napkin such that, when said sanitary napkin is in a functional position thereof in an undergarment, said strip means is located substantially opposite a location from which a sample of bodily substance is to be taken, wherein once at least a bodily substance has been collected by said strip means, at least said strip means can be retained for subsequent analysis of the bodily substance collected by said strip means.

Still further in accordance with the present invention, there is provided a collection device for collecting bodily substances from the genital, anal or urinary regions, comprising substantially flexible and comfortable collecting means, and attachment means adapted to secure said collecting means to a sanitary napkin such as to be located substantially opposite a location from which a sample of bodily substance is to be taken, wherein at least a bodily substance is collected at least partly by said collecting means for subsequent analysis thereof.

Still further in accordance with the present invention, there is provided a collection device for allowing a user to collect bodily substances, comprising collecting means and attachment means therefor, said collecting means being adapted to be externally worn by the user such that, when secured in position with said attachment means, said collecting

means is located substantially opposite a location of the user at which a sample of bodily substance is to be taken, whereby once sufficient bodily substance having contacted said collecting means has been at least partly collected thereby, said collecting means can be retained for subsequent analysis thereof.

Still further in accordance with the present invention, there is provided a method of self-collection of bodily substances, comprising the steps of:

(a) self-positioning collecting means externally on a user and at a location of the user at which a sample of bodily substance is to be taken; and

(b) collecting on said collecting means at least one bodily substance from the user.

BRIEF DESCRIPTION OF THE DRAWINGS

Having thus generally described the nature of the invention, reference will now be made to the accompanying drawings, showing by way of illustration a preferred embodiment thereof, and in which:

Fig. 1 is a perspective view of a modified sanitary napkin in accordance with the present invention;

Fig. 2 is a perspective view of the sanitary napkin of Fig. 1 but illustrated with its removable absorbent sampling strip partly removed therefrom;

Fig. 3 is a transversal cross-sectional view taken along line 3-3 of Fig. 2;

Fig. 4 is a longitudinal cross-sectional view taken along line 4-4 of Fig. 1; and

Fig. 5 is schematic perspective view of a variant of a collecting device also in accordance with the present invention which is shown in a partly detached position.

MODES FOR CARRYING OUT THE INVENTION

The present invention is concerned with the collection of samples of bodily substances (such as fluids, secretions, cells, microorganisms, infectious and non-infectious agents, etc.) and, more particularly, in view of some people's reticence in having these samples taken at a clinic or hospital, with a collection device and method which allow the patient to "self-collect" the samples, typically outside of any formal medical environment, which can then be properly packaged and forwarded for subsequent analysis thereof to any appropriate medical facility, e.g. laboratory.

In the present description as well as in the appended claims, the terms "substance" and "substances" are understood to include any bodily fluids, secretions, cells, microorganisms, infectious and non-infectious agents, etc., which can be externally recovered from the body.

For instance, and in accordance with the present invention, Fig. 1 illustrates a modified sanitary napkin N which is intended for collecting substances at the genital and anal regions and which includes a porous outer sleeve 10 having upper and lower sheets 12 and 14, respectively, which are joined at a first longitudinal end 16 thereof and which are open at an opposite second longitudinal end 18 of the sleeve 10. The upper and lower sheets 12 and 14 are at least partly made of a porous fabric, typically in the form of a close knit netting. Inside the sleeve 10, there is provided an absorbent layer 20, of the type well known in the art of sanitary napkins. The absorbent layer 20 is peripherally secured to the upper and lower sheets 12 and 14 of the porous sleeve 10, apart from at the second end 18 where the absorbent layer 20 is typically only secured to the lower sheet 14 such that the opening at the second end 18 is

defined between the upper sheet 12 and the absorbent layer 20, as best seen in Fig. 4.

Under or outwardly of the lower sheet 14, an insulating or impermeable layer 22 acting as a liquid impervious barrier is mounted to the lower sheet 14 and is provided with an adhesive coating on a side of the impermeable layer 22 opposite its side secured to the lower sheet 14 of the sleeve 10. A removable strip 24 is detachably mounted to the adhesive coating of the impermeable layer 22 such that it can be removed therefrom when the sanitary napkin N is to be attached to an undergarment.

Intermediate the upper sheet 12 of the sleeve 10 and the absorbent layer 20, a removable absorbent sampling filter or strip 26 is slidably received in a pocket 28 which is defined between the upper sheet 12 and the absorbent layer 20 and which is open at the second end 18, again as best seen in Fig. 4. The sampling strip 26 is provided at an outside end thereof with a handling tab 30. The sampling strip 26 can be made, for instance, of a semi-porous and absorbent material, e.g. a sheet-like filter made of paper, of synthetic or non-synthetic fabrics, etc., such as to allow the patient to collect substances, for instance vaginal secretions, as samples for subsequent analysis thereof in a laboratory or the like while allowing for excess secretions and fluids to pass therethrough and reach the absorbent layer 20 and to be collected thereon.

In the present embodiment of the invention which takes the form of the sanitary napkin N, the description might refer to vaginal secretions instead of the more general "substances" mentioned hereinabove, but this is only done for illustration purposes, that is as an example of a use of the present sanitary napkin N and is obviously not intended to restrict the scope of use of any collection device in accordance

with the present invention to the single collection of vaginal secretion samples.

More particularly, in use, the sanitary napkin N has the form generally shown in Fig. 1 with its removable strip 24 being removed therefrom such as to allow the sanitary napkin N to be attached to an undergarment. Subsequently, vaginal secretions, for example, will come into contact with the sanitary napkin N and, more particularly, with the upper sheet 12 of the sleeve 10 thereof. Through the netting of the upper sheet 12, the vaginal secretions will then reach the sampling strip 26, whereat some of the secretions will be absorbed and retained by the sampling strip 26 with the remainder of the secretions filtering therethrough and reaching the absorbent layer 20. Therefore, a sampling of vaginal secretions will have collected on the sampling strip 26 which, before the sanitary napkin N is discarded, is removed from the sanitary napkin N as per arrow 32 of Fig. 2, whereby the sampling strip 26 can then be properly packaged and sent, for instance, to a laboratory to be analyzed.

Therefore, the sanitary napkin N of the present invention which is intended to facilitate and render more accessible the uncovering, for example, of sexually transmitted diseases by reducing some people's resistance to showing up at clinics to be tested by way of the collection of samples for analysis purposes, is considered to meet this object as, clearly, the simple use in a typically well-known fashion of a substantially recognizable sanitary napkin N will allow for a proper sampling of bodily substances, such as vaginal secretions, to be easily obtained and forwarded to a laboratory, using the present absorbent sampling strip or filter 26 as a collection medium which is typically sealed in an appropriate container once it has been removed from the sanitary napkin N, and until it is ready to be analyzed in the laboratory.

In the laboratory, the sampling filter 26 can be analyzed by way of known techniques, such as polymerase chain reaction (PCR) and ligase chain reaction (LCR) techniques, etc.

Accordingly, the present sanitary napkin N which is based on modifications made to conventional sanitary napkins can be easily used by the patient as a collection and reception medium for various substances (e.g. secretions) provided externally of the genital, anal or urinary regions, from which a sample can then be obtained by removing the sampling strip 26 from the sanitary napkin N.

The present invention also contemplates having a non-removable, i.e. at the level of the end user, sampling filter or strip or collector installed in the sanitary napkin, whereby the complete sanitary napkin would be sent to the laboratory, whereat it would be appropriately dismantled to retrieve its sampling strip for the analysis thereof.

Furthermore, by the present invention, there is also provided a method of collecting samples of bodily substances, such as of secretions emitted at the genital, anal or urinary regions, by providing a collection medium which is adapted to be positioned at an appropriate location, for instance in the undergarment, and externally of the user, and which is further adapted to receive and/or collect samples of bodily substances, the samples being then typically properly packaged for the subsequent analysis thereof.

The present collection device, which has been herein preferably shown and described in the form of the sanitary napkin N for collecting vaginal secretions, as well as the present collection method can obviously be also used to collect various other bodily substances, such as biological fluids, blood, tissues, microorganisms or cells (again all herein generally referred to as substances), for instance,

from the genito-urinary tract or system and/or from the anal region.

Accordingly, various applications of the collection device are foreseen, such as (1) for the analysis of products accumulated in the sampling filter or strip 26, including research on and identification of infectious agents (e.g. chlamydia, HIV, gonorrhea, herpes, cytomegalovirus, human papillomavirus, mycoplasma, ureaplasma, candida and other infectious and non-infectious agents, etc.) or parasites (e.g. trichomonas) or any other biochemical particle or component originating from these agents with a view of identifying and treating these agents by known techniques as well as by techniques which will be developed; (2) for the analysis of cells from the genito-urinary or intestinal system for the chromosomal, histological, cytological, biochemical or biomolecular analysis thereof; (3) for the analysis of the menstrual blood, or its derivatives (e.g. antibodies) and of any other molecule detected in the sampling strip 26; (4) for the analysis of urine, of its derivatives and of any other molecule originating from the urinary system and detected in the sampling strip 26; and (5) for the analysis of products derived from the pilosebaceous system of the genital, anal and cutaneous sphere; etc.

With reference to Fig. 5 which illustrates a variant of the present invention, the sampling strip can alternatively take the form of a stand-alone collecting device D which is adapted to be used externally of a sanitary napkin (not illustrated), including conventional sanitary napkins. More particularly, the collecting device D comprises a sampling strip 50 made of a suitable absorbent material, a ring-shaped adhesive border or layer 52 provided peripherally on the underside of the absorbent sampling strip 50, and a removable backing sheet 54.

The sampling strip 50 resembles in function the sampling strip 26 of Figs. 1 to 4 but is intended to be affixed on the outside of a sanitary napkin, typically by the end user; this is achieved by peeling off the backing sheet 54 from the adhesive layer 52 of the sampling strip 50 and by then securing the latter to the sanitary napkin by way of the adhesive layer 52 with the sampling strip 50 being positioned on the sanitary napkin such as to collect substances discharged by the body. The sampling strip 50 can then be separated from the sanitary napkin and sent for analysis; alternatively, the sanitary napkin with the sampling strip 50 attached thereto can be forwarded for analysis.

Both the sampling strips 26 and 50 must be made of a suitable material, typically absorbent and flexible and, at least in the case of the sampling strip 50, of a smooth and comfortable material. Various materials could be used, including fabrics or paper or nylon-based materials. For instance, the sampling strip may be of any woven, non woven or knitted materials pervious to body fluids and having the capacity to absorb or adsorb the biological materials required for analysis by mechanical retention or chemical interaction. The sampling strip can be positively charged and may have ion-exchange properties. Also, the sampling strip may be composed of cationic, positively charged, fibers. Further, the sampling strip may be composed of fibers which are finished with positively charged monomer(s) and/or polymer(s).

Basically, the invention is intended to enable the patient to recover samples of secretions, fluids, etc. emitted from the body, as well as samples of cells, fluids, etc. which are present at the cutaneous level (e.g. for the collection of substances from sores, etc., such as in the case of some types of

herpetic infections which manifest on the skin) and to sealingly package the collected samples which can then be forwarded to a laboratory for the analysis thereof.

CLAIMS:

1. A collection device for collecting bodily substances from the genital, anal or urinary regions, comprising a substantially flexible and comfortable member adapted to be positioned such that a receiving surface of said member is located substantially opposite a location from which a sample of bodily substance is to be taken, collecting means being provided in communication with said receiving surface, wherein at least a bodily substance is collected at least partly by said collecting means for subsequent analysis thereof.

2. A collection device as defined in Claim 1, wherein said collecting means is located in said member and is adapted to be removed from said member by the user such that a bodily substance contacting said receiving surface is at least partly collected by said collecting means, wherein once sufficient bodily substance having contacted said receiving surface has been collected by said collecting means, said collecting means is removed from said member for subsequent analysis thereof.

3. A collection device as defined in Claim 2, wherein said collecting means comprises sampling strip means removably engaged in said member with said receiving surface being adapted to allow bodily substance to reach said sampling strip means.

4. A collection device as defined in Claim 3, wherein said member comprises sleeve means at least partly open ended at one longitudinal end thereof, and absorbent layer means in said sleeve means, said sleeve means comprising said receiving surface, said sampling strip means being removably received in said sleeve

means through said one end and between said absorbent layer means and said receiving surface.

5. A collection device as defined in Claim 4, wherein said sleeve means comprises upper and lower sheets, said upper sheet being at least partly comprised of said receiving surface, impermeable means being provided outwardly on said lower sheet with adhesive means being outwardly provided on said impermeable means for securing said member to the undergarment, a protective removable strip being provided outwardly on said adhesive means.

6. A collection device as defined in Claim 5, wherein said sampling strip means is slidably received in said sleeve and between said upper sheet and said absorbent layer means.

7. A collection device for allowing a user to collect bodily substances, comprising a member adapted to be externally worn by the user such that a receiving surface of said member is located substantially opposite a location of the user at which a sample of bodily substance is to be taken, collecting means in said member and in communication with said receiving surface, said collecting means being removable from said member by the user, whereby once sufficient bodily substance having contacted said receiving surface has been at least partly collected by said collecting means, said collecting means is removed from said member for subsequent analysis thereof.

8. A collection device as defined in Claim 7, wherein said collecting means comprises sampling strip means removably engaged in said member with said receiving surface being adapted to allow bodily substance to reach said sampling strip means.

9. A collection device as defined in Claim 8, wherein said member comprises sleeve means at least partly open ended at one longitudinal end thereof, and absorbent layer means in said sleeve means, said sleeve means comprising said receiving surface, said sampling strip means being removably received in said sleeve means through said one end and between said absorbent layer means and said receiving surface.

10. A collection device as defined in Claim 9, wherein said sleeve means comprises upper and lower sheets, said upper sheet being at least partly comprised of said receiving surface, impermeable means being provided outwardly on said lower sheet with adhesive means being outwardly provided on said impermeable means for securing said member to the undergarment, a protective removable strip being provided outwardly on said adhesive means, whereby said collection device is used for collecting bodily substances from the genital, anal or urinary regions.

11. A collection device as defined in Claim 10, wherein said sampling strip means is slidably received in said sleeve and between said upper sheet and said absorbent layer means.

12. A collection device as defined in Claim 11, wherein said sampling strip means is provided with tab means at least partly protruding from said one end for facilitating a removal of said sampling strip means from said sleeve means.

13. A method of self-collection of bodily substances, comprising the steps of:

(a) self-positioning collector means externally on a user and at a location of the user at which a sample of bodily substance is to be taken; and

(b) collecting on said collector means at least one bodily substance from the user.

14. A method as defined in Claim 13, wherein after step (b) the user substantially sealingly packages said collector means for the subsequent analysis thereof.

15. A method as defined in Claim 13, wherein said collector means comprise a member adapted to be positioned on the user such that a receiving surface of said member is located substantially opposite a location of the user at which a substance sample is to be taken, said collector means further comprising collecting means in said member and in communication with said receiving surface, whereby sufficient bodily substance contacting said receiving surface is at least partly collected by said collecting means for subsequent analysis thereof.

16. A method as defined in Claim 15, wherein in step (c), said collecting means is removed from said member by the user.

17. A method as defined in Claim 16, wherein after step (b), the user substantially sealingly packages at least said collecting means for the subsequent analysis thereof.

18. A method as defined in Claim 16, wherein said collector means comprises sampling strip means removably engaged in said member with said receiving surface being adapted to allow bodily substance to reach said sampling strip means.

19. A method as defined in Claim 18, wherein said member comprises sleeve means at least partly open ended at one longitudinal end thereof, and absorbent layer means in said sleeve means, said sleeve means comprising said receiving surface, said sampling strip means being removably received in said sleeve means through said one end and between said absorbent layer means and said receiving surface such as to be removable therefrom in step (c).

20. A method as defined in Claim 19, wherein in step (a), said collector means is positioned in an undergarment for collecting bodily substances from the genital, anal or urinary regions, and wherein said sleeve means comprises upper and lower sheets, said upper sheet being at least partly comprised of said receiving surface, impermeable means being provided outwardly on said lower sheet with adhesive means being outwardly provided on said impermeable means for securing said member to the undergarment, a protective removable strip being provided outwardly on said adhesive means.

21. A collection device for collecting bodily substances from the genital, anal or urinary regions, comprising absorbent sampling strip means adapted to be positioned with a sanitary napkin such that a receiving surface of said strip means is located substantially opposite a location from which a sample of bodily substance is to be taken, wherein once at least a bodily substance has been collected by said strip means, at least said strip means can be retained for subsequent analysis of the bodily substance collected by said strip means.

22. A collection device for collecting bodily substances from the genital, anal or urinary regions, comprising absorbent sampling strip means in combination with a sanitary napkin, said strip means being positioned relative to said sanitary napkin such that, when said sanitary napkin is in a functional position thereof in an undergarment, said strip means is located substantially opposite a location from which a sample of bodily substance is to be taken, wherein once at least a bodily substance has been collected by said strip means, at least said strip means can be retained for subsequent analysis of the bodily substance collected by said strip means.

23. A collection device for collecting bodily substances from the genital, anal or urinary regions, comprising substantially flexible and comfortable collecting means, and attachment means adapted to secure said collecting means to a sanitary napkin such as to be located substantially opposite a location from which a sample of bodily substance is to be taken, wherein at least a bodily substance is collected at least partly by said collecting means for subsequent analysis thereof.

24. A collection device as defined in Claim 23, wherein said attachment means comprise adhesive means provided on an underside of said collecting means, removable backing means being provided on said adhesive means prior to said collecting means being attached to the sanitary napkin.

25. A collection device for allowing a user to collect bodily substances, comprising collecting means and attachment means therefor, said collecting means being adapted to be externally worn by the user such that, when secured in position with said attachment

means, said collecting means is located substantially opposite a location of the user at which a sample of bodily substance is to be taken, whereby once sufficient bodily substance having contacted said collecting means has been at least partly collected thereby, said collecting means can be retained for subsequent analysis thereof.

26. A collection device as defined in Claim 24, wherein said attachment means comprise adhesive means provided on said collecting means, removable means being provided on said adhesive means prior to said collecting means being attached opposite said location.

27. A method of self-collection of bodily substances, comprising the steps of:

(a) self-positioning collecting means externally on a user and at a location of the user at which a sample of bodily substance is to be taken; and

(b) collecting on said collecting means at least one bodily substance from the user.

28. A method as defined in Claim 27, wherein said collecting means is adhesively secured in position substantially opposite a location of the user at which said sample of bodily substance is to be taken.

29. A collection device as defined in Claims 1 to 12 and 23 to 26, wherein said collecting means is made of any woven, non woven or knitted materials pervious to body fluids and having the capacity to absorb or adsorb the biological materials required for analysis.

30. A collection device as defined in Claim 29, wherein said collecting means are positively charged and have ion-exchange properties.

31. A collection device as defined in Claim 29, wherein said collecting means are composed of cationic, positively charged, fibers.

32. A collection device as defined in Claim 29, wherein said collecting means are composed of fibers which are finished with positively charged monomer(s) and/or polymer(s).

33. A method as defined in Claims 15 to 20, 27 and 28, wherein said collecting means is made of any woven, non woven or knitted materials pervious to body fluids and having the capacity to absorb or adsorb the biological materials required for analysis.

34. A method as defined in Claim 33, wherein said collecting means are positively charged and have ion-exchange properties.

35. A method as defined in Claim 33, wherein said collecting means are composed of cationic, positively charged, fibers.

36. A method as defined in Claim 33, wherein said collecting means are composed of fibers which are finished with positively charged monomer(s) and/or polymer(s).

37. A collection device as defined in Claims 21 and 22, wherein said sampling strip means is made of any woven, non woven or knitted materials pervious to body fluids and having the capacity to absorb or adsorb the biological materials required for analysis.

38. A collection device as defined in Claim 37, wherein said sampling strip means are positively charged and have ion-exchange properties.

39. A collection device as defined in Claim 37, wherein said sampling strip means are composed of cationic, positively charged, fibers.

40. A collection device as defined in Claim 37, wherein said sampling strip means are composed of fibers which are finished with positively charged monomer(s) and/or polymer(s).

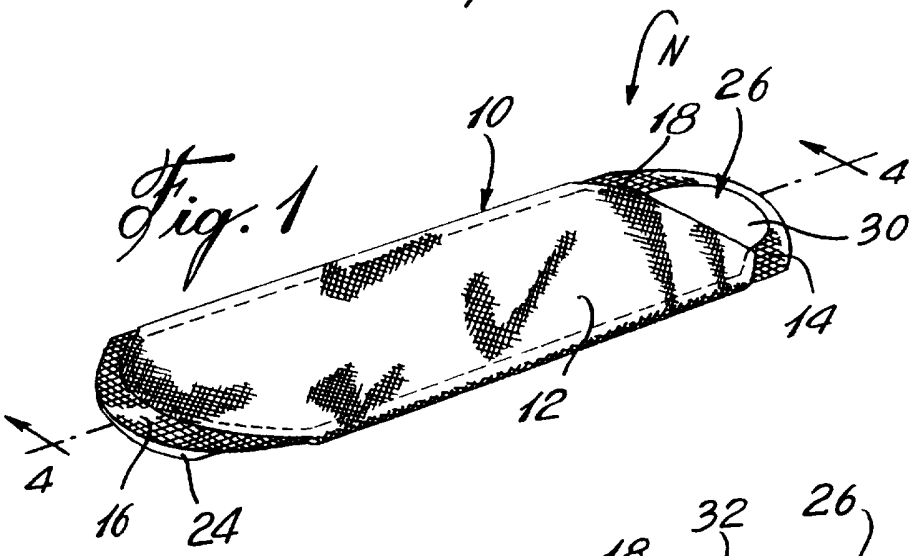

Fig. 1

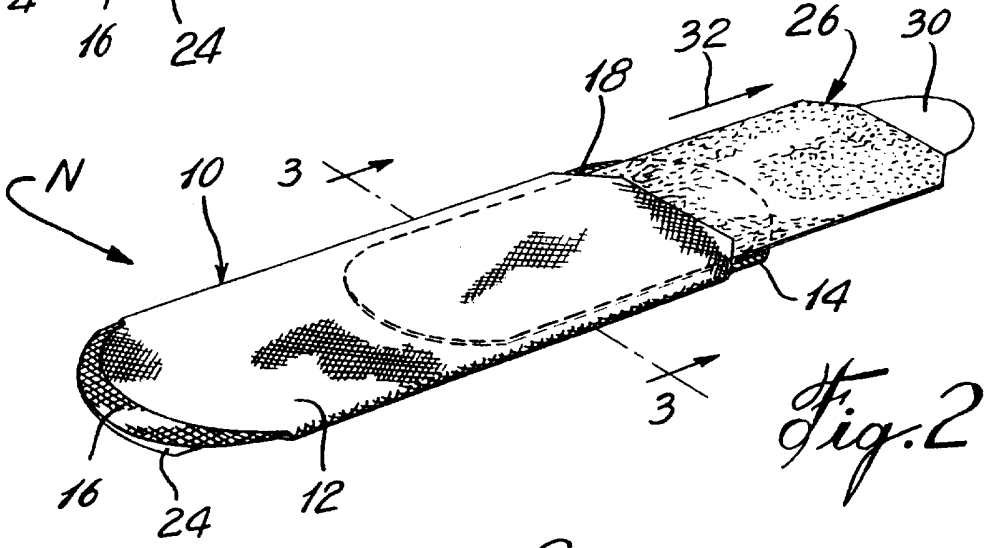

Fig. 2

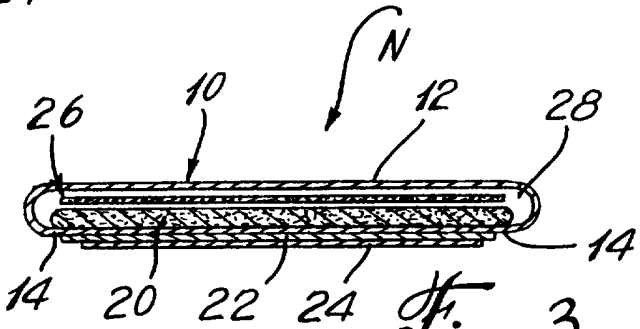

Fig. 3

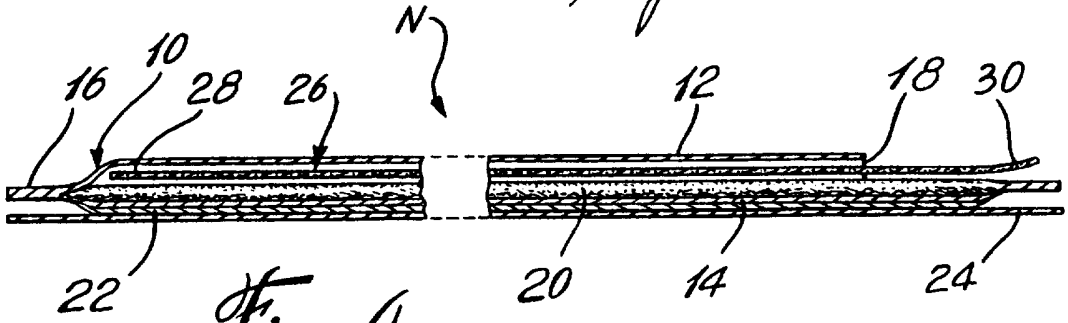

Fig. 4

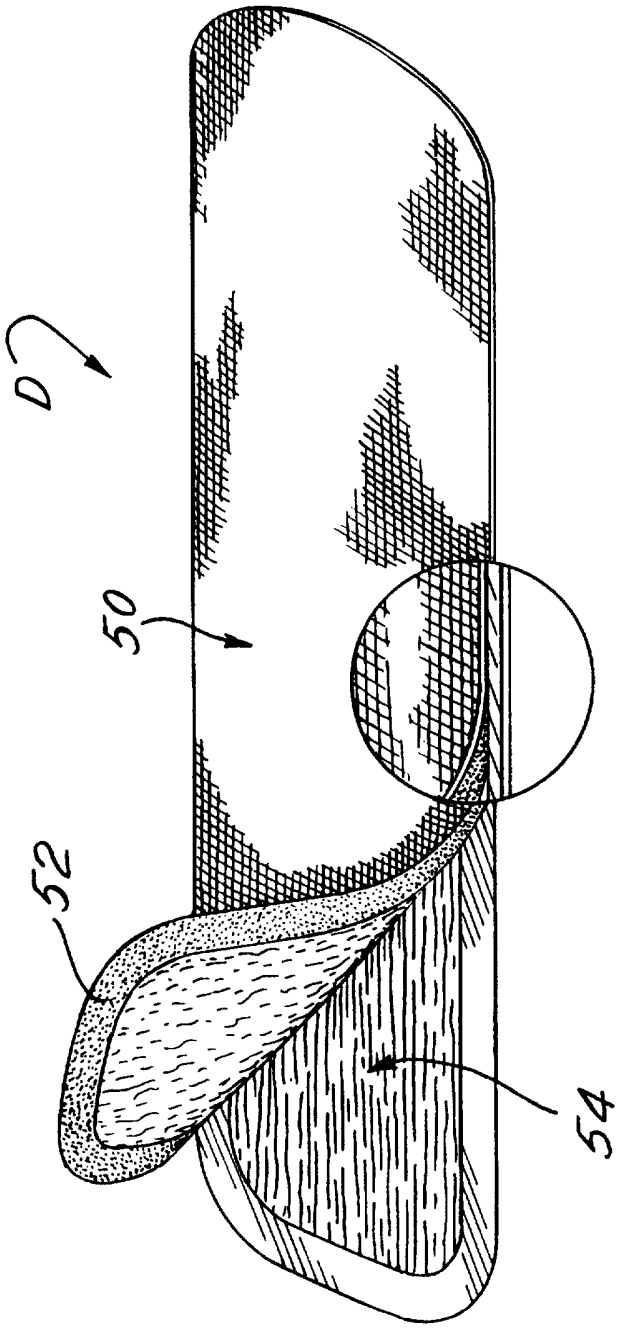

Fig. 5

INTERNATIONAL SEARCH REPORT

International Application No
PCT/CA 97/00435

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B10/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3 918 433 A (FUISZ RICHARD C) 11 November 1975	1,2,5,7, 13-17, 25,27, 29,33
A	see the whole document	5,8,10, 21-23

X	US 4 444 193 A (FOGT ERIC J ET AL) 24 April 1984	13,15, 25,27, 29,33
A	see the whole document	1,5,7,8, 10,18, 21,23,25

A	US 4 605 404 A (SNEIDER VINCENT R) 12 August 1986 see the whole document	1,13

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
13 October 1997	22. 10. 97

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

International Application No
PCT/CA 97/00435

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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