This Sheet Has Been Replaced

PORTABLE DEVICE FOR EXTEMPORANEOUS ANALYSIS OF A BODY FLUID

Background of the invention

The present invention relates to the extemporaneous analysis of a body fluid or liquid, which is present in an intracorporeal cavity, by means of a portable, and if appropriate disposable, device. By way of a non-limiting example of the scope of the present invention, the latter relates to the extemporaneous analysis of the cervical mucus which is present in the uterine neck of the vagina of the female body.

The subject of the present invention is a portable, and if appropriate disposable, device which is particularly simple as regards its use and which safeguards the intracorporeal cavity, and especially its mucous membrane, from any contact with analysis reagents.

Description of the prior art

In this respect, a device of this kind is already known which comprises a tube adapted for introduction into the intracorporeal cavity, a rod mounted slidably in this tube and itself having a gripping end which emerges from one side of said tube, and at the other end having elements for sampling of the body fluid, this rod being capable of assuming at least two relative positions with respect to the tube, the one retracted and the other deployed.

Summary of the invention

The subject of the present invention is more particularly a portable device, such as is defined above, which makes it possible at one and the same time to sample and also to measure the spinnbarkeit of the body fluid.

In accordance with the invention, the rod comprises at its other end, that is to say the end opposite the gripping end, two branches which can be spaced apart angularly, the free end of each of them having an element for sampling of the body fluid; and

these two branches are arranged in relation or with respect to the tube in such a way that, in the retracted position of the rod, the sampling elements of the two branches are drawn together and remain at the distal end of the tube, and in a deployed position these same sampling elements are spaced apart outside the tube, at its distal end.

The functioning of such a device is as follows:

- when the rod is in the retracted position with respect to the tube, the device is introduced into the intracorporeal cavity until contact is made between the distal end of the tube and the wall of said cavity, for example the mucous membrane of the cervix;
- by moving the distal end of the device, and the sampling elements protruding from said end, the latter are made to rub against the wall of the intracorporeal cavity, by means of which it is possible to remove body fluid, for example the cervical mucus, and to retain it on said elements;
- the whole of the device is then withdrawn from the intracorporeal cavity;
- outside the intracorporeal cavity, the rod is displaced gradually and slowly with respect to the tube, so as to pass from the retracted position to the deployed position, by which means the body fluid lengthens out, without breaking up, in a sort of continuous filament or thread between the two branches of the rod, and more particularly between the two sampling elements;
- finally, the thread or filament of the body fluid ruptures at a relative position of the rod with respect to the tube which can vary as a function of the spinnbarkeit of the body fluid; observation of the position of the rod with respect to the tube, corresponding to the rupture of the thread or filament of the body fluid, thus constitutes a measure of the spinnbarkeit of the analyzed body

fluid.

Description of the drawings

The present invention is now described with reference to the attached drawing, in which:

- Figure 1 represents a perspective view of the device according to a first embodiment of the invention, in its retracted position;
- Figure 2 is a view of the device represented in Figure 1, in the deployed position;
- Figure 3 represents a complementary embodiment of the present invention, consisting of a complementary analysis element;
- Figure 4 represents, within one and the same figure, two other embodiments of a device according to the invention, the right half with respect to the axis relating to a second embodiment, and the left half with respect to the same axis relating to a third embodiment of the invention;
- Figure 5 relates in part to a fourth embodiment of the invention; on the left of the figure, the rod and its two branches are shown in the retracted position, while on the right of this same figure they are in the partially deployed position.

Description of the preferred embodiments

A device according to the invention can be made of any suitable material, in particular biocompatible plastic. This device comprises in a general manner a tube 1 generally rounded at its distal end and having a shoulder at its proximal end. This tube is adapted in shape and dimensions for introduction into the intra-corporeal cavity, for example the vaginal cavity of the woman.

A rod 2 is mounted slidably in the tube 1 and comprises, at the proximal end 1c of the tube 1, a gripping end 21, and two branches 22 and 23 which emerge from the distal end 1a of the tube 1 and which are capable of being spaced apart angularly, with an

inherent elasticity bringing them back to the spaced-apart position. The free end of each branch 22 or 23 comprises an element 3 for sampling of the body fluid, said element 3 being in the form of hairs or filaments. The rod 1 is provided with serrations 2c, at the side opposite the branches 22 and 23, while a catch 16 forms an integral part of the tube 1, inside its bore, and makes it possible to immobilize the rod 1 in a relative position with respect to the tube 2.

The tube 1 can be covered if appropriate with a temporary protective means (not represented) such as a sheath surrounding or at least partially enclosing, and in a sealing manner, the tube 1 and the elements 3 for sampling of the body fluid. Such a sheath can comprise, or can be integral with, one end of an attachment, for example a pulling loop, with which it is possible to withdraw the sheath in order to expose the tube 1, and also the sampling elements 3 of the device, after the tube 1 has been introduced into the intracorporeal cavity.

The rod 2 is capable of assuming two relative positions with respect to the tube 1, the one retracted, as shown in Figure 1, in which the sampling elements 3 of the two branches 22 and 23 respectively are drawn together and emerge at a distal end 1a of the tube 1, and the other deployed, as represented in Figure 2, in which the branches 22 and 23 are spaced apart outside the tube 1, at its distal end 1a.

The device according to the invention is equipped with a means 4 for measuring, in particular for reading off, the relative displacement of the rod 2 with respect to the tube 1. This reading-off means 4 comprises markings 24 engraved or present on the rod 2, and a reading window 1b formed on the tube 1, and more specifically at its proximal end 1c.

In accordance with Figure 3, a complementary analysis element 5 for analyzing a constituent of the body fluid, for example an enzyme present in the

cervical mucus, or a chemical, biochemical or biological state, for example the pH of said fluid, is adapted to be brought into contact with the sampling elements 3 of one or both branches 22 and 23 of the rod 2. This complementary analysis element comprises a cup 6, in particular of transparent material, and reaction means 7, for example color oxidation-reduction reagents, distributed or disposed inside the cup 6 and capable of reacting, in a manner visible or perceptible to the user, with at least one constituent of the body fluid, or in the presence of the sought state of said fluid. The shape and the dimensions of this cup are adapted so as to bring the sampling elements 3 into contact with the reaction means 7; for example, as is shown in Figure 3, the cup has a hollow and spherical shape.

In order to permit the manipulation of the complementary analysis element 5 with respect to the branches 22 and 23 of the rod 2, the cup 6 has external manipulation studs 8.

The inside of the cup 6 has partitions 61 to 64 which delimit different reaction zones 71 to 75, respectively, in which respectively different reagents, in particular color reagents, are disposed.

The device represented in Figure 4 differs from that described with reference to Figures 1 and 2 in terms of the following characteristics:

- the branches 22 and 23 are arranged in relation with the tube 1 in such a way that, in the retracted position shown in Figure 4, the sampling elements 3 are disposed side by side and inside the tube 1, which is continued via the head 10 described hereinafter;
- the tube 1 comprises a distal part or a head 10 for the accommodation of the two branches 22 and 23 in the position in which they are drawn together and retracted; this head comprises an aperture 11 for the passage of the two branches 22

and 23, in the position in which they are drawn together, as shown in Figure 4, and a closure member 12 for the aperture 11, closing the latter when the rod 2 is in the retracted position, and freeing this same aperture for the passage of the two branches, which are drawn together, when the rod 2 is displaced toward the outside from the distal end 1a of the tube 1, for example toward its deployed position;

- the closure member 12 comprises two flap elements 131 and 132 mounted in a retractable manner in the aperture 11 of the head 10 and held in the closed position in this aperture; these two mutually facing flap elements 131 and 132 are retractable in the opposite direction with respect to one another, and are returned toward one another by the return means 14; in accordance with the representation on the right-hand half of Figure 4, this return means consists of a blade forming a spring which is integral with the actual flap element 131 or 132, bearing on the wall of the head 10, and fixed in position at its free end by sliding on the rod 2; in accordance with the representation on the left-hand half of Figure 4, the flap element 131 or 132 is guided in translation, perpendicular to the axis of the tube 1, by suitable bearing grooves cooperating with corresponding studs protruding from said element, and the return means 14, again integral with the flap element, consist of a return blade bearing at its free end against the wall of the tube 1, and more specifically of the head 10;
- each flap element 131 or 132 comprises its own means of retraction, under the effect of the displacement of each corresponding branch 22 or 23 toward the outside of the tube via the aperture 11; these retraction means consist of a ramp 131a or 132a cooperating with a corresponding shoulder

22a or 23a present on each corresponding branch 22 or 23;

- each flap element 131 or 132 comprises a locking means 15 for locking a corresponding branch 22 or 23 in the retracted position of the rod 2, it being understood that each branch 22 or 23 can escape from said locking means 15 when the rod 2 is displaced toward the outside of the tube 1; this locking means consists of a rib provided on a flap element 131 or 132, in line with a stud protruding laterally from a branch 22 or 23.

In accordance with the representation in Figure 5, each flap element 131 or 132 is articulated on the head 10 and comprises an active end in the form of a hook cooperating with a corresponding groove formed at the upper end of a branch 22 or 23. In this way, in the retracted position shown on the left of Figure 5, the flap elements 131 and 132 are blocked in the closed position of the closure member 12, while they escape from the same branches when the latter are displaced toward the outside of the tube 1, as is shown on the right of Figure 5, this displacement causing their rotation into the open position of the closure member.

The features which have been described with reference to Figures 4 and 5 make it possible at one and the same time to protect the sampling means 3 upon introduction of the device into the intracorporeal cavity, to free them or expose them to the body fluid in this cavity alone, then to bring them back into the retracted position, and thereby to protect them upon withdrawal of the device from the intracorporeal cavity, the deployed and spaced-apart position of the two branches being obtained outside this same cavity.

In summary, an analysis device is obtained, in accordance with the invention, which is particularly simple and effective and which protects the intracorporeal cavity from any contact with reagents.

* C L M S *

CLAIMS

1. A portable device for extemporaneous analysis of a body fluid in an intracorporeal cavity, comprising a tube adapted for introduction into said cavity, a rod mounted slidably in said tube and having a gripping end which emerges from one side of said tube, and at the other end having elements for sampling of said body fluid, said rod being capable of assuming two relative positions with respect to said tube, the one retracted (Fig. 1) and the other deployed (Fig. 2), wherein said rod has, at said other end, two branches which can be spaced apart angularly, the free end of each of them having a said element for sampling of said body fluid, and these branches being arranged in relation with said tube in such a way that, in the retracted position (Fig. 1), the sampling elements of the two branches are drawn together and remain at the distal end of said tube, and in the deployed position (Fig. 2) they are spaced apart outside said tube, at its distal end.

2. The device as claimed in claim 1, which comprises a means for measuring, in particular reading off, the relative displacement of the rod with respect to the tube.

3. The device as claimed in claim 2, wherein the reading-off means comprises markings present on the rod, and a reading window formed on the tube.

4. The device as claimed in claim 1, which comprises a complementary analysis element for analyzing a constituent of the body fluid, or a chemical, biochemical or biological state of said fluid, and adapted to be brought into contact with the sampling elements of one or both branches of the rod.

5. The device as claimed in claim 4, wherein the complementary analysis element comprises a cup, in particular of transparent material, and reaction means, distributed or disposed inside said cup and capable of reacting, in a manner visible or perceptible to the

This Sheet Has Been Replaced

user, with at least one constituent of the body fluid, or in the presence of said state of said fluid, and the shape and the dimensions of said cup being adapted so as to bring said sampling elements into contact with said reaction means.

6. The device as claimed in claim 5, wherein the cup has external manipulation studs.

7. The device as claimed in claim 5, wherein the inside of the cup has partitions which delimit different reaction zones, respectively, in which respectively different reagents, in particular color reagents, are disposed.

8. The device as claimed in claim 1, wherein the branches are arranged in relation with said tube in such a way that in the retracted position (Fig. 1) the sampling elements emerge from said tube.

9. The device as claimed in claim 1, wherein the branches are arranged in relation with the tube in such a way that in the retracted position (Fig. 4) the sampling elements are disposed inside said tube.

10. The device as claimed in claim 9, wherein the tube comprises a head comprising an aperture for the passage of the two branches, in the position in which they are drawn together, and a closure member for said aperture (Fig. 4), closing the latter when the rod is in the retracted position, and freeing said aperture for the passage of the two branches.

11. The device as claimed in claim 10, wherein the closure member comprises at least one flap mounted in a retractable manner in the aperture of the head and held in the closed position in said aperture, and means of retraction of the flap, under the effect of the displacement of the two branches toward the outside of the tube via said aperture.

12. The device as claimed in claim 11, which comprises two mutually facing flap elements which are retractable in the opposite direction with respect to one another and which are returned toward one another

This Sheet Has Been Replaced

* C L M S *

by return means.

13. The device as claimed in claim 11, wherein each flap element comprises its own means of retraction, consisting of a ramp cooperating with a corresponding shoulder present on each branch.

14. The device as claimed in claim 11, wherein each flap element comprises a locking means for locking a corresponding branch in the retracted position of the rod.

This Sheet Has Been Replaced