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(54) **SALIVA SAMPLING DEVICE**

SPEICHELENTNAHMEVORRICHTUNG

DISPOSITIF DE PRELEVEMENT D'ECHANTILLONS DE SALIVE

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Description

[0001] The present invention generally relates to fluid specimen collection devices, and more specifically relates to a saliva sampling device and method for extracting saliva for use in diagnostic tests.

[0002] Unlike other forms of fluid specimens such as blood or urine, collection of oral fluid, such as saliva, for diagnostic purposes is complicated by many factors, for example, the low volumes of salivary fluid secreted, the relatively high viscosity of the fluid, and the diverse anatomic dispersion of the salivary glands. These problems become compounded when a single saliva sample is to be divided into two or more portions as is sometimes desired. Most techniques for collection involve the use of capillary tubes, suction into micro pipettes, chewing on paraffin, and/or aspiration from the mouth into polypropylene syringes.

[0003] In addition, testing of salivary specimens has not yet been extensively developed. Blood and urine samples have for long been the primary fluids used for testing for disease as well as for evidence of substance abuse. However, it is now known that human saliva carries lymphocytes, plasma cells and immunoglobulins that are directly related to the immunoglobulins found in the blood. In addition, saliva carries immunoglobins that are believed to be peculiar to saliva, for example, the antibody known as secretory IgA. Because of the association between immunoglobulins of the blood and saliva, as well as the occurrence of secretory IgA, antigen-antibody tests have been conducted on salivary fluid to assess the value of such tests as screening tools for disease.

[0004] U.S. Patent No. 5,933,614 to Cesarczyk describes a Sample Collection Method with Extraction Sleeve. The device is designed for collecting saliva or urine samples using an absorbent, elongate foam member secured within a hollow tube and having a portion extending therefrom. The foam member is used to absorb a fluid specimen. The foam member and hollow tube are slidably mounted within an outer sleeve covering the foam member. Fluid is collected by a user exerting pressure against the sleeve to compress the foam member and thereby release the fluid. According to Cesarczyk, the device provides an aseptic, easy to use device for collecting a fluid sample such as saliva,

[0005] U.S. Patent No. 5,830,410 discloses an oral fluid sampling device for obtaining oral fluid samples for testing. The device includes a syringe having a plunger at the end of which an absorbent pad is attached.

[0006] Embodiments of the present invention exemplify an improved oral fluid collection device which is easier to use than other devices in the field that are those presently available.

[0007] Embodiments of the present invention provide an improved sampling device for collecting and delivering an oral fluid specimen such as saliva, for diagnostic testing.

SUMMARY OF THE INVENTION

[0008] In a first aspect the present invention provides a fluid specimen sampling device as defined in independent claim 1.

[0009] In a second aspect the present invention provides a method of obtaining a desired number of drops of a fluid sample, as defined in independent claim 21.

[0010] Optional features of the present invention are defined in the dependent claims.

[0011] An embodiment of the invention is described in detail below.

[0012] The method and device of the embodiment provided for both collecting and delivering a fluid sample, such as blood, urine or saliva for diagnostic testing. It is noted that the device is especially advantageous for samples of which only a low volume of sample is available for collection, specifically saliva.

[0013] In the embodiment, the device generally comprises an expresser, having a distal open end connected to a port, and a generally closed proximal end. The expresser is adapted to receive an absorbent member substantially saturated with a fluid specimen, through the distal opening. As the absorbent member is pulled through the distal opening and into the port, the port provides means for compressing the absorbent member to effect expression of the fluid specimen therefrom the absorbent member.

[0014] In the embodiment, connected to the expresser distal open end is a platform for collecting at least a portion of the specimen as it is expressed from the absorbent member. The platform preferably is adapted to provide means for testing the fluid specimen. For example, the platform may include a sample well for receiving drops of expressed fluid. To facilitate flow of the expressed fluid into the sample well, the expresser may be disposed at an angle with respect to the generally horizontal platform.

[0015] The sample well may include a first port and a second port, comprising, for example a test port and a confirmation port respectively. In addition, the platform may include a lateral flow test strip in fluid communication with the test port, and a confirmation container in fluid communication with the confirmation port. Preferably, the platform has a closed top surface encasing the test strip, and a viewing window exposing a portion of the strip.

[0016] In one especially advantageous embodiment, the device further comprises means for dividing the fluid expressed from the expresser. For example, a partition, disposed between the test and confirmation ports and extending at least partially into the expresser container is provided. A ratio of confirmation sample to lateral flow sample could be adjusted by changing location and/or configuration of the dividing partition.

[0017] In one embodiment of the invention, an absorbent member is provided, as well as tether means for enabling manual handling of the absorbent member. The expresser distal opening may include an inlet, sized for passage of the absorbent member, and a longitudinal

slot in communication with the inlet, sized for passage of the tether means. By controlling the pulling of the tether, the user may cleanly and controllably express the fluid, drop by drop, to be used for testing/diagnostic purposes.

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] The objects and advantages of the present invention will be more clearly understood and appreciated with reference to the following detailed description of an embodiment when considered in conjunction with the appended drawings of which:

Figure 1 shows a perspective view of a saliva sampling device in accordance with the present invention, including an expresser adapted to receive an absorbent member, the expresser including a port adapted to compress the absorbent member to effect expression of saliva fluid absorbed by the absorbent member, and collection means, comprising a platform connected to the expresser, for collecting the portion of fluid for testing;

Figure 2 shows a top view of the device in Figure 1;

Figure 3 shows a cross sectional view of the device taken along line 3-3 of Figure 2;

Figure 4 shows a cross sectional view of the device taken along line 4-4 of Figure 2;

Figures 5 shows a side view of an absorbent member and tether combination suitable for use in the device shown in Figures 1- 4;

Figure 6 shows a confirmation container useful in the device of the present invention for storing a portion of the expressed saliva fluid for processing at a later time;

and

Figure 7 shows an expresser cup useful with a method of the present invention.

DETAILED DESCRIPTION

[0019] Turning now to Figures 1 - 4, an embodiment of the fluid specimen sampling device 10 in accordance with the invention is shown. The device 10 generally comprises a substantially cylindrical member, hereinafter referred to as an "expresser" 12 for reasons which will later become apparent. The expresser 12 includes a proximal, generally closed end 14 and a distal, substantially open end 16. The expresser 12 is adapted to receive an absorbent member 17 (not in view in Figure 2) through the distal open end 16, said absorbent member 17 to be described in greater detail hereinafter. In accordance with a method of the present invention, a fluid specimen or sample is applied to the absorbent member 17 and is expressed therefrom for collection and testing. For example, the absorbent member 17 may comprise an absorbent sponge, foam swab or like material capable of absorbing a fluid specimen such as saliva, sized to be comfortably placed in a mouth of a patient or subject person (not shown). After the foam swab 17 is so placed in the mouth, it is allowed to remain in the mouth for a sufficient time to allow a sample of saliva fluid to be absorbed thereby. The time for absorption of a sufficient amount of specimen will generally vary depending upon the particular subject person.

[0020] The expresser 12 is designed to enable sanitary, effective expression of at least a portion of the fluid sample that has been absorbed by the foam swab 17 in an amount sufficient for testing and/or collection. Referring specifically now to Figures 3 and 4, the expresser 12 includes a port 20, defined by inner walls 22 thereof, the port terminating at the proximal end 14. The expresser port 20 provides means for compressing the foam swab 17 as the foam swab 17 is passed into the expresser 12. A tether 24, connected to the absorbent member 17 is provided for enabling a user to pull the absorbent member 17 into the port 20.

[0021] As shown in Figures 3 and 5 the tether 24 may comprise a flexible, plastic monofilament having a distal portion 30 passing through the absorbent member 17 with a hook 32 outside of the absorbent member 17, thereby providing a simple, yet secure engagement therebetween. A handle 34 (shown only in Figure 5) is provided for facilitating manual handling of the foam swab 17.

[0022] Referring back now to Figures 1-3, the device 10 further comprises means for collecting the expressed fluid sample. Specifically, for example, a platform 48 having a sample well 50 in communication with the expresser distal opening 16 may be provided wherein the platform 48 includes a plastic housing 52 supported by legs 54, skirt (not shown) or other suitable structure. The housing 52 is structured to accommodate at least one reagent strip or one lateral flow test strip 58 made of nitrocellulose or other suitable material, said lateral flow test strip 58 having a portion 60 being exposed to the sample well 50. Reagent strip 58 will not be further described in detail herein, as lateral flow test strips suitable for use with the embodiment are well known in the art of diagnostic testing devices.

[0023] Preferably, as shown most clearly in Figures 1 and 4, in order to effectively channel the flow of expressed fluid into the sample well 50, the expresser 12 is connected to the platform 48 at an inclined angle, for example, of about 45 degrees.

[0024] Upon deposit of the expressed sample fluid into the sample well 50, the fluid begins migration along the test strip 58. A window 60 in the platform 48 provides means for enabling viewing of a test strip portion 62 that reveals validity, positive/ negative or quantitative test results.

[0025] In one especially advantageous aspect of the embodiment, the sample well 50 may be divided into two or more sub-ports, for example, a first port 72 and a second port 74. The first port 72 and second port 74 will be hereinafter designated as a test port and a confirmation port, respectively, although it is contemplated that the

ports may both function as different test ports, for example. As shown in Figure 3, the test port 72 is in fluid communication with the lateral flow test strip 58 such that a first portion of the fluid, deposited in the test port 72, will immediately begin migration along the strip 58. Similarly, the confirmation port 74 may be in fluid communication with a confirmation container 78 for collecting and/or storing a second portion of the fluid for confirmation of patient identity, test validity or other processing steps to be performed at a later time.

[0026] Referring to Figures 1, 3 and 4, the confirmation container 78 is shown depending from the platform 48 immediately beneath the confirmation port 74. Preferably, as shown in Figure 4, suitable means, for example cooperating plug 80 depending from the platform, is provided for removably coupling the container 78 to the platform 48. Turning to Figure 6, additionally provided is a tamper evident closure cap 81 for sealing the confirmation container 78 after it has been removed from the platform 48.

[0027] Turning again to Figures 1-4, means for dividing the sample fluid is provided. More specifically, a partition 82, extending substantially normal to the platform 48 and at least partially into the expresser 12 is provided for dividing the fluid sample into two or more portions as the fluid is being expressed and collected. The partition 82 is secured to the platform 48 within the sample well 50 and may be substantially flush with the inner wall 22 defining the expresser port 20 (see Figures 3 and 4). As shown in Figure 3, the partition 82 functions to direct a portion of the expressed fluid into the test port 72 (flow portion represented by arrow 88) and another portion of the expressed fluid into the confirmation port 74 (flow represented by arrow 89). This feature enables a user to divide and perform multiple tests or procedures on an individual sample of a fluid, such as saliva which is typically difficult to collect in any substantial quantity.

[0028] It is contemplated that an alternative feature of the embodiment includes manually squeezable walls of the expresser 12, provided as an alternative or additional means for expressing fluid from the foam swab 17. More specifically, after the absorbent member 17 is pulled into the expresser 12, drops of the fluid may be extracted therefrom by the user manually applying pressure to, or squeezing, the expresser 12. A suitable material for the squeezable expresser is a low density polyethylene plastic.

[0029] Referring back now to Figures 1 and 2, the device 10 may further comprise means 96 for facilitating insertion of the absorbent member 17 and tether 24 into the expresser 12. Particularly, the expresser 12 may include a wide inlet 98 sized for substantially uncompressed passage of the absorbent member 17, and a longitudinal slot 102 in communication with the distal end inlet, sized for passage of the tether 24. As shown in Figure 2, the slot 102 extends from the wide inlet 98 through the proximal end 14 of the expresser 12.

[0030] The device 10 may further include means for holding the absorbent member 17 in a compressed position to enable a user to manually release the tether after the absorbent member 17 has been compressed without causing the absorbent member 17 to expand and potentially reabsorb the expressed fluid. The user may therefor attend to other tasks while waiting for the absorbed fluid to be expressed from the foam swab 17 and flow along the expresser inner walls 22. It noted that this feature is especially advantageous for use with high viscosity, cohesive fluids such as saliva which tend to flow relatively slowly.

[0031] Collecting and testing of a fluid specimen may be performed as follows. The absorbent foam 17, having the tether 24 secured thereto, is placed in the mouth of a patient, or subject person, and the foam 17 is kept in the mouth until it is substantially saturated with saliva fluid. A technician, or other user of the device 10 can thereafter sanitarily handle the absorbent member 17 by means of the handle 34. The technician places the saturated foam 17 into the wide inlet portion 98 of the slot means 96 and the tether 24 is gently pulled toward and into the slot 102 such that it eventually projects from the expresser 12 through the proximal end 14 thereof.

[0032] To express the absorbed fluid from the foam 17, the technician gently pulls the tether handle 34 to cause the foam 17 to enter the port 20 and become compressed thereby and eventually be squeezed within the expresser port 20.

[0033] A small disk 36, or the like, made for example of rubber or plastic, may be slidably engaged to the tether 24 such that the fluid specimen will be substantially prevented from leaking from the expresser 12 during the compression of the swab.

[0034] Expressed fluid is channeled toward the sample well 50 and divided by the partition 82. Means, such as a narrow end 104 of the slot 102, may be provided for locking the tether 24, thereby holding the foam 17 in a compressed position, such that the expressed fluid will not inadvertently be reabsorbed by the foam swab 17. A portion of the fluid is collected in the confirmation container 78 which is may then removed from the platform and sealed with cap 81. The technician may read test results through window 60.

[0035] Preferably, the device is configured on such a way that the reagent strip may be successfully photocopied or scanned to preserve a copy of the test results. For example the device 10 may structured such that the expresser is easily removable from the platform lowering the profile of the test device 10.

[0036] Turning now to Figure 7, the alternative saliva sampling device 110, comprising conical expresser 112, hereinafter referred to as "expresser cup" 112, is shown, with like parts being represented by like reference numerals. This device 110 is useful for collecting and testing an oral fluid sample, in accordance with a method the invention, and may be used independently and exclusively of the platform 48. For example, the device 110 may be used to provide a particular number of drops of

an absorbed fluid sample, to be deposited onto conventional fluid specimen testing apparatus or into collection canisters (not shown).

[0037] In this embodiment, the tether foam 17 is threaded through the expresser cup 112, without the expresser cup 112 being secured to the platform 48 of Figures 1-4. The assembled device 110 is then used in sampling with a proximal end 114 of the cup 112 located next to the tether handle 34. After the foam 17 is saturated the fluid specimen, the foam 17 is removed from the mouth and, with one hand of a user holding the expresser cup 92, and another hand holding the handle 34, the foam is gently pulled into the cup 112, causing the foam 17 to enter the narrowing expresser cup 92 until a desired number of drops of the oral fluid is expressed therefrom. An open distal end 122 of the cup 112 may be placed over a collection area whereon the expressed fluid may be dropped for immediate testing or collection for later confirmation or use thereof. In this example, a slot such as 96, is preferably not provided. Assembly of the device 110 may be accomplished by threading the tether 24 through a proximal end opening 125, and subsequently attaching the absorbent member 17 to the tether 24 using suitable means.

[0038] In another aspect of the embodiment, individual drops of fluid may be obtained by carefully controlling manual pulling of the absorbent member into the expresser 110. As an example, a first drop of fluid may be obtained by pulling the absorbent member 17 into the expresser cup 112 and allowing the absorbent member 17 to be sufficiently compressed thereby to cause expression of only a single first drop of fluid. The first drop is thereafter collected onto a collection area. One or more additional drops of the fluid sample may be obtained by continuing to pull the absorbent member 17 further into the port and allowing the additional drops to flow and drop from the expresser cup 112. These additional drops may be deposited onto the same collection area or onto a different collection area (for example, into a standalone confirmation canister) by simply positioning the expresser 112 over the desired collection area. The above steps may be repeated until the desired number of drops are obtained and collected. The method may further comprise separately processing the drops of fluid. For example, the step of separately processing may comprise directing a first drop onto a lateral flow test strip for testing, and storing a second drop in a canister or container for use in confirmation testing or otherwise processing at a later time.

[0039] It is to be appreciated that although the present devices 10, 110 were developed for use in the collecting and testing of oral fluid, for example saliva, with appropriate modification thereto, the devices 10, 110 may be adapted for the collection and testing of blood, plasma, serum, urine or other fluid specimens. For example, the absorbent member 17 may be made of materials presently known to those skilled in the art, to be suitable for the absorption of said other fluid specimens.

[0040] Although there has been hereinabove described a saliva sampling device, in accordance with the present invention, for the purpose of illustrating the manner in which the invention may be used to advantage, it will be appreciated that the invention is not limited thereto. Accordingly, any and all modifications, variations, or equivalent arrangements which may occur to those skilled in the art should be considered to be within the scope of the invention as defined in the appended claims.

Claims

1. A fluid specimen sampling device (10) comprising:

an expresser (12) having a distal opening (16) and adapted to receive an absorbent member (17) having a fluid absorbed therein;

means, including a port (20) of the expresser (12), for compressing the absorbent member (17) as the absorbent member (17) is passed into the expresser (12) to effect expression of at least a portion of the fluid from the absorbent member (17); and

collection means, connected to the expresser (12), for collecting the portion of fluid expressed from the absorbent member (17),

characterised in that the collection means comprises a platform (48) including a sample well (50) in fluid communication with the expresser distal opening (16).

2. The device of claim 1, further comprising tether means (24), connected to the absorbent member (17), for controlling passage of the absorbent member into the expresser (12).

3. The device according to claim 1 or 2 wherein the expresser (12) is slanted with respect to the platform (48) to facilitate a flow of the fluid expressed from the absorbent member (17) and into the sample well (50).

4. The device according to claim 1, 2 or 3 wherein the sample well (50) includes a first port (72) and a second port (74).

5. The device according to claim 4 wherein the first port (72) and the second port (74) comprise a test port and a confirmation port respectively.

6. The device according to claim 5 wherein the platform (48) includes a lateral flow test strip (58) in fluid communication with the test port, and a window for enabling viewing of at least a portion of the lateral flow test strip.

7. The device according to claim 5 or 6 wherein the collection means further includes a confirmation container (78) depending from the platform and in fluid communication with the confirmation port.

8. The device according to any one of claims 1 to 7 wherein the collection means comprises processing means, including a lateral flow test strip (58) and a confirmation container (78), for respectively testing and confirming the portion of fluid expressed from the absorbent member.

9. The device according to any one of claims 1 to 8 further comprising means (82) for dividing the portion of fluid as the fluid is expressed and collected in the collection means.

10. The device according to claim 9 wherein the means for dividing comprises a partition extending substantially normal to the platform (48) into the expresser distal opening (16) and disposed between the first port (72) and the second port (74).

11. The device according to any one of claim 1 to 10 wherein the expresser (12) is slanted with respect to the platform (48) to facilitate a flow of the portion of fluid expressed from the absorbent member (12) and into the sample well (50).

12. The device of any one of claims 1 to 11 further comprising said absorbent member (17).

13. The device according to claim 12 wherein the absorbent member (17) is capable of absorbing a saliva sample.

14. The device of any one of claim 2 to 13 wherein the expresser (12) further includes slot means (102) for facilitating insertion of the absorbent member (17) and tether means (24) into the expresser.

15. The device according to claim 14 further comprising means, including a narrow end (104) of the slot means (102), for locking the tether means (24) into the expresser (12) and holding the absorbent member (17) in a compressed position.

16. The device of claim 15 wherein the slot means (102) includes a distal end inlet, sized for substantially uncompressed passage of the absorbent member (17), and a longitudinal slot in communication with the distal end inlet, sized for passage of the tether means (24).

17. The device according to any one of claims 1 to 16 wherein the means (112) for compressing further includes manually squeezable walls of the expresser.

18. The device according to any one of claims 1 to 17 wherein the means for compressing (112) further includes a conical shape of the expresser (12).

19. The device according to any one of claims 1 to 18 wherein the absorbent member (17) is capable of absorbing saliva fluid.

20. The device according to any one of claims 1 to 19 wherein the expresser (12) includes an aperture in a proximal end thereof, and the device further comprises tether means (24), passing through the aperture and connected to the absorbent member (17), for enabling manual pulling of the absorbent member (17) into the expresser (12).

21. A method of obtaining a desired number of drops of a fluid sample, the method comprising the steps of :

providing an absorbent member (17);
providing an expresser (12) having an open distal end (16), a substantially closed proximal end, and an inner surface defining a port (20);
applying a fluid sample to the absorbent member (17) and allowing the fluid sample to be absorbed thereby;
obtaining a first drop of the fluid sample from the absorbent member (17) by compressing the absorbent member (17) by passing the absorbent member into the port (20), and allowing the absorbent member (17) to be compressed by the inner surface of the expresser (12) to cause the first drop to be expressed from the absorbent member (17);
collecting the first drop of the fluid sample by allowing the first drop to flow from the expresser (12) onto a collection area; and
obtaining and collecting additional drops of the fluid sample by continuing to pass the absorbent member (17) further into the port (20) and allowing the drops to flow onto the collection area until the desired number of drops are obtained and collected,

characterised in that the drops are collected by providing a platform (48) including a sample well (50) in fluid communication with the open distal end (16) of the expresser (12).

22. The method of claim 21 wherein a tether (24) is attached to the absorbent member (17), and wherein the absorbent member (17) is moved within the expresser (12) by pulling the tether (24).

23. The method of claim 21, or 22 wherein the step of providing an expresser (12) comprises providing an expresser (12) having a substantially conical cross section.

24. The method according to claim 21, 22, or 23 wherein the step of applying comprises placing the absorbent member (17) in a mouth of a patient and allowing the absorbent member (17) to absorb saliva from the mouth.

25. The method according to claim 21, 22, 23, or 24 further comprising separately processing the drops.

26. The method according to claim 25 wherein the step of separately processing comprises directing the first drop onto a lateral flow test strip for testing and storing another drop in a container for processing of the second portion at a later time.

Patentansprüche

1. Fluidprobenahme-Vorrichtung (10), die aufweist:

einen Auspresser (12) mit einer distalen Öffnung (16) und der so angepasst, ein absorbierendes Element (17) mit einem darin absorbierten Fluid aufzunehmen;
Mittel, das einen Kanal (20) des Auspressers (12) einschließt, um das absorbierende Element (17) zu Komprimieren, wenn das absorbierende Element (17) in den Auspresser (12) geführt wird, um das Auspressen zumindest eines Teils des Fluids aus dem absorbierenden Element (17) zu bewirken; und
ein Sammelmittel, das mit dem Auspresser (12) verbunden ist, zum Sammeln des vom absorbierenden Element (17) ausgepressten Teils des Fluids,

dadurch gekennzeichnet, dass das Sammelmittel eine Plattform (48) aufweist, einschließlich einer Probenvertiefung (50), die in fluidleitender Verbindung mit der distalen Öffnung (16) des Auspressers steht.

2. Vorrichtung nach Anspruch 1, die weiter ein Haltemittel (24) aufweist, das mit dem absorbierenden Element (17) verbunden ist, um den Durchgang des absorbierenden Elements in den Auspresser (12) zu steuern.

3. Vorrichtung nach Anspruch 1 oder 2, wobei der Auspresser (12) in Bezug auf die Plattform (48) abgeschrägt ist, um ein Fließen des vom absorbierenden Element (17) ausgepressten Fluids in die Probenvertiefung (50) zu erleichtern.

4. Vorrichtung nach Anspruch 1, 2 oder 3, wobei die Probenvertiefung (50) einen ersten Kanal (72) und einen zweiten Kanal (74) einschließt.

5. Vorrichtung nach Anspruch 4, wobei der erste Kanal (72) und der zweite Kanal (74) einen Testkanal beziehungsweise einen Bestätigungskanal aufweist.

6. Vorrichtung nach Anspruch 5, wobei die Plattform (48) einen Querfließ-Teststreifen (58), der in fluidleitender Verbindung mit dem Prüfkanal steht, und ein Fenster einschließt, um das Betrachten von zumindest einem Teil des Querfließ-Teststreifens zu ermöglichen.

7. Vorrichtung nach Anspruch 5 oder 6, wobei das Sammelmittel weiter einen Bestätigungsbehälter (78) einschließt, der von der Plattform herabhängt und in fluidleitender Verbindung mit dem Bestätigungskanal steht.

8. Vorrichtung nach einem der Ansprüche 1 bis 7, wobei das Sammelmittel ein Verarbeitungsmittel aufweist, einschließlich einem Querfließ-Teststreifen (58) und einem Bestätigungsbehälter (78) zum Prüfen beziehungsweise Bestätigen des vom absorbierenden Element (17) ausgepressten Teils des Fluids.

9. Vorrichtung nach einem der Ansprüche 1 bis 8, die weiter Mittel (82) zum Trennen des Teils des Fluids aufweist, wenn das Fluid ausgepresst und im Sammelmittel gesammelt wird.

10. Vorrichtung nach Anspruch 9, wobei das Mittel zum Trennen eine Zwischenwand aufweist, die sich im Wesentlichen senkrecht zur Plattform (48) in die distale Öffnung (16) des Auspressers erstreckt und zwischen dem ersten Kanal (72) und dem zweiten Kanal (74) angeordnet ist.

11. Vorrichtung nach einem der Ansprüche 1 bis 10, wobei der Auspresser (12) in Bezug auf die Plattform (48) abgeschrägt ist, um ein Fließen des vom absorbierenden Element (12) ausgepressten Teils des Fluides in die Probenvertiefung (50) zu erleichtern.

12. Vorrichtung nach einem der Ansprüche 1 bis 11, die weiter das absorbierende Element (17) aufweist.

13. Vorrichtung nach Anspruch 12, wobei das absorbierende Element (17) geeignet ist, eine Speichelprobe zu absorbieren.

14. Vorrichtung nach einem der Ansprüche 2 bis 13, wobei der Auspresser (12) weiter ein Schlitzmittel (102) einschließt, um das Einführen des absorbierenden Elements (17) und Haltermittels (24) in den Auspresser zu erleichtern.

15. Vorrichtung nach Anspruch 14, das weiter ein Mittel aufweist, das ein enges Ende (104) des Schlitzmit-

tels (102) einschließt, um das Haltemittel (24) im Auspresser (12) zu arretieren und das absorbierende Element (17) in einer komprimierten Position zu halten.

16. Vorrichtung nach Anspruch 15, wobei das Schlitzmittel (102) einen distales Einlassende, das für einen im Wesentlichen nicht-komprimierenden Durchgang des absorbierenden Elements (17) ausgelegt ist, und einen längslaufenden Schlitz einschließt, der in Verbindung mit dem distalen Einlassende steht und der für einen Durchgang des Haltemittels (24) ausgelegt ist.

17. Vorrichtung nach einem der Ansprüche 1 bis 16, wobei das Mittel (112) zum Komprimieren weiter manuell quetschbare Wände des Auspressers einschließt.

18. Vorrichtung nach einem der Ansprüche 1 bis 17, wobei das Mittel zum Komprimieren (112) weiter eine konische Form des Auspressers (12) einschließt.

19. Vorrichtung nach einem der Ansprüche 1 bis 18, wobei das absorbierende Element (17) geeignet ist, Speichelfluid zu absorbieren.

20. Vorrichtung nach einem der Ansprüche 1 bis 19, wobei der Auspresser (12) eine Öffnung an seinem proximalen Ende einschließt, und die Vorrichtung weiter ein Haltemittel (24) aufweist, das durch die Öffnung durchgeht und mit dem absorbierenden Element (17) verbunden ist, um ein manuelles Ziehen des absorbierenden Elements (17) in den Auspresser (12) zu ermöglichen.

21. Verfahren zum Erhalten einer gewünschten Anzahl von Tropfen einer Fluidprobe, wobei das Verfahren die Schritte aufweist:

Vorsehen eines absorbierenden Elements (17);
Vorsehen eines Auspressers (12) mit einem offenen distalen Ende (16), einem im Wesentlichen geschlossenen proximalen Ende und einer Innenfläche, die einen Kanal (20) festlegt;
Aufbringen einer Fluidprobe auf das absorbierende Element (17) und es der Fluidprobe ermöglichen, vom absorbierenden Element absorbiert zu werden;
Erhalten eines ersten Tropfens der Fluidprobe vom absorbierenden Element (17) durch Komprimieren des absorbierenden Elements (17) durch Führen des absorbierenden Elements in den Kanal (20) und es dem absorbierenden Element (17) ermöglichen, von der Innenfläche des Auspressers (12) komprimiert zu werden, um zu bewirken, dass der erste Tropfen vom absorbierenden Element (17) ausgepresst wird;
Sammeln des ersten Tropfens der Fluidprobe, durch Ermöglichen, dass der erste Tropfen vom Auspresser (12) auf einen Sammelbereich fließt; und
Erhalten und Sammeln zusätzlicher Tropfen der Fluidprobe durch fortgesetztes Führen des absorbierenden Elements (17) weiter in den Kanal (20), und es den Tropfen ermöglichen, auf den Sammelbereich zu fließen, bis die gewünschte Anzahl von Tropfen erhalten und gesammelt ist,

dadurch gekennzeichnet, dass die Tropfen gesammelt werden durch Vorsehen einer Plattform (48), die eine Probenvertiefung (50) einschließt, die in fluidleitender Verbindung mit dem offenen distalen Ende (16) des Auspressers (12) steht.

22. Verfahren nach Anspruch 21, wobei ein Halteelement (24) am absorbierenden Element (17) befestigt ist und wobei das absorbierende Element (17) innerhalb des Auspressers (12) durch Ziehen am Halteelement (24) bewegt wird.

23. Verfahren nach Anspruch 21 oder 22, wobei der Schritt des Vorsehens eines Auspressers (12) das Vorsehen eines Auspressers (12) mit einem im Wesentlichen konischen Querschnitt aufweist.

24. Verfahren nach Anspruch 21, 22 oder 23, wobei der Schritt des Aufbringens aufweist: Platzieren des absorbierenden Elements in einem Mund eines Patienten und es dem absorbierenden Element (17) ermöglichen, Speichel vom Mund zu absorbieren.

25. Verfahren nach Anspruch 21, 22, 23 oder 24, das weiter ein getrenntes Verarbeiten der Tropfen aufweist.

26. Verfahren nach Anspruch 25, wobei der Schritt des getrennten Verarbeitens ein Richten des ersten Tropfens auf einen Querfließ-Teststreifen zum Testen und ein Speichern eines anderen Tropfens in einen Behälter zum Verarbeiten des zweiten Teils zu einem späteren Zeitpunkt aufweist.

Revendications

1. Dispositif prélèvement d'échantillon de fluide (10) comprenant :

■ un dispositif d'expression (12) comportant une ouverture distale (16) et adapté pour recevoir un élément absorbant (17) dans lequel un fluide est absorbé ;
■ des moyens, comprenant un orifice (20) du dispositif d'expression (12), pour comprimer l'élément absorbant (17) alors que l'élément ab-

sorbant (17) passe dans le dispositif d'expression (12) pour effectuer l'expression d'au moins une partie du fluide de l'élément absorbant (17) ; et

■ des moyens de collecte, reliés au dispositif d'expression (12), pour collecter la partie de fluide exprimée de l'élément absorbant (17),

caractérisé en ce que les moyens de collecte comprennent une plateforme (48) comprenant une cavité à échantillon (50) en communication fluidique avec l'ouverture distale (16) du dispositif d'expression.

2. Dispositif selon la revendication 1, comprenant en outre des moyens formant attache (24), reliés à l'élément absorbant (17), pour contrôler le passage de l'élément absorbant dans le dispositif d'expression (12).

3. Dispositif selon la revendication 1 ou 2, dans lequel le dispositif d'expression (12) est incliné par rapport à la plateforme (48) pour faciliter un écoulement du fluide exprimé de l'élément absorbant (17) dans la cavité à échantillon (50).

4. Dispositif selon la revendication 1, 2 ou 3, dans lequel la cavité à échantillon (50) comprend un premier orifice (72) et un deuxième orifice (74).

5. Dispositif selon la revendication 4, dans lequel le premier orifice (72) et le deuxième orifice (74) comprennent un orifice de test et un orifice de confirmation, respectivement.

6. Dispositif selon la revendication 5, dans lequel la plateforme (48) comprend une bande de test d'écoulement latéral (58) en communication fluidique avec l'orifice de test, et une fenêtre pour permettre l'observation d'au moins une partie de la bande de test d'écoulement latéral.

7. Dispositif selon la revendication 5 ou 6, dans lequel les moyens de collecte comprennent en outre un récipient de confirmation (78) pendant de la plateforme et en communication fluidique avec l'orifice de confirmation.

8. Dispositif selon l'une quelconque des revendications 1 à 7, dans lequel les moyens de collecte comprennent des moyens de traitement, comprenant une bande de test d'écoulement latéral (58) et un récipient de confirmation (78) pour respectivement tester et confirmer la partie de fluide exprimée de l'élément absorbant.

9. Dispositif selon l'une quelconque des revendications 1 à 8, comprenant en outre des moyens (82) pour diviser la partie de fluide alors que le fluide est exprimé et collecté dans les moyens de collecte.

10. Dispositif selon la revendication 9, dans lequel les moyens pour diviser comprennent une séparation s'étendant sensiblement normalement à la plateforme (48) dans l'ouverture distale (16) du dispositif d'expression et disposée entre le premier orifice (72) et le deuxième orifice (74).

11. Dispositif selon l'une quelconque des revendications 1 à 10, dans lequel le dispositif d'expression (12) est incliné par rapport à la plateforme (48) pour faciliter un écoulement de la partie de fluide exprimée de l'élément absorbant (12) et dans la cavité à échantillon (50).

12. Dispositif selon l'une quelconque des revendications 1 à 11, comprenant en outre ledit élément absorbant (17).

13. Dispositif selon la revendication 12, dans lequel l'élément absorbant (17) est capable d'absorber un échantillon de salive.

14. Dispositif selon l'une quelconque des revendications 2 à 13, dans lequel le dispositif d'expression (12) comprend en outre des moyens formant fente (102) pour faciliter l'insertion de l'élément absorbant (17) et des moyens formant attache (24) dans le dispositif d'expression.

15. Dispositif selon la revendication 14, comprenant en outre des moyens, comprenant une extrémité étroite (104) des moyens formant fente (102), pour verrouiller les moyens formant attache (24) dans le dispositif d'expression (12) et maintenir l'élément absorbant (17) dans une position comprimée.

16. Dispositif selon la revendication 15, dans lequel les moyens formant fente (102) comprennent une entrée d'extrémité distale, dimensionnée pour le passage sensiblement non comprimé de l'élément absorbant (17), et une fente longitudinale en communication avec l'entrée d'extrémité distale, dimensionnée pour le passage des moyens formant attache (24).

17. Dispositif selon l'une quelconque des revendications 1 à 16, dans lequel les moyens (112) pour comprimer comprennent en outre des parois pouvant être pressées manuellement du dispositif d'expression.

18. Dispositif selon l'une quelconque des revendications 1 à 17, dans lequel les moyens pour comprimer (112) comprennent en outre une forme conique du dispositif d'expression (12).

19. Dispositif selon l'une quelconque des revendications

1 à 18, dans lequel l'élément absorbant (17) est capable d'absorber de la salive.

20. Dispositif selon l'une quelconque des revendications 1 à 19, dans lequel le dispositif d'expression (12) comprend une ouverture dans une extrémité proximale de celui-ci, et le dispositif comprend en outre des moyens formant attache (24), passant à travers l'ouverture et reliés à l'élément absorbant (17), pour permettre de tirer manuellement l'élément absorbant (17) dans le dispositif d'expression (12).

21. Procédé d'obtention d'un nombre souhaité de gouttes d'un échantillon de fluide, le procédé comprenant les étapes consistant à :

- fournir un élément absorbant (17) ;
- fournir un dispositif d'expression (12) comportant une extrémité distale (16) ouverte, une extrémité proximale sensiblement fermée et une surface intérieure définissant un orifice (20) ;
- appliquer un échantillon de fluide à l'élément absorbant (17) et permettre l'absorption de l'échantillon de fluide par celui-ci ;
- obtenir une première goutte de l'échantillon de fluide de l'élément absorbant (17) en comprimant l'élément absorbant (17) en faisant passer l'élément absorbant dans l'orifice (20), et permettre la compression de l'élément absorbant (17) par la surface intérieure du dispositif d'expression (12) pour provoquer l'expression de la première goutte de l'élément absorbant (17) ;
- collecter la première goutte de l'échantillon de fluide en permettant l'écoulement de la première goutte du dispositif d'expression (12) sur une zone de collecte ; et
- obtenir et collecter des gouttes supplémentaires de l'échantillon de fluide en continuant de faire passer l'élément absorbant (17) davantage dans l'orifice (20) et permettre aux gouttes de s'écouler sur la zone de collecte jusqu'à ce que le nombre souhaité de gouttes soit obtenu et collecté,

caractérisé en ce que les gouttes sont collectées en fournissant une plateforme (48) comprenant une cavité à échantillon (50) en communication fluidique avec l'extrémité distale (16) ouverte du dispositif d'expression (12).

22. Procédé selon la revendication 21, dans lequel une attache (24) est fixée à l'élément absorbant (17), et dans lequel l'élément absorbant (17) est déplacé dans le dispositif d'expression (12) en tirant l'attache (24).

23. Procédé selon la revendication 21 ou 22, dans lequel l'étape de fourniture d'un dispositif d'expression (12) comprend la fourniture d'un dispositif d'expression (12) ayant une section transversale sensiblement conique.

24. Procédé selon la revendication 21, 22 ou 23, dans lequel l'étape d'application comprend le placement de l'élément absorbant (17) dans la bouche d'un patient et le fait de permettre à l'élément absorbant (17) d'absorber de la salive de la bouche.

25. Procédé selon la revendication 21, 22, 23 ou 24, comprenant en outre le traitement des gouttes séparément.

26. Procédé selon la revendication 25, dans lequel l'étape de traitement séparé comprend le fait de diriger la première goutte sur une bande de test d'écoulement latéral pour tester et stocker une autre goutte dans un récipient pour le traitement de la deuxième partie ultérieurement.

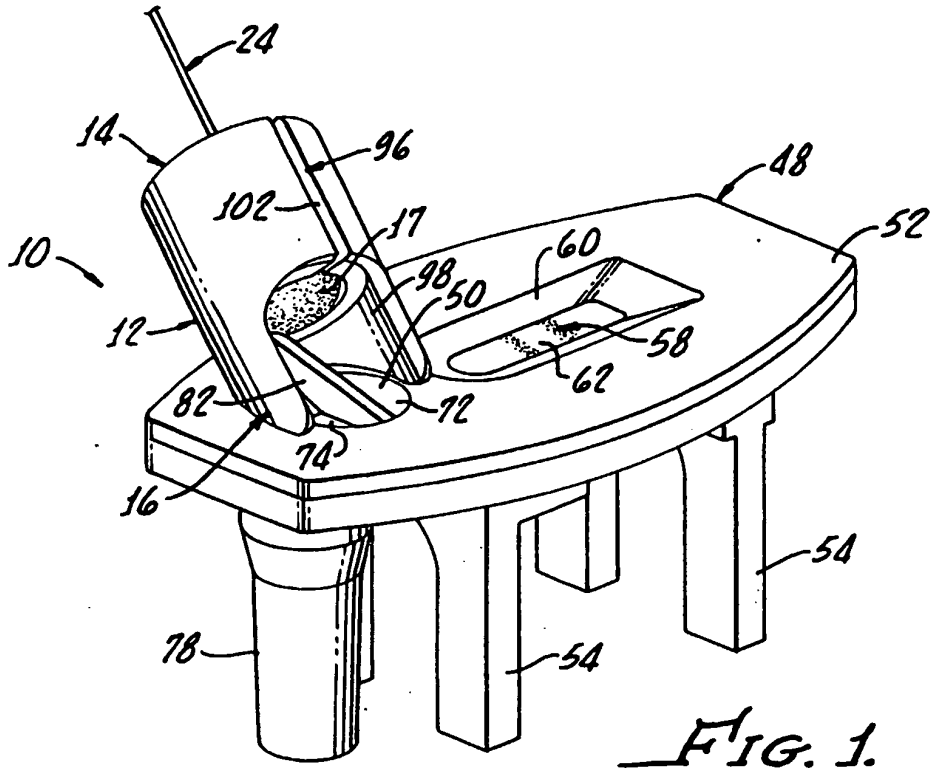

FIG. 1.

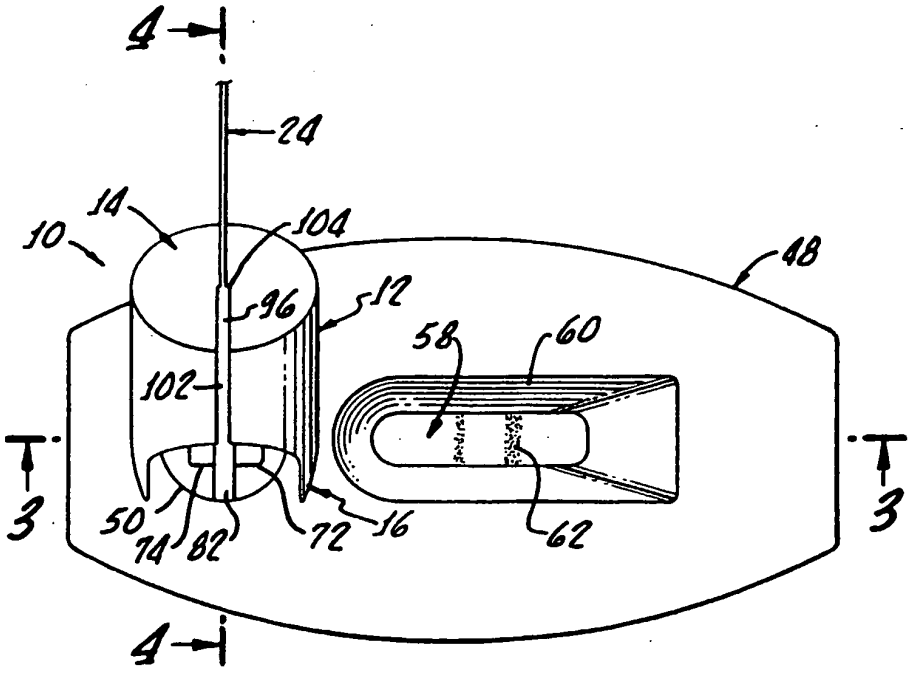

FIG. 2.

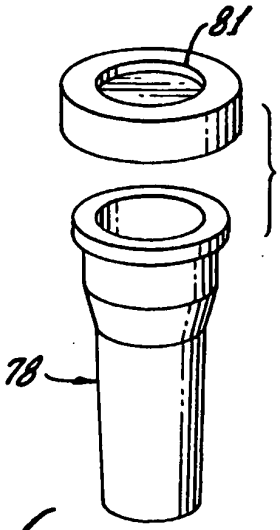

FIG. 6.

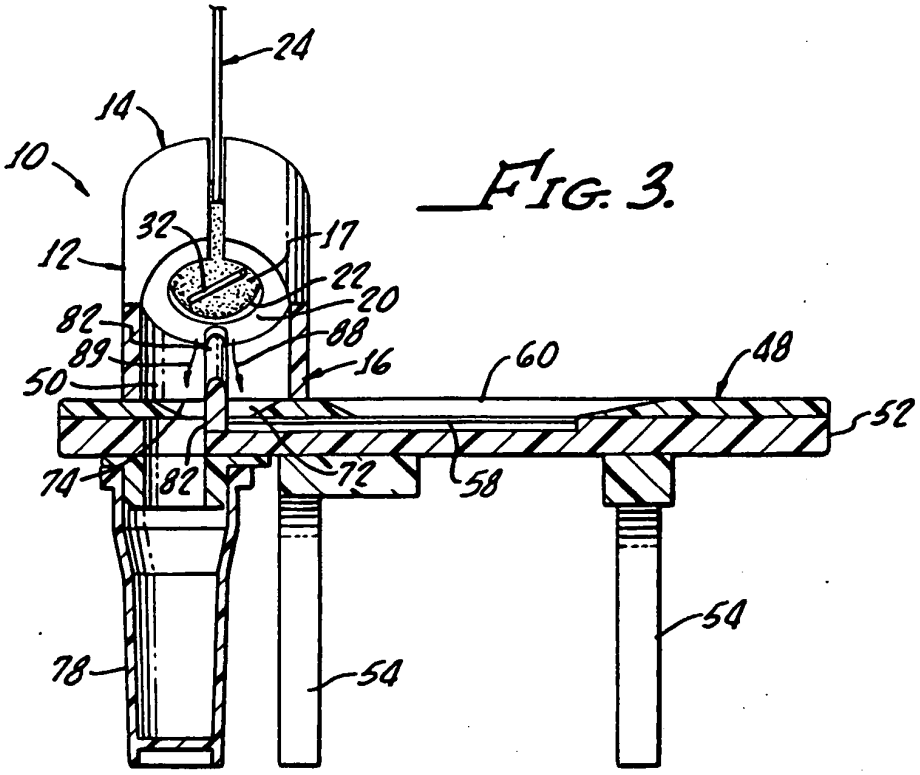

FIG. 3.

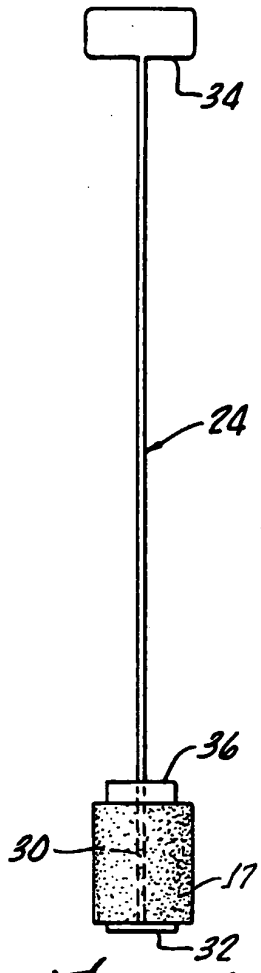

FIG. 5.

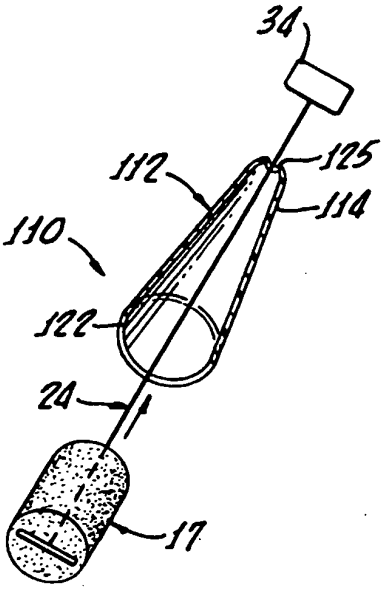

FIG. 7.

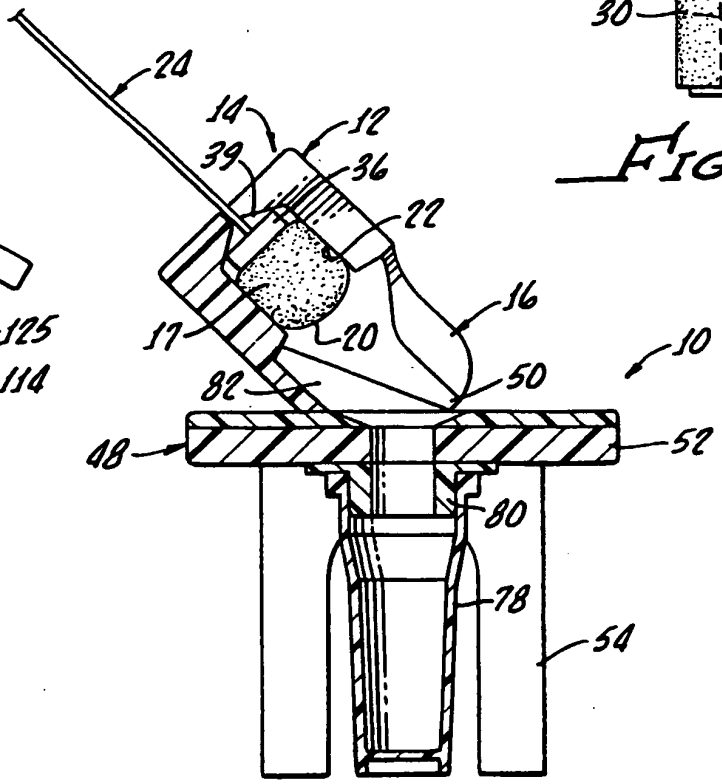

FIG. 4.

REFERENCES CITED IN THE DESCRIPTION

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专利名称(译)	唾液采样装置		
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[标]申请(专利权)人(译)	凡利安股份有限公司		
申请(专利权)人(译)	VARIAN，INC.		
当前申请(专利权)人(译)	VARIAN，INC.		
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优先权	09/477875 2000-01-05 US		
其他公开文献	EP1250415A1 EP1250415A4		
外部链接	Espacenet		

摘要(译)

唾液采样装置包括表达杯，能够吸收流体样本的吸收性泡沫拭子和固定在泡沫拭子上的柔性系绳。 泡沫拭子用于收集唾液等液体样本的样本，而系绳适于使用户将饱和的泡沫拭子卫生地吸入表达杯中，泡沫拭子在其中被压缩：吸收的液体 以此方式一滴一滴地表达出来。 该装置还可以包括具有试剂条的平台，该试剂条用于吸收表达的流体以显示测试结果。 该装置还可以包括分隔器，用于在测试之前将表达的流体分成两个或更多个等分试样，使得等分试样之一可以用于确认或稍后测试流体。 在一个实施例中，指示杯包括锥形横截面以实现泡沫拭子的逐渐压缩。