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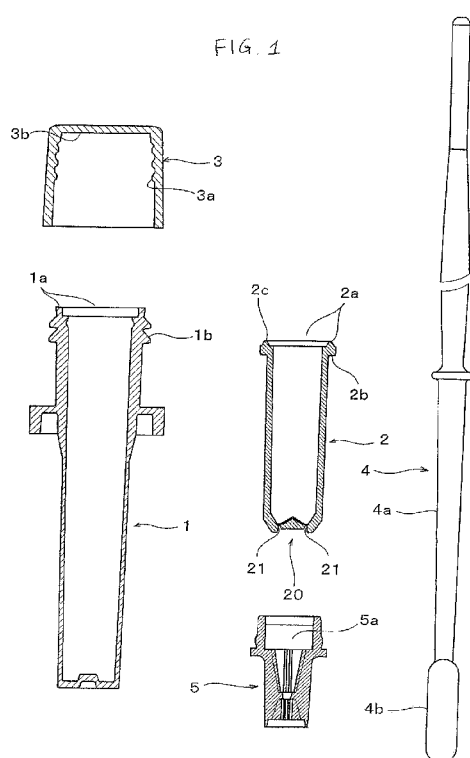
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(54) **Title:** TEST KIT



(57) **Abstract:** There is provided a test kit that can be used to test a test sample prepared by processing a specimen using two kinds of pharmaceutical agents. The test kit is compact, capable of readily and reliably preparing the test sample, and improved in user-friendliness. The test kit comprises a chamber (1), an inner chamber (2), a sealing member (3), and a specimen collecting tool (4). An annular groove (21) is formed in a peripheral portion of an outer surface on a bottom portion (20) of an inner chamber (2), and a thin film portion (23) constituting a side surfaces (21a) and (21b) facing each other constituting the groove (22) connects the bottom portion (20) with the other portions of the inner chamber 2. A specimen collecting tool (4) presses a predetermined position Q in the peripheral portion of the bottom portion, stretching the thin film portion. When the thin film portion thus stretches, tilting the bottom portion, side surfaces (21a) and (21b) constituting the groove (21) abut each other at a predefined position P in the peripheral direction of the bottom portion, and the stretch of the thin film portion (23) is restricted nearby. When the pressing force is further applied to the predefined position Q by the specimen collecting tool, the thin film portion (23) further stretches near the position Q to finally break, and the specimen collecting tool penetrates through the bottom portion of the inner chamber.

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TEST KIT**[0001]**

5 The present invention relates to a test kit and, more particularly, to a test kit used when a test sample prepared by processing a specimen collected from a patient's body such as his pharynx using two kinds of pharmaceutical agents is tested to test, for example, whether antigens of Group A Streptococcus
10 are present in the specimen.

[BACKGROUND ART]**[0002]**

 To test the presence or absence of antigens of Group A Streptococcus, forexample, a specimen collected from a patient's
15 body such as his pharynx (for example, specimen attached to a cotton ball of a cotton swab used as a specimen collector) is dipped in a mixture obtained by mixing a first pharmaceutical agent (for example, 2 mol/L of sodium nitrite) with a second pharmaceutical agent (for example, 0.3 mol/L of acetic acid),
20 and a resulting test sample, which is the mixture further including an adequate amount of the specimen transferred thereto (specimen extract), is tested to test the presence of antigens of Group A Streptococcus in the specimen.

[0003]

25 A test kit used in a test where mixing of the first and

second pharmaceutical agents is thus required, for example, includes a first container for housing the first pharmaceutical agent therein, a second container for housing the second pharmaceutical agent therein, a specimen collecting tool for collecting the specimen, and a processing container used to mix the first pharmaceutical agent with the second pharmaceutical agent and also dip the specimen collecting tool which collected the specimen in the resulting mixture to transfer the specimen thereto.

[0004]

To use the test kit, it is necessary to prepare the first and second containers separately and further the processing container. Thus, the test kit needs to be equipped with at least four structural elements separately, including the specimen collecting tool, and it is awkward to store such a test kit somewhat bulky.

[0005]

When the mixture to which the specimen is already transferred is transported to a laboratory, it is necessary to prepare a sealing member to seal the processing container, further increasing the structural elements.

[0006]

As illustrated in Figs. 7 and 8, another example of the test kit which requires mixing of the first and second pharmaceutical agents includes: a first container (chamber) 61

made of resin for housing a first pharmaceutical agent 51 therein;
a second container (inner chamber) 62 made of resin for housing
a second pharmaceutical agent 52 therein, the second container
62 being inserted in the first container 61 through an opening
5 61a of the first container 61 to seal the opening 61a of the
first container 61; a sealing member 63 provided to seal an opening
62a of the second container 62 inserted in the first container
61 to seal the opening 61a, the sealing member 63 further holding
the second container 62 engaged with the opening 61a of the first
10 container 61 to seal the opening 61a of the first container 61;
and a specimen collecting tool, for example, a cotton swab (not
illustrated in the drawings) having a specimen collector which
collects and retains a specimen such as a cotton ball at a first
end thereof.

15 **[0007]**

In the test kit, a flange portion 61b is provided in the
peripheral portion of the opening 61a of the first container
61, and a flange portion 62b is provided in the peripheral portion
of the opening 62a of the second container 62. When the flange
20 portion 62b of the second container 62 is engaged with the opening
61a of the first container 61, the second container 62 is held
in the opening 61a of the first container 61, and a lower surface
of the flange portion 62b abuts the opening 61a of the first
container 61, which further ensures the sealing of the first
25 container 61.

[0008]

The sealing member 63 used in the test kit is an aluminum foil having a resin film which joins the respective elements. When the aluminum foil (sealing member) 63 is bonded to the opening 61a of the first container 61, opening 62a of the second container 62, and flange portions 61b and 62b of the first and second containers 61 and 62 so as to cover all of these portions, the first container 61 and the second container 62 are held as a unit with the first and second pharmaceutical agents 51 and 52 enclosed therein.

[0009]

To further describe the test kit, after the specimen is collected and the sealing member 63 is removed, the specimen collector (for example, cotton ball) of the specimen collecting tool (for example, cotton swab) is inserted in the second container 62 and further pushed thereinto to penetrate through a bottom portion of the second container 62 so that the specimen collector (cotton ball) to which the specimen is attached arrives in the first container 61, the second pharmaceutical agent 52 of the second container 62 is guided into the first container 61 to be mixed with the first pharmaceutical agent 51 of the first container 61, and the specimen collector of the specimen collecting tool to which the specimen is attached is dipped in the resulting mixture including the first and second pharmaceutical agents so that the specimen is transferred to

the mixture. As a result, the test sample, which is the mixture including the first and second pharmaceutical agents further including the specimen transferred thereto, is obtained in the first container 61.

5 [0010]

The test kit, however, has some problems. When the test kit is used, the specimen collecting tool (cotton swab) is pushed into the second container 62 to break through the bottom portion thereof. However, the bottom portion may be too stretchy
10 depending on a material of the second container 62, and the specimen collecting tool (cotton swab), though pushed hard all the way in, possibly fails to penetrate through (break through) the bottom portion, or the bottom portion may be too thick for the specimen collecting tool to break therethrough unless a very
15 large force is applied thereto. Thus, these possible disadvantages of the test kit may deteriorate workability.

[0011]

Further, the first container of the test kit cannot be sealed after the aluminum foil, which is the sealing member 63,
20 is removed to transfer the specimen to the mixture. Therefore, it is practically infeasible to transport the test sample to the laboratory.

[DISCLOSURE OF THE INVENTION]

[PROBLEMS TO BE SOLVED BY THE INVENTION]

25 [0012]

The present invention has been made to solve the conventional problems. An object of the present invention is to provide a test kit that can be used to test a test sample prepared by processing a specimen collected from a patient's body such as his pharynx using two kinds of pharmaceutical agents to test, for example, whether antigens of Group A Streptococcus are present in the specimen. The test kit provided by the present invention is compact, capable of readily and reliably preparing the test sample and safely transporting the prepared test sample to a laboratory, and improved in user-friendliness.

[MEANS FOR SOLVING PROBLEMS]

[0013]

To achieve the above object, a test kit according to the present invention (claim 1) includes:

a) a chamber for housing a first pharmaceutical agent therein, the chamber being a cylindrical member having an opening at a first end thereof and a second end which is sealed;

b) an inner chamber for housing a second pharmaceutical agent therein, the inner chamber being a cylindrical member having an opening at a first end thereof and a second end which is sealed by a bottom portion and provided with a flange portion around the opening, the inner chamber being inserted into the chamber with the second end thereof first through the opening of the chamber to seal the opening of the chamber, the flange portion in the first end abutting the first end of the chamber

so as to be held at an abutting position;

c) a sealing member for sealing the opening of the inner chamber and making the flange portion of the inner chamber abut the opening at the first end of the chamber to seal the opening of the chamber; and

5 d) a specimen collecting tool including a specimen collector for collecting and retaining a specimen in at least one end of a member thereof having a shape of a shaft, wherein the specimen collector of the specimen collecting tool to which the collected specimen is attached is inserted into 10 the inner chamber through the opening so that the specimen collector penetrates through the bottom portion of the inner chamber to be seated in the chamber, the second pharmaceutical agent inside the inner chamber is guided into the chamber to be mixed with the first pharmaceutical agent in the chamber, 15 the specimen collector to which the specimen is attached is dipped in a resulting mixture including the first and second pharmaceutical agents so that the specimen is transferred into the mixture, and the specimen collecting tool as well as the 20 inner chamber is thereafter removed from the chamber so that a test sample, which is a mixture including the first and second pharmaceutical agents and further including the specimen transferred thereto, is obtained in the chamber,

an inner surface on the bottom portion of the inner chamber 25 is gradually raised upward from a peripheral portion toward a

central portion thereof,

an annular groove formed circumferentially along the bottom portion of the inner chamber is formed in a peripheral portion of an outer surface on the bottom portion of the inner chamber, a thin film portion constituting a bottom portion of the groove connects the bottom portion of the inner chamber with other portions, a predetermined location in the peripheral portion of the bottom portion of the inner chamber is pressed by the specimen collecting tool, side surfaces facing each other constituting the groove abut each other at a predetermined circumferential position of the bottom portion when the thin film portion stretches at the pressed location and a vicinity thereof, making the bottom portion tilted, and the thin film portion is restricted from stretching near the abutting position, and when the predetermined position is pressed by the specimen collecting tool, the thin film portion further stretches at a position where the stretch is not restricted to finally break so that the specimen collecting tool penetrates through the bottom portion of the inner chamber.

[0014]

As described above, the test kit according to the present invention is configured such that the annular groove formed circumferentially along the bottom portion of the inner chamber is formed in the peripheral portion of the outer surface on the bottom portion of the inner chamber, the thin film portion

constituting the bottomportion of the groove connects the bottom
portion of the inner chamber with the other portions of the inner
chamber, the predetermined location in the peripheral portion
of the bottom portion of the inner chamber is pressed by the
specimen collecting tool, side surfaces facing each other
5 constituting the groove abut each other at a predetermined
circumferential position of the bottom portion when the thin
film portion stretches at the pressed location and a vicinity
thereof, making the bottom portion tilted, and the thin film
portion is restricted from stretching near the abutting position,
10 and when the predetermined position is pressed by the specimen
collecting tool, the thin film portion further stretches at a
position where the stretch is not restricted to finally break
so that the specimen collecting tool penetrates through the
bottom portion of the inner chamber . Accordingly, the specimen
15 collecting tool which already collected the specimen can readily
and reliably break through the bottomportion of the inner chamber .
Thus , the first and second pharmaceutical agents are mixed after
the specimen is collected, and the specimen is transferred to
the resulting mixture. The present invention can provide the
20 test kit improved in user-friendliness and capable of readily
and reliably preparing the test sample by processing the specimen
using two kinds of pharmaceutical agents.

The first and second pharmaceutical agents are usually
25 pharmaceutical agents in a form of liquid. As disclosed in the

invention of claim 4, however, the first pharmaceutical agent may be a pharmaceutical agent in a form of powder, which will be described later.

[0015]

5 The test kit according to claim 2 further includes a drip chip for dripping the test sample into the chamber so that the test sample is tested, wherein the drip chip is attached to the opening of the chamber after the specimen collecting tool and the inner chamber are removed from the chamber.

10 [0016]

 When the drip chip attached to the opening of the chamber and used to drip the test sample into the chamber is further provided in the test kit, the test sample in the chamber, which is the mixture further including the specimen transferred thereto, can be readily and reliably tested after the specimen collecting tool and the inner chamber are removed from the chamber. This configuration can realize the effect of the present invention.

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[0017]

 In the test kit according to claim 3, the specimen collecting tool is a cotton swab having a cotton ball serving as the specimen collector in the at least one end thereof.

20

[0018]

 As described above, when the specimen collecting tool is the cotton swab having the cotton ball serving as the specimen collector in the at least one end thereof, it is possible to

25

provide a test kit that can collect the specimen without a specially designed tool. Further, when the specimen collecting tool (cotton swab) is pulled out after penetrating through the bottom portion with the cotton ball left caught in the through hole formed in the bottom portion, the specimen collecting tool and the inner chamber can be easily removed from the chamber. This configuration can further realize the effect of the present invention.

[0019]

In the test kit according to claim 4, the first pharmaceutical agent housed in the chamber is a pharmaceutical agent in a form of powder, and the second pharmaceutical agent housed in the inner chamber is a pharmaceutical agent in a form of liquid.

[0020]

The test kit according to the present invention is configured such that the specimen collecting tool which already collected the specimen penetrates through the bottom portion of the inner chamber. Therefore, the test kit according to the present invention is obviously applicable to the case where the first and second pharmaceutical agents are in the form of liquid, and is also applicable to the case where the first pharmaceutical agent housed in the chamber is the pharmaceutical agent in the form of powder, and the case where the second pharmaceutical agent housed in the inner chamber is the pharmaceutical agent

in the form of liquid as recited in claim 4. When the specimen
collecting tool penetrates through the bottom portion of the
inner chamber, the pharmaceutical agent in the form of liquid
housed in the inner chamber flows downward therefrom to be mixed
5 with the first pharmaceutical agent. Then, the first
pharmaceutical agent is dissolved in the pharmaceutical agent
in the form of liquid so that the mixture can be prepared.

[0021]

However, the second pharmaceutical agent in the form of
10 powder may dwell in the inner chamber, failing to fall downward
into the chamber even after the bottom portion of the inner chamber
is broken. Therefore, the second pharmaceutical agent to be
housed in the inner chamber is preferably a pharmaceutical agent
in the form of liquid.

15 **[0022]**

In the test kit according to claim 5, the sealing member
is a threaded cap in an inner peripheral surface thereof, the
thread of the cap being engaged with a thread formed in an outer
peripheral portion of the chamber, and an inner upper surface
20 of the cap abuts the opening of the inner chamber to seal the
inner chamber, the flange portion of the inner chamber abuts
the opening of the chamber to seal the chamber by using the inner
chamber, and the inner upper surface abuts the opening of the
chamber to seal the chamber after the inner chamber is removed
25 from the chamber.

[0023]

When the sealing member having the above configuration is used, the chamber and the inner chamber can be both sealed without fail with the pharmaceutical agents enclosed therein before the test, and the chamber housing therein the test sample prepared by transferring the collected specimen to the mixture (chamber after the inner chamber and the specimen collecting tool are already removed therefrom) can also be surely sealed. Then, the prepared test sample can be safely and reliably transported to, for example, a laboratory. This configuration can further realize the effect of the present invention.

[0024]

In the test kit according to claim 6, a region circumferentially along an inner peripheral surface of the chamber and a region circumferentially along an outer peripheral surface of the inner chamber abut each other at a position closer to the bottom portion of the inner chamber than an axially central portion thereof to seal the chamber.

[0025]

When the region circumferentially along the inner peripheral surface of the chamber and the region circumferentially along the outer peripheral surface of the inner chamber abut each other at the position closer to the bottom portion of the inner chamber than an axially central portion thereof to seal the chamber, the sealing effect by the sealing

member is enhanced by the sealing effect by the abutting portions of the inner peripheral surface of the chamber and the outer peripheral surface of the inner chamber. This sealing effect thus further ensured can prevent such an undesirable event that the pharmaceutical agent in the chamber (first pharmaceutical agent) may leak out near the opening of the chamber when the sealing member is removed during use. Thus, the test kit can be a more reliable device.

[0026]

The test kit according to claim 7 further includes a filter for filtering and removing solid matter in a passageway of the drip chip where the test sample travels.

[0027]

As described above, when the filter is provided in the passageway of the drip chip where the test sample travels, suspended matter or slurry-like matter, for example, resulting from the specimen can be removed, so that the test sample not including any solid matter can be tested.

[0028]

In the test kit according to claim 8, the test kit is used in a test for hemolytic streptococcal infection.

[0029]

When the test kit according to the present invention is used, a test for hemolytic streptococcal infection in which it is necessary to test a test sample prepared by processing a

specimen using two kinds of pharmaceutical agents can be tested efficiently and without fail.

[BRIEF DESCRIPTION OF THE DRAWINGS]

[0030]

5 Fig. 1 is an exploded view illustrating the configuration of a test kit (sectional views of main structural elements) according to an embodiment of the present invention;

 Fig. 2 is a sectional view of an assembled unit including a chamber in which a first pharmaceutical agent is housed, an inner chamber in which a second pharmaceutical agent is housed,
10 and a sealing member, which are structural elements of the test kit according to the embodiment of the present invention;

 Fig. 3 is an enlarged view of a main section of the test kit according to the embodiment of the present invention,
15 illustrating a method of using the test kit, wherein a specimen collecting tool abuts a bottom portion of the inner chamber;

 Fig. 4 is an enlarged view of a main section of the test kit according to the embodiment of the present invention, illustrating the method of using the test kit, wherein the
20 specimen collecting tool is pressed onto the bottom portion of the inner chamber to penetrate through the bottom portion of the inner chamber;

 Fig. 5 is a view of the method of using the test kit according to the embodiment of the present invention, wherein a specimen
25 collector of the specimen collecting tool is dipped in a mixture

of pharmaceutical agents in the chamber;

Fig. 6 is a view of a method of using the test kit according to the embodiment of the present invention, wherein a test sample prepared by transferring the specimen to the mixture is supplied to a test by way of a drip chip;

Fig. 7 is an exploded view of a conventional test kit; and

Fig. 8 is a sectional view of an assembled unit including a first container (chamber) and a second container (inner chamber) constituting the conventional test kit.

[BEST MODE FOR CARRYING OUT THE INVENTION]

[0031]

Hereinafter, the technical characteristics of the present invention are described in further detail referring to an embodiment .

[First Embodiment]

[0032]

In a first embodiment , a test sample prepared by processing a specimen using two kinds of pharmaceutical agents is tested. The description is given below referring to a test kit used to test whether antigens of Group A Streptococcus are present.

[0033]

As illustrated in Figs. 1 and 2, the test kit used in Embodiment 1 includes:

a) a chamber 1 made of resin for housing a first

pharmaceutical agent 11 therein (Fig. 2), the chamber 1 being a cylindrical member having an opening 1a at first end thereof and a second end which is sealed;

5 b) an inner chamber 2 made of resin for housing a second pharmaceutical agent 12 therein (Fig. 2), the inner chamber 2 being a cylindrical member having an opening 2a at a first end thereof and a second end which is sealed by a bottom portion 20 and provided with a flange portion 2b around the opening 2a, and the inner chamber 2 being inserted in the chamber 1 with
10 the second end thereof first through the opening 1a of the chamber 1 to seal the opening 1a of the chamber 1, and the flange portion 2b in the first end abutting the opening 1a at the first end of the chamber 1 to be held at the abutting portion;

c) a sealing member 3 for sealing the opening 2a of the
15 inner chamber 2 and making the flange portion 2b of the inner chamber 2 abut the opening 1a at the first end of the chamber 1 to seal the opening 1a of the chamber 1;

d) a specimen collecting tool 4 including a specimen collector 4b for collecting and retaining a specimen in at least
20 one end of a shaft-like member 4a; and

e) a drip chip 5 for dripping a test sample S obtained by transferring the specimen to a mixture of the first and second pharmaceutical agents 11 and 12 (Fig. 5) from the chamber 1 so that the test sample S can be tested.

25 [0034]

An example of the first pharmaceutical agent is 2 mol/L of sodium nitrite, and an example of the second pharmaceutical agent is 0.3 mol/L of acetic acid.

[0035]

5 Describing the specimen collecting tool 4 used in the embodiment, the shaft-like member 4a made of resin such as polystyrene is provided with on one end thereof a cotton ball serving as the specimen collector 4b for collecting and retaining the specimen, a generally called cotton swab. To obtain the
10 cotton ball, synthetic fiber is flock-finished so that the specimen can be collected and retained well.

[0036]

The specimen collecting tool 4 according to the present invention is not necessarily limited to the cotton swab, and
15 the cotton swab may have a brush on one end thereof. Any other specimen collecting tools can be used as far as the specimen can be thereby collected and retained.

[0037]

All of the structural elements but the *specimen collecting*
20 tool 4 in the test kit used in the embodiment are transparent or semi-transparent and made of materials having plasticity (low-density polyethylene in the embodiment). However, what materials are used to form the structural elements of the test kit according to the present invention is not particularly
25 limited, and various materials are usable unless the operational

effect of the present invention is not undermined.

[0038]

An inner surface on the bottom portion of the inner chamber 2 is gradually raised upward from its periphery toward center.

5 [0039]

In a peripheral portion of an outer surface on the bottom portion 20 of the inner chamber 2, an annular groove 21 is formed circumferentially along the bottom portion 20. As illustrated in Figs. 3 and 4, the bottom portion 20 of the inner chamber 2 is connected to the other portions of the inner chamber 2 with a thin film portion 23 constituting a bottom (groove bottom) 22 of the groove 21.

More clearly describing the structure, the groove 21 formed circumferentially along the bottom portion 20 includes side walls 21a and 21b facing each other, and the groove bottom portion (thin film portion) 22.

[0040]

To regulate the movement of the groove 21 when the specimen collecting tool is pressed onto the bottom portion 20 to penetrate therethrough as described later, the groove 21 is formed with an angle of a small degree in its depth direction relative to an axial direction of the inner chamber 2, and the side walls 21a and 21b facing each other are formed with a predefined angle so that an interval therebetween is smaller toward the groove bottom portion 22.

However, the structural characteristic of the groove 21 is not particularly limited, and the groove 21 can be structurally modified to meet the needs as far as the object of the present invention can be accomplished.

[0041]

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15

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After the specimen is collected, the specimen collector 4b of the specimen collecting tool 4 to which the specimen is attached is inserted in the inner chamber 2 through the opening 2a to penetrate through the bottom portion 20 so that the specimen collector 4b of the specimen collecting tool 4 to which the specimen is attached can arrive in the chamber 1. Further, the second pharmaceutical agent 12 in the inner chamber 2 is guided into the chamber 1 to be mixed with the first pharmaceutical agent 11 in the chamber 1, and the specimen collector 4b to which the specimen is attached is dipped in the mixture 13 of the first and second pharmaceutical agents 11 and 12 so that the specimen is transferred to the mixture 13. When the specimen is transferred to the mixture 13 of the first and second pharmaceutical agents 11 and 12 (Fig. 5), the test sample S is prepared. Then, the specimen collecting tool 4 is removed from the chamber 1 as well as the inner chamber 2. Thus, the test samples, which is the mixture 13 (Fig. 5) including the specimen transferred thereto, is obtained in the chamber 1.

[0042]

25

The sealing member 3 is a threaded cap in an inner peripheral

surface thereof, the thread 3a of the cap being engaged with a thread 1b formed in an outer peripheral portion of the chamber 1, and an inner upper surface 3b of the cap abuts the opening 2a of the inner chamber 2 (first end of the inner chamber 2) to seal the inner chamber 2, the flange portion 2b of the inner chamber 2 abuts the opening 1a of the chamber 1 (stepwise portion on the first end of the chamber 1) to seal the chamber 1 by using the inner chamber 2, and the inner upper surface 3b abuts the opening 1a of the chamber 1 to seal the chamber 1 after the inner chamber 2 is removed from the chamber 1.

A projected portion 2c is formed on an end surface of the inner chamber 2 to ensure close contact with the inner upper surface 3b of the sealing member (cap) 3 so that the sealing effect can be reliably exerted.

[0043]

To press the inner upper surface 3b against the opening 1a of the chamber 1 to seal the chamber 1 after the inner chamber 2 is removed from the chamber 1, a projected portion may be formed on one end surface of the chamber 1 where the opening 1a is provided so that the chamber 1 is more reliably sealed.

[0044]

In the test kit according to the embodiment, a small projected portion 1c is formed along an inner circumference of the chamber 1 at a position closer to the bottom portion than the axial center of the inner chamber 2 as illustrated in Fig.

2. In the presence of such a projected portion, the inner peripheral surface of the chamber 1 and the outer peripheral surface of the inner chamber 2 unfailingly abut each other so that the chamber 1 can be sealed well by the abutting portion.

5 [0045]

The projected portion is not the only option of the additional structural element which helps the inner peripheral surface of the chamber 1 and the outer peripheral surface of the inner chamber 2 unfailingly abut each other at a position closer to the bottom portion than the axial center of the inner chamber 2. A projected portion may be formed on the outer peripheral surface of the inner chamber 2 in a manner opposite to the embodiment.

Other than these examples, a shallow recessed groove may be formed along the outer peripheral surface of the inner chamber 2 as well as the projected portion formed on the inner peripheral surface of the chamber 1. The shallow recessed groove is formed at a predefined position on the outer peripheral surface of the inner chamber 2 so as to fit into the projected portion 1c.

It is an alternative option to form a recessed groove in the inner peripheral surface of the chamber 1 and a projected portion on the outer peripheral surface of the inner chamber 2. Thus, the additional structural element can have any structure as far as it helps the inner peripheral surface of the chamber 1 and the outer peripheral surface of the inner chamber

2 closely fit into each other.

[0046]

5 The drip chip 5 is used to drip the test sample S from the chamber 1 so that the test sample s, which is the mixture 13 of the first and second pharmaceutical agents 11 and 12 and further including the specimen transferred thereto, can be tested.

[0047]

10 The drip chip 5 is fitted in the opening 1a of the chamber 1 which is uncovered with the sealing member 3 as illustrated in Fig. 6, and a liquid passageway 5a through which the test sample S travels is provided inside thereof.

[0048]

15 The drip chip 5 may include a filter in a part of the liquid passageway 5a. When the filter is provided in the passageway (liquid passageway) 5a of the test sample S in the drip chip 5, suspended matter or slurry-like matter, for example, resulting from the specimen can be removed so that the filtered test sample S including no solid matter can be tested.

20 [0049]

As illustrated in Fig. 2, a description is given to a specimen processing method wherein the specimen is processed by the test kit in which the structural elements are assembled to test whether antigens of Group A Streptococcus are present 25 in the specimen.

[0050]

1) First, a specimen is collected from a patient's body such as his pharynx by using the specimen collecting tool 4.

[0051]

5 2) Then, the sealing member (cap) 3 of the test kit illustrated in Fig. 2 is removed, and the specimen collector 4a of the specimen collecting tool 4 to which the collected specimen is attached is inserted in the inner chamber 2 through the opening 2a.

10 As illustrated in Fig. 3, the specimen collector 4a on one end of the specimen collecting tool 4 is pushed against a predefined position on the bottom portion 20 in the inner chamber 2.

 In the test kit used in the embodiment, the inner surface
15 on the bottom portion 20 of the inner chamber 2 is gradually raised upward from its periphery toward center. Therefore, the specimen collector 4b of the specimen collecting tool 4 abuts a given position of the peripheral portion in the bottom portion 20 of the inner chamber 2 which is lower than the center portion
20 and pushes the given position.

[0052]

 When the specimen collecting tool 4 pushes the given position in the bottom portion 20 of the inner chamber 2 and thereby stretches the thin film portion 23 in the pushed position
25 as shown in Fig. 4, making the bottom portion 20 tilted, side

surfaces 21a and 21b facing each other constituting the groove 21 abut each other at a predefined position P in the peripheral direction of the bottom portion 20, in other words, a predefined position P (Fig. 4) to which the pressing force of the specimen collecting tool 4 is not applied. Then, the bottom portion 20 is not allowed to descend downward where the side surfaces abut each other, and the stretch of the thin film portion 23 is thereby restricted .

[0053]

When the bottom portion 20 is thereafter continuously pressed by the specimen collecting tool 4, the thin film portion 23 further stretches at a position Q where the stretch of the thin film portion 23 is not restricted (more distant from the position P, the stretch of the thin film portion 23 is less restricted). The stretched thin film portion 23 finally breaks, and the specimen collector 4a of the specimen collecting tool 4 penetrates through the bottom portion 20 of the inner chamber 2 to reach the chamber 1. As a result, the second pharmaceutical agent 12 of the inner chamber 2 flows downward into the chamber 1 through the broken bottom portion 20 of the inner chamber 2 and mixed with the first pharmaceutical agent of the chamber 1, and the mixture 13 is obtained.

[0054]

3) As illustrated in Fig. 5, the specimen collector 4 to which the specimen is attached is dipped in the mixture 13 in

the chamber 1 so that the specimen is transferred to the mixture
13.

[0055]

4) Then, the specimen collecting tool 4 is pulled out from
the chamber 1 along with the inner chamber 2. Then, the test
sample s, which is the mixture 13 including the specimen
transferred thereto, is obtained in the chamber 1.

When the specimen collecting tool 4 is pulled out, the
specimen collector (cotton ball) 4b provided on one end of the
specimen collecting tool 4 is caught in the broken portion of
the inner chamber 2, which is the periphery of the through hole
or a part of the bottom portion 20 still connected to the body
of the inner chamber 2. Therefore, the inner chamber 2 is usually
easily removed from the chamber 1 as well as the specimen
collecting tool 4 when the specimen collecting tool 4 is simply
pulled out.

[0056]

5) As illustrated in Fig. 6, the drip chip 5 is mounted
on the opening 1a of the chamber 1, and the opening 1a of the
chamber 1 with the drip chip 5 mounted thereon is directed downward
so that the test sample S is dripped by way of the drip chip
5 to be tested.

Thus, the test sample can be efficiently tested to test
whether antigens of Group A Streptococcus are present in the
specimen.

[0057]

In the embodiment described so far, the test sample S is tested immediately after the inner chamber 2 and the specimen collecting tool 4 are removed from the chamber 1 in the processing step of 4). The test sample S may be transported to a laboratory to be tested there, in which case the test sample can be safely transported to the laboratory by sealing the chamber 1 using the sealing member 3 mounted on the opening 1a thereof.

[0058]

The embodiment described so far employs the test kit used to test whether antigens of Group A Streptococcus are present in the specimen, wherein the liquid pharmaceutical agents as the first and second pharmaceutical agents are used (first pharmaceutical agent: 2 mol/L of sodium nitrite, second pharmaceutical agent: 0.3 mol/L of acetic acid). In the test kit according to the present invention may be used a solid pharmaceutical agent in the form of powder or granule as the first pharmaceutical agent, and a liquid pharmaceutical agent as the second pharmaceutical agent.

More specifically, the specimen collecting tool penetrates through the bottom portion of the inner chamber to guide the second pharmaceutical agent in the form of liquid into the chamber so that the first pharmaceutical agent (solid pharmaceutical agent) is dissolved in the second pharmaceutical agent (liquid pharmaceutical agent).

Thus, the test kit according to the present invention may use a solid pharmaceutical agent other than the liquid pharmaceutical agent as the first pharmaceutical agent housed in the chamber, thereby improving the degree of freedom in the range of applications.

[0059]

The present invention is not necessarily limited to the embodiment in any other aspect. The specific structures of the chamber, inner chamber, specimen collecting tool, and drip chip, and the specific structure of the groove which facilitates the break of the bottom portion of the inner chamber can be variously modified within the intended scope of the present invention.

[DESCRIPTION OF REFERENCE NUMERAL]

[0060]

- 15 1 chamber
 - 1a opening of chamber
 - 1b thread
 - 1c small projected portion formed along inner circumference of chamber
- 20 2 inner chamber
 - 2a opening of inner chamber
 - 2b flange portion
 - 2c projected portion formed on an end surface of inner chamber
- 3 sealing member
 - 25 3a thread (thread of inner peripheral surface of sealing

- member)
- 3b inner upper surface (inner upper surface of sealingmember)
- 4 specimen collecting tool
- 4a shaft-like member
- 5 4b specimen collector (cotton ball)
- 5 drip chip
- 5a liquid passageway of drip chip
- 11 first pharmaceutical agent
- 12 second pharmaceutical agent
- 10 13 mixture
- 20 bottom portion in inner chamber
- 21 groove (annular groove)
- 21a, 21b side surfaces facing each other constituting groove
- 22 bottom (groove bottom portion)
- 15 23 thin film portion (thin film portion constituting bottom)
- P position where side surfaces facing each other
constituting groove abut each other
- Q position where stretch of thin film portion is not
restricted
- 20 S test sample

CLAIMS

1) A test kit comprising:

a chamber (1) for housing a first pharmaceutical agent (11) therein, the chamber (1) comprising a substantially cylindrical member and having an opening (1a) at a first end thereof and a
5 second end which is sealed;

an inner chamber (2) for housing a second pharmaceutical agent (12) therein, the inner chamber (2) comprising a substantially cylindrical member and having an opening (2a) at a
10 first end thereof and a second end which is sealed by a bottom portion (20) and provided with a flange portion (2b) around the opening (2a), the inner chamber (2) being insertable into the chamber (1) with the second end thereof first through the opening of the chamber (1) to seal the opening (1a) of the
15 chamber (1), the flange portion (2b) in the first end abutting the first end of the chamber (1) so as to be held at an abutting position;

a sealing member (3) for sealing the opening (2a) of the inner chamber (2) and making the flange portion (2b) of the
20 inner chamber (2) abut the opening (1a) at the first end of the chamber (1) to seal the opening (1a) of the chamber (1); and

a specimen collecting tool (4) including a specimen collector (4b) for collecting and retaining a specimen in at least one end of a shaft-shaped member (4a) thereof, wherein the specimen
25 collector (4b) of the specimen collecting tool (4) to which the collected specimen is attached is insertable into the inner chamber (2) through the opening (2a) so that the specimen collector (4b) can penetrate through the bottom portion (20) of the inner chamber (2) to be seated in the chamber (1), in order
30 to guide the second pharmaceutical agent (12) from inside the inner chamber (2) into the chamber (1) to be mixed with the first pharmaceutical agent (11) in the chamber (1), so that the specimen collector (4b) to which the specimen is attached can be dipped in a resulting mixture including the first and second

pharmaceutical agents (11, 12) so that the specimen can be transferred into the mixture, and the specimen collecting tool (4) as well as the inner chamber (2) being thereafter removable from the chamber (1) and a test sample (s), which is a mixture including the first and second pharmaceutical agents (11, 12) and further including the specimen transferred thereto, can be obtained in the chamber (1).

2) Test kit according to claim 1 in which said bottom portion (20) of the inner chamber (2) comprises a thin film portion (23) which is breakable by the specimen collecting tool (4) when the specimen collecting tool (4) is pressed against the thin film portion (23), so that the specimen collecting tool (4) can penetrate through the bottom portion (20) of the inner chamber (2).

3) Test kit according to claims 1 or 2 in which an inner surface on the bottom portion (20) of the inner chamber (2) is gradually raised upward from a peripheral portion toward a central portion thereof; an annular groove (21) formed circumferentially along the bottom portion (20) of the inner chamber (2) is formed in a peripheral portion of an outer surface on the bottom portion (20) of the inner chamber (2); a thin film portion (23) constituting a bottom portion (22) of the groove (21) connects the bottom portion (20) of the inner chamber (2) with other portions of the inner chamber (2); a predetermined location in the peripheral portion of the bottom portion (20) of the inner chamber (2) is pressable by the specimen collecting tool (4), side surfaces (21a, 21b) facing each other constituting the groove (21) abut each other at a predetermined circumferential position of the bottom portion when the thin film portion (23) stretches at the pressed location and a vicinity thereof, making the bottom portion tilted, and the thin film portion (23) is restricted from stretching near the abutting position, so that when the predetermined position is pressed by the specimen collecting tool (4), the thin film portion (23) can be further

stretched at a position where the stretch is not restricted to finally break so that the specimen collecting tool (4) can penetrate through the bottom portion (20) of the inner chamber (2) .

5 4) Test kit according to any of the preceding claims further comprising a drip chip (5) for dripping the test sample (s) located in the chamber (1) to allow testing of the test sample (s) , wherein the drip chip (5) is configured to be attached to the opening (1a) of the chamber (1) after the specimen
10 collecting tool (4) and the inner chamber (2) are removed from the chamber.

5) Test kit according to any of the preceding claims, in which the specimen collecting tool (4) is a cotton swab having a cotton ball serving as the specimen collector (4b) in the at
15 least one end thereof.

6) Test kit according to any of the preceding claims in which the first pharmaceutical agent (11) housed in the chamber (1) is a pharmaceutical agent in powder form, and the second pharmaceutical agent (12) housed in the inner chamber (2) is a
20 pharmaceutical agent in liquid form.

7) Test kit according to any of the preceding claims, in which the sealing member (3) is a threaded cap in an inner peripheral surface thereof, the thread (3a) of the cap being engageable with a thread (1b) formed in an outer peripheral portion of the
25 chamber (1) , so that an inner upper surface (3b) of the cap abuts the opening (2a) of the inner chamber (2) to seal the inner chamber (2) , the flange portion (2b) of the inner chamber (2) abutting the opening (1a) of the chamber (1) to seal the chamber (1) by using the inner chamber (2), and the inner upper
30 surface (3b) abutting the opening (1) of the chamber to seal the chamber (1) after the inner chamber (2) is removed from the chamber (1) .

8) Test kit according to any of the preceding claims, in which a region circumferentially along an inner peripheral surface of

the chamber (1) and a region circumferentially along an outer peripheral surface of the inner chamber (2) abut each other at a position closer to the bottom portion (20) of the inner chamber (2) than an axially central portion thereof to seal the chamber (1) .

9) Test kit according to any of claims 4-8 further including a filter for filtering and removing solid matter in a passageway of the drip chip (5) where the test sample (s) travels.

10) Test kit according to any of the preceding claims, in which the test kit, the first pharmaceutical agent (11) and the second pharmaceutical agent (12) are adapted for use in a test for hemolytic streptococcal infection.

11) Test kit according to any of the preceding claims in which both the first pharmaceutical agent (11) housed in the chamber (1) and the second pharmaceutical agent (12) housed in the inner chamber (2) are pharmaceutical agents in liquid form.

12) Test kit according to any of the preceding claims, in which the specimen collecting tool (4) is a flocked swab having a flocked collecting portion with synthetic fiber serving as the specimen collector (4b) in the at least one end thereof.

13) Test kit according to any of the preceding claims, in which said chamber (1) and/or said inner chamber (2) and/or said sealing member (3) are made of resin and/or plastic material and/or polyethylene and/or in which said specimen collecting tool (4) is made of plastic material or polystyrene.

14) Use of a test kit comprising:
housing a first pharmaceutical agent (11) in a chamber (1) , the chamber (1) comprising a substantially cylindrical member and having an opening (1a) at a first end thereof and a second end which is sealed;

housing a second pharmaceutical agent (12) in an inner chamber (2), the inner chamber (2) comprising a substantially cylindrical member and having an opening (2a) at a first end thereof and a second end which is sealed by a bottom portion

(20) and provided with a flange portion (2b) around the opening (2a), the inner chamber (2) being inserted into the chamber (1) with the second end thereof first through the opening of the chamber (1) to seal the opening (1a) of the chamber (1), the
5 flange portion (2b) in the first end abutting the first end of the chamber (1) so as to be held at an abutting position;

sealing the opening (2a) of the inner chamber (2) with a sealing member (3) and making the flange portion (2b) of the inner chamber (2) abut the opening (1a) at the first end of the
10 chamber (1) to seal the opening (1a) of the chamber (1); and

collecting and retaining a specimen in a specimen collector (4b) provided in at least one end of a shaft-shaped member (4a) of a specimen collecting tool (4), wherein the specimen collector (4b) of the specimen collecting tool (4), to which the
15 collected specimen is attached, is inserted into the inner chamber (2) through the opening (2a) so that the specimen collector (4b) penetrates through the bottom portion (20) of the inner chamber (2) to be seated in the chamber (1), guiding the second pharmaceutical agent (12) from inside the inner chamber
20 (2) into the chamber (1) to be mixed with the first pharmaceutical agent (11) in the chamber (1), so that the specimen collector (4b) to which the specimen is attached is dipped in a resulting mixture including the first and second pharmaceutical agents (11, 12) so that the specimen is
25 transferred into the mixture, and the specimen collecting tool (4) as well as the inner chamber (2) are thereafter removed from the chamber (1) so that a test sample (s), which is a mixture including the first and second pharmaceutical agents (11, 12) and further including the specimen transferred thereto, is
30 obtained in the chamber (1).

15) Use of a test kit according to claim 14 in which said bottom portion (20) of the inner chamber (2) comprises a thin film portion (23) that is broken by the specimen collecting tool (4) when the specimen collecting tool (4) is pressed against the

thin film portion (23), so that the specimen collecting tool (4) penetrates through the bottom portion (20) of the inner chamber (2) .

16) Use of a test kit according to claims 14 or 15 in which an
5 inner surface on the bottom portion (20) of the inner chamber (2) is gradually raised upward from a peripheral portion toward a central portion thereof; an annular groove (21) formed circumferentially along the bottom portion (20) of the inner chamber (2) is formed in a peripheral portion of an outer
10 surface on the bottom portion (20) of the inner chamber (2) ; a thin film portion (23) constituting a bottom portion (22) of the groove (21) connects the bottom portion (20) of the inner chamber (2) with other portions of the inner chamber (2) ; a predetermined location in the peripheral portion of the bottom
15 portion (20) of the inner chamber (2) is pressed by the specimen collecting tool (4), side surfaces (21a, 21b) facing each other constituting the groove (21) abut each other at a predetermined circumferential position of the bottom portion when the thin film portion (23) stretches at the pressed location and a
20 vicinity thereof, making the bottom portion tilted, and the thin film portion (23) is restricted from stretching near the abutting position, so that when the predetermined position is pressed by the specimen collecting tool (4), the thin film portion (23) is further stretched at a position where the
25 stretch is not restricted and finally breaks so that the specimen collecting tool (4) penetrates through the bottom portion (20) of the inner chamber (2) .

17) Use of a test kit according to any of claims 14-16 further comprising removing the specimen collecting tool (4) and the
30 inner chamber (2) from the chamber (1) and then attaching a drip chip (5) , for dripping the test sample (s) located in the chamber (1) to allow testing of the test sample (s) , to the opening (1a) of the chamber (1) .

18) Use of a test kit according to any of claims 14-17, in which

the specimen collecting tool (4) is a cotton swab having a cotton ball serving as the specimen collector (4b) in the at least one end thereof.

19) Use of a test kit according to any of claims 14-18 in which
5 the first pharmaceutical agent (11) housed in the chamber (1) is a pharmaceutical agent in powder form, and the second pharmaceutical agent (12) housed in the inner chamber (2) is a pharmaceutical agent in liquid form.

20) Use of a test kit according to any of claims 14-19, in which
10 the sealing member (3) is a threaded cap in an inner peripheral surface thereof, the thread (3a) of the cap being engaged with a thread (1b) formed in an outer peripheral portion of the chamber (1), so that an inner upper surface (3b) of the cap abuts the opening (2a) of the inner chamber (2) to seal the inner chamber
15 (2), the flange portion (2b) of the inner chamber (2) abutting the opening (1a) of the chamber (1) to seal the chamber (1) by using the inner chamber (2), and the inner upper surface (3b) abutting the opening (1) of the chamber to seal the chamber (1) after the inner chamber (2) is removed from the chamber (1).

20 21) Use of a test kit according to any of claims 14-20, in which a region circumferentially along an inner peripheral surface of the chamber (1) and a region circumferentially along an outer peripheral surface of the inner chamber (2) abut each other at a position closer to the bottom portion (20) of the inner chamber
25 (2) than an axially central portion thereof to seal the chamber (1) -

22) Use of a test kit according to any of claims 16-21 further including using a filter for filtering and removing solid matter in a passageway of the drip chip (5) where the test sample (s)
30 travels .

23) Use of a test kit according to any of claims 14-22, in which the test kit is used in a test for hemolytic streptococcal infection.

24) Use of a the test kit according to any of claims 14-23 in

which both the first pharmaceutical agent (11) housed in the chamber (1) and the second pharmaceutical agent (12) housed in the inner chamber (2) are pharmaceutical agents in liquid form.

25) Use of a test kit according to any of claims 14-24, in which
5 the specimen collecting tool (4) is a flocked swab having a flocked collecting portion with synthetic fiber serving as the specimen collector (4b) in the at least one end thereof.

26) Use of a test kit according to any of claims 14-25, in which said chamber (1) and/or said inner chamber (2) and/or said
10 sealing member (3) are made of resin and/or plastic material and/or polyethylene and/or in which said specimen collecting tool (4) is made of plastic material or polystyrene.

27) Use of a test kit according to any of claims 14-26, in which the specimen collecting tool (4) is pulled out after penetrating
15 through the bottom portion (20) with the specimen collector (4b) left caught in the through hole formed in the bottom portion (20), and the specimen collecting tool (4) and the inner chamber (2) are removed from the chamber (1) .

28) Specimen processing method comprising the steps of:

20 collecting a specimen from a patient's body by using a specimen collector (4a) of a specimen collecting tool (4) ;

removing a sealing member (3) from a chamber (1) of a test kit, the chamber (1) having an inner chamber (2) inserted therein;

25 inserting in the inner chamber (2) of the test kit, through an opening (2a) , the specimen collector (4a) of the specimen collecting tool (4) to which the collected specimen is attached, the inner chamber (2) having a second pharmaceutical agent (12) therein;

30 pushing the specimen collector (4a) on one end of the specimen collecting tool (4) against a predefined position on the bottom portion (20) in the inner chamber (2) , in order to break a thin film portion (23) of the bottom portion (20) ;

penetrating with the specimen collector (4a) of the

specimen collecting tool (4) through the bottom portion (20) of the inner chamber (2) to reach the chamber (1) of the test kit, and allowing the second pharmaceutical agent (12) of the inner chamber (2) to flow downward into the chamber (1) through the broken bottom portion (20) of the inner chamber (2) and to mix
5 with a first pharmaceutical agent (11) disposed in the chamber (1), to obtain a mixture (13); and

dipping the specimen collector (4) to which the specimen is attached in the mixture (13) in the chamber (1) so that the
10 specimen is transferred to the mixture (13), to obtain a test sample (s), which is the mixture (13) including the specimen transferred thereto in the chamber (1).

29) Method according to the preceding claim further comprising the steps of:

15 removing the inner chamber (2) and the specimen collecting tool (4) from the chamber (1); and

mounting a drip chip (5) on the opening (1a) of the chamber (1).

30) Method according to the preceding claim further
20 comprising the steps of:

directing downwards the opening (1a) of the chamber (1) with the drip chip (5) mounted thereon; and

dripping the test sample (s) out from the chamber (1) by way of the drip chip (5), to allow the test sample (s) to
25 be tested.

31) Method according to any of claims 28, 29 or 30 further comprising the steps of:

sealing the chamber (1) using a sealing member (3) mounted on the opening (1a) thereof; and

30 transporting the test kit to a laboratory or location where the test sample (s) is dripped to be tested.

FIG. 1

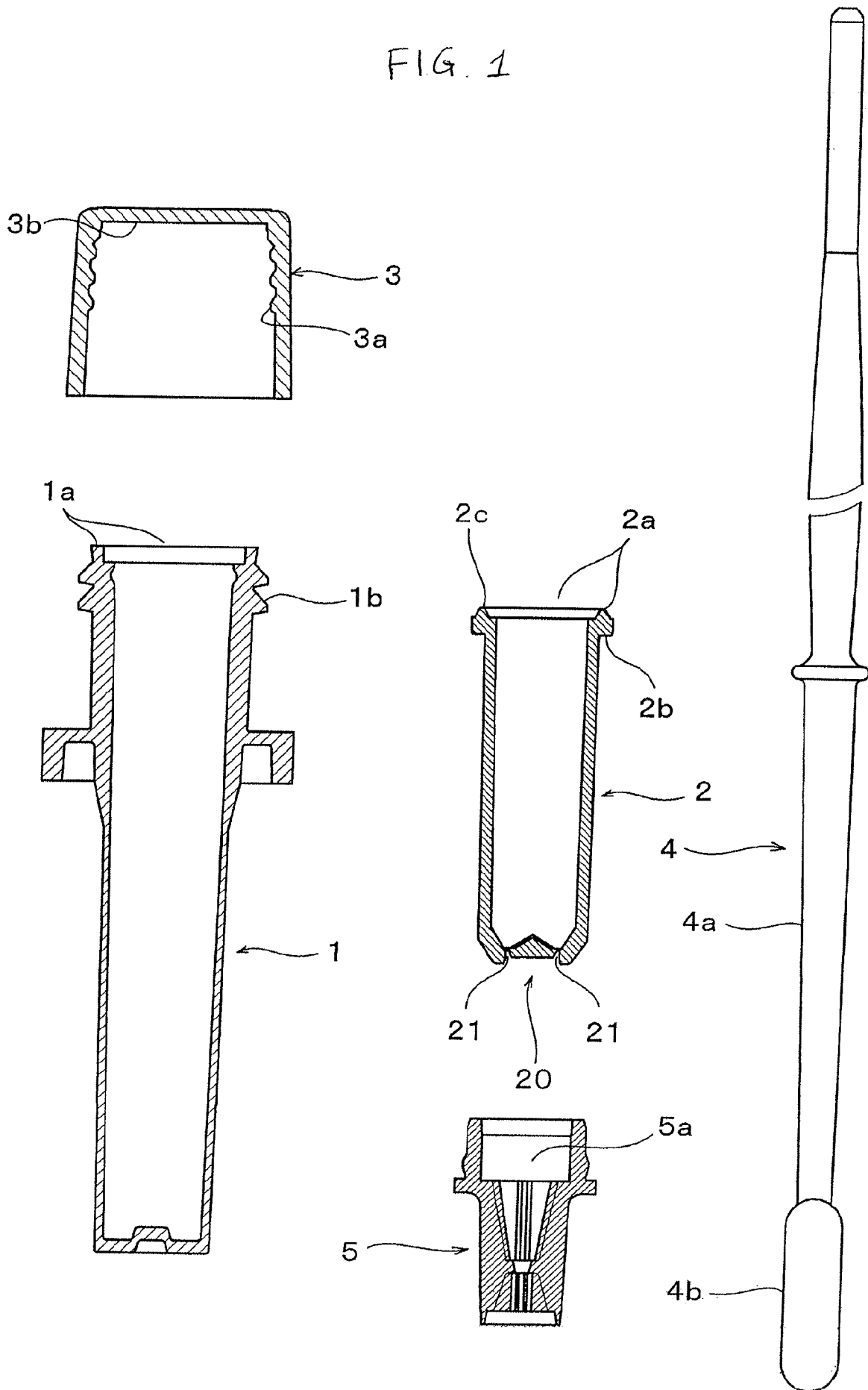


FIG. 2

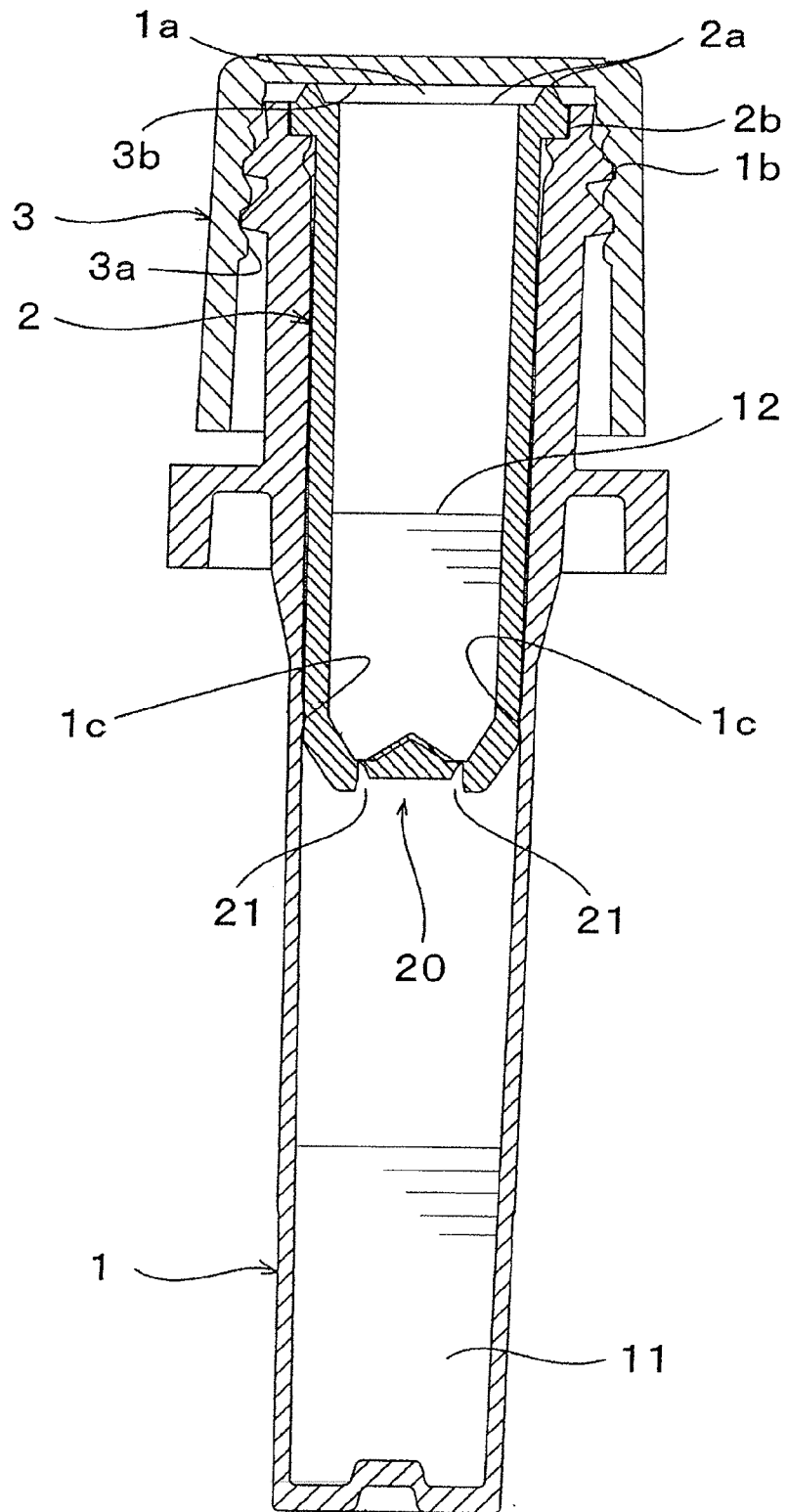


FIG 3

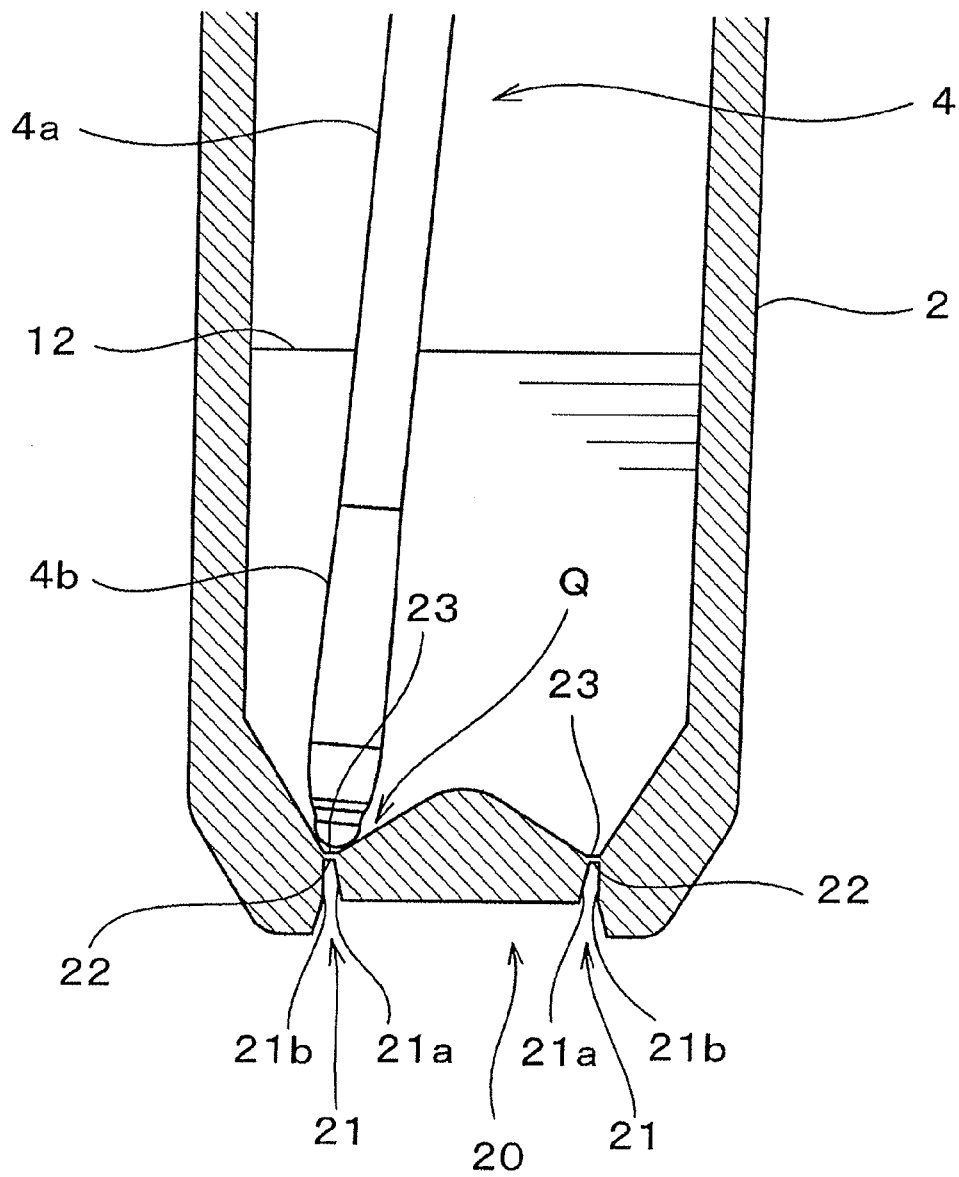


FIG. 4

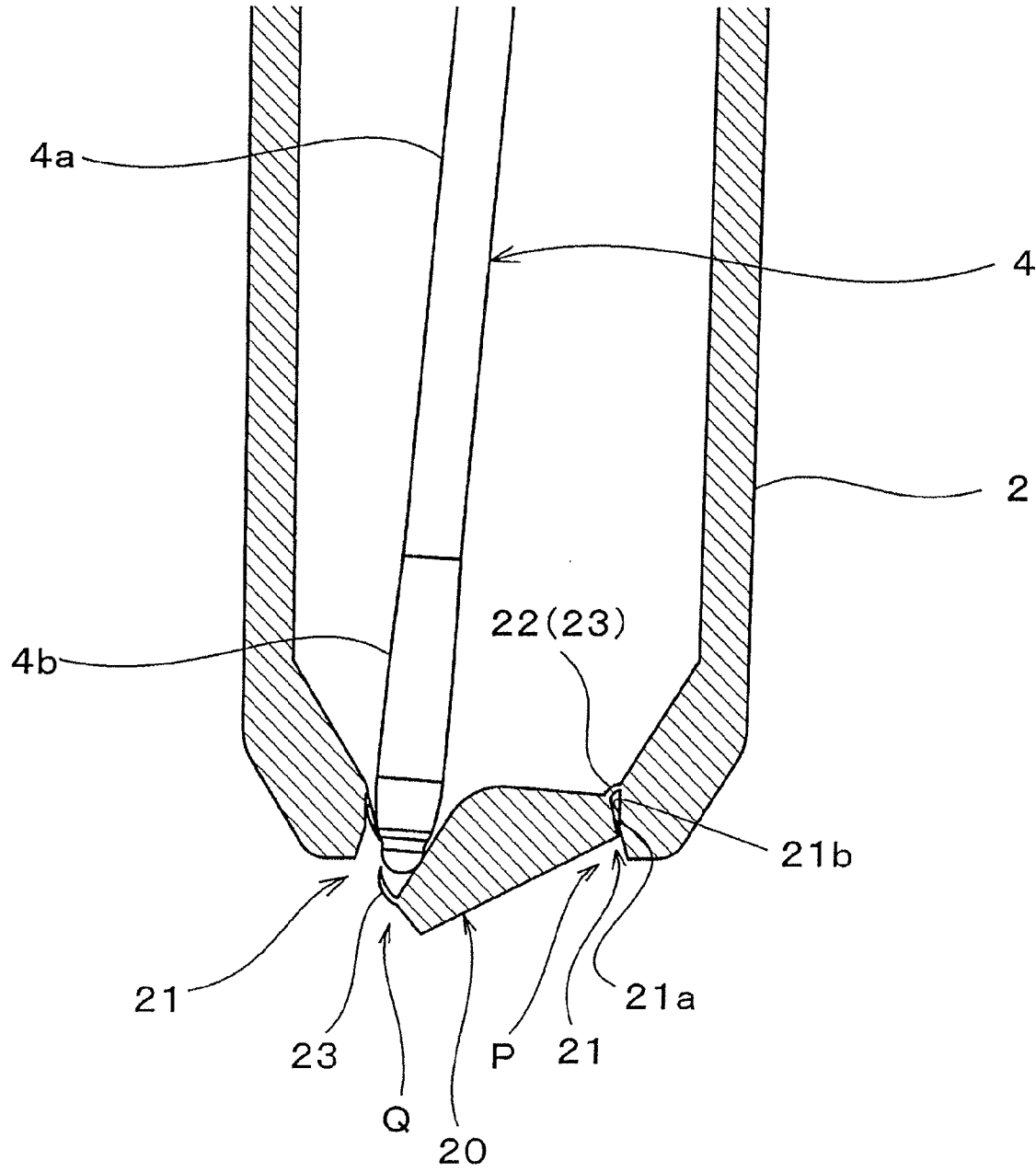


FIG. 5

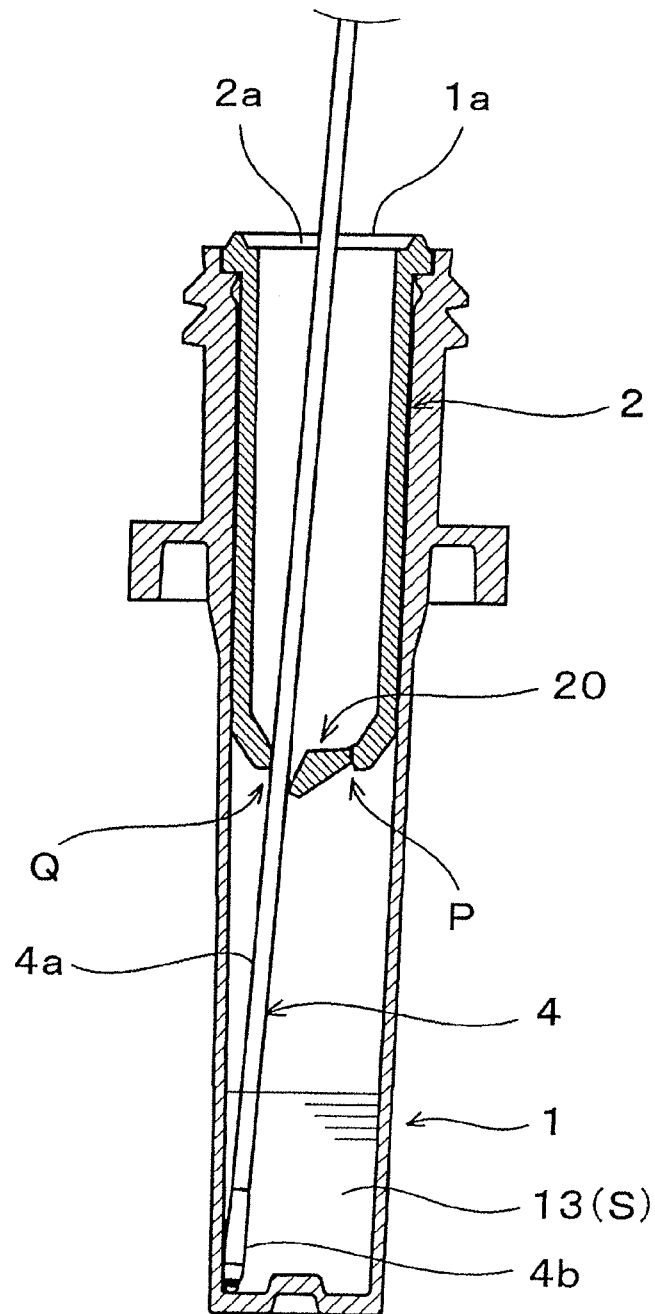


FIG. 6

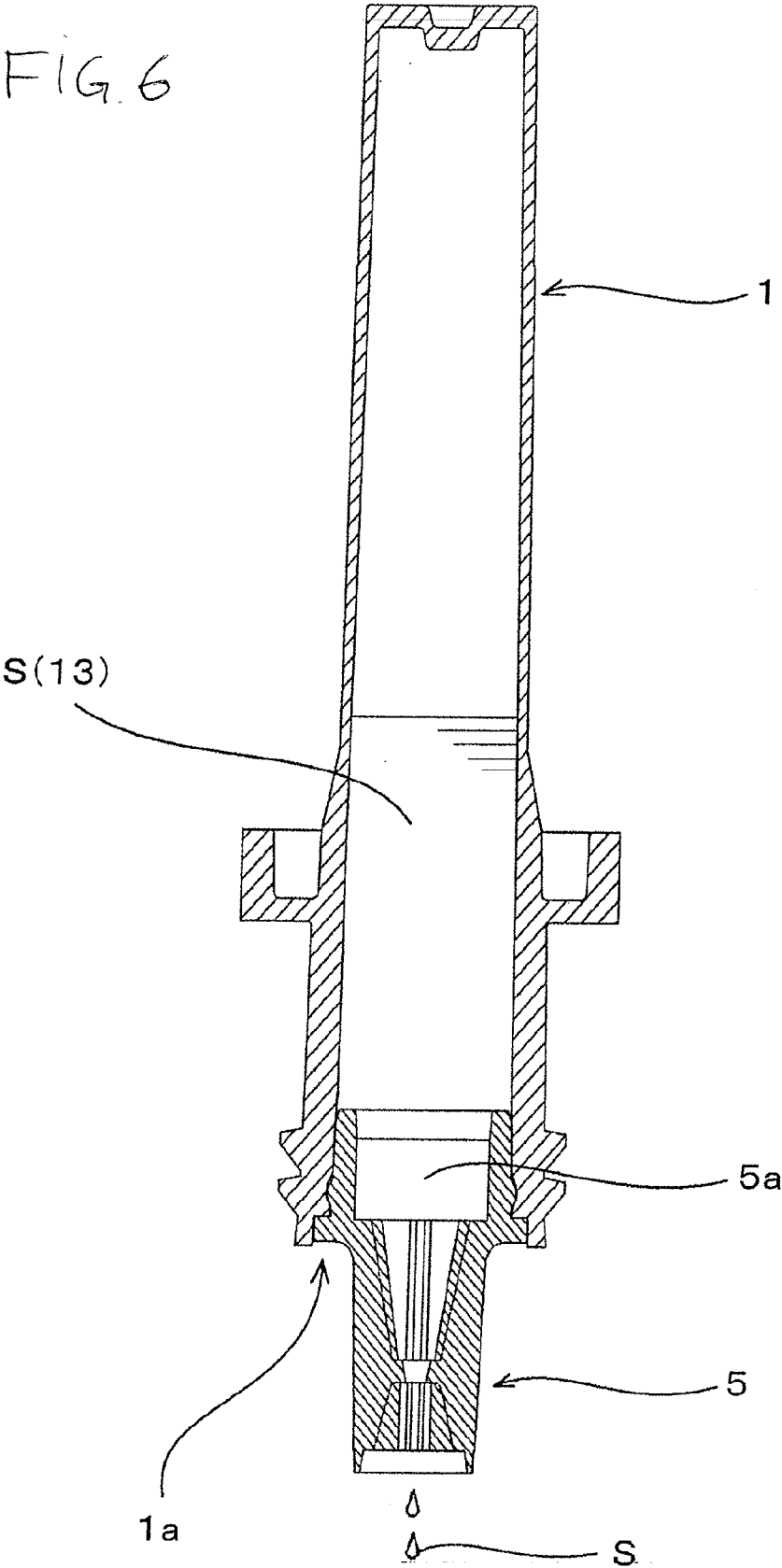
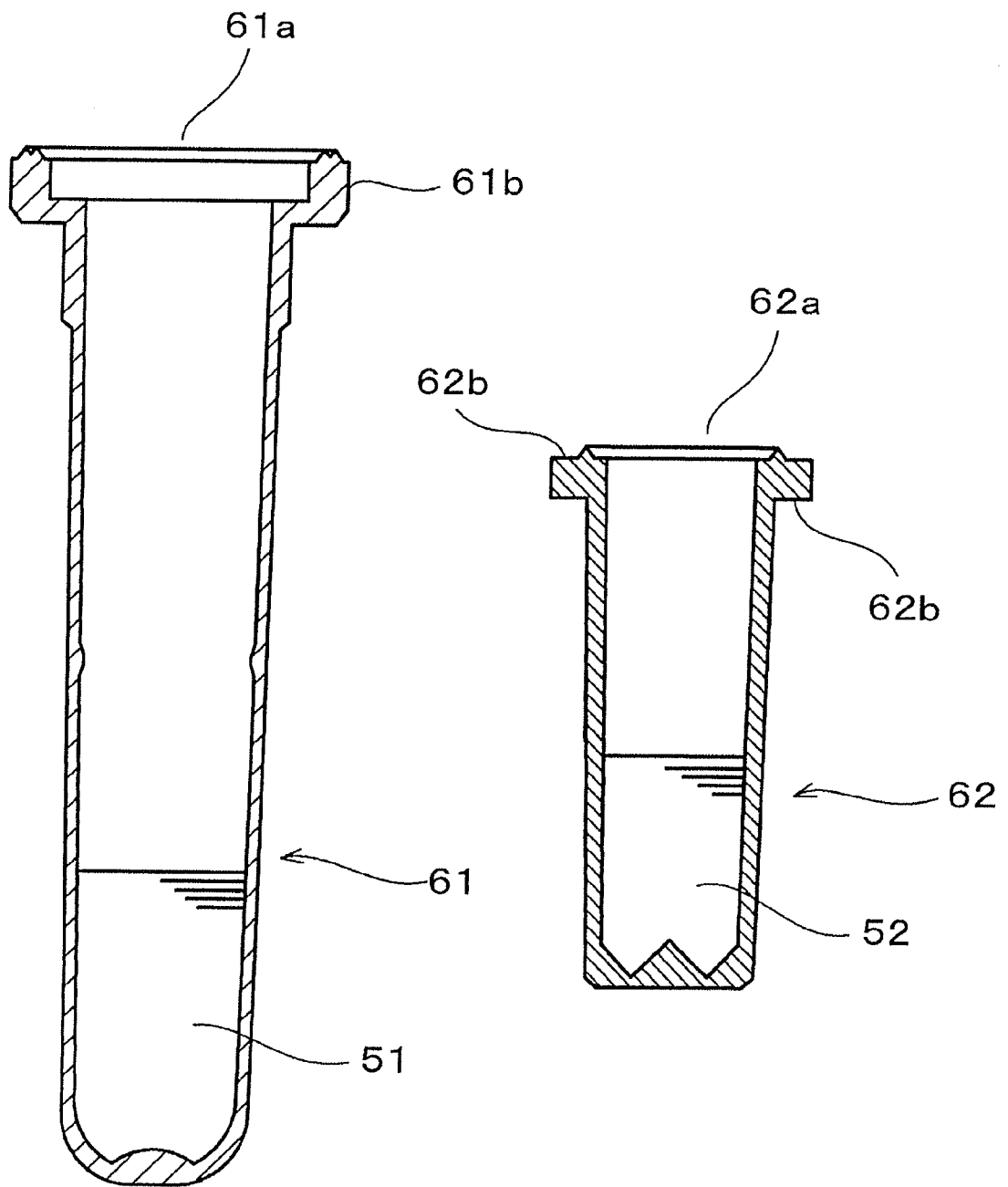


FIG. 7



INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2011/058990

A. CLASSIFICATION OF SUBJECT MATTER

INV. B01L3/00 B01L3/14 A61B10/00
ADD.

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)

BOIL 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)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Y	paragraphs [0002] , [0003] , [0013] - [0015] , [0018] , [0021] - [0029] , [0032] - [0037] , [0042] ; figures 1,4-6	3, 4, 9 , 16, 17 , 29, 30
Y	Wo 2005/071388 A1 (ORION DIAGNOSTICA OY [FI] ; ROSMAN ESA [FI] ; KYLMAE ANNA KAISA [FI] ; HA) 4 August 2005 (2005-08-04) page 11, lines 5-8; figures 1-2 , 5, 6 page 12, lines 2-18	3, 16
Y	wo 2009/075637 A1 (ASTRAZENECA AB [SE] ; BOECKELER MATTHEW [US]) 18 June 2009 (2009-06-18) figures 3, 4	3, 16



Further documents are listed in the continuation of Box C.



See patent family annex.

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"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

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Date of the actual completion of the international search

13 October 2011

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24/10/2011

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INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2011/058990

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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Y	EP 1 909 089 A1 (NIPRO CORP [JP]) 9 April 2008 (2008-04-09) paragraphs [0011], [0012], [0016] - [0018]; figure 1 -----	4, 9, 17, 22, 29, 30
Y	EP 1 867 972 A1 (NIPRO CORP [JP]) 19 December 2007 (2007-12-19) paragraph [0029]; figures 1-3 -----	4, 9, 17, 22, 29, 30
Y	W0 2008/038653 A1 (SHIN CORP [JP]; MATSUURA SHINJI [JP] ; UEDA KATSUHIRO [JP]) 3 April 2008 (2008-04-03) figures 1-13 -----	4, 9, 17, 22, 29, 30

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Information on patent family members

International application No

PCT/EP2011/058990

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