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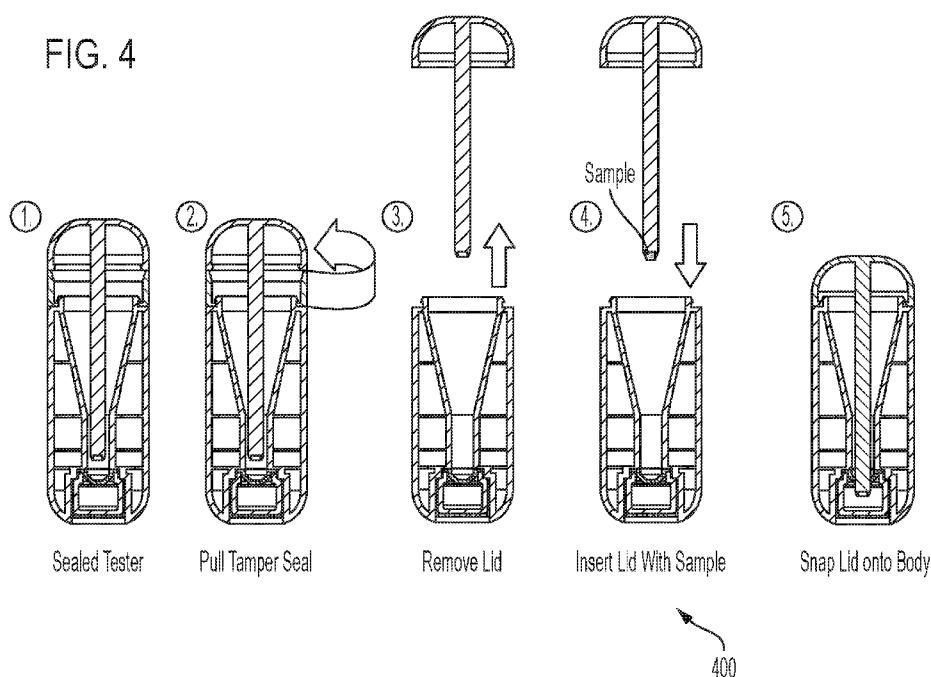
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(54) Title: DUAL-FUNCTION RECEPTACLE SEAL

FIG. 4



(57) Abstract: One aspect of the invention provides a system including: a detachable cap; a dipstick coupled to the detachable cap; a tamper-evident seal tearably coupled to the detachable cap; and a receptacle comprising: a sidewall terminating in a proximal end releasably engaged with the tamper-evident seal; a distal chamber; and a seal isolating the distal chamber. The detachable cap, the dipstick, the tamper-evident seal, and the receptacle are dimensioned such that: the dipstick is restrained by the tamper-evident seal from advancing distally and breaching the seal until the tamper-evident seal is removed from the detachable lid; and upon removal of the tamper-evident seal, the dipstick can be advanced distally to breach the seal.

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DUAL-FUNCTION RECEPTACLE SEAL

CROSS-REFERENCE TO RELATED APPLICATION

This application claims priority to U.S. Provisional Patent Application Serial No. 62/814,034, filed March 5, 2019. The entire content of this application is hereby
5 incorporated by reference herein.

BACKGROUND OF THE INVENTION

Test kits are sold for the detection of various substances.

SUMMARY OF THE INVENTION

One aspect of the invention provides a system including: a detachable cap; a dipstick
10 coupled to the detachable cap; a tamper-evident seal tearably coupled to the detachable cap; and a receptacle comprising: a sidewall terminating in a proximal end releasably engaged with the tamper-evident seal; a distal chamber; and a seal isolating the distal chamber. The detachable cap, the dipstick, the tamper-evident seal, and the receptacle are dimensioned such that: the dipstick is restrained by the tamper-evident seal from advancing distally and breaching the seal
15 until the tamper-evident seal is removed from the detachable lid; and upon removal of the tamper-evident seal, the dipstick can be advanced distally to breach the seal.

This aspect of the invention can have a variety of embodiments. The system can further include a reactant agent contained in the distal chamber. The tamper-evident seal's attachment to the detachable lid is indicative of an uncompromised status of the reactant agent. The tamper-
20 evident seal's removal from the detachable lid is indicative of a potentially compromised status of the reactant agent.

The dipstick can further include an end. The end can be dimensioned such that the dipstick is attachable to a test sample. Advancing the test sample into the reactant agent can result in a chemical reaction. The system can further include a transparent window within the
25 receptacle. An observer can view the chemical reaction via the transparent window. The transparent window can be adjacent to the distal chamber.

The detachable lid can be further dimensioned so that the detachable lid can be attached to the receptacle upon the tamper-evident seal being removed from the detachable lid. The receptacle, the tamper-evident seal, and the detachable lid can include complementary mating

features. The complementary mating features can include ridges. The ridges can be annular in shape.

Another aspect of the invention provides a method of performing a chemical analysis on a test sample using a system. The method includes: obtaining the system described herein;
5 removing the tamper-evident seal from the detachable cap; detaching the detachable cap from the receptacle; and advancing the dipstick distally to breach the seal and enter the distal chamber.

This aspect of the invention can include a variety of embodiments. The method can further include: coupling a test sample to an end of the dipstick; and advancing the test sample through the seal and into the reactant agent upon removal of the tamper-evident seal.

10 The method can further include attaching the detachable lid directly to the receptacle subsequent to the tamper-evident seal being removed from the detachable lid.

Another aspect of the invention provides a kit including: the system as described herein; and a set of instructions for implementing a chemical analysis test within the system.

BRIEF DESCRIPTION OF THE DRAWINGS

15 For a fuller understanding of the nature and desired objects of the present invention, reference is made to the following detailed description taken in conjunction with the accompanying drawing figures wherein like reference characters denote corresponding parts throughout the several views.

FIG. 1 depicts a dual-function receptacle seal and corresponding receptacle according to
20 an embodiment of the invention.

FIG. 2 depicts a cross-sectional view of a dual-function receptacle seal and corresponding receptacle according to an embodiment of the invention.

FIG. 3 depicts several views of a dual-function receptacle seal according to an embodiment of the invention.

25 FIG. 4 depicts a process for a dual-function receptacle seal and corresponding receptacle according to an embodiment of the invention.

FIG. 5 depicts an exemplary workflow process for performing a chemical analysis on a test sample using a container, according to an embodiment of the invention.

FIGS. 6 through 12 depict various receptacle assemblies according to embodiments of the
30 invention.

FIG. 13 depicts an immunoassay-based test according to an embodiment of the invention.

DEFINITIONS

The instant invention is most clearly understood with reference to the following definitions.

5 As used herein, the singular form “a,” “an,” and “the” include plural references unless the context clearly dictates otherwise.

Unless specifically stated or obvious from context, as used herein, the term “about” is understood as within a range of normal tolerance in the art, for example within 2 standard deviations of the mean. “About” can be understood as within 10%, 9%, 8%, 7%, 6%, 5%, 4%,
10 3%, 2%, 1%, 0.5%, 0.1%, 0.05%, or 0.01% of the stated value. Unless otherwise clear from context, all numerical values provided herein are modified by the term about.

As used in the specification and claims, the terms “comprises,” “comprising,” “containing,” “having,” and the like can have the meaning ascribed to them in U.S. patent law and can mean “includes,” “including,” and the like.

15 Unless specifically stated or obvious from context, the term “or,” as used herein, is understood to be inclusive.

Ranges provided herein are understood to be shorthand for all of the values within the range. For example, a range of 1 to 50 is understood to include any number, combination of numbers, or sub-range from the group consisting 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15,
20 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, or 50 (as well as fractions thereof unless the context clearly dictates otherwise).

DETAILED DESCRIPTION OF THE INVENTION

In certain aspects, the invention provides a dual-function seal and receptacle assembly. In
25 other aspects, the invention provides for a method of performing a chemical analysis with a receptacle assembly. In other aspects, the invention provides for a kit including a receptacle assembly and a set of instructions.

Receptacle Assembly

Various receptacles benefit from providing evidence of tampering. Allowing someone to discern whether a third party accessed the contents of the receptacle and potentially compromised the content or receptacle is of great use to a customer who may not know the chain of possession for the receptacle. Thus, seals have been used to indicate whether someone has previously opened the receptacle.

Test kits are used in order to determine whether a test sample includes a certain material or composition.

Conventional seals do not mitigate other challenges associated with test kits. Test kits may become compromised in various ways outside of third-party interference. For example, a user may improperly use the test kit. Conventional test kits may include several parts, some of which may need to be exposed to environs and different compositions at specific steps. If a user switches the order of the steps, or misses a step entirely, the test kit may return an inaccurate result. Some test kits may also allow for different tests to be conducted, where each test may include its own specific steps and exposure to different compositions. This may further complicate the test procedure.

Another example of improper use of a test kit involves the failure to properly perform a step of the test. For example, some conventional test kits include means for immersing a test sample into a chemical agent in order to identify whether the test sample is a specific composition. However, a user may fail to completely immerse the test sample, or may not immerse the test sample for the required amount of time.

In some cases, a compromised test kit or an improperly used test kit may return an inaccurate result. Some of these cases may be more serious than others. For example, if the test kit is utilized for identifying whether a test sample is fentanyl, receiving an inaccurate test result may prove fatal.

Referring to FIG. 1, one embodiment of the invention provides a dual-function seal and receptacle assembly 100. The receptacle assembly 100 can include a lid 105, a dipstick 110, a tamper-evident seal 115, a receptacle 120, a transparent window 125, a seal 130, and a reagent ampule 135. The receptacle assembly 100 enables a testing kit that is easy to use, includes a tamper-evident seal indicative of whether the testing kit is compromised, and minimizes the risk of contamination from external environs.

Further, the receptacle assembly 100 may be used for a variety of different purposes. For example, the receptacle assembly may be used for a variety of chemical testing, such as for pool testing kits, soil testing, glue mixtures (e.g., epoxy), or drug testing (e.g., fentanyl). While the below examples discussed may illustrate specific drug examples, it should be noted that the receptacle assembly 100 is not limited to those specific examples discussed below.

Tamper-Evident Seal

The assembly 100 can include a tamper-evident seal 115. In some cases, the tamper-evident seal 115 can form a ring or annulus. However, in general, the tamper-evident seal shape may be in such a shape so as to couple with the receptacle 120 and the lid 105. Thus, the shape of the tamper-evident seal 115 may be dependent upon the shape of the lid 105 and/or the shape of the receptacle 120, or vice versa.

The tamper-evident seal 115 may attach the lid 105 to the receptacle 120. The tamper-evident seal 115 may include dimensions to allow the tamper-evident seal 115 to attach directly to the receptacle 120. For example, the tamper-evident seal 115 may be threaded, allowing the tamper-evident seal 115 to be screwed onto the receptacle 120. Alternatively, the tamper-evident seal 115 may include one or more hooks. Shown in FIG. 2, the open end of the receptacle 120 includes a hook 205. The hook 205 may span the entire surface of the opening (e.g., the circumference) and thus be annular, or may alternatively may span only a portion of the surface, or there may be several hooks 205 that span the surface. Further, the tamper-evident seal 115 in FIG. 2 includes a lip 210. The lip 210 in some cases spans the entire surface of the tamper-evident seal 115 (e.g., the circumference of the tamper-evident seal 115) and is thus annular. When the lid 105 is pressed onto the receptacle 120, the lip 210 is pressed past the hook 205 of the receptacle 120, thereby allowing the tamper-evident seal 115 to be “snapped” to the receptacle opening and securely fastening the tamper-evident seal 115 to the receptacle 120. (Similarly, a press fit, a friction fit, a shrink fit, or an interference fit can be formed.) The tamper-evident seal 115 can be attached to the receptacle 120 such that the tamper-evident seal 115 may not be removed from the receptacle without first detaching the tamper-evident seal 115 from the lid 105 (e.g., a divide between the tamper-evident seal 115 and the receptacle 120 is tearable, perforated, and the like). Further, the tamper-evident seal 115, the receptacle 120, or both, may be engineered such that once removed, the tamper-evident seal 115 may be unable to be easily reattached to the receptacle 120.

The tamper-evident seal 120 may be tearably attached to the lid 105. For example, the lid 105 and the tamper-evident seal 115 may be composed of the same material (e.g., polypropylene) and can be molded in a single step. A divide between the lid 105 and the tamper-evident seal 115 may be a perforated or thinned portion. If enough force (e.g., torque) is applied to the tamper-evident seal 115, the perforated portion may break completely, allowing the lid 105 to be detached from the tamper-evident seal 115. Further, the tamper-evident seal 115 may include a portion to allow for ease of removal. For example, the tamper-evident seal 300 illustrated in FIG. 3, which may be an example of the tamper-evident seal 115, provides for a pull tab 305 attached to the ring portion 310 of the tamper-evident seal 300. The pull tab 305 may allow for a user to grip the pull tab 305 and pull the tamper-evident seal 300, rather than grip the ring portion 310 itself. Alternatively, the tamper-evident seal 300 may include ridges across the exterior of the tamper-evident seal 300, so as to allow for a better grip by a user.

The tamper-evident seal 115 may alter the locations of the lid 105 and the dipstick 110 with respect to the other components of the assembly 100, based on whether the tamper-evident seal 115 is attached or detached from the lid 105. For example, when the tamper-evident seal 115 is attached to the lid 105, the tamper-evident seal 115 may connect the lid 105 to the receptacle 120. The dipstick 110 may be dimensioned such that when the tamper-evident seal 115 is attached to the lid 105, the distal end of the dipstick 110 rests above the seal 125 and the reagent ampule 130 of the assembly 100 (e.g., the dipstick 110 does not penetrate the seal 125). Further, when the tamper-evident seal is detached from the lid 105, the lid 105 may be attached directly to the receptacle without sitting above the tamper-evident seal 115. Thus, the dipstick 110 may rest lower within the cavity of the receptacle 120 as compared to with the tamper-evident seal 115 attached. The dipstick 110 may be dimensioned such that, with the tamper-evident seal 115 detached, the distal end of the dipstick may penetrate the seal 125 and enter the reagent ampule 130.

Receptacle

The assembly 100 may include the receptacle 120, which may house various other components of the assembly 100. For example, the receptacle 120 may house a reagent ampule 135. Further, when the lid 105 is attached to the receptacle, the dipstick 110 resides within the cavity of the receptacle 120.

The receptacle 120 may include additional features to shape the cavity. For example, the receptacle 120 may include a tapered inner wall. The tapered inner wall may narrow from the receptacle opening to bottom of the receptacle (e.g., where the reagent ampule 135 resides). This tapering of the receptacle 120 may act as a guide for the dipstick 110, such that if the
5 dipstick 110 enters the cavity of the receptacle 120 at an angle, the tapered inner wall may direct the dipstick 110 further downward into the cavity. This may mitigate any issues with the dipstick failing to enter the reagent ampule 135, and thereby further mitigating the possibility of user error in using the assembly 100.

Reagent Ampule 135

10 The reagent ampule 135 may house or store a reagent for use in identifying a test sample. Reagents that the reagent ampule 135 may house include, but are not limited to, cobalt(II) thiocyanate, cobalt(II) acetate, glacial acetic acid, methanol, p-Dimethylaminocinnamaldehyde (DMACA), acetaldehyde, vanillin, ethanol, hydrochloric acid, chloroform, p-dimethylaminobenzaldehyde (DMAB), molybdic acid, sulfuric acid, ammonium molybdate,
15 gallic acid, gold(III) bromide, potassium nitrite, ammonium metavanadate, formaldehyde, mercuric chloride, potassium iodide, selenous acid, potassium tetraiodomercurate(II), nitric acid, acetaldehyde, acetone, sodium nitroprusside, sodium carbonate, potassium hydroxide, 1,3-dinitrobenzene, copper (II) sulfate, pyridine, or a combination thereof. In some cases, the reagent used can be added to the assembly prior to use, or can be replaced in order to conduct
20 additional testing.

Seal

A seal 130 may enclose the reagent ampule 135 from external environs, including other items located in the receptacle 120. In some cases, the seal 130 may be a duckbill valve (e.g., a Kalrez duckbill valve, a joker valve). In other cases, the seal 130 may include a thinned portion
25 (e.g., a metal or plastic foil, which can be perforated), which may include a weaker integrity from the rest of the seal 130, allowing an object to puncture the seal 130 with minimal force. Further, the seal may be composed of rubber, synthetic elastomer, or a similar composition.

Detachable Lid

A lid 105 may enclose the receptacle 120 and prevent contaminants from coming in
30 contact with other portions of the assembly 100 enclosed in the receptacle, as well as preventing the other components of the assembly 100 from accidentally being removed/falling out. When

detached, the lid 105 may act as a handle for the dipstick 110, allowing for easier use by a user in attaching a test sample and conducting a chemical analysis of the test sample.

Further, the lid 105 may include dimensions to allow the lid to attach directly to the receptacle 120. For example, the lid 105 may be threaded, allowing the lid 105 to be screwed
5 onto the receptacle 120. Alternatively, the lid 105 and/or an end of the receptacle 120 may include one or more hooks for a snap fit. As shown in FIG. 2, the open end of the receptacle 120 and the lid 105 include a hook 205. Further, the lid 105 in FIG. 2 includes a lip 215. The lip 215 in some cases spans the entire surface of the lid 105 (e.g., the circumference of the lid 105) and is thus annular. When the lid 105 is pressed onto the receptacle 120, the lip 215 is pressed past the
10 hook 205 of the receptacle 120, thereby allowing the lid 105 to be “snapped” to the receptacle opening and securely fastening the lid 105 to the receptacle 120. However, any other fastening means for securely attaching a lid to a container may be used (e.g., a press fit, a friction fit, an interference fit, and the like).

Dipstick or Straw

15 The lid 105 may be coupled to the dipstick 110. The dipstick 110 may be distal in shape, for example, an elongated rectangle, an elongated orthotope, a pipe, a cylinder, a pipette, a strip, and the like. The distal end of the dipstick 110 may allow for a test sample to be attached to the dipstick 110 (e.g., through surface tension, absorption, capillary action, adhesion, and the like). For example, the distal end may form a swab, a pipette, a straw, a pin, a hook, a claw, a strip, a
20 porous portion, or a similar structure or shape.

Further, the dipstick 110 may be dimensioned such that the location of the distal end of the dipstick 110 within the receptacle cavity is dependent upon whether the tamper-evident seal is attached to, or detached from, the assembly 100. For example, when the tamper-evident seal 115 is attached the lid 105, and when the lid 105 is attached to the receptacle 120, the
25 dipstick 100 may have a length such that the distal end of the dipstick 110 is located above the reagent ampule 135, thereby leaving the seal 130 intact. Alternatively, when the tamper-evident seal 115 is detached from the lid 105, and the lid 105 is directly attached to the receptacle 120, the length of the dipstick 110 may allow for the distal end of the dipstick 110 to enter the reagent ampule 135 by penetrating the seal 130. Thus, the penetration of the seal 130 and exposure of the
30 composition contained within the reagent ampule 135 is dependent upon whether the tamper-evident seal 115 has been removed from the assembly 100.

Observer Window

The assembly 100 may also include a viewing window 125. The observer window 125 may be transparent and may be coupled to the receptacle 120. The observer window 125 may be adjacent to the reagent ampule 135, which may allow a user of the assembly 100 to view the contents of the reagent ampule 135 without having to open the assembly 100. In the case of where the tamper-evident seal 115 is removed, allowing the dipstick 110 to penetrate the seal 130 and into the reagent ampule 135, the observer window 125 may allow a user to observe a chemical reaction (*e.g.*, by appearance of a color depending on the result) occurring if a test sample reacts positively to the reagent composition contained within the reagent 135. This may assist in minimizing exposing the assembly 100 to external contaminants and/or improper use of the assembly 100.

Exemplary Materials

As will be appreciated by one of ordinary skill in the art, the invention provided herein can be fabricated from a variety of materials such as plastic, rubber, metal, and the like by use of various manufacturing techniques such as molding, casting, machining, and the like. For example, components can be formed from polymeric materials such as polypropylene (PP), polyethylene terephthalate (PET), polycarbonate (PC), copolyesters (*e.g.*, PTCG and copolyesters available under the TRITAN™ mark from Eastman Chemical Company of Kingsport, Tenn.), polyphthalate carbonate (PPC), and the like.

Exemplary Workflow

FIG. 5 illustrates an exemplary process 500 for performing a chemical analysis on a test sample. In some cases, the exemplary process 500 may be implemented in conjunction with a container, such as assembly 100 as described with reference to FIG. 1. Additionally, FIG. 4 may provide an illustrated workflow process 400 for the assembly 100.

At Step 505, a container, such as assembly 100, may be obtained. At Step 510, a tamper-evident seal of the container may be removed from a detachable cap of the container. At Step 515, the detachable cap may be detached from a receptacle of the container. In some cases, the detachable lid may be attached directly to the receptacle subsequent to the tamper-evident seal being removed from the detachable lid. At Step 520, a dipstick of the container may be advanced distally to breach a seal of the container and enter a distal chamber of the container. In some cases, a test sample may be coupled to the dipstick prior to advancing the dipstick distally.

Exemplary Reagents

Although detection of fentanyl in opioids such as heroin is a particularly acute challenge, embodiments of the invention can be combined with other reagents to detect a variety of substances. Exemplary reagents and detectable substances are summarized below.

Reagent	Composition	Target(s)
Buffer	Any weak base or acid	Fentanyl
Mecke Reagent	Selenous acid and concentrated sulfuric acid Mandelin ammonium metavanadate and concentrated sulfuric acid	Alkaloids, chlorpromazine HCl, codeine, diacetylmorphine HCl (heroin), dimethoxy-meth HCl, doxepin HCl, DRISTAN® (oxymetazoline hydrochloride), EXEDRINE® (aspirin/paracetamol(acetaminophen)/caffeine), LSD, Methylenedioxyamphetamine HCl (MDA), Mescaline HCl, Morphine monohydrate, opium, oxycodone HCl, propoxyphene HCl, PMMA, and PMA
Ehrlich Reagent	P- dimethylaminobenzaldehyde	Indoles, urobilinogen, tryptamines (e.g., DMT), ergoloids (e.g., LSD), and opium
Marquis Reagent	Mixture of formaldehyde and concentrated sulfuric acid	Opiates (e.g., codeine, heroin) and phenethylamines (e.g., 2C-B, mescaline).

Reagent	Composition	Target(s)
Mandelin Reagent	Mixture of ammonium metavanadate and concentrated sulfuric acid	2C-T-7, acetaminophen, benzphetamine, chlorpromazine, cocaine, codeine, d-amphetamine, d-methamphetamine, diacetylmorphine (heroin), dimethoxy-meth, doxepin, DRISTAN® (oxymetazoline hydrochloride), EXEDRINE® (aspirin/paracetamol(acetaminophen)/caffeine), ketamine, MDA, MDMA, mescaline, methadone, methaqualone, methylphenidate, morphine monohydrate, opium, oxycodone, procaine, propoxyphene, psilocybin, paramethoxyamphetamine (PMA), paramethoxymethamphetamine (PMMA)

Reagent	Composition	Target(s)
Froehde Reagent	Mixture of molybdic acid or a molybdate salt dissolved in hot, concentrated sulfuric acid	Amphetamine, cathinone, methcathinone, 4-MMC, 3-FMC, MDMA, methylone, MDPV, butylone, 3,4-DMMC, naphyrone, PMA, PMMA, 4-MeO-PCP, methoxetamine, 3-HO-PCE, 5-MeO-DALT, 4-AcO-DALT, 4-HO-MET, 4-HO-MIPT, 4-AcO-DET, aMT, 5-IT, 5-APB, 6-APB, camfetamine, methiopropamine, MDAI, 5-IAI, allylescaline, 2C-T-2, 2C-B, 2C-P, b-methoxy-2C-D, acetaminophen, aspirin, alimemazine, chlorphentermine, chlorpromazine HCl, Contac HCl, dimethoxy-meth HCl, diphenhydramine, doxepin HCl, DRISTAN® (oxymetazoline hydrochloride), EXEDRINE® (aspirin/paracetamol(acetaminophen)/caffeine), flurazepam, LSD, MDA HCl, mescaline, meperidine, modafinil, morphine monohydrate, heroin HCl, opium, oxycodone HCl, codeine HCl, hydromorphone, hydrocodone, pentazocine, pethidine, phenoxymethylpenicillin, phenyltoloxamine, promazine, promethazine, propoxyphene HCl, propylhexadrine, salicylic acid, tetracycline, thioridazine, guaifenesin, methapyrilene, pyrilamine, trifluoperazine, and triflupromazine

Reagent	Composition	Target(s)
Liebermann Reagent	Mixture of potassium nitrite and concentrated sulfuric acid	Alprazolam, cocaine, morphine, atropine, yohimbine, PMA, PMMA, MDMA, amphetamine, methamphetamine, 4-FA, cathinone, methcathinone, 4-MMC, N,N-DMC, 3-FMC, 4-MOMC, methylone, MDPV, 4-Me-PPP, brephedrone, 4-MEC, pentedrone, 4-methylbuphedrone, buphedrone, butylone, 3,4-DMMC, naphyrone, benzedrone, JWH-307, AB-001, CB-13, JTE-907, UR-144, URB-597, URB602, URB754, AM-1248, AB-034, A-796,260, A-834,735, FUR-144, APINACA, JWH-073, JWH-018, JWH-200, AM-2201, JWH-203, RCS-4-C4 homolog, AM-694, MAM-2201, AM-2233, STS-135, 4-MeO-PCP, methoxetamine, ethketamine, 3-HO-PCE, 5-MeO-DALT, 4-methyl-aET, 4-AcO-DALT, 4-HO-MET, 4-HO-MIPT, 4-AcO-DET, DPT, aMT, 5-IT, 5-APB, 6-APB, camfetamine, methiopropamine, MDAI, 5-IAI, pethidine, mescaline, allylescaline, 2C-T-2, 2C-P, 2C-C, 2C-B, b-methoxy-2C-D

Embodiments of the invention can also be used in combination with other reagents that do not detect substances. For example, embodiments of the invention can be utilized to perform organic chemistry reactions (*e.g.*, in a laboratory).

Exemplary Multi-Component Dipsticks

5 Embodiments of the invention can be combined with a variety of test architectures. For example, FIG. 13 depicts a fentanyl testing kit. In the fentanyl testing kit, there is a pre-wetted (*e.g.*, at manufacture) swab on a rigid backer stick that is attached to the lid and can be wiped across a surface or through a sample. There is immunoassay paper mounted on the rigid backer just above the pre-wetted swab (after a dry separation area so the immunoassay paper is not
10 wetted ahead of testing). Upon obtaining a sample on the swab, the rigid backer stick is pressed

into the body of the kit and into the buffer solution (contained in the ampule) upon which the buffer solution is wicked up into the immunoassay paper (the level of the buffer liquid is such that it is higher than the dry separation area at this time).

EQUIVALENTS

5 Although preferred embodiments of the invention have been described using specific terms, such description is for illustrative purposes only, and it is to be understood that changes and variations may be made without departing from the spirit or scope of the following claims.

INCORPORATION BY REFERENCE

10 The entire contents of all patents, published patent applications, and other references cited herein are hereby expressly incorporated herein in their entireties by reference.

CLAIMS

1. A system comprising:
 - a detachable cap;
 - a dipstick coupled to the detachable cap;
 - a tamper-evident seal tearably coupled to the detachable cap; and
 - a receptacle comprising:
 - a sidewall terminating in a proximal end releasably engaged with the tamper-evident seal;
 - a distal chamber; and
 - a seal isolating the distal chamber;wherein the detachable cap, the dipstick, the tamper-evident seal, and the receptacle are dimensioned such that:
 - the dipstick is restrained by the tamper-evident seal from advancing distally and breaching the seal until the tamper-evident seal is removed from the detachable lid; and
 - upon removal of the tamper-evident seal, the dipstick can be advanced distally to breach the seal.
2. The system of claim 1, further comprising:
 - a reactant agent contained in the distal chamber.
3. The system of claim 2, wherein the tamper-evident seal's attachment to the detachable lid is indicative of an uncompromised status of the reactant agent.
4. The system of claim 2, wherein the tamper-evident seal's removal from the detachable lid is indicative of a potentially compromised status of the reactant agent.
5. The system of claim 2, the dipstick further comprising an end, wherein the end is dimensioned such that the dipstick is attachable to a test sample.
6. The system of claim 5, wherein advancing the test sample into the reactant agent results in a chemical reaction.

7. The system of claim 6, further comprising:
a transparent window within the receptacle, wherein an observer can view the chemical reaction via the transparent window.
8. The system of claim 7, wherein the transparent window is adjacent to the distal chamber.
9. The system of claim 1, wherein the detachable lid is further dimensioned so that the detachable lid can be attached to the receptacle upon the tamper-evident seal being removed from the detachable lid.
10. The system of claim 9, wherein the receptacle, the tamper-evident seal, and the detachable lid include complementary mating features.
11. The system of claim 10, wherein the complementary mating features comprise ridges.
12. The system of claim 10, wherein the ridges are annular in shape.
13. A method of performing a chemical analysis on a test sample using a system, the method comprising:
obtaining the system according to any one of claims 1-12;
removing the tamper-evident seal from the detachable cap;
detaching the detachable cap from the receptacle; and
advancing the dipstick distally to breach the seal and enter the distal chamber.
14. The method of claim 13, the method further comprising:
coupling a test sample to an end of the dipstick; and
advancing the test sample through the seal and into the reactant agent upon removal of the tamper-evident seal.
15. The method of claim 13, further comprising:
attaching the detachable lid directly to the receptacle subsequent to the tamper-evident seal being removed from the detachable lid.

16. A kit comprising:
the system of any one of claims 1-12; and
a set of instructions for implementing a chemical analysis test within the system.

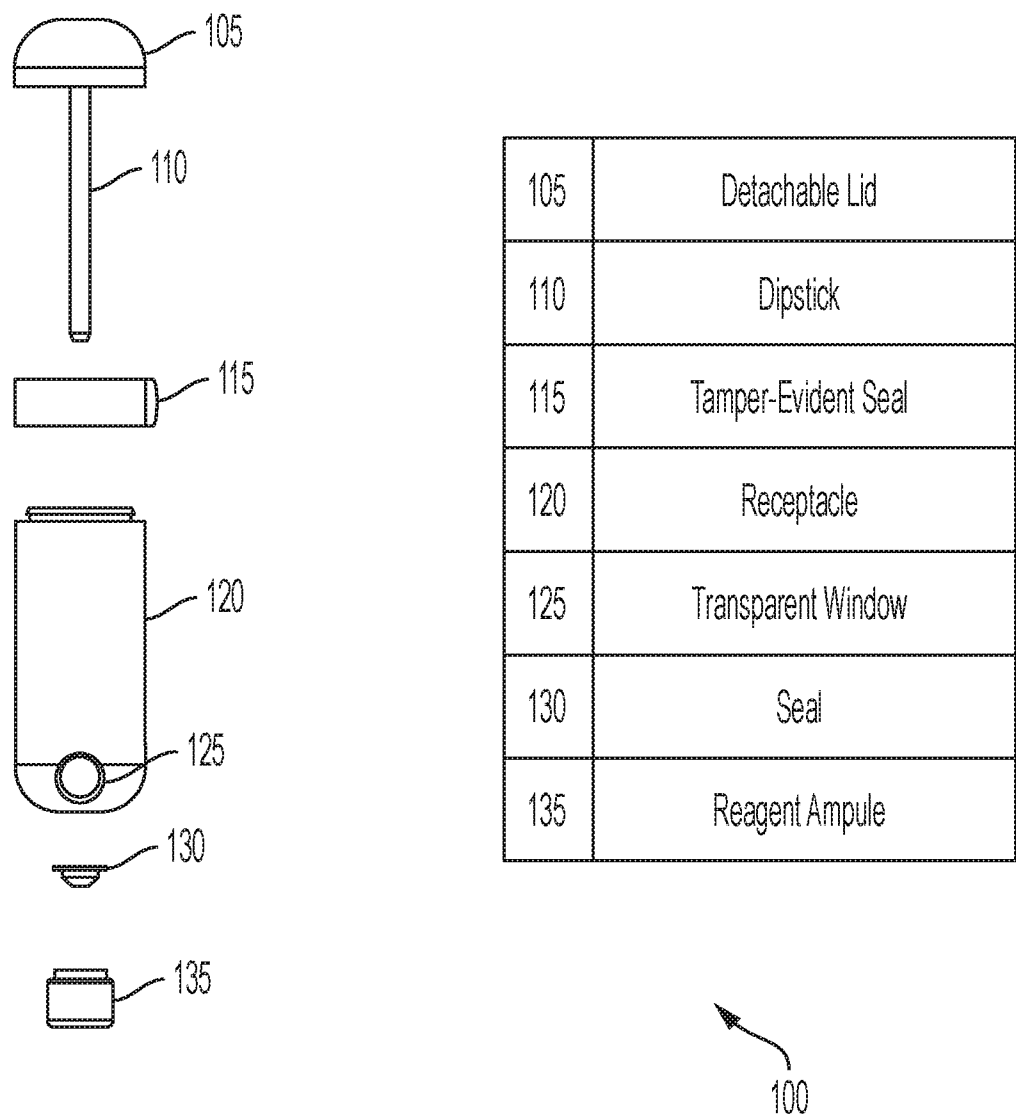


FIG. 1

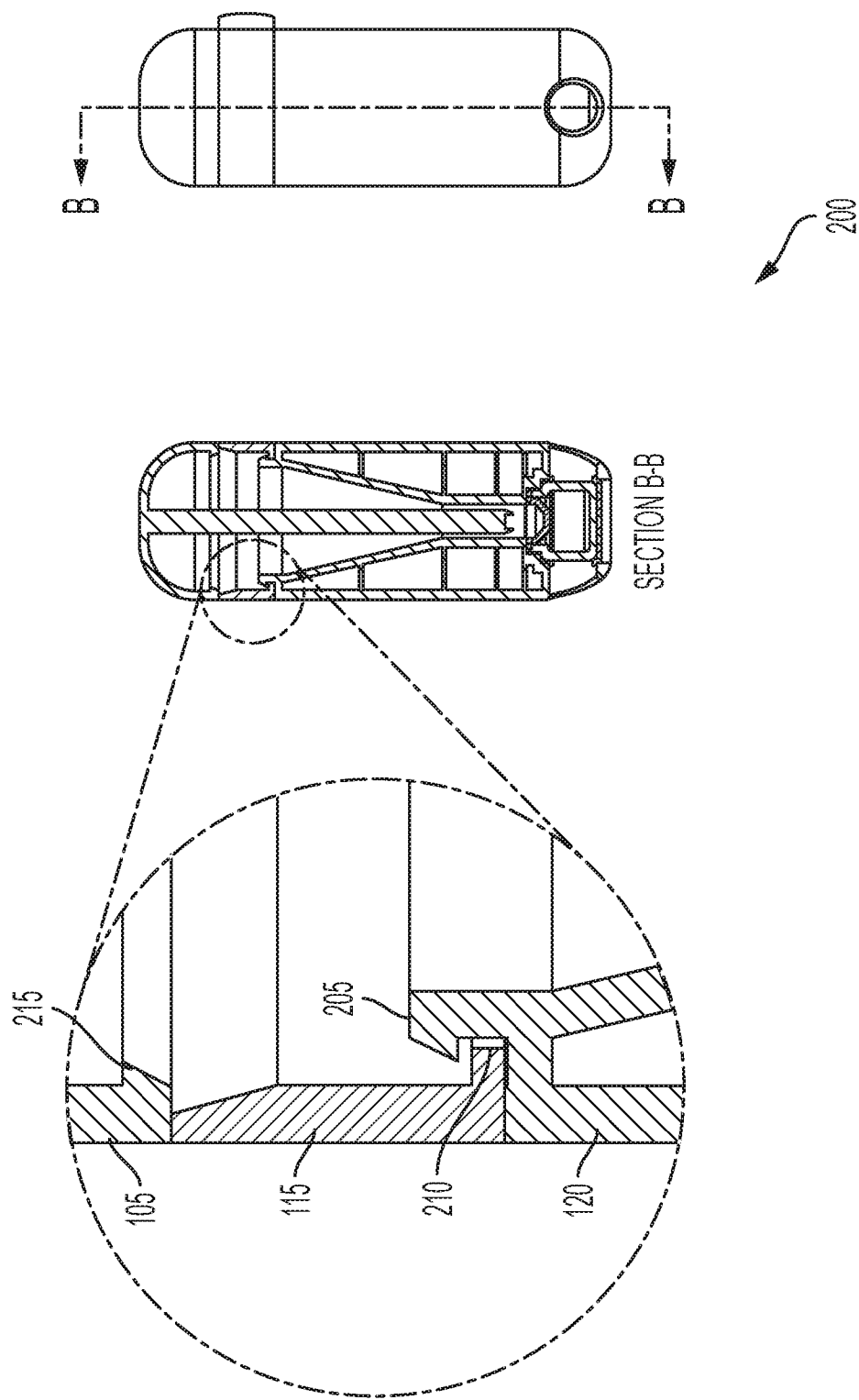


FIG. 2

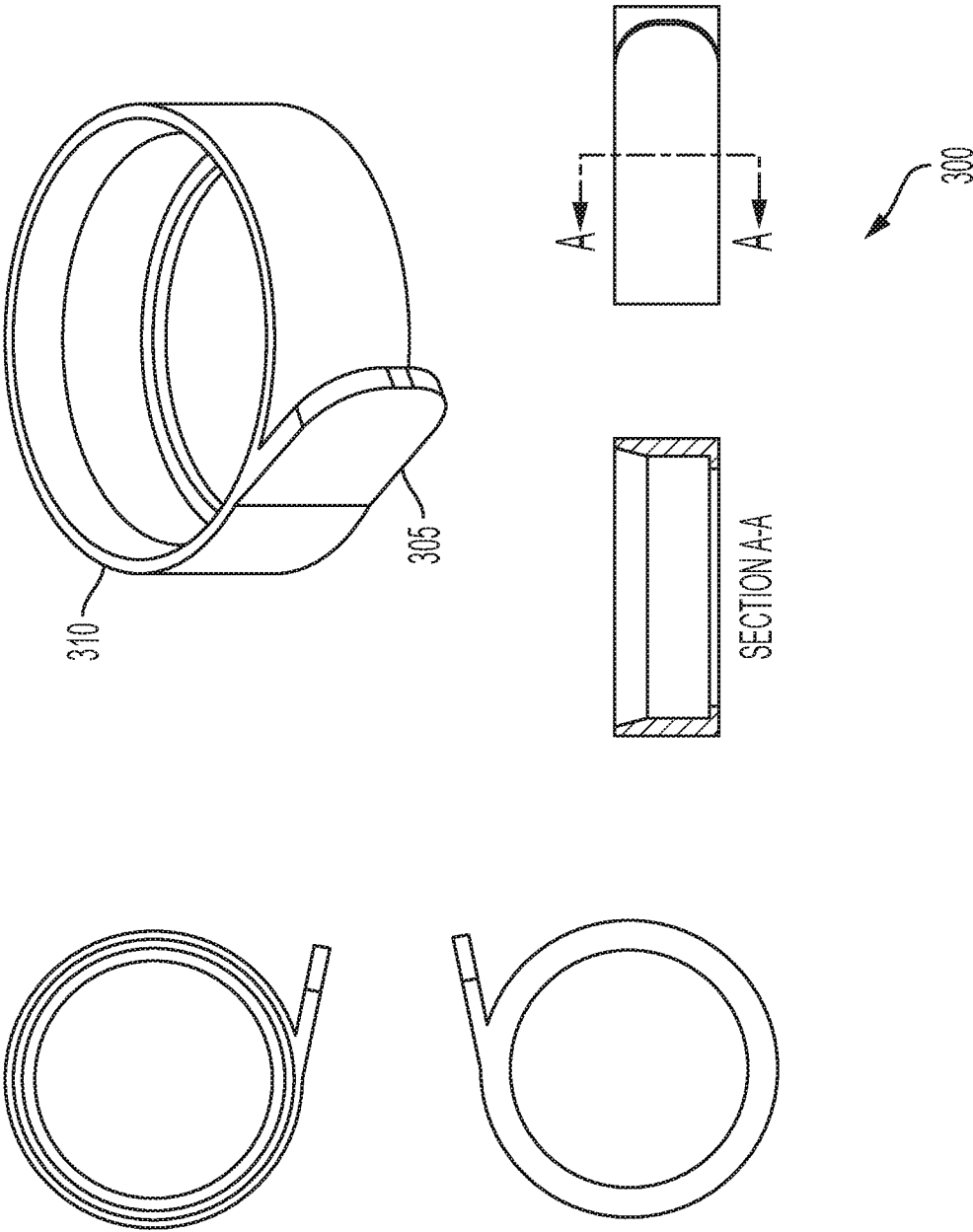


FIG. 3

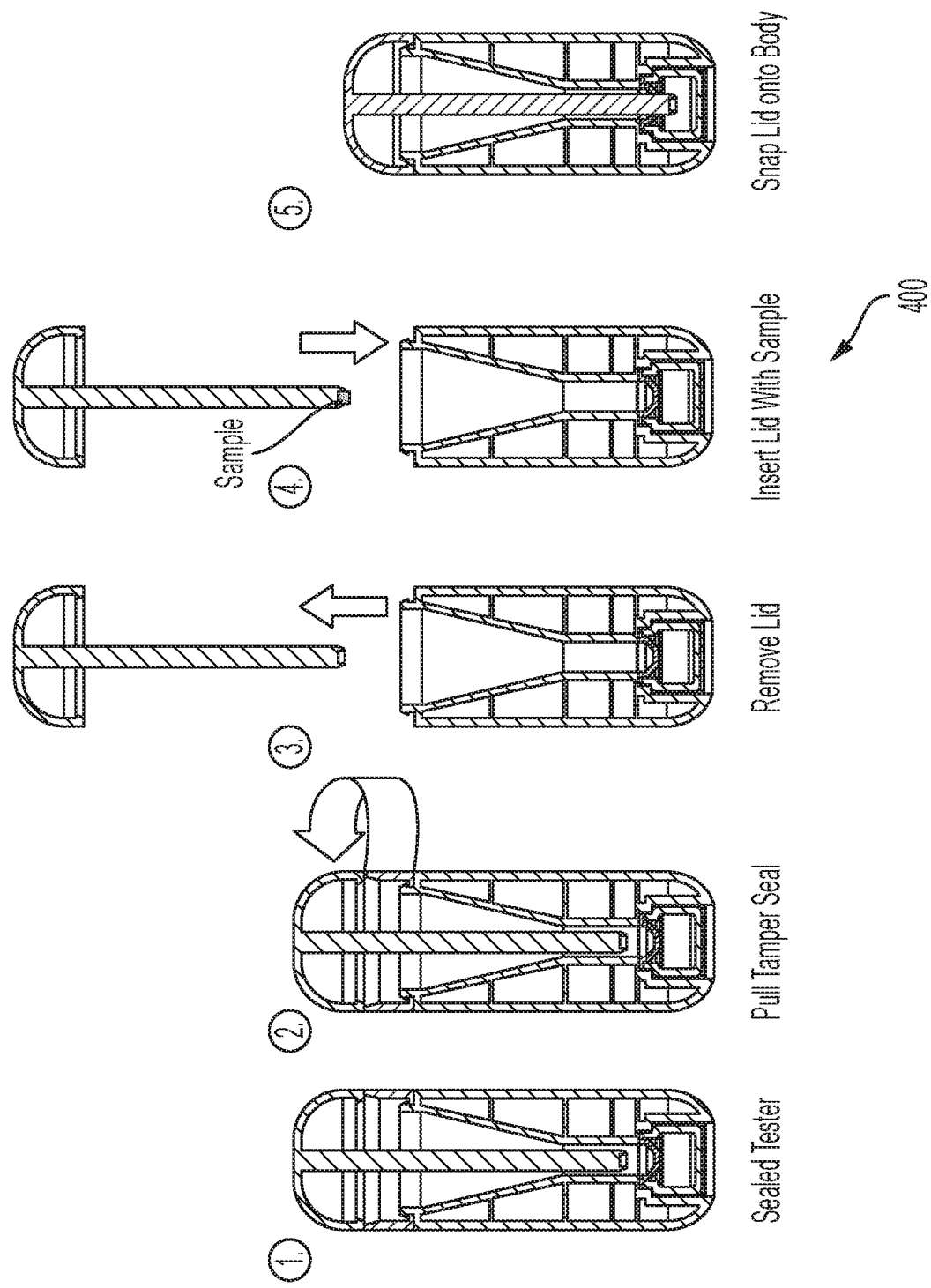


FIG. 4

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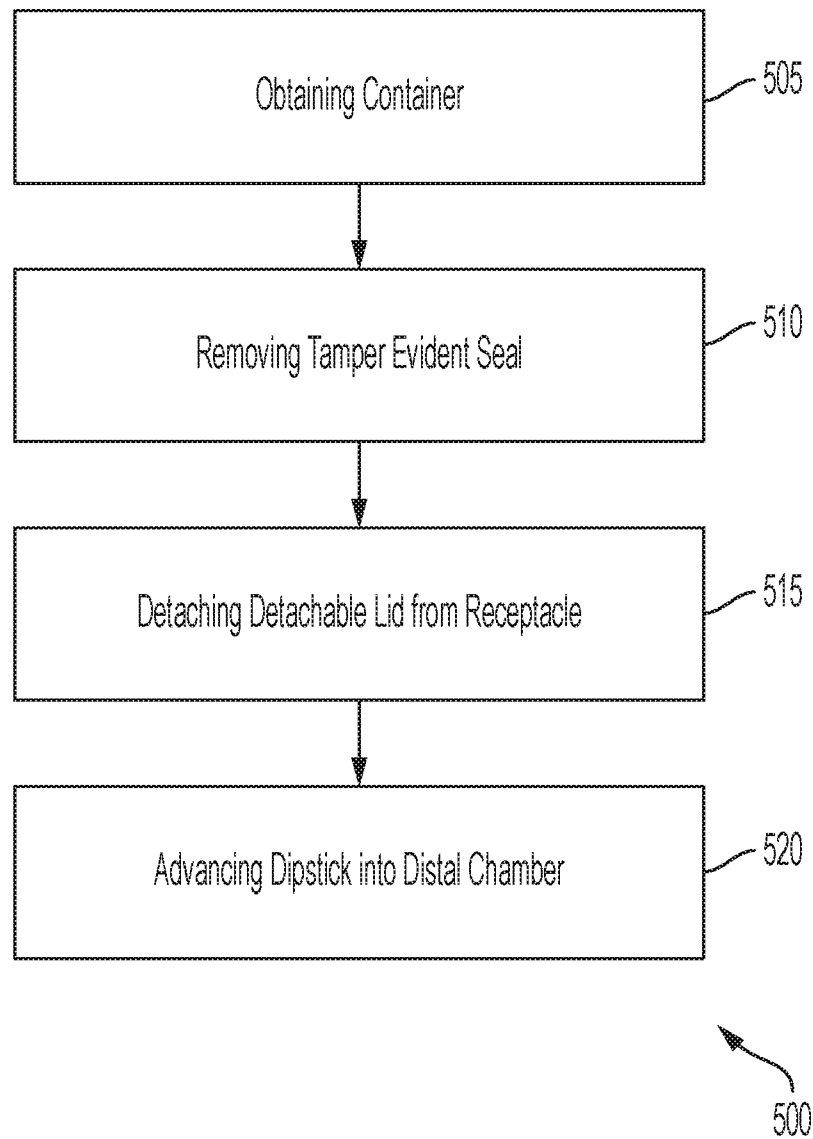


FIG. 5

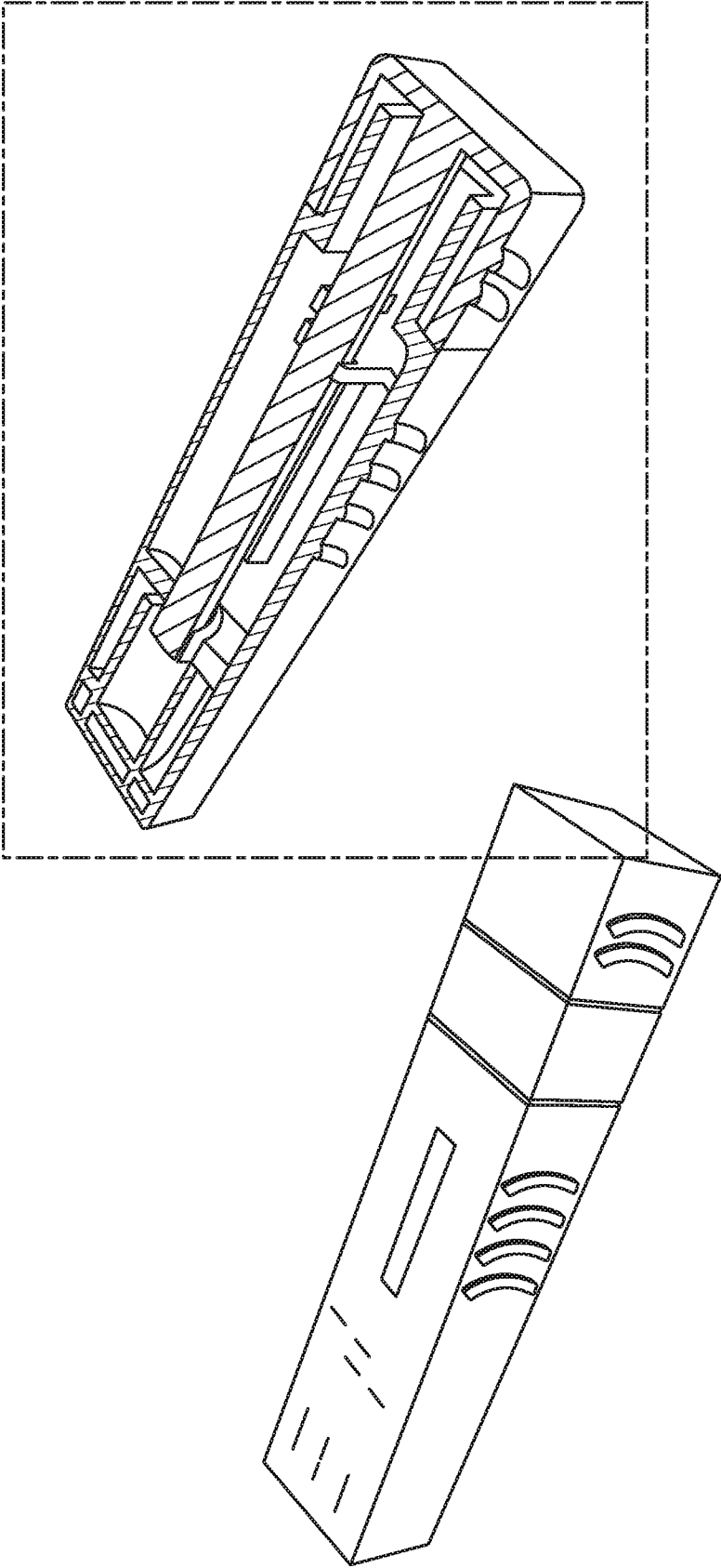


FIG. 6

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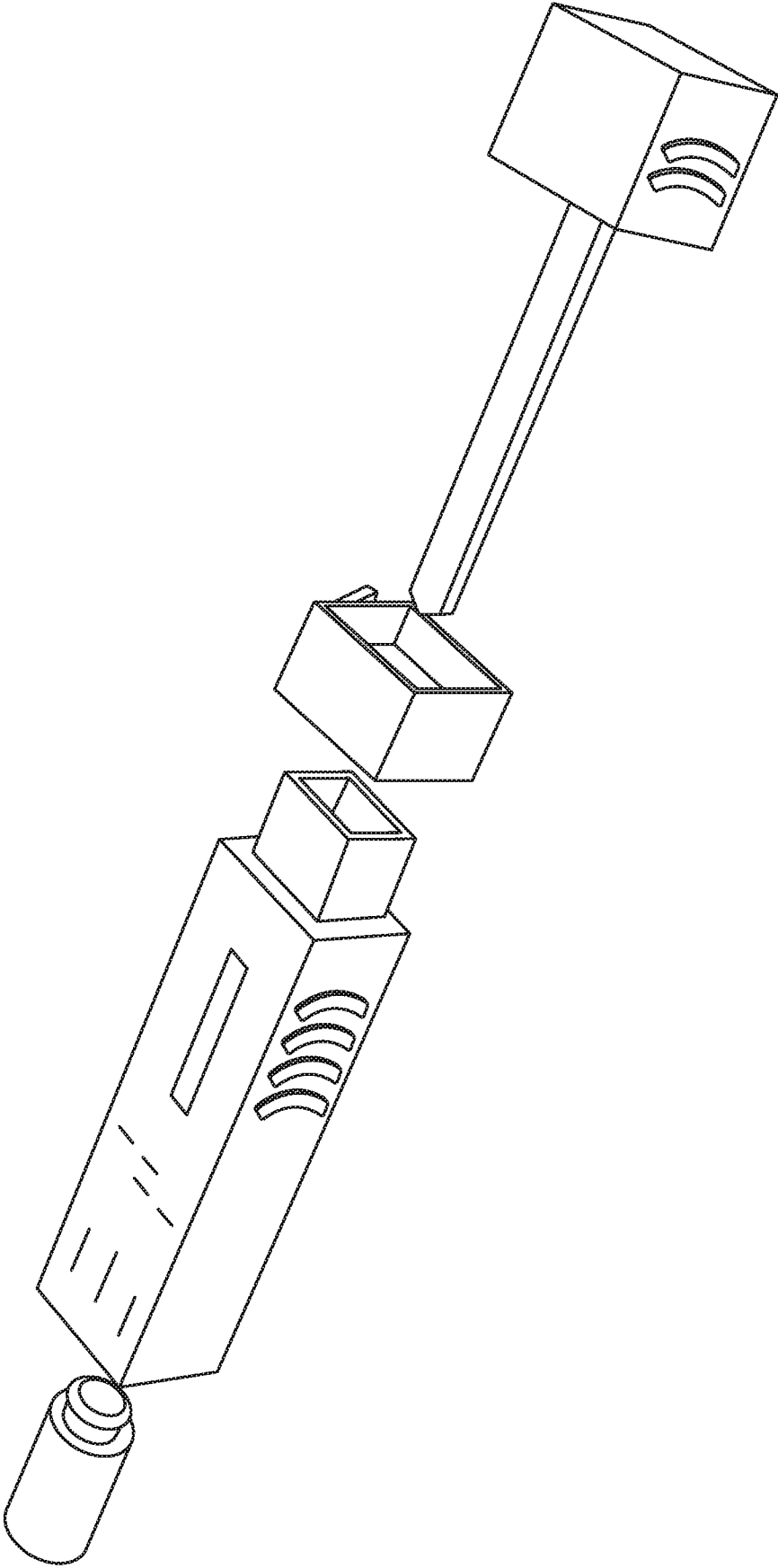


FIG. 7

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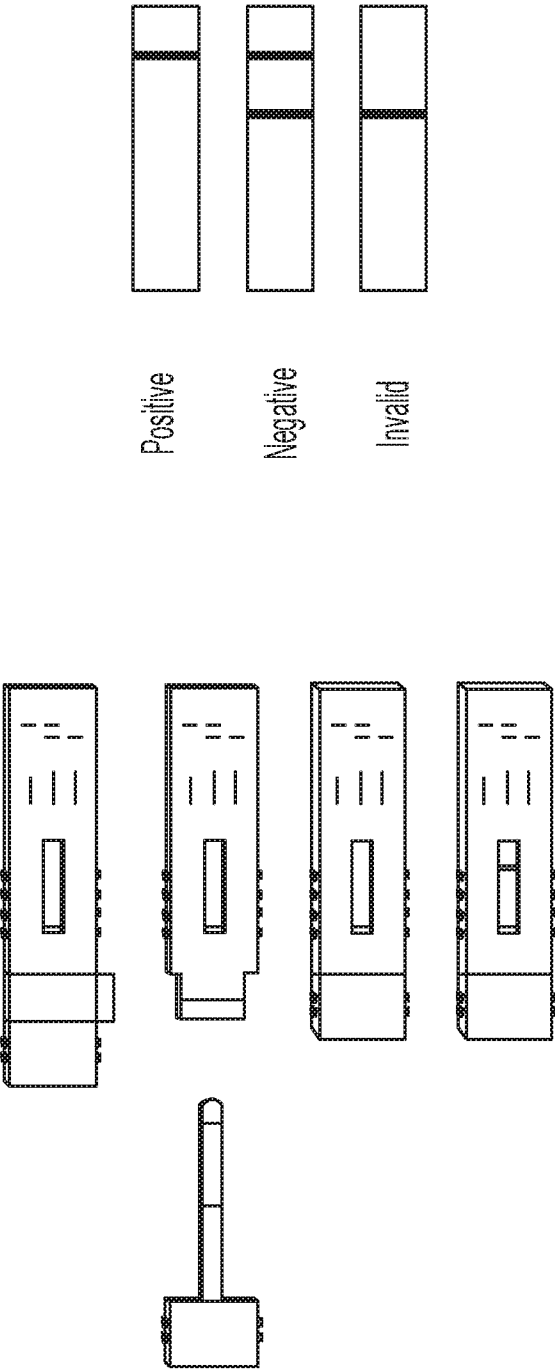


FIG. 8

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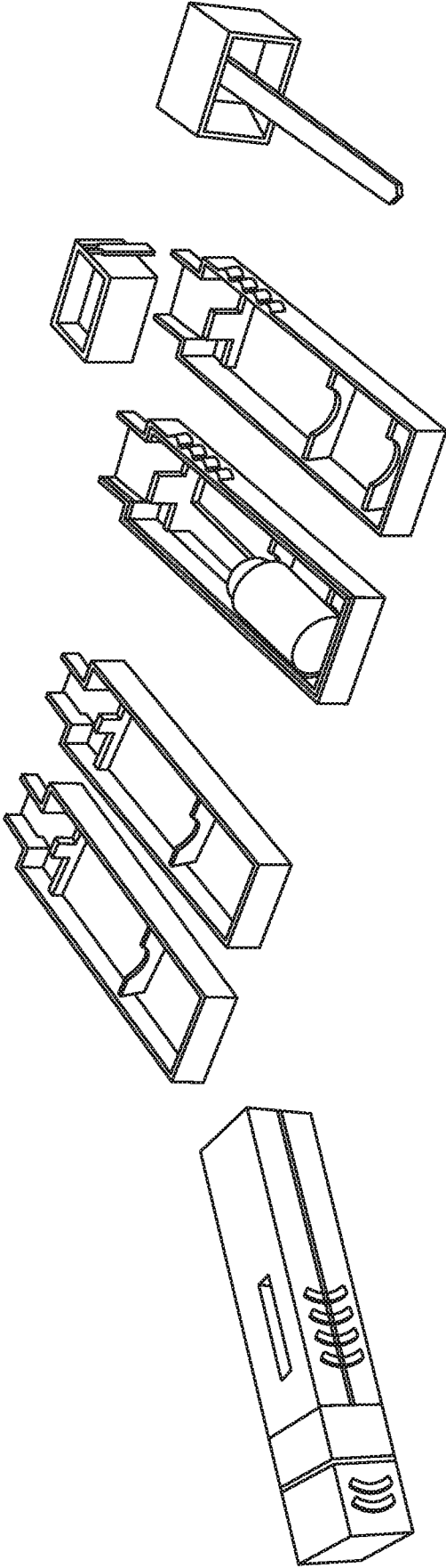


FIG. 9

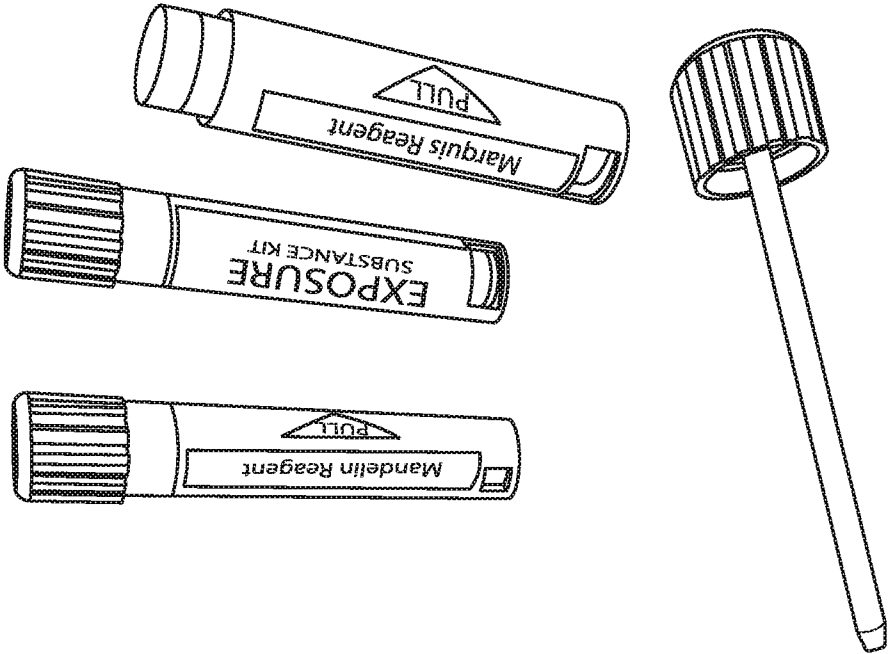


FIG. 10

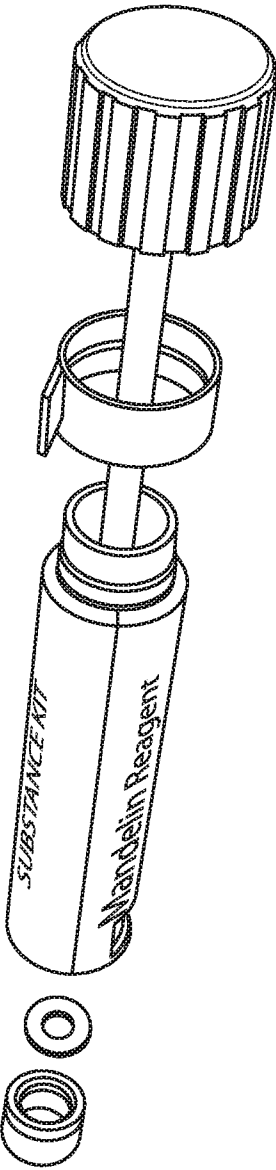


FIG. 11

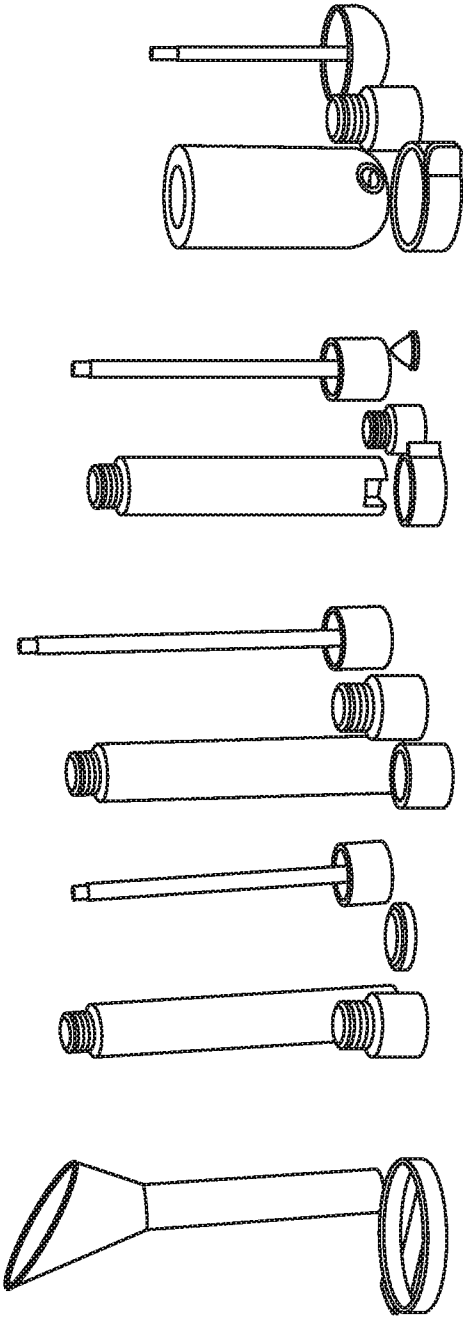


FIG. 12

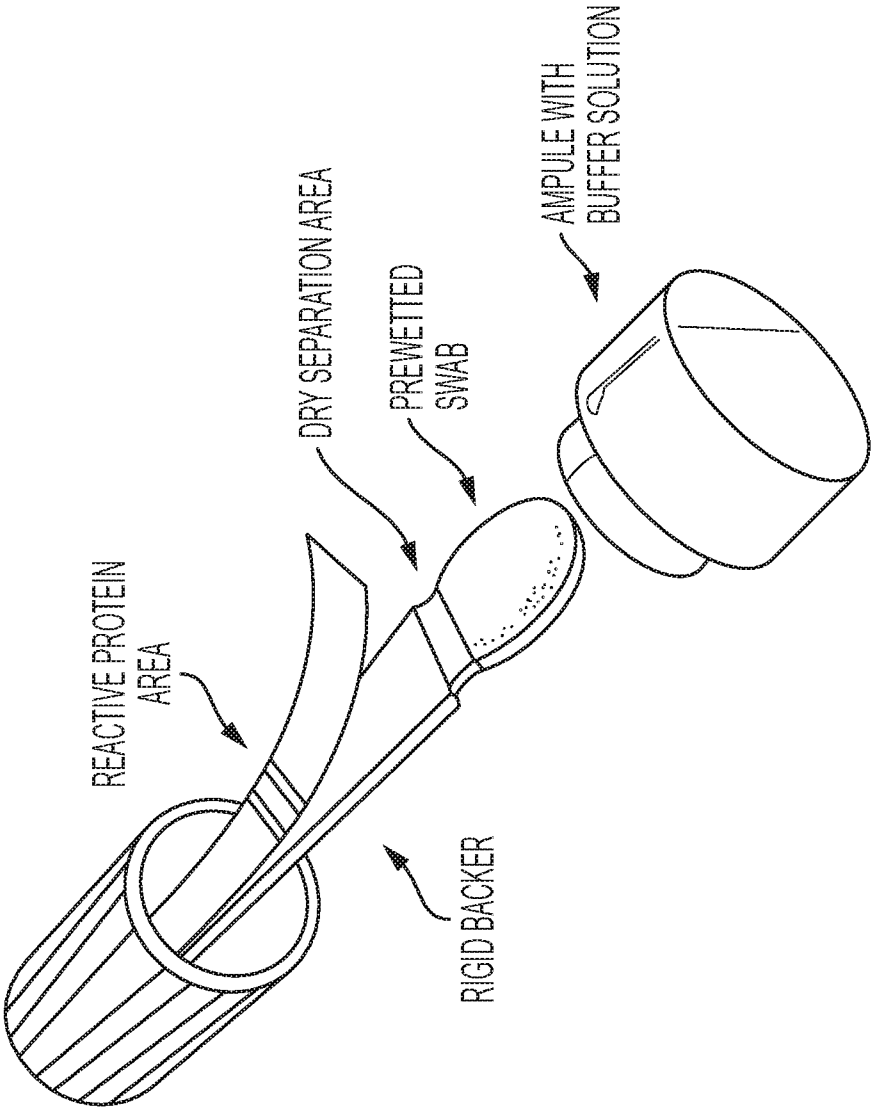


FIG. 13

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US20/19643

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61B 10/02; A61F 13/38 (2020.01)

CPC - A61B 10/0096, 10/02; A61F 13/38; A61M 35/006; B01L 3/5029; C12M 45/22, 23/06, 23/34, 33/02, 23/32

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)

See Search History document

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

See Search History document

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

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4,223,093 A (NEWMAN, H et al.) 16 September 1980; Figures 4-6; Column 5, Lines 9-14	1-16
Y	US 2014/0051178 A1 (NIGGEL, B et al.) 20 February 2014; Figures 1 and 6A-7D; Paragraphs [0029]-[0030]	1-16
Y	WO 1995/25948 A1 (CELSIS INTERNATIONAL PLC) 28 September 1995; Figure 1; Page 3, Lines 13-17	16
A	US 4,409,988 A (GREENSPAN, D) 18 October 1983; Figures 10-14; entire document	1-16
A	US 4,150,950 A (TAKEGUCHI, M) 24 April 1979; Figure 1; entire document	1-16
A	US 3,913,564 A (FRESHLEY, R) 21 October 1975; Figure 1; entire document	1-16
A	US 2017/0320060 A1 (EUROTROL B.V.) 09 November 2017; Figure 6; entire document	1-16
A	US 2018/0185840 A1 (ILLUMINA, INC.) 05 July 2018; Figure 3; entire document	1-16

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

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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

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"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

"&" document member of the same patent family

Date of the actual completion of the international search

28 April 2020 (28.04.2020)

Date of mailing of the international search report

15 MAY 2020

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents

P.O. Box 1450, Alexandria, Virginia 22313-1450

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