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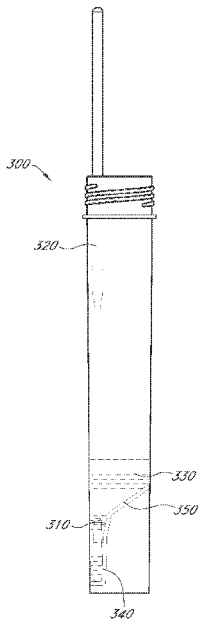


FIG. 3A

(57) Abstract: Systems and methods under the present disclosure include swabs and storage tubes for use in medical environments. The various embodiments can help prevent cross contamination in laboratories or make swabs and storage tubes more compatible with automated laboratory processes. Accurate positioning of swabs can help make any pipetting procedures more accurate, easier and quicker.

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SWAB COLLECTION SYSTEMS AND METHODS

BACKGROUND

Technical Field

[0001] This disclosure generally relates to swabs for nasopharyngeal, oropharyngeal, nasal, mid-turbinate, oral, vaginal, rectal sample collection with accompanying storage tubes.

Related Technology

[0002] Swabs are the go-to for diagnostic sampling, especially for respiratory infections. The majority of the swabs used are nasopharyngeal swabs, which are long, thin swabs that are inserted into the nostril up into the nasopharyngeal cavity. However, some swabs are shorter and only go to the nasal mid-turbinate, which is causing less discomfort for the person getting swabbed. Swabs are typically inserted in the tubes for storage and further processing. For some swab designs the shaft is broken to fit into a tube. Typically, the tube contains a liquid reagent that will maintain the viability of the sample for testing in a laboratory. The substance to be detected (such as viruses) is gradually released from swabs into the liquid reagent. These samples can be processed in the thousands and tens of thousands per day for large diagnostic labs, making throughput and ease of use very important. The swabs are free floating inside the tube and can be broken off at different lengths, making it difficult for automated processes to access the liquid sample material at the bottom of the test tube.

[0003] The swab shafts can get in the way of pipetting an aliquot of sample from the tube, for both automated and manual processes. The shaft can be hit by the pipet tip when inserted into the tube – causing an error on the liquid handler or potentially injuring the lab technician manually removing the sample. Also, the shaft can adhere to the pipet tip by surface tension and pull out of the tube, what is called "swab lift", which can be very problematic and cause cross-contamination.

[0004] Previously, labs have largely used manual pipetting so a person can visually see where the swab is to take the aliquot of sample out of the tube. This approach works but takes substantially longer time than using an automated workflow with instruments. It also puts more people at risk of exposure to the disease-causing agents typically present in the tubes.

[0005] Another way to overcome this problem is to have the medical technician cut the swab shaft off at the very top of the swab so there is minimal shaft in the tube to interfere with pipetting. Except for possible swab lift, this strategy helps, but again, takes quite a bit more time and runs the risk of sample cross contamination and having contaminated scissors lying around a medical facility.

[0006] The alternative approach to overcome this issue is to remove the swabs prior to using the liquid handlers. This again requires manual manipulation of the sample. A lab technician would manually have to remove all the swabs and discard them into biohazard trash. This method increases the risk of exposure to the technician by manipulating the samples. There is also the chance of cross-contamination by accidently dripping liquid from one swab into the tube of other samples. One would have to take lots of care and caution when using this method. And finally, some labs just take the chance of the liquid handler not hitting the swab shaft when left in the tube and have a technician watch the liquid handler work to ensure no cross-contamination via swab lift.

[0007] Thus, there is a need for better swab collection devices, especially devices compatible with automated liquid handlers and automated sample processing systems.

BRIEF SUMMARY

[0008] One embodiment of the present disclosure is an insert for a storage or specimen tube. The insert can comprise a rim configured to be inserted into a storage tube and to extend around at least a portion of an interior surface of the storage tube; and one or more indentations in the rim configured to receive one or more swabs between the one or more indentations and the interior surface of the tube.

[0009] Another embodiment comprises a swab for medical testing. The swab comprises a shaft; absorbent material at one end of the shaft; and one or more lateral extensions extending from the shaft and configured to hold the swab in place within a storage tube.

[0010] A further embodiment comprises a storage tube. The tube comprises an open end configured to receive test material therethrough; an elongated portion configured to contain test material; and a pocket within the elongated portion and distal to the open end, the pocket configured to receive a portion of one or more swabs therein and restrain the one or more swabs.

[0011] Another embodiment comprises a method of restraining a swab within a storage tube. The method can include inserting an insert into a tube, the insert comprising; a rim configured to be inserted into a storage tube and to extend around at least a portion of an interior surface of the tube; and one or more indentations in the rim configured to receive one or more swabs between the one or more indentations and the interior surface. The method can further include inserting one or more swabs into the tube such that one of the one or more indentations holds the one or more swabs in place along the interior surface.

[0012] Another embodiment comprises a method of restraining a swab within a storage tube. The method can include inserting a swab into a tube, the swab comprising; a shaft; absorbent material at one end of the shaft; and one or more lateral extensions extending from the shaft and configured to hold the swab in place within a storage tube.

[0013] Another embodiment comprises a method of restraining one or more swabs within a storage tube. The method can include inserting one or more swabs into a storage tube, the storage tube comprising: an open end configured to receive a swab therethrough; an elongated portion configured to contain test material; and a pocket within the elongated portion and distal to the open end, the pocket configured to receive a portion of one or more swabs therein and restrain at least some movement of the one or more swabs.

[0014] Another embodiment under the present disclosure comprises a method of manufacturing an insert for a storage tube. The method can comprise providing a rim configured to be inserted into a tube and to extend around at least a portion of an interior surface of the tube; and providing one or more indentations in the rim configured to receive one or more swabs between the one or more indentations and the interior surface.

[0015] Another embodiment under the present disclosure comprises a method of manufacturing a swab for a storage tube. The method can comprise providing a shaft; providing absorbent material at one end of the shaft; and providing one or more lateral extensions extending from the shaft and configured to hold the swab in place within a tube.

[0016] Another embodiment under the present disclosure comprises a method of manufacturing a storage tube. The method can comprise providing an open end configured to receive test material therethrough; providing an elongated portion configured to contain test material; and providing a pocket within the elongated portion and distal to the open end, the pocket

configured to receive a portion of one or more swabs therein and restrain at least some movement of the one or more swabs.

[0017] Another embodiment under the present disclosure comprises a specimen tube. The specimen tube can comprise an open end configured to receive test material therethrough; and an elongated portion. The elongated portion comprises a top portion fluidly coupled to the open end; an extended pocket fluidly coupled to the top portion and extending downward from the top portion; and a bottom portion fluidly coupled to the extended pocket; wherein the extended pocket is configured to receive a portion of one or more swabs therein and restrain the one or more swabs.

[0018] This summary is provided to introduce a selection of concepts in a simplified form that are further described below in the detailed description. This summary is not intended to identify key features or essential features of the claimed subject matter, nor is it intended to be used as an indication of the scope of the claimed subject matter.

[0019] The foregoing has outlined rather broadly the features and technical advantages of the present disclosure in order that the detailed description of the embodiments that follows may be better understood. Additional features and advantages of the disclosure will be set forth in the description which follows, and in part will be obvious from the description, or may be learned by the practice of the disclosure. The features and advantages of the disclosure may be realized and obtained by means of the instruments and combinations particularly pointed out in the appended claims. These and other features of the present disclosure will become more fully apparent from the following description and appended claims or may be learned by the practice of the disclosure as set forth hereinafter. It should be appreciated by those skilled in the art that the conception and specific embodiment disclosed may be readily utilized as a basis for modifying or designing other structures for carrying out the same purposes of the present invention. It should also be realized by those skilled in the art that such equivalent constructions do not depart from the spirit and scope of the invention as set forth in the appended claims. The novel features which are believed to be characteristic of the invention, both as to its organization and method of operation, together with further objects and advantages will be better understood from the following description when considered in connection with the accompanying figures. It is to be expressly understood, however, that each of the figures is provided for the purpose of illustration and description only and is not intended as a definition of the limits of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] In order to describe the manner in which the above recited and other advantages and features of the disclosure can be obtained, a more particular description of the disclosure briefly described above will be rendered by reference to specific embodiments thereof, which are illustrated in the appended drawings. It is appreciated that these drawings depict only typical embodiments of the disclosure and are not therefore to be considered to be limiting of its scope. The disclosure will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

[0021] FIGS. 1A, 1B and 1C show prior art swab, storage tube and cap embodiments;

[0022] FIGS. 2A-2C show insert embodiments under the present disclosure;

[0023] FIGS. 3A-3C show specimen tube embodiments under the present disclosure;

[0024] FIGS. 4A-4C show swab embodiments under the present disclosure;

[0025] FIG. 5 shows a flow chart of a method embodiment under the present disclosure;

[0026] FIG. 6 shows a flow chart of a method embodiment under the present disclosure;

[0027] FIG. 7 shows a flow chart of a method embodiment under the present disclosure;

[0028] FIG. 8 shows a flow chart of a method embodiment under the present disclosure;

[0029] FIG. 9 shows a flow chart of a method embodiment under the present disclosure;

[0030] FIG. 10 shows a flow chart of a method embodiment under the present disclosure; and

[0031] FIGS. 11A-11B show specimen tube embodiments under the present disclosure.

DETAILED DESCRIPTION

[0032] Before describing various embodiments of the present disclosure in detail, it is to be understood that this disclosure is not limited to the parameters of the particularly exemplified systems, methods, apparatus, products, processes, and/or kits, which may, of course, vary. Thus, while certain embodiments of the present disclosure will be described in detail, with reference to specific configurations, parameters, components, elements, etc., the descriptions are illustrative and are not to be construed as limiting the scope of the claimed invention. In addition, the terminology used herein is for the purpose of describing the embodiments and is not necessarily intended to limit the scope of the claimed invention.

[0033] To address some of the problems in the prior art, the present disclosure includes various embodiments of swab, storage tubes, and storage tube inserts that can assist holding swabs

stationary, or nearly stationary within a storage tube. The disclosed embodiments can be used for a variety of test tubes, storage tubes, specimen tubes and other containers.

[0034] Figures 1A, 1B and 1C show a prior art swab 5, storage tube 10, and tube cap 15. Prior art testing often involved putting the swab into the nasal cavity, holding it there for a period of time, possibly rotating the swab to collect mucus, removing the swab and inserting it into the test tube, and capping the test tube with the tube cap. Other procedures include oral swabs, skin swabs, vaginal swabs, rectal swabs. The movement of the swab 5 within the test tube 10 can create the problems described above.

[0035] One embodiment of isolating or holding the swab in place while also providing access to the sample is providing a test tube insert as is illustrated in Figures 2A-2C. Figures 2A-2C show several possible embodiments under the present disclosure. Inserts 210A, 210B and 210C can fit within a test tube 230 and can hold one or more swabs 220 stationary, or nearly so and still provide a path for a pipette or other instrument to reach the sample at the bottom of the tube. Insert 210A has a single indentation along a rim that can fit inside a test tube 220. Insert 210B has five indentations and insert 210C has eight indentations. An insert could comprise any number of indentations as long as it holds the swabs in place and provides access to the bottom of the tube. Test tube 230 can contain reagent 245 that may help preserve or test saliva, mucus, or other material, on a swab. Inserts 210A-210C can hold swabs 220 nearly stationary. Stationary in this situation means that movement is prevented that might cause problems with cross-contamination, problems with automated machinery, or prevents any other of the prior art problems identified above.

[0036] Figures 3A-3C show other possible embodiments of swab collection devices under the present disclosure. Test tube 300, shown in each Figure 3A-3C comprises a pocket 310 near its bottom edge. Pocket 310 can be sized to receive at least a portion of swab 320 and restrain at least some movement of one or more swabs 320. Test tube 300 can also contain reagent or saliva 330. Pocket 310 can comprise a generally vertical portion 340 and a false bottom portion 350 which could be angled to guide the swab into the vertical pocket or horizontal providing an equivalent bottom to the tube. Vertical portion 340 can extend upward, angled slightly, from the bottom or side of test tube 300. In a preferred embodiment pocket 310 is integrated into the test tube 300, forming one whole component. Pocket 310 can have various sizes. It can comprise a wide or thin radial swath of the test tube 300 surface. It can be tall or short within the test tube 300 interior.

Figure 3A shows a side view of test tube 300. Figure 3B shows a bottom/side perspective view. Figure 3C shows an angle/side view. The embodiments of Figures 3A-3C allow for a pipet tip to easily go into the tube to obtain a sample and remove the pipet tip without hitting the swab shaft or lifting the swab out of the tube. A medical technician taking the sample could insert the swab into the tube as normally done, but the slope of the false bottom 350 to the pocket 310 will guide the swab head to go into the pocket 310. Once the swab 320 is fully inserted into the pocket 310, the technician would then break off the swab handle as normal and screw on the cap as normal. The sample is ready to go to the lab for testing and the standard size tube and cap can allow compatibility with liquid handlers.

[0037] Figures 4A-4C show possible swab embodiments under the present disclosure. Swabs 400A-400C have lateral extensions or wings that can help keep the swab upright, or approximately stationary within a test tube. Swabs 400A-400C comprise a shaft 410A-410C and an absorbent end 420A-420C. Swab 400A comprises a single rounded extension 430A that approximately mimics the interior surface of a test tube and can keep swab 400A upright or in place within the test tube. Rounded extension 430A is located near a distal end of shaft 410A. Swab 400B comprises two rounded extensions 430B that can keep swab 400B upright or in place within a test tube. Rounded extensions 430B are located approximately in the middle of shaft 410B. Swab 400C comprises two wings 430C that extend outward from near the middle of shaft 410C. Wings 430C can be sized to hit the interior surface of a test tube. Wings 430C may even be size to extend a little past the interior surface of the test tube, such that they have to bend to fit within the test tube. Wings 430C may be angled on the side closes to the swab end to make insertion into the test tube easier, as flat sides might catch on a test tube rim. Wings 430C may extend straight out from the swab handle at a length slightly larger than the tube diameter such that when inserted the wings curve and force the swab to an inside surface of the tube. Wings 430C could also be pre-curved as with extensions 430B. Extensions 430A, 430B and wings 430C can comprise various dimensions, thicknesses, lengths, radial curves, and other variations. Location of extensions or wings can vary, such as near the middle, near an end, or elsewhere so long as they are below a desired break point for the swab handle. Multiple wings and extensions can be combined.

[0038] By restraining movement of a swab within a storage tube, these embodiments can help make the test tube and swab more amenable to automated processes or help prevent spillage or other events. In the embodiments of Figures 4A-4C, the swab can be compatible with existing

tubes and caps. Extensions 430A, 430B or wings 430C can cause the swab 400A-400C, when inserted into the tube, to stay to the side of the tube. This allows for a pipet tip to easily go into the tube to obtain a sample and remove the pipet tip without hitting the swab shaft 410A-410C or lifting the swab 400A-400C out of the tube. Advantages of the wings 430C of Figure 4C can be that their flexibility may allow the wings to adapt to slight variations within a tube diameter. Also, they can be packaged flat for easier transport prior to use. The medical technician can take the swab sample as normal and then gently press the wings 430C together while inserting into the tube. The wings 430C will then flex out to the sides of the tube, matching the curvature and keeping the swab to the side of the tube. Then the technician can break off the swab shaft as normal. Extensions 430A, 430B or wings 430C can provide a safety feature in some embodiments, in that the swab 400A-400C cannot be easily inserted into a nostril, or a test tube, past that point.

[0039] Figure 5 shows a method embodiment 500 of restraining a swab within a test tube under the present disclosure. Step 510 is inserting an insert into a storage tube, the insert comprising; a rim configured to be inserted into a test tube and to extend around at least a portion of an interior surface of the test tube; and one or more indentations in the rim configured to receive a swab between the one or more indentations and the interior surface. Step 520 is inserting a swab into the storage tube such that one of the one or more indentations holds the swab in place along the interior surface.

[0040] Figure 6 shows a method embodiment 600 of restraining a swab within a storage tube under the present disclosure. Step 610 is inserting a swab into a storage tube, the swab comprising; a shaft; absorbent material at one end of the shaft; and one or more lateral extensions extending from the shaft and configured to hold the swab in place within the storage tube.

[0041] Figure 7 shows a method embodiment 700 of restraining a swab within a storage tube under the present disclosure. Step 710 is inserting a swab into a storage tube, the storage tube comprising: an open end configured to receive a swab therethrough; an elongated portion configured to contain test material; and a pocket within the elongated portion and distal to the open end, the pocket configured to receive a portion of a swab therein and restrain at least some movement of the swab.

[0042] Figure 8 shows a method embodiment 800 of manufacturing an insert for a storage tube under the present disclosure. Step 810 is providing a rim configured to be inserted into a storage tube and to extend around at least a portion of an interior surface of the storage tube. Step 820 is

providing one or more indentations in the rim configured to receive a swab between the one or more indentations and the interior surface.

[0043] Figure 9 shows a method embodiment 900 of manufacturing a swab for medical testing under the present disclosure. Step 910 is providing a shaft. Step 920 is providing absorbent material at one end of the shaft. Step 930 is providing one or more lateral extensions extending from the shaft and configured to hold the swab in place within a storage tube.

[0044] Figure 10 shows a method embodiment 1000 of manufacturing a storage tube under the present disclosure. Step 1010 is providing an open end configured to receive test material therethrough. Step 1020 is providing an elongated portion configured to contain test material. Step 1030 is providing a pocket within the elongated portion and distal to the open end, the pocket configured to receive a portion of a swab therein and restrain at least some movement of the swab.

[0045] Figures 11A to 11B show another further specimen tube system embodiment 1100 under the present disclosure. Specimen tube 1130 is similar to the embodiments shown e.g., in Figures 3A to 3C, but with a longer pocket 1145 and some other additional components. As can be seen swab 1120 can be used to collect test material, such as mucus, and then be inserted into pocket 1145. Pocket 1145 is longer than in some other described embodiments. Tube 1130 can have reagent 1135 within. As shown in Figure 11A, reagent 1135 flows to the bottom portion 1160 which is connected to top portion 1150 by pocket 1145. Pocket 1145 can comprise an opening 1180 at bottom portion 1160. When swab 1120 is inserted it can extend downward into pocket 1145 and the absorbent end 1125 can rest in reagent 1135, allowing the reagent 1135 to mix with the mucus or other test material. Cap 1190 can be pressed, screwed, or otherwise coupled or attached to specimen tube 1130 to hold the materials within during transport or handling. Rim 1155 can be detachable or integrated, and can assist in holding specimen tube 1130 upright or in holding the materials within specimen tube 1130. One benefit of the embodiments of Figures 11A to 11B is easier use within laboratories for testing. For example, when specimen tube 1130 arrives at a lab it can be turned over, as shown in Figure 11B. Some of the reagent 1135 will flow to the top portion 1150. Swab 1120 will be held in place by pocket 1145. There is now a portion of reagent 1135 (containing test material like mucus) that is easily accessible by a pipet or other testing equipment. Rim 1155 can be removed and the testing sample can be pipetted easily with minimal risk of hitting the swab 1120. The embodiment of Figures 11A and 11B can result in

specimen tubes that are easier to integrate into automated testing or analysis procedures and machinery.

[0046] Any of the embodiments described herein can be combined. For instance, a storage tube with a pocket may be used with a swab comprising lateral extensions or wings. An insert embodiment could also be combined with storage tubes or swabs as described herein.

[0047] The storage tubes, inserts, and swabs described herein can be used in a variety of applications. For example, the described embodiments can be used for nasopharyngeal, oropharyngeal, nasal, mid-turbinate, oral, vaginal, rectal samples, environmental swabs and testing, lab swabs, equipment, food testing, and more.

[0048] The storage tube embodiments described can be prefilled with reagent before delivery to a lab. Or the tubes could be delivered empty and supplied with reagent by a lab or other entity. A variety of setups and procedures are possible.

Abbreviated List of Defined Terms

[0049] To assist in understanding the scope and content of this written description and the appended claims, a select few terms are defined directly below. Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which the present disclosure pertains.

[0050] The terms "approximately," "about," and "substantially," as used herein, represent an amount or condition close to the specific stated amount or condition that still performs a desired function or achieves a desired result. For example, the terms "approximately," "about," and "substantially" may refer to an amount or condition that deviates by less than 10%, or by less than 5%, or by less than 1%, or by less than 0.1%, or by less than 0.01% from a specifically stated amount or condition.

[0051] Various aspects of the present disclosure, including devices, systems, and methods may be illustrated with reference to one or more embodiments or implementations, which are exemplary in nature. As used herein, the term "exemplary" means "serving as an example, instance, or illustration," and should not necessarily be construed as preferred or advantageous over other embodiments disclosed herein. In addition, reference to an "implementation" of the present disclosure or invention includes a specific reference to one or more embodiments thereof,

and vice versa, and is intended to provide illustrative examples without limiting the scope of the invention, which is indicated by the appended claims rather than by the following description.

[0052] As used in the specification, a word appearing in the singular encompasses its plural counterpart, and a word appearing in the plural encompasses its singular counterpart, unless implicitly or explicitly understood or stated otherwise. Thus, it will be noted that, as used in this specification and the appended claims, the singular forms "a," "an" and "the" include plural referents unless the context clearly dictates otherwise. For example, reference to a singular referent (*e.g.*, "a widget") includes one, two, or more referents unless implicitly or explicitly understood or stated otherwise. Similarly, reference to a plurality of referents should be interpreted as comprising a single referent and/or a plurality of referents unless the content and/or context clearly dictate otherwise. For example, reference to referents in the plural form (*e.g.*, "widgets") does not necessarily require a plurality of such referents. Instead, it will be appreciated that independent of the inferred number of referents, one or more referents are contemplated herein unless stated otherwise.

[0053] As used herein, directional terms, such as "top," "bottom," "left," "right," "up," "down," "upper," "lower," "proximal," "distal," "adjacent," and the like are used herein solely to indicate relative directions and are not otherwise intended to limit the scope of the disclosure and/or claimed invention.

Conclusion

[0054] It is understood that for any given component or embodiment described herein, any of the possible candidates or alternatives listed for that component may generally be used individually or in combination with one another, unless implicitly or explicitly understood or stated otherwise. Additionally, it will be understood that any list of such candidates or alternatives is merely illustrative, not limiting, unless implicitly or explicitly understood or stated otherwise.

[0055] In addition, unless otherwise indicated, numbers expressing quantities, constituents, distances, or other measurements used in the specification and claims are to be understood as being modified by the term "about," as that term is defined herein. Accordingly, unless indicated to the contrary, the numerical parameters set forth in the specification and attached claims are approximations that may vary depending upon the desired properties sought to be obtained by the subject matter presented herein. At the very least, and not as an attempt to limit the application of

the doctrine of equivalents to the scope of the claims, each numerical parameter should at least be construed in light of the number of reported significant digits and by applying ordinary rounding techniques. Notwithstanding that the numerical ranges and parameters setting forth the broad scope of the subject matter presented herein are approximations, the numerical values set forth in the specific examples are reported as precisely as possible. Any numerical values, however, inherently contain certain errors necessarily resulting from the standard deviation found in their respective testing measurements.

[0056] Any headings and subheadings used herein are for organizational purposes only and are not meant to be used to limit the scope of the description or the claims.

[0057] The terms and expressions which have been employed herein are used as terms of description and not of limitation, and there is no intention in the use of such terms and expressions of excluding any equivalents of the features shown and described or portions thereof, but it is recognized that various modifications are possible within the scope of the invention itemed. Thus, it should be understood that although the present invention has been specifically disclosed in part by preferred embodiments, exemplary embodiments, and optional features, modification and variation of the concepts herein disclosed may be resorted to by those skilled in the art, and such modifications and variations are considered to be within the scope of this invention as defined by the appended items. The specific embodiments provided herein are examples of useful embodiments of the present invention and various alterations and/or modifications of the inventive features illustrated herein, and additional applications of the principles illustrated herein that would occur to one skilled in the relevant art and having possession of this disclosure, can be made to the illustrated embodiments without departing from the spirit and scope of the invention as defined by the items and are to be considered within the scope of this disclosure.

[0058] It will also be appreciated that systems, devices, products, kits, methods, and/or processes, according to certain embodiments of the present disclosure may include, incorporate, or otherwise comprise properties or features (*e.g.*, components, members, elements, parts, and/or portions) described in other embodiments disclosed and/or described herein. Accordingly, the various features of certain embodiments can be compatible with, combined with, included in, and/or incorporated into other embodiments of the present disclosure. Thus, disclosure of certain features relative to a specific embodiment of the present disclosure should not be construed as limiting application or inclusion of said features to the specific embodiment. Rather, it will be

appreciated that other embodiments can also include said features, members, elements, parts, and/or portions without necessarily departing from the scope of the present disclosure.

[0059] Moreover, unless a feature is described as requiring another feature in combination therewith, any feature herein may be combined with any other feature of a same or different embodiment disclosed herein. Furthermore, various well-known aspects of illustrative systems, methods, apparatus, and the like are not described herein in particular detail in order to avoid obscuring aspects of the example embodiments. Such aspects are, however, also contemplated herein.

[0060] All references cited in this application are hereby incorporated in their entireties by reference to the extent that they are not inconsistent with the disclosure in this application. It will be apparent to one of ordinary skill in the art that methods, devices, device elements, materials, procedures, and techniques other than those specifically described herein can be applied to the practice of the invention as broadly disclosed herein without resort to undue experimentation. All art-known functional equivalents of methods, devices, device elements, materials, procedures, and techniques specifically described herein are intended to be encompassed by this invention.

[0061] When a group of materials, compositions, components, or compounds is disclosed herein, it is understood that all individual members of those groups and all subgroups thereof are disclosed separately. When a Markush group or other grouping is used herein, all individual members of the group and all combinations and sub-combinations possible of the group are intended to be individually included in the disclosure. Every formulation or combination of components described or exemplified herein can be used to practice the invention, unless otherwise stated. Whenever a range is given in the specification, for example, a temperature range, a time range, or a composition range, all intermediate ranges and subranges, as well as all individual values included in the ranges given are intended to be included in the disclosure. All changes which come within the meaning and range of equivalency of the items are to be embraced within their scope.

[0062] Although the present invention and its advantages have been described in detail, it should be understood that various changes, substitutions and alterations can be made herein without departing from the spirit and scope of the invention as defined by the appended claims. Moreover, the scope of the present application is not intended to be limited to the particular embodiments of the process, machine, manufacture, composition of matter, means, methods and

steps described in the specification. As one of ordinary skill in the art will readily appreciate from the disclosure of the present invention, processes, machines, manufacture, compositions of matter, means, methods, or steps, presently existing or later to be developed that perform substantially the same function or achieve substantially the same result as the corresponding embodiments described herein may be utilized according to the present invention. Accordingly, the appended claims are intended to include within their scope such processes, machines, manufacture, compositions of matter, means, methods, or steps.

CLAIMS

What is claimed is:

1. An insert for a storage tube, comprising:

a rim configured to be inserted into a storage tube and to extend around at least a portion of an interior surface of the storage tube; and

one or more indentations in the rim configured to receive one or more swabs between the one or more indentations and the interior surface of the storage tube.

2. The insert of claim 1 wherein the one or more indentations comprise one indentation.

3. The insert of claim 1 wherein the one or more indentations comprise five indentations.

4. The insert of claim 1 wherein the one or more indentations comprise eight indentations.

5. The insert of any of claims 1 to 4 wherein the insert comprises a flexible material.

6. The insert of any of claims 1 to 5 wherein the insert comprises a plastic.

7. The insert of any of claims 1 to 5 wherein the insert comprises a rubber.

8. A swab for medical testing comprising:

a shaft;

absorbent material at one end of the shaft; and

one or more lateral extensions extending from the shaft and configured to hold the swab in place within a storage tube.

9. The swab of claim 8 wherein the shaft comprises a break point.

10. The swab of claims 8 or 9 wherein the one or more lateral extensions comprise one curved extension configured to engage an interior surface of the storage tube.

11. The swab of claims 8 or 9 wherein the one or more lateral extensions comprise one or more wings configured to engage an interior surface of the storage tube.

12. The swab of claims 8 or 9 wherein the one or more lateral extensions comprise two curved extensions configured to engage an interior surface of the storage tube.

13. A storage tube comprising:

an open end configured to receive test material therethrough;

an elongated portion configured to contain test material; and

a pocket within the elongated portion and distal to the open end, the pocket configured to receive a portion of one or more swabs therein and restrain the one or more swabs.

14. The storage tube of claim 13, wherein the pocket comprises;

a generally vertical portion extending upward from a bottom surface of the storage tube; and

an angled portion extending from the top of the generally vertical portion to a side surface of the storage tube.

15. The storage tube of claims 13 or 14 wherein the storage tube comprises a polymer.

16. The storage tube of claims 13 or 14 wherein the storage tube comprises a plastic.

17. A method of restraining one or more swabs within a storage tube, comprising:

inserting an insert into a storage tube, the insert comprising;

a rim configured to be inserted into a storage tube and to extend around at least a portion of an interior surface of the storage tube; and

one or more indentations in the rim configured to receive one or more swabs between the one or more indentations and the interior surface; and

inserting one or more swabs into the storage tube such that one of the one or more indentations holds the one or more swabs in place along the interior surface.

18. A method of restraining a swab within a storage tube, comprising:

inserting a swab into a storage tube, the swab comprising;

a shaft;

absorbent material at one end of the shaft; and

one or more lateral extensions extending from the shaft and configured to hold the swab in place within a storage tube.

19. A method of restraining one or more swabs within a storage tube, comprising:

inserting one or more swabs into a storage tube, the storage tube comprising:

an open end configured to receive a swab therethrough;

an elongated portion configured to contain test material; and

a pocket within the elongated portion and distal to the open end, the pocket configured to receive a portion of one or more swabs therein and restrain at least some movement of the one or more swabs.

20. The method of claim 19, wherein the pocket comprises;

a generally vertical portion extending upward from a bottom surface of the storage tube; and

an angled portion extending from the top of the generally vertical portion to a side surface of the storage tube.

21. A method of manufacturing an insert for a storage tube, comprising:

providing a rim configured to be inserted into a storage tube and to extend around at least a portion of an interior surface of the storage tube; and

providing one or more indentations in the rim configured to receive one or more swabs between the one or more indentations and the interior surface.

22. A method of manufacturing a swab for medical testing comprising:

providing a shaft;

providing absorbent material at one end of the shaft; and

providing one or more lateral extensions extending from the shaft and configured to hold the swab in place within a storage tube.

23. A method of manufacturing a storage tube, comprising:

providing an open end configured to receive test material therethrough;

providing an elongated portion configured to contain test material; and

providing a pocket within the elongated portion and distal to the open end, the pocket configured to receive a portion of one or more swabs therein and restrain at least some movement of the one or more swabs.

24. The method of claim 23, wherein the pocket comprises;

a generally vertical portion extending upward from a bottom surface of the storage tube; and

an angled portion extending from the top of the generally vertical portion to a side surface of the storage tube.

25. The method of claim 23 or 24 further comprising filling the storage tube with reagent prior to shipping the storage tube to a user.

26. The method of claim 23 or 24 further comprising shipping the storage tube to a user prior to filling the storage tube with reagent.

27. The swab of any of claims 8 to 12 wherein the swab is configured to be used for at least one of the following tests: nasopharyngeal, oropharyngeal, nasal, mid-turbinate, oral, vaginal, rectal, environmental, equipment, and food.

28. A storage tube comprising:

an open end configured to receive test material therethrough; and

an elongated portion comprising;

a top portion fluidly coupled to the open end;

an extended pocket fluidly coupled to the top portion and extending downward from the top portion; and

a bottom portion fluidly coupled to the extended pocket;

wherein the extended pocket is configured to receive a portion of one or more swabs therein and restrain the one or more swabs.

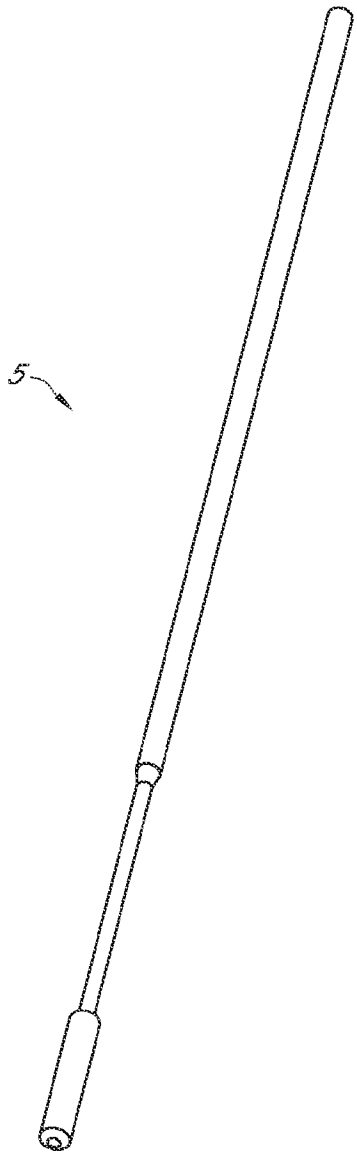


FIG. 1A
(PRIOR ART)

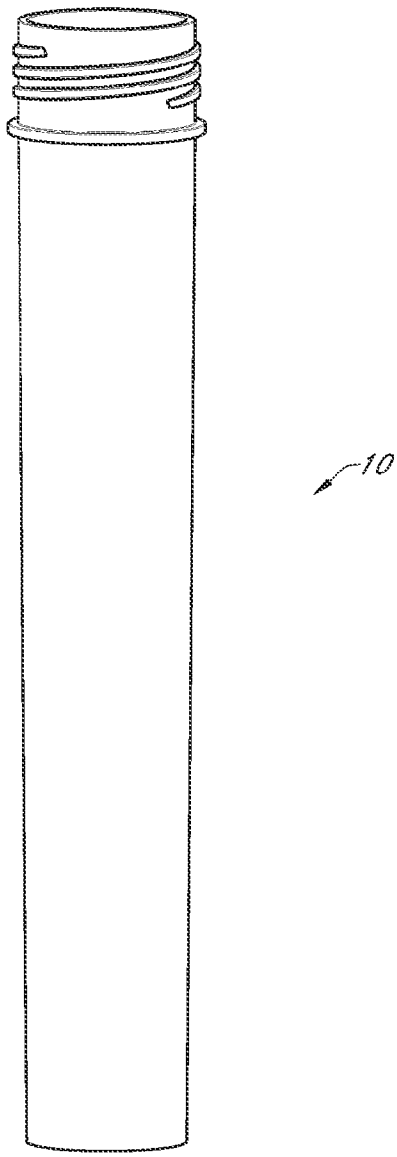


FIG. 1B
(PRIOR ART)

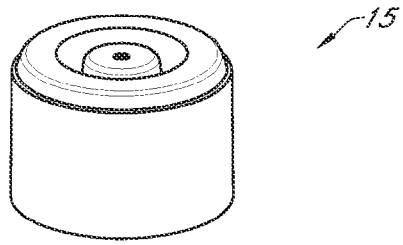


FIG. 1C
(PRIOR ART)

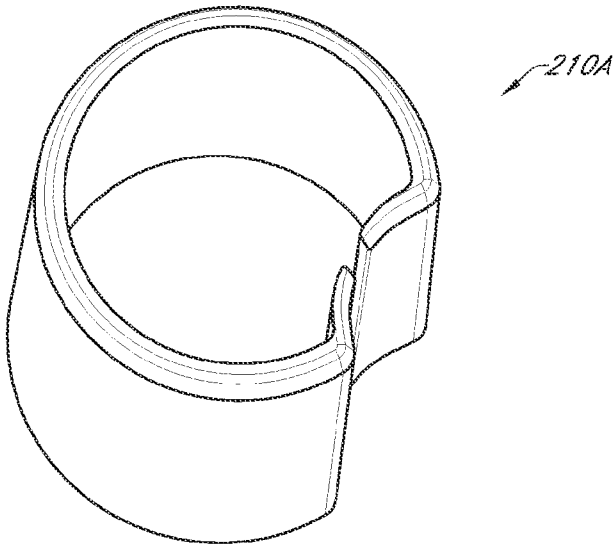


FIG. 2A

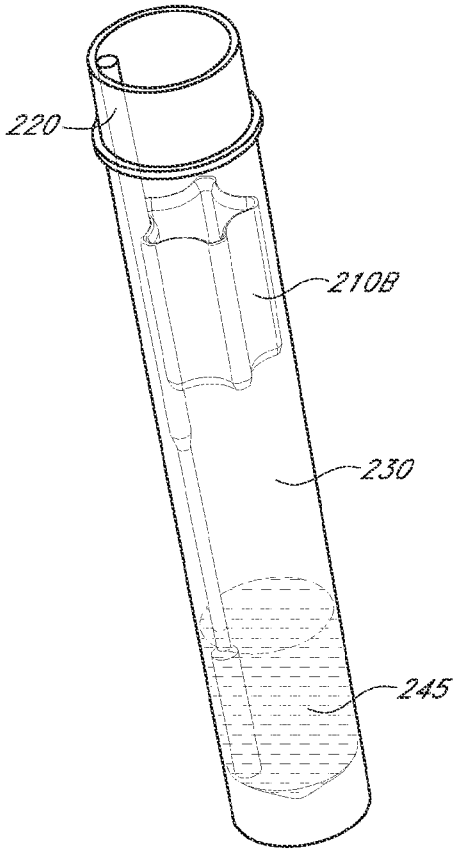


FIG. 2B

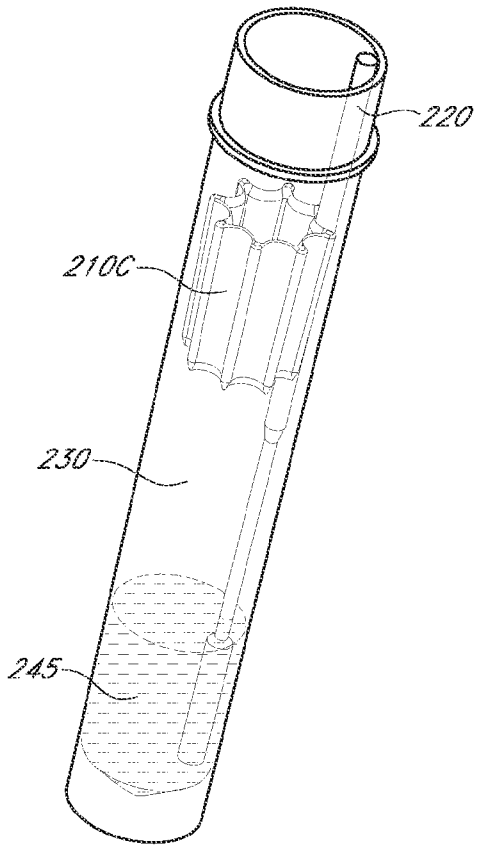


FIG. 2C

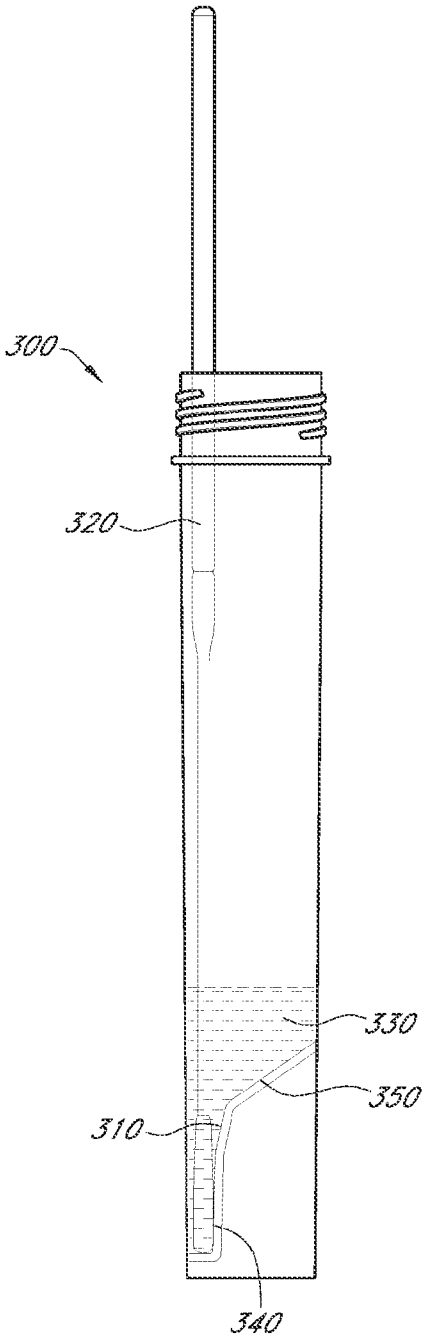


FIG. 3A

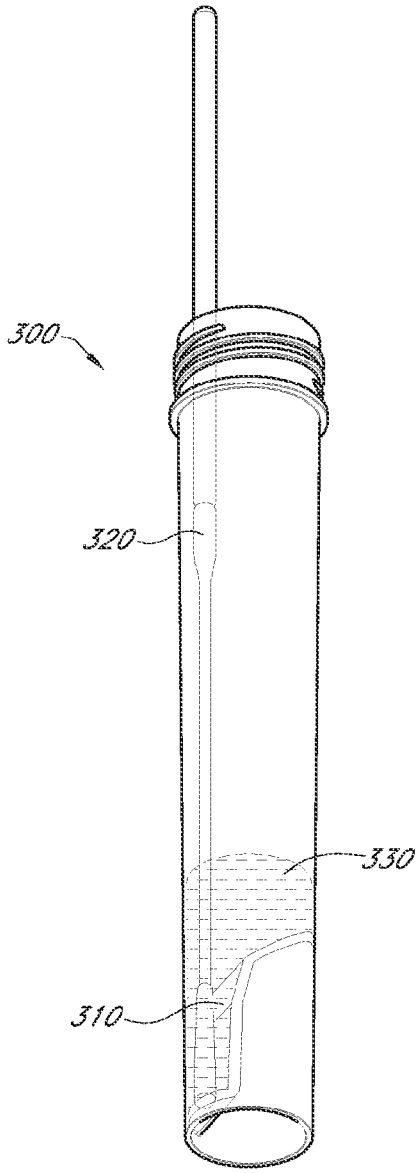


FIG. 3B

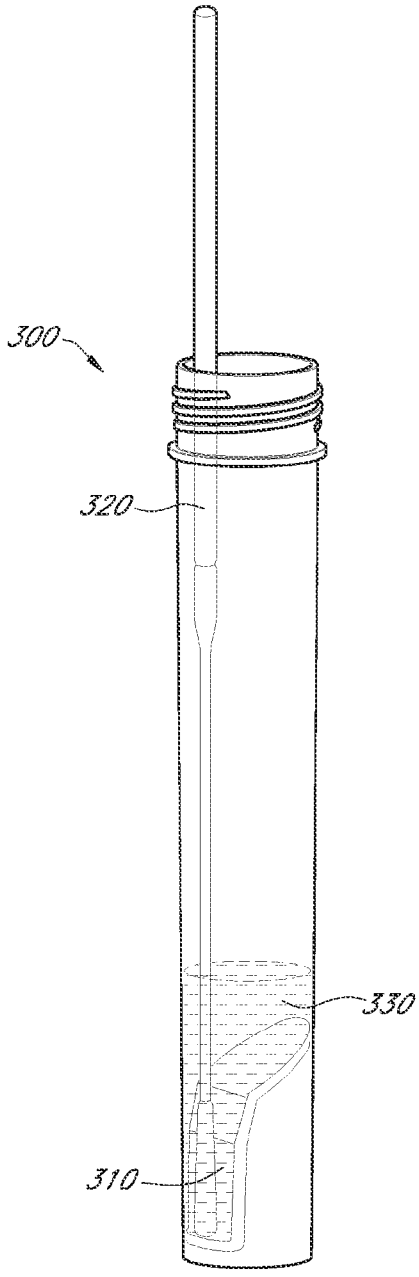


FIG. 3C

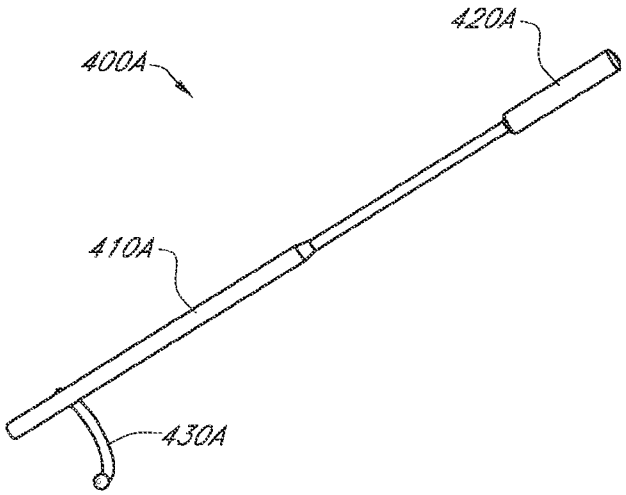


FIG. 4A

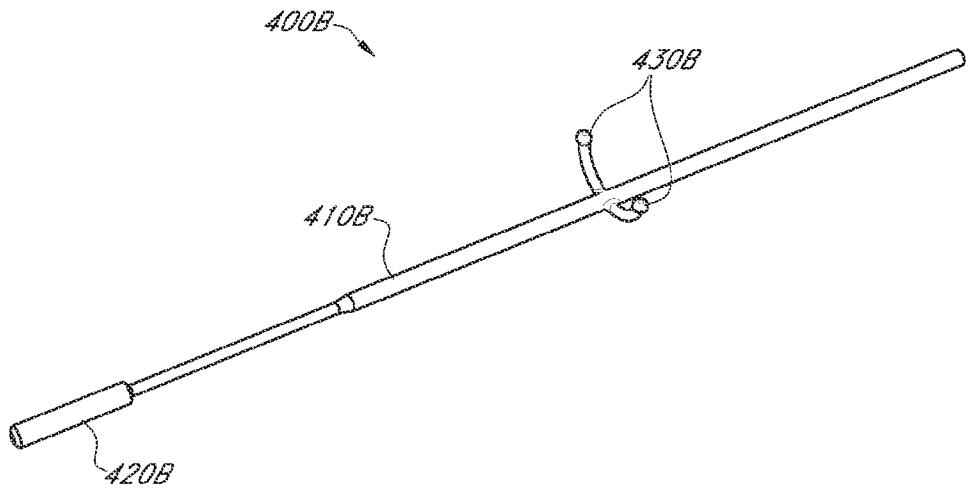


FIG. 4B

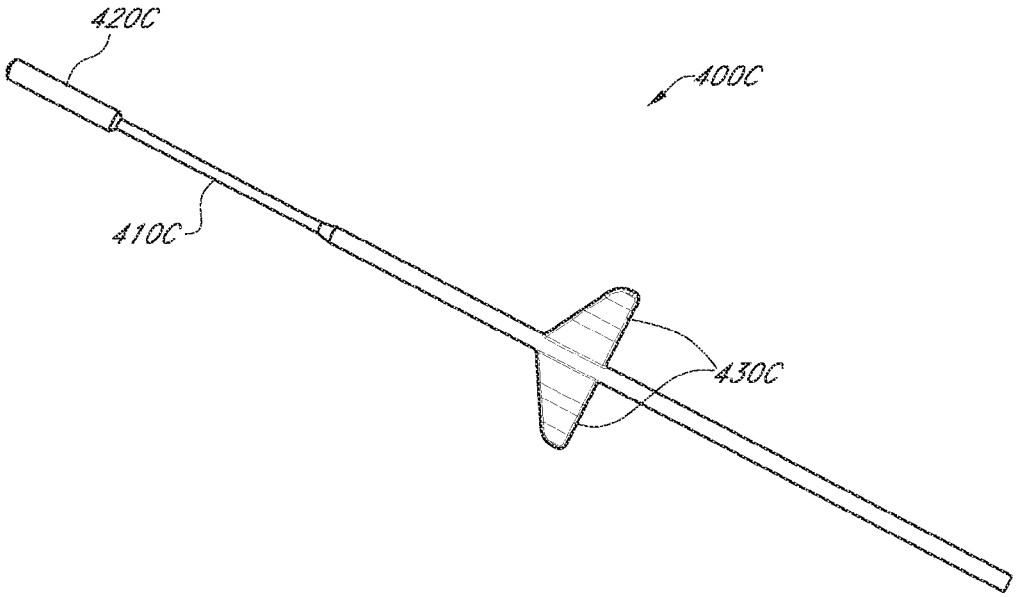


FIG. 4C

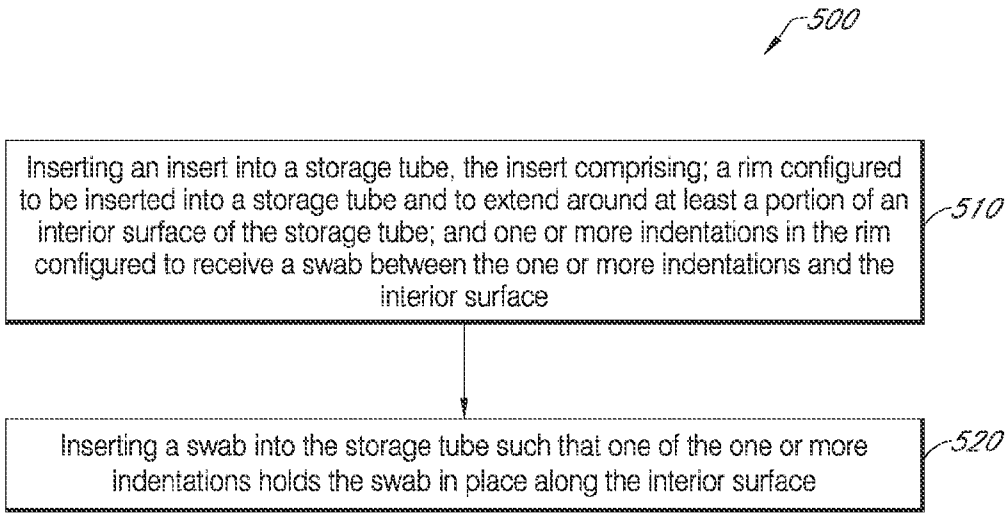

500
Inserting an insert into a storage tube, the insert comprising; a rim configured to be inserted into a storage tube and to extend around at least a portion of an interior surface of the storage tube; and one or more indentations in the rim configured to receive a swab between the one or more indentations and the interior surface
510
Inserting a swab into the storage tube such that one of the one or more indentations holds the swab in place along the interior surface
520

FIG. 5

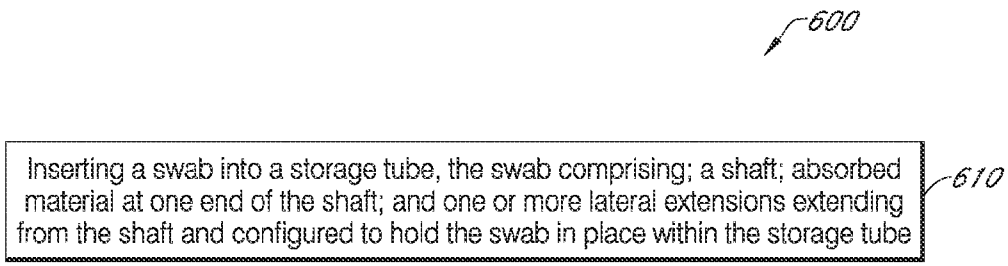

600
Inserting a swab into a storage tube, the swab comprising; a shaft; absorbed material at one end of the shaft; and one or more lateral extensions extending from the shaft and configured to hold the swab in place within the storage tube
610

FIG. 6

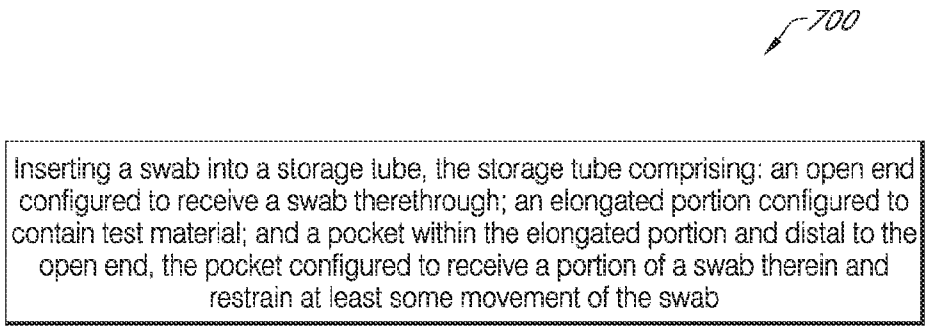

700
Inserting a swab into a storage lube, the storage tube comprising: an open end configured to receive a swab therethrough; an elongated portion configured to contain test material; and a pocket within the elongated portion and distal to the open end, the pocket configured to receive a portion of a swab therein and restrain at least some movement of the swab

FIG. 7

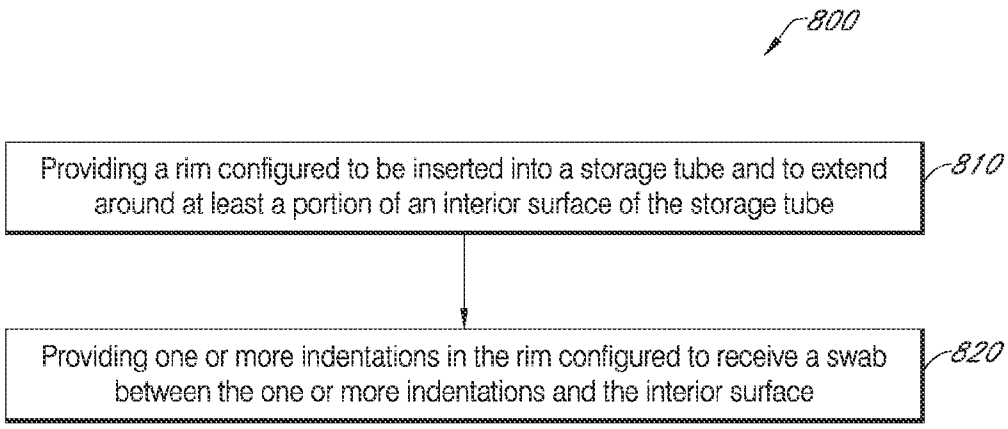

800
Providing a rim configured to be inserted into a storage tube and to extend around at least a portion of an interior surface of the storage tube
810
Providing one or more indentations in the rim configured to receive a swab between the one or more indentations and the interior surface
820

FIG. 8

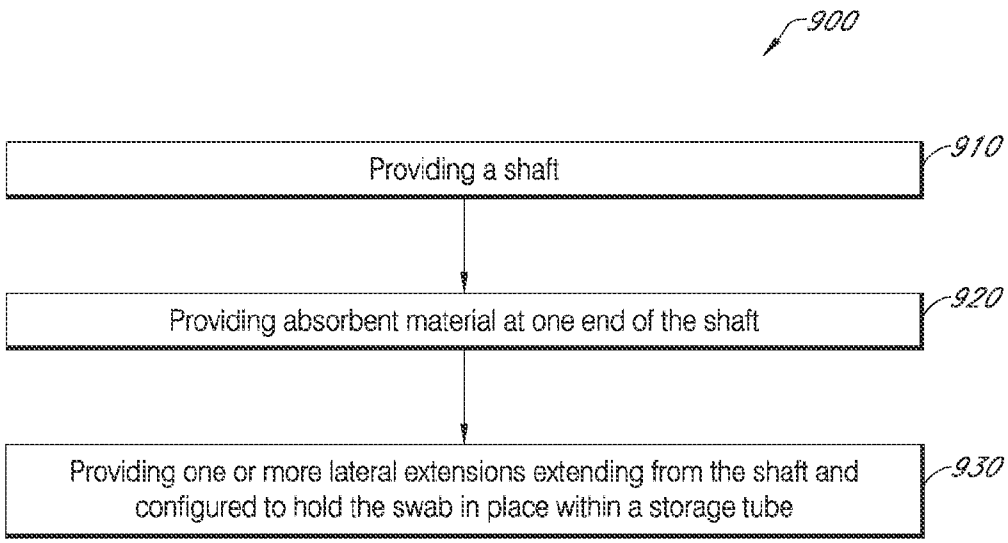

900
Providing a shaft
910
Providing absorbent material at one end of the shaft
920
Providing one or more lateral extensions extending from the shaft and configured to hold the swab in place within a storage tube
930

FIG. 9

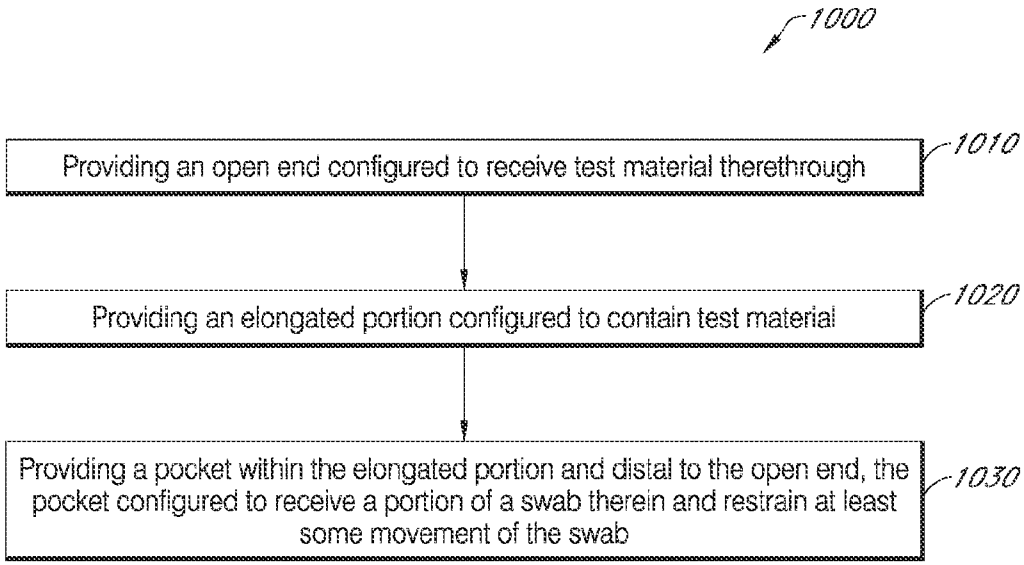

1000
Providing an open end configured to receive test material therethrough
1010
Providing an elongated portion configured to contain test material
1020
Providing a pocket within the elongated portion and distal to the open end, the pocket configured to receive a portion of a swab therein and restrain at least some movement of the swab
1030

FIG. 10

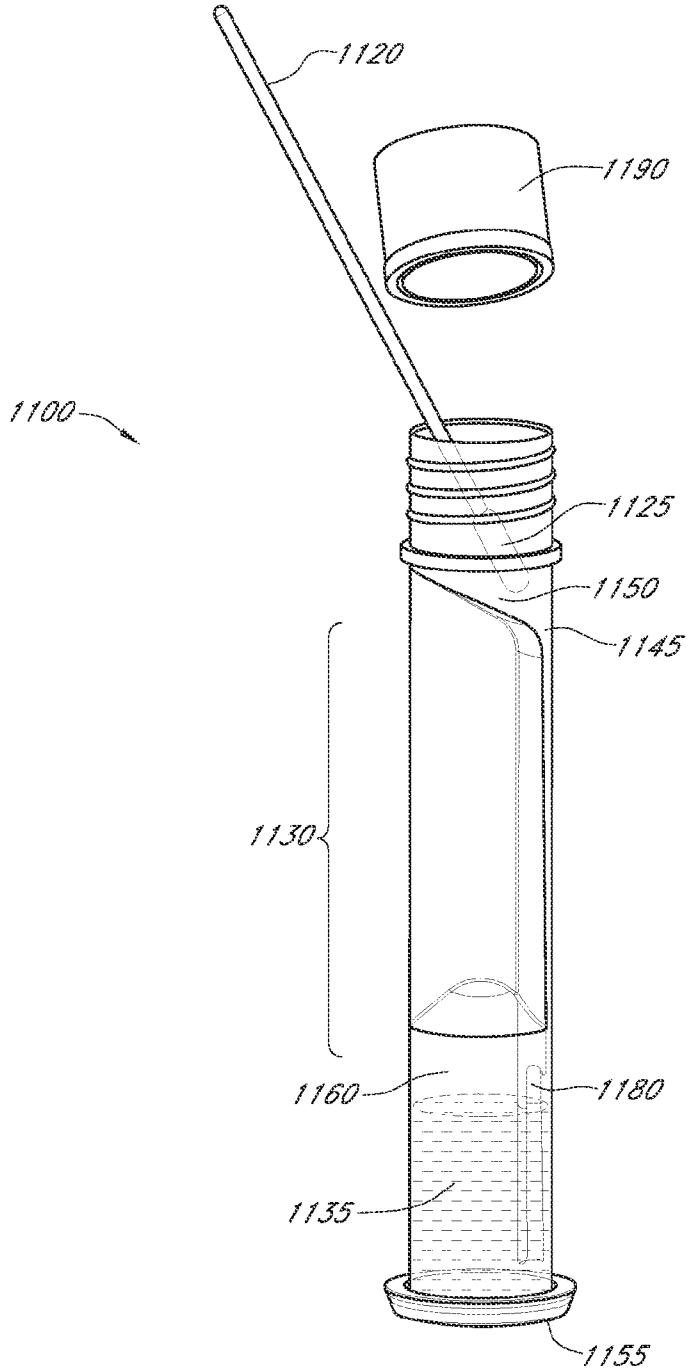


FIG. 11A

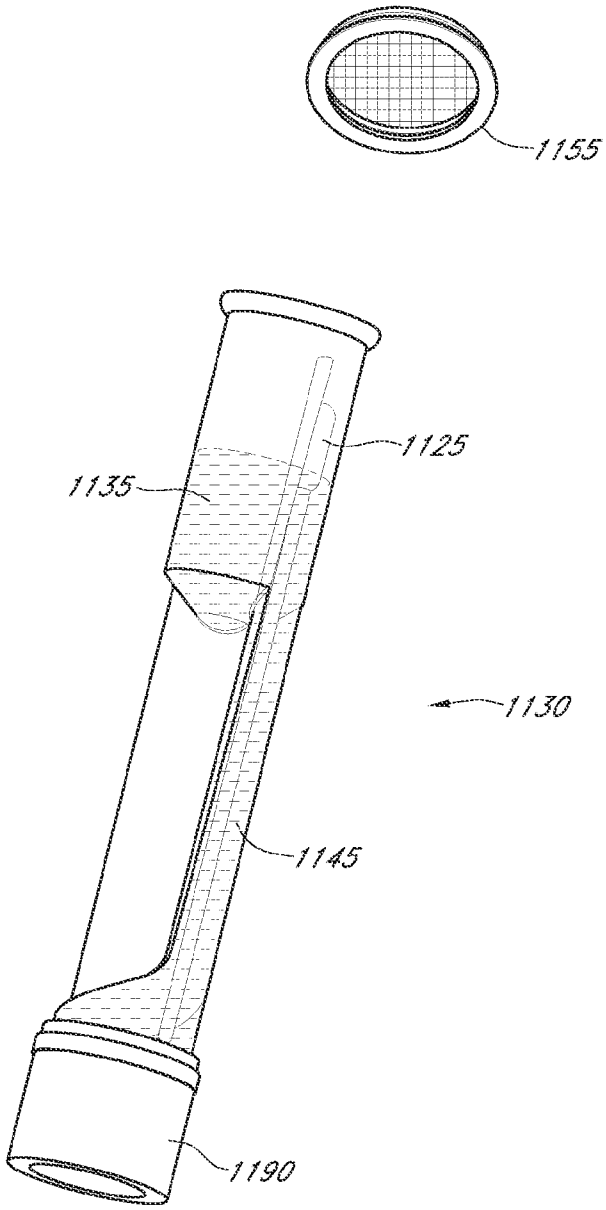


FIG. 11B

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2023/017355

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B10/00 B01L3/00
ADD. A61B10/02

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)
A61B B01L

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 practicable, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2022/037007 A1 (XIE YANGDA [CN]) 24 February 2022 (2022-02-24) page 4, line 17 - page 8, line 28; figures 1-3	1-7,17, 21
X	US 9 103 749 B2 (FAST FORWARD FORENSICS LLC [US]) 11 August 2015 (2015-08-11) column 4, line 23 - column 12, line 58; figures 1-16	1-7,17, 21
X	KR 2015 0057271 A (BODITECHMED INC [KR]) 28 May 2015 (2015-05-28) paragraphs [0060] - [0080]; figures 1,2,10-14	1-7,17, 21

-/--

[x] Further documents are listed in the continuation of Box C.

[x] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"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)

"O" document referring to an oral disclosure, use, exhibition or other means

"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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
13 July 2023	13/09/2023

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Hochrein, Marion

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Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2023/017355

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2018/372595 A1 (PAIS ANDREA MARIA DOMINIC [US] ET AL) 27 December 2018 (2018-12-27) paragraphs [0032] - [0034], [0043] - [0047]; figures 1-3	1-7,17, 21
X	JP 2003 014733 A (IATRON LAB) 15 January 2003 (2003-01-15) figures 1-5	1-7,17, 21

1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2023/017355

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims;; it is covered by claims Nos.:
1-7, 17, 21

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-7, 17, 21

An insert for a storage tube

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2. claims: 8-12, 18, 22

A medical swab comprising one or more lateral extensions configured to hold the swab in place

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3. claims: 13-16, 19, 20, 23-28

A storage tube comprising a pocket in the elongated potion to restrain a swab

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2023/017355

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2022037007 A1	24-02-2022	NONE	
US 9103749 B2	11-08-2015	US 2014105796 A1	17-04-2014
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