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APPLICATION FOR PATENT
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Title: Methods, Systems, and Devices for Preparing a Biological Testing Sample

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CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of co-pending U.S. Provisional Patent Application Serial No. 63/604,544, filed November 30, 2023 which is hereby incorporated by reference in its entirety.

FIELD OF THE DISCLOSURE

[0002] The present disclosure involves devices, systems, and methods for preparing a biological testing sample. Namely, devices, systems, and methods of the present disclosure involve a diluent container and a reagent container which can be coupled to one another to prepare a biological sample for testing.

BACKGROUND

[0003] Preparing a biological sample for testing involves mixing the biological sample into a liquid diluent and introducing a reagent to the mixture of the biological sample and the liquid diluent. The combination of the biological sample, the liquid diluent, and the reagent can then be deposited onto a testing surface for testing.

SUMMARY

[0004] In an example, a device for preparing a biological testing sample is described. The example device comprises a diluent container and a reagent container. The example diluent container comprises: (i) a diluent chamber comprising a liquid diluent, wherein the diluent chamber is configured to receive a biological sample; (ii) a receiving portion, wherein the receiving portion is in fluid communication with the diluent chamber; and (iii) a first sealant surface, wherein the first sealant surface is proximate to the receiving portion. The example reagent container comprises: (i) a reagent chamber comprising a reagent; (ii) a dispensing nozzle, wherein the dispensing nozzle is in fluid communication with the reagent chamber, and wherein the dispensing

nozzle comprises a break-away tab covering an opening of the dispensing nozzle; (iii) an insertion portion, wherein the insertion portion is in fluid communication with the reagent chamber, and wherein the insertion portion is configured to interface with the receiving portion of the diluent chamber; and (iv) a second sealant surface, wherein the second sealant surface is proximate to the insertion portion, and wherein the first sealant surface and the second sealant surface form a liquid seal when the insertion portion is interfaced with the receiving portion of the diluent chamber.

[0005] In another example, a method for preparing a biological testing sample is disclosed. In an example, the method comprises: (i) depositing a liquid diluent into a diluent chamber of a diluent container; (ii) depositing a reagent into a reagent chamber of a reagent container; (iii) receiving a biological sample in the diluent chamber of the diluent container; (iv) inserting an insertion portion of the reagent container into a receiving portion of the diluent container, wherein the receiving portion comprises a first sealant surface that interfaces with a second sealant surface of the insertion portion, and wherein the first sealant surface and the second sealant surface form a liquid seal when interfaced, and wherein the diluent chamber is in fluid communication with the reagent chamber when the insertion portion of the reagent container is inserted into the receiving portion of the diluent container; and (v) after inserting the insertion portion of the reagent container into the receiving portion of the diluent container, agitating the reagent with the liquid diluent and the biological sample.

[0006] The features, functions, and advantages that have been discussed can be achieved independently in various examples or may be combined in yet other examples. Further details of the examples can be seen with reference to the following description and drawings.

BRIEF DESCRIPTION OF THE FIGURES

[0007] The above, as well as additional features will be better understood through the following illustrative and non-limiting detailed description of example embodiments, with reference to the appended drawings.

[0008] Fig. 1A illustrates an example diluent container.

[0009] Fig. 1B illustrates a diluent container, according to an example embodiment.

[0010] Fig. 1C illustrates a diluent container, according to another example embodiment.

[0011] Fig. 1D illustrates the diluent container of Fig. 1C, according to another example embodiment.

[0012] Fig. 1E illustrates a diluent container, according to another example embodiment.

[0013] Fig. 1F illustrates the diluent container of Fig. 1E, according to an example embodiment.

[0014] Fig. 2A illustrates a reagent container, according to an example embodiment.

[0015] Fig. 2B illustrates the reagent container of Fig. 2A, according to another example embodiment.

[0016] Fig. 2C illustrates a reagent container, according to an example embodiment.

[0017] Fig. 3A illustrates an assembled device for preparing a biological testing sample according to one or more of the components of Fig. 1A-Fig. 2C, according to an example embodiment.

[0018] Fig. 3B illustrates an assembled device for preparing a biological testing sample according to one or more of the components of Fig. 1A-Fig. 2C, according to an example embodiment.

[0019] Fig. 4 illustrates a method, according to an example embodiment.

[0020] All the figures are schematic, not necessarily to scale, and generally only show parts which are necessary to elucidate example embodiments, wherein other parts may be omitted or merely suggested.

DETAILED DESCRIPTION

[0021] Example embodiments will now be described more fully hereinafter with reference to the accompanying drawings. That which is encompassed by the claims may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided by way of example. Furthermore, like numbers refer to the same or similar elements or components throughout.

[0022] Within examples, the present disclosure is directed to devices, systems, and methods for preparing a biological sample for testing.

[0023] Testing and/or analyzing, as referred to herein, may include, for example, capturing one or more images related to a sample. For example, testing can involve capturing images of a biological sample from an imaging sensor and determining a stain intensity. In examples, testing can further involve modifying an intensity of a light source, then capturing one or more additional images from the imaging sensor. One or more machine learning models can then be implemented to analyze the captured images and perform one or more computational actions, including identifying a characteristic of the biological sample.

[0024] In another example, in the images come from competitive immunoassays for detection of antibodies in the biological sample. A competitive immunoassay may be carried out in the following illustrative manner. A sample, e.g. from an animal's body fluid, potentially containing an antibody of interest that is specific for an antigen, is contacted with the antigen attached to the particle and with the anti-antigen antibody conjugated to a detectable label. The antibody of interest, present in the sample, competes with the antibody conjugated to a detectable label for binding with the antigen attached to the particles. The amount of the label associated with

the particles can then be determined after separating unbound antibody and the label. The signal obtained is inversely related to the amount of antibody of interest present in the sample.

[0025] In an alternative example embodiment of a competitive immunoassay, a sample, e.g. from an animal's body fluid, potentially containing an analyte, is contacted with the analyte conjugated to a detectable label and with an anti-analyte antibody attached to the particle. The antigen in the sample competes with analyte conjugated to the label for binding to the antibody attached the particle. The amount of the label associated with the particles can then be determined after separating unbound antigen and label. The signal obtained is inversely related to the amount of analyte present in the sample.

[0026] Antibodies, antigens, and other binding members (e.g., aptamers) may be attached to the particle or to the label directly via covalent binding with or without a linker or may be attached through a separate pair of binding members as is well known (e.g., biotin:streptavidin, digoxigenin:anti-digoxigenin). In addition, while the examples herein reflect the use of immunoassays, the particles and methods of the disclosure may be used in other receptor binding assays, including nucleic acid hybridization assays, that rely on immobilization of one or more assay components to a solid phase.

[0027] Generally, preparing a biological sample for such testing involves mixing the biological sample into a liquid diluent and introducing one or more reagents to the mixture of the biological sample and the liquid diluent prior to imaging, testing, and/or other analytical methods. The combination of the biological sample, the liquid diluent, and the reagent can be used to form a biological testing sample, which can then be deposited onto a testing surface (e.g., a slide or cartridge) for testing, such as imaging.

[0028] To date, such devices and methods for preparing a biological testing sample require significant manual user handling. Historically, preparation of a biological sample for testing involves a user (e.g., a clinician) manually measuring and handling the liquid diluent to be mixed with the biological sample. Similarly, the preparation may involve the user manually handling and measuring a liquid reagent to agitate and mix with the liquid diluent and biological sample. This process can be time intensive, result in user error in measurement and handling, and produce waste from these potential user errors.

[0029] Further, there are advantages to utilizing a particular reagent and/or form of reagent, such as a lyophilized reagent, rather than a liquid reagent. For instance, a lyophilized reagent may be more uniform than a liquid reagent. Uniformity of the reagent can result in one or more improvements to associated testing protocols, including better imaging and more accurate test results. Further, lyophilization of the reagent can help with preservation of the reagent so that it does not deteriorate over time or become contaminated. Moreover, lyophilized reagents can be stored at room temperature, whereas liquid reagents typically have to be refrigerated. As such, lyophilized reagents may have a longer shelf life and be easier to store than liquid reagents. Even further, the lyophilized reagent does not require a user measurement and requires less user handling, which in turn can reduce testing time, increase repeatability and consistency among tests, and help ensure the right quantity of reagent is used.

[0030] The example systems, devices, and methods disclosed herein address some of these issues. An example device of the present disclosure is configured to receive a biological sample, mix the biological sample with liquid diluent, introduce a reagent to the mixture, and then dispense a biological testing sample containing the biological sample, liquid diluent, and reagent onto a testing surface. More particularly, an example device includes a diluent container, which houses a

liquid diluent and is configured to receive a biological sample. The device also includes a reagent container, which houses a reagent and is configured to be coupled to the diluent container. Once the biological sample is deposited into the diluent container, the diluent container and the reagent container can be connected and/or otherwise interfaced (e.g., one container is inserted into the other), thereby introducing the reagent to the mixture of the liquid diluent and the biological sample. In examples, the reagent container also includes features to allow for use of lyophilized reagent. In examples, the reagent container additionally includes a dispensing nozzle for dispensing the biological testing sample (e.g., the mixture of the liquid diluent, the biological sample, and the reagent) onto a testing surface.

[0031] Now referring to the figures, Figs. 1A and 1B illustrate a diluent container 100A, according to an example embodiment. The diluent container 100A is configured to house a liquid diluent and receive the biological sample. As shown in Fig. 1A, the diluent container 100A includes a diluent chamber 102, a receiving portion 104 in fluid communication with the diluent chamber 102, and a first sealant surface 106, proximate to the receiving portion 104. Additionally, in example embodiments, the diluent container 100A includes a sealant mechanism 110 covering an opening of the receiving portion 104.

[0032] In example embodiments, the diluent chamber 102 houses a liquid diluent. Some example liquid diluents include, but are not limited to Phosphate-Buffered Saline (PBS), Tris-Buffered Saline (TBS), water, saline solution, and glycerol based buffer solution. Other example diluents are possible.

[0033] Further, the diluent chamber 102 is configured to hold a sufficient amount of liquid diluent to prepare the biological testing sample, while still allowing space for a biological testing sample. For instance, in some example embodiments, the diluent chamber 102 may include

between 250 μ L and 2 mL of liquid diluent. In other example embodiments, the diluent chamber 102 may include between 200 μ L and 3 mL of liquid diluent. Many example volumes of liquid diluent are possible and can vary based on the intended use of the diluent container 100A (e.g., type of biological sample being tested, type of testing performed, etc.). According to an example embodiment, having an appropriate volume of liquid diluent in the diluent chamber 102 eliminates the need for a user to manually measure and prepare the liquid diluent. This configuration may improve testing time and eliminate any potential user error in measurement and/or preparation. Reducing manual user handling of the liquid diluent may additionally reduce the risk of contaminating the liquid diluent and/or the diluent chamber 102.

[0034] During fabrication of the diluent container 100A, after the liquid diluent is deposited into the diluent chamber 102, the diluent container 100A can be sealed by way of the sealant mechanism 110. The sealant mechanism 110 creates a liquid and airtight seal to help preserve the diluent container 100A during transportation, storage, and handling. In examples, the sealant mechanism 110 can adhere to a perimeter of an opening of the receiving portion 104. In some example embodiments, the sealant mechanism 110 can include foil. Additionally, or alternatively, the sealant mechanism 110 can include plastics. Other example materials and configurations are possible. In practice, according to example embodiments, the sealant mechanism may remain intact until the diluent container 100A is ready for use.

[0035] When the diluent container 100A is ready for use, the sealant mechanism 110 can be removed to expose the receiving portion 104 and the diluent chamber 102. In some example embodiments, the sealant mechanism 110 is configured to be removed by a user (e.g., a clinician). In some examples, the sealant mechanism 110 is configured to be removed by way of peeling or

puncturing. For instance, in some examples, the sealant mechanism 110 can include a pull tab and/or perforations for ease of removal. Other examples removal methods are possible.

[0036] Once the sealant mechanism 110 is removed, a biological sample can be deposited into the diluent container 100A. More particularly, in examples, the biological sample can be deposited into the diluent chamber 102 to be mixed with the liquid diluent. In some examples, the biological sample is a liquid biological sample such as: (i) blood; (ii) urine; (iii) saliva; (iv) fecal matter; (v) secretion; (vi) excretion; (vii) Fine Needle Aspirate (FNA); (viii) lavage fluids; (ix) body cavity fluids; (x) semen; and (xi) bacteria. In example embodiments, these liquid biological samples may be collected and deposited into the diluent chamber 102 by way of a syringe, for example. In additional examples, the biological sample is a solid biological sample, such as: (i) ear wax; (ii) skin cells; (iii) fecal matter; and (iv) biopsied samples. In example embodiments, as further detailed in connection with Figs. 1C- 1F, these solid biological samples may be collected and deposited into the diluent chamber via an applicator (e.g., a cotton swab).

[0037] In examples where the biological sample is a liquid biological sample, the diluent chamber 102 and receiving portion 104 may be large enough to allow a user to insert a syringe to the bottom of the diluent chamber 102 and dispense the biological sample into the liquid diluent without overflow or spillage of the biological sample and/or the liquid diluent. Similarly, in examples where the biological sample is a solid biological sample, the diluent chamber 102 and receiving portion 104 are large enough to allow a user to insert an applicator to the bottom of the diluent chamber 102 and deposit the biological sample into the liquid diluent without overflow or spillage of the biological sample and/or the liquid diluent.

[0038] In examples, the diluent container 100A is made of a compliant material so that the user can compress (e.g., pinch or squeeze) the diluent container 100A. This is beneficial for

depositing a biological sample, such as ear wax, into the diluent container 100A as the user can utilize the friction between the side walls to extract the sample from an application. Additionally, this is beneficial for depositing the biological testing sample (e.g., onto a cartridge) for testing. As such, in some example embodiments, the diluent container 100A includes compliant material, such as Linear Low Density Polyethylene (LLDPE) or Low Density Polyethylene (LDPE). Other example materials are possible.

[0039] In some example embodiments, the diluent container 100A includes a base 112 to stabilize diluent container 100A and allow the diluent container 100A to stand vertically without additional support. For instance, the base 112 may include a ring around an outer perimeter of the diluent container 100A. This allows a user to more easily dispense or deposit the biological sample into the diluent chamber 102. Further, the base 112 can help prevent spillage of the liquid diluent and/or the biological sample.

[0040] After the biological sample is deposited into the diluent chamber 102 and the liquid diluent, the diluent container 100A may then be ready to receive a reagent container (e.g., 200A or 200B as shown in Figs. 2A-3B). More particularly, the receiving portion 104 of the diluent container 100A is configured to be coupled to the reagent container. The receiving portion 104 includes a first sealant surface 106 that, when interfaced with a second sealant surface of the reagent container (shown in Figs. 2A-3B), creates a liquid seal between the diluent container 100A and the reagent container.

[0041] To facilitate receiving the reagent container, in some examples, the receiving portion 104 includes a support shoulder 108. The support shoulder 108 supports and stabilizes the reagent container (as shown in Figs. 2A-3B), when a portion of the reagent container is inserted into the receiving portion 104 of the diluent container 100A. More particularly, when the reagent

container is inserted into the receiving portion 104 of the diluent container 100A, the bottom of the reagent container is supported by the support shoulder 108. This helps stabilize the reagent container to remain in position and prevents the reagent container from being inserted too far into the diluent container 100A.

[0042] Now referring to Figures 1C and 1D, vertical and horizontal cross-sectional views of a diluent container 100B are illustrated according to an example embodiment. In Figs. 1C and 1D, the diluent container 100B includes largely the same features as the diluent container 100A, shown in Figs. 1A-1B and described in the corresponding description. As shown in Figs. 1C and 1D, however, the diluent container 100B additionally includes extraction ribs 114 in the diluent chamber 102. The extraction ribs 114 aid in extracting the biological sample and supporting the reagent container, as described in further detail below.

[0043] As shown in the example configuration in Figs. 1C and 1D (a top down view of Fig. 1C), in example embodiments, the extraction ribs 114 can extend vertically from the base of the diluent chamber 102. Additionally, in examples, the extraction ribs 114 can include 5 extraction ribs 114 extending radially from one another. Many example configurations of extraction ribs are possible. For instance, in some examples, the diluent container 100B can include fewer extraction ribs 114 (e.g., 2, 3, or 4). In other examples, the diluent container 100B can include more extraction ribs 114 (e.g., 6, 7, 8, etc.). Additionally or alternatively, in example embodiments extraction ribs may extend radially inward from the side walls of the diluent chamber 102, rather than vertically from the base of the diluent chamber 102.

[0044] As noted above, in practice, some biological samples (e.g., ear wax) are collected via an applicator, such as a cotton swab. Removal of the biological sample from the applicator can be challenging because the biological sample may stick to the applicator. To better facilitate

removal of the biological sample from the applicator, the user can place the applicator into the diluent chamber 102, making contact with the extraction ribs 114. The user can then press the applicator against the extraction ribs 114 to scrape the biological sample from the applicator. Additionally or alternatively, the user can spin the applicator when inserted into the diluent chamber 102 to remove the biological sample from the applicator. Further, as noted above, the diluent container 100B is compliant such that the user can pinch or squeeze the diluent container 100B. As such, the user can also pinch the diluent container 100B, creating or increasing friction between the applicator and the extraction ribs 114 to remove the biological sample from the applicator and into the diluent chamber 102.

[0045] Additionally, the extraction ribs 114 aid in supporting and stabilizing the reagent container (as shown in Figs. 2A-3B), when a portion of the reagent container is inserted into the receiving portion 104 of the diluent container 100B. More particularly, when the reagent container is inserted into the insertion portion 104 of the diluent container 100B, the bottom of the reagent container is supported by the top of extraction ribs 114. This holds the reagent container in a proper position and prevents the reagent container from being inserted too far into the diluent container 100B. This configuration is shown in Figure 3 and further described in the associated section.

[0046] Now referring to Figures 1E and 1F, vertical and horizontal cross-sectional views of a diluent container 100C are illustrated according to an example embodiment. In Figs. 1E and 1F, the diluent container 100C includes largely the same features as the diluent containers 100A and 100B, shown in Figs. 1A-1D and described in the corresponding description. As shown in Figs. 1E and 1F, the diluent container 100C includes a support shoulder 108 and extraction ribs 114 in the diluent chamber 102. In the example shown in Figs. 1E and 1F, the extraction ribs 114 may be shorter in some examples (e.g., as compared to the extraction ribs 114 shown in Fig. 1C).

[0047] Now referring to Fig. 2A and 2B, an example reagent container 200A is disclosed. In examples, a reagent container 200A includes a reagent chamber 202 to hold the reagent, an insertion portion 204 (e.g., to be inserted in the receiving portion 104 of the diluent chamber 102), and a second sealant surface 206 to interface with the first sealant surface 106 of the diluent chamber 102. Additionally, in example embodiments, the reagent container 200A includes a dispensing nozzle 208 to dispense the biological testing sample, once prepared, onto a testing surface, such as a slide or cartridge. In examples, the reagent container 200A may additionally include a sealant mechanism covering an opening 210 of the reagent chamber 202, to preserve the reagent and reagent chamber 202.

[0048] As noted above, in examples, the reagent chamber 202 contains one or more reagents. In some examples, the reagent is a liquid reagent. In some examples, the liquid reagent includes quality control beads. Additionally or alternatively, in some examples, the liquid reagent includes one or more fluorescent stains. During fabrication, the liquid reagent can be deposited into the reagent chamber 202 via the opening 210 of the reagent chamber 202. In some examples, the reagent chamber 202 is then sealed via the sealant mechanism for transportation, storage, and/or handling.

[0049] Additionally or alternatively, in some examples, the reagent is a solid reagent. As noted above, lyophilized reagents are beneficial for particular types of testing. As such, in some example embodiments, during fabrication, the reagent is deposited into the reagent chamber 202 then lyophilized to form a solid lyophilized reagent. For instance, in some examples, the lyophilized reagent may include quality control beads. Additionally or alternatively, the lyophilized reagent may include one or more fluorescent stains. Once, the reagent is lyophilized,

the reagent chamber 202 can then be sealed via the sealant mechanism for transportation, storage, and/or handling.

[0050] In example embodiments, the reagent chamber 202 includes one or more reagent retention mechanisms to help prevent the lyophilized reagent from dislodging during fabrication, transportation, storage, and/or handling. For instance, in some example embodiments, the reagent chamber 202 includes a ring portion 212 on the inside of the reagent chamber 202 to act as a reagent retention mechanism. During lyophilization, the reagent can solidify around the surface of the ring portion 212. This prevents the lyophilized reagent from moving or dislodging from the reagent chamber 202. For example, the ring portion 212 helps prevent dislodging when the sealant mechanism is removed from the opening 210 of the reagent container 200A. Further, the ring portion 212 increases the surface area of the lyophilized reagent, thereby increasing the surface tension between the lyophilized reagent and the reagent chamber 202. In examples, the increase in surface tension may further prevent the lyophilized reagent from dislodging from the reagent chamber 202 during manufacturing, transportation, storage, and/or handling. Further, in some examples, the reagent chamber 202 includes one or more fins 214 on the inside of the reagent chamber 202 to act as a reagent retention mechanism. During lyophilization, the reagent can solidify on the surface of the fins 214, preventing torsional movement and/or rotation during fabrication, transportation, storage, and/or handling. For example, the fins 214 helps prevent the lyophilized reagent from shifting or dislodging when the sealant mechanism is removed from the opening 210 of the reagent container 200A. Further, the fins 214 increase the surface area of the lyophilized reagent, thereby increasing the surface tension between the lyophilized reagent and the reagent chamber 202. The increase in surface tension further prevents the lyophilized reagent from

dislodging from the reagent chamber 202 during fabrication, transportation, storage, and/or handling.

[0051] As noted above, during fabrication, in example embodiments, after the reagent (whether liquid or solid) is deposited and/or prepared in the reagent chamber 202, the reagent chamber 202 is then sealed via the sealant mechanism 222 for transportation, storage, and/or handling. The sealant mechanism 222, shown in Fig. 2B, creates a liquid and/or airtight seal to help preserve the reagent and reagent chamber 202. Further, the sealant mechanism 222 can prevent contamination, deterioration, and/or aging of the reagent. In examples, the sealant mechanism 222 can adhere to the perimeter of the opening 210 of the reagent chamber 202. In some example embodiments, the sealant mechanism 222 includes foil. Additionally or alternatively, the sealant mechanism 222 can include plastics. Other example materials and configurations are possible.

[0052] Once the biological testing sample is prepared, the sealant mechanism 222 can be removed or punctured such that the reagent is exposed via the opening 210. In some example embodiments, the sealant mechanism 222 is configured to be removed by a user (e.g., a clinician), for example by way of peeling or puncturing. For instance, in some examples, the sealant mechanism can include a pull tab and/or perforations for ease of removal. Additionally or alternatively, in some examples the diluent container 100A, 100B, or 100C can include a puncturing mechanism to puncture the sealant mechanism. Other examples are possible.

[0053] Once the sealant mechanism 222 is removed or punctured, the insertion portion 204 of the reagent container 200A can be inserted into the receiving portion 104 of the diluent container 100A, 100B, or 100C (as shown in Figure 3). When the diluent container 100A, 100B, or 100C and reagent container 200A are coupled in this manner, the first sealant surface 106 and the second

sealant surface 206 create a liquid seal between the diluent container 100A, 100B, or 100C and the reagent container 200A. The liquid seal prevents spillage or leakage of the liquid diluent, the biological sample, and/or the reagent.

[0054] In some examples, the second sealant surface 206 includes a sealant ring 220 configured to interface with the first sealant surface 106 of the diluent container 100A, 100B, or 100C. In example embodiments, the sealant ring 220 includes one or more flat portions. The one or more flat portions aid in venting the diluent container 100A, 100B, or 100C as the reagent container 200 is inserted into the diluent container 100 to prevent the diluent chamber 102 from pressurizing. If the diluent chamber is pressurized, fluid (e.g., the biological testing sample) could eject from the opening 218 when the opening 218 is exposed (e.g., when a break-away tab 216 is removed).

[0055] Additionally, once the insertion portion 204 of the reagent container 200A is inserted into the receiving portion 104 of the diluent container 100A, 100B, or 100C, the diluent chamber 102 is in fluid communication with the reagent chamber 202 (as shown in Figure 3). As such, the diluent container 100A, 100B, or 100C and reagent container 200A or 200B can be specifically handled, inverted, and/or shaken, to agitate the reagent and mix it with the liquid diluent and the biological sample to form the biological testing sample. In examples where the reagent is a solid lyophilized reagent, agitation of the reagent with the liquid diluent can liquefy the reagent. This allows the reagent, liquid diluent, and biological sample to mix and prepare the biological testing sample for dispensing and testing.

[0056] Once the biological testing sample is prepared, the biological testing sample can be dispensed onto a testing surface (e.g., a slide or a cartridge) by way of the dispensing nozzle 208. The dispensing nozzle 208 is in fluid communication with the reagent chamber 202 and includes

an opening 218, the opening 218 being sealed until the biological testing sample is prepared. In examples, the opening 218 is covered by the break-away tab 216. In examples, the break-away tab 216 includes perforations for ease of removal. For instance, the user can apply force to twist or bend the break-away tab 216 to remove it from the dispensing nozzle 208 and expose the opening 218.

[0057] In examples, when the break-away tab 216 is removed and the opening 218 of the dispensing nozzle 208 is exposed, the biological testing sample can be dispensed, for example, onto a testing surface, such as a slide or cartridge. In examples, the opening 218 of the dispensing nozzle 208 is configured to dispense the biological testing sample at a particular flow rate. For example, the opening of the dispensing nozzle 208 may be configured to effectuate a particular flow rate for a particular liquid, such as a biological testing sample that is to be deposited onto a testing surface (e.g., a slide or cartridge) for testing, such as imaging. More particularly, the opening 218 has a particular cross-sectional area to achieve a desired flow rate of the biological sample. Dispensing the biological testing sample onto a testing surface, such as a slide or cartridge, at a particular flow rate can help control the placement of the biological testing sample onto the testing surface and prevent splatter.

[0058] Turning to Fig. 2B, the example reagent container 200A of Fig. 2A is disclosed, with the sealant mechanism 222 covering opening 210 of the reagent chamber, to preserve the one or more reagents in the reagent chamber. As shown in Fig. 2B, the sealant mechanism 222 includes a pull tab and may be made of one or more of the materials described above (e.g., foil, plastic, etc.). Other examples are possible.

[0059] Now referring to Fig. 2C, another example of a reagent container 200B, according to an example embodiment. In Fig. 2C, the reagent container 200B includes largely the same

features as the reagent container 200A, shown in Fig. 2A-2B and described in the corresponding description. As shown in Fig. 2C, the reagent container 200B can include an additional ring portion 224 on the inside of the reagent chamber 202 to act as a reagent retention mechanism, in addition to the ring portion 212 and the one or more fins 214. During lyophilization, the reagent can solidify around the surface of the ring portion 224. This prevents the lyophilized reagent from moving or dislodging from the reagent chamber 202. For example, the ring portion 224 helps prevent dislodging when the sealant mechanism is removed from the opening 210 of the reagent container 200. Further, the ring portion 212 increases the surface area of the lyophilized reagent, thereby increasing the surface tension between the lyophilized reagent and the reagent chamber 202. In examples, the increase in surface tension may further prevent the lyophilized reagent from dislodging from the reagent chamber 202 during manufacturing, transportation, storage, and/or handling.

[0060] Moreover, in some examples, during fabrication, the reagent can be deposited into the reagent chamber 202 while the reagent container 200B is inverted. In other words, the opening 218 is towards the “bottom” of the reagent container 200B while the reagent is deposited. Accordingly, the reagent fills from at or near the opening 218 towards the reagent chamber 202. In examples where smaller volumes of reagent are utilized, the reagent may not reach the ring portion 212. Ring portion 224 can be positioned closer to the opening 218 than ring portion 218 (i.e., between opening 218 and ring portion 218) so that, in examples where the reagent does not reach the ring portion 212, the ring portion 224 can act as a reagent retention mechanism.

[0061] Now referring to Fig. 3, a device 300A for preparing a biological sample, according to an example embodiment. The device 300A includes the diluent container 100B of Figs. 1C and 1D and the reagent container 200A of Figs. 2A and 2B coupled to one another. As described above,

the diluent container 100B includes a receiving portion 104 configured to receive an insertion portion 204 of the reagent container 200. The first sealant surface 106 of the receiving portion 104 interfaces with the second sealant surface 206 of the insertion portion 204 to form a liquid seal between the diluent container 100B and the reagent container 200.

[0062] In example embodiments where the diluent container 100B includes extraction ribs 114, as shown in Fig. 3, the extraction ribs 114 can support and stabilize the reagent container 200. More particularly, the bottom of the reagent container 200A is supported by the extraction ribs 114. This holds the reagent container in a proper position and prevents the reagent container 200A from being inserted too far into the diluent container 100B.

[0063] As shown in Fig. 3, the diluent chamber 102 is in fluid communication with the reagent chamber 202, allowing the reagent to mix with the liquid diluent and the biological sample. The device 300A can be handled, for example, inverted and/or shaken, to agitate the reagent and mix it with the liquid diluent and the biological sample to form the biological testing sample. In examples where the reagent is a solid lyophilized reagent, agitation of the reagent with the liquid diluent can liquefy the reagent. This allows the reagent, liquid diluent, and biological sample to mix and prepare the biological testing sample for dispensing and testing. During such handling, spillage or leakage of the fluids (e.g., the liquid diluent, the biological sample, and the reagent) is prevented by way of the liquid seal created by the interface of the first sealant surface 106 and the second sealant surface 206.

[0064] Once the biological testing sample is prepared, the biological testing sample can be dispensed onto a testing surface (e.g., a slide and/or a cartridge) by way of the dispensing nozzle 208. The dispensing nozzle 208 is in fluid communication with the reagent chamber 202 and the diluent chamber 102. In examples, the dispensing nozzle includes an opening 218, the opening

218 being sealed until the biological testing sample is prepared. In examples, the opening 218 is sealed by way of a break-away tab 216. In examples, the break-away tab 216 includes perforations for ease removal. For instance, the user can twist or bend the break-away tab 216 to remove it from the dispensing nozzle 208 and expose the opening 218.

[0065] As noted above in reference to Fig. 2B, in example embodiments, second sealant surface 206 may include one or more flat portions. The one or more flat portions aid in venting the diluent container 100B as the reagent container 200A is inserted into the diluent container 100B to prevent the diluent chamber 102 from pressurizing. If the diluent chamber is pressurized, fluid (e.g., the biological testing sample) could eject from the opening 218 when the break-away tab 216 is removed.

[0066] When the break-away tab 216 is removed and the opening 218 of the dispensing nozzle 208 is exposed, the biological testing sample can be dispensed from the device 300A onto a testing surface, such as a slide or cartridge. In examples, the opening of the dispensing nozzle 208 is configured to dispense the biological testing sample at a particular flow rate. More particularly, the opening 218 has a particular cross-sectional area to achieve a desired flow rate of the biological sample. Dispensing the biological testing sample onto a testing surface, such as a slide or cartridge, at a particular flow rate can help control the placement of the biological testing sample onto the testing surface and prevent splatter.

[0067] Additionally, as noted above, the diluent container 100A, 100B, or 100C is made of a compliant material (e.g., LLDPE and/or LDPE) so that the user can pinch or squeeze the diluent container 100 to dispense the biological testing sample onto the testing surface. In example embodiments, the compliant material is configured to dispense the biological sample at a particular

flow rate. This helps further control placement of the biological testing sample onto the testing surface and prevent splatter.

[0068] Moreover, the first sealant surface 106 and the second sealant surface 206 are configured to maintain the liquid seal while the diluent container 100B is pinched or squeezed to prevent leakage and/or spillage as the biological testing sample is dispensed.

[0069] Now referring to Fig. 3B, another example of a device 300B for preparing a biological sample, according to an example embodiment. The device 300B includes the diluent container 100C of Figs. 1E and 1F and the reagent container 200B of Fig. 2C coupled to one another. In Fig. 3B, the example device 300B includes largely the same features as the example device 300A shown in Fig. 3A and described in the corresponding description. However, as shown in Fig. 3B, the diluent container 100C includes a support shoulder 108.

[0070] While Fig. 3A illustrates the combination of diluent container 100B and reagent container 200A and Fig. 3B illustrates the combination of diluent container 100C and reagent container 200B, many example combinations of diluent containers and reagent containers are possible. For instance, diluent container 100A may be coupled to reagent container 100A or 100B. Further, diluent container 100B may be coupled to reagent container 200B. And, diluent container 100C can be coupled to reagent container 200A. Many example implementations are possible.

[0071] In some example embodiments, the biological testing sample can be used for a variety of tests. For instance, these tests may include imaging of one or more of the following: (i) blood; (ii) urine; (iii) saliva; (iv) fecal matter; (v) secretion; (vi) excretion; (vii) FNA; (viii) lavage fluids; (ix) body cavity fluids; (x) semen; (xi) ear wax; (xii) skin cells; (xiii) biopsied samples, (xiv) exotics; (xv) cultured cells; (xvi) bacteria; (xvii) worms; (xviii) parasites; and (xix) ear mites, among other possibilities. Test may additionally include one or more of the following: blood

coagulation test, polymerase chain reaction (PCR) test, and/or immunoassay, among other possibilities. For example, in some example embodiments, these tests may include one or more of the following blood chemistry tests: SDMA, Total T4 (TT4), Bile Acids, C-reactive Protein (CRP), Progesterone, Fructosamine, and/or Phenobarbital (PHBR), among other possibilities. For example, in some example embodiments, these tests may include one or more of the following blood chemistry profile tests that measure one or more of the following: ALB, ALB/GLOB, ALKP, ALT, AMYL, AST, BUN, BUN/CREA, Ca, CHOL, CK, Cl, CREA, CRP, FRU, GGT, GLOB, GLU, K, LAC, LDH, LIPA, Mg, Na, NH₃, PHOS, TBIL, TP, TRIG and/or URIC, among other possibilities. Other examples are possible.

EXAMPLE METHODS AND ASPECTS

[0072] Now referring to Fig. 4, an example method of preparing a biological testing sample is disclosed. Method 400 shown in Fig. 4 presents an example of a method for preparing a biological testing sample that could be used with the components shown in Figs. 1A-3, for example. Further, devices or systems may be used or configured to perform logical functions presented in Fig. 4. In other examples, components of the devices and/or systems may be arranged to be adapted to, capable of, or suited for performing the functions, such as when operated in a specific manner. Method 400 may include one or more operations, functions, or actions as illustrated by one or more of blocks 402-410. Although the blocks are illustrated in a sequential order, these blocks may also be performed in parallel, and/or in a different order than those described herein. Also, the various blocks may be combined into fewer blocks, divided into additional blocks, and/or removed based upon the desired implementation.

[0073] At block 402, method 400 involves depositing a liquid diluent into a diluent chamber of a diluent container. In some examples, the diluent chamber is in fluid communication

with the reagent chamber when the insertion portion of the reagent chamber is interfaced with the receiving portion of the diluent chamber. In some examples, the diluent chamber further comprises one or more chambers configured to receive a liquid biological sample. In some examples, the biological sample comprises a liquid biological sample. In some examples, the liquid biological sample comprises one or more of the following: (i) blood; (ii) urine; (iii) saliva; (iv) fecal matter; (v) secretion; (vi) excretion; (vii) Fine Needle Aspirate (FNA); (viii) lavage fluids; (ix) body cavity fluids; and (x) semen. In some examples, the diluent chamber further comprises one or more extraction ribs configured to extract a biological sample. In some examples, the biological sample comprises ear wax. In examples, the diluent container further comprises a sealant mechanism covering an opening of the receiving portion

[0074] At block 404, method 400 involves depositing a reagent into a reagent chamber of a reagent container. In some examples, block 402 additionally involves lyophilizing the reagent to form a solid reagent. In some examples, the reagent comprises a liquid reagent. In some examples, the reagent comprises a solid reagent. In some examples, the solid reagent comprises a lyophilized reagent. In some examples, the lyophilized reagent comprises one or more quality control beads. In some examples, the lyophilized reagent comprises one or more fluorescent stains. In some embodiments, the reagent chamber further comprises a reagent retention mechanism. In examples, the reagent retention mechanism comprises a ring portion inside the reagent chamber. In some examples, the reagent retention mechanism comprises one or more fins inside the reagent chamber. In some examples, the reagent container further comprises a sealant mechanism covering an opening of the insertion portion.

[0075] At block 406, method 400 involves receiving a biological sample into the diluent chamber of the diluent container.

[0076] At block 408, method 400 involves inserting an insertion portion of the reagent container into a receiving portion of the diluent container, wherein the receiving portion comprises a first sealant surface that interfaces with a second sealant surface of the insertion portion, and wherein the first sealant surface and the second sealant surface form a liquid seal when interfaced, and wherein the diluent chamber is in fluid communication with the reagent chamber when the insertion portion of the reagent container is inserted into the receiving portion of the diluent container.

[0077] At block 410, method 400 involves, after inserting the insertion portion of the reagent container into the receiving portion of the diluent container, agitating the reagent with the liquid diluent and the biological sample.

[0078] In some example embodiments, method 400 additionally involves dispensing the reagent, the liquid diluent, and the biological from a dispensing nozzle, wherein the dispensing nozzle is in fluid communication with reagent container. In some examples, an opening of the dispensing nozzle is configured to dispense the biological sample at a particular flow rate.

[0079] In some example embodiments, the biological testing sample of method 400 comprises a mixture of a liquid diluent, a biological sample, and a reagent.

[0080] The singular forms of the articles “a,” “an,” and “the” include plural references unless the context clearly indicates otherwise. For example, the term “a compound” or “at least one compound” can include a plurality of compounds, including mixtures thereof.

[0081] Various aspects and embodiments have been disclosed herein, but other aspects and embodiments will certainly be apparent to those skilled in the art. Additionally, the various aspects and embodiments disclosed herein are provided for explanatory purposes and are not intended to be limiting, with the true scope being indicated by the following claims.

CLAIMS

What is claimed is:

1. A device for preparing a biological testing sample, wherein the device comprises:
a diluent container comprising:
 - a diluent chamber comprising a liquid diluent, wherein the diluent chamber is configured to receive a biological sample;
 - a receiving portion, wherein the receiving portion is in fluid communication with the diluent chamber; and
 - a first sealant surface, wherein the first sealant surface is proximate to the receiving portion; anda reagent container comprising:
 - a reagent chamber comprising a reagent;
 - a dispensing nozzle, wherein the dispensing nozzle is in fluid communication with the reagent chamber, and wherein the dispensing nozzle comprises a break-away tab covering an opening of the dispensing nozzle;
 - an insertion portion, wherein the insertion portion is in fluid communication with the reagent chamber, and wherein the insertion portion is configured to interface with the receiving portion of the diluent chamber; and
 - a second sealant surface, wherein the second sealant surface is proximate to the insertion portion, and wherein the first sealant surface and the second sealant surface form a liquid seal when the insertion portion is interfaced with the receiving portion of the diluent chamber.

2. The device of claim 1, wherein the diluent chamber is in fluid communication with the reagent chamber when the insertion portion of the reagent chamber is interfaced with the receiving portion of the diluent chamber.
3. The device of claim 1, wherein the biological testing sample comprises a mixture of the liquid diluent, the biological sample, and the reagent.
4. The device of claim 1, wherein the diluent chamber further comprises one or more chambers configured to receive a liquid biological sample.
5. The device of claim 4, wherein the biological sample comprises a liquid biological sample comprising one or more of the following: (i) blood; (ii) urine; (iii) saliva; (iv) fecal matter; (v) secretion; (vi) excretion; (vii) Fine Needle Aspirate (FNA); (viii) lavage fluids; (ix) body cavity fluids; (x) semen; and (xi) bacteria.
6. The device of claim 1, wherein the diluent container is made of a compliant material such that when compressed, when the diluent chamber is in fluid communication with the reagent chamber and the insertion portion of the reagent chamber is interfaced with the receiving portion of the diluent chamber, the biological testing sample is dispensed from the dispensing nozzle.
7. The device of claim 1, wherein the diluent chamber further comprises one or more extraction ribs configured to extract a biological sample.

8. The device of claim 7, wherein the biological sample comprises ear wax.
9. The device of claim 1, wherein the diluent container further comprises a sealant mechanism covering an opening of the receiving portion.
10. The device of claim 1, wherein the reagent comprises a liquid reagent.
11. The device of claim 1, wherein the reagent comprises a solid reagent.
12. The device of claim 11, wherein the solid reagent comprises a lyophilized reagent.
13. The device of claim 12, wherein the lyophilized reagent comprises one or more quality control beads.
14. The device of claim 12, wherein the lyophilized reagent comprises one or more fluorescent stains.
15. The device of claim 1, wherein the reagent chamber further comprises a reagent retention mechanism.
16. The device of claim 15, wherein the reagent retention mechanism comprises a ring portion inside the reagent chamber.

17. The device of claim 15, wherein the reagent retention mechanism comprises one or more fins inside the reagent chamber.

18. The device of claim 1, wherein the reagent container further comprises a sealant mechanism covering an opening of the insertion portion.

19. The device of claim 1, wherein the opening of the dispensing nozzle is configured to dispense the biological sample at a particular flow rate.

20. A method for preparing a biological testing sample, the method comprising:
depositing a liquid diluent into a diluent chamber of a diluent container;
depositing a reagent into a reagent chamber of a reagent container;
receiving a biological sample in the diluent chamber of the diluent container;
inserting an insertion portion of the reagent container into a receiving portion of the diluent container, wherein the receiving portion comprises a first sealant surface that interfaces with a second sealant surface of the insertion portion, and wherein the first sealant surface and the second sealant surface form a liquid seal when interfaced, and wherein the diluent chamber is in fluid communication with the reagent chamber when the insertion portion of the reagent container is inserted into the receiving portion of the diluent container; and
after inserting the insertion portion of the reagent container into the receiving portion of the diluent container, agitating the reagent with the liquid diluent and the biological sample.