(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
28 May 2009 (28.05.2009)

PCT

(10) International Publication Number
WO 2009/067513 A1

(51) International Patent Classification:
B01L 3/00 (2006.01) *G01N 1/38* (2006.01)

(21) International Application Number:
PCT/US2008/084035

(22) International Filing Date:
19 November 2008 (19.11.2008)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/989,175 20 November 2007 (20.11.2007) US

(71) Applicant *(for all designated States except US)*: **3M INNOVATIVE PROPERTIES COMPANY** [US/US]; 3M Center, Post Office Box 33427, Saint Paul, Minnesota 55133-3427 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **HALVERSON, Kurt J.** [US/US]; 3M Center, Post Office Box 33427, Saint Paul, Minnesota 55133-3427 (US). **JOSEPH, Stephen C.P.** [GB/US]; 3M Center, Post Office Box 33427, Saint Paul, Minnesota 55133-3427 (US). **RAJAGOPAL, Raj** [US/US]; 3M Center, Post Office Box 33427, Saint Paul, Minnesota 55133-3427 (US). **REIER, Matthew D.** [US/US]; 3M Center, Post Office Box 33427, Saint Paul, Minnesota 55133-3427 (US). **VELASQUEZ, David J.** [US/US]; 3M Center, Post Office Box 33427, Saint Paul, Minnesota 55133-3427 (US). **ZOOK, Cynthia D.** [US/US]; 3M Center, Post Office Box 33427, Saint Paul, Minnesota 55133-3427 (US). **CHANDRAPATI, Sailaja** [IN/US]; 3M Center, Post Office Box 33427, Saint Paul, Minnesota 55133-3427 (US).

(74) Agents: **EINERSON, Nicole J.** et al.; 3M Center, Office of Intellectual Property CounselPost Office Box 33427, Saint Paul, Minnesota 55133-3427 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK,

[Continued on next page]

(54) Title: SAMPLE PREPARATION CONTAINER AND METHOD

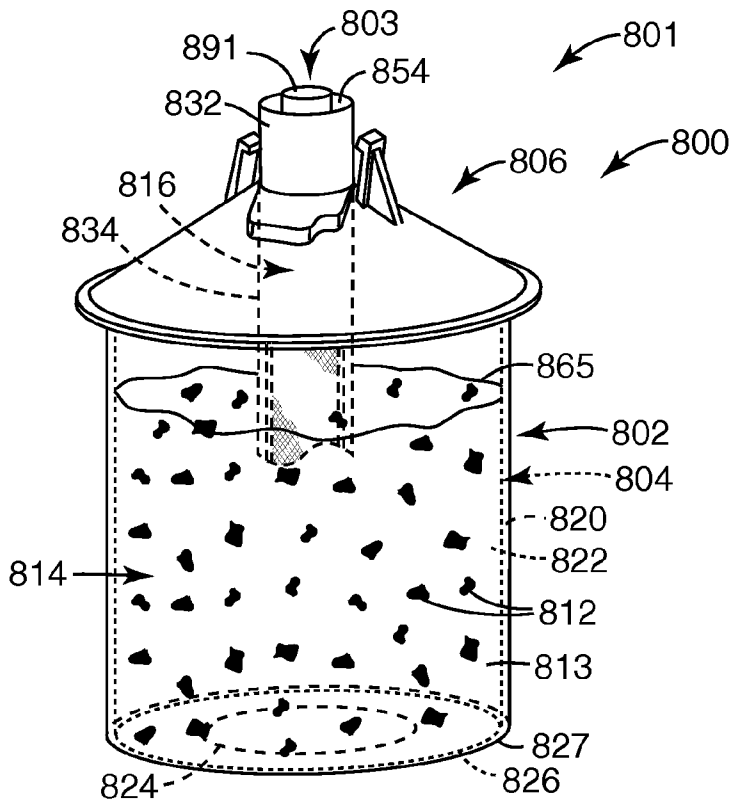

FIG. 14

(57) Abstract: A system and method for preparing and delivering samples for analyte testing. The system can include a sample preparation system and a sample delivery system coupled to the sample preparation system. The sample preparation system can include a deformable self-supporting receptacle comprising a reservoir adapted to contain a liquid composition comprising a source and a diluent. The sample delivery system can include a valve positioned in fluid communication with the reservoir and adapted to control the removal of a sample from the sample preparation system. The method can include applying pressure to the deformable self-supporting receptacle to remove a sample from the sample preparation system via the sample delivery system.

WO 2009/067513 A1

LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

Published:

— *with international search report*

SYSTEM AND METHOD FOR PREPARING AND DELIVERING SAMPLES

BACKGROUND

In a variety of applications, food and non-food sources may need to be tested for microorganisms (e.g., bacteria, viruses, fungi, spores, etc.) and/or other analytes of interest (e.g., toxins, allergens, hormones, etc.). For example, foods grown, purchased and consumed by the general population may contain or acquire microorganisms or other analytes, which can flourish or grow as a function of the environment in which they are located. This growth may lead to accelerated spoilage of the food product or to the proliferation of pathogenic organisms, which may produce toxins or multiply to infective doses. By way of further example, a variety of analytical methods can be performed on samples of non-food sources (e.g., groundwater, urine, etc.) to determine if the sample contains a particular analyte. For example, groundwater can be tested for a microorganism or a chemical toxin; and urine can be tested for a variety of diagnostic indicators to enable a diagnosis (e.g., diabetes, pregnancy, etc.).

SUMMARY

The present disclosure relates to a sample preparation and delivery system and method, and particularly, to a sample preparation and delivery system and method for analyte testing, the sample preparation and delivery system comprising a sample preparation system and a sample delivery system coupled to the sample preparation system that accomplishes removal (or separation) of samples from the sample preparation system and/or delivery of the samples to another location or device.

Some embodiments of the present disclosure provide a system for preparing and delivering samples for analyte testing. The system can include a sample preparation system and a sample delivery system coupled to the sample preparation system. The sample preparation system can include a deformable self-supporting receptacle comprising a reservoir. The reservoir can be adapted to contain a liquid composition comprising a source and a diluent. The sample delivery system can include a valve positioned in fluid communication with the reservoir and adapted to control the removal of a sample from the sample preparation system.

Some embodiments of the present disclosure provide a system for preparing and delivering samples for analyte testing. The system can include a sample preparation system and a sample delivery system coupled to the sample preparation system. The sample preparation system can include a freestanding container comprising a first reservoir, a deformable self-supporting receptacle dimensioned to be received in the first reservoir of the freestanding container and comprising a second reservoir, and a lid adapted to be coupled to at least one of the freestanding container and the deformable self-supporting receptacle. The second reservoir can be adapted to contain a liquid composition comprising a source and a diluent. The freestanding container can be more rigid than the deformable self-supporting receptacle. The sample delivery system can include a valve positioned in fluid communication with the second reservoir and adapted to control the removal of a sample from the sample preparation system.

Some embodiments of the present disclosure provide a method for preparing and delivering samples for analyte testing. The method can include providing a sample preparation system comprising a deformable self-supporting receptacle comprising a reservoir, providing a liquid composition comprising a source and a diluent, and positioning the liquid composition in the reservoir of the deformable self-supporting receptacle. The method can further include providing a sample delivery system adapted to be coupled to the sample preparation system. The sample delivery system can include a valve positioned in fluid communication with the reservoir. The method can further include applying pressure to the deformable self-supporting receptacle to remove a sample from the sample preparation system via the sample delivery system.

Other features and aspects of the invention will become apparent by consideration of the detailed description and accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic flow chart depicting a sample preparation and delivery method according to one embodiment of the present disclosure.

FIG. 2 is an exploded perspective view of a sample preparation system according to one embodiment of the present disclosure, the sample preparation system including a lid.

FIG. 3 is close-up cross-sectional view of the lid of FIG. 2, taken along line 3-3 in FIG. 2.

FIG. 4 is a perspective view of a sample preparation system according to another embodiment of the present disclosure.

FIG. 5 is a bottom view of a lid of a sample preparation system according to another embodiment of the present disclosure.

FIG. 6 is a cross-sectional view of the lid of FIG. 5, taken along line 6-6 in FIG. 5.

FIG. 7 is a perspective view of a sample preparation system according to another embodiment of the present disclosure.

FIG. 8 is a perspective view of a sample preparation system according to another embodiment of the present disclosure.

FIG. 9 is an exploded side view of a sample preparation system according to another embodiment of the present disclosure, the sample preparation system including a filter, and a lid assembly that includes a lid and a cover.

FIG. 10 is a perspective view of the lid assembly and filter of FIG. 9, with the filter in a compressed state.

FIG. 11 is a perspective view of the lid assembly and filter of FIGS. 9 and 10, with the filter in an uncompressed state.

FIG. 12 is a top perspective view of the cover of FIGS. 9-11.

FIG. 13 is a side view of a lid assembly of a sample preparation system according to another embodiment of the present disclosure.

FIG. 14 is a perspective view of a sample preparation and delivery system according to one embodiment of the present disclosure.

FIG. 15 is a perspective view of the sample preparation and delivery system of FIG. 14, shown in use with a detection system.

FIG. 16 is a perspective view of a sample preparation and delivery system according to another embodiment of the present disclosure, the sample preparation and delivery system coupled to an enrichment device.

FIGS. 17A-17C are cross-sectional schematic views of a sample delivery system according to one embodiment of the present disclosure.

FIGS. 18A-18C are cross-sectional schematic views of a sample delivery system according to another embodiment of the present disclosure.

FIGS. 19A-19C are cross-sectional schematic views of a sample delivery system according to another embodiment of the present disclosure.

FIGS. 20A-20D are cross-sectional schematic views of a sample delivery system according to another embodiment of the present disclosure.

FIGS. 21A-21B are cross-sectional schematic views of a sample preparation and delivery system according to another embodiment of the present disclosure.

DETAILED DESCRIPTION

Before any embodiments of the invention are explained in detail, it is to be understood that the invention is not limited in its application to the details of construction and the arrangement of components set forth in the following description or illustrated in the accompanying drawings. The invention is capable of other embodiments and of being practiced or of being carried out in various ways. Also, it is to be understood that the phraseology and terminology used herein is for the purpose of description and should not be regarded as limiting. The use of "including," "comprising," "containing," or "having" and variations thereof herein is meant to encompass the items listed thereafter and equivalents thereof as well as additional items. Unless specified or limited otherwise, the terms "supported," and "coupled" and variations thereof are used broadly and encompass both direct and indirect supports and couplings. It is to be understood that other embodiments may be utilized, and structural or logical changes may be made without departing from the scope of the present disclosure. Furthermore, terms such as "front," "rear," "top," "bottom," and the like are only used to describe elements as they relate to

one another, but are in no way meant to recite specific orientations of the apparatus, to indicate or imply necessary or required orientations of the apparatus, or to specify how the invention described herein will be used, mounted, displayed, or positioned in use.

The present disclosure is generally directed to a system and method for preparing and delivering samples. The samples can be further concentrated, enriched, and/or analyzed for the presence or absence of a variety of analytes.

The term "source" is generally used to refer to the food or nonfood desired to be tested for analytes. The source can be a solid, a liquid, a semi-solid, a gelatinous material, and combinations thereof. In some embodiments, the source can be provided by a substrate that was used, for example, to collect the source from a surface of interest. In some embodiments, the liquid composition can include the substrate, which can be further broken apart (e.g., during an agitation or dissolution process) to enhance retrieval of the source and any analyte of interest. The surface of interest can include at least a portion of a variety of surfaces, including, but not limited to, walls (including doors), floors, ceilings, drains, refrigeration systems, ducts (e.g., airducts), vents, toilet seats, handles, doorknobs, handrails, bedrails (e.g., in a hospital), countertops, tabletops, eating surfaces (e.g., trays, dishes, etc.), working surfaces, equipment surfaces, clothing, etc., and combinations thereof. All or a portion of the source can be used in the sample preparation system and method. When a portion of the source is used, this can sometimes be referred to as a "sample" of the source. However, the term "sample" is generally used herein to refer to a volume or mass of material that is extracted from the sample preparation system for further analysis (e.g., detection of analytes).

The term "food" is generally used to refer to a solid, liquid (e.g., including, but not limited to, solutions, dispersions, emulsions, suspensions, etc., and combinations thereof) and/or semi-solid comestible composition. Examples of foods include, but are not limited to, meats, poultry, eggs, fish, seafood, vegetables, fruits, prepared foods (e.g., soups, sauces, pastes), grain products (e.g., flour, cereals, breads), canned foods, milk, other dairy products (e.g., cheese, yogurt, sour cream), fats, oils, desserts, condiments, spices, pastas, beverages, water, animal feed, other suitable comestible materials, and combinations thereof.

The term "nonfood" is generally used to refer to sources of interest that do not fall within the definition of "food" and are generally not considered to be comestible. Examples of nonfood sources can include, but are not limited to, clinical samples, cell lysates, whole blood or a portion thereof (e.g., serum), other bodily fluids or secretions (e.g., saliva, sweat, sebum, urine), feces, cells, tissues, organs, biopsies, plant materials, wood, soil, sediment, medicines, cosmetics, dietary supplements (e.g., ginseng capsules), pharmaceuticals, fomites, other suitable non-comestible materials, and combinations thereof.

The term "fomite" is generally used to refer to an inanimate object or substrate capable of carrying infectious organisms and/or transferring them. Fomites can include, but are not limited to, cloths, mop heads, towels, sponges, wipes, eating utensils, coins, paper money, cell phones, clothing (including shoes), doorknobs, feminine products, diapers, etc., portions thereof, and combinations thereof.

The term "analyte" is generally used to refer to a substance to be detected (e.g., by a laboratory or field test). A source can be tested for the presence or absence of particular analytes or for quantitation of particular analytes. Such analytes can be present within a source (e.g., on the interior), or on the exterior (e.g., on the outer surface) of a source. Examples of analytes can include, but are not limited to, microorganisms, parasites (some of which are also microorganisms), biomolecules, chemicals (e.g. pesticides, antibiotics), metal ions (e.g. mercury ions, heavy metal ions), metal-ion-containing complexes (e.g., complexes comprising metal ions and organic ligands), and combinations thereof.

A variety of testing methods can be used to identify and/or quantitate an analyte, including, but not limited to, microbiological assays, biochemical assays (e.g. immunoassay), or a combination thereof. Specific examples of testing methods that can be used include, but are not limited to, lateral flow assays, titration, thermal analysis, microscopy (e.g., light microscopy, fluorescent microscopy, immunofluorescent microscopy, scanning electron microscopy (SEM), transmission electron microscopy (TEM)), spectroscopy (e.g., mass spectroscopy, nuclear magnetic resonance (NMR) spectroscopy, Raman spectroscopy, infrared (IR) spectroscopy, x-ray spectroscopy, attenuated total reflectance spectroscopy, Fourier transform spectroscopy, gamma-ray

spectroscopy, etc.), spectrophotometry (e.g., absorbance, fluorescence, luminescence, etc.), chromatography (e.g., gas chromatography, liquid chromatography, ion-exchange chromatography, affinity chromatography, etc.), electrochemical analysis, genetic techniques (e.g., polymerase chain reaction (PCR), transcription mediated amplification (TMA), hybridization protection assay (HPA), DNA or RNA molecular recognition assays, etc.), adenosine triphosphate (ATP) detection assays, immunological assays (e.g., enzyme-linked immunosorbent assay (ELISA)), cytotoxicity assays, viral plaque assays, techniques for evaluating cytopathic effect, culture techniques such as those that can be done using a growth medium (e.g., agar) and/or 3M™ Petrifilm™ Plates (e.g., and imaged, quantified and/or interpreted using a 3M™ Petrifilm™ Plate Reader (3M Company, St. Paul, MN)), other suitable analyte testing methods, or a combination thereof.

The term "microorganism" is generally used to refer to any prokaryotic or eukaryotic microscopic organism, including without limitation, one or more of bacteria (e.g., motile or vegetative, Gram positive or Gram negative), viruses (e.g., *Norovirus*, *Norwalk virus*, *Rotavirus*, *Adenovirus*, DNA viruses, RNA viruses, enveloped, non-enveloped, human immunodeficiency virus (HIV), human *Papillomavirus* (HPV), etc.), bacterial spores or endospores, algae, fungi (e.g., yeast, filamentous fungi, fungal spores), prions, mycoplasmas, and protozoa. In some cases, the microorganisms of particular interest are those that are pathogenic, and the term "pathogen" is used to refer to any pathogenic microorganism. Examples of pathogens can include, but are not limited to, members of the family *Enterobacteriaceae*, or members of the family *Micrococaceae*, or the genera *Staphylococcus* spp., *Streptococcus*, spp., *Pseudomonas* spp., *Enterococcus* spp., *Salmonella* spp., *Legionella* spp., *Shigella* spp., *Yersinia* spp., *Enterobacter* spp., *Escherichia* spp., *Bacillus* spp., *Listeria* spp., *Campylobacter* spp., *Acinetobacter* spp., *Vibrio* spp., *Clostridium* spp., and *Corynebacteria* spp. Particular examples of pathogens can include, but are not limited to, *Escherichia coli* including enterohemorrhagic *E. coli* e.g., serotype O157:H7, *Pseudomonas aeruginosa*, *Bacillus cereus*, *Bacillus anthracis*, *Salmonella enteritidis*, *Salmonella typhimurium*, *Listeria monocytogenes*, *Clostridium botulinum*, *Clostridium perfringens*, *Staphylococcus aureus*, methicillin-resistant *Staphylococcus aureus*, *Campylobacter jejuni*, *Yersinia enterocolitica*, *Vibrio vulnificus*,

Clostridium difficile, vancomycin-resistant *Enterococcus*, and *Enterobacter sakazakii*. Environmental factors that may affect the growth of a microorganism can include the presence or absence of nutrients, pH, moisture content, oxidation-reduction potential, antimicrobial compounds, temperature, atmospheric gas composition and biological structures or barriers.

The term "parasite" is generally used to refer to an organism that lives in (i.e., an endoparasite) or on (i.e., an ectoparasite) a second organism (i.e., a host), and typically causes the second organism harm. Parasites can include, but are not limited to, microorganisms, and worms (e.g., roundworms, threadworms, hookworms, macroscopic multicellular worms, pinworms, whipworms, etc.). Specific examples of parasites can include, but are not limited to, *Cryptosporidium* spp., *Giardia* spp., *Blastocystis hominis*, *Endolimax nana*, *Cryptosporidium parvum*, *Entamoeba histolytica*, *Entamoeba coli*, *Entamoeba hartmanni*, *Giardia lamblia*, *Chilomastix mesnili*, *Cyclospora cayetanensis*, *Helminths* (macroscopic multicellular worms), *Ascaris lumbricoides* (human roundworm), *Strongyloides stercoralis* (threadworm), *Ancylostoma duodenale* (hookworm), *Necator americanus* (hookworm), *Enterobius vermicularis* (pinworm), and *Trichuris trichiura* (whipworm).

The term "biomolecule" is generally used to refer to a molecule, or a derivative thereof, that occurs in or is formed by an organism. For example, a biomolecule can include, but is not limited to, at least one of an amino acid, a nucleic acid, a polypeptide, a protein, a polynucleotide, a lipid, a phospholipid, a saccharide, a polysaccharide, and combinations thereof. Specific examples of biomolecules can include, but are not limited to, a metabolite (e.g., staphylococcal enterotoxin), an allergen (e.g., peanut allergen(s), egg allergen(s), pollens, dust mites, molds, danders, or proteins inherent therein, etc.), a hormone, a toxin (e.g., *Bacillus* diarrheal toxin, aflatoxin, *Clostridium difficile* toxin etc.), RNA (e.g., mRNA, total RNA, tRNA, etc.), DNA (e.g., plasmid DNA, plant DNA, etc.), a tagged protein, an antibody, an antigen, ATP, and combinations thereof.

The terms "soluble matter" and "insoluble matter" are generally used to refer to matter that is relatively soluble or insoluble in a given medium, under certain conditions. Specifically, under a given set of conditions, "soluble matter" is matter that goes into

solution and can be dissolved in the solvent (e.g., diluent) of a system. "Insoluble matter" is matter that, under a given set of conditions, does not go into solution and is not dissolved in the solvent of a system. A source can include soluble matter and insoluble matter (e.g., cell debris). Insoluble matter is sometimes referred to as particulate(s) or debris and can include portions of the source material itself (i.e., from internal portions or external portions (e.g., the outer surface) of the source) or other source residue or debris resulting from an agitation process. The analyte of interest can be present in the soluble matter or the insoluble matter.

The term "agitate" and derivatives thereof is generally used to describe the process of giving motion to a liquid composition, for example, to mix or blend the contents of such liquid composition, or to liquefy a solid source by blending with a liquid. A variety of agitation methods can be used, including, but not limited to, manual shaking, mechanical shaking (e.g., linear shaking), ultrasonic vibration, vortex stirring, manual stirring, mechanical stirring (e.g., by a mechanical propeller, a magnetic stirbar, or another agitating aid, such as ball bearings), manual beating, mechanical beating, blending, kneading, and combinations thereof.

The term "filtering" is generally used to describe the process of separating matter by size, charge and/or function. For example, filtering can include separating soluble matter and a solvent (e.g., diluent) from insoluble matter, or it can include separating soluble matter, a solvent and relatively small insoluble matter from relatively large insoluble matter. A variety of filtration methods can be used, including, but not limited to, passing the liquid composition through a filter, settling followed by aspiration or decanting, other suitable filtration methods, and combinations thereof. "Settling" is used to refer to allowing the insoluble matter in the liquid composition to settle. Settling may occur by gravity or by centrifugation. The insoluble matter (or relatively large insoluble matter) can then be separated from the soluble matter (or soluble matter and relatively small insoluble matter) and solvent by aspirating the soluble matter and solvent from the insoluble matter, decanting the soluble matter and solvent, or a combination thereof.

A "filter" is generally used to describe the device used to separate the soluble matter (or soluble matter and relatively small insoluble matter) and solvent from the

insoluble matter (or relatively large insoluble matter) in a liquid composition. Examples of filters can include, but are not limited to, a woven or non-woven mesh (e.g., a wire mesh, a cloth mesh, a plastic mesh, etc.), a woven or non-woven polymeric web (e.g., comprising polymeric fibers laid down in a uniform or nonuniform process, which can be calendered), a surface filter, a depth filter, a membrane (e.g., a ceramic membrane (e.g., ceramic aluminum oxide membrane filters available under the trade designation ANOPORE from Whatman Inc., Florham Park, NJ), a polycarbonate membrane (e.g., track-etched polycarbonate membrane filters available under the trade designation NUCLEOPORE from Whatman, Inc.)), a polyester membrane (e.g., comprising track-etched polyester, etc.), a sieve, glass wool, a frit, filter paper, foam, etc., and combinations thereof.

The term "filtrate" is generally used to describe the liquid remaining after the insoluble matter (or at least the relatively large insoluble matter) has been removed from the liquid composition. Because filtering includes a broad range of methods, the term "filtrate" can also be used to refer to the supernatant that results from allowing insoluble matter (or relatively large insoluble matter) in a mixture to settle.

FIG. 1 illustrates a sample preparation and delivery method 10 according to one embodiment of the present disclosure. As shown in FIG. 1, the sample preparation and delivery method 10 can begin with obtaining a source 12. A diluent 13 can be combined with all or a portion of the source 12 and agitated to form a liquid composition 14 comprising the source 12 dissolved, dispersed, suspended and/or emulsified in the diluent 13. As such, the liquid composition 14 is generally a mixture, and can be a solution, an emulsion, a dispersion, a suspension, or a combination thereof.

The source 12, when combined with the diluent 13, can include soluble matter and insoluble matter 15, such that some portions of the source 12 can be dissolved in the diluent 13, while other portions of the source 12 are suspended, dispersed or emulsified in the diluent 13. The liquid composition 14 is then filtered to form a filtrate 16 that comprises the analyte of interest (if present). The analyte of interest can be present in the soluble matter or the insoluble matter of the liquid composition 14. If the analyte of interest is present in the insoluble matter, and if a filter is employed to remove the analyte

of interest from debris or unwanted material, the filter is typically adapted to allow the analyte of interest (and perhaps other similarly-sized insoluble matter) to pass through the filter as filtrate 16, while restricting relatively large insoluble matter 17 from passing through the filter. Therefore, it should be understood that the filtrate 16 can also include some insoluble matter, and insoluble matter 17 is shown in FIG. 1 as being removed from the liquid composition 14 for simplicity and by way of example only. A sample 18 can then be formed from at least a portion of the filtrate 16, and the sample 18 can be delivered for incubation, analysis, etc. Samples 18 from a variety of sample preparation systems can be pooled together for one or more of enrichment, concentration, analysis, etc.

Throughout the present disclosure, one or more of the liquid composition 14, the filtrate 16, and any samples 18 thereof, may be described as including the analyte of interest. However, in some embodiments, the liquid composition 14 may not include the analyte of interest and may lead to a negative test result when the sample is analyzed. For example, if a sample is prepared from a food source, and the sample is then is tested for a bacterium, and the food source did not include that bacterium, the liquid composition 14 formed from that food, and any filtrates 16 and samples 18 thereof will also not include that bacterium of interest. Thus, even if one or more of the liquid composition 14, the filtrate 16, and any samples 18 taken therefrom are described as including the analyte of interest, it should be understood that this would only be the case if the analyte of interest was present.

The sample preparation and delivery method 10 illustrated in FIG. 1 and described above is illustrated and described by way of example only. However, one of ordinary skill in the art should understand that the sample preparation and delivery method of the present disclosure need not include every step illustrated in FIG. 1 and described above. For example, in some embodiments of the present disclosure, the sample preparation and delivery method does not include the filtering step, but rather a sample of the liquid composition 14 is delivered for incubation, analysis, etc.

The diluent 13 is generally a liquid and, in some embodiments, is a sterile liquid. In some embodiments, the diluent 13 can include a variety of additives, including, but not

limited to, surfactants, or other suitable additives that aid in dispersing, dissolving, suspending or emulsifying the source for subsequent analyte testing; rheological agents; antimicrobial neutralizers (e.g., that neutralize preservatives or other antimicrobial agents); enrichment or growth medium comprising nutrients (e.g., that promote selective growth of desired microorganism(s)) and/or growth inhibitors (e.g., that inhibit the growth of undesired microorganism(s)); pH buffering agents; enzymes; indicator molecules (e.g. pH or oxidation/reduction indicators); spore germinants; an agent to neutralize sanitizers (e.g., sodium thiosulfate neutralization of chlorine); an agent intended to promote bacterial resuscitation (e.g., sodium pyruvate); or a combination thereof. In some embodiments, the diluent 13 includes sterile water (e.g., sterile double-distilled water (ddH_2O)); one or more organic solvents to selectively dissolve, disperse, suspend, or emulsify the source; aqueous organic solvents, or a combination thereof. In some embodiments, the diluent 13 is a sterile buffered solution (e.g., Butterfield's Buffer, available from Edge Biological, Memphis TN). In some embodiments, the diluent 13 is a selective or semi-selective nutrient formulation, such that the diluent 13 may be used in the selective or semi-selective growth of the desired analyte(s) (e.g., bacteria). In such embodiments, the diluent 13 can be incubated with the source 12 for a period of time (e.g., at a specific temperature) to promote such growth of the desired analyte(s).

Examples of growth medium can include, but are not limited to, Tryptic Soy Broth (TSB), Buffered Peptone Water (BPW), Universal Pre-enrichment Broth (UPB), Listeria Enrichment Broth (LEB), Lactose Broth, Bolton broth, or other general, non-selective, or mildly selective media known to those of ordinary skill in the art. The growth medium can include nutrients that support the growth of more than one desired microorganism (i.e., analyte of interest).

Examples of growth inhibitors can include, but are not limited to, bile salts, sodium deoxycholate, sodium selenite, sodium thiosulfate, sodium nitrate, lithium chloride, potassium tellurite, sodium tetrathionate, sodium sulphacetamide, mandelic acid, selenite cysteine tetrathionate, sulphamethazine, brilliant green, malachite green oxalate, crystal violet, Tergitol 4, sulphadiazine, amikacin, aztreonam, naladixic acid, acriflavine, polymyxin B, novobiocin, alafosfalin, organic and mineral acids, bacteriophages,

dichloran rose bengal, chloramphenicol, chlortetracycline, certain concentrations of sodium chloride, sucrose and other solutes, and combinations thereof.

In some embodiments, the source 12 includes the diluent 13, such that the liquid composition 14 includes the source 12 and the diluent 13, but the diluent 13 was not added separately. For example, a food source that includes a substantial amount of water or other liquid can be mixed to form the liquid composition 14 comprising the source 12 and the diluent 13, without requiring the addition of a separate diluent 13. In some embodiments, the source 12 may be substantially dissolved in the diluent 13, such that the liquid composition 14 includes a minimal amount of insoluble matter 15, making the filtering step unnecessary.

FIG. 14 illustrates a sample preparation and delivery system 801 according to one embodiment of the present disclosure. The sample preparation and delivery system 801 includes a sample preparation system 800 and a sample delivery system 803 coupled to the sample preparation system 800, such that the sample delivery system 803 is in fluid communication with the sample preparation system 800. The sample preparation system 800 prepares a sample from a source 812, and the sample delivery system 803 is configured to remove the sample from the sample preparation system and/or deliver the sample for incubation, analysis (e.g., identification of the presence or absence of an analyte of interest), etc.

FIGS. 2-13 illustrate various embodiments of the sample preparation system according to the present disclosure, FIGS. 14-16 illustrate various embodiments of the sample preparation and delivery system according to the present disclosure (including various embodiments of the sample preparation system and the sample delivery system), and FIGS. 17A-21B illustrate various embodiments of the sample delivery system according to the present disclosure.

FIG. 2 illustrates a sample preparation system 100 according to one embodiment of the present disclosure. As shown in FIG. 2, the sample preparation system 100 includes a container 102, a liner 104, a lid 106, a collar 108, and a cover 109. In some embodiments, one or more of the components of the sample preparation system 100 are sterile or

sterilizable by sterilization and disinfection procedures such as steam, gamma radiation, ethylene oxide, hydrogen peroxide, peracetic acid, hydro-alcoholic solutions, bleach, and combinations thereof. A system having similar features to that of the sample preparation system 100 is described in PCT Publication No. WO 98/32539, US Patent No. 6,536,687 and US Patent No. 6,588,681, PCT Publication No. 2004/060574, PCT Publication No. 2004/060575, US Publication No. 2004/0164182, PCT Publication No. 2004/094072, PCT Publication No. WO 2007/079143, PCT Publication No. WO 2007/079188, each of which is incorporated herein in its entirety by reference.

Some embodiments of the present disclosure employ a plurality of sample preparation systems 100 to allow multiple sample preparation systems 100 be employed in parallel (or to have samples pooled) to expedite sample preparation and increase productivity/output. In such embodiments, the plurality of sample preparation systems 100 can be at least partially integrally formed, or they can be separately formed. For example, in some embodiments, multiple liners 104 can be used in one relatively large container 102 (e.g., with multiple reservoirs for the liners 104).

In some embodiments, as shown in FIG. 2, the container 102 is freestanding and/or self-supporting and includes a base 127 and a sidewall 129. The term "freestanding" is generally used to refer to an object that is capable of standing on its own without collapsing or distorting, and without being held by another object. The term "self-supporting" is generally used to refer to an object that does not collapse or deform under its own weight. For example, a bag is typically not "self-supporting" in that it does not maintain its shape, but rather collapses or distorts, under its own weight. A self-supporting object is not necessarily freestanding.

The container 102 can be formed of a variety of materials including, but not limited to, polymeric materials, metals (e.g., aluminum, stainless steel, etc.), ceramics, glasses, and combinations thereof. Examples of polymeric materials can include, but are not limited to, polyolefins (e.g., polyethylene, polypropylene, combinations thereof, etc.), polycarbonate, acrylics, polystyrene, high density polyethylene (HDPE), polypropylene, other suitable polymeric materials capable of forming a freestanding and/or self-supporting container, or a combination thereof. The container 102 can be translucent (or

even transparent), or opaque, and can be any suitable size, depending on the type, amount and size of source to be analyzed. For example, in some embodiments, the container 102 can have a capacity of 50 mL, 100 mL, 250 mL, or larger.

In some embodiments, as shown in FIG. 2, the sample preparation system 100 includes a liner 104, which is shaped and dimensioned to be received within the container 102. The liner 104 can be disposable (e.g., made for one-time use), to allow the container 102 to be reused without substantial risk of contamination and without extensive cleaning required between uses. As described in greater detail below and illustrated in FIG. 9, in some embodiments, the sample preparation system includes a liner without a container. When the liner is used without a container, it is not functioning as a "liner," per se, and can be referred to generally as a receptacle or container.

As shown in FIG. 2, the container 102 defines a first reservoir 120, and the liner 104 defines a second reservoir 122. The liner 104 is shaped and dimensioned to be received within the first reservoir 120 of the container 102. In some embodiments, a source 112 and a diluent 113 can be added to the first reservoir 120. In some embodiments, as shown in FIG. 2, the liner 104 is employed, and the source 112 and diluent 113 are positioned within the second reservoir 122, and the liner 104 is positioned within the first reservoir 120. Whether added to the first reservoir 120 or the second reservoir 122, the source 112 and the diluent 113 can be combined (and agitated) to form a liquid composition 114. In some embodiments, the liner 104 is freestanding, and the liner 104 or the container 102 can serve as a freestanding receptacle that can contain the liquid composition 114.

The source 112 can be added to the container 102 or the liner 104 first, followed by addition of the diluent 113, the diluent 113 can be added first, followed by the source 112, or the source 112 and the diluent 113 can be added simultaneously. Alternatively, the source 112 and diluent 113 can be combined prior to being added to the sample preparation system 100.

In some embodiments in which the diluent 113 is added to the container 102 or the liner 104 first, a pre-measured amount of the diluent 113 (e.g., a sterile liquid diluent) can

be sealed in the container 102 or the liner 104 with a removably coupled cover (e.g., a one-time use removable barrier film that is coupled to the container 102 or the liner 104 by one or more of an adhesive, heat sealing, ultrasonic welding, or any of the other coupling means described below), so that the cover can be removed just prior to adding the source 112. Alternatively, in some embodiments, a pre-measured amount of a dry powdered media (e.g., nutrient media for analyte(s) of interest and/or growth inhibitors for analyte(s) not of interest) can be sealed in the container 102 or the liner 104 with a removably coupled cover, or the desired media can be coated or adsorbed onto an inner surface of the container 102 or the liner 104. In such embodiments, the cover can be removed and a solvent (e.g., ddH_2O) can be added to form the diluent 113, either prior to or at the same time as the source 112 is added. Alternatively, if the source 112 includes enough of a liquid capable of dissolving the media, the source 112 can be added to the dry powdered media to form the liquid composition 114 that comprises the source 112 and a diluent 113 (e.g., the media dissolved in a solvent provided by the source 112).

In some embodiments, the container 102 and/or the liner 104 (if the liner 104 is employed) can be compartmentalized to include more than one first reservoir 120 and/or more than one second reservoir 122, respectively. Multiple reservoirs 120/122 can be used, for example, for multi-stage enrichment, for parallel or simultaneous enrichment of different microorganisms, or a combination thereof. By way of example, the liner 104 can include two second reservoirs 122 (referred to in this example as reservoir A and B for simplicity). A first enrichment media can be positioned in reservoir A for primary enrichment of a microorganism, and a second enrichment media can be positioned in reservoir B for secondary enrichment of the same microorganism. Reservoirs A and B can be positioned, for example, such that both are accessible for positioning of the media but that the source 112 can be added to one without being added to the other. After the liquid composition 114 has been formed and primary enrichment has occurred in reservoir A, the liquid composition 114, or a portion thereof, can be moved to reservoir B for secondary enrichment. The liquid composition 114 can be moved to reservoir B in a variety of ways, including agitation of the sample preparation system 100, breaking of a frangible barrier between the two reservoirs A and B, etc.

In some embodiments, one container 102 can be employed with a plurality of liners 104, such that one container 102 can include one or more first reservoirs 120, and/or one or more liners 104 (each including one or more second reservoirs 122) can be positioned in the container 102. Other configurations are possible, and one of ordinary skill in the art will recognize the different permutations possible for achieving multiple compartments. No matter what the configuration, the multiple reservoirs or compartments can be positioned side-by-side, vertically, concentrically, or a combination thereof.

The liner 104 can be formed of a variety of materials, including a variety of polymeric materials, including, but not limited to, a polyolefin, including, but not limited to polypropylene (e.g., low density polyethylene (LDPE)), polyethylene, and poly(methylpentene), polyamide (e.g., NYLON®), or a combination thereof. In some embodiments, the liner 104 is formed from a molding process, such as a thermoforming process. The liner 104 can be translucent (or even transparent), or opaque.

In some embodiments, as illustrated in FIG. 2, the liner 104 is freestanding and/or self-supporting, either of which can allow the source 112 and diluent 113 to be loaded into the liner 104 prior to positioning the liner 104 within the container 102, without the liner 104 collapsing or distorting. In addition, a freestanding and/or self-supporting liner 104 can aid in weighing, source 112 and/or diluent 113 addition, transporting, handling, and/or sample removal.

In some embodiments, the liner 104 is self-supporting and/or freestanding while also being deformable. The term "deformable" is used to refer to a structure that can be altered from its original shape or state by pressure (e.g., positive or negative) or stress. In embodiments employing a deformable liner 104, pressure can be applied to the liner 104 to reduce its size from its original (i.e., unstressed) dimensions. Such pressure can be used to promote removal of the liquid composition 114 (or a filtrate thereof) from the liner 104. In such embodiments, the liner 104 can serve as a deformable self-supporting receptacle that can contain the liquid composition 114. In some embodiments, the deformable self-supporting receptacle is also freestanding.

In some embodiments, as shown in FIG. 2, the container 102 includes an aperture 124 formed in its base 127, through which a user can access the liner 104 to apply pressure to the liner 104 to cause it to deform. Such pressure can be applied directly by hand, or by an additional device, and could be a manual or automated process. The aperture 124 can be shaped and dimensioned according to the desired application of use. In some embodiments, base 127 of the container 102 is nothing more than the bottom of the sidewall 129, or a slight inward projection of the sidewall 129, such that the liner 104 is easily accessible at the bottom of the container 102. Said another way, in some embodiments, the aperture 124 of the container 102 defines a majority of the bottom of the container 102 (e.g., a majority of the cross-sectional area of the container 102), and the base 127 is only a small portion of the container 102 surrounding the aperture 124. In embodiments that do not employ the liner 104, the container 102 need not include the aperture 124.

In some embodiments, the liner 104 includes a relatively rigid base 126 and a relatively thin and deformable sidewall 128, such that when pressure is applied to the base 126 in a direction parallel to the longitudinal axis of the liner 104 (e.g., via the aperture 124 in the container 102), the liner 104 deforms in the longitudinal direction (e.g., by virtue of the sidewall 128 collapsing rather than the base 126). Alternatively, or in addition, the base 126 can be thicker than the sidewall 128. By way of example only, in some embodiments, the thickness of the sidewall 128 is at least 50 μm, in some embodiments, at least 100 μm, in some embodiments, at least 150 μm, and in some embodiments, at least 200 μm. In some embodiments, the thickness of the base 126 is at least 225 μm, in some embodiments, 275 μm, in some embodiments, at least 300 μm, and in some embodiments, at least 350 μm.

The liner 104 can further include one or more of baffles, pleats, corrugations, seams, joints, gussets, weakened portions (e.g., annular weakened portions), or a combination thereof, which may be incorporated to assist in controlling the deformability of the liner 104, and/or can further reduce the internal volume of liner 104. In some embodiments, as described in greater detail below and illustrated in FIG. 9, the liner 104 includes an accordion-type configuration. In some embodiments, liner 104 does not

include any grooves on its internal surface, particularly, at the internal junction between the base 126 and the sidewall 128.

In some embodiments, the liner 104 is deliberately deformed to impart a disruption to the surface geometry of the liner 104. Such a disrupted surface geometry can assist in the breakup of the source 112 during agitation. For example, in some embodiments, an obstruction (e.g., a relatively rigid material) can be positioned between the sidewall 128 of the liner 104 and the container 102 to create a different surface geometry in the sidewall 128 of the liner 104.

As shown in FIG. 2, the container 102 can include indicia 130 to indicate the level (i.e., volume) of contents within the container 102. The indicia 130 can be used to achieve a desired weight ratio of the liquid composition 114, for example, where the weight ratio of the source 112 to the diluent 113 ranges from 1:100 to 1:1. One example of suitable indicia is described in US Patent No. 6,588,681. Alternatively, or in addition, the liner 104 can include indicia. To enable the use of the indicia 130 on the container 102 and/or the liner 104, the container 102 and/or the liner 104 can be translucent, or even transparent to afford seeing the liquid composition 114 through the sidewall 129 of the container 102 and/or the sidewall 128 of the liner 104. The sidewalls 128 and 129 may also bear other types of markings, such as trademarks, brand names, and the like. The indicia 130 can also be provided on a film that is dimensioned to be received within the container 102 or the liner 104 and which can be formed of a material that includes sufficient internal stresses to cause the film to press outwardly (i.e., radially) against an inner surface of the container 102 or the liner 104.

In the embodiment illustrated in FIG. 2, the lid 106 is removably coupled to the liner 104, and the collar 108 is employed to further secure the lid 106 to the container 102. For example, in FIG. 2, the container 102 includes threads 131 at the upper end of the outer surface of the sidewall 129, which are shaped and dimensioned for the collar 108 (having internal threads 133 capable of engaging with the threads 131 on the container 102) to be screwed onto the upper end of the container 102. As an alternative to using the collar 108 for securing the lid 106 to the container 102, other coupling means can be employed including clamping and/or any of the other coupling means described below. In

some embodiments, the liner 104 is not employed, and the lid 106 can be coupled directly to the container 102. In such embodiments, the collar 108 need not be employed. Thus, the lid 106 can form a seal (e.g., a hermetic seal) with either the container 102 or the liner 104. In some embodiments, the lid 106 and the container 102 (or the lid 106 and the liner 104) are integrally formed or permanently coupled together.

A variety of coupling means can be employed either between the lid 106 and the liner 104, the lid 106 and the container 102, and/or the collar 108 and the container 102 to allow the respective components to be removably coupled to one another, including, but not limited to, gravity (e.g., one component can be set atop another component, or a mating portion thereof), screw threads, press-fit engagement (also sometimes referred to as "friction-fit engagement" or "interference-fit engagement"), snap-fit engagement, magnets, adhesives, heat sealing, other suitable removable coupling means, and combinations thereof. In some embodiments, the sample preparation system 100 need not be reopened after the source 112 and the diluent 113 are added, such that the container 102, the liner 104, the lid 106 and the collar 108 need not be removably coupled to one another, but rather can be permanently or semi-permanently coupled to one another. Such permanent or semi-permanent coupling means can include, but are not limited to, adhesives, stitches, staples, screws, nails, rivets, brads, crimps, welding (e.g., sonic (e.g., ultrasonic) welding), any thermal bonding technique (e.g., heat and/or pressure applied to one or both of the components to be coupled), snap-fit engagement, press-fit engagement, heat sealing, other suitable permanent or semi-permanent coupling means, and combinations thereof. One of ordinary skill in the art will recognize that some of the permanent or semi-permanent coupling means can also be adapted to be removable, and vice versa, and are categorized in this way by way of example only.

As shown in FIGS. 2 and 3, the lid 106 further includes a port 132, which can be coupled to a filter 134, a cylindrical portion 136 that is dimensioned to be received within the liner 104, and a generally conical (e.g., frusto-conical) portion 138 that extends from the cylindrical portion 136 to the port 132. At the junction between the cylindrical portion 136 and the conical portion 138, the lid 106 further includes a lip 140 that extends radially outwardly from the cylindrical portion 136 and the conical portion 138.

In some embodiments, the filter 134 is coupled directly to the lid 106. In some embodiments, as shown in FIGS. 2-3, the filter 134 can be supported by a frame 135 and coupled to the lid 106 via the frame 135. The frame 135 can form a portion of the filter 134, the frame 135 can be a part of the lid 106, or the frame 135 can be a separate element that is coupled to both the filter 134 and the lid 106. The frame 135 can be formed of a variety of materials, including, but not limited to, a variety of polymers, metals, ceramics, glasses, and combinations thereof. In the embodiment illustrated in FIGS. 2-3, the filter 134 is formed of a metal mesh, and the frame 135 is formed of a polymer that is bonded to the metal filter 134. The frame 135 is coupled to the lid 106, as described in greater detail below.

The filter 134 and the frame 135 of the embodiment illustrated in FIGS. 2 and 3 are shaped and dimensioned so as to extend below the bottom end of the lid 106, such that when the sample preparation system 100 is assembled, the filter 134 and the frame 135 extend into the second reservoir 122 of the liner 104 (or the first reservoir 120 of the container 102). However, the filter 134 and frame 135 can take on a variety of shapes and sizes. In some embodiments, for example, the frame 135 can include a rigid upper portion (e.g., that is coupled to the lid 106) and a rigid lower portion, and the filter 134 can be coupled therebetween, and the filter 134 can be collapsible. Such an embodiment is described in greater detail below and illustrated in FIG. 9.

The cylindrical portion 136 of the lid 106 includes a plurality of circumferential outwardly-projecting protrusions 142 to allow the cylindrical portion 136 to be snap-fit or press-fit to the inner surface of the liner 104. In some embodiments, the inner surface of the liner 104 can include inwardly-projecting protrusions that are used either in lieu of the outwardly-projecting protrusions 142, or in addition to the outwardly-projecting protrusions 142 (e.g., to form a mating relationship therewith).

The liner 104 can include a lip 144 that projects radially outwardly from the sidewall 128 of the liner 104, and which can form an abutting relationship with an upper surface 146 of the container 102 and the lip 140 of the lid 106, such that when the sample preparation system 100 is assembled, the lip 144 of the liner 104 is positioned between the lip 140 of the lid 106 and the upper surface 146 of the container 102, and a seal (e.g., a

hermetic seal) is formed. As shown in FIG. 2, the collar 108 includes an inwardly-projecting lip 156, such that when the collar 108 is coupled to the container 102, the lip 156 of the collar 108 presses the lip 140 of the lid 106 into contact with the lip 144 of the liner 104, which is pressed into contact with the upper surface 146 of the container 102 (e.g., to form a higher integrity seal). The above-described means for assembling the sample preparation system 100 and for forming a seal between the components of the sample preparation system 100 are described and illustrated by way of example only. One of ordinary skill in the art will understand, however, that a variety of other mechanisms could be employed to assemble the components of the sample preparation system 100 and to form a seal (e.g., a liquid-tight seal, a hermetic seal, or a combination thereof), such that the sample preparation system 100 is inhibited from leaking under normal operating conditions.

While the lid 106 of the embodiment illustrated in FIGS. 2 and 3 is illustrated as having a generally conical or frusto-conical shape. It should be understood that the lid 106 could have a variety of other shapes, including, but not limited to, a cylindrical shape, a tubular shape having a rectangular or square cross-sectional area, or other shapes suitable to being coupled to the other components of the sample preparation system 100. Similarly, the container 102, the liner 104, and the collar 108 could have a variety of other shapes than the substantially cylindrical shapes illustrated in FIG. 2. In addition, the lid 106 can be dimensioned to accommodate the other components of the sample preparation system 100.

The lid 106 can be formed of a variety of materials, including the materials listed above with respect to the container 102. The lid 106 can be translucent (or even transparent), or opaque, depending on the application of use.

The collar 108 can be formed of a variety of materials, including, but not limited to a variety of polymeric materials, metal materials, and combinations thereof. For example, the collar 108 can be formed of a molded plastic component, or a machined metal (such as aluminum) component. In some embodiments, the collar 108 is formed of a molded plastic component comprising glass fiber reinforced polypropylene.

As shown in FIG. 2, the port 132 of the lid 106 is generally cylindrical and tubular in shape, such that the port 132 defines a portion 152 of the inner surface 153 of the lid 106 and an opening 154 in the lid 106. The lid 106 is hollow and is in fluid communication with the second reservoir 122 when the sample preparation system 100 is assembled. The port 132 does not need to be cylindrical and can instead take on any shaped necessary for a given application. In the embodiment illustrated in FIGS. 2 and 3, the filter 134 is coupled to the port 132 (i.e., via the frame 135) such that the filter 134 is in fluid communication with the lid opening 154, as well as the second reservoir 122.

In the embodiment shown in FIG. 2, the cover 109 is shaped and dimensioned to receive at least a portion of the port 132. As a result, the cover 109 can be coupled to the port 132 of the lid 106 to close the opening 154 in the lid 106 and to seal (e.g., hermetically seal) the sample preparation system 100 from the environment. The cover 109 can be coupled to the lid 106 using any of the above-described coupling means. The cover 109 can be integrally formed with the lid 106 (e.g., a flip-top snap-on cover, as described in greater detail below and illustrated in FIG. 13), or the cover 109 can be separate from the lid 106 (e.g., a screw-on cover, as described in greater detail below and illustrated in FIGS. 9-12). The cover 109 can be formed of a variety of materials, including the materials listed above with respect to the container 102 or the collar 108.

In some embodiments, the lid 106 includes a frangible or penetrable barrier or a removable film separating at least a portion of the interior of the lid 106 from the environment, such that the barrier can be punctured or pierced or the film removed to access the interior of the lid 106. In such embodiments, the cover 109 need not be employed.

As shown in FIG. 3, the inner surface 153 of the lid 106 can include a variety of inner circumferential edges to which other components (e.g., additional or alternative filters, the concept of which is illustrated in FIGS. 5-6 and described below) can be coupled. The inner circumferential edges can have any orientation desired, depending on what other components are desired to be coupled to the edges. In some embodiments, the inner circumferential edges are oriented substantially orthogonally to the central longitudinal axis of the lid 106, such that the edges are substantially horizontal in FIG. 3.

In addition, the lid 106 can include a variety of inwardly-extending members to which other components (e.g., filters) can be coupled. For example, as shown in FIG. 3, the filter 134 is supported by the frame 135, and the lid 106 includes inwardly-extending members 155 to which the frame 135 can be coupled via a variety of coupling means, including, but not limited to, any of the coupling means described above. The inwardly-extending members 155 can be integrally formed with the lid 106.

The filter 134 can be of any geometrical shape to sufficiently filter the liquid composition 114. In some embodiments, the filter 134 is deformable and/or collapsible (i.e., such that the filter 134 folds under its own weight). In some embodiments, the filter 134 is rigid and retains its shape (i.e., does not fold under its own weight). The size and number of filters 134 used in a sample preparation system 100, and porosity thereof, may vary, depending on the desired analyte(s) and the insoluble matter in the source 112.

By way of example only, in some embodiments, the liquid composition 114 comprises food, the desired analyte is bacteria, and the insoluble matter is food particles or debris. In such embodiments, for example, the filter 134 can be selected to retain and/or separate the food particles, while allowing the bacteria of interest (if present) to pass through the filter 134 for subsequent analysis. By way of further example, in some embodiments, the liquid composition 114 comprises a lysed bacterial cell culture, the desired analyte is one or more of DNA, RNA, a protein, or a metabolite, and the insoluble matter is cellular debris. In such embodiments, for example, the filter 134 can be selected or treated (e.g., derivatized with biomolecule-binding agents, such as antibodies) to retain and/or separate the cellular debris, while allowing the desired DNA, RNA, protein, and/or metabolite to pass through the filter 134 for subsequent analysis. Alternatively, for example, the filter 134 can be selected or treated to retain the desired DNA, RNA, protein and/or metabolite, while allowing the cellular debris to pass through the filter 134.

The filter 134 can have a variety of pore sizes sufficient for retaining particles from the liquid composition 114, while allowing the desired analyte(s) (if present) in the liquid composition 114 to pass through the filter 134 for extraction and/or sampling. Alternatively, the filter 134 can be sized, charged and/or functionalized to retain the desired analyte(s), while allowing undesired material to pass through the filter 134. In

such embodiments, the sample can include at least a portion of the filter 134, which can be further processed (e.g., enriched, concentrated, analyzed, etc.).

In some embodiments, the filter 134 has an average pore or mesh size of at least 2 μm, in some embodiments, at least 5 μm, in some embodiments, at least 40 μm, in some embodiments, at least 80 μm, and in some embodiments, at least 120 μm. In some embodiments, the filter 134 has an average pore or mesh size of at most 2000 μm, in some embodiments, at most 1000 μm, in some embodiments, at most 500 μm, in some embodiments, at most 200 μm, in some embodiments, at most 50 μm, in some embodiments, at most 10 μm and in some embodiments, at most 1 μm (e.g., if it is desired to restrict bacteria from passing through the filter 134).

In the embodiment illustrated in FIGS. 2 and 3, the filter 134 is located in the lid 106, generally in line with the central longitudinal axis of the lid 106. However, in some embodiments, the filter 134 is positioned in an "off-axis" position of the lid 106. For example, an aperture 158 is shown in dashed lines in FIG. 2 to represent a possible "off-axis" position for the filter 134 in the lid 106. An alternative or an additional port can be positioned at the location of the aperture 158 and coupled thereto. The filter 134 can be permanently or removably coupled at one or both locations.

In some embodiments, particularly embodiments that do not employ the liner 104, the filter 134 can alternatively, or additionally, access the interior of the sample preparation system 100 (i.e., the first reservoir 120 of the container 102) via an aperture 160 in the sidewall 129 of the container 102 or the aperture 124 in the base 127 of the container 102 (or an aperture formed in a different location of the base 127 of the container 102). In such embodiments, the filter 134 can be permanently or removably coupled to the sidewall 129 or the base 127 of the container 102. An alternative or additional port can be positioned at the location of the apertures 160 and 124 and coupled thereto. In some embodiments, the sample preparation system 100 can include more than one port, such as the port 132 in the lid 106, an additional port at the location of the aperture 158 in the lid 106, an additional port at the location of the aperture 160 in sidewall 129 of the container 102, and/or an additional port at the location of the aperture

124 in the base 127 of the container 102. The cover 109 or a similar closure device can be used to seal any of the ports at any location on the sample preparation system 100.

Because of the different locations possible for the filter 134, the filter 134 can be shaped and dimensioned to accommodate its position in the sample preparation system 100 and the particular application of use. In any of the possible locations for the filter 134, the filter 134 can be positioned wholly above or wholly below the level 165 of the liquid composition 114, or the filter 134 can be positioned partially above and partially below the level 165 of the liquid composition 114, depending on the type of filtering desired, and how the filter 134 is intended to filter the liquid composition 114. For example, in the embodiment illustrated in FIG. 2, the filter 134 is coupled to the port 132 and, depending on how high the level 165 of the liquid composition 114 is, would typically extend from the port 132 into the interior of the sample preparation system 100, such that the filter 134 is positioned partially above and partially below the level 165 of the liquid composition 114.

The filter 134 is in fluid communication with the interior of the liner 104 and the liquid composition 114 and acts to filter the liquid composition 114 to form a filtrate 116. The filtrate 116 is disposed within the volume of the filter 134 and can be extracted and/or sampled from the adjacent port 132. In embodiments employing filters 134 at multiple locations, the filtrate 116 can be sampled from any of the ports or apertures described above.

The filter 134 can be formed from a variety of materials, including, but not limited to one or more of nylon, fluorinated polymers (e.g., polytetrafluoroethylene (PTFE)), cellulosics (e.g., modified celluloses such as cellulose acetate and nitrocellulose), fiberglass, papers, and combinations thereof. In some embodiments, the filter 134 can be formed of a woven web, a nonwoven web, a molded structure, a foam, fabric, a fibrous web, and combinations thereof. The surface area of the filter 134 can be increased by pleating the filter 134, or by other similar techniques. The thickness of the filter 134 can be controlled by calendering or felting processes.

In some embodiments (no matter which location the filter 134 is in), the filter 134 can be used as a retainer or holder of the source 112. An example of this concept is illustrated in FIG. 4 and described below.

As mentioned above, the liner 104 can be disposable. In addition, in some embodiments, one or more of the lid 106, the cover 109 and the filter 134 can also be disposable. For example, in some embodiments, the lid 106 can be coupled to the liner 104, and the cover 109 and the filter 134 can be coupled to the lid 106. The liner 104, the lid 106, the filter 134 and the cover 109 can form a disposable portion of the sample preparation system 100 that can be used without contaminating the container 102 or the collar 108. The disposable portion can be removed from the container 102 and disposed. The container 102 and collar 108 can then be reused with a new liner 104, lid 106, filter 134 and cover 109.

FIG. 4 illustrates a sample preparation system 200 according to another embodiment of the present disclosure, wherein like numerals represent like elements. The sample preparation system 200 shares many of the same elements and features described above with reference to the illustrated embodiment of FIGS. 2-3. Accordingly, elements and features corresponding to elements and features in the illustrated embodiment of FIGS. 2-3 are provided with the same reference numerals in the 200 series. Reference is made to the description above accompanying FIGS. 2-3 for a more complete description of the features and elements (and alternatives to such features and elements) of the embodiment illustrated in FIG. 4.

The sample preparation system 200 includes a container 202 and a lid 206. The sample preparation system 200 does not include a liner, and the lid 206 is coupled directly to the container 202. The sample preparation system 200 further includes a filter 234 which is fluidly coupled to an aperture 260 formed in a sidewall 229 of the container 202. Unlike the filter 134 of the sample preparation system 100, the filter 234 functions as a retainer or holder for the source 212.

The filter 234 can be permanently coupled to the container 202 and the source 212 can be added to the filter 234, or the filter 234 can be removably coupled to the container

202, and the source 212 can be added to the filter 234 prior to or after the filter 234 is coupled to the container 202. In some embodiments, the filter 234 can be free-floating within the first reservoir 220 of the container 202, such that the filter 234 contains the source 212 and the diluent 213 is able to flow in and out of the interior of the filter 234 to mix with the source 212.

The source 212 is positioned within the filter 234, and the filter 234 is positioned at least partially below the level of the diluent 213 in the container 202 and is in fluid communication with the interior of the container 202, such that the source 212 can be combined with the diluent 213 to form a liquid composition 214 within the filter 234. The liquid composition 214 positioned within the filter 234 includes the analyte(s) of interest (if present) in the diluent 213, as well as any other soluble or insoluble matter from the source 212. During agitation, the source 212 and the diluent 213 can be mixed to allow the source 212 to be dissolved, dispersed, suspended and/or emulsified in the diluent 213. The pore size of the filter 234 will be adapted such that the diluent 213 and any analyte(s) of interest (if present) in the diluent 213 are free to flow in and out of the filter 234, such that the resulting filtrate 216 is positioned outside of the filter 234 and within the reservoir 220 of the container 202, and includes the diluent 213 and any present analyte(s) of interest.

The filtrate 216 can be sampled from any of a variety of ports or apertures, including the port 232 in the lid 206, the aperture 258 in the lid 206, an additional aperture in the sidewall 229 of the container 202, and/or an aperture 224 in the base 227 of the container 202. In addition, instead of being coupled to the sample preparation system 200 via the aperture 260, the filter 234 can instead be coupled to the sample preparation system 200 via any of a variety of ports or apertures, including the port 232 in the lid 206, the aperture 258 in the lid 206, and/or an aperture 224 in the base 227 of the container 202. In some embodiments, as shown in FIG. 4, one or more of the ports can include an additional filter 234' that functions in the same way as the filter 134 of the sample preparation system 100. In such embodiments, the filtrate 216 can be further filtered by the filter 234', and the resulting filtrate 216' is disposed within the filter 234' and can be extracted and/or sampled from the adjacent port (i.e., port 232 in FIG. 4).

The sample preparation system 200 can further include a liner, in which case the diluent 213 and resulting filtrate 216 can be positioned within the liner, provided that sufficient sealing is provided between the liner and the container 202 at the location of the aperture 260.

FIGS. 5-6 illustrate a sample preparation system 300 according to another embodiment of the present disclosure, wherein like numerals represent like elements. The sample preparation system 300 shares many of the same elements and features described above with reference to the illustrated embodiment of FIGS. 2-3. Accordingly, elements and features corresponding to elements and features in the illustrated embodiment of FIGS. 2-3 are provided with the same reference numerals in the 300 series. Reference is made to the description above accompanying FIGS. 2-3 for a more complete description of the features and elements (and alternatives to such features and elements) of the embodiment illustrated in FIGS. 5-6.

FIGS. 5-6 show only the lid 306 of the sample preparation system 300. The other components of the sample preparation system 300 can be assumed to include any of the other respective components of the sample preparation systems described above and illustrated in FIGS. 2-4, and thus for simplicity, are not shown in FIGS. 5-6.

The lid 306 is substantially similar to the lid 106 described above and illustrated in FIGS. 2-3, except that the lid 306 includes a filter 334 that is substantially planar and coupled to the inner surface 353 of the lid 306. The inner surface 353 of the lid 306 includes an upper inner circumferential edge 370 and a lower inner circumferential edge 368. As shown in FIG. 5, the upper inner circumferential edge 370 includes a downwardly facing surface that extends from an outer circumference 371 to an inner circumference 373. Similarly, the lower inner circumferential edge 368 includes a downwardly facing surface that extends from an outer circumference 376 to an inner circumference 378. The outer periphery of the filter 334 is coupled to the upper inner circumferential edge 370 of the inner surface 353. In addition, the filter 334 is in contact with retaining walls 372. The retaining walls 372 extend downwardly from the inner surface 353 of the lid 106 to retain the outer periphery of the filter 334.

The filter 334 can be coupled to the lid 306 using the same coupling means described above with respect to the lid 106. The filter 334 can be permanently or removably coupled to the lid 306. The degree of coupling between the filter 334 and the lid 306 may vary depending on a number of factors including, but not limited to, the filter 334 material, the lid 306 material, the size and texture of the coupled surface area, and the type of coupling means used. For example, if the filter 334 includes frayed edges, a wider and/or knurled coupling surface area may be used (e.g., the upper inner circumferential edge 370 can be knurled). Such a wider and/or knurled ultrasonic weld may capture frayed edges of the filter 334. To minimize the amount of fraying, the filter 334 can be cut using a laser, which can fuse the edges of the filter 334. Because the resulting laser-cut filter 334 would include a minimum amount of fraying, if any, a narrower coupling area can be used. In some embodiments, the coupling area extends completely around the outer periphery of the filter 334. In some embodiments, the coupling area can have an average width (i.e., a dimension within the same plane and substantially perpendicular to the outer periphery of the filter 334) of up to 5.0 mm, and in some embodiments, ranging from 1.0 mm to 3.0 mm. Alternatively, the filter 334 can be integrally formed with the lid 306, for example, by a molding process.

The filter 334 can be formed of the same material as the lid 306 or a different material. The filter 334 may be flexible, or semi-rigid. In some embodiments, the filter 334 is formed from a nylon nonwoven or woven fabric, while the lid 306 is an injection molded part formed of a polymer, such as polypropylene. In such embodiments, the nylon filter 334 can be coupled to the lid 306 via an ultrasonic welding technique. During ultrasonic welding, at least a portion of the upper inner circumferential edge 370 can melt to mechanically bond the filter 334. Since nylon has a higher melting temperature than polypropylene, the nylon filter 334 can maintain its structural integrity during the ultrasonic welding process. In such embodiments, at least a portion of the upper inner circumferential edge 370 can enter into a portion of filter 334, thereby encapsulating a portion of the filter 334.

The filter 334 can have dimensions and shapes that vary for a given application. The filter 334 can have any desired shape including, but not limited to, a circular shape, a square shape, a rectangular shape, a triangular shape, a polygonal shape, a star shape,

other suitable shapes, and combinations thereof. In the embodiment illustrated in FIGS. 5 and 6, the filter 334 has a substantially circular shape.

The dimensions of the filter 334 may vary depending on the size of the lid 306. In some embodiments, the filter 334 has a largest dimension (i.e., length, width, or diameter) ranging from 15 mm to 100 mm, although the filter 334 may have smaller or larger dimensions. For example, in some embodiments, the filter 334 can have a circular shape and a diameter of 56 mm.

With continued reference to FIGS. 5 and 6, the retaining walls 372 can be integrally formed with the lid 306. In some embodiments, as shown in FIG. 5, the lid 306 comprises two or more retaining walls 372, wherein (i) each retaining wall 372 has a circumferential length greater than its thickness, (ii) each retaining wall 372 is positioned along an outer periphery of the filter 334, and (iii) the total circumferential length of the two or more retaining walls 372 is less than the total circumferential length of the outer periphery of the filter 334.

As shown in FIG. 5, the lid 306 includes four retaining walls 372 equally spaced from one another along outer circumference 371 of the upper inner circumferential edge 370. In some embodiments, each retaining wall 372 has a thickness ranging from 800 μm to 1200 μm, a length (i.e., in this exemplary embodiment, an arc length) extending a distance ranging from 1.0 mm to 22.0 mm along outer circumference 371, and a height ranging from 1.0 mm to 5.0 mm. In some embodiments, each retaining wall 372 has a segmented configuration so as to not inhibit (or to minimize the effect on) fluid flow around the retaining wall 372.

The lid 306 includes an opening 354 and inwardly-extending members 355. The inwardly-extending members 355 can be used to couple an additional filter (not shown) to the lid 306 in the same way that the filter 134 is coupled to the lid 106 in FIGS. 2 and 3. In such embodiments, the filter 334 is located below the additional filter, and the additional filter can have a length dimension less than the distance from the top the lid 306 to the filter 334.

In some embodiments, as shown in FIGS. 5 and 6, the filter 334 has a total surface area that is greater than a smallest cross-sectional area of the lid 306. In the lid 306, the smallest cross-sectional area is the cross-sectional area of lid opening 354. In some embodiments, more than one filter is coupled to the lid 306 in a similar manner as the filter 334. For example, in some embodiments, the filter 334 or an additional filter (not shown) can be coupled to the lower inner circumferential edge 368. That is, one or more filters 334 can be coupled to the lid 306 and positioned anywhere along the inner surface 353 of the lid 306. In embodiments employing more than one filter 334, the filters 334 can be similar to one another or different from one another. That is, the filters 334 can be formed of the same or different materials, and the filters 334 can have the same or sequentially smaller pore sizes.

As an example, a first filter 334 can be coupled to the upper inner circumferential edge 370 and can have a diameter of 56 mm, an element pore size of 80 μm, and can be at least partially surrounded by one or more retaining walls 372, while a second filter 334 can be coupled to the lower inner circumferential edge 368 and can have a diameter of 96 mm, an element pore size of 200 μm, and can be at least partially surrounded by the inner surface 353 of the lid 306.

Any of the above-described filters 134, 234 and 334 can be used in combination with one another in one sample preparation system. For example, as described above, the filter 134 can be used in combination with the filter 234 and/or the filter 334, to provide a series of filters for different applications, and/or for the removal of successively smaller particulates from the liquid composition.

Alternatively, or in addition, more than one of each type of filter 134, 234 or 334 can be employed (and in some embodiments, can be nested) for the removal of successively smaller particulates from the liquid composition. For example, the filters may be arranged where a coarse filter acts as a pre-filter with a larger pore size relative to subsequent filters, which have successively smaller pore sizes for the collection of a filtrate. The filters may be arranged for use of the sample preparation system in an upright position, and/or the filters may be arranged for use of the sample preparation system when it is tipped or inverted.

FIG. 7 illustrates a sample preparation system 400 according to another embodiment of the present disclosure, wherein like numerals represent like elements. The sample preparation system 400 shares many of the same elements and features described above with reference to the illustrated embodiments of FIGS. 2-3 and 5-6. Accordingly, elements and features corresponding to elements and features in the illustrated embodiment of FIGS. 2-3 and 5-6 are provided with the same reference numerals in the 400 series. Reference is made to the description above accompanying FIGS. 2-3 and 5-6 for a more complete description of the features and elements (and alternatives to such features and elements) of the embodiment illustrated in FIG. 7.

The sample preparation system 400 includes a container 402 having a first reservoir 420, a liner 404 having a second reservoir 422 and dimensioned to be received in the first reservoir 420 of the container 402, a lid 406, a collar 408, and a plunger 437. The lid 406 is similar to that of lids 106, 206 and 306 described above and illustrated in FIGS. 2-6, but further includes two upwardly-extending projections 439, which allow the sample preparation system 400 to be coupled to other devices, or provide coupling means for a cover (not shown). The lid 406 includes a port 432, which includes a plurality of ridges 441 that can provide alternative or additional coupling means for coupling the sample preparation system 400 to a cover or other devices. The lid 406 further includes a filter 434 that is substantially similar to the filter 334 shown in FIGS. 5-6 and described above.

In some embodiments, as shown in FIG. 7, the plunger 437 is configured to apply positive pressure to the exterior of the liner 404 when the plunger 437 is moved in a first direction D_1 toward the top of the container 402. As shown in FIG. 7, when the plunger 437 is used to apply pressure to the exterior of the liner 404, the liner 404 is compressed, the volume in the second reservoir 422 is reduced, and a liquid composition 414 (including a source 412 and a diluent 413) is forced through the filter 434 to form a filtrate 416 that collects inside the lid 406 (e.g., when the sample preparation system 400 is inverted as shown in FIG. 7). The filtrate 416 can then be moved out of the sample preparation system 400 via the port 432.

In some embodiments, the plunger 437 is configured to apply negative pressure to the interior of the liner 404. For example, in some embodiments, the plunger 437 is

coupled to the liner 404, such that when the plunger 437 is moved in a second direction D_2 opposite the first direction D_1, toward the bottom of the container 402, the liner 404 expands, which creates a reduced pressure in its interior (i.e., the second reservoir 422), and which establishes a pressure differential between the second reservoir 422 and the exterior of the sample preparation system 400. This pressure differential can cause fluid to move into the second reservoir 422 via the port 432, for example. As a result of the plunger 437 cooperating with the exterior of the liner 404 to create a pressure differential, the plunger 437 can be used without contacting the liquid composition 414 and can be reused without risk of contamination.

In some embodiments, as shown in FIG. 7, the plunger 437 can include a handle 443 that is dimensioned to be received in an aperture 424 of the base 427 of the container 402. In some embodiments, the handle 443 of the plunger 437 can be sized more closely to the size of the aperture 424, and/or a sealing means (e.g., an o-ring) can be positioned between the handle 443 and the aperture 424 to form a seal. In the embodiment illustrated in FIG. 7, the handle 443 has a smaller diameter than the portion of the plunger 437 that contacts the liner 404 (e.g., a base 426 of the liner 404). The portion of the plunger 437 that contacts the liner 404 is dimensioned to be received in the first reservoir 420 of the container 402. However, in some embodiments, the plunger 437 has a uniform cross-section or a gradually decreasing cross-section (e.g., in the second direction D_2), and the aperture 424 in the container 402 is sized accordingly. The plunger 437 shown in FIG. 7 is shown by way of example only, but one of ordinary skill in the art should understand that a variety of shapes and sizes of plungers can be used without departing from the spirit and scope of the present disclosure.

The plunger 437 can be formed of a variety of materials, including the materials listed above with respect to the container 102, and the plunger 437 can be solid or hollow. The plunger 437 can be translucent (or even transparent), or opaque, depending on the application of use.

FIG. 8 illustrates a sample preparation system 500 according to another embodiment of the present disclosure, wherein like numerals represent like elements. The sample preparation system 500 shares many of the same elements and features described

above with reference to the illustrated embodiments of FIGS. 2-3 and 7. Accordingly, elements and features corresponding to elements and features in the illustrated embodiments of FIGS. 2-3 and 7 are provided with the same reference numerals in the 500 series. Reference is made to the description above accompanying FIGS. 2-3 and 7 for a more complete description of the features and elements (and alternatives to such features and elements) of the embodiment illustrated in FIG. 8.

As shown in FIG. 8, the sample preparation system 500 includes a container 502 that includes a first reservoir 520, a liner 504 dimensioned to be received in the first reservoir 520 and including a second reservoir 522, and a lid 506. A collar (not shown) can also be employed to further secure the components of the sample preparation system 500 together. The second reservoir 522 is adapted to contain a liquid composition 514 comprising a source 512 and a diluent 513. The sample preparation system 500 further includes a plunger 537 coupled to a filter 534. The filter 534 is adapted to filter the liquid composition 514 to form a filtrate 516 that comprises the analyte of interest (if present).

The container 502 includes a base 527, a sidewall 529, and an aperture 524 defined in the base 527. The liner 504 includes a sidewall 528 and a base 526 that can be accessed, for example, via the aperture 524 in the base 527 of the container 502. The lid 506 includes a port 532 that defines an opening 554 in the lid 506 and the sample preparation system 500. The plunger 537 includes a handle 543 that is dimensioned to be received in the port 532, such that the handle 543 can be accessed from outside of the sample preparation system 500 to force the filter 534 through the liquid composition 514. In some embodiments, the handle 543 of the plunger 537 can be sized more closely to the size of the opening 554, and/or a sealing means (e.g., an o-ring) can be positioned between the handle 543 and opening 554 to form a seal. The lid 506 further includes an off-axis aperture 558 defined in a second port of the lid 506, which can serve, for example, as a degassing outlet to allow for the release of pressure from within the sample preparation system 500.

In some embodiments, as shown in FIG. 8, the filter 534 can be dimensioned to fit within the second reservoir 522 of the liner 504. In such embodiments, the filter 534 can form a seal with the sidewall 528 of the liner 504 by virtue of the deformability of the liner

504 and does not necessarily require additional sealing means between the outer surface of the filter 534 and the inner surface of the sidewall 528 of the liner 504. The deformability of the liner 504 can also allow for wider tolerances, such that the filter 534 does not have to be sized within a narrow range to still be able to cooperate with the liner 504.

Alternatively, in some embodiments, the sample preparation system 500 does not include a liner 504, and the filter 534 can be configured to cooperate with the container 502. For example, the filter 534 can be sized to fit within the first reservoir 520 of the container 502. In some embodiments, the sample preparation system 500 can include sealing means (e.g., an o-ring) positioned between the filter 534 and the sidewall 529 of the container 502. In some embodiments, the sidewall 529 of the container 502 is straight up and down (i.e., perpendicular to the base 527) to facilitate sealing the filter 534 with the sidewall 529. In some embodiments, the filter 534 includes an outer deformable (e.g., elastomeric) flange to allow the filter 534 to accommodate a taper in the sidewall 529 of the container 502. Such a flange could also be incorporated into embodiments employing the filter 504.

As the plunger 537 is pressed downwardly along a direction D_1, the filter 534 moves downwardly through the liquid composition 514, such that relatively large insoluble matter (i.e., any particulates having a size greater than the pore size of the filter 534) are maintained below the filter 534, and any soluble matter and relatively small insoluble matter (i.e., any particulates having a size less than the pore size of the filter 534) pass through the filter, such that the filtrate 516 is formed above the filter 534 in the second reservoir 522. The plunger 537 can be pressed in the direction D_1 to a set position (e.g., the liner 504, the filter 534 and/or the plunger 537 can include one or more stops, the plunger 537 can be sized to only accommodate a certain depth in the second reservoir 522, etc.), or to a position where any remaining insoluble matter in the liquid composition 514 is at least partially compressed by the filter 534.

In some embodiments, the handle 543 of the plunger 537 can be hollow and in fluid communication with the second reservoir 522. In such embodiments, at least a portion of the filtrate 516 can be received in the interior of the handle 543 of the plunger 537 and can be removed from the sample preparation system 500 via the handle 543. In

such embodiments, the plunger 537 can include a cover dimensioned to receive the upper end of the handle 543. Alternatively, the plunger 537 can be hollow and not covered at its base by the filter 534, such that at least a portion of the liquid composition 514 can be received in the interior of the handle 543 of the plunger 537. Such embodiments can allow the liquid composition 514 to take up less space in the bottom of the second reservoir 522 and can allow the filter 534 to be moved further down in the second reservoir 522 along the direction D_1.

FIGS. 9-12 illustrate a sample preparation system 600 according to another embodiment of the present disclosure, wherein like numerals represent like elements. The sample preparation system 600 shares many of the same elements and features described above with reference to the illustrated embodiment of FIGS. 2-3. Accordingly, elements and features corresponding to elements and features in the illustrated embodiment of FIGS. 2-3 are provided with the same reference numerals in the 600 series. Reference is made to the description above accompanying FIGS. 2-3 for a more complete description of the features and elements (and alternatives to such features and elements) of the embodiment illustrated in FIGS. 9-12.

As shown in FIG. 9, the sample preparation system 600 includes a receptacle 604, a lid 606, a cover 609, and a filter assembly 633. The receptacle 604 is deformable, self-supporting and freestanding. The receptacle 604 includes a base 626 and a sidewall 628. The sidewall 628 includes an accordion-type configuration and includes a plurality of pleats or folds 645 to allow the sidewall 628 to be folded at each pleat 645 and to facilitate the collapse of the receptacle 604 substantially along its longitudinal axis, and particularly, to facilitate the collapse of the receptacle 604 substantially uniformly substantially along its longitudinal axis. In the embodiment illustrated in FIG. 9, the sidewall 628 includes a plurality of pleats or folds 645 by way of example only. However, it should be understood that the sidewall 628 can include other structures that would allow the sidewall 628 to collapse substantially uniformly substantially along its longitudinal axis, such as annular weakened portions in the sidewall 628 that are less rigid and/or less thick than the remainder of the sidewall 628 to allow the sidewall 628 to buckle at the locations of the annular weakened portions. Other suitable structures are also possible and within the spirit and scope of the present disclosure.

The base 626 of the receptacle 604 can be reinforced, made of a more rigid material, and/or made to be thicker relative to the sidewall 628 to encourage the receptacle 604 to collapse along its longitudinal axis. The receptacle 604 includes a reservoir 622 that is adapted to contain a liquid composition that comprises a source and a diluent.

The receptacle 604 can be formed of a variety of materials, including the materials listed above with respect to the liner 104. The receptacle 604 can be translucent (or even transparent), or opaque, depending on the application of use. Any or all of the components of the sample preparation system 600 can be disposable (e.g., made for one-time use).

The lid 606 includes a port 632, which can be coupled to the filter assembly 633, a cylindrical portion 636 that is dimensioned to be received within the receptacle 604, and a generally conical (e.g., frusto-conical) portion 638 that extends from the cylindrical portion 636 to the port 632. At the junction between the cylindrical portion 636 and the conical portion 638, the lid 106 further includes a lip 640 that extends radially outwardly from the cylindrical portion 636 and the conical portion 638. The port 632 of the lid 606 is generally cylindrical and tubular in shape, such that the port 632 includes an inner surface 652 and defines an opening 654 in the lid 606, and in the sample preparation system 600, when assembled.

The cylindrical portion 636 of the lid 606 includes a plurality of circumferential outwardly-projecting protrusions 642 to allow the cylindrical portion 636 to be snap-fit or press-fit to the inner surface of the receptacle 604. The receptacle 604 can include an upper surface 644 that can form an abutting relationship with the lip 640 of the lid 606. The lid 606 and the receptacle 604 can be coupled together using any of the above removable or permanent coupling means in order to form a seal (e.g., a liquid-tight seal, a hermetic seal, or a combination thereof), such that the sample preparation system 600 is inhibited from leaking during normal operation. For example, the plurality of circumferential outwardly-projecting protrusions 642 can be ultrasonically-welded to the inner surface of the receptacle 604.

The filter assembly 633 includes a frame 635 and a filter 634. The frame 635 includes an upper portion 635a and a lower portion 635b, and the filter 634 is coupled therebetween. The upper portion 635a of the frame 635 is shaped and dimensioned to be coupled to the port 632 of the lid 606 and received within the port 632 of the lid 606 and the reservoir 622 of the receptacle 604. The frame 635 need not include the lower portion 635b, but the lower portion 635b gives the filter 634 additional weight and aids in exposing the filter 634 to the liquid composition in the reservoir 622 of the receptacle 604.

The upper portion 635a includes a tubular body 647 dimensioned to be received in the port 632 of the lid 606, a lip 649 coupled to the upper end of the tubular body 647 dimensioned to sit atop the port 632 of the lid 606, and a plurality of ribs 651. The ribs 651 are circumferentially-spaced about the tubular body 647. The embodiment illustrated in FIG. 9 includes two ribs 651, but as few or as many as necessary can be used. The ribs 651 are shaped to be coupled to the lid 606 in a snap-fit engagement. Particularly, the ribs 651 each include a cam surface 675 adapted to slide along the inner surface 652 of the port 632 as the upper portion 635a of the frame is moved into the port 632. In addition, the cam surface 675 of each rib 651 causes the respective rib 651 to be forced radially inwardly as the tubular body 647 is moved into the port 632, and further allows the respective rib 651 to snap (e.g., radially outwardly) into position under the bottom of the port 632 (i.e., on the inside of the lid 606).

The filter assembly 633 can then be removed from the lid 606 by pulling upwardly on the lip 649 of the frame 635 with sufficient force to move at least one rib 651 inwardly far enough to bring its cam surface 675 into contact with the inner surface 652 of the port 632, and to continue sliding the cam surface 675 upwardly along the inner surface 652 until the rib 651 is released from contact with the inner surface 652 of the port 632. Alternatively, the filter assembly 633 can be removed from the lid 606 by moving at least one rib 651 radially inwardly while applying an upward force to bring the cam surface 675 of the respective rib 651 into contact with the inner surface 652 of the port 632, or by squeezing the ribs 651 toward one another (e.g., radially inwardly) and moving the upper portion 635a of the frame 635 upwardly out of the port 632.

The filter 634 illustrated in FIG. 9 is collapsible and can be caused to hang downwardly in the reservoir 622 of the receptacle 604 at least partially by the weight of the lower portion 635b of the frame 635.

The cover 609 is shaped and dimensioned to receive at least a portion of the port 632. As a result, the cover 609 can be coupled to the port 632 of the lid 606 to close the opening 654 in the lid 606 and to seal (e.g., hermetically seal) the sample preparation system 600 from ambience. The cover 609 can be coupled to the lid 106 using any of the above-described coupling means. In the embodiment illustrated in FIG. 9, the port 632 of the lid 606 includes a plurality of threads 674 adapted to matingly engage with threads (not shown) on the inside of the cover 609, such that the cover 609 can be screwed onto the port 632. However, any of the other coupling means described above can be employed to couple the cover 609 to the lid 606 to close the opening 654 in the lid 606. The cover 609 and the lid 606 can together form a lid assembly 677, and the lip 649 of the filter assembly 633 can be sandwiched between the cover 609 and the upper end of the port 632 of the lid 606 when the sample preparation system 600 is assembled and closed.

FIG. 10 illustrates the lid assembly 677 and the filter assembly 633 with the cover 609 coupled to the lid 606, and the filter assembly 633 coupled therebetween. The filter 634 is shown in a compressed state, such that the filter assembly 633 is contained in the interior of the lid 606. The lower portion 635b of the filter frame 635 is rigid relative to the collapsible filter 634, which aids in collapsing the filter 634 along its longitudinal axis, such that the filter 634 can be compressed into the interior of the lid 606 by pressing upwardly on the lower portion 635b of the frame 635. A removable barrier film 679 can be coupled to a lower surface 681 of the lid 606 to maintain the filter 634 in a compressed state within the interior of the lid 606. The lid assembly 677 can be sterilized and packaged with the filter 634 in its compressed state and the filter assembly 633 contained inside the lid 606 by the removable barrier film 679. A user can then remove the removable barrier film 679 prior to use (e.g., in a sterile environment) to allow the filter 634 (and the lower portion 635b of the frame 635, if employed) to hang below the lid assembly 677 in an uncompressed state. The removable barrier film 679 can also be removed just prior to coupling the lid 606 to the receptacle 604 to allow the filter 634 to

drop into the reservoir 622 of the receptacle 604. The uncompressed state of the filter 634 following removal of the removable barrier film 679 is shown in FIG. 11.

The removable barrier film 679 can be coupled to the lid 606 using any of the coupling means described above, and can be formed of a variety of materials, including, but not limited to, a polyolefin, including, but not limited to polypropylene (e.g., low density polyethylene (LDPE)), polyethylene; poly(methylpentene); polyamide (e.g., NYLON®); compressed blown microfiber (cBMF); urethane; polyester; polycarbonate; and combinations thereof. In some embodiments, the removable barrier film 679 can include, for example, a heat sealed "strippable" film, such as a 3M™ SCOTCHPAK™ release liner (3M Company, St. Paul, MN). The removable barrier film 679 can be translucent (or even transparent), or opaque. The removable barrier film 679 can be formed by a variety of processes, including, but not limited to a molding process, extrusion, a blow film forming process, etc., and combinations thereof.

In some embodiments, as shown in FIG. 12, the cover 609 includes a frangible barrier 683 which can be punctured to access either the reservoir 622 of the receptacle 604, or the volume within the filter 634. The barrier 683 can include a membrane, a non-porous film, and combinations thereof. In addition, the frangible barrier 683 can be formed of a variety of materials that allow the barrier 683 to be frangible (e.g., punctured by a pipette tip), including, but not limited to, a polyolefin, including, but not limited to polypropylene (e.g., low density polyethylene (LDPE)), polyethylene; poly(methylpentene); polyamide (e.g., NYLON®); compressed blown microfiber (cBMF); urethane; polyester; polycarbonate; synthetic or natural elastomers; 3M™ TEGADERM™ film dressing (3M Company, St. Paul, MN), and combinations thereof. In some embodiments, the barrier 683 is instead formed over the opening 654 in the lid 606. In such embodiments, the cover 609 can be solid and can be used to cover the lid 606, for example, after the barrier 683 has been punctured, or the cover 609 can include an additional barrier. Alternatively, in embodiments in which the barrier 683 is formed over the opening 654 in the lid 606, a cover 609 need not be employed. Whether employed with the lid 606 or the cover 609, or both, or another portion of the sample preparation system 600, the barrier 683 can include the additional functionality of being

gas-permeable to allow for gas exchange between the interior of the reservoir 622 and ambience (e.g., to provide oxygen to aerobic bacteria of interest).

FIG. 13 illustrates a sample preparation system 700 according to another embodiment of the present disclosure. FIG. 13 shows only the lid assembly 777 of the sample preparation system 700. The other components of the sample preparation system 700 can be assumed to include any of the other respective components of the sample preparation systems described above and illustrated in FIGS. 2-12, and thus for simplicity, are not shown in FIG. 13.

The lid assembly 777 includes a lid 706 and a cover 709 coupled to the lid 706 via a hinge 785. In some embodiments, as shown in FIG. 13, the hinge 785 is a living hinge, and the cover 709 is integrally formed with the lid 706. In some embodiments, the hinge 785 is formed separately from one or both of the lid 706 and the cover 709. The cover 709 is a flip-top cover and can be coupled with the lid 706 via a snap-type engagement. In the embodiment illustrated in FIG. 13, the cover 709 includes a projection 787 that can be snapped onto a ridge 789 on the lid 706. The cover 709 can include other sealing means (e.g., an o-ring), such that when the cover 709 is closed over the lid 706, the cover 709 forms a seal (e.g., a liquid tight seal, a hermetic seal, etc.) with the lid 706.

As mentioned above, FIGS. 14 and 15 illustrate a sample preparation and delivery system 801 that includes a sample preparation system 800 and a sample delivery system 803. As shown in FIG. 14, the sample preparation system 800 is similar to that of the sample preparation system 400 illustrated in FIG. 7, but includes a filter 834 that is similar to that of the filter 134 illustrated in FIGS. 2-3 and described above. The sample preparation system 800 shares many of the same elements and features described above with reference to the illustrated embodiments of FIGS. 2-3 and 7. Accordingly, elements and features corresponding to elements and features in the illustrated embodiments of FIGS. 2-3 and 7 are provided with the same reference numerals in the 800 series. Reference is made to the description above accompanying FIGS. 2-3 and 7 for a more complete description of the features and elements (and alternatives to such features and elements) of the embodiment illustrated in FIGS. 14-15. Any of the previously-described sample preparation systems 100, 200, 300, 400, 500, 600, 700 illustrated in FIGS. 2-13

can be employed in the sample preparation and delivery system 801. The sample preparation system 800 is shown by way of example only and is not intended to be limiting.

As shown in FIG. 14, the sample preparation system 800 includes a container 802 having a first reservoir 820, a liner 804 having a second reservoir 822 and being positioned in the first reservoir 820, and a lid 806. A liquid composition 814 is positioned within a second reservoir 822 of the liner 804. The liquid composition 814 includes a source 812 and a diluent 813. The second reservoir 822 is in fluid communication with the filter 834 to allow the liquid composition 814 to be filtered by the filter 834 to form a filtrate 816.

The sample delivery system 803 is coupled to the sample preparation system 800 via a port 832 of the lid 806. In embodiments employing the port 832, at least a portion of the sample delivery system 803 can be dimensioned to be received in the port 832. In some embodiments, however, the sample delivery system 803 can be coupled to an aperture in the sample preparation system 800 and need not be coupled to a port. The sample delivery system 803 includes a one-way pressure-activated valve 891 that is coupled to and at least partially received in the port 832 of the lid 806 of the sample preparation system 800. The valve 891 is coupled to an opening 854 in the lid 806 and positioned in fluid communication with the interior of the filter 834 (or with the second reservoir 822 if the filter 834 is not employed). The valve 891 is adapted to allow the filtrate 816 (or the liquid composition 814 if the filter 834 is not employed) to be removed from the sample preparation system 800 when a sufficient pressure differential is established between the second reservoir 822 and ambience (or another device coupled to the sample preparation and delivery system 801). That is, the valve 891 is activated by applying pressure to the liner 804. When a sufficient pressure differential is established, the valve 891 can control how the filtrate 816 is dispensed from the sample preparation system 800. For example, depending on the type of valve 891 used, the filtrate 816 can be caused to exit the sample preparation and delivery system 801 in a continuous stream, in a drop-wise fashion, or in another suitable flow configuration.

The one-way pressure-activated valve 891 illustrated in FIG. 14 is a SUPRAVALVE™ duckbill check valve (Small Parts, Inc., Miami Lakes, FL) and functions by allowing the duckbill to open when the upstream pressure exceeds a minimum threshold pressure or the downstream pressure falls below a maximum threshold pressure. The "flaps" of the duckbill remain closed until a threshold pressure is achieved.

As shown in FIG. 15, when a positive pressure is applied to the exterior of the liner 804 (e.g., by accessing the liner 804 (e.g., a base 826 of the liner 804) via an aperture 824 formed in the base 827 of the container 802), and the pressure within the second reservoir 822 exceeds a threshold value, the valve 891 in the sample delivery system 803 will open, allowing the filtrate 816 to be delivered out of the sample preparation system 800 via the sample delivery system 803. Pressure can be applied to the exterior of the liner 804 by hand, or manually or automatically using an additional device (such as a plunger).

In some embodiments, the pressure differential for opening the valve 891 can be established by applying negative pressure to the second reservoir 822 of the liner 804 (i.e., negative pressure to the downstream side of the valve 891), instead of applying positive pressure to the exterior of the liner 804. Negative pressure (or a vacuum) can be applied to the second reservoir 822 of the liner 804, for example, by coupling a vacuum source to the valve 891. A vacuum source can include, but is not limited to, a mechanical pump that creates a reduced pressure, or a manual pump (e.g., a syringe-plunger combination), and combinations thereof.

In some embodiments, the pressure differential for opening the valve 891 can be established by the mass of liquid on the upstream side of the valve 891. For example, the liquid composition 814 or the filtrate 816 can cause sufficient pressure (e.g., head pressure when the sample preparation system 800 or the sample preparation and delivery system 801 is tipped or inverted) to open the valve 891.

In some embodiments, when the valve 891 is in a closed state, the sample preparation and delivery system 801 is sealed from the environment, such that fluid (liquid or gas) is inhibited from entering or exiting the sample preparation and delivery system

801 until the valve 891 is activated to open. However, in some embodiments, when the valve 891 is in a closed state, various components of the sample preparation and delivery system 801 (e.g., the lid 806, the liner 804 and/or the container 802) are gas-permeable, such that gases are free to move in and out of the sample preparation and delivery system 801 (e.g., to provide oxygen to aerobic bacteria within the sample preparation system 800) but that liquids are inhibited from entering or exiting the sample preparation and delivery system 801 until the valve 891 is activated to open to allow liquid to exit.

In addition, in some embodiments, the components of the sample preparation and delivery system 801 are not gas-permeable, but if gases are developing in the sample preparation and delivery system 801 (e.g., if bacteria in the sample preparation and delivery system 801 are producing gas, or if a reaction is taking place between the source 812 and the diluent 813 that produces gas, or if the agitation process produces a build-up of gas) and enough pressure develops within the second reservoir 822 of the liner 804, gas can be released via the valve 891. Therefore, in some embodiments, the valve 891 has the additional function (or an additional valve 891 or port can be employed) of allowing for outgassing from the sample preparation and delivery system 801.

Furthermore, in embodiments in which the components of the sample preparation and delivery system 801 are not gas-permeable, anaerobic bacteria may be positioned (and cultured) in the sample preparation system 800 by replacing the air in the sample preparation system 800 with an oxygen-free environment such as carbon dioxide. In such embodiments, the replacement gas can be introduced into the sample preparation system 800 via a valve or an inlet tube, and air can be removed from the sample preparation system 800 via the valve 891, or via a port (e.g., the port 832) of the sample preparation system 800. As a result, the valve 891 can further allow for outgassing when the atmosphere in the sample preparation system 800 is replaced.

The valve 891 can further control the flow of the filtrate 816, such that a desired volume of filtrate 816 (e.g., a sample, which can include all or a portion of the filtrate 816) is removed from the sample preparation system 800 at a time, to achieve a desired volumetric flow rate. In some embodiments, as shown in FIG. 15, a sample of the filtrate 816 can be delivered from the sample preparation system 800 via the sample delivery

system 803 into a detection system 895 to be analyzed for the analyte of interest. The detection system 895 can be adapted to perform any of the above-described testing methods to identify and/or quantitate the analyte of interest. Alternatively, the sample delivery system 803 can deliver a sample to an enrichment device, in which the sample can be enriched with nutrients, and optionally, incubated (see FIG. 16), or into a concentration device to concentrate the sample (e.g., by centrifugation, filtration, etc.).

The sample delivery system 803, and particularly the valve 891, can be formed of a variety of materials including, but not limited to, polymeric materials, elastomeric materials (e.g., synthetic or natural), metals (e.g., aluminum, stainless steel, etc.), ceramics, glasses, and combinations thereof. Examples of polymeric materials can include, but are not limited to, polyolefins (e.g., polyethylene, polypropylene, combinations thereof, etc.), polycarbonate, acrylics, polystyrene, high density polyethylene (HDPE), polypropylene, other suitable polymeric materials, or a combination thereof. The valve 891 can include a housing and internal parts (e.g., movable internal parts), and the housing and internal parts can be formed of the same or different materials. For example, in some embodiments, the housing of the valve 891 is formed of a more rigid material, while the internal parts are formed of an elastomeric material. The valve 891, or any portion thereof, can be translucent (or even transparent), or opaque. The valve 891 can be any suitable size, depending on the type, amount and size of source to be analyzed.

The one-way pressure-activated valve 891 is shown and described by way of example only, but one of ordinary skill in the art will understand that a variety of valves can be employed in the sample delivery system 803 without departing from the spirit and scope of the present disclosure. For example, the sample delivery system 803 (or the valve 891) can include a variety of manual or automatic valves, an electronic pressure transducer, other types of check valves (e.g., ball check valves, diaphragm check valves, swing check valves, stop check valves, lift check valves, etc.) or other types of valves, such as stopcock valves, butterfly valves, metering valves, constant volume metering valves, timer valves, other one-way valves, other suitable valves, and combinations thereof.

Furthermore, in some embodiments, the sample delivery system 803 can include a valve that can be activated by another object or device. For example, the sample delivery system 803 can include a valve that has a movable part (e.g., a single gate, a double gate, a disc, a diaphragm, a ball, etc.) that can be moved into an open position by another object or device being coupled to the sample delivery system 803, such as a syringe or pipette tip. In such embodiments, the sample delivery system 803 can include the additional device, or the additional device can be part of a separate device.

In addition, in some embodiments, the sample delivery system 803 can include a valve that does not include any movable parts but rather includes a restricted opening, such as a tip that is coupled to the port 832 of the sample preparation system 800 that has a gradually decreasing cross-sectional area. In such embodiments, the filtrate 816 (or the liquid composition 814) will not be able to pass through the restricted opening until sufficient pressure is established in the second reservoir 822 of the liner 804 (e.g., by applying pressure to the liner 804) to force the filtrate 816 out of the restricted opening.

The sample delivery system 803, or a portion thereof, can be disposable with any disposable portion of the sample preparation system 800. For example, in the embodiment illustrated in FIGS. 14-15, the lid 806 and the liner 804 can be disposable, and the container 802 can be reused. The sample delivery system 803, which is coupled to the lid 806, can either be disposed of with the lid 806 and/or liner 804, or it can be removed from the lid 806 after use, cleaned and reused. In some embodiments, a portion of the sample delivery system 803 can be disposed with the disposable portion of the sample preparation system 800, and a portion of the sample delivery system 803 can be reused.

FIG. 16 illustrates a sample preparation and delivery system 901 according to another embodiment of the present disclosure, wherein like numerals represent like elements. The sample preparation and delivery system 901 shares many of the same elements and features described above with reference to the illustrated embodiment of FIGS. 14-15. Accordingly, elements and features corresponding to elements and features in the illustrated embodiment of FIGS. 14-15 are provided with the same reference numerals in the 900 series. Reference is made to the description above accompanying

FIGS. 14-15 for a more complete description of the features and elements (and alternatives to such features and elements) of the embodiment illustrated in FIG. 16.

The sample preparation and delivery system 901 includes a sample preparation system 900 and a sample delivery system 903 coupled to the sample preparation system 900, such that the sample delivery system 903 is in fluid communication with the sample preparation system 900. The sample preparation system 900 includes a liner 904 positioned within a first reservoir 920 of a container 902, and a liquid composition 914 positioned within a second reservoir 922 of the liner 904. The liquid composition 914 includes a source 912 and a diluent 913. The second reservoir 922 is in fluid communication with a filter 934 to allow the liquid composition 914 to be filtered by the filter 934 to form a filtrate 916.

The sample delivery system 903 includes a valve 991 that is activated by another device. The valve 991 is coupled to a lid 906 of the sample preparation system 900 via an off-axis aperture 958, such that the valve 991 is positioned in fluid communication with the second reservoir 922 of the liner 904 and with the filter 934.

In some embodiments, as shown in FIG. 16, the sample delivery system 903 can be coupled to an enrichment device 997, such that the sample delivery system 903 can control the flow of filtrate 916 from the sample preparation system 900 into the enrichment device 997. The enrichment device 997 can be removably coupled to the sample delivery system 903, such that the enrichment device 997 can be removed from the sample delivery system 903 after a sample 918 (which can include all or a portion of the filtrate 916) has been transferred into the enrichment device 997, and moved to a different location for incubation. In the embodiment illustrated in FIG. 16, the valve 991 is activated to open by coupling the enrichment device 997 to the valve 991. In embodiments in which the enrichment device 997 is removably coupled to the valve 991, the valve can be activated to close when the enrichment device 997 is decoupled from the valve 991.

As shown in FIG. 16, positive pressure can be applied to the exterior of the liner 904 (e.g., to the base 926 of the liner 904, e.g., via an aperture 924 in a base 927 of the

container 902) to cause the pressure within the second reservoir 922 to encourage the movement of the filtrate 916 to the enrichment device 997 via the sample delivery system 903. In some embodiments, the valve 991 can be pressure-activated, similar to the valve 891 described above, and the pressure in the second reservoir 922 can exceed a threshold value and cause the valve 991 to open to allow the filtrate 916 to move from the sample preparation system 900 to the enrichment device 997 via the sample delivery system 903. Alternatively, in such embodiments, negative pressure can be applied to the interior of the liner 904 (e.g., via the enrichment device 997) to activate the valve 991 to open and to move the filtrate 916 from the sample preparation system 900 to the enrichment device 997.

The enrichment device 997 can include nutrients to selectively or semi-selectively grow and enrich the analyte(s) of interest (if present) in the sample 918. In some embodiments, the enrichment device 997 can include the nutrients coated or adsorbed onto an inner surface thereof. Furthermore, in some embodiments, the enrichment device 997 can include indicia (e.g., similar to the indicia 130 on the container 102 illustrated in FIG. 2) to facilitate retrieval of a specific volume of filtrate 916 (or liquid composition 914 when the filter 934 is not employed).

In the embodiment illustrated in FIG. 16, the enrichment device 997 is a syringe that can be removably coupled to the sample delivery system 903 (e.g., via a luer lock type coupling). The syringe includes a plunger 919, and as the syringe is filled with the sample 918 (e.g., by applying pressure to the liner 904), the plunger is forced outwardly, allowing the sample 918 to continue filling the syringe to a desired volume. A syringe can be useful as an enrichment device 997 because it allows the sample 918 to be transferred to the syringe, and for the syringe to be removed from the sample preparation and delivery system 801 (and optionally capped) in a sterile environment, before transporting the syringe to an incubation environment. In addition, the plunger 919 in the syringe can be pulled outwardly from a barrel 921 to draw the sample 918 into the syringe. The liner 904 can deform in response to pulling the plunger 919, which can aid in moving the sample 918 to the syringe.

The syringe is shown and described above by way of example only, but one of ordinary skill in the art should understand that a variety of enrichment devices can be coupled to the sample delivery system 903 of the sample preparation and delivery system 901 to allow the sample 918 to be transferred from the sample preparation and delivery system 901, and particularly, to be transferred without being exposed to ambience. In addition to enrichment devices, a variety of receptacles or devices that serve as intermediates (i.e., a receptacle or device that can be transferred to another device or assay system) in any of the above described analytical methods can be coupled (e.g., removably coupled) to the sample delivery system 903. Furthermore, in some embodiments, a plurality of sample preparation systems 900 can be coupled to and in fluid communication with the same sample delivery system 903 (and any downstream devices, such as the enrichment device 997), such that samples from the plurality of sample preparation systems 900 are pooled together prior to delivery or any downstream analysis or further processing (e.g., the samples can be pooled together for delivery before or after enrichment, concentration, etc.).

In some embodiments, the phrase "without exposing to ambience" and derivations thereof refers to not removing the sample 918 from the sample preparation and delivery system 901 (e.g., to prevent spills or contamination) either during its transfer between the sample preparation system 900 and the sample delivery system 903 or during its transfer from the sample delivery system 903 to another device (e.g., the enrichment device 997), such that the sample 918 remains in the fluid path of the sample preparation and delivery system 901 from preparation to delivery or even to another step, but does not necessarily mean that the sample preparation and delivery system 901 is closed to gas-exchange or that other liquids cannot get into the sample preparation and delivery system 901.

In addition to, or in lieu of, the valves 891 and 991 illustrated in FIGS. 14-16 and described above, a variety of valves and/or volumetric metering devices can be employed in the sample delivery system of the present disclosure. FIGS. 17A-21B illustrate various embodiments of the sample delivery system of the present disclosure that include a variety of types of volumetric metering devices. FIGS. 17A-21B illustrate schematic views of various embodiments of the sample delivery system of the present disclosure; however, one of ordinary skill in the art will understand that the sample preparation and delivery

systems 801 and 901 illustrated in FIGS. 14-16 can each employ any or all of the features of the sample delivery systems illustrated in FIGS. 17A-21B and described below.

FIGS. 17A-17C illustrate a sample delivery system 1203 according to an embodiment of the present disclosure. The sample delivery system 1203 includes a dual-valve volumetric metering system and includes an inlet 1202 (e.g., coupled to and in fluid communication with a sample preparation system), a first valve 1204 spaced a distance from, positioned in series with, and in fluid communication with a second valve 1206, and an outlet 1208 (e.g., in fluid communication with ambience outside of a sample preparation system, or with another device, such as an enrichment device). A section of conduit 1210 separates the first valve 1204 and the second valve 1206 and defines a volume V that is generally dependent on the distance D between the first valve 1204 and the second valve 1206 (i.e., the length of the conduit 1210 between the first and second valves 1204 and 1206) and the cross-sectional area A of the conduit 1210.

Each of the first and second valves 1204 and 1206 is a quarter turn valve, and particularly, is a ball valve. Each valve 1204, 1206 has an open state and a closed state and includes a ball 1205, 1207 that is rotatable about an axis S, T, respectively, to move between the open and closed state. Each ball 1205, 1207 includes a channel 1209, 1211, so that when the ball 1205, 1207 is turned such that the channel 1209, 1211 is in line with both ends of the respective valve 1204, 1206 (i.e., in line with the inlet 1202 and the outlet 1208), flow will occur. The ball 1205, 1207 of each of the valves 1204, 1206 can be rotated 90 degrees (i.e., a quarter turn) about the axis S, T to change the valve 1204, 1206 from an open state to a closed state, and vice versa.

As shown in FIGS. 17A-17C, the first and second valves 1204, 1206 are each a full port ball valve, and each include an oversized ball 1205, 1207, such that the channel 1209, 1211 has the same cross-sectional size as the inlet 1202, the conduit 1210, and the outlet 1208. This configuration minimizes friction loss and allows for unrestricted flow through the valves 1204 and 1206. However, other types of suitable valves, including other types of quarter turn valves or other types of ball valves can be employed without departing from the spirit and scope of the present disclosure. Furthermore, the first and second valves 1204, 1206 need not be quarter turn valves. That is, in some embodiments,

the first and second valves 1204, 1206 can be allowed to move less than or more than 90 degrees at a time to change the valve 1204, 1206 between an open state and a closed state.

FIGS. 17A-17C, in sequence, illustrate the process of using the sample delivery system 1203 to meter a specific volume V of filtrate (or liquid composition) from a sample preparation system.

FIG. 17A shows the first valve 1204 in an open state (i.e., the channel 1209 of the ball 1205 is in line with the inlet 1202 and the conduit 1210) and the second valve 1206 in a closed state (i.e., the channel 1211 is positioned out of line with, e.g., perpendicular to, the conduit 1210 and the outlet 1208) to allow a volume V of filtrate (i.e., a sample) to enter the conduit 1210 via the inlet 1202. FIG. 17B shows the first valve 1204 in a closed state (i.e., after the ball 1205 has been rotated 90 degrees clockwise or counter clockwise about the axis S) and the second valve 1206 still in a closed state, illustrating a volume V of filtrate residing in the conduit 1210. Finally, FIG. 17C illustrates the first valve 1204 in a closed state and the second valve 1206 in an open state (i.e., after the ball 1207 has been rotated 90 degrees clockwise or counter clockwise about the axis T), allowing the desired volume V of filtrate to exit the sample delivery system 1203 via the outlet 1208.

FIGS. 18A-18C illustrate a sample delivery system 1303 according to another embodiment of the present disclosure. The sample delivery system 1303 includes a dual-valve volumetric metering system and includes an inlet 1302 (e.g., coupled to and in fluid communication with a sample preparation system), a first valve 1304 spaced a distance from, positioned in series with, and in fluid communication with a second valve 1306, and an outlet 1308 (e.g., in fluid communication with ambience outside of a sample preparation system, or with another device, such as an enrichment device). A section of conduit 1310 separates the first valve 1304 and the second valve 1306 and defines a volume V that is generally dependent on the distance D between the first valve 1304 and the second valve 1306 (i.e., the length of the conduit 1310 between the first and second valves 1304 and 1306) and the cross-sectional area A of the conduit 1310.

The sample delivery system 1303 includes a first side 1312 and second side 1314 positioned in parallel and slidable relative to one another. In the embodiment illustrated in

FIGS. 18A-18C, the second side 1314 is shown as being fixed, and the first side 1312 is shown as being slidable (i.e., up and down in the plane of the page of FIGS. 18A-18C) relative to the second side 1314. The inlet 1302 and the outlet 1308 are positioned in the first side 1312, and the conduit 1310 separating the first and second valves 1304 and 1306 is positioned in the second side 1314. Each valve 1304, 1306 is a gate valve and includes a gate 1305, 1307, respectively, that is slidable between an opened position and a closed position to change the respective valve 1304, 1306 between an open and closed state. The gates 1305 and 1307 slide together as the first side 1312 is moved relative to the second side 1314 (or as the first and second sides 1312 and 1314 are moved relative to one another).

FIGS. 18A-18C, in sequence, illustrate the process of using the sample delivery system 1303 to meter a specific volume V of filtrate (or liquid composition) from a sample preparation system.

FIG. 18A shows the first valve 1304 in an open state and the second valve 1306 in a closed state to allow a volume V of filtrate (i.e., a sample) to enter the conduit 1310 via the inlet 1302. Specifically, a sample of filtrate enters the first side 1312 of the sample delivery system 1303 via the inlet 1302 and moves from the first side 1312 into the second side 1314 via the open first valve 1304 into the conduit 1310. FIG. 18B shows the first valve 1304 in a closed state and the second valve 1306 is still in a closed state (i.e., the first side 1312 has been slid downwardly relative to the second side 1314, causing the gate 1305 to be slid into a closed position while maintaining the gate 1307 in a closed position), illustrating a volume V of filtrate residing in the conduit 1310. Finally, FIG. 18C illustrates the first valve 1304 in a closed state and the second valve 1306 in an open state (i.e., the first side 1312 has been slid downwardly even further relative to the second side 1314, causing the gate 1307 to be slid into an opened position, while maintaining the gate 1305 in a closed position), allowing the desired volume V of filtrate to exit the sample delivery system 1303 via the outlet 1308.

FIGS. 19A-19C illustrate a sample delivery system 1403 according to an embodiment of the present disclosure. The sample delivery system 1403 includes a single valve volumetric metering system and includes an inlet 1402 (e.g., coupled to and in fluid

communication with a sample preparation system), a valve 1404, and an outlet 1408 (e.g., in fluid communication with ambience outside of a sample preparation system, or with another device, such as an enrichment device).

The valve 1404 is a ball valve. The valve 1404 has two open states, a first open state in which the valve 1404 is open toward the inlet 1402, and a second open state in which the valve 1404 is open toward the outlet 1408, and a closed state. The valve 1404 includes a ball 1405 that is rotatable about an axis X to move between the two open states and the closed state. The ball 1405 includes a channel 1409 fluidly coupled to a substantially spherical interior 1411 of the ball 1405, so that when the ball 1405 is turned such that the channel 1409 is in line with either the inlet 1402 or the outlet 1408, flow will occur, either into the ball 1405 or out of the ball 1405. The channel 1409 and the interior 1411 of the ball 1405 together define a volume V that can be metered from the inlet 1402 to the outlet 1408. The ball 1405 can be rotated 90 degrees (i.e., a quarter turn) about the axis X to change the valve 1404 from a first open state to a closed state and vice versa, and from a first open state to a second open state and vice versa. In the embodiment illustrated in FIGS. 19A-19C, the valve 1404 is a quarter turn valve, but it should be understood that the valve 1404 can be configured to move less than or greater than 90 degrees to change the valve 1404 between open states or between an open state and a closed state.

FIGS. 19A-19C, in sequence, illustrate the process of using the sample delivery system 1403 to meter a specific volume V of filtrate (or liquid composition) from a sample preparation system.

FIG. 19A shows the valve 1404 in a first open state (i.e., the channel 1409 of the ball 1405 is in line with the inlet 1402) to allow a volume V of filtrate (i.e., a sample) to enter the interior 1411 of the ball 1405 via the inlet 1402. FIG. 19B shows the valve 1404 in a closed state (i.e., after the ball 1405 has been rotated 90 degrees clockwise or counter clockwise about the axis X), illustrating a volume V of filtrate residing in the ball 1405. Finally, FIG. 19C illustrates the valve 1404 in a second open state (i.e., after the ball 1405 has been rotated another 90 degrees in the same direction about the axis X), allowing the desired volume V of filtrate to exit the sample delivery system 1403 via the outlet 1408.

FIGS. 20A-20D illustrate a sample delivery system 1503 according to another embodiment of the present disclosure. The sample delivery system 1503 shares many of the same elements and features described above with reference to the illustrated embodiment of FIGS. 17A-17C. Accordingly, elements and features corresponding to elements and features in the illustrated embodiment of FIGS. 17A-17C are provided with the same reference numerals in the 1500 series. Reference is made to the description above accompanying FIGS. 17A-17C for a more complete description of the features and elements (and alternatives to such features and elements) of the embodiment illustrated in FIGS. 20A-20D.

The sample delivery system 1503 includes a single valve volumetric metering system and includes a first conduit 1502 that can function as an inlet (e.g., when coupled to and in fluid communication with a sample preparation system) and an outlet (e.g., after being removed from being in fluid communication with the sample preparation system and while in fluid communication with ambience outside of a sample preparation system, or with another device, such as an enrichment device). The sample delivery system 1503 further includes a valve 1504 which, when in an open state, can be in fluid communication with a second conduit 1510 having a closed end opposite the valve 1504. The second conduit 1510 defines a volume V that is generally dependent on the length L of the second conduit 1510 and the cross-sectional area A of the second conduit 1510.

Similar to the valves 1204, 1206 described above and illustrated in FIGS. 17A-17C, the valve 1504 is a quarter turn valve, and particularly, is a ball valve. The valve 1504 has an open state and a closed state and includes a ball 1505 that is rotatable about an axis Y to move between the open and closed state. The ball 1505 includes a channel 1509, so that when the ball 1505 is turned such that the channel 1509 is in line with both ends of the valve 1504 (i.e., in line with the first conduit 1502 and the second conduit 1510), flow will occur. The ball 1505 can be rotated 90 degrees (i.e., a quarter turn) about the axis Y to change the valve 1504 from an open state to a closed state, and vice versa.

The valve 1504 is a full port ball valve, and includes an oversized ball 1505, such that the channel 1509 has the same cross-sectional size as the first conduit 1502 and the second conduit 1510. This configuration minimizes friction loss and allows for

unrestricted flow through the valve 1504. However, other types of suitable valves, including other types of quarter turn valves or other types of ball valves can be employed without departing from the spirit and scope of the present disclosure. Furthermore, the valve 1504 need not be a quarter turn valve, but rather can be allowed to move less than or more than 90 degrees at a time to change the valve 1504 between an open state and a closed state.

FIGS. 20A-20D, in sequence, illustrate the process of using the sample delivery system 1503 to meter a specific volume V of filtrate (or liquid composition) from a sample preparation system.

FIG. 20A shows the valve 1504 in an open state (i.e., the channel 1509 of the ball 1505 is in line with the first conduit 1502 and the second conduit 1510) to allow a volume V of filtrate (i.e., a sample) to enter the second conduit 1510 via the first conduit 1502 when the first conduit 1502 is functioning as an inlet. FIG. 20B shows the valve 1504 in a closed state (i.e., after the ball 1505 has been rotated 90 degrees clockwise or counter clockwise about the axis Y), illustrating a volume V of filtrate residing in the second conduit 1510. FIG. 20C shows the sample delivery system 1503 after it has been decoupled from the sample preparation system and flipped over, the valve 1504 remaining in a closed state, and the volume V of filtrate still residing in the second conduit 1510. Finally, FIG. 20D illustrates the valve 1504 in an open state (i.e., after the ball 1505 has been rotated 90 degrees about the axis Y), allowing the desired volume V of filtrate to exit the sample delivery system 1503 via the first conduit 1502, the first conduit 1502 functioning as an outlet.

Even though the sample delivery system 1503 is decoupled from the sample preparation system to deliver the volume V of filtrate, the sample delivery system 1503 still allows a sample of the filtrate to be moved into the sample delivery system 1503 without first being exposed to ambience. The sample delivery system 1503 can then be transported to another location (e.g., a sterile environment) before the volume V of filtrate is delivered from the sample delivery system 1503 into the desired location (e.g., a detection device, an enrichment device, etc.).

FIGS. 21A-21B schematically illustrate a sample preparation and delivery system 1601 that includes a sample preparation system 1600 and a sample delivery system 1603 according to another embodiment of the present disclosure. The sample delivery system 1603 includes a dual-valve volumetric metering system that is coupled to and in fluid communication with the sample preparation system 1600.

The sample delivery system 1603 includes a first one-way valve 1604, a conduit 1610, and a second one-way valve 1606 positioned in series with, and in fluid communication with, the first one-way valve 1604. The first valve 1604 is configured to allow fluid to move from the sample preparation system 1600 into the conduit 1610 but inhibits flow of fluid from the conduit 1610 into the sample preparation system 1600. The second valve 1606 is configured to allow fluid to move from the conduit 1610 to ambience (or to another device coupled to the sample delivery system 1603) but inhibits flow of fluid from ambience into the conduit 1610. The conduit 1610 defines a volume V of filtrate that can be metered from the sample preparation system 1600, held in the sample delivery system 1603, and then delivered out of the sample delivery system 1603. By way of example only, the conduit 1610 is shown as having a generally parallelepiped shape, and particularly, as being a rectangular prism. However, one of ordinary skill in the art should understand that a variety of suitable three-dimensional shapes can be used to define a volumetric space between the first and second valves 1604, 1606.

Each of the first and second valves 1604 and 1606 can include any of a variety of valves, but are shown schematically by way of example only to be a clapper check valve. Each valve 1604, 1606 has an open state and a closed state and includes a gate 1605, 1607 that pivots about a hinge 1613, 1615 when a threshold upstream cracking pressure has been exceeded. Alternatively, the first and second valves 1604 and 1606 can be activated by gravity, rather than by a threshold cracking pressure. One of ordinary skill in the art will understand that a variety of valves suitable for controlling flow into and out of the sample delivery system 1603 can be used for the first and second valves 1604 and 1606 without departing from the spirit and scope of the present disclosure, including, but not limited to, other check valves (e.g., ball check valves, diaphragm check valves, swing check valves, stop check valves, lift check valves, etc.), other suitable valves (e.g., those described above), and combinations thereof. Furthermore, the same type of valve does not

need to be used for the first valve 1604 and the second valve 1606, but rather a mix of valve types can be employed in the sample delivery system 1603.

FIGS. 21A-21B, in sequence, illustrate the process of using the sample delivery system 1603 to meter a specific volume V of filtrate (or liquid composition) from the sample preparation system 1600.

FIG. 21A shows the first valve 1604 in an open state (i.e., the gate 1605 has been pivoted about the hinge 1613 into an opened position due to the pressure upstream of the valve 1604 exceeding a threshold cracking pressure), and the second valve 1606 is in a closed state (i.e., the gate 1607 remains in a closed position because the pressure within the conduit 1610 has not exceeded a threshold cracking pressure for the second valve 1606) to allow a volume V of filtrate (i.e., a sample) to enter the conduit 1610.

FIG. 21B shows the sample preparation and delivery system 1601 after it has been inverted, and after a sample of the filtrate has been allowed to enter the conduit 1610. The first valve 1604 is in a closed state (i.e., the gate 1605 has pivoted about the hinge 1613 back to a closed position in response to the upstream pressure falling below the threshold cracking pressure) and the second valve 1606 is in an open state (i.e., the gate 1607 has been pivoted about the hinge 1615 into an open position due to the pressure in the conduit 1610 exceeding a threshold cracking pressure), allowing the desired volume V of filtrate to exit the sample delivery system 1603.

As mentioned above, FIGS. 17A-21B are schematic illustrations of various embodiments of sample delivery systems according to the present disclosure. Other elements or modifications may be necessary to allow the sample delivery systems 1203, 1303, 1403, 1503, 1603 to function properly. Such elements or modifications would be understood by one of ordinary skill in the art, including, for example, adding a release vent, valve or other similar device to any of the conduits 1210, 1310, 1510, 1610 (or the interior 1411 of the ball 1405), or any other portion of the respective sample delivery system, to allow any trapped air (or other gas) to be released in order for liquid to be allowed to enter. Such vents or valves can be configured to (or can be coupled to another

device configured to) allow gases to exit while inhibiting liquids from exiting (e.g., an air lock or another similarly functioning device).

Any of the sample preparation and delivery systems 801, 901 and 1601 comprising any of the sample preparation systems 100, 200, 300, 400, 500, 600, 700, 800, 900 and 1600 and any of the sample delivery systems 803, 903, 1203, 1303, 1403, 1503 and 1603 described herein, and portions and combinations thereof, can be used together to prepare and deliver samples by generally following the sample preparation and delivery method 10 described above and illustrated in FIG. 1. One of ordinary skill in the art will also understand that various components from one sample preparation system described herein can be used in combination with other components from another sample preparation system described herein, without departing from the spirit and scope of the present disclosure. For example, the receptacle 604 can be used in place of the liner 804 in the sample preparation system 800. Similarly, various components from one sample preparation and delivery system can be used in combination with other components from another sample preparation and delivery system, and various components from one sample delivery system can be used in combination with other components from another sample delivery system. An exemplary method will now be described in detail using the sample preparation and delivery system 801 of FIG. 14.

A source 812 and a diluent 813 can be added to the second reservoir 822 of the liner 804 and combined to form a liquid composition 814. The lid 806 can be coupled to the liner 804 prior to or after the liner 804 is positioned within the container 802. A collar (not shown) can be coupled to the container 802 to further secure the components of the sample preparation system 800 together, and the lid opening 854 can be closed using a cover (not shown).

The liquid composition 814 can be agitated to mix the source 812 and the diluent 813 and to dissolve, disperse, suspend and/or emulsify the source 812 in the diluent 813. Agitation may include any of the above-described processes, and for example, can be linear, in a circular orbit, an elliptical orbit, a random orbit, a combination thereof, or of other means to ensure effective and efficient mixing of the source 812 and the diluent 813.

The sample preparation system 800 may be further secured by clamping or other means during agitation to minimize spillage and/or loss of the liquid composition 814.

In some embodiments, the liquid composition 814 can be agitated by coupling the sample preparation and delivery system 801 to a Burell Model 75 Wrist Action Shaker (Burrell Scientific, Pittsburgh, PA), and agitating the sample preparation and delivery system 801 at a frequency of 10 to 2000 cycles/minute, and in some embodiments, at a frequency of 200 to 500 cycles/minute for a selected duration of time. In some embodiments, the sample preparation and delivery system 801 can be mounted at a distance from the shaker arm from between 5 cm and 50 cm, and in some embodiments, between 10 cm and 20 cm. In some embodiments, the sample preparation and delivery system 801 can inscribe an arc of 5 degrees to 30 degrees, and in some embodiments, between 15 degrees and 20 degrees. The liquid composition 814 may be agitated for at least 10 seconds, in some embodiments, at least 15 seconds, in some embodiments, at least 30 seconds, in some embodiments, at least 40 seconds, and in some embodiments, at least 60 seconds. In some embodiments, the liquid composition 814 can be agitated for at most 15 minutes, in some embodiments, at most 10 minutes, in some embodiments, at most 5 minutes, and in some embodiments, at most 3 minutes.

In some embodiments, the liquid composition 814 can be vortexed in a VX-2500 Multi-Tube Vortexer (VWR Scientific Products, West Chester, PA) at an agitation frequency of 200 to 5000 rpm, and in some embodiments, of 1000 to 3000 rpm for a selected duration of time. The vortex orbit can be linear, circular, elliptical, random, or a combination thereof. In some embodiments, the orbit is between 0.25 cm and 5 cm, and in some embodiments, between 1 cm and 3 cm.

A plurality of sample preparation and delivery systems can be agitated simultaneously, by being placed on a plate, an arm or other device, and secured by gravity, clamping or other means for subsequent agitation. For example, in some embodiments, one to about fifty sample preparation and delivery systems are agitated simultaneously, and in some embodiments, about 10 to about 25 sample preparation and delivery systems are agitated simultaneously on a single agitation device or with multiple agitation devices.

In some embodiments, the liquid composition 814 can be agitated by the addition of a mechanical stirrer having a shaft and stirring blades, which may be inserted through any of the possible apertures described above that are not occupied. Agitation of the liquid composition 814 may be further accomplished with steel ball bearings, magnetic stirring bars, blades, and other means to assist in breaking up and/or dispersing the source 812 in the diluent 813 to release any analyte(s) of interest from the source 812. The agitation methods described above are included by way of example only and are not intended to be limiting. One of ordinary skill in the art will understand that other similar agitation methods can be employed.

The liquid composition 814 can be filtered using the filter 834 to form a filtrate 816 positioned within the filter 834 that includes the diluent 813 and any analyte(s) of interest (if present) that were small enough to pass through the filter 834 or which are dissolved in the diluent 813.

All or a portion (e.g., a sample) of the filtrate 816 can be removed from the interior of the filter 834 for further analysis using the sample delivery system 803. Particularly, a pressure differential can be established that causes the liner 804 to deform, to cause the liquid composition 814 to be forced through the filter 834, and to cause the filtrate 816 to be forced into the sample delivery system 803, and to activate the valve 891 of the sample delivery system 803 to open to allow the filtrate 816 to flow out of the sample delivery system 803 when the cracking pressure of the valve 891 has been exceeded. As mentioned above, the pressure differential can be established by applying a positive pressure to the exterior of the liner 804 (e.g., to the base 826 of the liner 804 via the aperture 824 in the base 827 of the container 802) or by applying a negative pressure to the interior of the liner 804 (e.g., via the valve 891). The valve 891 can further control the flow configuration of the filtrate 816 from the sample delivery system 803.

In some embodiments, the level 865 of the liquid composition 814 is high enough that the filter 834 is positioned partially above and partially below the level 865 of the liquid composition 814. In some embodiments, the level 865 of the liquid composition 814 is below the bottom of the filter 834, such that the filter 834 is positioned wholly above the level 865 of the liquid composition 814. In such embodiments, the sample

preparation and delivery system 801 can be tipped or inverted to cause the liquid composition 814 to be filtered by the filter 834 prior to applying pressure to the liner 804, or the application of pressure to the liner 804 can move the level 865 of the liquid composition 814 to cause the liquid composition 814 to pass through the filter 834.

As shown in FIG. 15, the sample delivery system 803 can deliver a sample of the filtrate 816 to a detection system 895 for analysis of the sample (e.g., to a conjugate pad of a lateral flow device or strip). Alternatively, the sample delivery system 803 can deliver a sample of the filtrate 806 to another device, such as an enrichment device.

The above description of the use of the sample preparation and delivery system 801 is described by way of example only and is not intended to be limiting. Based on the above descriptions of the sample preparation and delivery method 10, and the various embodiments of the sample preparation and delivery system described above, one of skill in the art should understand the various ways in which the sample preparation and delivery system of the present disclosure can be used to prepare and deliver samples.

The embodiments described and exemplified above and illustrated in the figures are presented by way of example only and are not intended as a limitation upon the concepts and principles of the present invention. As such, it will be appreciated by one having ordinary skill in the art that various changes in the elements and their configuration and arrangement are possible without departing from the spirit and scope of the present invention. Various features and aspects of the invention are set forth in the following claims.

WHAT IS CLAIMED IS:

1. A system for preparing and delivering samples for analyte testing, the system comprising:

a sample preparation system comprising:

a deformable self-supporting receptacle comprising a reservoir, the reservoir adapted to contain a liquid composition comprising a source and a diluent;

a sample delivery system coupled to the sample preparation system, the sample delivery system comprising a valve, the valve being positioned in fluid communication with the reservoir and adapted to control the removal of a sample of the liquid composition from the sample preparation system.

2. The system of claim 1, wherein the analyte includes at least one of a microorganism, a parasite, a biomolecule, a chemical, a metal ion, a metal-ion-containing complex, and combinations thereof.

3. The system of claim 1, wherein the analyte comprises at least one of *Salmonella* spp., *Acinetobacter* spp., *Vibrio* spp., *Listeria monocytogenes, Escherichia coli, Staphylococcus aureus, Clostridium perfringens, Campylobacter jejuni, Pseudomonas aeruginosa, Bacillus anthracis*, *Bacillus cereus*, *Clostridium difficile*, methicillin-resistant *Staphylococcus aureus*, vancomycin-resistant *Enterococcus*, *Norovirus*, *Norwalk virus*, *Rotavirus*, *Adenovirus*, and a combination thereof.

4. The system of claim 1, wherein the analyte comprises at least one of staphylococcal enterotoxin, *Bacillus* diarrheal toxin, *Clostridium difficile* toxin, aflatoxin, peanut allergen, egg allergen, and a combination thereof.

5. The system of claim 1, wherein the source comprises the diluent.

6. The system of claim 1, wherein the source includes at least one of a food source and a non-food source.

7. The system of claim 1, wherein the diluent includes at least one of a surfactant, a rheological agent, an antimicrobial neutralizer, a nutrient, a growth inhibitor, a pH buffering agent, an enzyme, an indicator molecule, sterile water, an organic solvent, and a combination thereof.

8. The system of claim 1, wherein the analyte includes a microorganism, and wherein the diluent includes enrichment media adapted to enrich the microorganism.

9. The system of claim 1, wherein the sample preparation system further comprises enrichment media positioned on an inner surface of the deformable self-supporting receptacle, the enrichment media adapted to grow at least the analyte.

10. The system of claim 1, wherein the valve is pressure-activated.

11. The system of claim 1, wherein the valve is further adapted to remove gas from the reservoir of the sample preparation system.

12. The system of claim 1, wherein the valve comprises a one-way valve adapted to allow fluid to move out of the sample preparation system while inhibiting fluid from moving into the sample preparation system.

13. The system of claim 1, wherein the valve is adapted to control the flow of the sample from the sample preparation system into a detection system.

14. The system of claim 1, further comprising an enrichment device coupled to the valve, the enrichment device including nutrient media adapted to enrich the analyte, the valve adapted to control the flow of the sample from the sample preparation system into the enrichment device.

15. The system of claim 1, wherein the valve forms at least a portion of a volumetric metering device.

16. The system of claim 1, wherein the sample delivery system further comprises a volumetric metering device.

17. The system of claim 16, wherein the volumetric metering device includes a dual-valve system.

18. The system of claim 17, wherein the volumetric metering device includes a plurality of valves positioned in series.

19. The system of claim 18, wherein each of the plurality of valves is a gate valve or a ball valve.

20. The system of claim 16, wherein the volumetric metering device includes a single ball valve.

21. The system of claim 16, wherein the volumetric metering device includes two one-way valves positioned in series to allow a desired volume of the sample to pass through a first one-way valve into a conduit having the desired volume, and to then pass through a second one-way valve from the conduit.

22. The system of claim 1, wherein the sample delivery system is adapted to contain the sample having a desired volume and is adapted to be removed from the sample preparation system for delivery of the sample from the sample delivery system.

23. The system of claim 1, wherein the deformable self-supporting receptacle is freestanding.

24. The system of claim 1, wherein the sample preparation system further comprises a freestanding container dimensioned to receive the deformable self-supporting receptacle, the freestanding container being more rigid than the deformable self-supporting receptacle.

25. The system of claim 24, wherein the freestanding container includes a base and an aperture defined in the base, and wherein the deformable self-supporting receptacle is accessible via the aperture.

26. The system of claim 1, wherein the deformable self-supporting receptacle includes a sidewall, and wherein the sidewall includes an accordion-type configuration.

27. The system of claim 1, wherein the deformable self-supporting receptacle includes a longitudinal axis and a sidewall, and wherein the sidewall is adapted to collapse substantially uniformly substantially along the longitudinal axis.

28. The system of claim 1, wherein the deformable self-supporting receptacle includes a sidewall, and wherein the sidewall includes at least one fold adapted to allow the sidewall to collapse.

29. The system of claim 1, wherein the deformable self-supporting receptacle includes a sidewall that is adapted to collapse, such that the deformable self-supporting receptacle includes a first state in which the reservoir defines a first volume and a second state in which the reservoir defines a second volume, the second volume being less than the first volume.

30. The system of claim 29, wherein the deformable self-supporting receptacle is in the second state prior to and after use.

31. The system of claim 1, wherein the sample preparation system further comprises a filter in fluid communication with the reservoir and adapted to filter the liquid composition to form a filtrate, and wherein the sample comprises at least a portion of the filtrate.

32. The system of claim 31, wherein the filter is coupled to a plunger, and wherein the filter is adapted to be moved through the liquid composition by the plunger to form a filtrate.

33. The system of claim 1, wherein the sample preparation system further comprises a plunger adapted to compress the deformable self-supporting receptacle.

34. The system of claim 1, wherein the sample preparation system further comprises a lid coupled to the deformable self-supporting receptacle, and wherein the sample delivery system is coupled to the lid.

35. The system of claim 34, wherein the sample preparation system further comprises a cover adapted to be coupled to the lid, and wherein at least one of the lid and the cover includes a frangible barrier.

36. The system of claim 34, wherein the sample delivery system is coupled to a port of the lid.

37. The system of claim 1, wherein the sample preparation system further comprises a freestanding container dimensioned to receive the deformable self-supporting receptacle, the freestanding container being more rigid than the deformable self-supporting receptacle.

38. The system of claim 1, wherein the sample comprises at least a portion of the liquid composition.

39. A system for preparing and delivering samples for analyte testing, the system comprising:

a sample preparation system comprising:

a freestanding container comprising a first reservoir,

a deformable self-supporting receptacle dimensioned to be received in the first reservoir of the freestanding container and comprising a second

reservoir, the second reservoir adapted to contain a liquid composition comprising a source and a diluent, the freestanding container being more rigid than the deformable self-supporting receptacle, and

a lid adapted to be coupled to at least one of the freestanding container and the deformable self-supporting receptacle; and

a sample delivery system coupled to the sample preparation system and comprising a valve, the valve positioned in fluid communication with the second reservoir and adapted to control the removal of a sample of the liquid composition from the sample preparation system.

40. The system of claim 39, wherein the analyte includes at least one of a microorganism, a parasite, a biomolecule, a chemical, a metal ion, a metal-ion-containing complex, and combinations thereof.

41. The system of claim 39, wherein the analyte comprises at least one of *Salmonella* spp., *Acinetobacter* spp., *Vibrio* spp., *Listeria monocytogenes, Escherichia coli, Staphylococcus aureus, Clostridium perfringens, Campylobacter jejuni, Pseudomonas aeruginosa, Bacillus anthracis*, *Bacillus cereus*, *Clostridium difficile*, methicillin-resistant *Staphylococcus aureus*, vancomycin-resistant *Enterococcus*, *Norovirus*, *Norwalk virus*, *Rotavirus*, *Adenovirus*, and a combination thereof.

42. The system of claim 39, wherein the source comprises the diluent.

43. The system of claim 39, wherein the source includes at least one of a food source and a non-food source.

44. The system of claim 39, wherein the diluent includes at least one of a surfactant, a rheological agent, an antimicrobial neutralizer, enrichment media, a pH buffering agent, an enzyme, an indicator molecule, sterile water, an organic solvent, and a combination thereof.

45. The system of claim 39, wherein the valve is pressure-activated.

46. The system of claim 39, wherein the valve is further adapted to provide outgassing of the sample preparation system.

47. The system of claim 39, wherein the valve comprises a one-way valve adapted to allow fluid to move out of the sample preparation system while inhibiting fluid from moving into the sample preparation system.

48. The system of claim 39, wherein the valve is adapted to control the flow of the sample from the sample preparation system into a detection system.

49. The system of claim 39, further comprising an enrichment device coupled to the valve, the enrichment device including nutrient media adapted to enrich the analyte, the valve adapted to control the flow of the sample from the sample preparation system into the enrichment device.

50. The system of claim 39, wherein the valve forms at least a portion of a volumetric metering device.

51. The system of claim 39, wherein the sample delivery system further comprises a volumetric metering device.

52. The system of claim 39, wherein the deformable self-supporting receptacle is freestanding.

53. The system of claim 39, wherein the sample delivery system is coupled to the lid.

54. The system of claim 39, wherein the sample delivery system is coupled to a port in the lid.

55. The system of claim 39, wherein the sample delivery system is coupled to a central port in the lid.

56. The system of claim 39, wherein the sample preparation system further comprises a filter in fluid communication with the second reservoir and adapted to filter the liquid composition to form a filtrate, and wherein the sample comprises at least a portion of the filtrate.

57. The system of claim 39, wherein the sample preparation system further comprises a plunger, at least a portion of the plunger dimensioned to be received in the first reservoir to compress the deformable self-supporting receptacle.

58. The system of claim 39, wherein the sample preparation system further comprises a cover adapted to be coupled to the lid, and wherein at least one of the lid and the cover includes a frangible barrier.

59. A method for preparing and delivering samples for analyte testing, the method comprising:

providing a sample preparation system comprising:

a deformable self-supporting receptacle comprising a reservoir;

providing a liquid composition comprising a source and a diluent;

positioning the liquid composition in the reservoir of the deformable self-supporting receptacle;

providing a sample delivery system adapted to be coupled to the sample preparation system, the sample delivery system comprising a valve, the valve positioned in fluid communication with the reservoir; and

applying pressure to the deformable self-supporting receptacle to remove a sample of the liquid composition from the sample preparation system via the sample delivery system.

60. The method of claim 59, wherein the analyte includes at least one of a microorganism, a parasite, a biomolecule, a chemical, a metal ion, a metal-ion-containing complex, and combinations thereof.

61. The method of claim 59, wherein the source comprises the diluent.

62. The method of claim 59, wherein the source includes at least one of a food source and a non-food source.

63. The method of claim 59, wherein the diluent includes at least one of a surfactant, a rheological agent, an antimicrobial neutralizer, a nutrient, a growth inhibitor, a pH buffering agent, an enzyme, an indicator molecule, sterile water, an organic solvent, and a combination thereof.

64. The method of claim 59, wherein the valve is pressure-activated, and wherein applying pressure to the deformable self-supporting receptacle activates the valve to open.

65. The method of claim 59, wherein the sample delivery system comprises a volumetric metering device, and wherein applying pressure to the deformable self-supporting receptacle includes moving the sample through the volumetric metering device.

66. The method of claim 59, wherein the valve is a check valve, and wherein applying pressure to the deformable self-supporting receptacle causes the check valve to exceed its cracking pressure to allow fluid to flow out of the sample preparation system.

67. The method of claim 59, wherein the sample preparation system further comprises a filter, and further comprising filtering the liquid composition with the filter to form a filtrate, and wherein the sample comprises at least a portion of the filtrate.

68. The method of claim 67, wherein the filter is coupled to a plunger, and wherein filtering the liquid composition with the filter includes pressing the plunger to move the filter through the liquid composition to form a filtrate.

69. The method of claim 59, further comprising filtering the liquid composition to form a filtrate, and wherein the sample comprises at least a portion of the filtrate.

70. The method of claim 59, wherein the sample preparation system further comprises a freestanding container that is more rigid than the deformable self-supporting receptacle, and wherein the deformable self-supporting receptacle is dimensioned to be received in the freestanding container, and further comprising positioning the deformable self-supporting receptacle in the freestanding container.

71. The method of claim 70, wherein the freestanding container includes an aperture through which the deformable self-supporting receptacle can be accessed, and wherein applying pressure to the deformable self-supporting receptacle includes applying positive pressure to the exterior of the deformable self-supporting receptacle via the aperture.

72. The method of claim 70, wherein the deformable self-supporting receptacle includes a base, wherein the freestanding container includes a base comprising an aperture defined therein, and wherein applying pressure to the deformable self-supporting receptacle includes applying pressure to the base of the deformable self-supporting receptacle via the aperture in the base of the freestanding container.

73. The method of claim 59, wherein the sample preparation system further comprises a lid, and wherein the sample delivery system is coupled to the lid, and further comprising coupling the lid to the deformable self-supporting receptacle.

74. The method of claim 59, further comprising agitating the liquid composition.

75. The method of claim 59, further comprising coupling a lid to the deformable self-supporting receptacle.

76. The method of claim 59, further comprising analyzing the sample for the analyte.

77. The method of claim 76, wherein analyzing the sample comprises analyzing using at least one of a microbiological assay, a biochemical assay, an immunoassay, a lateral flow assay, titration, a thermal analysis, microscopy, spectroscopy, spectrophotometry, chromatography, an electrochemical analysis, a genetic technique, an adenosine triphosphate (ATP) detection assay, a cytotoxicity assay, a viral plaque assay, a cytopathic effect assay, a culture technique, and a combination thereof.

78. The method of claim 76, wherein analyzing the sample for the analyte includes at least one of identifying the analyte and quantifying the analyte.

79. The method of claim 59, further comprising moving the sample from the sample delivery system to a detection device.

80. The method of claim 79, further comprising analyzing the sample for the analyte with the detection device.

81. The method of claim 59, further comprising:

coupling an enrichment device to the sample delivery system, such that the reservoir of the sample preparation system and the enrichment device are in fluid communication, the enrichment device including nutrient media adapted to grow the analyte; and

wherein applying pressure to the deformable self-supporting receptacle includes moving the sample into the enrichment device.

82. The method of claim 81, further comprising:

decoupling the enrichment device from the sample delivery system, and

incubating the enrichment device to promote growth of the analyte.

83. The method of claim 59, wherein positioning the liquid composition in the reservoir of the deformable self-supporting receptacle includes at least one of:

positioning the source comprising the diluent in the reservoir,

adding the source and the diluent to the reservoir simultaneously,

adding the source to the reservoir prior to adding the diluent to the reservoir,

adding the diluent to the reservoir prior to adding the source to the reservoir, and

combining the source and the diluent to form a liquid composition, and adding the liquid composition to the reservoir.

84. The method of claim 59, wherein the sample preparation system comprises a disposable portion comprising the deformable self-supporting receptacle and a lid coupled to the deformable self-supporting receptacle, and wherein the sample delivery system is coupled to the lid and includes a disposable portion, and further comprising disposing of the disposable portion of the sample preparation system and the disposable portion of the sample delivery system.

85. The method of claim 59, wherein the sample comprises at least a portion of the liquid composition.

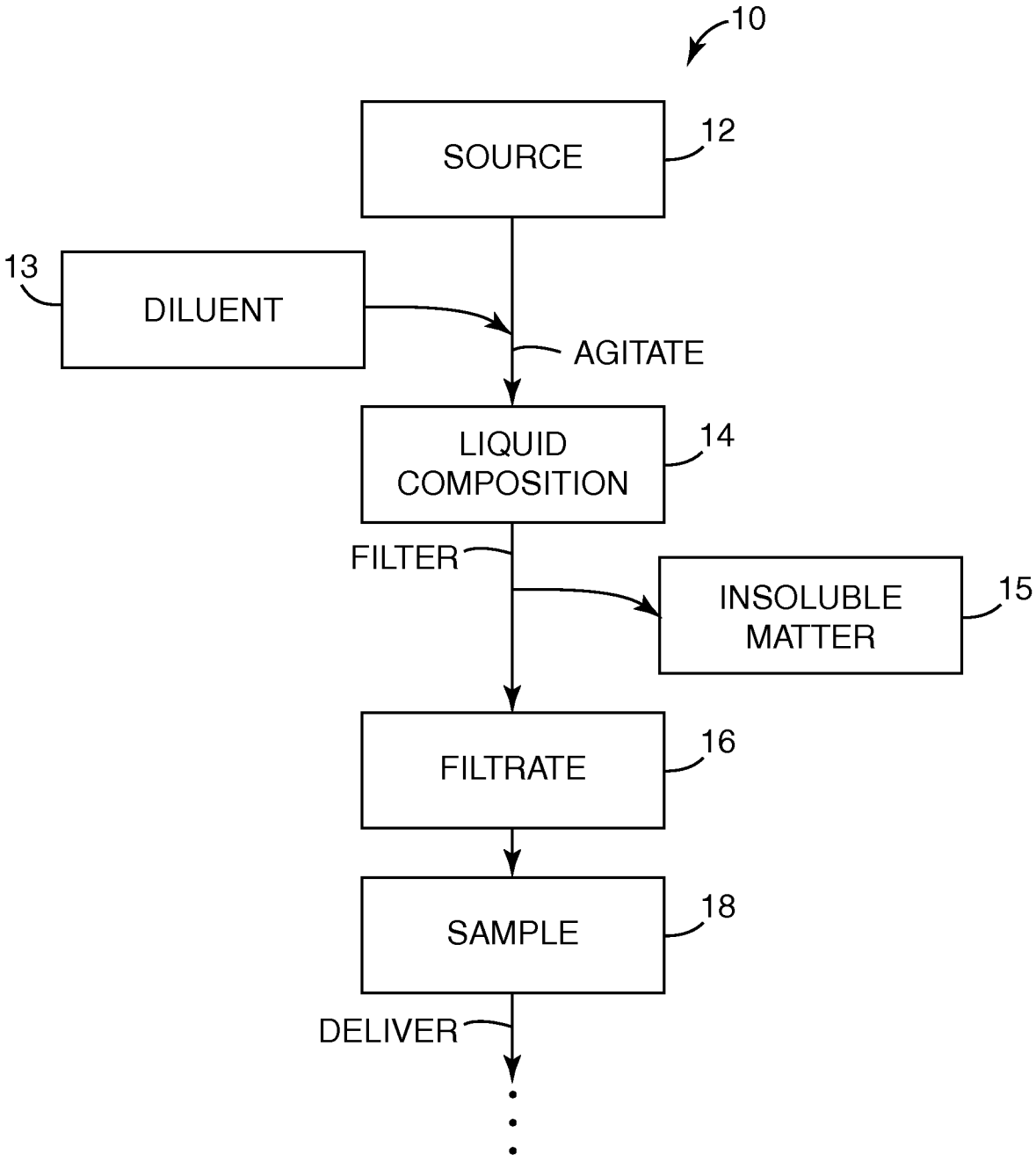
10
SOURCE
12
13
DILUENT
AGITATE
LIQUID COMPOSITION
14
FILTER
INSOLUBLE MATTER
15
FILTRATE
16
SAMPLE
18
DELIVER

FIG. 1

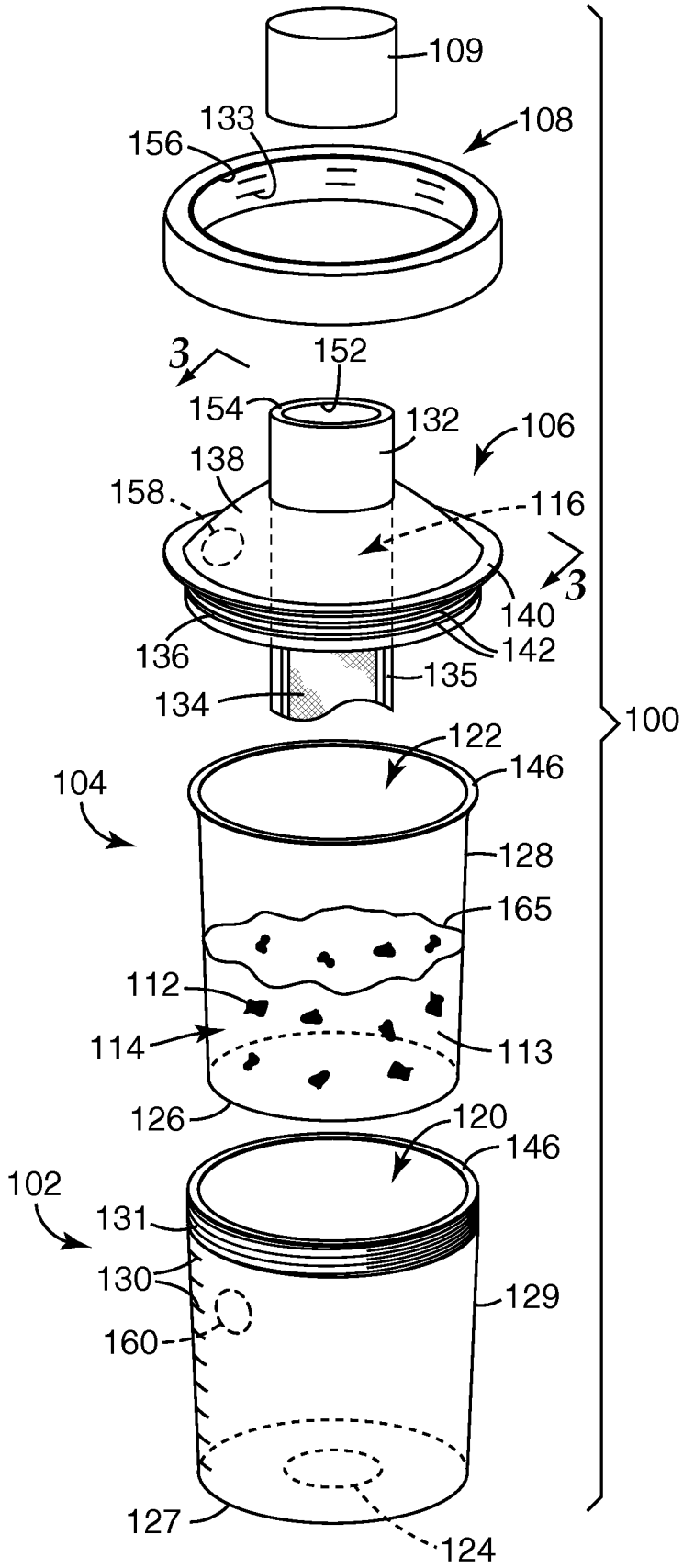
109
133
156
108
3
152
154
132
106
138
158
116
3
140
142
136
135
134
100
122
146
104
128
165
112
114
113
126
120
146
102
131
130
129
160
127
124

FIG. 2

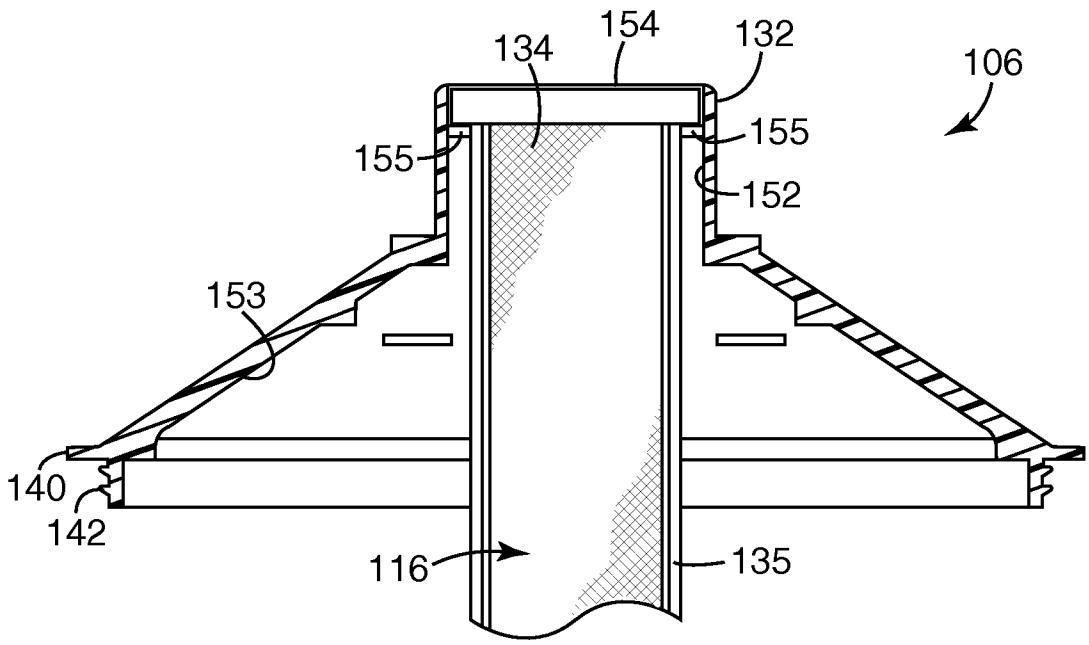
154
134
132
106
155
155
152
153
140
142
116
135

FIG. 3

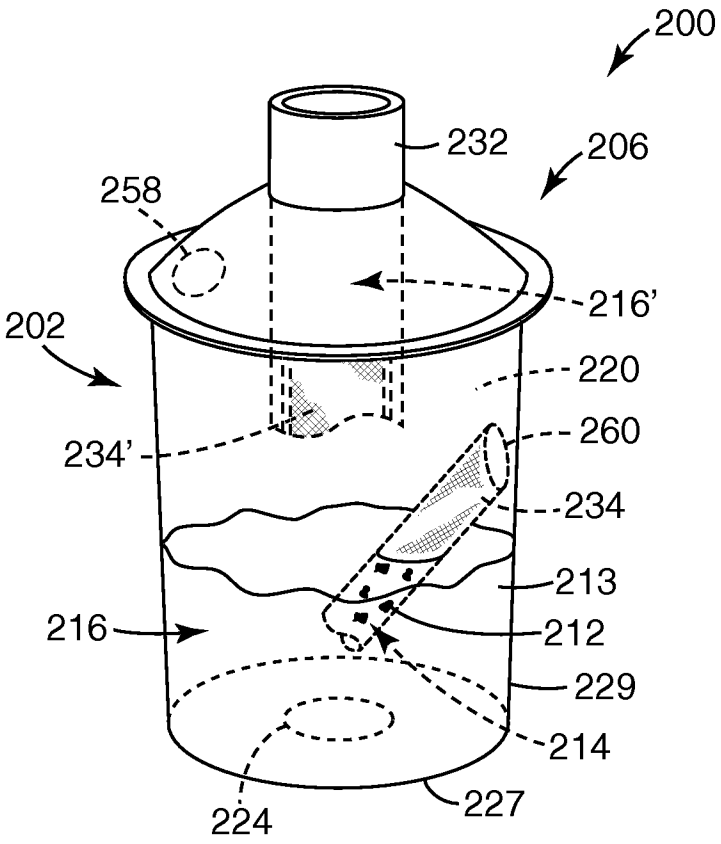
200
232
206
258
216'
202
220
234'
260
234
213
216
212
229
214
227
224

FIG. 4

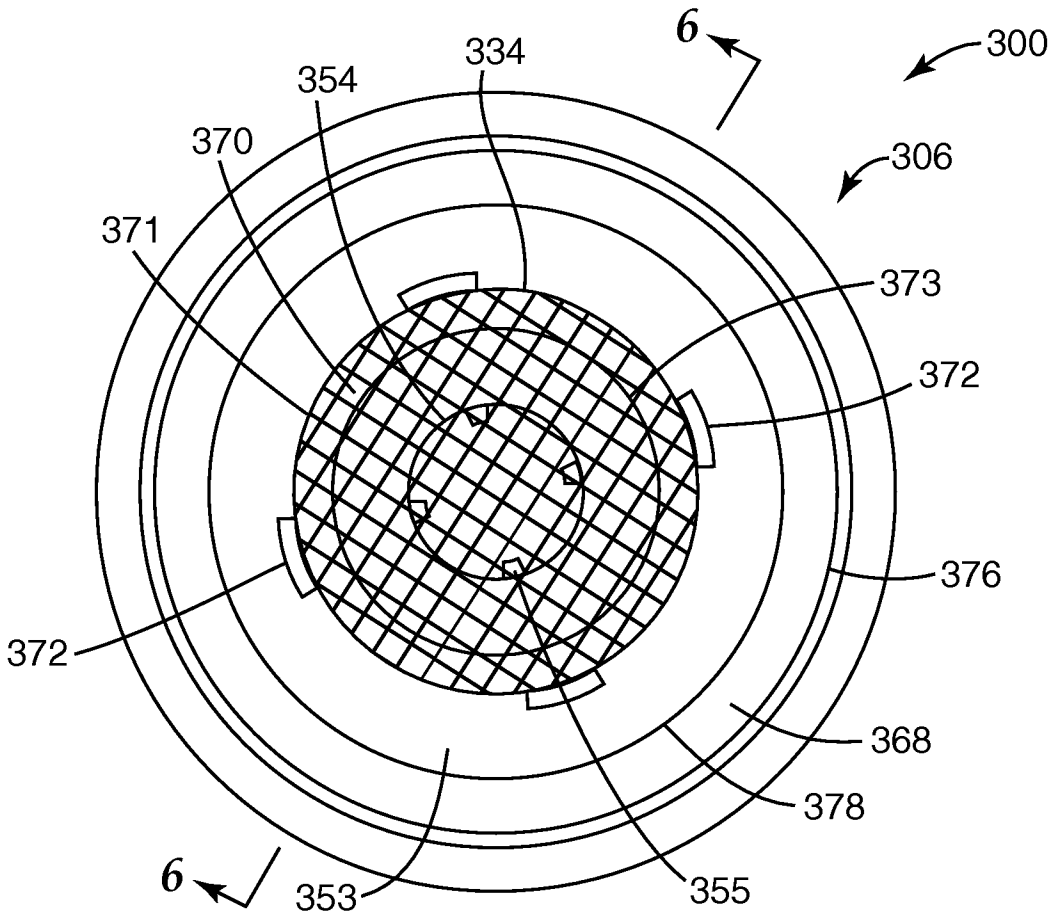
6
300
334
354
370
306
371
373
372
376
372
368
378
6
353
355

FIG. 5

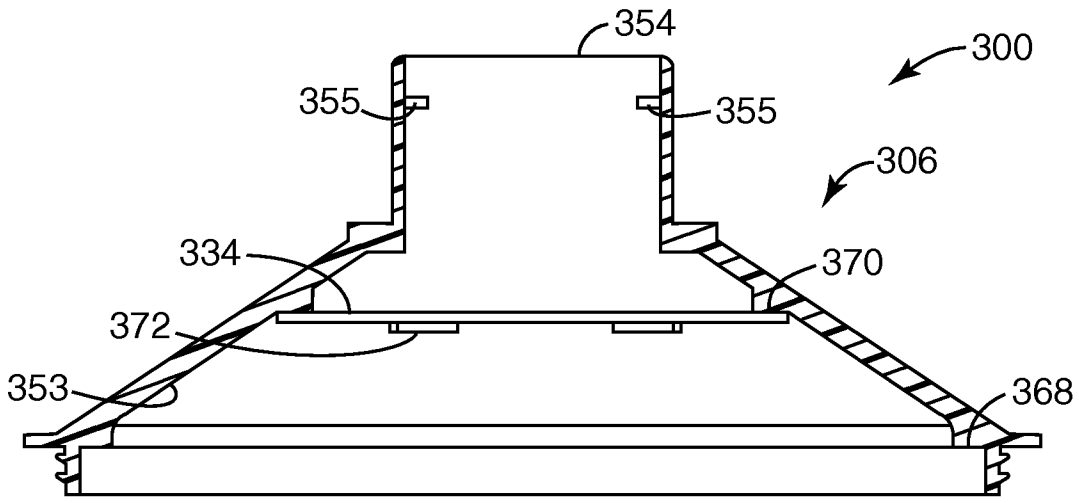
354
300
355
355
306
334
370
372
353
368

FIG. 6

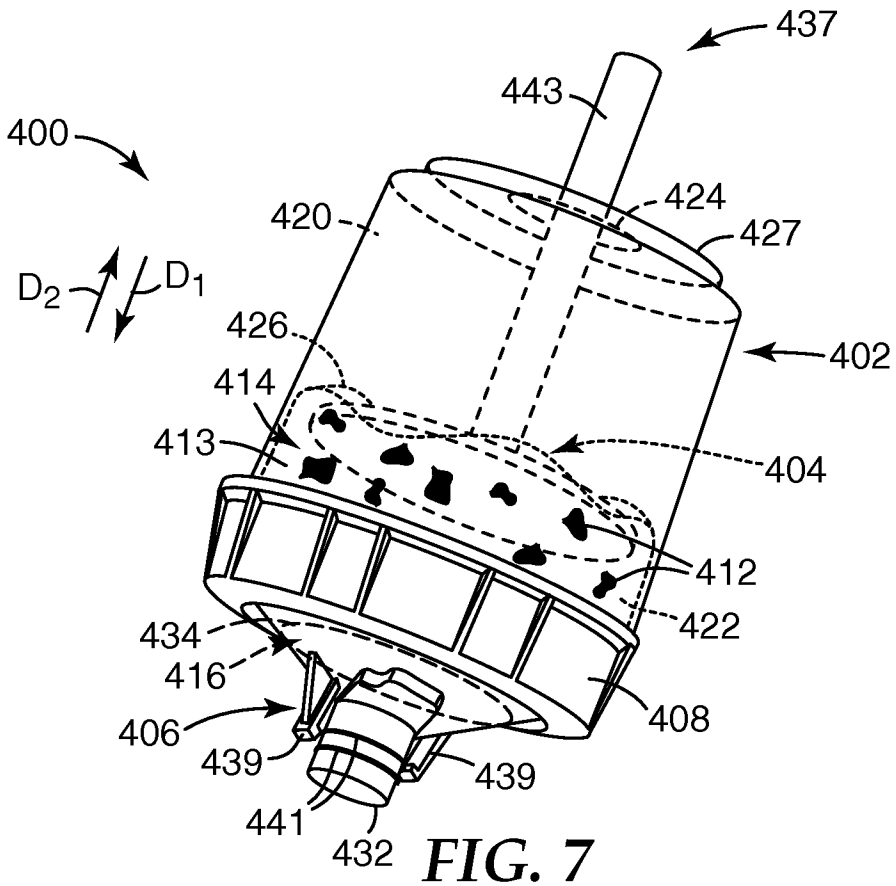
437
443
400
424
420
427
D2
D1
426
402
414
413
404
412
422
434
416
406
408
439
439
441
432

FIG. 7

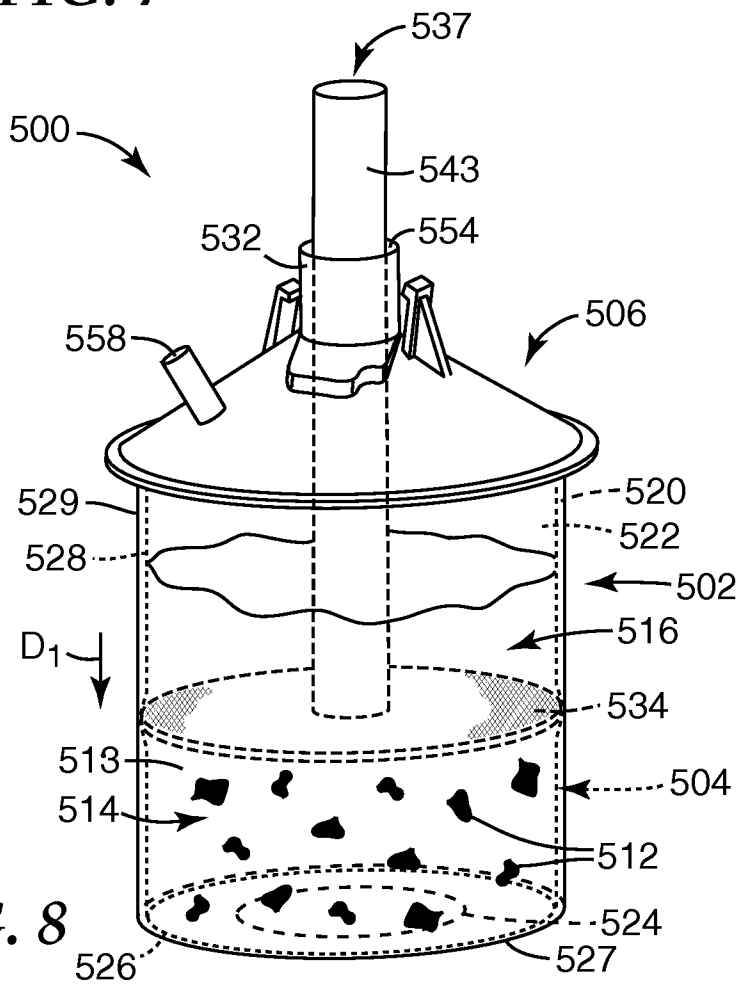
537
500
543
532
554
506
558
529
520
522
528
502
D1
516
534
513
504
514
512
524
526
527

FIG. 8

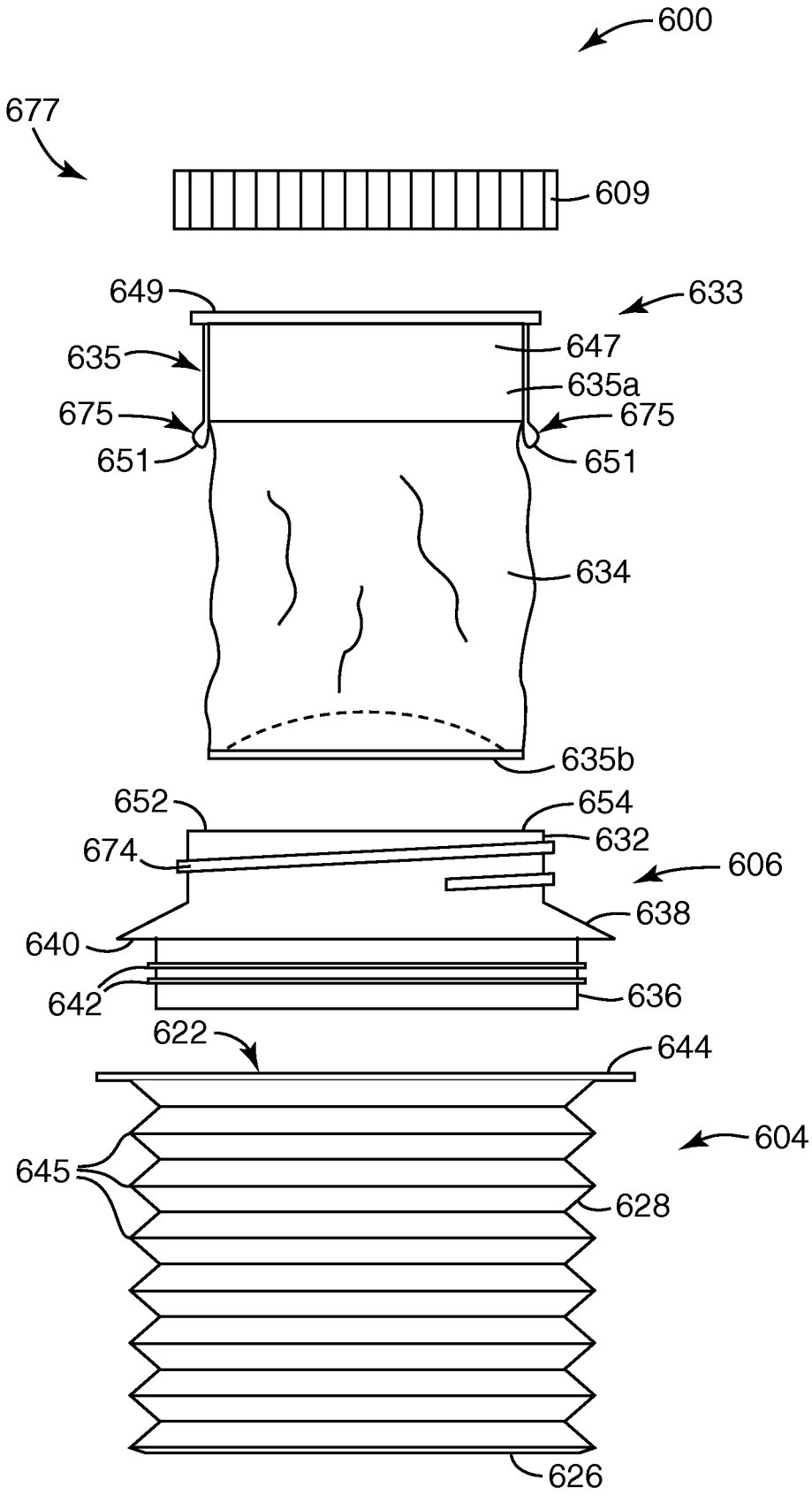
600
677
609
649
633
635
647
635a
675
675
651
651
634
635b
652
654
674
632
606
638
640
642
636
622
644
604
645
628
626

FIG. 9

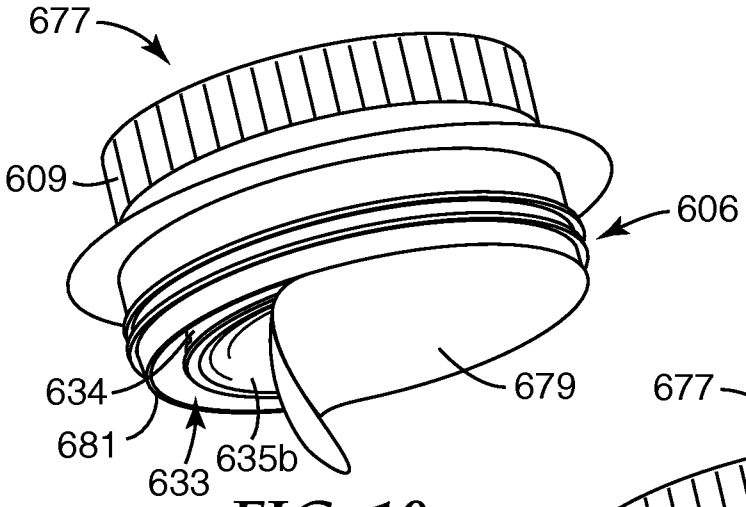

FIG. 10

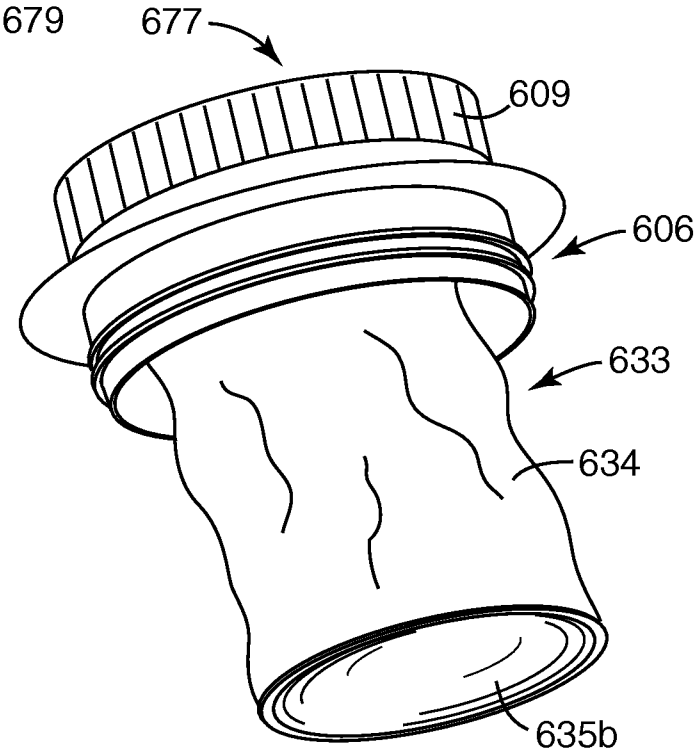

FIG. 11

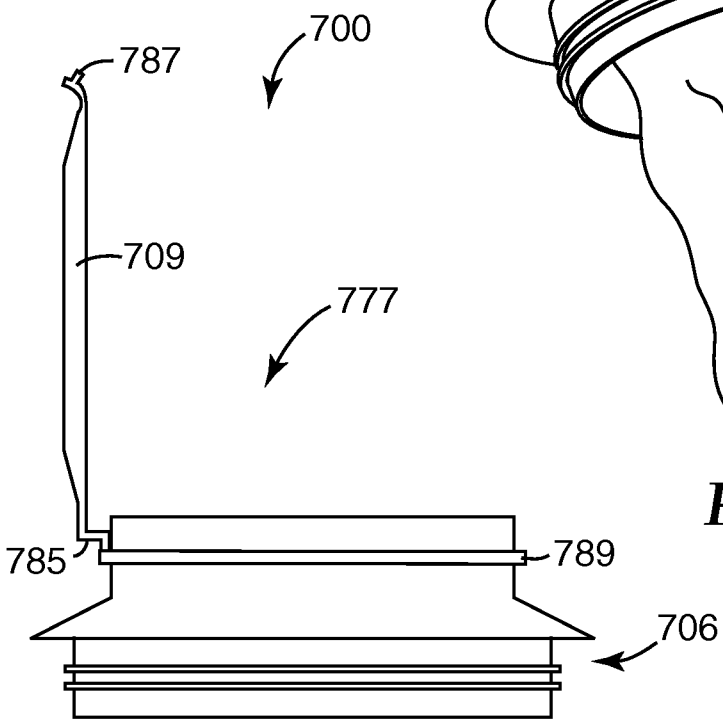

FIG. 13

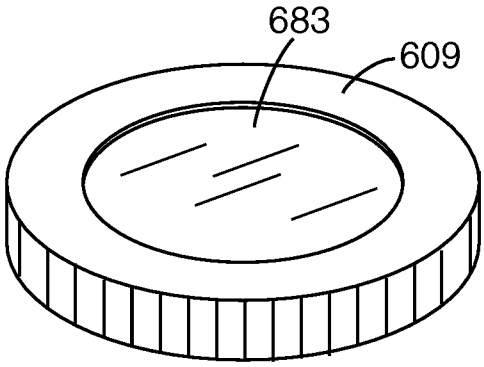

FIG. 12

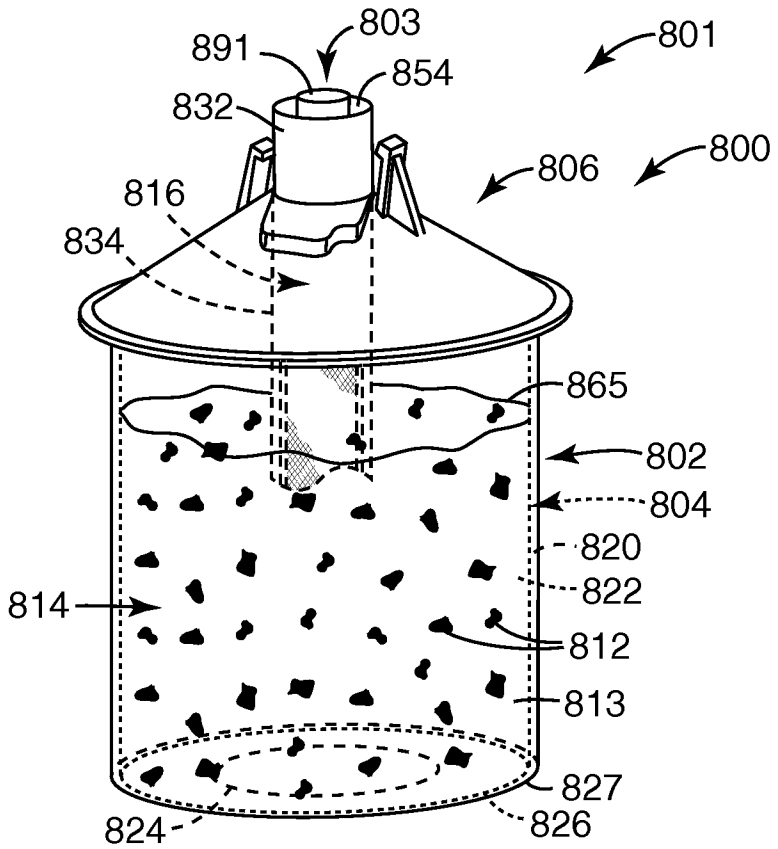
803
891
801
854
832
806
800
816
834
865
802
804
820
822
814
812
813
827
824
826

FIG. 14

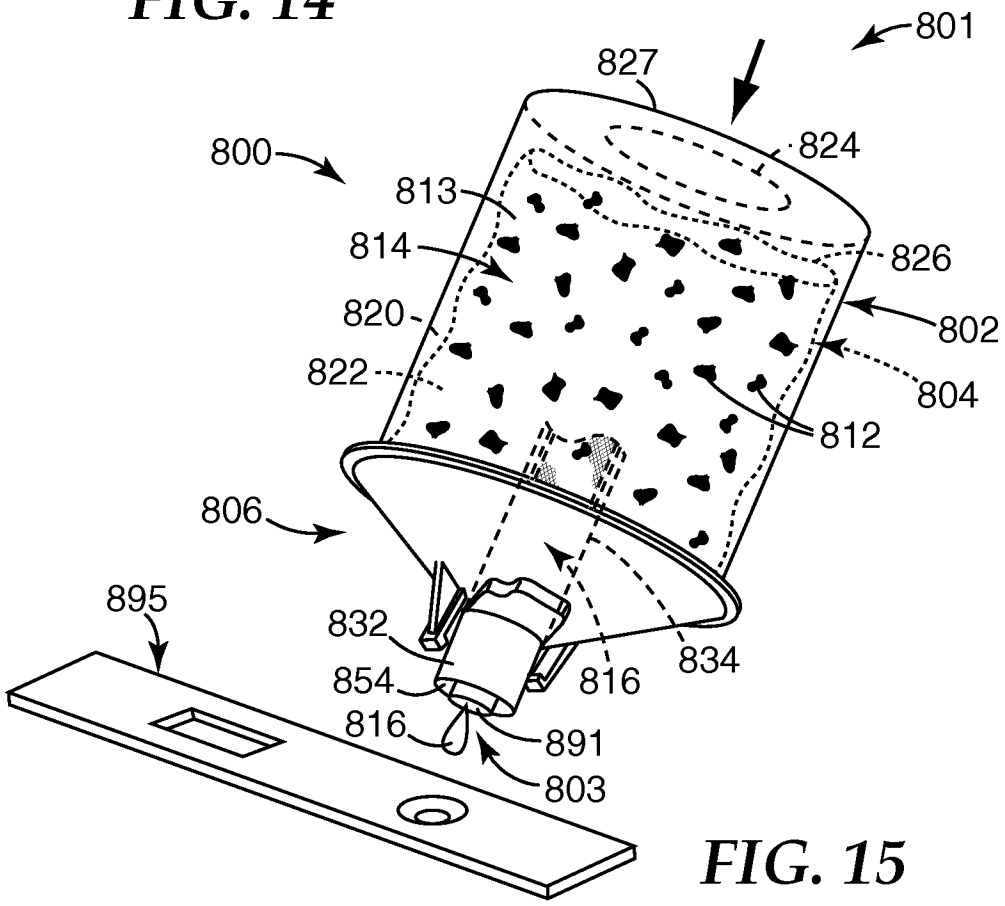
801
827
824
800
813
814
826
820
802
822
804
812
806
895
832
834
854
816
816
891
803

FIG. 15

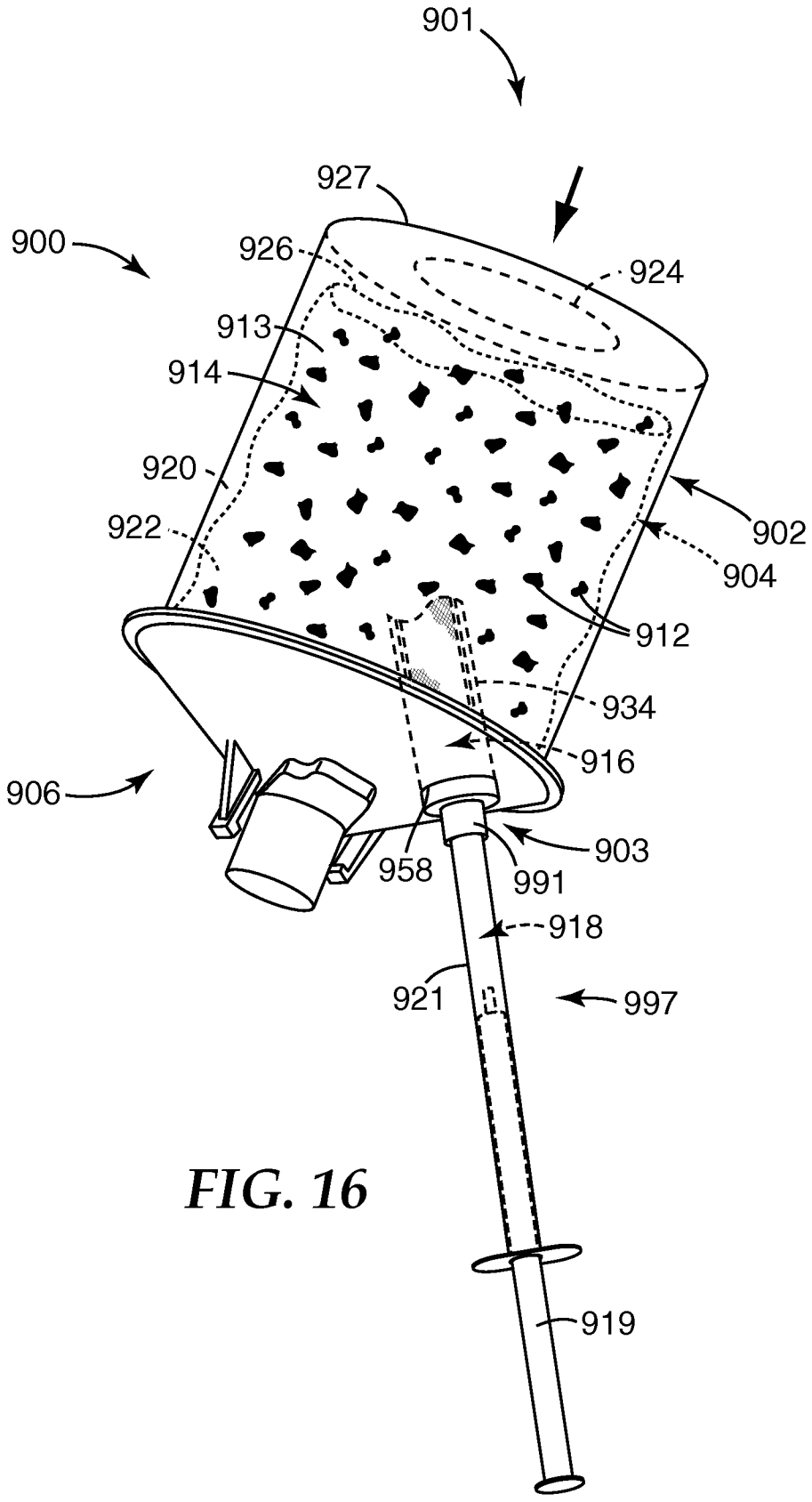
901
927
900
926
924
913
914
920
922
902
904
912
934
916
906
903
958
991
918
921
997
919

FIG. 16

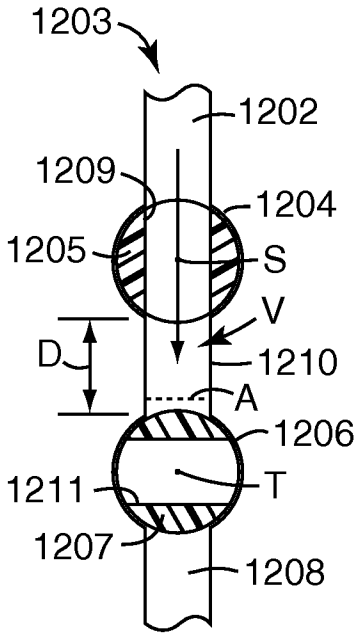

Fig. 17A

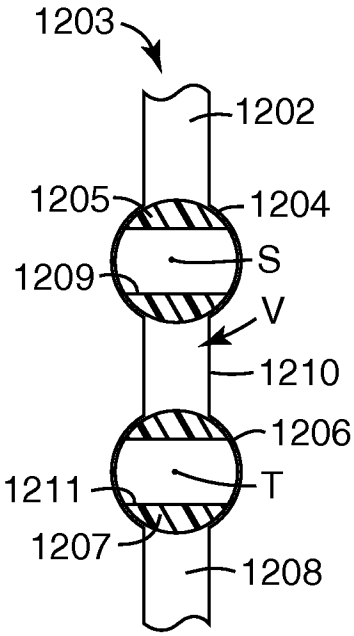

Fig. 17B

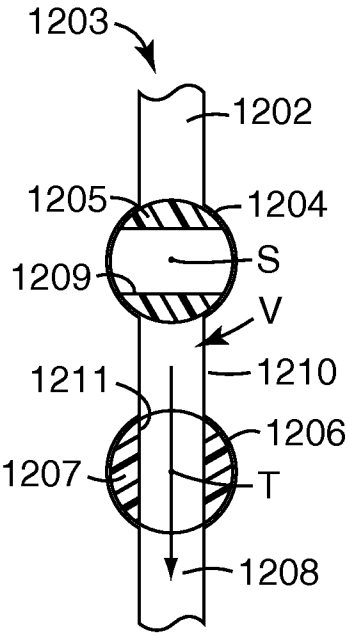

Fig. 17C

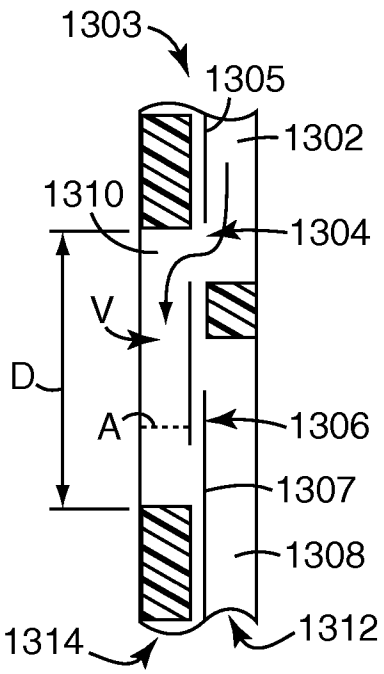

Fig. 18A

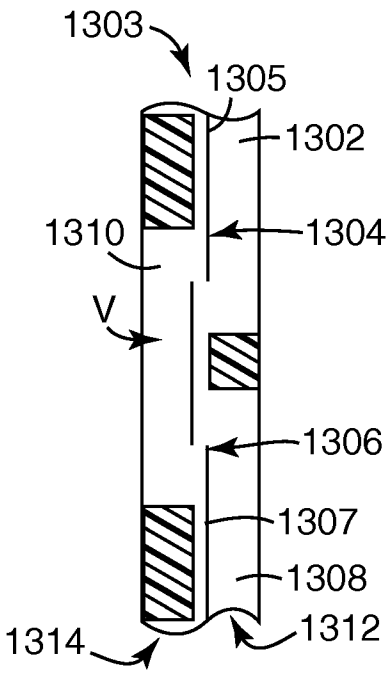

Fig. 18B

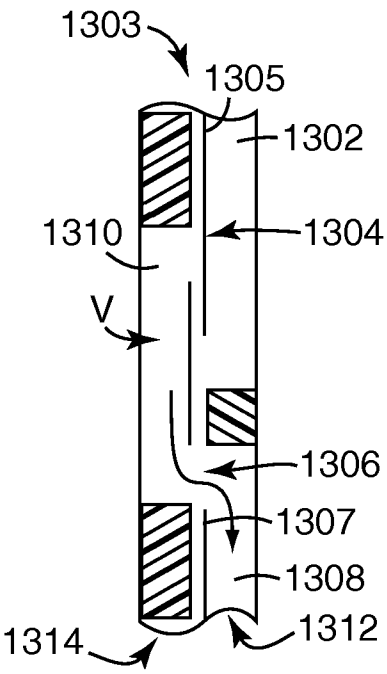

Fig. 18C

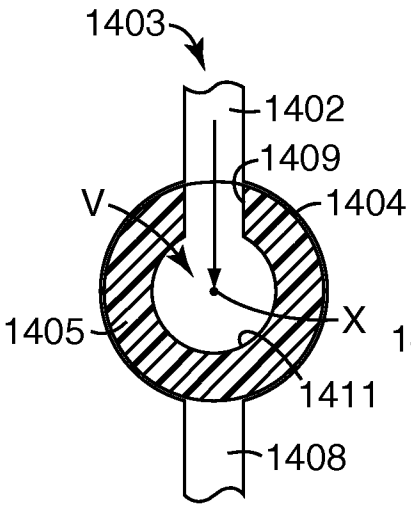

Fig. 19A

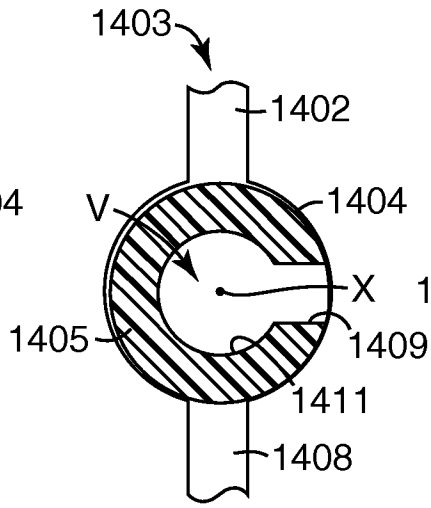

Fig. 19B

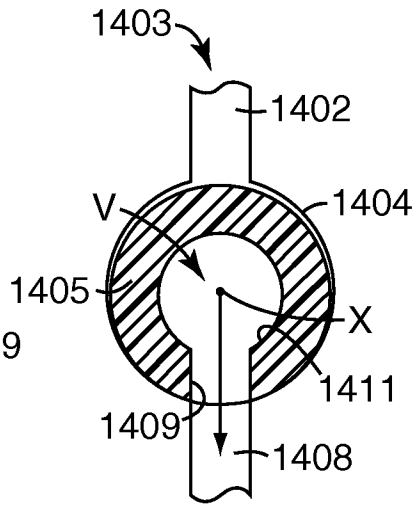

Fig. 19C

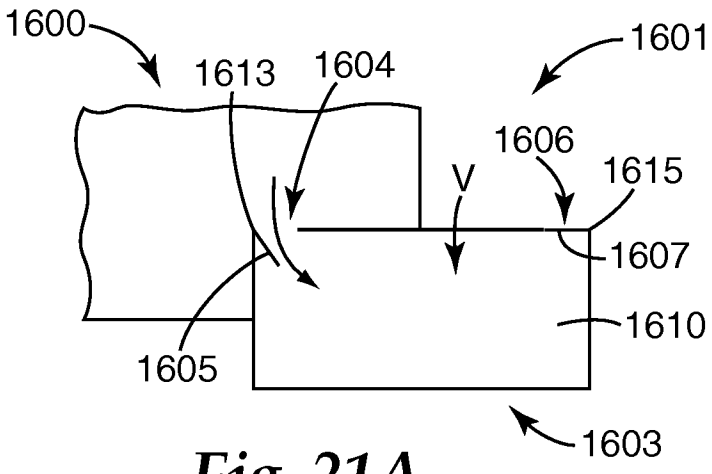

Fig. 21A

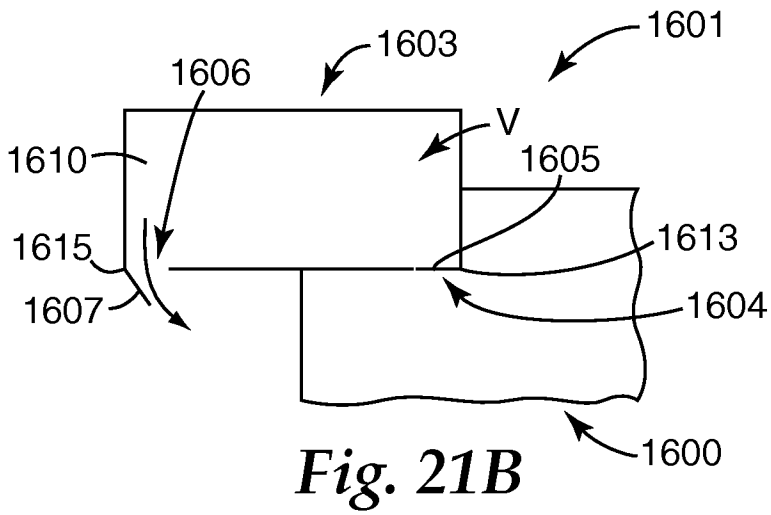

Fig. 21B

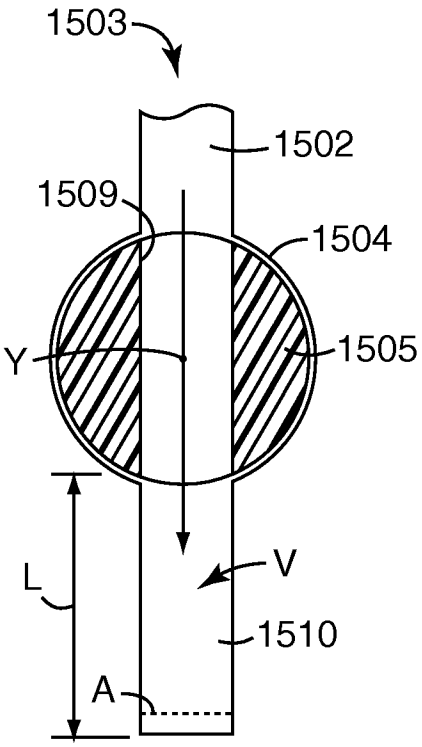

Fig. 20A

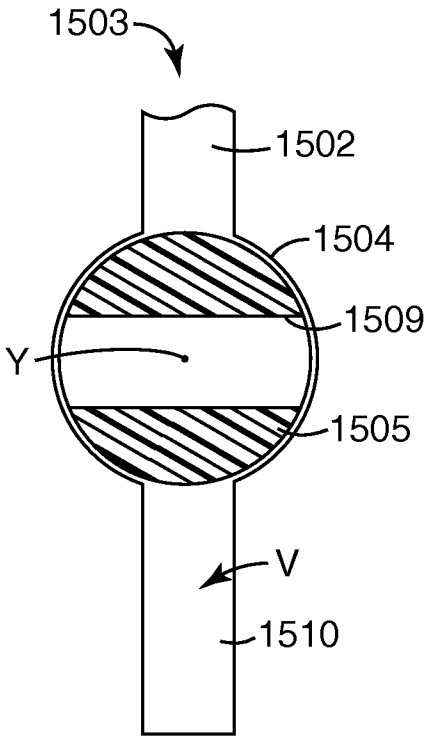

Fig. 20B

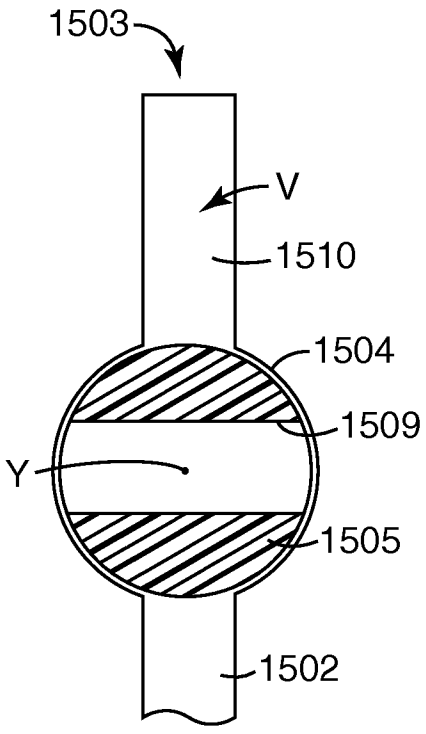

Fig. 20C

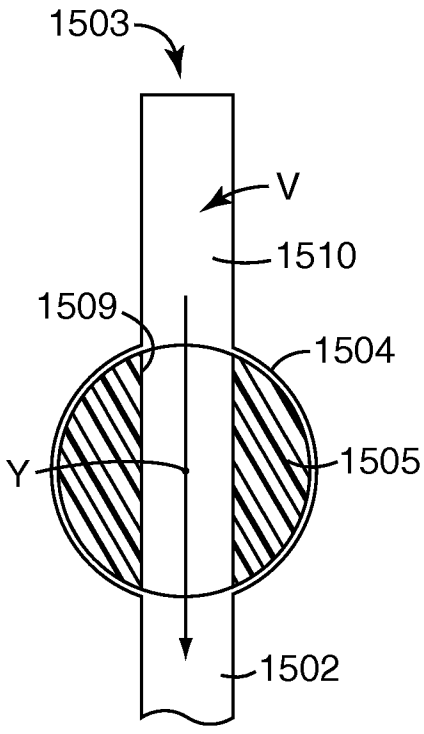

Fig. 20D

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/084035

A. CLASSIFICATION OF SUBJECT MATTER
INV. B01L3/00 G01N1/38

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)
B01L G01N

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 576 193 B1 (CUI SHUJIE [US] ET AL) 10 June 2003 (2003-06-10) column 4 - column 5 column 7 figures 1,2	1-85
A	BE 849 898 A1 (RECHERCHE ET INDUSTRIE THERAPEUTIQUES) 28 June 1977 (1977-06-28) page 1, lines 2-4,32-38 page 3, line 27 - page 4, line 29	1-85
A	WO 2007/016691 A (3M INNOVATIVE PROPERTIES CO [US]; BOMMARITO G MARCO [US]; BURTON SCOTT) 8 February 2007 (2007-02-08) page 8 - page 11 figures 1,3a	1-85

-/--

[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 document 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 February 2009	24/02/2009

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	Timonen, Tuomo

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/084035

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2004/031734 A (SECR DEFENCE [GB]; LEE MARTIN ALAN [GB]; SQUIRRELL DAVID JAMES [GB]; B) 15 April 2004 (2004-04-15) figure 3 page 22 - page 23	1-85
A	WO 98/32534 A (UNIFILL INTERNATIONAL AG [CH]; ADLER NILS PETER [NO]) 30 July 1998 (1998-07-30) figures 1-6	1-85
A	WO 2004/105949 A (SMITHS DETECTION EDGEWOOD INC [US]; GREEN DOUGLAS JASON [US]; HOLMES C) 9 December 2004 (2004-12-09) paragraph [0030]; figures 1,6	1-85
A	US 2004/237674 A1 (WU YUCHANG [CN] ET AL) 2 December 2004 (2004-12-02) figure 8	1-85
A	US 3 449 081 A (HUGHES LEONARD A) 10 June 1969 (1969-06-10) column 3, line 62 - column 4, line 17	1-85
A	US 2005/132775 A1 (LAUGHARN JAMES A JR [US] ET AL LAUGHARN JR JAMES A [US] ET AL) 23 June 2005 (2005-06-23) figure 2A	1-85
A	US 7 022 289 B1 (SCHLEIN MARK S [US] ET AL) 4 April 2006 (2006-04-04) column 9, line 15 - line 61	1-85
A	US 5 849 505 A (GUIRGUIS RAOUF A [US]) 15 December 1998 (1998-12-15) figure 2	1-85

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2008/084035

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 6576193 B1	10-06-2003	US 2003206829 A1	06-11-2003
BE 849898 A1	28-06-1977	NONE	
WO 2007016691 A	08-02-2007	AU 2006275343 A1	08-02-2007
		CA 2617427 A1	08-02-2007
		CN 101278183 A	01-10-2008
		EP 1910799 A2	16-04-2008
		KR 20080033457 A	16-04-2008
		US 2009019953 A1	22-01-2009
WO 2004031734 A	15-04-2004	AU 2003299150 A1	23-04-2004
		CA 2500073 A1	15-04-2004
		CN 1703614 A	30-11-2005
		EP 1546674 A1	29-06-2005
		JP 2006501460 T	12-01-2006
		US 2006002826 A1	05-01-2006
WO 9832534 A	30-07-1998	AU 5337698 A	18-08-1998
		ZA 9800620 A	27-07-1998
WO 2004105949 A	09-12-2004	AU 2004242961 A1	09-12-2004
		CA 2527304 A1	09-12-2004
		EP 1628770 A1	01-03-2006
		JP 2007515943 T	21-06-2007
US 2004237674 A1	02-12-2004	NONE	
US 3449081 A	10-06-1969	NONE	
US 2005132775 A1	23-06-2005	US 2008105063 A1	08-05-2008
US 7022289 B1	04-04-2006	US 7393694 B1	01-07-2008
US 5849505 A	15-12-1998	NONE	