

can be utilized. Metal silicates are known and can be chemically synthesized by known methods or obtained through the mining and processing of raw ores that are naturally-occurring.

[0081] Some amorphous metal silicates are commercially available. For example, amorphous, spheroidized magnesium silicate is commercially available for use in cosmetic formulations (for example, as 3M Cosmetic Microspheres CM-111, available from 3M Company, St. Paul, Minn.).

[0082] In addition to amorphous metal silicates, the concentration agents can also include other materials including oxides of metals (for example, iron or titanium), crystalline metal silicates, other crystalline materials, and the like, provided that the concentration agents have the above-described surface compositions. In an embodiment, a concentration agent contains essentially no crystalline silica.

[0083] The concentration agents can be used in any form that is amenable to sample contact and microorganism capture. In an embodiment, the concentration agents are used in particulate form. In an embodiment, the concentration agent is in the form of microparticles. In an embodiment, the concentration agent is in the form of microparticles having a particle size in the range of about 1 micrometer (in an embodiment, about 2 micrometers) to about 100 micrometers (in an embodiment, about 50 micrometers; in another embodiment, about 25 micrometers; in yet another embodiment about 15 micrometers; where any lower limit can be paired with any upper limit of the range).

[0084] Microbial concentration or capture using concentration agents is generally not specific to any particular strain, species, or type of microorganism and therefore provides for the concentration of a general population of microorganisms in a sample. Specific strains of microorganisms can then be detected from among the captured microorganism population using any known detection method with strain-specific probes. Thus, the concentration agents can be used for the detection of microbial contaminants or pathogens (particularly food-borne pathogens such as bacteria) in clinical, food, environmental, or other samples.

[0085] In carrying out the process of the invention, the concentration agents can be used in any form that is amenable to sample contact and microorganism capture (for example, in particulate form or applied to a support such as a dipstick, film, filter, tube, well, plate, beads, membrane, or channel of a microfluidic device, or the like). Preferably, the concentration agents are used in particulate form.

[0086] Optionally, the cell concentration agent may comprise a binding partner (e.g., an antibody, an antibody fragment, an antigen-binding domain, a lectin (e.g., Concanavalin A), a receptor, a phage receptor, or the like), which can couple to a microorganism. The coupling can be direct or indirect. The coupling can be selective for certain microorganism types or it can be nonselective.

[0087] The amount of concentration agent used to capture microorganisms from a sample can depend at least in part on the type of concentration agent utilized, the sample size, the receptacle type and size, sample mixing, the particular application, other factors not specifically discussed herein, or a combination thereof. The capture efficiency (the percent of microorganisms in the sample bound to concentration agent) can generally be increased by allowing increased time for the microorganism to come in contact with the concentration agent. The capture efficiency can also be increased by having a higher concentration of concentration agent, which

decreases the mean diffusion distance a microorganism must travel to be captured, leading to a shorter incubation time. Therefore, as a generality, the more concentration agent added, the shorter incubation time necessary to capture the same amount of microorganisms.

[0088] In an embodiment, an appropriate amount of concentration agent can vary given the time necessary to wait for the microorganisms to be bound to the concentration agent (referred to as "capture time"). For example, for a capture time of 1 minute, 1000 mg of concentration agent per 10 mL of sample could be appropriate; for a capture time of 10 minutes, 100 mg of concentration agent per 10 mL of sample could be appropriate; and for a capture time of 60 minutes, 10 mg of concentration agent per 10 mL of sample could be appropriate. In an embodiment, from about 1 mg to about 100 mg of concentration agent per 10 mL of sample can be utilized. In an embodiment, from about 1 mg to about 50 mg of concentration agent per 10 mL of sample can be utilized. In an embodiment, from about 10 mg to about 25 mg of concentration agent per 10 mL of sample can be utilized. In an embodiment utilizing a metal silicate concentration agent for example, about 10 mg of a metal silicate concentration agent per 10 mL of sample can be utilized. In an embodiment utilizing a metal silicate concentration agent for example, about 25 mg of a metal silicate concentration agent per 10 mL of sample can be utilized.

Detection Devices:

[0089] The present disclosure provides devices that can be used to detect microorganisms in a sample. The devices can include a housing comprising at least two receptacles with a passageway therebetween, an optional cell concentration agent disposed in an upper receptacle of the housing, a means for isolating at least two receptacles in the housing, and means for transferring the cell concentration agent from the upper receptacle to a lower receptacle of the housing. In some embodiments, the housing can include the means (e.g. a frangible seal) for isolating the two receptacles. In some embodiments, the housing can include the means (e.g., a valve) for transferring the cell concentration agent from the upper receptacle to the lower receptacle of the housing. In some embodiments, the devices further can include a reagent for detecting microorganisms. In certain embodiments, the devices further can include a hydrogel comprising a cell extractant. The cell extractant can facilitate the detection of a biological analyte from the microorganism.

[0090] Turning now to the drawings, FIG. 1A shows a cross-sectional view of the components of one embodiment of a detection device **100** according to the present disclosure. The detection device components comprise a housing **110** and a plunger **150**. The housing **110** includes an upper part **112** adjacent a lower part **114**. The upper part **112** and lower part **114** can be formed separately from polymeric material, such as polyethylene or polypropylene, by processes that are well-known in the art such as, for example, molding. The parts can be dimensioned such that they can be press-fit together to provide a substantially liquid-tight coupling or, alternatively, they can be coupled together by means that are known in the art (e.g., by an adhesive, sonic welding, or the like). Alternatively, the housing could be formed as a single unit by processes that are known in the art, such as extruding a hollow body, molding the passageway, and sealing the bottom of the housing with a process involving heat, for example. In other embodiments, an insert part, comprising the narrow