

receptacles with a passageway therebetween. An upper receptacle in the housing comprises an opening configured to receive a sample. A lower receptacle in the housing comprises a detection reagent disposed therein. The kit further comprises a cell concentration agent and means for transferring the cell concentration agent from the upper receptacle to the lower receptacle. In some embodiments, the cell concentration agent is disposed in the upper receptacle of the housing. In some embodiments, the kit further comprises hydrogel comprising a microbial cell extractant. In some embodiments, the kit further comprises a somatic cell extractant. In some embodiments, the kit further comprises a sample acquisition device.

#### GLOSSARY

**[0016]** “Biological analytes”, as used herein, refers to molecules, or derivatives thereof, that occur in or are formed by an organism. For example, a biological analyte can include, but is not limited to, at least one of an amino acid, a nucleic acid, a polypeptide, a protein, a nucleotide, a polynucleotide, a lipid, a phospholipid, a saccharide, a polysaccharide, and combinations thereof. Specific examples of biological analytes can include, but are not limited to, a metabolite (e.g., a small molecule, such as ATP, or a polypeptide, such as protein A), an allergen (e.g., peanut allergen(s), a hormone, a toxin (e.g., *Bacillus* diarrheal toxin, aflatoxin, etc.), RNA (e.g., mRNA, total RNA, tRNA, etc.), DNA (e.g., plasmid DNA, plant DNA, etc.), a tagged protein, an antibody, an antigen, and combinations thereof.

**[0017]** “Liquid sample”, as used herein, refers to a sample material that comprises a liquid. The sample may, in its original form, comprise a liquid such as, for example, water, milk, juice, blood, wound exudate, and the like. Alternatively, the liquid sample can be a suspension of solids in a liquid suspending medium (e.g., water, an aqueous buffer). For example, a solid, semisolid, or gelatinous sample can be collected with a sample acquisition device and suspended in a liquid to form a liquid sample.

**[0018]** “Clarified liquid sample” refers to the bulk of a liquid sample that remains after the liquid sample has been contacted with a cell concentration agent and the cell concentration agent has been partitioned (e.g., by sedimentation, filtration, centrifugation, or precipitation) from the bulk of the liquid.

**[0019]** “Sample acquisition device” is used herein in the broadest sense and refers to an implement used to collect a liquid, semisolid, or solid sample material. Nonlimiting examples of sample acquisition devices include swabs, wipes, sponges, scoops, spatulas, pipettes, pipette tips, and siphon hoses.

**[0020]** “Dead-end valve”, as used herein, refers to a type of valve that is used to regulate the transfer of material (e.g., liquids, solids, or a suspension of solids in a liquid) between two or more receptacles in the housing of a detection device. The dead-end valve is designed such that the cavity in the valve that is used to transfer the material can only be in fluid communication with one of the receptacles at a time.

**[0021]** As used herein, the term “hydrogel” refers to a polymeric material that is hydrophilic and that is either swollen or capable of being swollen with a polar solvent. The polymeric material typically swells but does not dissolve when contacted with the polar solvent. That is, the hydrogel is insoluble in the polar solvent. The swollen hydrogel can be dried to remove at least some of the polar solvent.

**[0022]** “Cell extractant”, as used herein, refers to any compound or combination of compounds that alters cell membrane or cell wall permeability or disrupts the integrity of (i.e., lyses or causes the formation of pores in) the membrane and/or cell wall of a cell (e.g., a somatic cell or a microbial cell) to effect extraction or release of a biological analyte normally found in living cells.

**[0023]** “Detection system”, as used herein, refers to the components used to detect a biological analyte and includes enzymes, enzyme substrates, binding partners (e.g. antibodies or receptors), labels, dyes, and instruments for detecting light absorbance or reflectance, fluorescence, and/or luminescence (e.g. bioluminescence or chemiluminescence).

**[0024]** The words “preferred” and “preferably” refer to embodiments of the invention that may afford certain benefits, under certain circumstances. However, other embodiments may also be preferred, under the same or other circumstances. Furthermore, the recitation of one or more preferred embodiments does not imply that other embodiments are not useful, and is not intended to exclude other embodiments from the scope of the invention.

**[0025]** The terms “comprises” and variations thereof do not have a limiting meaning where these terms appear in the description and claims.

**[0026]** As used herein, “a,” “an,” “the,” “at least one,” and “one or more” are used interchangeably. Thus, for example, a housing that comprises “a” detection reagent can be interpreted to mean that the housing can include “one or more” detection reagents.

**[0027]** The term “and/or” means one or all of the listed elements or a combination of any two or more of the listed elements.

**[0028]** Also herein, the recitations of numerical ranges by endpoints include all numbers subsumed within that range (e.g., 1 to 5 includes 1, 1.5, 2, 2.75, 3, 3.80, 4, 5, etc.).

**[0029]** The above summary of the present invention is not intended to describe each disclosed embodiment or every implementation of the present invention. The description that follows more particularly exemplifies illustrative embodiments. In several places throughout the application, guidance is provided through lists of examples, which examples can be used in various combinations. In each instance, the recited list serves only as a representative group and should not be interpreted as an exclusive list.

#### BRIEF DESCRIPTION OF THE FIGURES

**[0030]** FIG. 1A shows a cross-sectional view of one embodiment of a housing comprising two receptacles and a cross-sectional view of a plunger adapted for use with the housing, which are both components of a sample preparation and detection device according to the present disclosure.

**[0031]** FIG. 1B shows a cross-sectional view of the assembled device of FIG. 1A with the plunger disposed in the housing in a first position and including a cell concentration agent in an upper receptacle of the housing.

**[0032]** FIG. 1C shows a cross-sectional view of the device of FIG. 1B with the plunger disposed in the housing in a second position and including a liquid sample in the upper receptacle of the housing.

**[0033]** FIG. 1D shows a cross-sectional view of the device of FIG. 1C with the plunger in the first position and the cell concentration agent in a lower receptacle of the housing.

**[0034]** FIG. 2A shows a cross-sectional view of one embodiment of a housing comprising three receptacles sepa-