

**[0038]** FIGS. 9A-E is a sequential view of the steps of a method in which a representative specimen collection device fitted with a disposable external sanitary skin is used to collect a specimen on a swab.

**[0039]** FIG. 10 is a block diagram of the steps of a method for collecting a biohazardous swab in a swab collection device fitted with a disposable external sanitary skin.

**[0040]** FIG. 11 is a block diagram of the more general steps of a method for collecting a biohazardous specimen in a specimen collection device fitted with a disposable external sanitary skin.

**[0041]** FIGS. 12A and B show a detail of a tab on the disposable external cover for use in removing the protective cover after the specimen is collected.

**[0042]** FIG. 13 is a second embodiment of a specimen collection device for a swab or tampon, and includes operator interface and real-time point-of-care data display that is hidden under the cap of a protective removable overlayer during specimen collection.

**[0043]** FIG. 14 is a section down the long axis of a third embodiment of a specimen collection device for a swab or tampon, and includes operator interface and real-time point-of-care data display that is hidden under a protective removable overlayer during specimen collection.

**[0044]** FIGS. 15A and B is a first embodiment of a specimen collection device for a swab where the specimen collection device has no analytical capacity.

#### DETAILED DESCRIPTION

##### Definitions:

**[0045]** The following definitions are provided as an aid in interpreting the claims and specification herein. Where works are cited or incorporated by reference, and any definition contained therein is inconsistent with that supplied here, the definition used therein shall not supersede or limit the definition supplied herein.

**[0046]** Fomite: An inanimate object or substance, such as a doorknob, utensil, soap bar, or specimen container, that is capable of transmitting infectious organisms (broadly bacterial and viral) from one individual to another, typically by hand-to-hand or hand-to-mouth exposure to a biological residue on the surface of the inanimate object or substance.

**[0047]** Test samples: Representative biosamples taken by swab include, for example: gingival, buccal, and mucosal epithelial materials, saliva, wound exudates, pus, surgical specimens, lung and other respiratory secretions, nasal secretions, sinus drainage, sputum, blood, urine, medial and inner ear contents, ocular secretions and mucosa, cyst contents, cerebral spinal fluid, stool, diarrhoeal fluid, tears, mammary secretions, ovarian contents, ascites fluid, mucous, gastric fluid, gastrointestinal contents, urethral discharge, vaginal discharge, vaginal mucosa, synovial fluid, peritoneal fluid, meconium, amniotic fluid, semen, penile discharge, or the like may be presented for testing on a swab. Assay from swabs representative of mucosal secretions and epithelia are acceptable, for example mucosal swabs of the throat, tonsils, gingival, nasal passages, vagina, urethra, rectum, lower colon, and eyes. Besides physiological fluids, samples of water, industrial discharges, food products, milk, air filtrates, and so forth are also likely test specimens. Particularly preferred as samples are biosamples collected on swabs or tampons, where a tampon is essentially a handleless swab that is sometimes worn internally before testing.

**[0048]** Biohazard: A biohazard is a material, either biologically active or inanimate, that poses a risk or threat to health. Also included in this category as biohazards, *sensu lato*, as defined here, are materials of likely biological origin that are visually, tangibly, or odorously objectionable or repulsive, and those materials which are not in fact a threat, but which potentially are a threat until tested negative. Biohazards include potentially infectious material of any kind, and may contain infectious agents from multiple biological categories, including but limited to, bacteria and viruses, either singly or in one or more combinations thereof, and microbial products such as toxins.

**[0049]** Bioassay Target Molecule: or “analyte of interest”, or “target molecule”, may include a nucleic acid, a protein, an antigen, an antibody, a carbohydrate, a cell component, a lipid, a receptor ligand, a small molecule such as a drug, and so forth. Target nucleic acids include genes, portions of genes, regulatory sequences of genes, mRNAs, rRNAs, tRNAs, siRNAs, cDNA and may be single stranded, double stranded or triple stranded. Some nucleic acid targets have polymorphisms, deletions and alternate splice sequences. Multiple target domains may exist in a single molecule, for example an immunogen may include multiple antigenic determinants. An antibody includes variable regions, constant regions, and the Fc region, which is of value in immobilizing antibodies. The microfluidic analytical devices of the present invention are configured to detect a bioassay target molecule of these sorts, singly or in combinations.

**[0050]** Such bioassay target molecules may be associated with a pathogenic condition: which is taken as a condition of a mammalian host characterized by the absence of health, i.e., a disease, infirmity, morbidity, or a genetic trait associated with potential morbidity.

**[0051]** Microfluidic cartridge: a “device”, “card”, or “chip” with fluidic structures and internal channels having microfluidic dimensions. These fluidic structures may include chambers, valves, vents, vias, pumps, inlets, nipples, and detection means, for example. Generally, microfluidic channels are fluid passages having at least one internal cross-sectional dimension that is less than about 500  $\mu\text{m}$  and typically between about 0.1  $\mu\text{m}$  and about 500  $\mu\text{m}$ , but we extend the upper limit of the range to 600  $\mu\text{m}$  because the macroscopic character of the bead suspensions sometimes used as analytical aids require it. Therefore, as defined herein, microfluidic channels are fluid passages having at least one internal cross-sectional dimension that is less than 600  $\mu\text{m}$ .

**[0052]** Microfluidic cartridges may be fabricated from various materials using techniques such as laser stenciling, embossing, stamping, injection molding, masking, etching, and three-dimensional soft lithography. Laminated microfluidic cartridges are further fabricated with adhesive interlayers or by adhesiveless bonding techniques, such by thermal or pressure treatment of oriented polypropylene or by ultrasonic welding. The microarchitecture of laminated and molded microfluidic cartridges can differ according to the limitations of their fabrication methods.

**[0053]** Microfluidic pumps: include for example, bulbs, bellows, diaphragms, or bubbles intended to force movement of fluids, where the substructures of the pump have a thickness or other dimension of less than 1 millimeter. Such pumps include the mechanically actuated recirculating pumps described in U.S. Pat. No. 6,743,399 to Weigl and US 2005/0106066 to Salzman, commonly assigned to the applicant. Such pumps may be robotically operated or operated by