

sort are disclosed, and which is herein incorporated in full by reference. Also useful are absorbent bats.

[0078] Preferably, the devices are self-contained and contain at least on-board reagent for conducting the analysis. In some cases the reagent is a fluid, for example an extraction buffer or a lysis reagent, but in other cases the reagent is a dried biological, for example a primer mix, an antibody, a polymerase, a divalent cation, or a dried weak acid and its salt. By designing the device to be self-contained, single entry use at the point-of-care is enabled. Liquid reagent storage may be achieved by supplying the reagents in sachets, which are ruptured when needed, by methods known in the art. These methods typically supply a sharp upon which the sachet is compressed so that it ruptures. Compression of the sachet may be by manual means or by pneumatic means.

[0079] FIG. 4 shows an exploded view of disposable external skins (2,3) applied to a device body (45). Here, both the upper skin (2) and lower skin (3) are shown. A ribbed surface (44) is provided for gripping the device. These skins may be applied as decals. The upper and lower skins may be made from a flexible plastic film or sheet, such as polyethylene, vinyl, polyvinyl chloride, PET or polyurethane, and are typically applied to the device with a removable, pressure sensitive adhesive that can be removed without residue. Candidate commercially available films include 3M™ Scotchcal™ Graphic Film Series 3470 or 3M™ Scotchcal™ Graphic Film Series 8000 available from 3M (St. Paul, Minn.) and adhesives include ROBOND™ PS-8211 latexes available from Rohm And Haas (Philadelphia, Pa.). Other suitable decal materials include paper sheet, waxed paper sheet, and fiber/plastic or plastic/plastic composite sheets or films, such as polyethylene film bonded over cloth scrim. These sheets or films are typically printed with graphics and written instructions for the user. Optionally the instructions are printed onto the device body and the film cover is transparent. The adhesive is typically an acrylate derivative. Examples of repositionable and removable adhesives are emulsified polymers made from "soft" monomers such as n-butyl acrylate, isooctyl acrylate, or the like, or ionomeric copolymers made from a soft component, such as isobutylene, n-butyl acrylate, isooctyl acrylate, ethyl hexyl acrylate, or the like; in combination with a polar monomer such as acrylic acid, acrylonitrile, acrylamide, methacrylic acid, methyl methacrylate, trimethylamine methacrylimide, trimethylamine p-vinyl benzimide, ammonium acrylate, sodium acrylate, N,N-dimethyl-N-(.beta.-methacryloxyethyl)ammonium propionate betaine, 1,1-dimethyl-1-(2-hydroxypropyl)amine methacrylimide, 4,4,9-trimethyl-4-azonia-7-oxo-8-oxa-9-decene-1-sulphonate, 1,1-dimethyl-1-(2,3-dihydroxypropyl)amine methacrylimide, and maleic anhydride or the like. Non-spherical polyacrylate adhesives are commercially available, for example, as the Rohm and Haas Rhoplex™ line of adhesives. The adhesive applied to the film is typically repositionable or removable without residue, the adhesive may be selected from any adhesive that may be repeatedly adhered to and removed from a substrate without substantial loss of adhesion capability. An example of such an adhesive is disclosed in U.S. Pat. No. 3,691,140 to Silver, which relates to solid tacky microspheres. Preferred adhesives are water resistant when dry. Repositionable adhesives are also known in which microspheres contained in the adhesive are non-tacky. A disclosure of this type of adhesive is provided in U.S. Pat. No. 4,735,837 to Miyasaka, which describes removable adhesives containing elastic micro-balls with the desired proper-

ties. The decal to be applied to the device is typically supplied on a release liner and has good moisture and chemical resistance and the adhesive has a working life of greater than 6 months. The decal may be a composite multilayered sheet to achieve these objectives. Multilayered decals variously fabricated from overlayer, liquid crystalline polymer, plastic, silicone, rubber, thermoplastic, paper, interlaid fiber, underlayer, microporous plastic, backing, scrim, cloth, and adhesive are anticipated for this use.

[0080] FIG. 5 shows a representation of how a disposable protective cover can be applied using tubestock of heatshrink plastic (50), as is readily commercially available. Once the device is inside a suitable length of the heatshrink material, heat is applied to form the coverlayer to the shape of the device. The swab receiving orifice can be provided with an adhesive-backed decal or appliqué that would be removed immediately before use, exposing the orifice, and also serves as a tamper-evident seal. A tearstrip may similarly be applied to the heatshrink wrapping so that the entire skin can be removed with a single motion. Candidate heat shrinkable thermoplastic films include those polyethylene composites described in U.S. Pat. No. 7,235,607, the polyethylene terephthalate esters of U.S. Pat. No. 6,623,821, and the thermoplastics of U.S. Pat. No. 3,655,503, for example.

[0081] FIG. 6 describes a similar protective cover, but made out of a soft plastic bag such as a polyethylene or polyolefin, or out of paper. The paper may be impregnated with a water repellent material or may be absorbent. The plastic or paper bag (60) is formed to include a male sealing rib (61) that mates with a corresponding female locking groove (62) on the exterior circumference of the device body. A tearstrip is provided for ease of removal. The swab receiving orifice 6 can be configured to a variety of swab dimensions and shapes. When the swab is safely captured within the device, closure 7 is pushed across the opening to seal the device.

[0082] The theme is repeated in the composite device (70) of FIG. 7. Here the disposable outer skin consists of a Styrofoam block or similar expanded material formed by molding, which is fabricated to fit the lower half of the device (71), and a partial lid fitted to the upper half of the device (72), leaving the swab receiving orifice 6 exposed. A tearstrip (73) serves the dual function of adhering the two halves of the outer skin together during sample collection, and is then torn or peeled away so that the halves can be separated and the device removed for further processing or analysis. The tearstrip typically includes a freehanging tab to facilitate this. The lower block and upper lid are discarded after the device is removed.

[0083] Note that the shape of the blocks forming the outer skin 70 is variable. A clamshell formed of right and left halves is equally suitable, as are more complex interdigitated two part blocks. A single block is useful. The dual block system has the advantage that squeezing pressure applied to the lower block has the effect of holding the device in place while the tear strip and upper lid are removed. The device can then be pulled out of the lower block with clean hands and presents an uncontaminated exterior, the closure having been pulled over the swab receiving orifice from its protected position under the upper lid.

[0084] FIG. 8 shows a conceptual view of a more general form of the composite sample collection device (80) with disposable outer skin (81). Here the disposable outer layer material can be a quilted material, a composite of waterproof and absorbent layers, a diaper, a foil composite, and so forth. The material is knit or fused around the edges into a pouch