

holding the device, and is torn away at a frangible or pre-weakened tear point after the sample is collected. U.S. Pat. No. 4,279,344 describes a packaging laminate which is heat sealable and peelable suitable for this construction.

[0085] FIG. 9 is a pictorial representation of the essential features of the swab capture method, and shows a multistep process with steps A-E and a representative device (1) and swab (20). In FIG. 9A and B, the swab (20) is oriented to the swab receiving orifice (6) of the device body (1) and the tip of the swab (25) is inserted into the device. In step C, the handle (22) is broken away and discarded. The locking closure (7) is then slid over the orifice (6) to irreversibly capture and seal the swab tip in the device, as shown in FIG. 9D. In step E, the disposable external skins, or “decals”, are then peeled away (shown is the upper skin 2 peeling away), refreshing the external surfaces and removing any extraneous material inadvertently deposited when collecting the sample. The fresh external surfaces are used to label the specimen contents and patient identification, or optionally a label with that information can be applied to those surfaces.

[0086] FIG. 10 is a block diagram of these steps of the general method for swab capture. The steps are: collect a specimen on a swab; insert the swab tip into the collection device as designed for receiving the swab, and break off the swab handle; seal the swab in the device using a locking closure; remove the disposable skin or skins from the external surfaces of the collection device, taking care to avoid contaminating the freshly exposed surfaces. Optionally, an analysis may then be performed on the swab in the device without further exposure to the biohazardous sample.

[0087] Note that the order of the steps is not strictly followed if the swab handle is broken off and the device sealed after the external skins are removed, and it may be that handling the device in this way is more convenient. However, the preferred method is to capture the swab and seal the device before removing and discarding the external protective skins. As claimed, the invention is not limited by the order of these steps.

[0088] FIG. 11 is a block diagram of a more general method for specimen capture. The specimen is first collected and inserted in a suitable container, the container having been supplied with disposable external skin or skins; the container is then sealed; and the external skins or skins are removed and discarded.

[0089] FIGS. 12A and 12B are overview and detail, respectively, of the tab members (4,5) used as a peelaway strip for removing the external skins of a representative device. As shown in detailed view 12B, the tabs are freestanding at the edges of the body of the device, and are easily grasped between finger and thumb. The entire protective film or pad is then readily peeled away.

[0090] FIG. 13 is an alternate embodiment of a combination specimen collection container and sheath (130), showing an alternate form of the external protective skin and internal specimen collection device. Here the analytical device (131) shown is fitted with internal analytical works and a user interactive panel and display window.

[0091] In use, the body of the sample collection device 131 is encased in an outer sleeve member (132) and cap member (133). The outer sleeve member is supplied with an endwise swab receiving orifice (134) and internal swab receiving chamber for collecting the swab. A ball valve type closure is used to capture and seal the swab in the device and a knob is provided (135) for rotating the ball valve from open to closed.

The control head 136 may also be rotated, and serves to power a spring-driven pressure source for the pumps, and to initiate the assay protocol. Assay status is shown in the leftmost window 137. Assay results are shown in the rightmost window 138.

[0092] After the sample is collected, the outside protective sleeve 132 is removed and the sample receiving chamber is closed with the ball valve 135. The cap can then be removed and the apparatus is generally free of external contamination. The sample entry end can be covered. The control head is then rotated and the assay commenced. In a few minutes, the assay result is read in the display window. Status and validity of the assay is displayed in the left panel. Optionally, the device can be inserted into a machine and the assay conducted by machine-aided power and control. The outer sleeve and cap are discarded as contaminated medical waste. At the completion of the assay, the device is also discarded along with its entrained specimen.

[0093] Note that the embodiment is illustrative of a general concept, and is not limited by its specificity. The outside protective sleeves are disposable external skins. The sleeves may be replaced by decals as described in FIG. 4, wherein the decals are adapted for a cylindrical body form. Similarly, the disposable protective overlayer may be as provided in FIGS. 5-8.

[0094] This device is also suitable for collection of tampons, which lack the handle characteristic of swabs. The tampon, however, must be inserted into the swab receiving orifice with tweezers or by other means and the orifice must be dimensioned appropriately. Tampons are useful sample collection devices, and their use is hereby taken within the scope of the invention described herein.

[0095] This device is conceived as part of a kit, the kit consisting of a sterile swab, the combination specimen collection device and sheath 130, and a tray. The tray optionally may also contain surgical gloves, instructions, and labeling aids.

[0096] A variation of composite device 130 is shown in FIG. 14. Here the sample is inserted through orifice (141) in external disposable cap (142) into device (140), the body of which contains a sample receiving chamber with threaded neck (143). After the sample is deposited in the device, the cap 142 is immediately removed and a clean, sterile lid (not shown) is threaded onto the neck. The device body thus functions as bottle. Holding the assembly by the clean lid, the lower outside protective sheath (144) is then removed.

[0097] The external surfaces of the device are now clean and safely handled without gloves. Objectionable materials deposited on the outside sheath are discarded along with the disposable sheaths, which function as an external protective skin.

[0098] In this embodiment, the operator then presses the start button (146); the instrument cycles, its status continuously displayed in status bar 147, and the raw data is read from nucleic acid hybridization array 148. The machine is placed under a modified bar code reader or strip reader and the data is electronically displayed on the reader and transmitted as an electronic medical record to the patient's chart.

[0099] These various analytical features are not presently viewed as limitations of the present invention. The present invention relates to methods and devices for collecting specimens and for analyzing specimens in which a pre-formed disposable external skin is removed from the collection device or sample holder after the specimen is deposited in it.