

venting cross-sample contamination, and just as importantly, to prevent exposure of those persons handling the specimens to objectionable or potentially infectious materials. As has been noted, (Nelson, D. B. et al. 2003. "Self-Collected Versus Provider-Collected Vaginal Swabs for the Diagnosis of Bacterial Vaginosis: an Assessment of Validity and Reliability," J Clin Epidemiol, 56:862-866), there is an increasing trend toward patient self-collection of samples, often with swabs or cups. Typically the patient is not provided with means to ensure that the external surfaces of the sample collection device does not become contaminated with the sample or related biological fluids during handling. These swabs or cups are typically then processed or handled by ungloved couriers and paraprofessionals and must then be transferred to the analytical device or further handled and processed by nursing and laboratory personnel. The sample collection device thus becomes a fomite potentially capable of spreading infectious disease to numerous persons, and a method or means for eliminating or at least reducing the exposure of health workers to the contaminated exterior of the sample collection vials, bottles, cups, tubes, and so forth, has been a longstanding and unmet need in the healthcare industry.

[0021] Furthermore, awareness of the dangers of unsafe handling of biological fluids and specimens has increased dramatically in the last two decades, and single-entry devices are increasingly needed that seamlessly integrate sample preparation, extraction, and analysis without unnecessary operator exposure. A further objective we have identified is the need to fully integrate the device into a disposable format, so that once a sample is collected, either by patient or by a health professional, all remaining steps of the analysis, up to and including display of the result, are performed without further personal exposure to the sample. A critical step in this process is thus the refreshing or disinfecting of the external surface sample collection container (whether it is also the analytical device or not), and to our knowledge, satisfactory solutions to this problem have not been recognized or brought forward prior to our disclosure herein.

BRIEF SUMMARY

[0022] Swabs are extremely useful for collecting specimens. Following collection of a specimen on a swab, the swab must be generally protected during subsequent transport and processing for analysis. During initial handling, contamination of the external surfaces of the swab collection container by contact with residues of specimen or unrelated patient-derived bodily material, which may be unhygienic and grossly objectionable, is almost inevitable. Gloves are protective only to the hands on which they are worn, not to the swab collection container. We see a solution to this problem as an unrecognized and unmet need with significant potential benefits, particularly in reduction of nosocomial infections, for example, and more generally in reduction of disease transmission to health care workers, and also in improvement of sample quality, which is mandatory for tests such as PCR, where false positives due to cross-contamination will invalidate any testing system.

[0023] Cross-contamination by transmission on the surfaces of fomites is a longstanding problem. We find that this problem can be alleviated or significantly reduced by applying a disposable external skin to the collection device, and by removing the skin after the risk of exposure to further contamination is ended. Contamination risk is most great during the act of specimen collection itself, and decreases greatly

after the specimen collection container is removed from the sampling site. Contamination of the external surfaces of an article passed from hand-to-hand, or hand-to-machine, with normal flora and normal squamous epithelial cells, is significantly less likely to result in false diagnostic positives for a pathogenic condition.

[0024] We disclose a biohazard swab collection device or container, comprising a body with external surfaces, an internal hollow volume, and a sealable closure for separating said external surfaces from said internal hollow volume, said external surface further comprising a disposable external skin layer, whereby after the biohazardous swab is enclosed and sealed within the internal hollow volume, any biohazardous residues accumulated on the external surfaces are removed by removing and disposing of the disposable external skin layer, and further optionally comprising a valve separating said internal hollow volume into a swab receiving chamber and a microfluidic assay circuit with a microfluidic channel and an on-board liquid reagent.

[0025] We further disclose a method wherein the specimen is not limited to a swab and the specimen collection device is not limited to an analytical device. The general method comprises the steps of:

[0026] a) providing a sample and a specimen collection container with body and with sample receiving orifice, said body with external surface and internal hollow volume, said external surface with disposable skin or skins, said sample receiving orifice with sealable closure;

[0027] b) inserting said sample into said sample receiving orifice;

[0028] c) closing said sealable closure said sample receiving orifice; thereby capturing said sample; and,

[0029] d) removing said disposable skin or skins from said external surface; thereby renewing said external surface.

BRIEF DESCRIPTION OF THE FIGURES

[0030] FIG. 1 is a perspective view of a representative specimen collection device with external skins and with integrated sample processing and analytical assay capability.

[0031] FIG. 2 is a perspective view of a sample swab with frangible handle.

[0032] FIG. 3A is a plan view of the upper surface of the device of FIG. 1, and shows section plane 3B. FIG. 3B is a section of the device of FIG. 1 on plane 3B, and shows the swab receiving chamber and inner workings of an embodiment of the integrated device. Representative inner workings are indicated schematically.

[0033] FIG. 4 is an exploded view of protective external disposable skins applied to a representative specimen collection device.

[0034] FIG. 5 is a conceptual illustration of the manufacture of a heat-shrink external disposable skin on a representative specimen collection device.

[0035] FIG. 6 is an illustration of the assembly of a disposable bag applied to a representative specimen collection device.

[0036] FIG. 7 is an exploded view of a Styrofoam or composite coverblock assembly applied to a representative specimen collection device.

[0037] FIG. 8 is a sketch of a device with composite cover formed in place over and around the device.