

**SANITARY SWAB COLLECTION SYSTEM,
MICROFLUIDIC ASSAY DEVICE, AND
METHODS FOR DIAGNOSTIC ASSAYS**

CROSS-REFERENCE TO RELATED
APPLICATIONS

This application is a continuation of International PCT Patent Application No. PCT/US2008/071810, filed Jul. 31, 2008, now pending, which claims the benefit under 35 U.S.C. §119(e) of U.S. Provisional Application No. 60/953,045, filed Jul. 31, 2007. The foregoing applications are incorporated herein by reference in their entireties.

STATEMENT OF GOVERNMENT INTEREST

This invention was made with government support under Contract No. U01 AI070801 awarded by National Institutes of Health. The government has certain rights in this invention.

BACKGROUND

1. Technical Field

The invention relates to medical and veterinary sample collection devices and to medical and veterinary analytical devices of specialized form and function, and to integrated microfluidic devices for both sample collection and analysis. The invention further relates to a method for biohazard sample collection.

2. Description of the Related Art

The art relating to handling of swabs is well established, but remains in need of improvement, both to ensure the integrity of the clinical sample and its protection from contamination, but also to ensure that healthcare professionals are not unnecessarily or inadvertently exposed to biological material on the exterior surfaces of the swab container. Once the external surfaces are contaminated during sample collection, exposure readily occurs when a swab container is passed from hand to hand, and no on-board means is known to refresh or cleanse the outside surfaces of the sample container.

We have reviewed the patent literature, and found little or no teaching that comments on this problem. U.S. Pat. No. 4,803,998 to Kezes relates to a swab retaining vial cap and describes a combination containment vial with cap and with swab mounted inside the cap, the vial containing a medium for preserving a sample on the swab during shipment. The swab is removed from the cap to collect a sample and the swab tip can then be broken off when inserted into the vial so that the swab tip drops to the bottom of the vial without contamination by the user. The cap is then sealed. FIG. 4 shows a swab with frangible shaft. The patent is indicative of early efforts to protect a sample from contamination. This seems to accurately reflect the overall state of the art as it exists at this filing. We note that while the interior of the vial is carefully protected from contamination, the exterior is subject to contamination during handling, and becomes a fomite vector for infectious disease. Samples collected in this way are frequently removed for analysis at a separate location, and those who handle the sample container may inadvertently be exposed to material on the exterior surface of the sample container.

U.S. Pat. No. 6,991,898 to O'Connor (Jan. 31, 2006) describes a self-contained diagnostic test device for collection and detection of an analyte in a biological specimen. The device comprises a tubular swab and reagent dispensing cap.

The reagent dispensing cap delivers one or more selected reagents to an assay chamber upon the rotation of the reagent chamber.

In U.S. Pat. No. 7,098,040 to Kaylor, a swab-based diagnostic test device is provided. The test device contains a reagent and a rupturable seal for adding the reagent to the sample after the swab is sealed inside the device.

U.S. Pat. No. 6,277,646 to Guirguis provides a device for both collecting and testing a fluid specimen. A fluid specimen is collected and an aliquot is transferred to an isolation chamber, from which a flow path to a test chamber is opened.

U.S. Pat. No. 6,565,808 to Hudak describes a fluid flow actuating device or structure, such as a valve, which separates the sample receiving chamber from the test platform. The test method involves collecting a sample, contacting the sample with the proprietary test device, and detecting the analyte in the sample.

U.S. Pat. No. 6,248,294 to Nason relates to a self-contained diagnostic test unit for use in the collection and analysis of a biological specimen. The test unit comprises is tubular housing for capturing a swab. A reagent dispenser cap delivers reagents to the specimen chamber and a diagnostic strip assembly is mounted on the housing so a portion of the specimen can flow by wick action through the test strip, producing a visible color change.

U.S. Pat. Nos. 5,266,266 and 5,879,635 to Nason relate to a reagent dispenser which includes a pair of reagent chambers with selected reagents therein, and a dual nib for hermetically sealing the reagent chambers. A portion of the dispenser is deformable to break or otherwise to displace the nib in a manner permitting the two reagents to flow together and mix within one of the reagent chambers. The deformable portion or the dispenser can then be squeezed to express the mixed reagents for delivery to contact the specimen to be analyzed. In a preferred form, the dispenser is a cap assembly on an open-ended tubular housing configured for receiving a swab.

Similarly, U.S. Pat. No. 6,890,484 to Bautista relates to in-line test device and describes a swab receiving port integrated into the body of a lateral flow strip. No means for protecting the exterior of the test apparatus is described. Goodfield, in Sampling and Assay Device (WO1997/23596), discloses a swab and swab container with liquid assay reagents accessible by rupture of foil liners, again with no outer disposable protective layer.

All the above devices and methods are deficient for the present purpose in that the operator is exposed to contamination of the external surfaces of the specimen collection container by contact with residues of specimen or unrelated patient-derived bodily material, which may be unhygienic and grossly objectionable. This problem is apparently not considered.

United States Patent Application 2005/0009200 to Guo relates to a sanitary and compact fecal occult blood collector kit. The swab tip in this case is covered "for hygienic purposes". Also disclosed is a package for the swab and the cover. However, on closer study, the purpose of the cover is again to protect the sample, not the handle of the swab contacted by the operator or the external surfaces of the swab collection container, and the exterior of the package cannot be cleaned of contaminating matter that accumulates during sampling. Further, the swab must again be retrieved from the package. Thus while the sample is protected, the user is potentially exposed at multiple levels.

Miniaturizing some of the processes involved in clinical analyses, including nucleic acid, immunological and enzymatic analysis, or combinations thereof, has been achieved using microfluidic devices. Microfluidic techniques known in