

[0100] Thus in FIG. 15, a swab collection container is shown with no analytical capabilities. The composite swab holder consists of an internal bottle and an external skin or sheath, so that after the swab is collected and sealed within the internal bottle, the external sheath is removed and the swab in its bottle, or other sealed vessel, is safely transported and handled with the assurance that any biohazardous external residues have been disposed of with the external sheath.

[0101] Swab collection container (150) is shown in FIG. 15A. Internal swab collection container (151) is shown in FIG. 15B. The two figures illustrate essentially a “before” and “after”, wherein the device is supplied as shown in FIG. 15A without collected swab, and in FIG. 15B with collected swab. The steps involve capturing the swab and removal of the external skins, so that the product of the method is the slender, clean swab holder shown in FIG. 15B.

[0102] As supplied, the swab collection container 150 has a swab receiving port (153) formed of disposable funnel (154) and barbed lip (164) of the internal swab receiving channel (156), also termed herein an “internal hollow volume (156)”. The temporary shipping cap (160) is first removed and the swab is inserted tip-down into the internal hollow volume (156). Note that the disposable funnel serves to protect the barbed rim (164) of the internal sheathed tube (157) from contamination with specimen residues. Following collection of the swab and placement within the inner tube, the sealing strip, or tear strip (168), is removed and the upper protective skin (155) is lifted up and away from the device, along with the disposable funnel 154, both of which are discarded. This exposes the uppermost beveled rim 164 of the inner cylinder. Now, as shown in FIG. 15B, a sealing closure (165) with locking lip or flange (166) and plug (167) can be locked in place over the barbed bezel of the inner cylinder, and the outer lower protective sheath 159 is slid off the inner cylinder and discarded. The sealing closure is supplied separately. After these steps, the swab is now isolated within the internal hollow volume 156, separated from the external surfaces (169) by closure 165, and the external surfaces are as clean as supplied by the factory.

[0103] Note that the removal of the outer shells is a two part process. With a gloved hand, the contaminated outer shell is grasped and the upper shell is removed. A clean hand is then used to install the closure, and the upper part of the inner cylinder is held while the lower shell is removed. The final specimen container is now free of contamination and can be handled without gloves. To later gain access to the swab, fracture lines such as described in U.S. Pat. No. 6,516,947 may be formed in the internal cylinder, which can be formed generally as described in FIG. 1 of that publication. In that way, it is never necessary to touch the directly swab again. Alternatively, the closure of the device of FIG. 15 can be a threaded closure, and the internal cylinder may be formed with a mating threaded rim and sealing flange. Various combinations are anticipated.

[0104] If a patient were to collect the sample, we envisage that the patient will place the swab in the device and return it, outer shell intact, to a healthcare professional or laboratory technician. The technician will then complete the steps of removing the upper shell, inserting and sealing the cap, and then removing the lower shell, taking care to avoid contaminating the external surfaces of the inner cylinder during the process. Between steps of the process, the device 150 may be stood on its base, which can be formed with a foot as would be useful for stability.

[0105] A kit for this process may contain, in a tray, the device 150, a swab 20, and a closure, along with any instructions and labeling.

[0106] It will be appreciated by persons skilled in the art that numerous variations, combinations of elements, and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

## EXAMPLES

### Example 1

[0107] A swab is provided in a sterile packet, the shaft of the swab being formed with a notch separating the handle from the sampling tip. The swab is rubbed in the gingiva separating the teeth from the gums of a child and inserted into a collection device of the invention. The swab handle is bent vigorously so that it breaks at the notch, releasing the swab tip with specimen into the device. The swab insertion channel is then covered with a sliding closure that rides in tracks in the housing, and sealed irreversibly, the sliding closure having a ratcheted underside which mates and locks over a locking tooth or spur on the body of the device. The professional then removes a protective external skin from the device, taking care not to contaminate the freshly exposed surfaces, and hands the device to an aide for processing.

### Example 2

[0108] A swab is provided in a sterile envelope, the shaft of the swab being formed of a material suitable for cutting with a blade. The patient is asked to provide a self-collected specimen of the vaginal mucosa and is given instructions. The patient collects the sample and inserts the soft tip of the swab into the sample collection device that was provided. The patient hands the device to a health professional, who takes it with gloved hands. The health professional closes the cover of the device, cutting free the swab handle and discarding it, and then removes the disposable external skins on the device, taking care not to contaminate the freshly exposed surfaces. After removing the skins, the health professional inserts the device into a semi-automated analytical apparatus and completes the assay. The result is read and the device with sample is then discarded. The analytical apparatus is equipped with networking capability so as to transmit identifying and “smart” electronic data as an electronic medical record to a database on a server.

What is claimed is:

1. A sample collection device, the device comprising:

- a) a body having an external surface and an internal hollow volume;
- b) a removable disposable external skin layer or shell covering a first portion of the external surface of the body and dividing the external surface into a covered area and an uncovered area, the uncovered area defining a swab receiving orifice for inserting a swab into the internal hollow volume, the swab receiving orifice compatible with a sealable closure that may be sealably closed over the swab receiving orifice; and,

wherein the removable disposable external skin layer or shell comprises a first gripping surface and the uncovered area comprises a second gripping surface, said first