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Horlach

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[54] **SPECIMEN HOLDING KIT**

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[52] **U.S. Cl.** **195/139;** 195/127

[51] **Int. Cl.**[2] **C12B 1/00**

[58] **Field of Search** ..... 195/103.5, 127, 139; 23/259 TP; 128/2 W

[56] **References Cited**

UNITED STATES PATENTS

3,039,938	6/1962	Charm	195/139
3,102,082	8/1963	Brewer	195/139
3,450,129	6/1969	Avery et al.	195/139

Primary Examiner—A. Louis Monacell
Assistant Examiner—R. B. Penland

[57] **ABSTRACT**

A disposable kit for collecting, holding and transporting biological specimens in a saturated medium environment.

A flat elongated resilient pouch of inert material is formed with two sterile hermetically sealed compartments. A rupturable transverse closure across one of the compartments defines a sealed chamber containing a transport medium. The second compartment contains a specimen collecting swab having an elongated stem. The pouch is adapted to be opened at one end to permit the swab to be removed and, after the specimen has been collected, reinserted, thrust through the rupturable closure, and immersed in the transport medium. The pouch is resealable to secure the swab in the medium containing chamber and to prevent exposure to the atmosphere during transport and storage.

10 Claims, 7 Drawing Figures

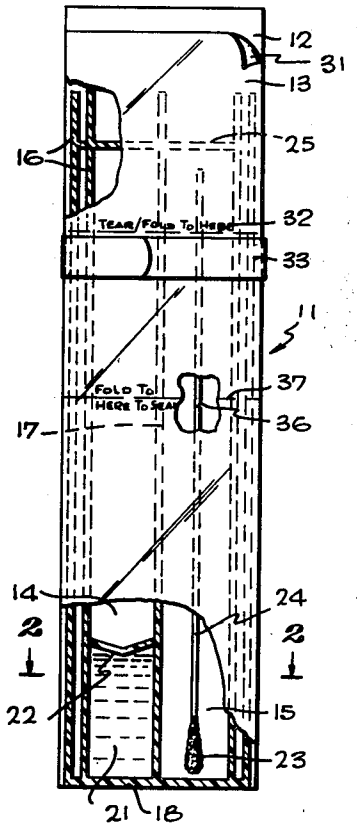


Fig. 1

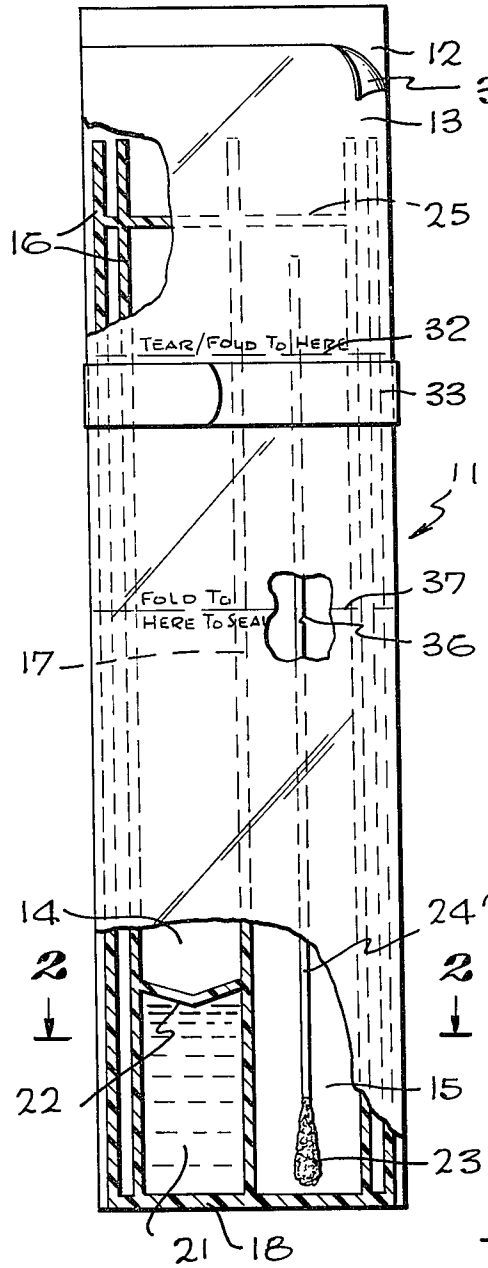


Fig. 4

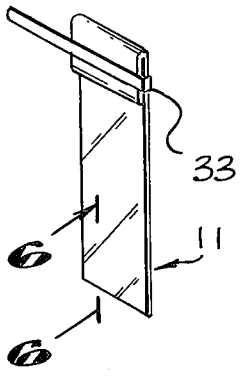


Fig. 3

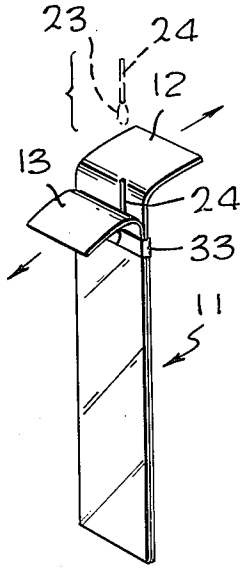
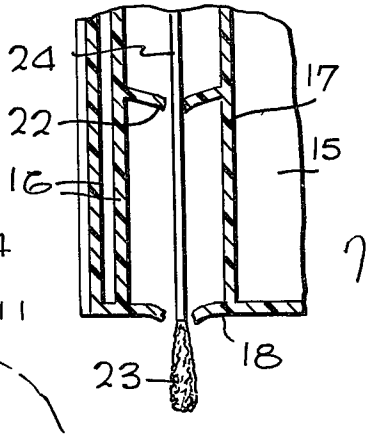


Fig. 6



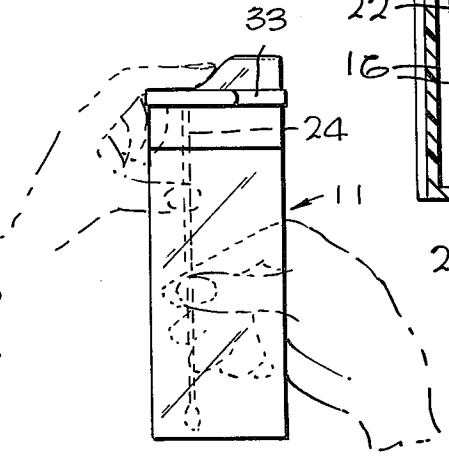


Fig. 5

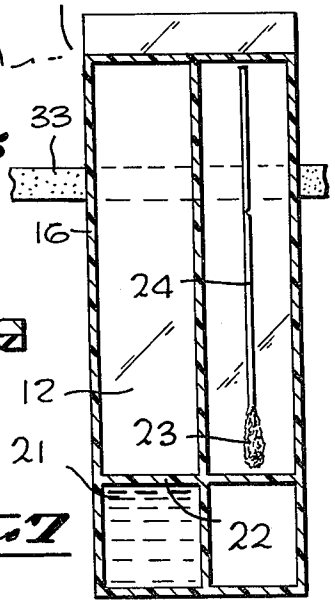


Fig. 7

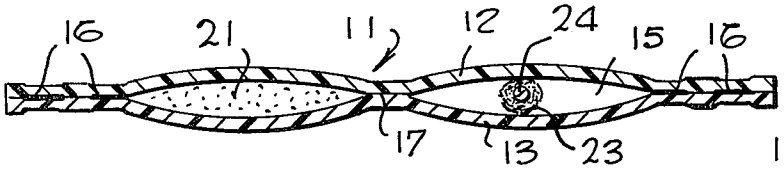


Fig. 2

SPECIMEN HOLDING KIT

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to kits for collecing, holding and transporting biological specimens in a saturated medium environment, and more particularly to a unitary system wherein a sterile specimen collector and a transport medium are dispensed in an unbreakable disposable container.

Over the past decade or more the importance of microbiological analysis, testing and experimentation in the fields of public health and clinical medicine, in the food, drug, cosmetics and chemical industries, and in the realm of pure research has burgeoned to the point it is estimated that in excess of three billion microbiological specimens were collected and examined in the United States alone during 1973. The need for a mass-produced, inexpensive, easily used disposable system for collecting, holding and transporting such specimens has become acute.

2. Description of the Prior Art

The traditional method for sample collection is to use a separately packaged single sterile swab and a glass screw cap vial containing sterile culture medium. This method is cumbersome in that it requires the requisition, storage and handling of huge quantities of individual swabs and vials. Glass vials are notoriously fragile and require careful handling. Additionally, their initial cost makes their reuse almost madatory, thereby creating the need for expensive and time consuming reprocessing. Disposable vials of plastic have by and large proved to be no more satisfactory.

A variety of prior art devices have been introduce employing compartmentalized containers for microbiological use. U.S. Pat. No. 3,589,983 is illustrative of one such container. In addition to being difficult and expensive to produce, devices of this type are much too bulky and cumbersome for convenient use on a mass scale.

Disposable culturing devices, such as those depicted in U.S. Pat. Nos. 3,450,129 and 3,308,039, come closer to resolving the need, but they too suffer from deficiencies which render their use impracticable.

The object of the subject invention is to provide an inexpensive, unbreakable, disposable unitary specimen handling kit which overcomes all of these deficiencies.

SUMMARY OF THE INVENTION

Essentially, this invention comprises a flat elongated resilient pouch of inert material formed with two sterile hermetically sealed internal compartments. Preferably, the pouch is formed by joining a pair of elongated thin sheets of resilient material along their sides and ends and along a medial line extending between their ends. A sealed chamber containing a culture transport medium is formed at the lower end of one of the compartments, preferably by joining the two sheets along a transverse line extending across the compartment. The upper end of the sealed chamber is adapted to be easily ruptured. A specimen collecting swab having an elongated stem is provided in the second compartment, and both the transport medium and the swab are sterilized.

The pouch is constructed so that its upper end may be opened manually to expose the two compartments. In the preferred embodiment the two resilient sheets are joined along a line spaced from one end of the pouch to permit them to be grasped and separated easily.

With the pouch thus opened, the swab is removed to collect the desired specimen and then is reinserted into the compartment having the chamber at its lower end and thrust through the rupturable closure and into the transport medium.

The pouch is resealed by folding the opened end over on itself and securing it in place by means of an adhesive band or similar device. Thus folded over, the pouch itself retains the swab fully immersed in the transport medium and protects both the swab and the medium from accidental airborne contamination.

In the preferred embodiment, the swab stem is scored to permit it to be broken after immersion of the swab in the culture medium. This facilitates the resealing of the pouch and makes for a shorter and more compact unit for handling, transporting and storing.

The specimen may be recovered without removing the adhesive band by grasping the pouch near its lower end between the thumb and fingers of one hand and forcing the swab stem downwardly with the other hand to thrust the swab through the lower end of the transport medium-containing chamber.

The details of construction and use of the subject invention will become more readily apparent from a reading of the following description of its preferred embodiment, taken in connection with the appended drawings in which:

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a frontal view of a specimen holding kit embodying the subject invention with portions of the front facing sheet cut away for illustrative purposes;

FIG. 2 is a sectional view taken in the direction 2—2 of FIG. 1;

FIG. 3 is a perspective view of the device of FIG. 1 showing the two resilient sheets forming the pouch separated to expose the internal compartments and the upper end of the swab stem;

FIG. 4 is a perspective view of the pouch of FIG. 3 after it has been resealed;

FIG. 5 is an enlarged frontal view of the pouch of FIGS. 3 and 4 illustrating the preferred method for recovering the specimen;

FIG. 6 is an enlarged detailed sectional view of the cavity containing the transport medium illustrating method of removing the swab from the pouch; and

FIG. 7 is a sectional view of another embodiment of the subject invention taken between the two sheets comprising the pouch to illustrate the manner in which they are joined.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIGS. 1 and 2, the specimen holding kit of the subject invention is a fully self-contained unit comprising a flat, flexible, light-weight pouch 11, preferably formed of two thin resilient sheets 12, 13 of flexible, light-weight, substantially inert hydrophobic plastic material, such as polyethylene, or the like. In addition to its other characteristics, polyethylene's transparency makes it particularly satisfactory for this purpose. For certain applications a backing sheet 12 of polyethylene coated metallic foil or paper and a facing sheet 13 of translucent polyethylene have proved to be a nearly ideal combination.

Backing sheet 12 and facing sheet 13 are joined along their lateral edges and at one end and along a longitudinal medial line to form a pair of internal compartments 14, 15. Joining may be accomplished by the use of any appropriate epoxy cement or other cementious material, but thermoplastic welding has been found preferable for this purpose.

Using well known thermoplastic welding techniques, the sheets 12, 13 may be welded along one or more lines 16 adjacent their lateral edges and in their medial region 17. Preferably a single weld 18 is used to join them at their lower ends.

A suitable bacteriological transport medium 21, such as Stuarts or Amies-Charcoal solution is introduced into the lower end of the first compartment 14 and sealed in place by joining the sheets 12, 13 using any of the techniques previously described for joining the sheets 12, 13. As mentioned earlier, thermoplastic welding has been found to be the most satisfactory means for this purpose. Preferably the closure 22 forming the cavity containing transport medium 21 is formed with a wide V-shaped weld which is intentionally made somewhat weaker than those joining sheets 12, 13 along their lateral edges. As will be seen presently, the purpose of this is to allow closure 22 to be ruptured relatively easily.

A swab 23, preferably of Dacron polyester or some other non-toxic absorbtive material and having an elongated stem 24 is positioned in the second compartment 15.

Sheets 12, 13 are joined across the width of pouch 11, as along line 25, by any of the means previously mentioned, again thermoplastic welding being the preferable one, thereby hermetically sealing compartments 14 and 15 and their contents. The portions of sheets 12, 13 extending above the joinder line 25 are intentionally left unjoined.

Sterile materials and techniques may be used in the formation and filling of pouch 11 to insure the sterility of transport medium 21 and swab 23 or, in the alternative, the entire pouch 11 with its contents may be sterilized by conventional autoclaving or irradiation techniques as one of the last steps in the manufacturing process. Whichever method is used, the medium 21, swab 23 and stem 24 will remain sterile until pouch 11 is opened at the time of use.

When a specimen is to be taken, backing sheet 12 and facing sheet 13 are grasped firmly between the fingers and peeled downwardly and apart. To facilitate this operation backing sheet 12 may be made slightly longer than facing sheet 13 to enable the user to grasp a corner 31 of facing sheet 13.

As illustrated in FIG. 3, sheets 12, 13 are pulled apart with sufficient force to open the welds 16 and 25, thereby exposing the upper ends of compartments 14, 15 and the upper end of swab stem 24. A "tear line" 32 with an appropriate legend may be printed on facing sheet 13 to advise the user when the pouch 11 has been opened sufficiently. In a preferred embodiment of the invention a removeable adhesive strip 33, which may have a label printed on its reverse side for entry of information concerning the specimen, is wrapped around pouch 11 and, in addition to the purpose which will be described subsequently, may be used to provide a mechanical stop to prevent the sheets 12, 13 from being separated over a greater length than necessary.

By grasping the exposed end of swab stem 24, the swab 23 may be withdrawn from pouch 11 and used in a conventional manner to collect the microbiological specimen. Therafter, with the separated upper ends of sheets 12, 13 apart, the swab 23 with the specimen in place is inserted and slipped downwardly into compartment 14 until the swab 23 contacts rupturable closure 22. With pouch 11 grasped firmly, a sharp downward thrust of stem 24 will rupture closure 22 and immerse swab 23 and the specimen in transport medium 21.

By grasping stem 24 through pouch 11 near its lower end and bending its upper end sharply, the upper end of stem 24 is broken off and discarded. To facilitate this step a notch 36 may be provided near its midpoint.

To reseal pouch 11 and secure the swab 23 in place fully immersed in transport medium 21, sheets 12, 13 are once again brought together and folded downwardly, preferably in a double fold, over facing sheet 13. A "fold line" with an appropriate legend may be provided as shown at numeral 37 to assist the user.

As shown in FIGS. 4 and 5, the adhesive strip 33 mentioned earlier is preferably made with its ends folded over one another on facing sheet 13. These ends are separated prior to folding the upper ends of sheets 12, 13 downwardly, and are refolded over the doubled upper portion of pouch 11 to prevent it from unfolding. This reseals pouch 11 and protects transport medium 21, swab 23 and the fully immersed specimen from accidental airborne contamination. Additionally, as long strip 33 remains secured around the doubled portion of pouch 11, swab 23 and its contents will remain saturated until removed and little if any evaporation, oxidation or deterioration will occur.

Sealed in this fashion, pouch 11 and its contents may readily be stored for as long as desired and transported at will without fear of external contamination or breakage. Furthermore, because of their compact size and extremely light-weight, a number of these units may be handled simultaneously with ease.

When the specimen is to be utilized for analysis, testing or experimentation, swab 23 may be removed from pouch 11 by either of two methods. If desired, the adhesive strip 33 may be removed, the upper end of pouch 11 unfolded, and swab 23 withdrawn from compartment 14 by means of stem 24. FIGS. 5 and 6 illustrate the second method, wherein the pouch 11 is grasped firmly between the thumb and forefingers of one hand and the upper end of stem 24 is forced sharply downwardly with the other hand causing swab 23 to rupture the weld 18 joining the lower ends of backing sheet 12 and facing sheet 13. With this method, the pouch 11 itself serves as an enlarged holder for stem 24. Regardless of the removal method used, when the kit has served its purpose it may be discarded without concern for breakage and without the taking of a great deal of space.

FIG. 7 depicts a slightly varied alternative method of sealing pouch 11 to form the cavity for transport medium 21. In this method, rupturable closure 22 is formed by joining sheets 12, 13 transversely across their entire width, rather than merely across the width of compartment 14 as in the embodiment of FIG. 1. It will be noted that in this illustration sheets 12, 13 are joined at their lateral edges by a single weld 16, rather than by the plurality of welds shown in FIG. 1.

While the foregoing description is illustrative of two preferred embodiments of the subject invention, it will

be apparent to those skilled in the art that many other variations and modifications may be embodied within the scope of the invention as hereinafter claimed.

I claim:

1. A specimen holding kit comprising:

a flat, elongated resilient pouch having first and second hermetically sealed compartments positioned side-by-side therein, said first compartment having a rupturable transverse closure therein defining an hermetically sealed chamber at one end thereof;

a culture transport medium contained in said chamber;

a specimen collecting swab positioned in said second compartment;

means for opening the end of the pouch remote from said chamber to expose both of said compartments, thereby allowing said swab to be removed from said second compartment and, after collection of the specimen, to be inserted into said first compartment and thrust through said transverse closure into said chamber and in contact with the culture transport medium; and

means for securely closing the opened end of said pouch thereby closing said first compartment and retaining said swab in said chamber.

2. The specimen holding kit of claim **1** wherein said pouch comprises a pair of elongated thin sheets of resilient material joined along their sides and ends and along a medial line intermediate said sides to form said first and second sealed compartments.

3. The specimen holding kit of claim **2** wherein said rupturable closure is formed by joining said pair of sheets in a narrow region lying transverse to their longer dimension and extending between said medial line and the joined region at one of their sides.

4. The specimen holding kit of claim **3** wherein the region of joinder of said sheets at one of the ends thereof is spaced inwardly of the edges of said sheets at said end, leaving an unjoined region at said edges whereby said sheets may be grasped and manually separated.

5. The specimen holding kit of claim **4** wherein said sheets are joined by releasable means whereby one may be readily stripped from the other to open one end of said pouch by application of manual force.

6. The specimen holding kit of claim **5** wherein said sheets are so joined by means of a cementious material.

7. The specimen holding kit of claim **5** wherein at least one of said sheets is of thermoplastic material and is so joined to the other of said sheets by thermofusion.

8. The specimen holding kit of claim **7** wherein said specimen collecting swab is provided with a frangible elongated handle.

9. The specimen holding kit of claim **8** wherein said handle is scored to facilitate its fracture after said swab has been thrust through said closure into said chamber and in contact with said culture transport medium.

10. The specimen holding kit of claim **9** wherein said means for closing the opened end of said pouch comprises an adhesive strip for securing the ends of said sheets doubled over the portion of said pouch wherein said sheets have not been separated.

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