

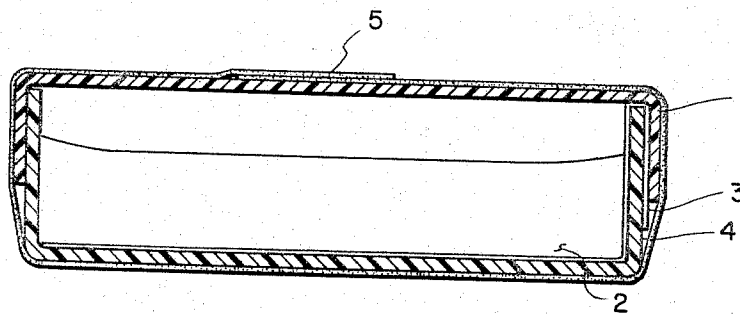
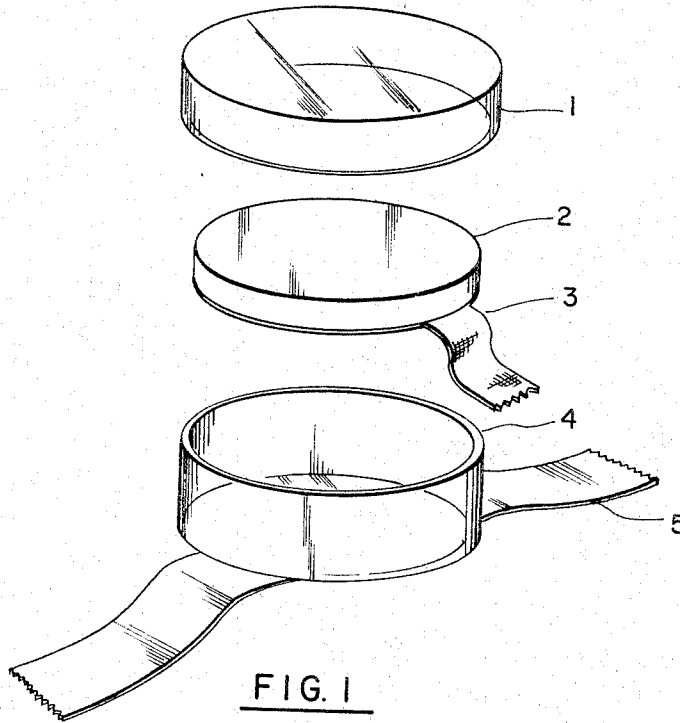
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CONTAINER WITH FLEXIBLE STERILITY MEASURING PAD

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CONTAINER WITH FLEXIBLE STERILITY MEASURING PAD

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This invention relates to an improved sterility tester and/or microorganism detector for surfaces, and more particularly for surfaces which are not smooth and flat.

A very serious problem is encountered, primarily, although not exclusively, in hospitals, in determining whether a particular surface is sterile or in some cases to determine the nature of microorganisms on said surface. This is often a problem with bed sheets, surgical masks, surfaces in an operating room, or surfaces on the body of the patient. In the past the practice most widely used involved extensive preparation of materials, and the steps involved in performing a sterility test required considerable effort, time and manipulation. For instance, for performing a sterility test on a single, flat, nonporous area, the procedure most widely accepted as being the most accurate is normally referred to as the swab-dilution-plating technique. Materials required, include sterile cotton-tipped applicators packaged in test tubes or other sterile individual containers, plastic templates, 4 sq. in. each aseptically packaged, 5 dilution blanks each containing 9.0 ml. of a suitable sterile non-toxic diluent in sterile test tubes, 6 serologic pipettes 1.0 ml. capacity, 6 Petri plates 15 mm. x 120 mm. containing a suitable sterile agar medium. The test is performed by placing aseptically the template over the area to be tested; dipping aseptically a cotton-tipped applicator into a dilution blank of diluent; removing the applicator and swabbing the 4 sq. in. area within the confines of the template; placing the swab back into the dilution blank and returning same to the laboratory where the blank is diluted serially in 10-fold dilutions to 1-100,000 or more final dilutions. One ml. aliquots of the dilutions from 0 to the highest final dilution are pipetted aseptically to respective sterile, empty, marked Petri dishes. Then 10 ml. of sterile agar in test tubes are melted, cooled and added to each Petri dish containing the 1.0 ml. of the respective dilution of the test sample. The contents are allowed to solidify, incubated from 18 to 24 hours in an incubator at 37° C., after which the number and types of microorganisms are reported as the number and kind of organisms per dilution which then, by proper calculation, can be reported as the number and kind of organisms per a given area, viz., organisms and kinds per sq. in. of surface tested. Obviously, this procedure involves a great deal of labor, equipment, and an enhanced possibility of foreign contamination. Furthermore, on curved areas such as some parts of the body as the finger, curved utensils, and particularly on such porous and absorbent objects as face masks, bed sheets, operating gowns, drapes, and similar items of paramount importance in hospital sterility, this procedure is not reliable. It is with a solution of this problem to provide an easier, less expensive and safer tester that the present invention deals.

Essentially in the present invention there is cut a round or other shape of cloth with a tab at one side. Although the shape of the cloth is not the feature that distinguishes the present invention it is normally easier and preferable to use a round piece of cloth with a tab at one side and in the remainder of the specification this preferred form will be referred to, it being understood that the invention is not limited to the particular shape. The cloth is sterilized and then both sides are coated under aseptic conditions with a moist sterile layer of agar. The agar

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coated cloth is then sealed in an aseptic container, preferably a small round box of transparent plastic, and the tab is placed so that when the container is opened it can be reached without touching the remainder of the cloth. In the case of the preferred form of container, a round plastic box, the tab is carried up and over the side of the lower portion of the box and held down when the upper lid is placed in position. Sealing of the box can then be effected by conventional means such as sterile tape and the device is then ready for use. A somewhat more detailed description follows in conjunction with the drawings in which:

FIG. 1 is an isometric exploded view of the preferred form of the device, and

FIG. 2 is a vertical section in the drawings.

The lower part of the box is shown at 1 with a round piece of cloth 2 covered on one side with sterile agar in the box and a tab at one side of the piece of cloth 3 being brought over the edge of the box. The cover is shown at 4. The exploded view is one just after the box has been opened for use. In FIG. 2 the tab 3 is shown bound tightly against the side of the box 1 by the side of the cover 4. The sealing tape for the box is shown at 5.

In use the box is opened, the nurse or other personnel grasps the tab 3 with forceps and removes the agar coated round piece of cloth without touching it and therefore without any possibility of contamination. She then places the agar impregnated piece of cloth on the area where a sterility of bacterial test is to be made. For example, this may be a surgical drape and surgical mask, the surface of an operating table including the edge, and/or the skin of the patient itself. The application is made while the tab 3 is still held by the forceps. The cloth itself is quite flexible and because of the thick agar layers on both sides which imparts to it a fair amount of weight, it tends to curve itself over any irregularity in the surface to which it is applied. For example in a surgical drape or bed sheet it can curve over a wrinkle or fold and will pick up microorganisms which might otherwise be missed. In the case of the human skin, the fact that the piece of cloth curves to adapt itself to the contour or whatever surface it is applied to, makes possible the determination of that bacterial presence or particular bacteria on parts of the human body which are quite sharply curved, for example fingers, wrinkles in the face and the like.

After the test is made the agar coated cloth, still held by the tab in the nurses forceps, is placed in the box 1 and the lid 4 applied. This again folds the tab 3 down over the side of the box itself, sealing is then effected with the pressure sensitive adhesive tape 5. The boxes are then taken down to the microbiology laboratory, placed in an incubator and incubated overnight. The next morning the agar coated pieces of cloth clearly show the presence and types of microorganisms. It is, of course, easy to mark the boxes at time of coupling, for example with a soft crayon on the top lid after they have been closed so that the report the next day can give identification of where the agar coated cloth was applied. Such marking as well as transport of the closed box is perfectly free from possibilities of contamination because only the outside of the box and lid is touched.

The great saving in labor and material which the present invention permits may be brought out by comparing it with the swab-dilution-plating technique described above. The improved reliability of the present invention is illustrated by the fact that if there is a wrinkle on the patient's skin, unless the swab has actually been forcefully inserted into such a cavity it will not pick up microorganisms which might be present. The agar coated cloth of the present invention, however, sinks down into all

depressions, the agar of course being in semifluid form, and there is no possibility of missing the sterility tests. In the case of the present invention the boxes are in the operating room, no one needs to come up from the microbiology laboratory, the nurse opens a box, grasps the tab with forceps, applies quickly the coated cloth to the particular surface she is testing, puts it back into the box and reseals. Then she opens another one until the surfaces which the doctor wishes to test, or which in the judgement of the nurse should be tested, have been subjected to contact with the agar coated cloths. The boxes then can remain in the operating room after they have been marked for identification until the end of the day or until the end of an operating session. Then all boxes can be taken down to the pathology microbiology laboratory by unskilled help. The saving in labor is very great and over a year in a busy hospital can amount to many thousands of dollars. At the same time the tests are just as reliable and actually more reliable and cost of the boxes and pieces of cloth are insignificant. Another advantage is that the boxes can be sterilely packed ahead of time and the agar will not dry out in the sealed container for many days or weeks and so it is possible to pack up the boxes for a week or several weeks ahead or to buy them from a pharmaceutical house where they are packed under aseptic conditions. This renders them very cheap and very reliable test devices.

It has been pointed out above that there is a very great saving in labor in a hospital but even if the cost were greater, and it is not, still the additional reliability which the present test provides by conforming the agar coated cloth to the irregularities of the surface, would render the present invention desirable. After all if a certain drape, mask or the patient's skin is not sterile when it should have been, serious infection can occur and so the additional safety of the present invention is just as important an advantage as the very great saving in labor which is permitted in a hospital. In addition, in the present method, the number and kinds of microorganisms are determined directly by counting the number and kinds on the agar surface after overnight incubation and reporting the results in terms of number and kinds of microorganisms per unit area, viz., per square inch. No dilution techniques or other manipulations are necessary.

One other advantage of the present invention merits brief mention. While the principle use of sterility or bacteriological identification is in a hospital this is not the only use. Sometimes a doctor calling on a patient at his home or in the case of office calls may wish to make tests of selected areas. These are more apt to be tests in which the identification of the microorganism is of importance, but sometimes they are also sterility tests. The doctor can keep a supply of boxes of the present invention in his office and have a few with him in his bag and can make the tests and then send the boxes to a suitable laboratory, for example at the nearest hospital. This convenience, even for the individual doctor is of importance and of course the enhanced reliability of the tests is just as important whether it is made by an individual physician or is made in conjunction with a surgical team of a hospital.

Reference has been made to sales of the containers of the present invention by pharmaceutical houses. It is quite true that the agar coated cloth does not dry out quickly because the container is hermetically sealed but nevertheless eventually the agar will dry out to some extent and become stiff. Therefore when the boxes of the present invention are to be sold they should be dated and used within the period of weeks or usually months within which they still will remain sufficiently moist and flexible for reliable testing.

The description of the invention has been in connection with cloth pieces of various shapes having tabs. Cloth is of course not the only type of fabric which can be used. It is possible to use strong paper or any other flexible

fabric which can be completely sterilized. However since a certain amount of mechanical strength is needed in the tab there is an advantage in using pieces of cloth. The additional cost over similar pieces of paper is so small as not to be a serious factor and the additional strength of the fabric has some real advantages. Accordingly, while the invention is not limited to the use of cloth as a fabric, this is preferred.

The description has referred to a coating of agar. This is the normal material which is used for making sterility tests and so will be the most common one used. However it should be understood that any other surface which is moist and flexible and which serves for incubation of microorganisms may replace the agar. In the case of some microorganisms special surfaces for incubation result in greater growth and so in some cases it may be desirable to make a test both from an agar coated fabric and a second test with a fabric coated with some other flexible growth medium. The present invention can be used and regardless of the nature of the medium it is perfectly easy to have more than one kind in a supply of containers. This is an additional advantage of the present invention.

This method also is invaluable in determining the number and kinds of microorganisms in various areas and on equipment in kitchens, food processing plants, and similar establishments.

Plastic boxes have been described and this constitutes the preferred form of the present invention because it is convenient to dispose of a box when it has been used once and plastic boxes are very cheap permitting single use without excessive cost. Obviously of course the nature of the container has nothing to do with the present invention and any container which can be sterilized and which will make a tight seal is suitable. Where a more expensive container material such as glass is used it is of course possible to resterilize the box and put in a new sterile agar coated patch of fabric. In some large hospitals where there is a facility for aseptic packing this may be advantageously used, but in most cases it is far better and usually cheaper to have the boxes packed by a pharmaceutical house under the best conditions and with the very best machinery which can be justified when many thousands are made at one time.

I claim:

1. A test device for determining the presence of microorganisms on a surface comprising,

(a) a sterilized two-piece box,

(b) a removable piece of flexible fabric in said box and having a tab at one side carried over the edge of the box and bent down and firmly held by application of the cover,

(c) the flexible fabric in the box being coated with a moist, sterile medium for bacterial incubation in the sterile box, whereby on opening the box the tab carried over the edge thereof can be grasped without touching the fabric within the box coated with the bacterial incubating medium and the said fabric can be removed from the box.

2. A test device according to claim 1 in which the fabric is woven cloth.

3. A testing device according to claim 1 in which the coating for bacterial incubation is a coating of moist, sterile agar and the coating is applied to both sides of the fabric.

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