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[54] **DIAGNOSTIC DEVICE**

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[52] **U.S. Cl.** ..... **195/139**, 195/103.5 R

[51] **Int. Cl.** **C12k 1/10**

[58] **Field of Search** ..... 195/103.5 R, 127, 195/139

[56] **References Cited**

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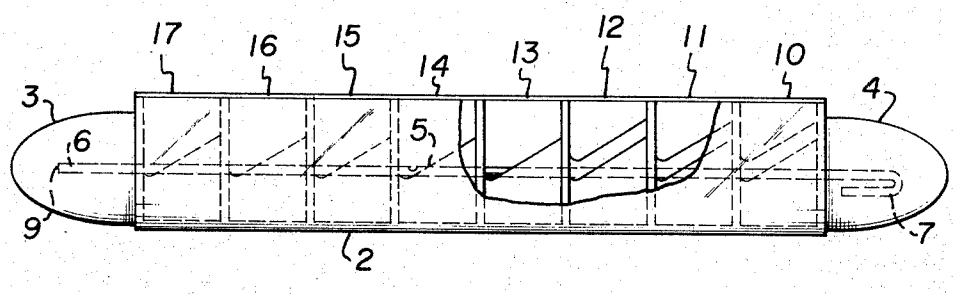
[57] **ABSTRACT**

Compartmented tube containing pre- prepared culture media for the differential identification of microorganisms, particularly, organisms of the family *Enterobacteriaceae*. The improvement comprises inserting a rigid member into the device after innoculation is effected, said rigid member being preferentially provided by severing a scored innoculation wire rod which extends through the tube. It further comprises the use of a material to overlay the media which biochemically reacts under anaerobic conditions.

6 Claims, 4 Drawing Figures



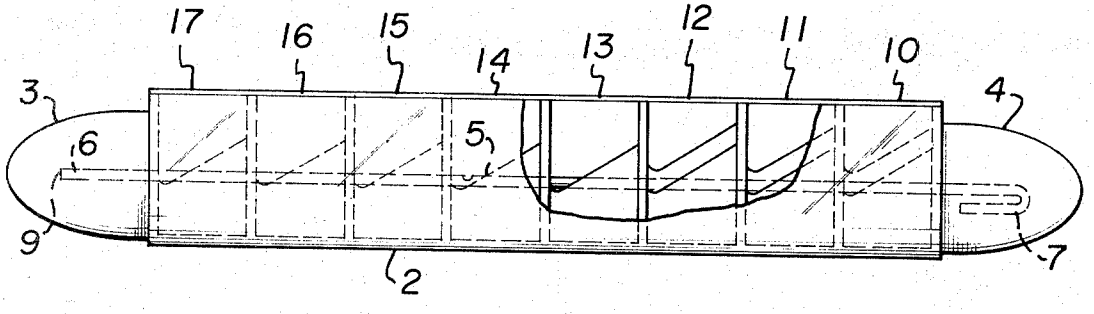


FIG. 1

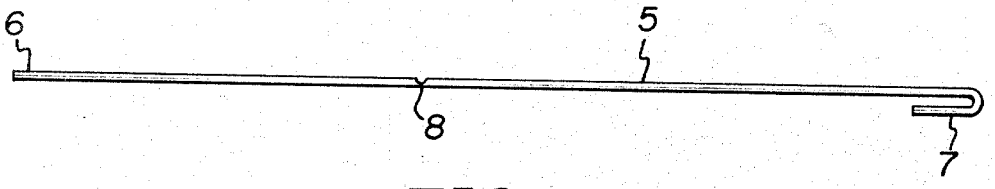


FIG. 2

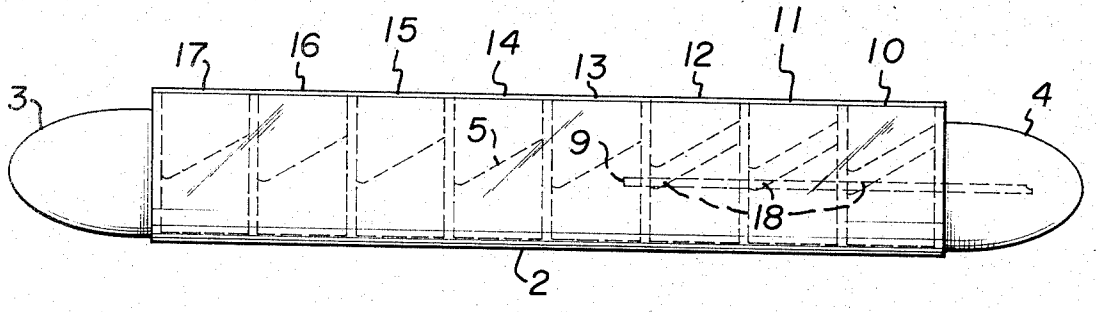


FIG. 3

FIG. 4

DIAGNOSTIC DEVICE

DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to an improved device for determining the presence of bacteria in a specimen sample.

Disposable diagnostic devices comprising several media-containing compartments and a wire rod extending through said compartments are known. In such devices, each compartment contains a conventional test medium which is suitable for determining the biochemical characteristics of an organism. In operation of the prior art devices, one end of the rod is brought into contact with isolates obtained from a specimen sample which may be sputa, blood and the like. The innoculation rod is then drawn through the various compartments so that any microorganisms contained on the said one end is a source of innoculum for the test media.

However, one problem observed with prior art devices is that certain test media which perform better under anaerobic conditions are affected by exposure to air. Air may enter prior art devices via the space formerly occupied by the innoculation rod after it is withdrawn and/or may be present in the space above the media in the compartment in which it is contained.

It is an object of the present invention to avoid the problems observed with prior art devices in connection with test media which are adversely affected by aerobic conditions. In achieving this object, a scored innoculation wire rod is provided. Upon severing the innoculation rod at its scored portion, the portion so severed can be reinserted into those compartments which contain media adversly affected by aerobic conditions. Thereby, the entry of air into such compartments is limited.

It is another object of this invention to provide a nonporous overlay over any media which is adversely affected by aerobic conditions. By this expedient, the overlay preferably a wax-overlay in cooperation with the scored portion can further assure the efficaciousness of media which performs better under anaerobic conditions.

Other objects will be apparent from the following descriptions and with reference to drawings.

In the drawings:

FIG. 1 is a side view of a disposable diagnostic device.

FIG. 2 is a view of the elongated innoculation instrument.

FIG. 3 is a view of the device after innoculation.

FIG. 4 illustrates an alternate rigid member utilizable for the purposes of the present invention.

In FIG. 1, the disposable diagnostic device is illustrated. The device comprises a tubular member 2 made of clear plastic. The ends of the tubular member are secured to screw-type caps 3 and 4. The tubular member is shown as being divided into eight compartments for receiving culture media indicated by dotted line. It is, of course, to be understood that the tubular member can comprise more or less than eight compartments. Regardless of the number of compartments, each will contain a different culture media known to determine the presence of a particular organism.

In each of the walls which define the compartments, there is provided an opening. Each of said openings are axially aligned whereby they can slidably receive a rod

or wire member 5. One end of the rod member 5 projects from one end of the tubular member and is provided with an innoculation means 6 which may be the end of the rod member 5. The other end of the rod member 5 projects from the other end of the tubular member 2 and is provided with a handle means 7. The rod member 5 is provided with a scored portion 8.

In operation, the innoculation means 6 is contacted with isolates obtained, for example, from urine, sputa and the like. After such contact, the handle means 7 is grasped by the user and the rod member 5 is pulled through the tubular member. As the innoculation means 6 passes through the compartments, it innoculates the media contained therein. After a suitable period, the container is visably examined for biochemical changes, evidenced by changes in characteristics of the media, e.g. change of color of the medium. Evidence of biochemical changes provides diagnostically significant information.

In practice, the disposable device contains media such as dextrose, lysine or ornithine or similar type media in compartments 10, 11 and 12. The biochemical process occurs preferably in such type media under anaerobic conditions. Compartments 10, 11 and 12 are disposed sequentially at the end of the device adjacent the handle means 7 and are each covered by a wax overlay 18.

After passing the innoculation means 6 through all of the compartments, the innoculation end 6 of rod member 5 is then reinserted into the tubular member 2. The rod member 5 enters tubular member 2 via the centrally disposed openings contained in the compartment walls until its tip 9 passes into compartment 13. Compartment 13 does not contain a media which is adversely affected by aerobic conditions, whereas as indicated above compartments 10, 11 and 12 do. At this point, the scored portion is about adjacent the outer wall of compartment 10. Rod member 5 is then broken at the scored portion. Then, the portion of the rod member 5 from the scored portion to the handle means 7 is discarded. The remaining portion of the rod member 5 is now positioned in the openings in the walls which define compartments 10, 11 and 12 as seen in FIG. 3. Thus, the openings in the walls defining compartments 10, 11 and 12 are closed.

The improved device of the present invention, therefor provides a simple, reliable and rapid method for the identification of organisms, particularly, organisms of the Gram-negative bacteria of the family *Enterobacteriaceae* which is characteristic of prior art devices and yet improves upon the prior art devices in that it avoids the problems inherent in the use of anaerobic test media in the prior art devices.

The culture media found in the various compartments of the device may be selected from among the many suitable for the purposes of the present invention by a person skilled in the art.

All that is required of the test media is that it be a nutrient media which when innoculated with a particular type of bacteria undergoes chemical changes which can be observed via the transparent compartment case. These changes permit the observation of diagnostically significant features.

A typical device will contain the following media: dextrose (compartment 10), lysine (11) and ornithine (12) which biochemically react, preferably, in the absence of air. The device may also contain H_2S-indole in

compartment **13**; lactose (**14**), PA-Dalcitol (**15**), urea (**16**), citrate (**17**) or any suitable medium in any suitable number of compartments which biochemically react in the presence of air.

Thus, as is evident from the above, the score provided in rod member **5** provides a convenient means of insuring that media changes not be effected by aerobic conditions.

Thus, it should be apparent that one of the advantages of the present invention is in the use of an innoculation rod that is scored and hence breakable, which innoculation rod can be broken and a portion thereof can be reinserted into the device to lessen the possibility of air entering those compartments which contain media, the biochemical changes of which would be adversely affected by the presence of air.

To further assure that the media in compartments **10, 11** and **12** be protected from contact with the atmosphere, a protecting layer may be positioned thereon and in a preferred embodiment, a wax overlay is utilized. As can be seen in FIGS. **1** and **3**, the wax overlay overlies the media completely in the compartment and hence engages all of the four walls which define same. While a wax is preferred for the purposes of providing the overlay material, it is, of course, to be understood that other materials can also be efficaciously utilized. Among other materials suitable for the purposes of the present invention can be included petroleum distillates such as vasoline, cosmoline and the like. The overlay material should be pliable, should cover the media completely, should be non-porous and if a wax, should free flow above about 65° C. and be solid below about 50° C.

In an alternate embodiment, the reinsertable portion can be between the handle **7** and the scored portion. In this embodiment, the rod **5** is removed, broken and then the portion containing the handle end is reinserted in the device. It is, of course, to be understood that in this embodiment, the portion between the handle end and the scored portion will be slightly greater than the sum of the distances between the walls which define compartments **10, 11** and **12.**

In an alternate embodiment, the scored portion on the rod member may be eliminated and a separate rod **30** as seen in FIG. **4** can be provided for reinsertion into the tubular member.

While compartments containing **3** "anaerobic" and **5** "aerobic" materials have been illustrated, it is, of course to be understood, that more or less than **8** compartments can be employed and more or less than **3** "anaerobic" media can be utilized. All that is required to accommodate any such modification is that the scored portion on rod **5** be so-situated thereon that when rod **5** is broken, the broken portion will pass through all the walls defining the compartments containing "anaerobic" media (preferably coated with a wax overlay) and will not pass completely through a compartment containing "aerobic" media.

While as is evident from the above, in a preferred embodiment, there is utilized in connection with the diagnostic device, media which detect the presence of organism of the family *Enterobacteriaceae*. Nevertheless, it should be readily apparent to those skilled in the art that the presence of other organisms which are not in the family *Enterobacteriaceae* can similarly be detected utilizing the device of the present invention. Representative of other organisms are clostridia, pseudomonas, Brucella. All that is required of a suitable media for any organism is that it be solid at a temperature below 55° C. and that it biochemically react to determine the presence of pathogenic organisms, i.e., by evidencing a change in physical characteristics that can be observed by physical observations.

We claim:

1. A disposal diagnostic device which comprises a tubular member, said tubular member comprising several compartments, at least one of such compartments containing a medium whose optimum performance is under anaerobic conditions, an innoculation member extending longitudinally through the said tubular member and including an innoculation end extending from one end of the tubular member, a handle end extending from the other end of the tubular member and a scored portion positioned between the handle end and the innoculation end, any compartment containing a media which biochemically reacts under anaerobic conditions being disposed adjacent to an end of the tubular member, the distance between the scored portion and one end of the innoculation member being slightly greater than the sum of the distances between the walls defining any compartment which contains a media which biochemically reacts under anaerobic conditions.

2. A device as in claim **1** wherein any media which biochemically reacts under anaerobic conditions is coated with a nonporous, pliable material which is solid below about 50° C.

3. A device as in claim **2** wherein the material coated on the media is a wax.

4. A device as in claim **3** wherein the distance between the innoculation end and the scored portion is slightly greater than the said sum and any said compartment which contains a medium which biochemically reacts under anaerobic conditions being disposed adjacent the handle end.

5. A device as in claim **4** wherein the innoculation member is a wire rod.

6. A device as contained in claim **5** wherein the said compartments are of equal dimensions.

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