

[54] **DISPOSABLE DILUTION SYSTEM**

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[51] Int. Cl. **B011 3/02**

[58] Field of Search **128/2 F, 2 R, 2 G, 275, 128/275.1, 304, 314; 73/425.4 P, 425.4 R, 425.6; 23/230 B, 259, 292; 215/6**

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Primary Examiner—**Kyle L. Howell**

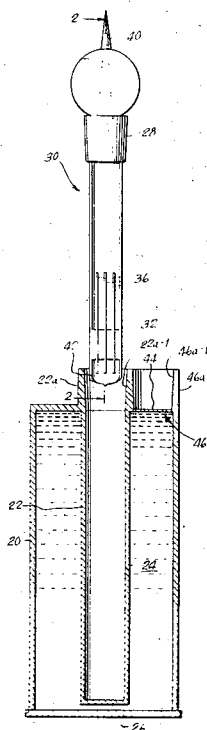
Attorney, Agent, or Firm—**Cooper, Dunham, Clark, Griffin & Moran**

[57]

ABSTRACT

A disposable dilution system particularly suited for blood testing. A container for containing a diluent includes a capillary tubing assembly holder therein that is sealed from the diluent. The holder terminates in an upper portion thereof that is adapted to engage the upper portion of a capillary tubing assembly which is stored within the holder. An access opening to the container is provided adjacent to the holder. The access opening is closed by a penetrable membrane which may be pierced by an end of the capillary tubing assembly when the latter is withdrawn from the holder. The capillary tubing assembly includes a neck portion that engages the upper portion of the holder prior to usage of the device. A collar is positioned below the neck portion and provides the sole means for containing one or more capillary tubes. The tubes may be separately formed, in which case they are detachably held by the collar, or the tubes may be formed integrally within the collar. The upper ends of the capillary tubes are spaced below the neck portion of the capillary tubing assembly. The neck portion includes a passage therethrough and also an inspection port for colorimeter testing. A volume-occupying plug may be employed at the lower end of the container, the plug including a cut-out portion to permit it to be positioned about the lower part of the capillary tubing assembly holder and the lower portion of the capillary tubing assembly when the latter is positioned in the diluent upon its removal from the holder.

18 Claims, 15 Drawing Figures



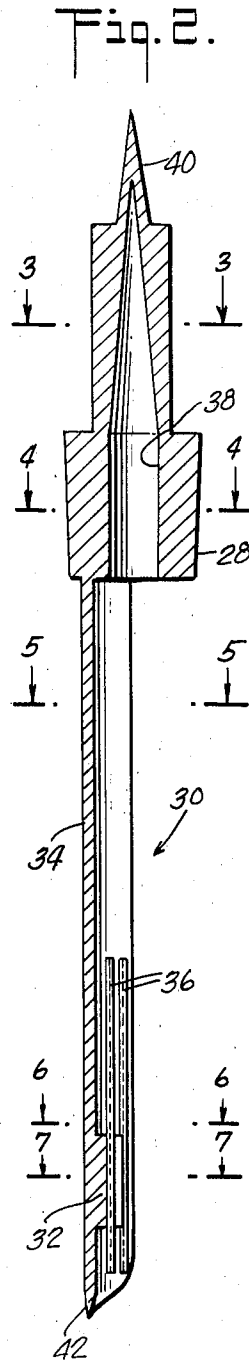
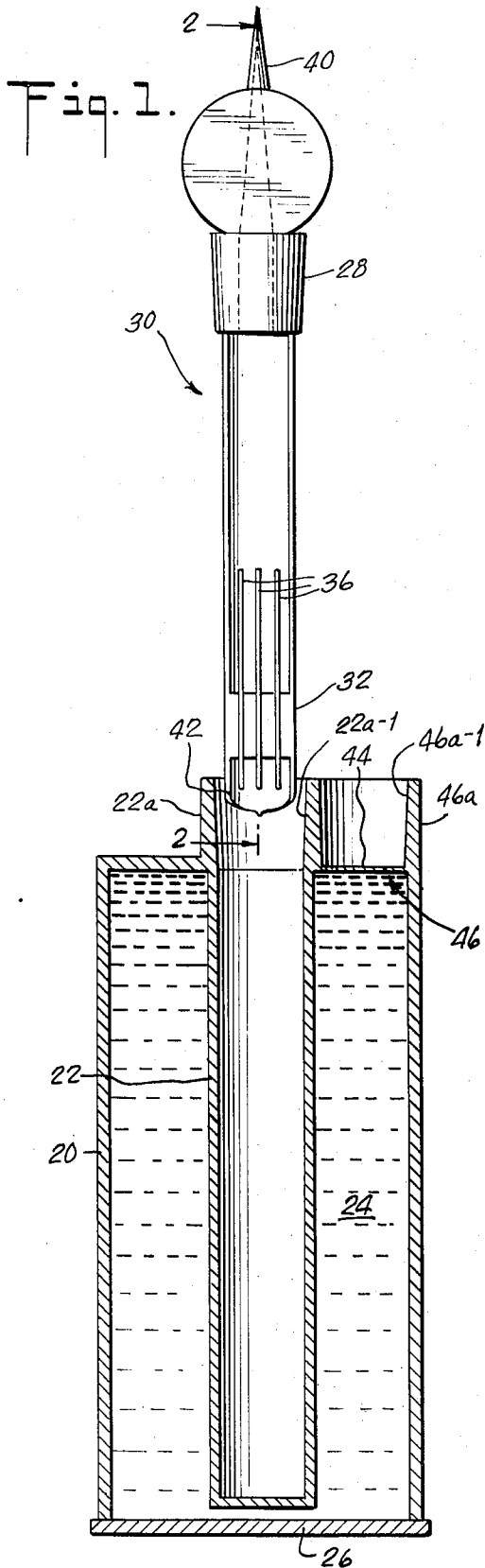


Fig. 3.

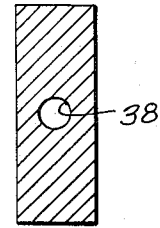


Fig. 4.

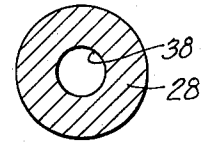


Fig. 5.



Fig. 6.

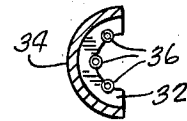
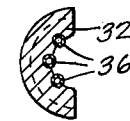
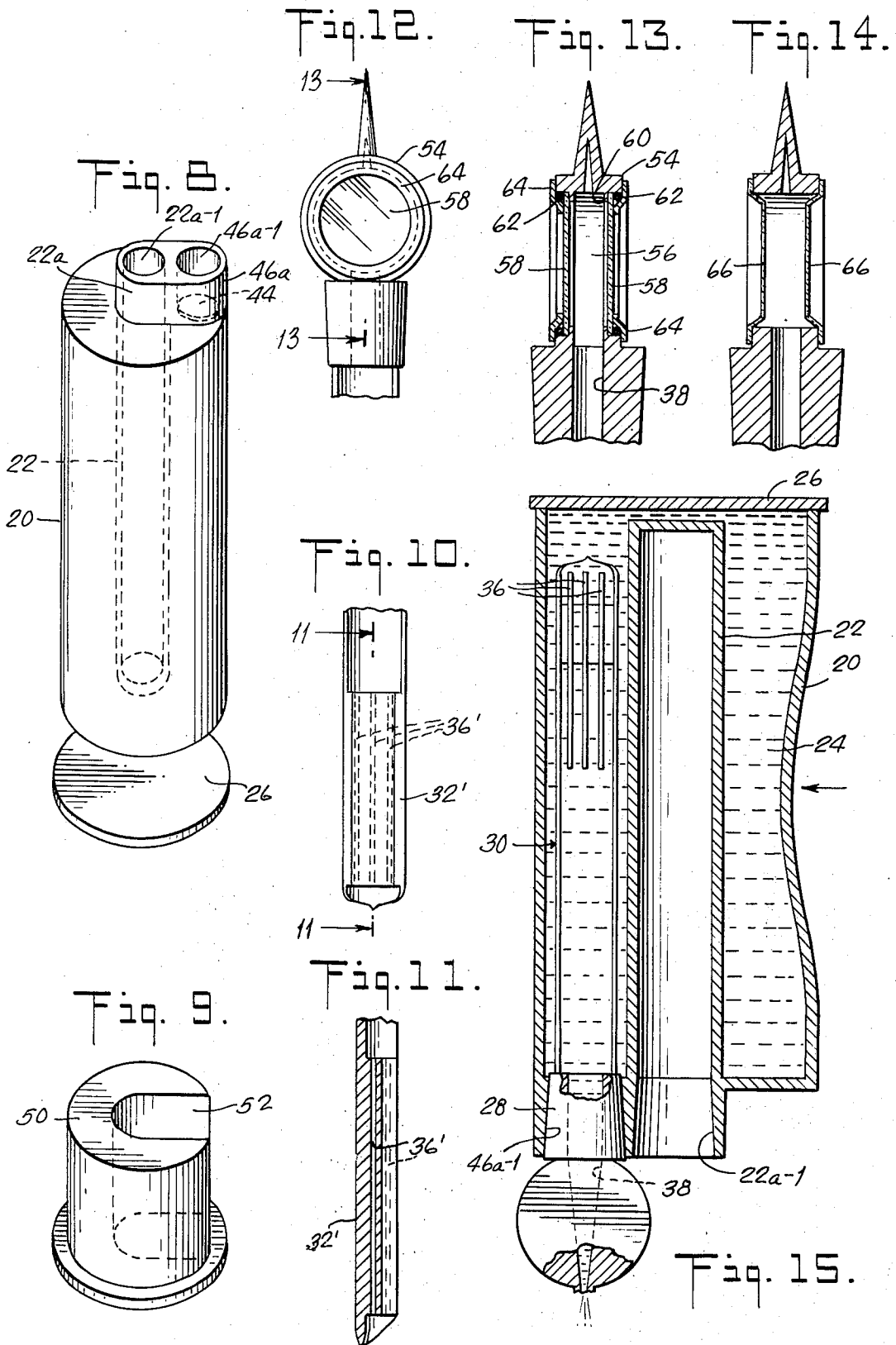


Fig. 7.





DISPOSABLE DILUTION SYSTEM

BACKGROUND AND BRIEF DESCRIPTION OF THE INVENTION

This invention relates to dilution apparatus, and particularly to a disposable dilution device.

Disposable dilution devices are known. See, for example, Konkol U.S. Pat. No. 3,603,156 issued Sept. 7, 1971 and the references cited therein. The present invention is directed to a disposable dilution device which is easy and inexpensive to make, is accurate, and may be utilized by relatively inexperienced personnel.

The invention contemplates use of a container for containing a diluent. A holder for holding a capillary tubing assembly is included within the container and sealed from the diluent. The holder terminates in an upper portion that engages the neck portion of the capillary tubing assembly. The capillary tubing that forms part of the assembly is positioned below the neck portion within a collar. Thus, the capillary tubing assembly is maintained in a sealed environment free from contamination. One or more capillary tubes may be detachably held by the collar, or the capillary tubing may be integrally formed with the collar. The upper end of the capillary tubing is spaced below the neck portion of the assembly. Typically, the neck portion is ring shaped in cross section, while the collar is semi-ring shaped in cross section. The collar and the neck portion may be joined together by an intermediate semi-ring shaped portion which is slightly less in thickness than the collar, to result in a saving of material.

The neck portion of the capillary tubing assembly includes a passage therethrough which is sealed at its outer end by a breakable closure. The closure is broken to unseal the passage during use of the device. The neck portion includes an upper inspection port for colorimeter testing. The inspection port comprises a transparent plate member that closes off an opening in the neck portion that communicates with the passage therethrough. In this fashion the device may be used directly with a colorimeter.

Adjacent to the upper portion of the capillary tubing assembly holder is an opening to the container providing access to the diluent therein. This opening is advantageously sealed by a penetrable membrane which may be broken by a sharpened lower end of the capillary tubing assembly when the latter is withdrawn from the holder. The assembly may then be placed within the container through the access opening. The access opening may be formed to sealingly engage the neck portion of the capillary tubing assembly.

The container may advantageously include a plate or a volume-occupying plug closing off the bottom portion thereof. The plug includes a cut-out portion to permit the plug to be positioned about the lower end of the capillary tubing assembly holder as well as the lower portion of the capillary tubing assembly when the latter is positioned through the access opening and in the diluent upon removal of the assembly from the holder. In this fashion the container may be made of standard size, with volume-occupying plugs of different sizes being individually employed to provide containers of differing volumes of diluent to satisfy different testing procedures.

The device is typically used as follows, for example, in connection with blood testing. The skin of a patient

is punctured to obtain a drop of blood. The capillary tubing assembly is withdrawn from the container and a specific volume of blood is drawn into the capillary tubing by capillary action. The sharpened lower end of the tubing assembly is then used to penetrate the membrane closing off the access opening to the diluent. The capillary tubing assembly is then positioned within the container and within the diluent, with the neck portion of the tubing assembly sealingly engaging the access opening. The container is then shaken, shaking the blood within the capillary tubing into the diluent. The breakable closure at the outer end of the passage through the neck portion of the capillary tubing assembly is then broken to unseal the passage. Diluent may then be dispensed from the container by squeezing the container, which is advantageously made of plastic for this purpose. In the event that a colorimeter test is desired, diluent containing blood is made to fill the passage through the neck portion of the capillary tubing assembly, visible through the inspection port usable with a typical colorimeter.

The invention will be more completely understood by reference to the following detailed description of representative and presently preferred embodiments thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a view, partly in section, of a container and capillary tubing assembly in accordance with the invention;

FIG. 2 is a sectional view of the capillary tubing assembly of FIG. 1, taken along the section line 2—2 of FIG. 1;

FIGS. 3—7 are sectional views of the capillary tubing assembly shown in FIG. 2, taken along the section lines 3—3 through 7—7 in FIG. 2;

FIG. 8 is a perspective view of a container in accordance with the invention, including one form of bottom closure;

FIG. 9 is a perspective view of a volume-occupying plug forming a second form of bottom closure for the container of FIG. 8;

FIG. 10 is a view of a bottom portion of capillary tubing assembly including integrally formed capillary tubes;

FIG. 11 is a sectional view of the structure of FIG. 10, taken along the section 11—11 in FIG. 10;

FIG. 12 is a view of a top portion of a capillary tubing assembly adapted for use in colorimeter testing;

FIG. 13 is a sectional view of the structure of FIG. 12, taken along the section 13—13 in FIG. 12;

FIG. 14 is a sectional view similar to that of FIG. 13, showing an alternative structure;

FIG. 15 is a sectional view of a device such as shown in FIG. 1 in use to dispense diluent in connection with a blood test, for example.

DETAILED DESCRIPTION

Referring to FIG. 1, a container 20 is shown. The container advantageously may be made of plastic material which is easily squeezed so that it may be deformed, for example, as shown in FIG. 15. The container 20 includes a capillary tubing assembly holder 22 therein which is sealed from diluent 24 within the container. The bottom of the container may be closed by a plate 26. At the top of the container, the holder 22 terminates in an upper portion 22a that includes a ta-

pered inner portion 22a-1 shaped to sealingly engage neck portion 28 of a capillary tubing assembly 30 when the latter is positioned within the holder 22.

The capillary tubing assembly 30 is shown in section in FIG. 2. As noted from the sectional view of FIG. 4, the neck portion 28 is ring shaped in cross section. The assembly includes a collar 32 at the lower end thereof which is semi-ring shaped in cross section as shown by the sectional view of FIG. 7. The collar 32 and neck portion 28 are spaced apart from each other and are connected by a semi-ring shaped intermediate portion 34 that is of a thickness that is less than that of collar 32 in order to save material. The collar 32, which is longitudinally spaced from the neck portion 28, constitutes the sole means for containing one or more capillary tubes 36. The capillary tubes may be separately formed, as shown in FIGS. 1 and 2, in which case they are detachably held by the collar 32. The collar thus includes one or more channels for holding the separate capillary tubes. Advantageously, the collar is flexed to initially receive the tubes, and then securely hold the tubes after they have been positioned within the channels in the collar. Alternatively, the capillary tubing may be integrally formed within the collar 32 such as shown in FIGS. 10 and 11. As shown in those figures, collar 32' includes integral passages 36' therein which constitute capillary tubing.

The upper end of the capillary tubing is spaced from the neck portion 28. The neck portion 28 includes a passage 38 therethrough which is sealed at its outer end by a breakable closure 40. This closure seals the passage until it is broken. At the lower end of the capillary tubing assembly 30, the collar terminates in a membrane-breaking end portion 42. This lower end portion 42 is for breaking membrane 44 that closes off and seals an opening portion 46 of the container adjacent to the upper end portion 22a of the capillary tubing assembly holder 22. The membrane-sealed opening portion 46 provides access to the diluent 24 within the container 20. This opening portion includes an upper part 46a thereof that includes a tapered inner surface 46a-1 similar to the tapered surface 22a-1 described above and for the purpose of sealingly engaging the neck portion 28 of the capillary tubing assembly 30.

In use the capillary tubing assembly 30 is initially positioned within the holder 22, with the capillary tubing 36 sealed from the atmosphere and from contamination. In this case the neck portion 28 sealingly engages the inner surface 22a-1 of the upper portion of the holder 22. The skin of a patient is pricked, for example, to provide a sample of blood. The capillary tubing assembly 30 is withdrawn from the holder 22, and the lower end of the capillary tubing 36 is placed in contact with the blood to draw blood within the tubing by capillary action. As noted, one or more capillary tubes may be provided, and one or more of such tubes may be filled with blood as desired for a particular test. In any event, a measured amount of blood is drawn into the capillary tubing. Next, the assembly 30 is used to pierce the membrane 44 sealing the opening portion 46 to the container and providing access to the diluent 24 within the container. The capillary tubing assembly is lowered through the opening portion 46 into the diluent, and the neck portion 28 of the assembly sealingly engages the surface 46a-1 of the upper part of the opening portion 46. Next, the container is shaken so that the blood within the capillary tubing is mixed with the diluent.

The entire container may then be inverted, as shown in FIG. 15, with the breakable closure 40 broken off to permit diluent-containing blood to be squeezed from the container. The blood-containing diluent passes through the now-open passage 38 in the neck portion of the capillary tubing assembly.

Different tests may require different amounts of diluent. In order to adapt the container shown in FIG. 1 and FIG. 8 to differing volumes of diluent, different bottom closures to the container may be provided. For example, as shown in FIG. 8, the bottom closure may comprise a simple plate 26. On the other hand, a volume-occupying plug 50 as shown in FIG. 9 may be employed. The plug 50 includes a cut-out portion 52 which permits the plug to be positioned about the lower portion of the capillary tubing assembly holder 22 as well as the lower portion of the capillary tubing assembly 30 when the latter is positioned in the diluent upon removal of the assembly from the holder 22 and the repositioning of the assembly in the container through the opening portion 46. In this fashion the only change that need be provided is a different bottom assembly for the container to accommodate differing volumes of diluent.

FIGS. 12, 13 and 14 show arrangements by which the capillary tubing assembly may be adapted for colorimeter testing. Specifically, the neck portion of the assembly includes an inspection port. As shown in FIGS. 12 and 13 the neck portion terminates in a circular terminal part 54 which is essentially a ring. A chamber 56 is provided which is closed by transparent windows 58. The windows 58 may be seated against ledges 60 that are formed integrally with the ring-shaped upper part of the neck portion of the assembly. The transparent windows 58 may be held in place through the use of O-ring seals 62 and rings 64. In the event that the parts just described are made of plastic, the rings 64 may be ultrasonically welded in place to provide a leakproof hollow cylinder at the upper part of the capillary tubing assembly which may be used directly for colorimeter testing. This upper part of the assembly may be fitted directly into a standard colorimeter for suitable tests to be made of the diluent within the chamber 56. In this regard the chamber 56 communicates with the passage 38 through the neck portion of the assembly.

FIG. 14 shows a slightly different arrangement. In this case, transparent membranes 66 are employed to close off the ends of the inspection port.

In all of the above embodiments it should be noted that, after the breakable closure 40 is broken off, the closure which is pointed or tapered, may be employed as a plug to seal the open passage 38 by forcing the pointed end of the closure into the passage.

Representative embodiments of the invention have been described above. It will be apparent to those skilled in the art that modifications may be made without departing from the spirit of the invention. Accordingly, the invention should be taken to be defined by the following claims.

I claim:

1. An assembly for holding capillary tubing in a blood analysis device or the like, comprising a neck portion having a fluid passage therethrough and an outer surface for sealingly engaging an opening portion of a diluent container that is normally closed by a penetrable membrane, detachable means sealing one end of said passage, a capillary tubing support member joined to

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said neck portion at the other end of said passage for holding one or more capillary tubes, said capillary tubing support member including means a terminal part thereof for piercing the penetrable membrane.

2. A device according to claim 1, including one or more capillary tubes integrally formed within said capillary tubing support member.

3. A device according to claim 2, in which each of said capillary tubes has an open end for receiving liquid in the tube, and said terminal part of said capillary tubing support member extends beyond said open ends of said one or more capillary tubes.

4. A device according to claim 1, including one or more capillary tubes detachably held by said capillary tubing support member.

5. A device according to claim 4, in which said capillary tubing support member is grooved in an outer surface thereof with one or more grooves semi-circular in cross-section to provide for the detachable holding of said one or more capillary tubes.

6. A device according to claim 1, in which said capillary tubing support member is semi-ring shaped in cross-section.

7. A device according to claim 6, including an intermediate support member that joins together said neck portion and said capillary tubing support member, said intermediate support member being semi-ring shaped in cross-section.

8. A device according to claim 7, in which the thickness of said intermediate support member is less than that of said capillary tubing support member.

9. A device according to claim 1, in which said neck portion includes a sealed inspection port for colorimeter testing.

10. A device according to claim 9, in which said inspection port comprises a transparent plate member that closes off an opening in said neck portion that communicates with said passage in said neck portion.

11. A device according to claim 1, in combination with a container having a chamber therein for containing a diluent, said container having a holder therein sealed from said diluent chamber and holding said capillary tubing assembly.

12. A device according to claim 11, including an opening portion of said container providing access to said diluent chamber and sealed by a membrane pene-

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trable by said piercing means.

13. A device according to claim 11, including a plug within said diluent chamber and having a cut-out portion thereof positioned about said terminal portion of said capillary tubing assembly when the latter is positioned in said diluent chamber upon removal of the latter from said holder and repositioning of same in said container opening portion.

14. A device according to claim 1, in which said detachable sealing means comprises by a breakable closure which is broken to unseal said passage.

15. A device according to claim 14, in which said breakable closure includes a pointed end which may be inserted into said passage to reseal said passage.

16. A capillary tubing holder and colorimeter testing assembly for a blood analysis device or the like, comprising a neck portion having a fluid passage therethrough and an outer surface for sealingly engaging an opening portion of a diluent container detachable means sealing one end of said passage, a capillary tubing support member joined to said neck portion at the other end of said passage for holding one or more capillary tubes, and means joined to said neck portion and defining an inspection port for colorimeter testing and comprising a chamber communicating with said fluid passage and closed by a transparent window.

17. An assembly for holding capillary tubing in a blood analysis device or the like, comprising a neck portion having a fluid passage therethrough and an outer surface for sealingly engaging an opening portion of a diluent container that is normally closed by a penetrable membrane, detachable means sealing one end of said passage, a capillary tubing support member for holding one or more capillary tubes and being semi-ring shaped in cross-section, and an intermediate support member at the other end of said passage joining together said neck portion and said capillary tubing support member, said intermediate support member being semi-ring shaped in cross-section, and said capillary tubing support member including means on a terminal part thereof for piercing the penetrable membrane.

18. A device according to claim 17, in which the thickness of said intermediate support member is less than that of said capillary tubing support member.

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