United States Patent [19]

Green

[11] **3,885,549**

[45] **May 27, 1975**

[54] **APPARATUS FOR PRODUCING A VACUUM IN A TEST TUBE**

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[22] Filed: **May 29, 1974**

[21] Appl. No.: **474,236**

Related U.S. Application Data

[63] Continuation of Ser. No. 266,396, June 26, 1972, abandoned.

[52] **U.S. Cl.** ..... **128/2 F;** 128/DIG. 5; 128/220; 128/276; 128/278

[51] **Int. Cl.** **A61b 5/14;** A61m 1/00

[58] **Field of Search** ..... 128/2 F, DIG. 5, 275, 276, 128/278, 220, 218 P, 218 D; 215/47; 417/566

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[57] **ABSTRACT**

Apparatus is provided for forming a vacuum in a test tube in the field. A cap is mounted on an insertion tool by having a projection on the tool cam out a detent on the cap as it passes. The cap is then rammed into a test tube by use of the tool, a flange on the cap bending back to permit air to escape. With the whole cap in the tube, the detent is prevented from being cammed out, permitting the tool to be used to withdraw the cap from the tube. As the cap is withdrawn, the flange is forced against the walls of the tube to prevent air reentering the tube. When the upper portion of the cap leaves the tube, the detent is again cammed out by the projection on the tool, releasing the tool.

The lower portion of the cap, including the flange, remains in the tube to seal it.

7 Claims, 6 Drawing Figures

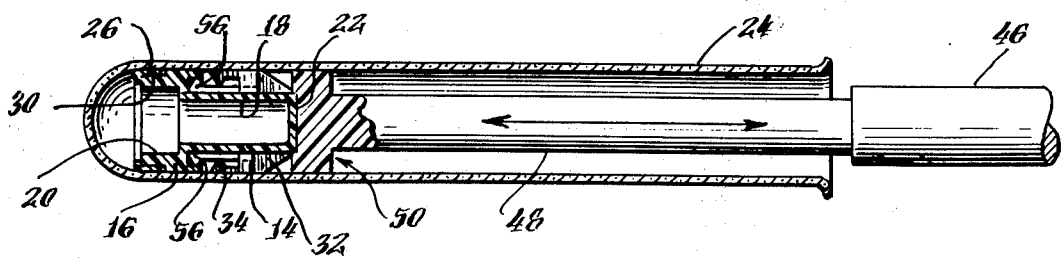


Fig. 1.

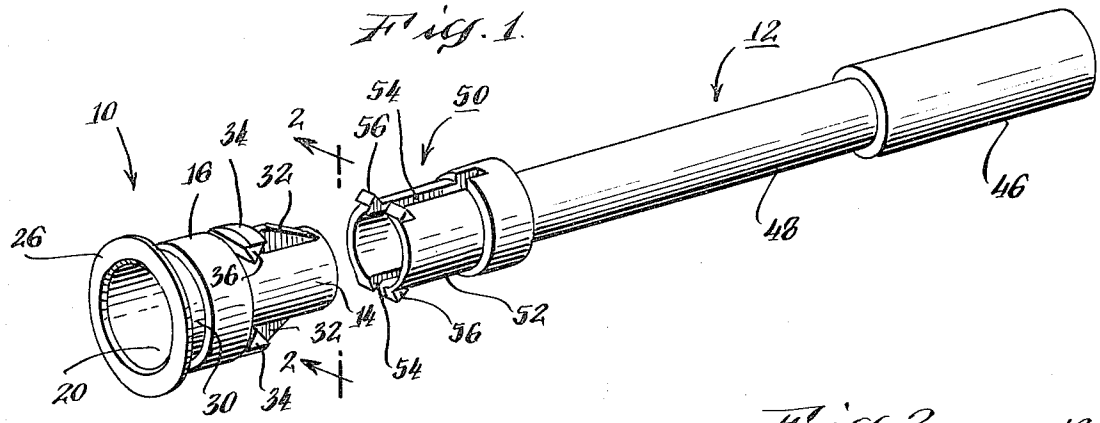


Fig. 2.

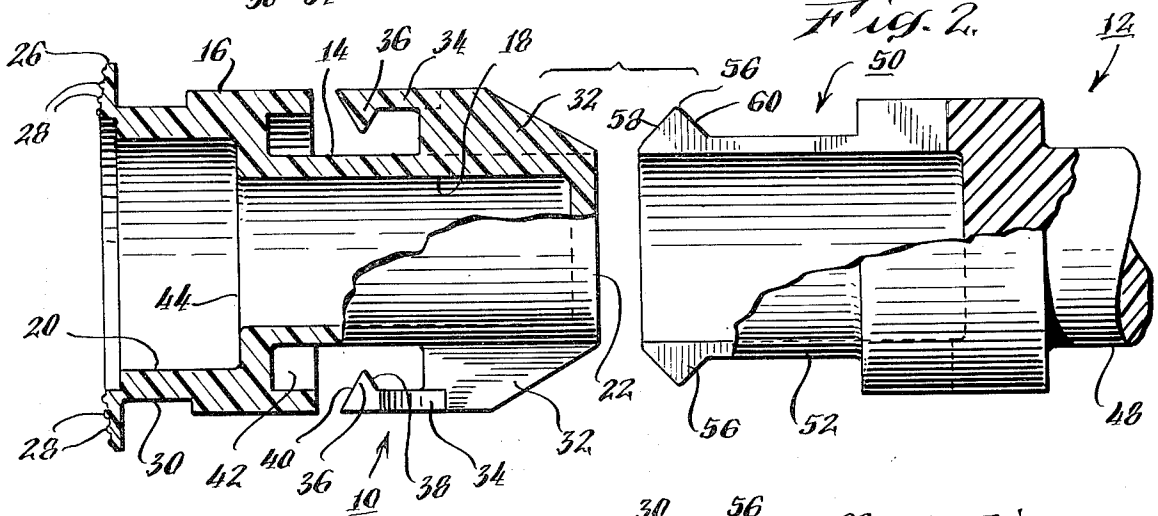
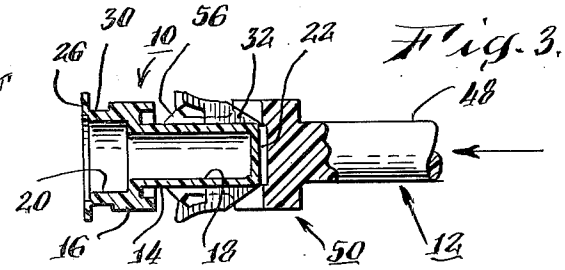


Fig. 3.



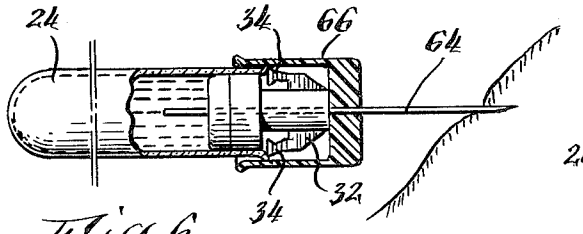


Fig. 6.

Fig. 4.

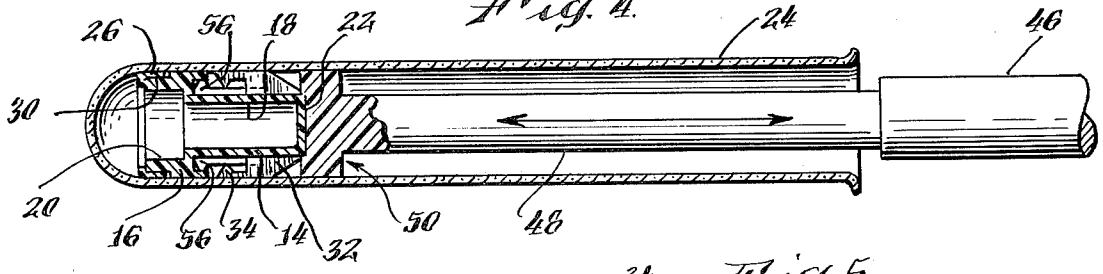
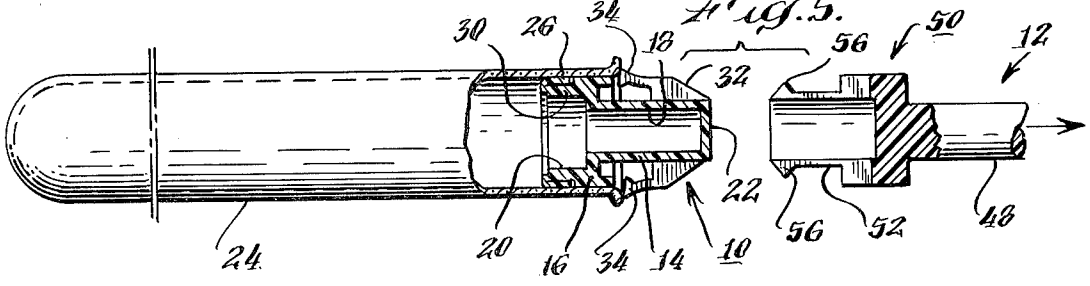


Fig. 5.



APPARATUS FOR PRODUCING A VACUUM IN A TEST TUBE

RELATED APPLICATIONS

This application is a continuation of my earlier copending application, Ser. No. 266,396, filed June 26, 1972, and now abandoned.

BACKGROUND OF THE INVENTION

This invention relates to apparatus for creating a vacuum in a test tube and more particularly to such an apparatus which permits tests tubes to be vacuumized in the field without requiring complex or expensive equipment.

For many years sealed, vacuumized test tubes have been sold to hospitals, doctors, and other medical organizations for use in drawing blood and other biological samples. Vacuumized tubes have been found preferable for these applications over standard hypodermic needles or syringes for at least two reasons. First, when a hypodermic needle is utilized to draw blood from a vein, there is a possibility that a careless attendant might accidentally depress the plunger while the needle is in the vein, injecting air into the vein. Air inadvertently injected into an individual's veins could result in a fatal stroke or embolism. Secondly, depressing the hypodermic plunger to remove blood therefrom may break up or otherwise damage corpuscles in the blood, introducing the possibility of inaccurate test results. Similar problems may exist when a hypodermic needle is utilized to draw other biological samples.

While the prevacuumized test tubes presently available overcome the problems indicated above, and have thus enjoyed substantial commercial success, they do present certain problems. First, while the cost of cleaning the tubes after use is relatively low, the cost of shipping the tubes back to the manufacturer after use to be revacuumized is high enough so that this procedure is not economically feasible. Thus, most of the tubes are now thrown away after a single use. Second, relatively expensive rubber caps must be used rather than plastic caps to seal the tubes. This requirement exists because plastic is slightly porous, and the shelf life of a vacuumized tube with a plastic cap would thus be minimal.

From the above it is apparent that the cost of utilizing vacuumized test tubes could be substantially reduced if a procedure could be provided for permitting the tubes to be revacuumized at the site. Further, if the revacuumizing could be accomplished within a short time before use (for example within a day or two before use) relatively inexpensive plastic sealing caps could be substituted for the rubber caps now utilized.

An additional problem which could be solved by providing a capability of vacuumizing test tubes at the site is that of storing cultures which can breed only in a vacuum. At present, expensive equipment is required at facilities working with these cultures.

Another shortcoming of existing pre-vacuumized test tubes is that, where a substance such as an anticoagulant is required to be mixed with the biological sample applied to the tube, the substance is normally placed in the tube before it is vacuumized and sits in the bottom of the tube when the sample flows in. When a tube is filled, the attendant must shake the tube to insure proper mixing of the substance with the sample. Should the attendant inadvertently forget to shake the tube after the sample is drawn, damage to the sample may occur. Further, certain substances are of a type which may not be stored in a vacuum, and the mixing of these samples presents special problems with existing prevacummized tubes. A requirement therefore exists for a procedure to permit the storage of substances to be mixed with a biological sample under nonvacuum conditions and in a manner so as to insure substantial mixing of the substance and the sample.

SUMMARY OF THE INVENTION

In view of the above, this invention provides an apparatus for forming a vacuum in a test tube and of sealing the tube. The apparatus involves the use of a cap which is adaptable for use with a simple insertion tool. The cap consists of a body formed of a cylindrically shaped upper portion and an enlarged cylindrically shaped lower portion with the diameter of the lower portion being less than that of the test tube to be vacuumized. The upper portion of the cap is sealed at its top and has an internal bore which terminates in an enlarged counterbore in the lower portion. A flexible flange ring is formed as an integral part of the base of the lower portion, the diameter of the flange being greater than the test tube diameter. A detent means is mounted on the upper portion of the body, the detent means being shaped and positioned to be cammed out of the way of the cap insertion tool to permit the tool to be passed in or out of the cap when the upper portion of the cap is out of the test tube. However, when the upper portion of the cap is in the test tube, the walls of the test tube inhibit the camming out of the detent means. Thus, the insertion tool is held in the cap by the detent means so long as the upper portion of the cap is in the test tube. This permits the cap to be lowered into the test tube by the tool, with air escaping around the flange ring as this is done. The tool is then used to draw the cap out of the tube, the flange coacting with the walls of the tube to form a seal to prevent air from reentering the tube. When the upper portion of the cap is out of the tube, the tool is released, the lower portion of the cap and the flange remaining in the tube to form a vacuum seal.

The foregoing and other objects, features, and advantages of the invention will be apparent from the following more particular description of a preferred embodiment of the invention as illustrated in the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of the sealing cap and insertion tool of a preferred embodiment of the invention.

FIG. 2 is a cutaway side view along the line of a 2—2 of FIG. 1 of a cap and a portion of the insertion tool of the preferred embodiment of the invention.

FIG. 3 is a partially cutaway sideview showing the cap partially mounted on the insertion tool.

FIG. 4 is a partially cutaway side view illustrating the cap fully mounted on the tool and inserted in the test tube.

FIG. 5 is a partially cutaway side view illustrating the cap sealing the tube with the insertion tool released.

FIG. 6 is a partially cutaway sideview illustrating the vacuumized test tube with the cap mounted on a needle assembly and being utilized for drawing a biological sample.

DETAILED DESCRIPTION

Referring now to the figures, it is seen that this invention includes a test tube sealing cap **10** and a cap insertion tool **12.** The body of the cap is formed of an upper cylindrical portion **14** and a lower cylindrical portion **16** of enlarged diameter. Portion **14** has a bore **18** which terminates at one end in an enlarged counterbore **20** in portion **16** and is sealed at the other end by the top of the cap **22.** The diameter of enlarged portion **16** of the cap is slightly less than the diameter of test tube **24** with which the cap is to be utilized.

A flexible flange ring **26** is formed as an integral part of and projects from the lower end of enlarged portion **16.** The lower surface **28** of ring **26** is preferably ridged for reasons which will be described shortly. An annular groove **30** is formed in portion **16** just above flange **26.** As will be seen shortly, flange **26** may be bent back into groove **30** when the cap is inserted in test tube **24.**

A pair of webs **32** project from opposite sides of upper portion **14** of cap **10.** As may be best seen in FIG. **2,** the depth of the web is greater at the bottom of the web than at the top. Similarly the width of the web may also be greater at the bottom. Projecting from the bottom of each web **32** is a cantilevered detent arm **34** at the end of which is mounted a detent **36** having a triangular cross section. Each detent **36** has a tapered leading edge **36** and a tapered trailing edge **40.**

Another feature of cap **10** is a ring-shaped groove **42** formed in the upper surface of lower portion **16.** An optional feature of cap **10** is a rupturable seal **44** across the lower end of bore **18.** An anticoagulant or other substance may be sealed in bore **18** by seal **44.** While cap **10** may be constructed of rubber, for reasons of cost and ease of fabrication it is preferably formed of a plastic. Seal **44** may be formed of a suitable material such as an elastomer.

Tool **12** consists of a handle **46,** a shank **48,** and a head **50.** Head **50** consists of a pair of cantilevered arms **52** which are spaced at their ends by a distance slightly greater than the width of a web **32.** Arms **52** may be formed by cutting a pair of grooves **54** in a short cylindrical tube. A projection **56** having a triangular cross-section with an angled leading edge **58** and an angled trailing edge **60** is formed at each end of each arm **52** adjacent to slots **54.** The length of each arm **52** is slightly greater than the height of upper portion **14** of cap **10.**

Operation

In operation, a cap **10** is first fitted onto a tool **12.** This is accomplished by inserting the upper portion **14** of the cap into the hollow center of the head **50** with webs **32** being positioned in grooves **54.** When the leading edges **58** of projections **56** come into contact with the leading edges **38** of detents **36,** angled edges **38** and **58** coact to cam projections **36** out of the way of projections **56.** FIG. **3** illustrates the cap and the tool in this partially assembled condition. As cap **10** is moved further into the head of tool **12,** projections **56** pass detents **36** and come to rest positioned partially in groove **42.** The natural resiliency of the plastic material of arms **34** causes the arms **34** and detents **36** to return to substantially their initial position once projections **56** have passed. FIG. **4** illustrates the relative position of the cap and tool when they are fully mated. When cap **10** is mounted onto tool **12,** the attendant uses the tool to insert the cap into the mouth of test tube **24** and to push the cap all the way to the bottom of the tube. FIG. **4** illustrates the arrangement of the various elements with cap **10** inserted all the way into tube **24.** It is noted that since flange ring **26** has a diameter greater than that of the test tube, it is folded back to a position partially into groove **30** when the cap is in the test tube. As the cap is inserted into the tube, the pressure of the air trapped ahead of the cap presses against flange **26** forcing flange **26** out of contact with the walls of tube **24** and further into groove **30.** Since the diameter of the remainder of cap **10** is slightly smaller than the diameter of the test tube, air ahead of the cap is permitted to escape as the cap is inserted into the tube. Thus with cap **10** all the way into the tube, as shown in FIG. **4,** there is virtually no air remaining in the portion of the tube under the cap.

The next step in the operation is to withdraw cap **10** from the tube, again, using tool **12** for this purpose. When a force is initially applied to tool **12** in a direction to remove the tool from tube **24,** the tool moves relative to the cap until trailing edges **40** and **60** engage. Since these surfaces are both angled, the interaction of the surfaces has a tendency to cam detent **36** out of the way of projections **56.** However, as seen in FIG. **4,** the walls of tube **24** are in close proximity to arms **34** and detents **36,** preventing them from being cammed out to the positions shown in FIG. **3.** Cap **10** is thus held in tool **12** by the interaction of detent **36** with projections **56,** permitting the tool to be utilized to draw the cap out of tube **24.** As cap **10** is withdrawn from tube **24,** the reduced pressure remaining in the area of the tube under the cap draws flange **26** down into the tube. This action is opposed by the walls of tube **24.** The pressure differential between the front and back of flange **26** is thus effective at this time to force the flange against the walls of the tube, providing a seal that prevents air from leaking back into the area of the tube under the cap. Ridges **28** on the underside of flange **26** provide a larger contacting area between the flange and the tube, improving the sealing action. A substantial vacuum therefore remains in tube **24** in the portion thereof under cap **10.**

When cap **10** has been removed to the position shown in FIG. **5,** with its upper portion **14** out of tube **24,** arms **34** and detents **36** are no longer restrained by the walls of tube **24** and are cammed out to permit the passage of projections **56.** Cap **10** is thus, at this stage of the operation, removed from tool **12.** As detents **36** are cammed out, they frictionally engage the upper edge of tube **24.** This frictional engagement holds the detents in the position shown in FIG. **5,** where they coact with the upper surface of the tube to prevent the cap from being drawn back into the tube.

From the above it is apparent that a three-step operation has been provided for vacuumizing a test tube. The operation may be performed rapidly, normally in a matter of seconds, by a minimally trained individual utilizing simple and inexpensive equipment.

FIG. **6** illustrates a vacuumized test tube **24** sealed with a cap **10** as it is utilized for drawing a biological sample. For this operation, one end of a hollow needle **64** is inserted into, for example, a vein of the individual from whom a biological sample is to be drawn. Needle **64** is mounted and sealed in a cup-shaped holder **66** which may, for example, be constructed of glass or a plastic material. The capped end of tube **24** is inserted

into holder **66** to a position where the other end of needle **64** pierces end **22** of cap **10.** When this occurs, the pressure differential between, for example, the vein at one end of needle **64** and the vacuum at the other end of needle **64** causes the blood or other biological sample to flow through needle **64** into tube **24.** Fluid continues to flow through needle **64** until the pressure at its two ends has been equalized. If the tube has been properly evacuated, this will occur when tube **24** has been substantially filled. When tube **24** is full, needle **64** is removed from the individual and tube **24,** with cap **10** still in place, removed from the holder and needle assembly. The hole made in cap **10** by needle **64** will normally seal adequately to permit the sample to be stored and shipped in the tube.

If there is a substance to be mixed with the sample stored in bore **18** behind seal **44,** the increased pressure differential across seal **44** when needle **64** pierces the cap will rupture the seal, permitting the substance and the sample to flow together into tube **24.** Since the sample flows through the substance on entering the tube, and the two elements enter the tube together, a good mixing action is effected, eliminating the need for subsequent shaking by the attendant. Should a seal **44** be required which is strong enough so as not to be rupturable by the pressure differential created when the needle enters cap **10,** the length of bore **18** and of the needle may be selected so that the needle penetrates seal **44** causing it to rupture.

While in the description above, it has been assumed that the tube **24** is empty when it is vacuumized, it is apparent that a culture or other substance to be stored in vacuum could be in the tube at that time. Further, while a particular detent mechanism **36** and means for mounting it has been shown, it is apparent that all that is required is that a detent mechanism be provided which may be cammed out of the way of a suitably designed insertion tool when the upper portion of the cap body is out of the tube but is restrained from being cammed when the upper portion of the cap is in the tube. Thus, while the invention has been particularly shown and described above with reference to a preferred embodiment thereof, it will be apparent to those skilled in the art that the foregoing and other changes in form and details may be made therein by those skilled in the art without departing from the spirit and scope of the invention.

What is claimed is:

1. A device for forming a vacuum in a test tube when inserted, moved along the length therein and then partially withdrawn therefrom, the partial withdrawal sealing the test tube to maintain the vacuum produced therein, comprising

a. a test tube which is desired to be evacuated having walls therein,

b. a cap on said test tube having an integral body formed of a cylindrically shaped upper portion sealed on one end thereof, and an enlarged cylindrically shaped lower portion of diameter less than that of said test tube, whereby said cap may be inserted, moved therein, and partially withdrawn from said test tube,

c. a flexible flange ring formed as an integral part of said lower portion, the diameter of said flange being greater than the diameter of said test tube, said flexible flange being bent back on said lower portion of said body when said cap is inserted and moved along the length of said test tube, the pressure of air trapped ahead of said cap forcing said flexible flange ring out of contact with the walls of said test tube, allowing the trapped air to escape between the walls of said test tube and the smaller diameter of said integral body, said flexible flange contacting the walls of said test tube as said cap is partially withdrawn thereform to maintain the vacuum in said test tube below said cap,

d. an insertion tool having detachable mounting means positioned on one end thereof engaging said cap and moving said cap in said test tube, and

e. flexible detent means mounted on said upper portion of said body engaging said detachable mounting means of said insertion tool, said detent means and said detachable mounting means defining means whereby said insertion tool remains mounted on said cap so long as the walls of said test tube are in contact with said flexible detent means, said flexible detent means releases said insertion tool from said cap when said upper portion of said cap is removed from said test tube, said flexible detent means being deflected by said detachable mounting means on removal from said test tube, thereby gripping the top of said test tube by said cap to prevent said cap from moving back into said test tube which has been evacuated thereby.

2. A device as claimed in claim **1** wherein said flexible detent means comprise a pair of flexible detent means each mounted on a web extending from said upper portion of said body.

3. A device as claimed in claim **2** wherein each of said flexible detent means includes a cantilever arm extending from the corresponding web with a projection having angled forward and trailing edges mounted at the end of said cantilever arm.

4. The device claimed in claim **3** wherein said insertion tool comprises a rod terminating in a pair of cantilever arms spaced sufficiently to permit said webs of said body to pass between said arms, and at least one projection having angled forward and trailing edges mounted at the end of each arm adapted to deform said flexible detent means thereby positioning said rod on said cap.

5. A device as claimed in claim **1** wherein said flexible flange ring has a ridged lower surface thereon.

6. A device as claimed in claim **1** including an annular groove formed in said lower portion just above said flexible flange ring, said groove receiving said flexible flange ring when said cap is being inserted and moved in the test tube to permit air to pass said flexible flange ring.

7. A device as claimed in claim **1** including a bore formed from said seal in said upper portion through the remainder of said cap, and including a rupturable seal formed across said bore at a point along the length thereof, and a substance which is desired to be mixed with a fluid which may be applied to said test tube being stored in said bore above said seal.

* * * * *