

Oct. 1, 1957

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SEROLOGY SAMPLE CONTAINER
Filed June 21, 1955

2,808,053

Fig. 1.

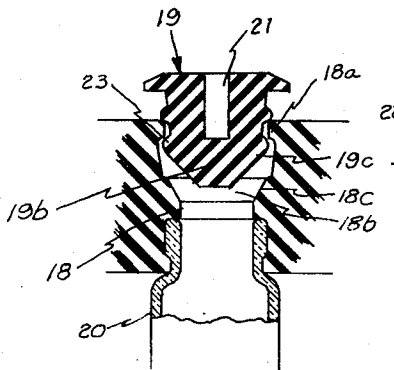
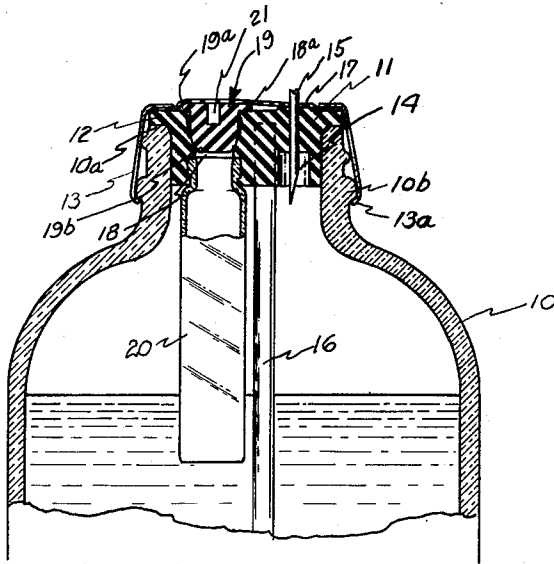


Fig. 2

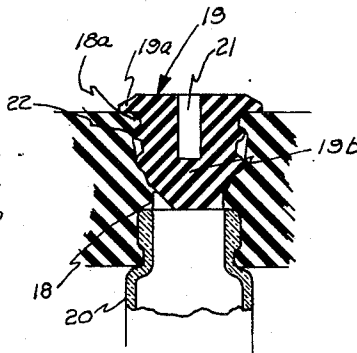


Fig. 3

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2,808,053

SEROLOGY SAMPLE CONTAINER

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Application June 21, 1955, Serial No. 516,838

2 Claims. (Cl. 128—272)

This invention relates to a serology sample container and, more particularly, to a serology sample container incorporated into the closure of a blood collection and storage container.

In the collection and storage of blood it is necessary that the character of the blood be determined in order to make sure that the blood will be given to a recipient whose blood has the same characteristics as the stored blood. Prior to the discovery of blood characteristics, recipients often died due to receiving blood of a type antagonistic to theirs. The primary characteristics which are ascertained relate to the "grouping" (A, B, O and the like) and Rh factors. Present medical practice dictates that not only should the blood be "typed" at the time of collection, but that the character be again determined just prior to administration.

More importantly, it is necessary to mix samples of the blood to be administered and blood from the recipient in order to detect any unidentified incompatibility. This practice necessitates the provision of a sample of the blood external to the main volume for such later typing and cross-matching for unknown factors. The importance of a properly protected and labeled sample for cross-matching can be appreciated from the fact that there are many blood factors incompatible with each other that are not ascertained by known typing procedures used at the time of collection. It is distinctly unfeasible to use a portion of the collected blood for this purpose, since the aseptic conditions of storage would quite possibly be destroyed. It is also desirable to provide a source of clotted blood for sampling.

In the past, the problem of providing a separate serology sample has been met in a number of ways. One has been to provide a separate vial in the nature of a test tube which is shipped separately from the empty blood collection bottle, making it subject to breakage. At the time of blood collection this tube is secured to the blood collection bottle by taping, or is mounted on an attached cardboard rack or the like. It is immediately apparent that such an expedient is not foolproof since, in the ordinary blood bank, there are a large number of containers of stored blood and the serology vials may become detached and inadvertently switched.

Another expedient to provide a separate serology sample container which is an improvement over the previously mentioned expedient, has been to form the blood collection container with a longitudinal recess adapted to receive the serology vial. The vial is then maintained in this recess by taping, or through the use of a metal band. This structure eliminates to some extent the danger of inadvertent switching of sample vials, but at the expense of seriously weakening the blood storage container bottle. The formation of such a recess causes strains which may later result in breakage of the major container and loss of its contents—perhaps at a time when the need for the contents is critical.

The importance of preserving a collected quantity of blood can be appreciated from a realization that bloods vary significantly in character through combination of

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the grouping and typing characteristics referred to above. For example, there are approximately seven different groupings of blood and at least six different typings (Rh factor) which result in a large number of possible combinations. In the event a rare combination is needed, it would indeed be critical if such a quantity of blood were lost through breakage of the container.

Essentially, the serology sample container of our invention includes a sample vial mounted in the resilient selfsealing closure, usually provided with the major blood collection and storage container. The sample vial, according to our invention, extends inwardly of the container. In this fashion, we eliminate completely the possibility of inadvertent detachment. Further, there is no weakening of the container structure and the sample is readily accessible at all times.

Our invention will be explained in conjunction with the accompanying drawing, in which Fig. 1 is an elevational view, partially in cross section, showing a blood collection and storage container equipped with a closure incorporating the serology sample container of our invention; and Figs. 2 and 3 are enlarged cross-sectional views of the serology sample container stopper in different positions of mounting within the blood collection and storage container stopper.

Referring to the drawing, the numeral 10 denotes a glass bottle adapted to collect and store whole blood. The usual practice is to provide containers for this purpose in such sizes as to receive 150 cc., 250 cc., and 500 cc. of blood. The containers are somewhat larger than the indicated volumes in order to accommodate an anticoagulant solution.

The usual blood collection container 10 is provided with a resilient stopper 11 mounted in the neck portion of the container. Since the approved technique in furnishing such containers is to provide them with their content under a pressure less than atmospheric (upwards of 28 inches Hg vacuum), the stopper must also act as an air seal. For this purpose the stopper is usually constructed of a resilient material such as rubber in order to conform to the neck of the container so as to prevent infiltration of air. Stopper 11 is also usually provided with an integral annular flange portion 12 at one end thereof. Flange 12 is adapted to rest on the lip 10a of container 10, thereby preventing the accidental "sucking in" of stopper 11 due to the evacuated condition in container 10.

Stopper 11 is maintained in its position in the neck of container 10 by the cooperation of metal cap 13, which is rolled under annular bead 10b of container 10, as shown at 13a.

Among other characteristics of stopper 11 which are usually incorporated, but which do not form part of our invention, is the provision of passage 14 extending part-way through stopper 11. During the course of collection, a hypodermic needle 15 is thrust through stopper 11, so as to communicate with passage 14. Hypodermic needle 15 is part of a blood collection set which has its other end extending into the vein of a donor (not shown). Once collection is achieved, needle 15 is removed and the substantial thickness of stopper lying between passage 14 and the top surface of stopper 11 causes the puncture made by needle 15 to become resealed.

Extending inwardly of container 10 is air tube 16 which is mounted in another passageway in stopper 11. This is a conventional expedient to permit air to enter the container during administration to replace the withdrawn blood. Rubber sealing disc 17 overlies the top of stopper 11 and is further secured thereto by the inwardly extending flange of cap 13. In general practice,

another metal disc and cap member are superimposed on the closure structure shown.

Stopper 11 is provided with a passage 18 extending therethrough. Mounted in the outer end of passage 18 is smaller resilient stopper generally designated 19. Mounted in the inner end of passage 18 is serology sample container 20.

In our preferred embodiment we make use of a separate smaller stopper 19 rather than resorting to the use of an integral diaphragm, as might be inferred from the structure associated with passage 14. We find the use of two stoppers or, more correctly, a stopper within a stopper, desirable, since we can evacuate both container 10 and vial 20 in a single operation. It is also desirable to use two stoppers, since the smaller stopper 19 can be removed yielding access to the interior of vial 20 for the removal of clots and the like and without opening the larger container. Often it is necessary to introduce a pipette to remove clots, which would be virtually impossible if an integral diaphragm were used in place of stopper 19.

Another design feature of our invention is the mounting of stopper 19 in passageway 18 rather than in the neck of vial 20. This feature is shown in enlarged form in Figs. 2 and 3. In this fashion we are able to make use of a rubber-to-rubber seal, which it is felt is more effective as an air seal glass-to-rubber, which would be the case if stopper 19 were inserted into vial 20. However, this same type seal could be achieved even if stopper 19 were inserted into vial 20 by the cooperation of annular flange 19a with the top of stopper 11.

To prevent vial 20 from being loosened in its mounting in stopper 11 when stopper 19 is pushed into passage 18, I have provided a relatively large or expanded recess as at 18b (best seen in Fig. 2) in the upper portion of passage 18. Thus, the receipt of stopper 19 into recess 18b does not tend to expand the inward portion of passage 18. Further, the compression effected by inserting stopper 19 would appear to be directed downwardly and laterally so that the grip of stopper 11 on vial 20 is actually tightened. Plug 19 is provided with a bottom tapered portion as at 19c which meets a tapered portion in passage 18 as denoted 18c, so that any downward compression is directed laterally and about that portion of stopper 11 holding vial 20, stopper 11 being restricted from outward lateral expansion by the neck portion of container 10.

Yet another feature to be noted is the provision of passage 21 in stopper 19. Passage 21 extends partway through stopper 19, commencing at the outer surface. Passageway 21 not only provides a guide for inserting a hypodermic needle but, more importantly, tends to prevent the inadvertent removal of stopper 19 from passage 18 during extraction of the hypodermic needle.

Helping to oppose the inadvertent removal of stopper 19 are annular ribs 22 and 23, integral in the side wall of stopper 19. As shown in Fig. 3, rib 22 cooperates with inwardly extending integral flange 18a of stopper 11 to hold smaller stopper 19 in sealed engagement with stopper 11. As shown in Fig. 2, rib 23 cooperates with flange 18a to loosely maintain stopper 19 in passageway 18 prior to and during the evacuation step, thereby preventing inadvertent removal or detachment. Since blood collection and storage containers are generally mass produced, as on a moving conveyor, prevention of dislocation of the various elements is an important consideration.

Manufacturing procedure

The usual procedure for manufacturing a blood collection and storage container, which procedure is followed when our invention is practiced, is as follows: a washed container 10 is provided with a suitable quantity of anticoagulant solution, such as ACD, manufactured according to the formulation found in edition XIV of the

U. S. Pharmacopoeia at page 500. Stopper 11 is provided with vial 20 inserted therein and stopper 19 mounted loosely in passage 18, as shown in Fig. 2. Stopper 11 is then mounted loosely in the neck of container 10. The assembly thus effected is then introduced into a vacuum chamber, which is provided with a ramming element to drive stoppers 11 and 19 home after container 10 has been evacuated, resulting in the combination shown in Figs. 1 and 3. After removal from the vacuum chamber the assembly is provided with cap 13, disc 17, and any other closure elements, after which the entire unit is subjected to steam sterilization.

Operation

After a bottle has been prepared according to the foregoing manufacturing procedure and suitably tested in accordance with the requirements of the Food and Drug Administration, the unit is ready for use. At a typical blood bank the container is attached to the prospective donor through a blood donor set. The blood donor set generally consists of a pair of hypodermic needles connected by a length of flexible tubing so as to provide a conduit from the patient's vein to the interior of container 10. As mentioned before, one needle is thrust through stopper 11 so as to communicate with passage 14. Passage 14 is considered desirable in order to effect superior reseal of stopper 11 upon withdrawal of hypodermic needle 15. This structure is set forth in Wayne D. Brandon Patent No. 2,457,120.

After a suitable quantity of blood has been drawn from the donor, a smaller quantity is introduced into vial 20. It is considered desirable to first fill container 10, since otherwise vial 20 might be loosened in its mounting in stopper 11 due to the differential pressure existing between vial 20 and container 10.

When a small sample of blood is introduced into vial 20, a hypodermic needle similar to that denoted 15 is inserted into passage 21 and thrust through the shortened length of stopper 19b inward of passage 21. Upon withdrawal of the hypodermic needle, it is to be noted that the forces exerted on stopper 19 are more lateral than they would be in the event that the diaphragm portion 19b were located at the top of passage 21. These forces are so distributed as to act through the body and side walls of stopper 19 against the walls of passage 18. Thus, I have effectively minimized the possibility of inadvertent withdrawal of stopper 19, as is the case where integral diaphragm portion 19b is located in the outer portion of passage 21.

The filled units are then stored under refrigeration until ready for use. Ordinarily, a separate sample is taken from the donor for immediate typing and testing purposes, and the results of such analysis are written on the bottle label. It is part of these results which are checked by the analysis made upon the contents of vial 20 just prior to administration.

The foregoing detailed description has been given for clearness of understanding only, and no unnecessary limitations are to be inferred therefrom. A modification considered embraced within my invention is where the smaller stopper 19 is molded as an integral part of larger stopper 11, being connected thereto by a flexible strap united as the two stoppers at the sides of the respective flange portions.

I claim:

1. An improved closure structure for a blood collection and storage container comprising a resilient self-sealing plug adapted to be mounted in the neck of said container, said plug having a passage extending therethrough, a serology sample container mounted in the inner end portion of said passage and a smaller resilient plug mounted in the outer end portion of said passage, said smaller plug being provided with a hypodermic needle-size passage extending partway therethrough from its top surface.

2. An improved closure structure for a storage container, comprising a resilient closure plug adapted to be

mounted in the neck of said container, said plug having a passage extending therethrough, a small container mounted in the inner end portion of said passage, said passage having a tapered portion above said small container, and a smaller resilient plug mounted in the outer end portion of said passage and abutting said tapered portion to compress the same for increasing the grip of the closure plug about said small container.

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