United States Patent [19]

Blaivas

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[54] **BLOOD COLLECTION CONTAINER**

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[52] **U.S. Cl.** **233/26**

[51] **Int. Cl.** **B04b 9/12**

[58] **Field of Search** ..... 233/1 A, 1 R, 26; 210/83; 23/292

[56] **References Cited**

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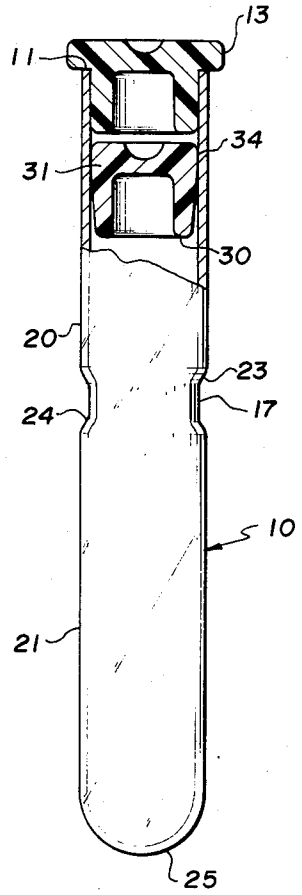
[57] **ABSTRACT**

An improved blood collection container having a reduced portion disposed between its closed longitudinal ends and a stopper means disposed therein and adopted under the influence of centrifugal force to be securely received in the reduced portion is described.

1 Claim, 5 Drawing Figures



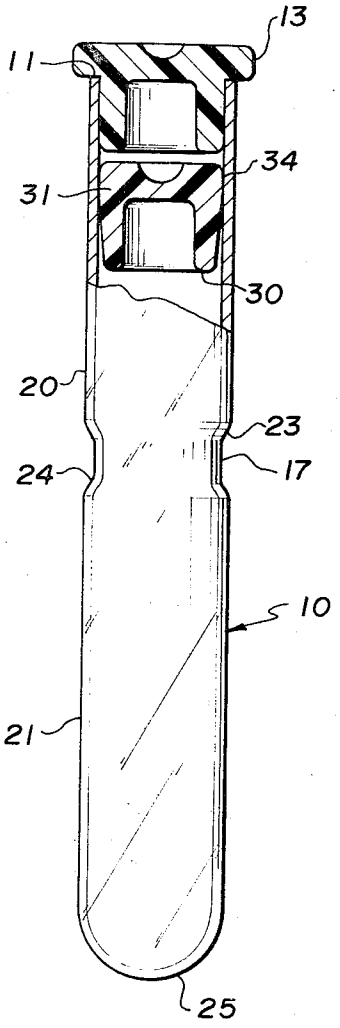


FIG. 1

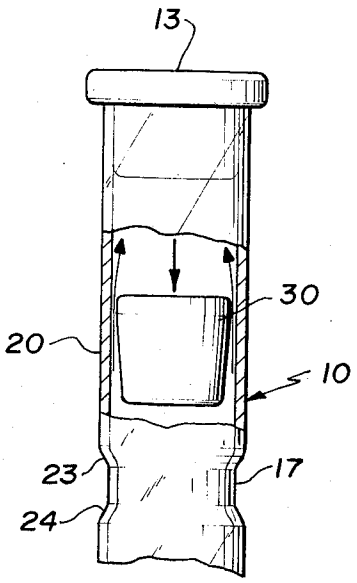


FIG. 2

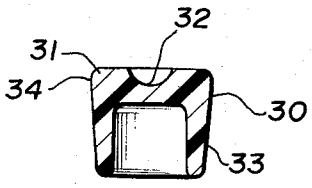


FIG. 3

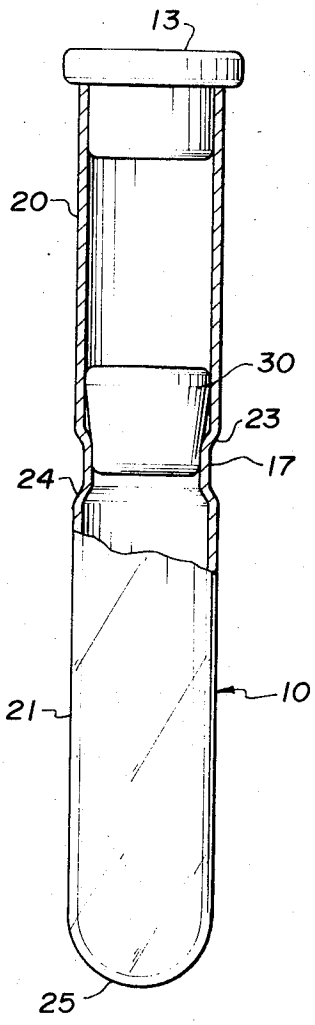


FIG. 4

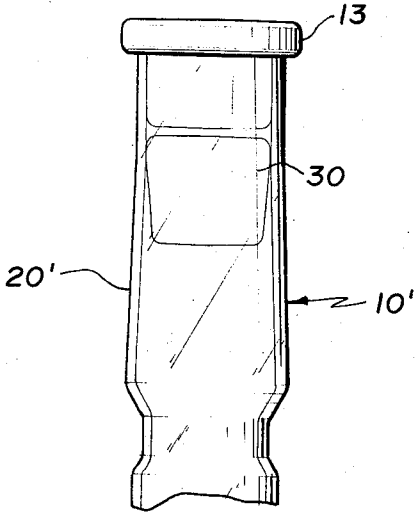


FIG. 5

BLOOD COLLECTION CONTAINER

DETAILED DESCRIPTION OF THE INVENTION

The invention relates to an improved container for collecting, stabilizing and storing for long periods of time a blood specimen and methods therefor. More particularly, the present invention relates to a new and improved vacuum container for collecting and stabilizing blood which comprises a container member having one end which may be integrally closed and the other end closed by a plug, a reduced portion disposed between the longitudinal ends of said container member and a closure means disposed therein and adopted under the influence of centrifugal force to be securely received in the reduced portion.

Vacuum-type containers for collecting blood specimens are well known in the art. In use, such containers comprise a hollow tubular member provided with a hypodermic needle which is inserted directly or via a cannula into the container. The blood so-obtained, after appropriate treatment and separation, is tested for physiologically significant indications. For example, the blood sample may be treated with an anticoagulant and centrifuged whereby the plasma is separated from the particulate matter, i.e. red and white cells and platelets and, thereafter, the plasma can be analyzed utilizing appropriate biochemical and serological tests. Alternatively, the blood sample may be allowed to clot without prior treatment and then centrifuged whereby the serum is separated from the particulate matter, and thereafter the serum can be analyzed utilizing biochemical and serological tests. In both instances, it is important that the liquid portion of the blood, that is, the plasma or serum, be physically separated from the particulate matter to insure stabilization of the plasma or the serum and, consequently, insure that the data obtained from the biochemical and serological tests accurately reflects the condition of the patient.

While prior art devices do function efficaciously to obtain blood samples, they require that the collected sample be promptly analyzed due to the fact that upon standing blood deteriorates, i.e. its constituents interact and thereby causes inaccurate analysis. Thus, prior art devices suffer from the defect of lacking means for preventing blood deterioration from occurring, that is, means which insure stabilization, if the blood sample is permitted to stand for extended periods of time.

As is known, a breakdown of the components of blood will occur if blood is permitted to stand for a period of time. The major cause of such deterioration can be attributed to the biochemical makeup of the blood sample and particularly the interaction between plasma or serum and the cellular portion of the blood, that is, the particulate matter found in blood. If biochemical changes occur in the sample, inaccurate analyses will result. Prompt separation of plasma or serum from the particulate matter, i.e. red and white blood cells and platelets, stabilizes the plasma or the serum. If the particulate matter can be separated from the plasma or serum soon after the blood sample is collected, the blood sample can be stored for long period of time or subjected to the rigors of transit, i.e. from a doctor's office to a clinical laboratory. By separating the plasma or the serum from the particulate matter the likelihood of deterioration is lessened and accurate analyses can be effected on both the plasma and/or the serum content of the specimen sample long after the blood sample has been collected.

Accurate diagnosis of a blood sample for physiological indications is indeed of critical importance in assuring proper medical care to the patient. In many circumstances, however, the patient is removed from the laboratory facilities which possess the capability of performing accurate multiple analysis of the sample. Thus, the transmittal of the sample to the laboratory for analysis thereof inherently presents problems.

It is an object of the present invention to provide the art with a blood collecting and stabilizing container and a method which assures the stabilization of blood even after the sample has been stored for long periods of time.

It is another object of the present invention to provide in a single apparatus means for collecting a blood sample and means for separating the liquid portion of blood from its particulate matter.

It is a further object of the present invention to furnish an apparatus which will include relatively few parts and which is capable of ready and economical manufacture.

It is a still further object of the present invention to provide a method performable on a conventional centrifugal machine.

In achieving the objects of the present invention, an evacuated tubular container made of suitable material, preferably glass or plastic, is provided with a section which is tapered to provide a reduced tapered portion intermediate its end, preferably, no more than mid-way down the upper end of the tubular container. After blood is collected, the vessel is subject to varying centrifugal forces. Under the influence of a lower centrifugal force, the plasma or serum separates from the particulate matter. Thereafter, a deformable member positioned in the container is moved under the influence of a higher centrifugal force to a position whereby it is securely received in said tapered position. In this position, the deformable member is positioned between the portions of the container which contains, respectively, the plasma or serum and the particulate matter. In this manner, the plasma or serum remain separated and contact with the particulate matter is avoided.

The centrifugal force required to move the deformable member and to separate the plasma or the serum from the particulate matter is provided by any conventional centrifuge. Physicians, laboratory technicians and the like use centrifuges to spin or whirl containers or vessels containing blood sample to subject the sample to centrifugal force. Such devices usually consist of a rotor adopted to spin about a horizontal plane. The machine is equipped with a series of elongated recepticles pivotally mounted near the open ends so as to depend vertically when the rotor is at its rest position. The lower portions of the recepticles are adopted to swing outwardly and upwardly to bring the recepticles substantially radially upon rotation of the rotor. The recepticles of the centrifugal machine are loaded with the sample containing vessels by dropping the latter therein while the recepticles rest in depending positions. Such centrifugal devices can be activated so that the rotor can rotate at varying speeds. As should be evident, such machines are well known in the art.

For a full understanding of the nature and objects of the invention, reference should be had to the following

detailed description taken in connection with the accompanying drawings in which:

FIG. 1 is a side view with parts in cross section of an apparatus embodying the invention before use;

FIG. 2 is a side view with parts in cross section of an apparatus embodying the invention showing transition of the closure means with respect to the reduced portion of the container;

FIG. 3 is a side view in cross section of an embodiment of the closure means of the apparatus of the invention;

FIG. 4 is a side view with parts in cross section of an apparatus embodying the invention after use; and

FIG. 5 is a side view with parts in cross section of another apparatus embodying the invention before use.

Referring now to the drawings and particularly to FIG. 1, a tubular member, vessel or container **10** formed from any suitable material, preferably, glass or plastic, is provided with an open end **11** and a reduced intermediate section **17.**

A stopper **13** is removably received in the open end **11.** The stopper **13** is made of rubber or any other suitable composition. The stopper **13** may be provided with a needle means not shown. The tubular member **10** is evacuated so that upon release of the vacuum, blood from a patient can be drawn into the tubular member in accordance with conventional techniques. Evacuation may be effected by passing an evacuating means through the stopper **13** and closure means **30** which evacuating means is connected to an evacuating mechanism.

The tubular member, vessel or container **10** comprises two sections **20** and **21** and a reduced portion **17** which are integrally connected. Section **20** extends from end **11** which is closed by stopper **13** to the reduced portion **17.** Section **20** includes a tapered portion **23.** Section **21** extends from closed end **25** to the reduced portion **17** and includes tapered portion **24.** The reduced portion **17** is positioned at the juncture of tapered portions **23** and **24.** As can be seen from FIG. **1,** the opening defined by reduced portion **17** and by the inner walls of tapered portion **23** and **24** is of a diameter which is less than the diameter of the opening defined by the longitudinal walls of the vessel **10** which are not tapered.

In another embodiment of the invention, as shown in FIG. **5,** in tubular member, vessel or container **10'**, the longitudinal walls of section **20'** are tapered so that the diameter of the opening defined by the upper end of section **20'** opposite to closure member **30** is smaller than the diameter of the opening defined by the lower end of section **20'** nearer to reduced portion **17,** and the opening defined by reduced portion **17** and by the inner walls of tapered portions **23** and **24** are of a diameter which is less than the diameter of the opening defined by the upper end of section **20'** opposite closure member **30.**

Referring still to FIG. **1** but now including FIG. **3** disposed within section **20** is closure means **30** which may be of rubber, plastic or other suitable elastomeric deformable material. The closure means **30** comprises a tapered body portion **31** which centrally defines a diaphragm **32.** The contiguous outer wall of said tapered body portion is adapted to engage the upper end of the inner surface of section **20** below stopper **13.** The tapered body portion **31** of closure means **30** should be so sized that the upper portion thereof **34** will bear against the adjacent inner wall of vessel **10** and not move toward the reduced portion **17** under normal conditions or under the influence of a centrifugal force which will cause separation of the plasma or the serum from the particulate matter.

Extending downwardly from diaphragm **32** is a deformable tapered portion **33.** When in deformed condition, the configuration of tapered portion **33** conforms to the tapered portion **23** of section **20.**

In accordance with this invention, container **10** should be constructed so that preferably the total volume contained within section **20** is approximately 40 percent of the total volume contained within the entire tube. Hence, the volume contained within section **21** is approximately 60 percent of the total volume contained in the entire tube.

In operation, blood is collected in the evacuated container according to conventional procedures, by puncturing simultaneously the stopper **13** and the diaphragm **32** of closure means **30.** The container is then placed on a centrifuge of conventional design. Upon centrifuging at lower speeds, e.g., from about 1,500 RPM to 3,000 RPM, the serum or plasma is separated from the particulate matter with the serum or plasma being received in section **20** and particulate matter being received in section **21.** After separation of the serum or the plasma from the particulate matter, the speed of the centrifuge is increased, preferably to about twice the speed employed to separate the plasma or the serum, however, speeds from about 2,500 RPM to about 4,000 RPM should be sufficient. As shown in FIG. **2,** the tapered end **33** of the closure means **30** is driven toward the reduced orifice **17** under the influence of the increased centrifugal force until it is wedged into tapered portion **23** as seen in FIG. **4.** Thus, the plasma or the serum is permanently separated from the particulate and cross-reaction of one with the other is precluded.

The device in FIG. **2** is shown as being under the influence of an increased centrifugal speed. At this speed, the closure means **30** has begun its downward path toward the tapered portion **17.** Under the influence of the increased centrifugal force, as depicted by the downwardly extending arrow in FIG. **2,** the closure means **30** is deformed thereby permitting fluid to pass between its sides and the inner walls of section **20,** as represented by the upwardly directioned arrows.

Thus, deterioration of the plasma or the serum caused by contact with blood cells or platelets after blood is removed from the human body is avoided. Also, the blood can be stored for long periods of time without degradation or biochemical changes occurring.

By proceeding in this simple manner utilizing readily available equipment, blood specimen samples can be withdrawn from the patient and the sample separated and stabilized into serum or plasma. After separation, the sample, can be transmitted to a laboratory where proper testing thereof can be undertaken. Blood specimen transmitted in this fashion yield accurate data for diagnostically significant parameters. Additionally, the device or apparatus of the present invention provides a simple means for withdrawing, collecting, stabilizing, and transmitting blood samples without the necessity of utilizing separate devices. In this manner, the aseptic transfer of blood is accomplished in one apparatus without having to transfer the blood into separate de-

vices or containers thereby subjecting the blood to additional sources of contamination by exposure to the atmosphere.

Particularly noteworthy is also the fact that blood exposed to the atmosphere even for short periods of time will rapidly deteriorate. By utilizing the device which is the present invention, it is assured that the serum or the plasma are separated under aseptic conditions.

I claim:

1. A method for stabilizing a blood sample after collection in a hollow container, which container comprises two closed ends connected by elongated sides, said sides having formed therein a reduced portion which extends inwardly into the interior of the hollow container, said container including a movable elastomeric closure means disposed in the interior of the hollow container between one of said closed ends in close proximity to the last-mentioned closed end and the reduced portion, such closure means having a deformable end extending toward the reduced portion, the other end of the closure means under normal conditions being in resilient engagement with the inner walls of said sides, which comprises (1) centrifuging said container at a speed that effects separation of the blood sample contained therein into two discrete phases, one phase consisting predominantly of the liquid constituent of the blood sample and the other consisting predominantly of the particulate phase; (2) increasing the centrifugal speed, to a speed which causes movement of the resilient member toward the reduced portion; and (3) centrifuging at such rate until the deformable end is securely received in the reduced portion.

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