

Sept. 25, 1973

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METHOD AND APPARATUS FOR SEPARATING BLOOD
CONSTITUENT COMPONENTS
Filed May 8, 1972

3,761,408

FIG. 1.

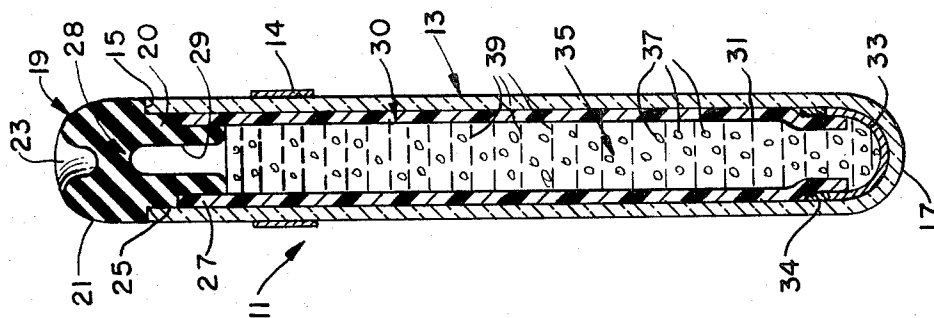


FIG. 2.

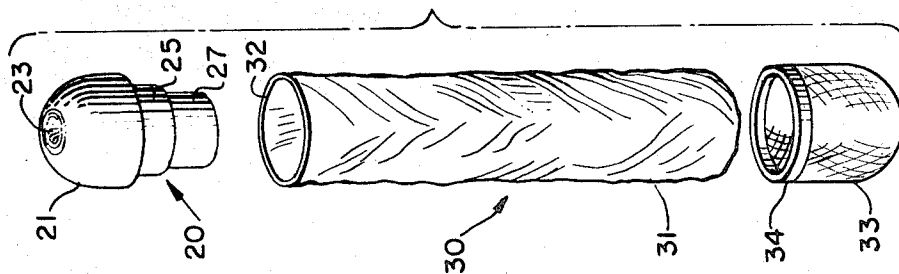


FIG. 3.

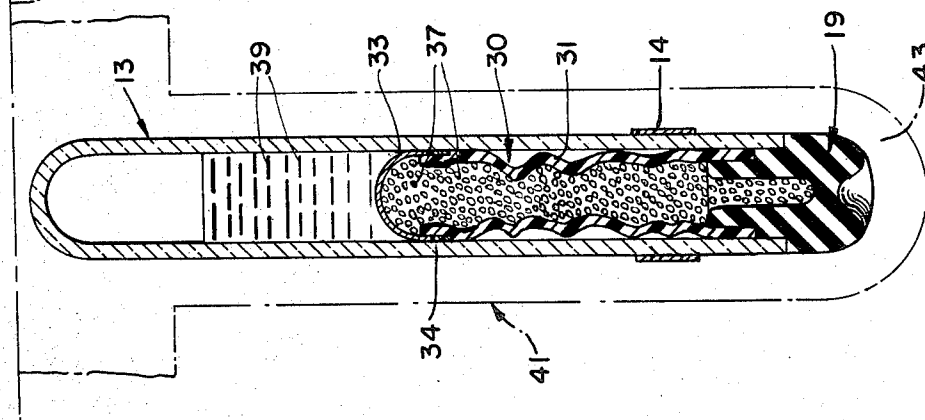
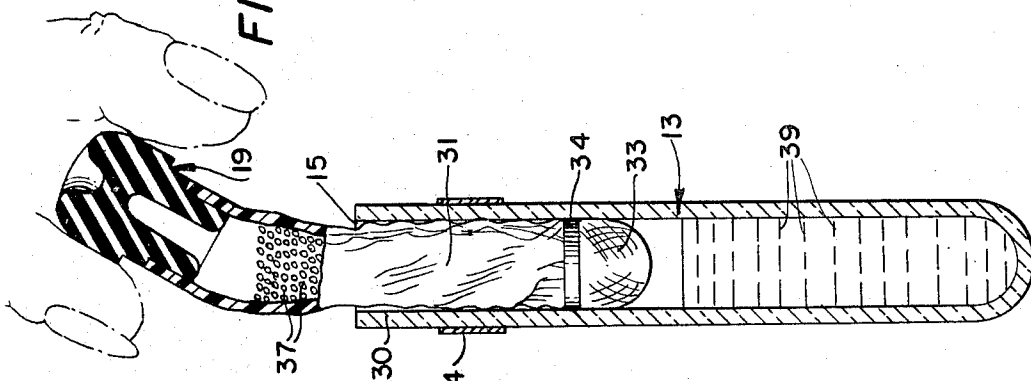


FIG. 4.



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METHOD AND APPARATUS FOR SEPARATING BLOOD CONSTITUENT COMPONENTS

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Continuation-in-part of abandoned application Ser. No. 127,312, Mar. 23, 1971. This application May 8, 1972, Ser. No. 250,891

Int. Cl. B01d 27/04

U.S. Cl. 210—23

8 Claims

ABSTRACT OF THE DISCLOSURE

A method and apparatus for separating blood into constituent components for medical blood tests. An impervious container having an open mouth is fitted with a selectively removable closure covering the open mouth for sealing the container. The sealed container is preferably evacuated and includes a flexible membrane therewithin which is sealingly secured to the closure and forms a blood collection bag. The membrane has at least a portion thereof effective to permit the passage of blood plasma or serum and protein free filtrate having particles less than predetermined sizes into the container and traps the remaining blood constituent components within the flexible membrane during a centrifuging operation and upon removal of the closure including the flexible membrane.

This application is a continuation-in-part of my copending application Ser. No. 127,312, filed Mar. 23, 1971, now abandoned.

BACKGROUND OF THE INVENTION

The present invention relates to a blood component constituent separating method and apparatus, and more particularly to a blood filtration apparatus for separating the blood into plasma or serum and cells, and for separating the blood into protein free filtrate and cells within a vacuum collection appliance.

In medical and biological fields, it is frequently necessary to collect blood samples for various laboratory tests. Evacuated container assemblies, such as that described in U.S. Pat. No. 3,366,103, granted Jan. 30, 1968, have been successfully employed in drawing blood from the donor to be collected within an impervious disposable container without the need for a more sophisticated plunger device. These containers are generally suitably sealed by an elastomeric stopper which serves both to maintain the blood drawing vacuum within the container and to provide a path for the insertion and removal of a double-ended cannula. The cannula is inserted to initiate the blood collection cycle and communicates the tapped blood supply to the evacuated area within the container. After the blood has been collected, the cannula may be removed, and the elastomeric stopper will reseal.

For subsequent laboratory analysis, it is desirable to separate fibrin free and cell free serum from blood cells. This separation is generally carried out in a centrifuge wherein the sealed container having the blood therein is spun for a predetermined period of time until the suspended blood cells, leukocytes and blood platelets are forced to the bottom of the container with the liquid plasma or serum which is to be further processed floating thereabove. This centrifuging step is usually carried out after the blood has clotted. Once the centrifugal separation has been made, the serum is delicately separated, such as by use of a pipette, from the blood cells and deposited within a second container for subsequent chemical hemotological or immunological assay. The original blood collection container is provided with an identifying label at an appropriate location on an outer surface. This separa-

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tion is generally carried out manually, thus requiring the use of two containers for each blood sample. A second label must also be prepared and properly adhered to the second container.

The separation process, after the centrifuging has taken place, is a time consuming operation requiring a technician's careful attention and effort to manually transfer the plasma or serum from one container to the other. Additionally, a new label has to be affixed to the second newly filled container having the separated plasma or serum therein. Upon occasion, mislabeling of the new container having the plasma or serum sample has occurred. The use of the second container to receive the blood plasma or serum thus involves costs relating to both providing the container and also for labeling the provided container.

Once the centrifugal separation is completed, as noted, a careful separation of plasma from blood by the above manual technique is required. The plasma or serum which generally floats above the cells after centrifuging also presents a transition zone where the cells and the plasma or serum are intermixed. To obtain pure plasma or serum, it is often necessary to leave a small portion of the plasma floating above the blood cells within the collecting container in this transition zone. Thus, it is not generally possible to obtain the entire amount of available separated plasma or serum since a portion of it is left behind to ensure that the plasma or serum is substantially cell free.

Additional biological tests may require that the separated plasma or serum be filtered to obtain a protein free serum. The large blood cells pressing against a filter membrane, which must be constructed from extremely fine pored material, may restrict the passage of protein free serum. The use of such filters is therefore not always successfully employed in centrifuge separation. Prior art separation techniques thus frequently required the separation of the blood into plasma or serum and cells, and then an additional separation of the plasma or serum to produce a protein free serum.

OBJECTS AND SUMMARY OF THE INVENTION

It is a general object of the present invention to provide a novel apparatus and method for efficiently separating blood constituent components for medical tests while generally obviating the foregoing disadvantages present in the prior art.

Another object is to provide a novel blood constituent component separating method and apparatus which reduces handling of blood samples and the likelihood of mislabeling these blood samples.

A further object is to provide a novel blood constituent component separating apparatus wherein blood is received in a flexible membrane which is carried within an impervious container for separating the blood into cells and plasma or serum and protein free filtrate, the cells remaining within the membrane while the serum or protein free filtrate passes through a filter portion of the membrane and remains within the container and the filter pore size being chosen to correspond to separation requirements.

A still further object is to provide a novel method of separating blood constituent components wherein centrifugal forces generated during the separation process cause the blood cells to remain within a flexible membrane while plasma or serum passes through a filtering portion of the membrane to be captured within the container. The flexible membrane collapses during centrifuging with the filtering portion thereof pressing against the blood and forcing the plasma or serum to pass there-through while holding the blood cells within a bag formed by the membrane.

Yet another object of the invention is to provide a flexible membrane holding the cells to collapse during

centrifuging with the serum passing through the filter portion of the membrane which is floating on the cells.

THE DRAWINGS

FIG. 1 is a side elevation in section of the blood separating apparatus;

FIG. 2 is an exploded perspective view of a membrane portion of the separating apparatus;

FIG. 3 is a side elevation in perspective of the positioning of the blood separating apparatus during centrifuging; and

FIG. 4 is a side elevation, partially in perspective, illustrating the removal of blood cells subsequent to centrifuging.

DETAILED DESCRIPTION

Referring to FIGS. 1-2, there is shown a preferred form of a blood separating apparatus 11 according to the present invention.

The separating apparatus includes an impervious outer container 13 having an open mouth 15. The container 13 may be suitably constructed of glass or plastic and may conventionally include a curved and sealed bottom 17. The container 13 may be a conventional 13 or 16 millimeter vacuum tube. This container may also include an identifying label 14 which may be paper and be appropriately secured to the exterior of the container 13, such as with a suitable adhesive.

A penetrable elastomeric closure or stopper 19 preferably seals the open mouth 15 of the container 13. This stopper may be force fit into the container mouth, and comprise a generally cylindrical plug portion 20 and an enlarged flange-like head 21 at the upper end thereof. The head includes a recess 23 which forms a depression centrally of the stopper. The upper periphery of the head 21 is generally curved and conforms substantially to the shape of the container bottom 17.

The plug portion 20 of the stopper includes a container engaging surface 25 forming an annular shoulder which is in abutting and sealing engagement within the inner periphery of the open mouth 15. A second annular shoulder 27 is formed below the engaging surface and is fitted with a flexible membrane 30, to be subsequently described. The plug portion 20 also includes a recess 29 which extends upwardly in general alignment with the recess 23, forming a cannula penetrable zone 28 therebetween.

This recess 29 is generally of a greater depth than the recess 23 with the elastomeric material on the periphery of the recess 29 forming a channel to guide the cannula into the open membrane 30. This additional depth aids considerably in avoiding accidental puncturing of the membrane walls by the cannula.

The membrane 30 is constructed of flexible material which may be, for example, any of a number of thin-walled plastics, rubber, or other suitable thin, soft, pliable sheet materials. The membrane 30 includes a generally cylindrical, tubular, impervious section 31 and a filter portion or cap 33. The filter portion may be fastened to section 31 by any suitable means such as glueing or heat sealing. The upper end of section 31 at 32 has a cross-sectional area slightly wider than the annular groove 27. A suitable adhesive may be employed to secure the membrane at 32 to the stopper shoulder 27 so that removal of the membrane can be effected when the stopper 19 is removed (see FIG. 4).

While a filter portion 33 is illustrated, other filtering arrangements may be employed. For example, the entire membrane may be constructed of material having the desired porosity. A membrane of this type may be advantageous in reducing manufacturing costs.

The filtering portion 33 may have a pore size of between 2-5 μ microns when plasma or serum is being separated from whole blood, and of between about 4-7(m μ) millimicrons when protein free serum is being separated

from the blood. Any number of commercially available filter membranes may be suitable for the filter portion 33 or the entire membrane 30. For example, a "Chemware" filter membrane made by Chemplast Incorporated, of Wayne, N.J., having a pore size of from 2-5(μ)microns (catalog number 5143-C05) may be used for plasma separation and "Dialyzer" tubing manufactured by Arthur H. Thomas Co., of Philadelphia, Pa., having an average pore size of 4.8(m μ)millimicrons may be used for protein free serum separation.

A weight member 34 may be included at the filter portion 33 and is preferably positioned at the lower end of the membrane 30. This weight member, which may be a plastic sleeve or a heavier filler portion, as will be subsequently understood, aids considerably in the centrifugal separation process by precipitating the collapse of the membrane during centrifuging.

OPERATION

Referring now to FIGS. 1, 3 and 4, the separating operation which may be employed with the above-described apparatus will be more clearly understood.

The separating apparatus 11, as noted, is provided with the stopper 19 having attached thereto the membrane 30, including the filter portion 33 (FIG. 2). The interior of the container 13 is evacuated. A cannula, not shown, suitably penetrates the stopper and delivers whole blood 35 into the membrane 30, the blood being drawn by the vacuum within the container 13. As previously noted, the recess 29 in the stopper 19 has a length sufficient to militate against the accidental piercing of the membrane 30 by the cannula during the collecting process. The whole blood 35 contains blood cells 37 which are suspended in a liquid plasma or serum and protein-free filtrate.

After a sufficient amount of blood has been collected, the cannula is removed and the stopper seals itself to again provide a fluid-tight closure. The container 13 may then be suitably labeled to indicate the appropriate blood identification. Advantageously, the vacuum within the apparatus 11 is sufficient to draw the necessary blood without a plunger or other device. While an evacuated container, such as that disclosed in U.S. Pat. No. 3,366,103, is preferable, the invention may find application in other blood collecting devices.

After the blood 35 has been collected in the container 13 and suitably labeled, the separator 11 is placed in a centrifuge 41 (illustrated schematically and in phantom in FIG. 3). The separator is inserted with the stopper portion resting in a support portion or pocket 43 of the centrifuge 41. This support pocket may be of the type used in the prior art to receive the container 13 in its upright position and need not be modified to be suitable for practicing the separating method employed by the present invention. As noted, the outer periphery of the stopper 19 is desirably curved to conform generally to the shape of centrifuge pocket 43 which in the past has received the container bottom at 17. Forces that are generated during the centrifuging step are thus applied evenly to the stopper, thereby keeping the container positively sealed.

The pocket 43 is caused to spin rapidly about a central axis 45 of the centrifuge 41, thereby forcing the larger blood cells suspended in the plasma to move against the stopper 19. The membrane 30 forming a bag of flexible material will be caused to collapse and also be forced toward the stopper 19. The filter portion 33 will thus float above the cells 37 which are trapped within the membrane 30. The serum or protein free serum, depending upon the filter size chosen, will pass through to the container 13 while the membrane bag 30 will collapse while retaining the blood cells therein (FIG. 3). It will be noted that the force of the larger suspended blood cells 37 is not applied to the filter portion; rather, the filter portion floats on and moves with and against the cells 37.

Usually, the centrifuging operation, as mentioned, is

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carried out after the blood clots. The conventional speed of centrifuging is maintained at approximately 3,000 r.p.m. for about 10 minutes to obtain the maximum desired constituent separation.

Once the centrifuging is completed, the separator apparatus 11 is removed and upended (see FIG. 4) and the stopper 19 is withdrawn, carrying with it the membrane 30 containing the trapped blood cells 37. The protein free serum or plasma or serum 39 is left in the container 13 which still has the blood identifying label 14 thereon. The container 13 may then be used for subsequent chemical analysis without the danger of mislabeling. The membrane bag 30 containing the blood cells 37 may then be suitably discarded or kept for future tests.

The present invention may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. The presently disclosed embodiments are therefore to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than by the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.

What is claimed and intended to be covered by Letters Patent is:

1. An apparatus for separating blood into constituent components for medical blood test comprising:

an impervious container having an open mouth;
selectively removable closure means covering said open mouth for sealing said container and maintaining a blood collecting vacuum therein;
said closure means being constructed from elastomeric material and including:

an enlarged flange portion having a substantially rounded outer periphery,
a plug portion having a first annular shoulder in sealing abutment with the inner periphery of said container, a second annular shoulder having a diameter smaller than the diameter of said first annular shoulder, and membrane puncture prevention means including a recess positioned centrally of the plug portion and extending upwardly toward said flange portion;

flexible membrane means within said container sealingly secured to said second annular shoulder forming a bag and removably received within the inside walls of said container for receiving a supply of blood through said open mouth,

said membrane means including a filter portion at a lower end thereof opposite from said closure means effective to permit the passage of plasma or serum having particles less than a predetermined size into said container and trapping the remaining blood constituent components within said flexible membrane means upon removal of the closure means including said flexible membrane means.

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2. The apparatus according to claim 1 wherein said filter portion has a pore size of between about 2-5 microns for separating plasma or serum from whole blood.

3. The apparatus according to claim 1 wherein said filter portion has a pore size of between about 4-7 microns for separating protein free serum from whole blood.

4. The apparatus according to claim 3 wherein said filter portion includes weighted member means for aiding in the collapse of said membrane during the blood separation operation.

5. A method of separating blood into constituents comprising the steps of:

inserting a flexible membrane within an impervious container;
collecting blood within the flexible membrane;
applying centrifugal forces to said container and membrane causing said membrane to collapse;
filtering plasma having particles of a predetermined size through a portion of said membrane and into said container, thereby trapping cells having a greater size within said membrane; and
removing the membrane having the cells therein.

6. The method of separating blood according to claim 5, including:

drawing blood into said membrane by means of vacuum;
sealing said container with an elastomeric stopper having the flexible membrane attached thereto; and
centrifuging said container and membrane with said stopper being in abutment with the centrifuge, whereby said centrifuging step is carried out while said container is upside down.

7. The method of separating blood according to claim 6 wherein a weighted member aids to collapse said membrane to filter plasma through the filter portion thereof.

8. The method according to claim 7 wherein plasma passes through said filter as said filter compresses the blood cells trapped therein, said plasma moving through the pores of said filter portion.

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U.S. Cl. X.R.

210-78, 455, DIG. 23; 233-26