

- [54] **VACUTAINER WITH POSITIVE SEPARATION BARRIER**
- [75] Inventors: **Clyde P. Glover; Michael P. O'Neill**, both of Rochester, N.Y.
- [73] Assignee: **Eastman Kodak Company**, Rochester, N.Y.
- [22] Filed: **Aug. 17, 1973**
- [21] Appl. No.: **389,275**
- [52] **U.S. Cl. 210/516; 210/DIG. 23; 210/DIG. 24**
- [51] **Int. Cl. B01d 21/26**
- [58] **Field of Search 210/DIG. 23, DIG. 24, 516-518, 210/443, 446, 361, 359, 83, 84; 233/2, 2 B, 26, 1 A, 1 R; 23/259; 128/214 R, 2 F, 272, 218 M**

[56] **References Cited**

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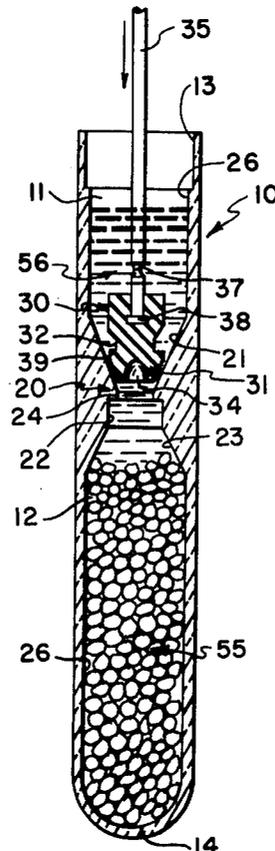
3,508,653	4/1970	Coleman.....	210/DIG. 23
3,647,070	3/1972	Adler.....	210/516
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Primary Examiner—Charles N. Hart
 Assistant Examiner—F. F. Calvetti
 Attorney, Agent, or Firm—D. M. Schmidt

[57] **ABSTRACT**

Apparatus providing a physical barrier between the phases of a two-phase liquid, such as whole blood stratified into a serum phase and a cells phase, which includes a transparent tubular receptacle having a rigid wall capable of holding a vacuum. The receptacle has an internal constriction for receiving a resilient plug, which divides the receptacle into an upper chamber and a lower chamber. In the preferred embodiment, the plug has a lower portion, a neck portion and an upper portion. The end of the lower portion is shaped to provide an open pocket for holding a volume of air. A rod of suitable length is detachably mounted through the upper portion of the plug to enable one to urge the plug through the serum in the upper chamber and in sealing engagement with the constriction. The air entrapped in the pocket at the lower portion of the plug creates a slight increase in pressure in the lower chamber as the plug is deformably urged into sealing engagement with the constriction thereby sealingly urging the lower portion of the plug against the constriction. The rod is thereafter detached from the plug and the serum may be aspirated out or decanted for analysis, or the open end of the receptacle may be sealed with a stopper thereby making the receptacle ready for use, storage or transportation.

7 Claims, 8 Drawing Figures



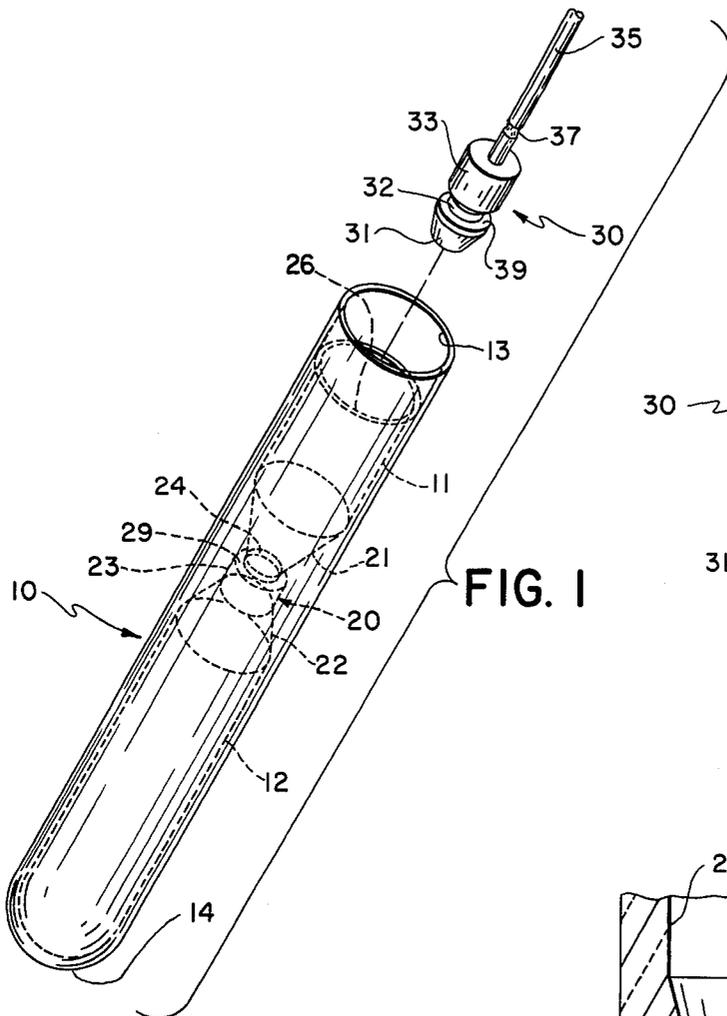


FIG. 1

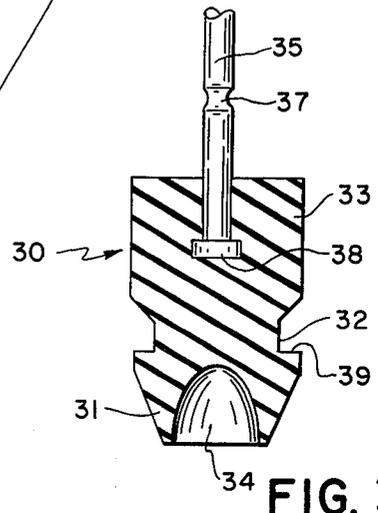


FIG. 3

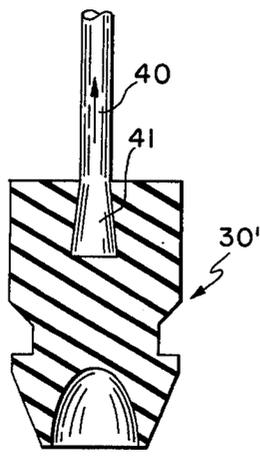


FIG. 8

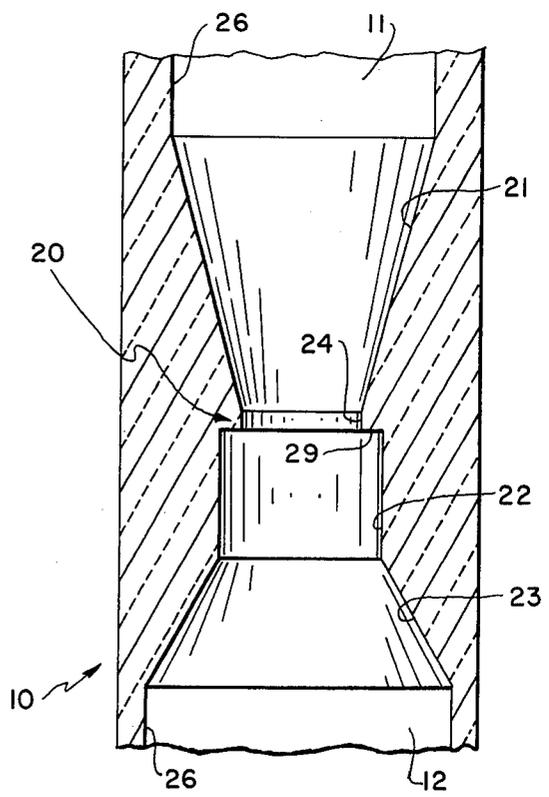


FIG. 2

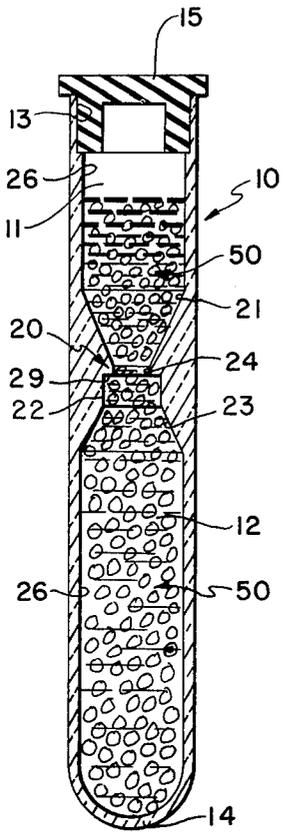


FIG. 4

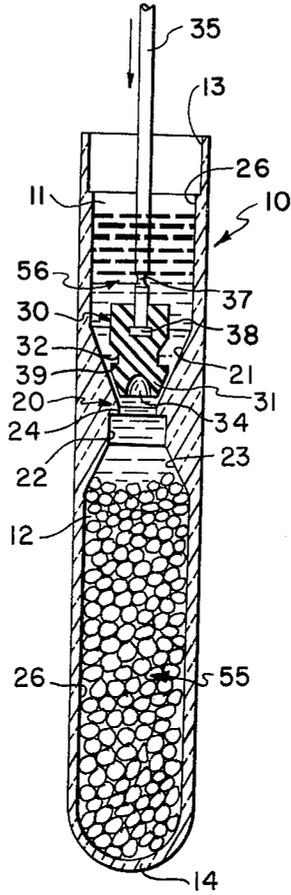


FIG. 5

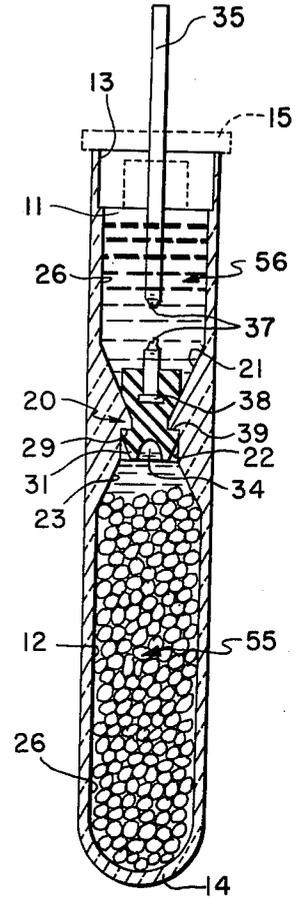


FIG. 7

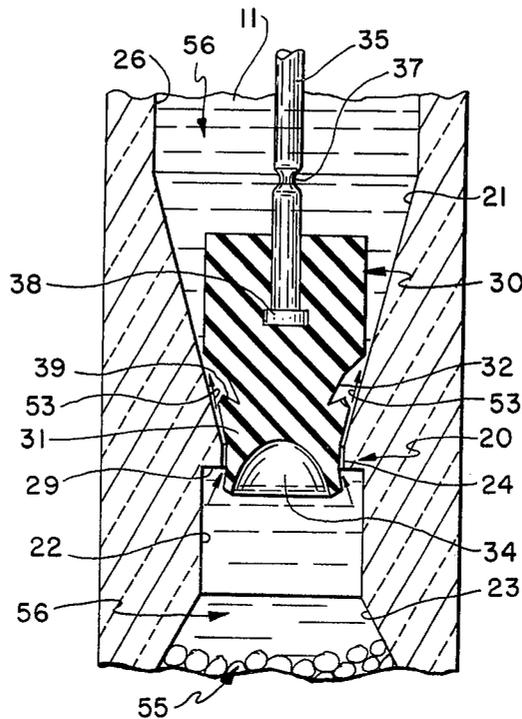


FIG. 6

VACUTAINER WITH POSITIVE SEPARATION BARRIER

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates generally to apparatus for the physical separation of one phase from the remainder of a liquid having at least two phases. More specifically, it relates to the separation by a physical barrier of blood serum from blood cells after the blood has been stratified, e.g., by centrifugation, in a tubular receptacle.

2. Description of the Prior Art

The analysis of blood serum or plasma, extracted from whole blood, is an invaluable tool to the medical profession in diagnosing and treating a multiplicity of human disorders and diseases. The separation of this blood serum or plasma from whole blood is an important step in arriving at a correct medical analysis from which proper medication or treatment can be prescribed. Currently, a specimen of serum or plasma is obtained by injecting one end of a hollow needle, open at both ends, into an appropriate vein of the donor followed by injection of the other end of the needle into an evacuated tube through a rubber stopper capable of holding a vacuum; the negative pressure in the evacuated tube causes whole blood to flow from the vein into the tube. Ordinarily, such containers are designed to collect approximately 10 milliliters of blood, although there are also containers designed for collecting 5 milliliters of blood.

Once a specimen of blood has been collected in the stoppered container, if serum is the end product desired for analysis, the technician will remove the stopper and add a clotting agent to the specimen or let the blood stand for some period of time (around one-half hour) to allow the blood to clot. The blood thereafter undergoes centrifugation in the same container to separate the lighter serum from the heavier cells. If plasma is the desired end product for analysis, an anticoagulation agent is added to the specimen or it is centrifuged immediately upon collection, before appreciable coagulation occurs. In either case, the result of centrifugation is the stratification of blood into a lighter phase and a heavier phase. Since the more usual laboratory practice in blood analysis is to work with serum rather than plasma, the lighter phase of the stratified blood will be assumed to be serum, although it is understood that it could equally be plasma.

Following stratification of the blood into serum and cells, the serum is isolated from the cells by being aspirated or decanted from the first container into a second container. Isolation of the serum is desirable to prevent possible chemical or physical interaction, between the two interfaced phases, during storage or transportation which could lead to erroneous results in the analysis. Since some turbulence is normally unavoidable in the process of transferring the serum, a second centrifugation may follow to collect the remaining cells at the bottom of the second container.

The aforementioned procedure in obtaining serum obviously involves a number of time consuming steps. More significantly, however, the transfer of the serum from the first container to the second increases the risk of contamination, spillage, and loss of identity of the donor. Therefore, an improved device for separating serum from cells would preferably embody or provide

a number of desirable attributes, e.g., (1) obtaining a sample of blood and achieving separation of the two phases under sterile conditions; (2) minimizing the risk of loss of identity of the donor of the blood throughout the entire clinical process; (3) minimizing the migration of cells once the blood has been stratified into cells and serum; (4) utilizing, storing, or transporting the serum without interplay between the serum and the cells; (5) economic feasibility in manufacturing a disposable device; (6) the ability to physically separate the container at a particular location determinable by the purpose of the test; (7) rapidity and simplicity in inserting the physical barrier to separate the serum from the cells.

Recently, some developments in the art have provided devices having some of these attributes. Two such examples are found in U.S. Pat. Nos. 3,508,653 to Coleman and 3,647,070 to Adler. The Coleman patent discloses a method and apparatus for urging a piston through the lighter upper phase, to the interface between the serum and the cells. The container in the Coleman patent is a tubular receptacle of regular cross-section. The piston is formed of resilient material and has an undeformed cross-section slightly larger than the inner diameter of the tubular receptacle. To position the piston at the interface of the two phases, a force is applied, either by pushing the piston with a rod or through centrifugation, which causes the piston to move toward the closed end of the receptacle while the fluid pressure of the light phase causes the piston to be deformed sufficiently to allow the liquid to flow around the piston toward the open end of the receptacle. The force is removed when the piston reaches the interface between the light phase and the heavy phase of the two-phase blood.

The Adler patent also discloses a device in which a physical barrier is formed in a tubular container of regular cross-section at the interface between the lighter phase and the heavier phase of a two-phase liquid. Prior to insertion, the barrier has a cross-section smaller than the inner diameter of the tubular container. It has a specific gravity greater than the heavier phase but less than the lighter phase so barrier sinks through the lighter phase until it reaches the interface of the two phases. Thereafter, through chemical reaction with the serum, the barrier expands to form a seal. Also disclosed in the Adler patent is a two-part container assembly including a tube which has a sleeve insertable therein. The sleeve is generally shaped as a hopper, i.e., it terminates in a generally truncated cone-shaped end portion which has external threads for receiving a like-threaded cap. To physically separate the cells from the serum, a plug is provided which is fixedly attached to one end of a rod; the other end of the rod is fixedly attached to the inner portion of the stopper. The length of the rod is such that when the stopper is inserted into the sleeve, the plug is forced into the truncated opening at the bottom of the sleeve thereby providing a physical barrier between the serum in the sleeve and the cells in the tube. The sleeve is then removed from the tube and the threaded cap is screwed into the truncated end.

Although the art has been advanced by the Coleman and Adler patents, there remains an opportunity for improvement. For example, in the Coleman patent due to the configuration of the piston, a large force, either centrifugal or direct action as with a rod, must be ap-

plied in order to deform the piston so that the serum will flow around it. This may entail the necessity of obtaining new centrifugation equipment to comply with the added force requirement. In the case of using a detached rod to push the piston, problems may arise in aligning the rod with the center of the piston to avoid unequal forces in the piston, as well as in applying the proper deforming force to avoid possible contaminating spillage, or turbulence which can disturb the compacted cells and contaminate the serum. The chemically activated barrier formed in the Adler patent has the disadvantage that it is designed to be formed at the interface between the light and heavy phase of a two-phase liquid having a particular density differential. For example, if for a particular purpose, such as to save time, only a small amount of serum is required relative to the amount of whole blood, the density change in the heavier phase may be insufficient to buoy the barrier at the interface. Moreover, there is a waiting period in which the physical barrier expands to form the seal at the interface. That is, the container must be held in place until the barrier expands to form the seal. This may inconvenience the technician and add valuable time to the test schedule. Since it is made up of numerous parts, the two-part container disclosed by Adler has the disadvantages of complexity, expense and a multiplicity of handling operations.

Regarding the desirable attributes enumerated above, it is clear that the prior art does not disclose or provide a device having all of them.

Accordingly, it is an object of the invention to provide a disposable receptacle for containing blood stratified into a lighter phase and a heavier phase wherein a physical barrier can be inserted rapidly and easily to separate the lighter phase from the remaining liquid.

It is another object of the invention to provide a device for physically separating blood serum from the cells wherein no migration of the cells or contamination of the serum occurs once the physical barrier is positioned in place.

It is another object of the present invention to provide a disposable receptacle for the separation of serum from cells which is economically feasible and simple to manufacture.

It is another object of the invention to provide a disposable receptacle for the separation of serum from cells in which the location of the constriction receiving the physical barrier can be varied in manufacture according to the purpose of the test.

SUMMARY OF THE INVENTION

These and other objects are accomplished according to the preferred embodiment of the present invention by forming a constriction, for sealingly receiving a plug, in a tubular receptacle used in containing a specimen of blood from a donor. The constriction defines an aperture which divides the receptacle into a lower chamber and an upper chamber, and which has a cross-sectional dimension smaller than the smallest interior cross-sectional dimension of the upper chamber of the receptacle. After centrifugation of the blood, the cells are compacted into the lower chamber while the serum remains in the upper chamber. A plug is then deformingly inserted into the constriction thereby placing a physical barrier between the lower chamber and the upper chamber. The resilient plug is symmetrical about a centerline and at its widest diameter is smaller in cross-

section than the largest internal cross-sectional dimension of the upper chamber. The plug has a lower portion, a neck portion and an upper portion for sealingly engaging the constriction at, respectively, the lower chamber, the aperture, and the upper chamber. Detachably mounted to the upper portion of the plug, coincident with the centerline thereof, is a rod of operative length for urging the plug into sealing engagement with the constriction, the rod being thereafter removable from the plug.

In one embodiment of the invention, the lower portion of the plug has an undeformed cross-section larger than the aperture of the constriction and a configuration operatively related to the constriction for guiding the lower portion of the plug through the aperture and into the lower chamber in response to a plug deforming force applied through the rod. The neck portion has a cross-section slightly larger than the aperture and is compressed into sealing engagement with the constriction as the lower portion is urged into place in the lower chamber. The upper portion of the plug has a larger cross-section than the neck portion for maintaining the neck portion in sealing engagement with the constriction. The sealing properties of the plug can be further improved by forming an open pocket at the end of the lower portion to receive a volume of air and retain it as the plug is urged through the serum and as the lower portion is deformingly urged through the constriction. The effect of the trapped air is to increase slightly the pressure in the lower chamber thereby sealingly urging the lower portion of the plug against the constriction.

The invention and its objects and advantages will become more apparent in the detailed description of the preferred embodiment presented below.

BRIEF DESCRIPTION OF THE DRAWINGS

In the detailed description of the preferred embodiment of the invention presented below, reference is made to the accompanying drawings in which:

FIG. 1 is an isometric view of the preferred embodiment of the invention showing a tubular receptacle having a constriction and a resilient plug with a detachable handle;

FIG. 2 is an enlarged longitudinal cross-sectional view of the constriction, the other portions of the receptacle cut-away for clarity;

FIG. 3 is a longitudinal cross-sectional view of the plug of the preferred embodiment showing a break-away rod and an open pocket at the lower portion of the plug;

FIG. 4 is a cross-sectional view of the receptacle of the invention following the collection of a specimen of whole blood;

FIG. 5 is a longitudinal cross-sectional view of the receptacle after the whole blood has been subjected to centrifugation and the plug is about to be inserted in the constriction to effect physical separation;

FIG. 6 is an enlarged view of the constriction and plug shown in FIG. 5 also showing the deformation of the lower portion of the plug as the plug is urged into sealing engagement with the constriction;

FIG. 7 is a longitudinal cross-sectional view of the receptacle showing the plug in sealing engagement with the receptacle and the handle being detached from the plug thereby effecting physical separation between the cells in the lower chamber and the serum in the upper chamber; and

FIG. 8 is a longitudinal cross-sectional view of another embodiment of the plug showing a pull-away rod.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to the drawings wherein like referenced numerals have been used in several views and figures for like elements, FIG. 1 illustrates a tubular receptacle generally indicated by reference numeral 10 and a resilient plug generally indicated by reference numeral 30, having rod means 35. The receptacle is integrally formed with a lower closed end 14 and an upper open end 13. "Upper" and "lower" are used throughout this specification in relation to a tubular receptacle which is parallel to a gravitational vector. The constriction 20 formed in receptacle 10 divides the receptacle into an upper chamber 11 and a lower chamber 12. It is common practice in blood analysis to draw approximately 10 milliliters of blood from a donor. Receptacle 10 is designed to accept approximately 10 milliliters of blood and the constriction is positioned such that lower chamber 12 has approximately 55 percent of the usable volume and upper chamber 11 has the remaining 45 percent. After centrifugation, the compacted cells normally make up slightly over 50 percent of the volume. Hence, all the cells will be in the lower chamber 12 leaving only serum in the upper chamber 11. If appropriate, e.g., where a small amount of serum is needed relative to the total blood specimen, the relative volume in upper chamber 11 may be reduced by forming constriction 20 closer to open end 13.

The tubular receptacle can be made from a variety of materials by a variety of manufacturing techniques, both materials and techniques being well known in the art and neither forming any part of the present invention. For example, it can be made economically from synthetic resins such as Plexiglass by, e.g., injection blow-molding techniques. Structurally, the receptacle must be capable of withstanding the pressure differential on the walls resulting from the evacuation of air from the interior; chemically, it must not appreciably react with the blood; esthetically, it is usually made of a transparent material. A tubular receptacle made of, e.g., Plexiglass would satisfy these requirements since the tubular design would give it the structural strength required, the molding material does not react appreciably with blood, and it is transparent. However, a material of substantially comparable characteristics would serve as well.

The plug 30 can be formed from a variety of materials, e.g., rubber, which are resilient and do not interact chemically with serum or plasma. It is clear that constriction 20 may assume a variety of shapes so long as plug 30, which provides a barrier at the constriction, is formed in operative relation to the shape of the constriction. For example, there should be an obvious relationship between the shape and size of the constriction at the aperture and that of the plug at the sealing area; similarly, the shape of the constriction in the upper chamber and the end of the plug which first comes in contact with the constriction should be so related that the plug can be mechanically guided into place. As seen more clearly in FIG. 3, plug 30 in the preferred embodiment includes a lower portion 31 having an open pocket 34, a neck portion 32 and an upper portion 33 from which detachable rod 35 protrudes. The toe 38 of rod 35 may be located in upper portion 33,

as shown in FIG. 3, or it may extend through the upper portion and into the lower portion 31, above open pocket 34 (not shown). The latter location would enable lower portion 31 to stretch in response to a force transmitted through rod 35, thereby facilitating insertion of plug 30 into constriction 20. Ordinarily, however, the location of the toe 38 is determined by such factors as the resilience of the plug, the relative dimensions and configurations of the plug and the constriction, and the manner in which the rod is to be detached from the plug.

In upper chamber 11, constriction 20, terminating in cylindrical aperture 24, flares conically from aperture 24 to meet the interior cylindrical wall 26 of upper chamber 11. In lower chamber 12, the constriction steps from cylindrical aperture 24 to cylindrical bore 22 whose cross-sectional dimension is greater than that of aperture 24 but ordinarily less than that of the interior cylindrical wall 26 of lower chamber 12. The cross-sectional dimension of cylindrical bore 22 is slightly less than that of the largest cross-section of lower portion 31 of plug 30 so that lower portion 31, by being slightly compressed, fits snugly in the lower chamber. The annular wall 29 defined by the difference between cylindrical aperture 24 and cylindrical bore 22 is sealingly engaged by annular shoulder 39 of plug 30 defined by the difference in cross-section between neck portion 32 and lower portion 31. See FIG. 3. Following cylindrical chamber 22, the constriction flares at 23 to meet interior cylindrical wall 26 of lower chamber 12.

FIG. 4 is a view of the receptacle filled with approximately 10 milliliters of whole blood from a donor. The method for drawing blood is well known in the art and will not be described in great detail. Ordinarily the empty receptacle has a resilient stopper 15 which is capable of holding a vacuum. One end of a double-ended needle is injected into a donor and the other end is injected into the evacuated receptacle 10 through stopper 15. The negative pressure in the receptacle draws approximately 10 milliliters of blood, and afterwards the double-ended needle is removed first from the receptacle and then from the donor. It is seen that if the evacuated container and double-ended needle are sterile, the blood, schematically represented by numeral 50, will not be contaminated. It should be noted that the stopper, the double-ended needle, and the mechanism for evacuating the receptacle, form no part of this invention and are presented only in the interest of clarity and understanding of the invention. However, it is contemplated that these features will be used in the practice of the invention.

After obtaining a specimen of blood as shown in FIG. 4, the stopper 15 is removed and a clotting agent is introduced into the specimen or the receptacle is allowed to stand, open to the atmosphere, long enough for coagulation of the blood to occur. Thereafter, the receptacle undergoes centrifugation until the cells 55 are compacted in the lower chamber 12, as shown in FIG. 5. Upper chamber 11 will then contain pure serum. Alternatively, if plasma is desired rather than serum, the blood may be centrifuged immediately following the collection of the blood in the receptacle, or an anticoagulation agent may be added to the specimen.

Once the cells are compacted through centrifugation in lower chamber 12 as shown in FIG. 5, plug 20 is inserted into the constriction. As seen more clearly in FIG. 6, as the plug is urged through constriction 20 by

a force applied through rod 35, the lower portion 31 of the resilient plug 30 is deformed to comply with the smaller cross-section of aperture. The deformation of lower portion 31 of the plug 30 also allows the flow of a small amount of serum from above the compacted cells in lower chamber 12 to pass into upper chamber 11 to replace the volume occupied by lower portion 31 of the plug 30. This flow is schematically illustrated in FIG. 6 as arrows 53. The amount of serum that must flow upward is determined by the size of lower portion 31 of plug 30. Normally, the flow is slight and will not cause any disturbing turbulence.

As lower portion 31 of the plug is deformingly urged through the constriction, the air bubble in open pocket 34 is slightly compressed. The slight increase in pressure in lower chamber 12 created by the air bubble in pocket 34 forces the annular shoulder 39 of lower portion 31 of the plug, against the annular wall 29 of the constriction 20. The result is a barrier producing a positive seal between the compacted cells 55 in lower chamber 12 and the serum 56 in upper chamber 11. Once the plug is seated in position, rod 35 may be twisted and broken off at the weakened area 37. The handle portion of the rod may then be removed and the serum may then be decanted, aspirated, etc. for analysis purposes. Alternatively, stopper 15 may be replaced at the open end of the receptacle for shipping and/or storage purposes.

FIG. 8 illustrates another embodiment of the plug 30 of the invention. Plug 30' has the same configuration as plug 30 of the preferred embodiment; detachable handle 40, however, pulls-away rather than breaks-away. Conical toe 41 is embedded in the resilient plug and is simply pulled out once plug 30' is sealingly positioned in the constriction.

It is readily apparent to those skilled in the art that the receptacle and plug of the present invention provides a disposable apparatus for physically separating stratified blood which: can receive a specimen of blood under sterile conditions; minimizes the risk of loss of identity of the donor; effectively halts the migration of cells into the lighter phase once the plug has been inserted and prevents chemical interaction between the two phases; and which attains physical separation quickly and easily at a location in the receptacle determined by the location of the constriction.

The invention has been described in detail with particular reference to a preferred embodiment thereof, but it will be understood that variations and modifications can be effected within the spirit and scope of the invention.

We claim:

1. Apparatus for separating with a physical barrier one phase from the remainder of a liquid having at least two phases, comprising:

- a. a tubular unitary receptacle open at one end and closed at the opposite said one end, for containing such liquid, said receptacle having an internal constriction defining an aperture which divides said receptacle into a first chamber for containing such one phase only and a second chamber for containing the remainder of such liquid, said aperture having a cross-sectional dimension smaller than the smallest internal cross-sectional dimension of said first chamber;

b. a resilient plug for sealingly engaging said constriction to form a physical barrier between said first chamber and said second chamber,

said plug being symmetrical about a centerline and smaller in cross-section at its widest diameter than the largest internal cross-sectional dimension of said first chamber, and having a first portion, a neck portion, and a second portion for engaging said constriction at, respectively, said first chamber, said aperture, and said second chamber; and

c. rod means detachably mounted through said first portion of said plug in coincidence with said centerline for urging said plug into sealing engagement with said constriction, said rod means being thereafter removable from said plug.

2. The invention as defined in claim 1 wherein:

said second portion of said plug has an undeformed cross-section at its widest diameter larger than such cross-sectional dimension of said aperture, and a configuration operatively related to said constriction for guiding said second portion through said aperture and into said second chamber in response to a force applied through said rod means,

said neck portion of said plug has an undeformed cross-section slightly larger than such cross-sectional dimension of said aperture and being compressible for sealing engagement with said constriction at said aperture as said second portion is urged into place in said second chamber, and said first portion of said plug has a larger cross-section than said neck portion for maintaining said neck portion in sealing engagement with said constriction.

3. The invention as defined in claim 2 wherein said second portion of said plug includes an open pocket at the end remote from said neck portion for receiving a volume of air and retaining said air as said plug is urged through such one phase of such liquid and as said second portion is deformingly urged through said constriction.

4. In an apparatus for maintaining separation by a physical barrier of a stratified two-phase liquid, such as a blood specimen following stratification of the heavier cells from the lighter fluid, of the type having a tubular unitary receptacle open at one end and closed at the end opposite said one end, and a resilient plug forming said physical barrier, the improvement comprising:

an internal constriction in said receptacle defining an aperture which divides said receptacle into a first chamber and a second chamber, and which is of smaller cross-sectional dimension than the smallest internal cross-sectional dimension of said first chamber, for receiving said resilient plug in sealing engagement therewith to form said physical barrier separating the lighter fluid in said first chamber from the remaining liquid, which includes said heavier cells, in said second chamber; said plug having a first portion, a second portion, and a neck portion between said first and second portions for engaging said constriction at, respectively, said first chamber, said second chamber, and said aperture.

5. The invention as defined in claim 4 wherein said second chamber comprises about 55 percent of the operatively usable volume of said tubular receptacle.

6. In an apparatus for maintaining the separation by a physical barrier of a stratified two-phase liquid, such

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as a blood specimen following stratification of the heavier cells from the lighter fluid, of the type having a tubular receptacle, open at one end and closed at the end opposite said one end, with an internal constriction defining an aperture which divides said receptacle into a first chamber and a second chamber, the improvement comprising:

- a. a resilient plug for sealingly engaging said constriction to form said physical barrier between said first chamber and said second chamber, said resilient plug being symmetrical about a centerline and having a first portion, a neck portion, and a second portion for engaging said constriction at, respectively, said first chamber, said aperture, and

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- said second chamber; and
- b. rod means detachably mounted through said upper portion in coincidence with said centerline for urging said plug into sealing engagement with said constriction, said rod means being thereafter removable from said plug.

7. The invention as defined in claim 6, wherein said second portion of said resilient plug includes an open pocket at the end remote from said neck portion for receiving a volume of air and retaining said air as said plug is urged through such lighter fluid of such liquid and as said second portion is urged through said constriction.

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UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 3,879,295

DATED : April 22, 1975

INVENTOR(S) : Clyde P. Glover and Michael P. O'Neill

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Abstract, line 22, "asperated" should read ---aspirated---

Column 1, line 52, "perated" should read ---pirated---

Column 2, line 66, "provement." should read ---provements.---

Column 7, line 3, "aperture." should read ---aperature 24.---

In the title, "Vacutainer" should read -- Evacuated Blood
Serum Separation Device --.

Signed and Sealed this

seventh Day of October 1975

[SEAL]

Attest:

RUTH C. MASON

Attesting Officer

C. MARSHALL DANN

Commissioner of Patents and Trademarks