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Bennett et al.

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[54] **METHOD OF COLLECTING BLOOD AND SEPARATING CELLULAR COMPONENTS THEREOF**

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[73] Assignee: **Becton, Dickinson and Company**, Rutherford, N.J.

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[21] Appl. No.: **82,240**

[52] **U.S. Cl.** ..... **128/2 G**, 23/230 B, 23/259, 23/292, 128/272, 210/78, 215/1 R, 215/6, 233/1 R, 233/26

[51] **Int. Cl.** **A61b 19/00**

[58] **Field of Search** ..... 128/2 R, 2 F, 2 G, 128/214 R, 214 Z, 272, 276; 215/1 R, 6; 195/1.8, 127, 146; 23/230 B, 259, 258.5; 233/1 R, 26; 210/78, 361, 512

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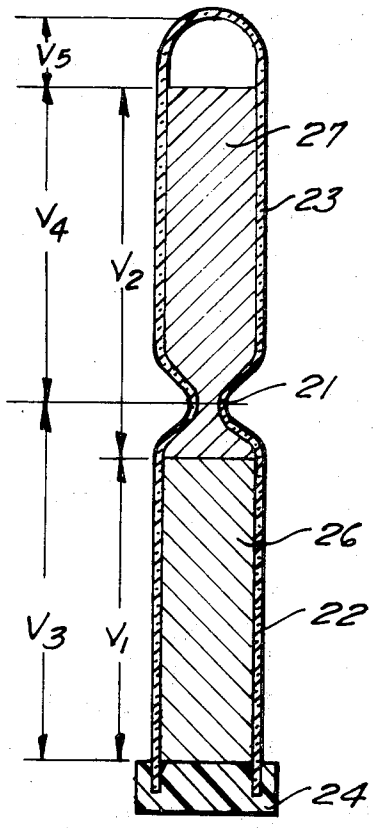
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[57] **ABSTRACT**

A separator tube which allows the separation of serum or plasma from the cells in blood to avoid contamination of the serum or plasma by the red cells. The tube is divided into two chambers formed by a constriction in the tube, which constriction has an inside diameter sufficient to allow the passage of serum or plasma, but not so large as to prevent the formation of an "air lock" between the chambers when the tube containing the blood is held horizontally. Blood is introduced into the tube, the tube is centrifuged or allowed to settle so that the cells go to the one end and the serum or plasma goes to the other end, the tube is fractured at the constriction into two containers, leaving only serum or plasma in one container and cells in the other. The container holding the serum or plasma can be closed with a stopper, cap or sealing material for transporting to a laboratory for analysis. Such container may be provided with various features to facilitate dispensing of the fluid portion.

14 Claims, 16 Drawing Figures



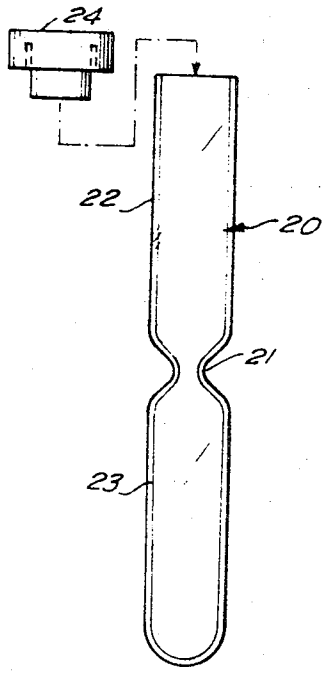


FIG. 1

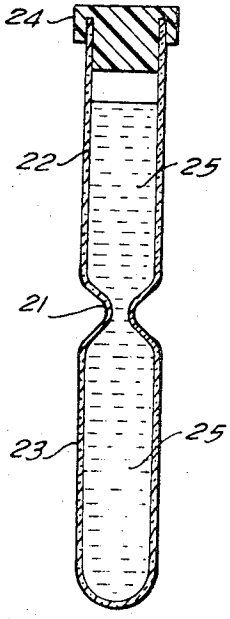


FIG. 2

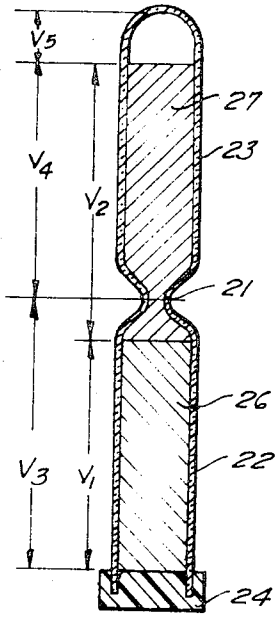


FIG. 3

FIG. 4

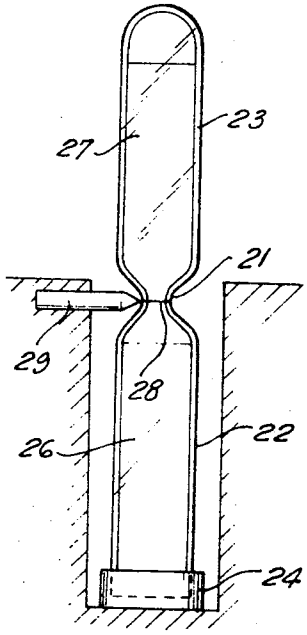
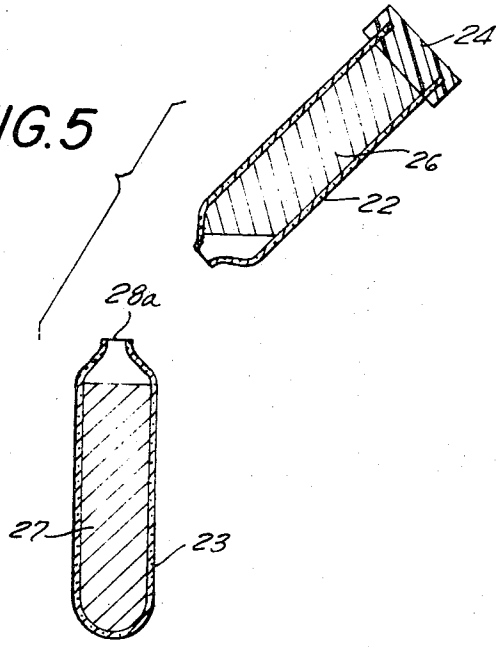
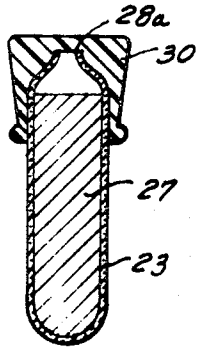


FIG. 5



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FIG. 6



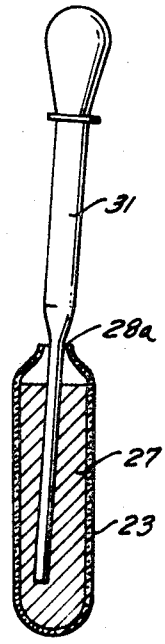


FIG. 7

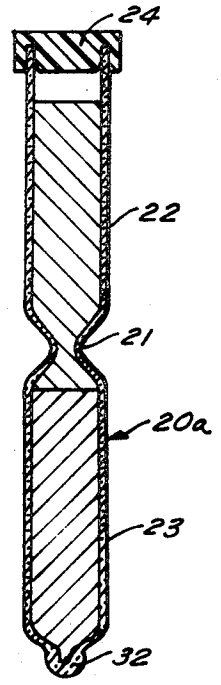
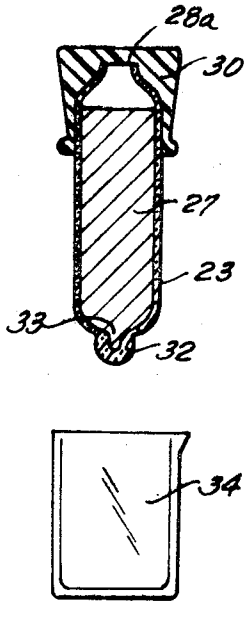


FIG. 8

FIG. 9



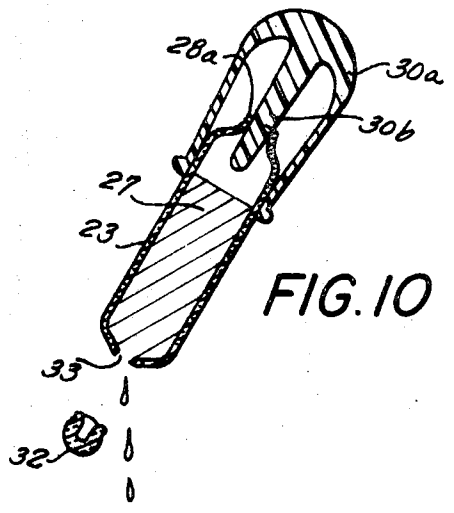


FIG. 10

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FIG. 11

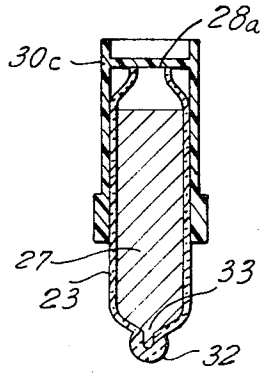


FIG. 12

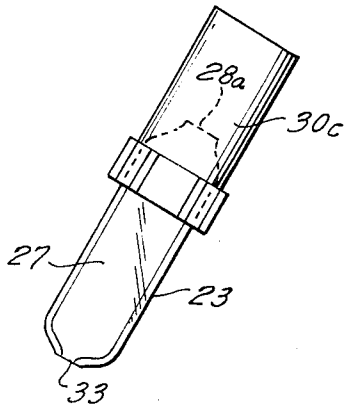


FIG. 13

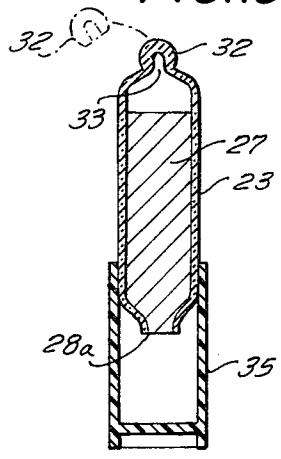


FIG. 14

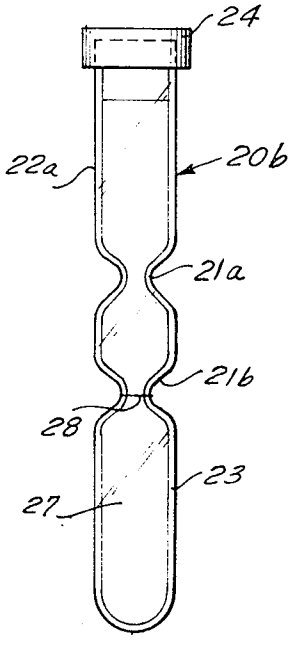


FIG. 15

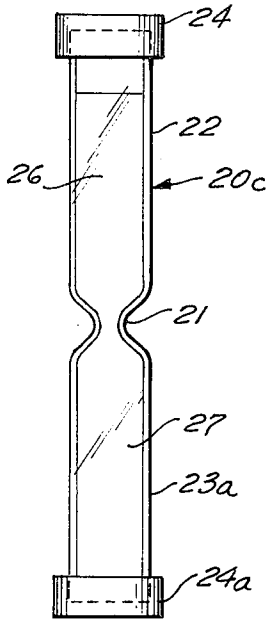
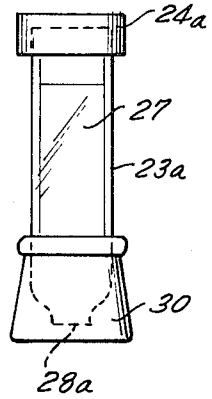


FIG. 16



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METHOD OF COLLECTING BLOOD AND SEPARATING CELLULAR COMPONENTS THEREOF

BACKGROUND OF THE INVENTION

The present invention relates generally to the separation of blood serum or plasma (herein referred to as the "fluid portion") from the blood cells (herein referred to as the "cellular components") and more particularly to a device and method for carrying out such separation.

It is common practice to remove blood from a donor into a tube, which tube will contain an anticoagulant if plasma is to be collected. The tube is then centrifuged to separate the serum or plasma from the cells in blood and the serum or plasma is drawn off by decanting (pouring it off) or removing with an aspirating device such as a pipette or syringe. Such removal methods are not entirely satisfactory because the transfer of the serum or plasma to a secondary vessel may contaminate the serum or plasma. There is also the extra expense of handling the serum or plasma in this manner.

SUMMARY OF THE INVENTION

It is an object of this invention to provide a separator tube, divided into two chambers by a constriction, which tube will receive blood from a patient, which blood in the case of serum will be allowed to clot, can be centrifuged or allowed to settle so that the serum or plasma will go into one chamber and the cells into the other chamber, and is adapted to be fractured at the constriction into the two chambers, with the chamber containing the serum or plasma so constructed that the container can be sealed for shipment and then be adapted for dispensing the fluid.

It is a further object to provide a separator tube which will allow for the collection of blood and the separation of serum or plasma from the blood cells without contamination between the two parts.

It is a further object to provide a method for positively separating serum or plasma from the blood cells in a simple manner and without contamination of the serum or plasma by the red cells.

It is a further object to provide a tube for the separation of serum or plasma from the blood cells which is simple, inexpensive to manufacture and requires no additional parts with the exception of a sealing cap.

It is a further object to provide a tube for the separation of serum or plasma from the blood cells which is so constructed that the portion containing the serum or plasma, after shipment to a laboratory, can be easily adapted for dispensing of the fluid.

BRIEF DESCRIPTION OF THE DRAWINGS

Other objects and advantages will become apparent from the following description which is to be taken in conjunction with the accompanying drawings, in which

FIG. 1 is a longitudinal sectional view of a separator tube embodying this invention showing a stopper to be used if tube is to be evacuated;

FIG. 2 is a view of the tube of FIG. 1 provided with a stopper after blood has been drawn from the patient;

FIG. 3 is a view of the tube of FIG. 2 with the tube inverted after centrifuging or settling;

FIG. 4 is a view of the tube of FIG. 3 after the tube has been scored in a typical scoring device;

FIG. 5 is a view of the tube of FIG. 4 after the tube has been inverted and fractured into two containers;

FIG. 6 is a view of the bottom container of FIG. 5, containing the plasma or serum with a seal cap fitted over the container for shipping;

FIG. 7 is a view of the container of FIG. 6 with the cap removed and a device inserted in the container for drawing off the serum;

FIG. 8 is a view of a tube similar to that of FIG. 2 with the tube provided with a nipple at the bottom;

FIG. 9 is a view of the bottom container of the tube of FIG. 8, similar to that of FIG. 6, preparatory to the nipple being broken off and the fluid being dispensed from the bottom into another vessel;

FIG. 10 is a view of the container of FIG. 9 with the cap substituted with a combination cap and bulb having a center plug and the nipple being broken off to permit dispensing the fluid as with an eye dropper;

FIG. 11 is a view of the container of FIG. 9 with the cap replaced with a modified form of cap which can be used either as a vessel or as an eye dropper;

FIG. 12 is a view of the container and cap of FIG. 11 with the nipple broken off and the cap used as an eye dropper;

FIG. 13 is a view of the container and cap of FIG. 11 with the cap used as a vessel into which the fluid can be poured from the container;

FIG. 14 is a view of a tube similar to that of FIGS. 1 and 2, but provided with two constrictions;

FIG. 15 is a view of a tube similar to that of FIGS. 1 and 2, but open at both ends and provided with stoppers; and

FIG. 16 is a view of the bottom container of FIG. 15 with container inverted and provided with a cap at the fractured end.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to the drawings, there is shown in FIG. 1 an empty tube **20** with a constriction **21**, located in this view approximately in the center of the tube, which constriction in effect forms two chambers **22** and **23** with a shape somewhat like an hourglass or egg timer. Such tube is evacuated and provided with a penetrable self-sealing stopper **24** as shown in FIG. 2. Blood **25** is drawn from a patient or donor into the tube by a conventional method using a collecting tube, holder and needle. After the blood is drawn the tube is inverted and placed stopper downwards in a centrifuge cup or allowed to settle (FIG. 3).

The tube is centrifuged so that the cellular components **26** go to the stoppered end and the fluid portion **27** goes to the other end of the tube. After removing the tube from the centrifuge it is kept in an upright position; with the stopper at the bottom, and scored along a line **28** with a file or other device **29** (FIG. 4). It will be understood that the tube can be prescored at the line **28**, in which case such scoring step will not be necessary. It is then turned to the horizontal and quickly fractured leaving only serum or plasma in the container **23**. The top opening **28***a* of such container **23** can then be closed with a stopper, cap or sealing material **30** and transported to a laboratory for analysis (FIG. 6).

Although the use of an evacuated tube as described herein is preferred and desirable, it will be understood that the tube need not be evacuated, in which case the stopper will not be necessary and the tube will not be

inverted for centrifuging as hereinafter described. In such case, after centrifuging or settling the fluid portion will end up in the upper chamber having the open end. Such end must then be stoppered to permit fracturing the tube into two containers. The fractured end of this container holding the fluid portion must then be capped or sealed for shipping and analysis.

When the serum or plasma arrives at the laboratory for analysis it should be in a form which enables it to be easily dispensed. The following FIGS. 7 through 16 illustrate various ways in which this can be performed in conjunction with the tube of this invention.

The seal cap 30 fitted over the container 23 for shipping, as shown in FIG. 6, can be removed on arrival at the laboratory. The serum or plasma may then be drawn off by pipette, or other similar device 31, or loaded directly into a blood analysis machine (FIG. 7).

The tube can be provided with a nipple 32, as shown in FIG. 8. Such tube 20a is used in the same manner as tube 20. However, when the nipple is broken off, the seal cap 30 can be drawn back allowing the fluid to flow from the nipple opening 33 into a vessel 34 (FIG. 9). The seal cap 30a can be made as a combination cap and bulb. When the nipple 32 is broken off, the bulb may be drawn back and used to dispense the fluid as with an eye dropper. A center plug 30*b* can be incorporated in the bulb 30*a* to further seal off the opening 28*a* (FIG. 10).

FIG. 11 shows the container 23 with a nipple 32 at the bottom and a modified form of cap 30*c* closing the top opening 28*a*. Such cap 30*c* can be used in different ways. The tube can be inverted, the nipple is then broken off and the tube is drawn back from the cap thus transferring the fluid into the cap. Such cap can then be used as a sample vessel and loaded directly into a blood analysis machine. As an alternative, the cap may be left in place and drawn back part way without breaking the seal, thus acting as an eye dropper bulb for dispensing the fluid (FIG. 12). As another alternative, the cap is removed completely, the nipple is broken off and the fluid is poured into another vessel 35 (FIG. 13).

The tube may be made with two constrictions 21*a* and 21*b*, as shown in FIG. 14. Such tube 20*b* is used in substantially the same manner as tube 20. Upon arrival at the laboratory the tube can be snapped in two. The container 23 holding the serum or plasma can be placed directly into the blood analysis machine. The stopper on the other container can be replaced with a bulb so that the fluid in such container can be dispensed for other laboratory tests. A double ended tube 20*c*, with stoppers 24 and 24*a* at both ends (FIG. 15) is used in the same manner as tube 20. However, on arrival at the laboratory the seal cap can be left in place and the fluid dispensed by removing the stopper (FIG. 16).

It has been found that there are certain limits on the size and position of the constriction necessary for satisfactory operation of the tube. When the inside diameter of the constriction is too large the "air lock," which forms between the two chambers when the tube is held horizontally, will not form. There would then be a possibility of the cells and serum or plasma mixing when the tube is broken. This will usually occur if the orifice is greater than 55 percent of the inside diameter. For the majority of sizes used for blood collection purposes the appropriate diameter appears to be about 0.180 inch diameter. When the inside diameter of the constriction is too small, in the case of serum tubes, a blood clot will not pass through the constriction. If the tubes are to have an anticoagulent, for the collection of plasma, the diameter of the constriction could be as small as 0.010 inch. If the tube is to be used for the collection of serum, the minimum diameter of the constriction should not be less than 0.050 inch.

There are also certain volumetric proportions of the tube which should be taken into consideration. These can be better explained by referring to FIG. 3 on which certain V numbers indicate the volumes of the contents of the tube as follows:

V_1 — packed red cells
V_2 — serum/plasma
V_3 — stoppered end
V_4 — serum/plasma collected
V_5 — trapped air.

The ratio of cells to serum/plasma will vary considerably with sex, age, altitude and physical condition of the patient. However, investigations have shown that in about 95 percent of all cases the volume of packed red cells will be less than 54 percent of the total volume of blood. In addition, the cell line will vary according to the vacuum in the tube since the volume V_5 will vary. If the volume at the stoppered end (V_3) is decreased, then the volume of trapped air (V_5) must be increased to compensate. For example, if V_3 is reduced to 25 percent total volume, then the volume of trapped air would have to be increased to 54.5 percent to compensate. This would require a tube of 15.4 ml in order to collect 3.15 ml serum/plasma. If V_3 is less than 10 percent, an unduly long tube, with a very low vacuum, would have to be used. Alternatively, if V_3 is increased then the volume of trapped air must be decreased in order to obtain the same yield of serum/plasma. For example, if V_3 is increased to 75 percent total volume, then at least 13 ml blood would have to be drawn in order to obtain 3.15 ml serum/plasma and a very high vacuum would have to be drawn to fill the tube as high as possible. If V_3 is in excess of 80 percent total volume, the waste of serum/plasma and the high vacuum would make it impractical.

The use and operation of the separator tube should be apparent from the foregoing description. Thus, the aforenoted objects and advantages are most effectively obtained. Although several preferred embodiments of the invention have been disclosed and described in detail herein, it should be understood that this invention is in no sense limited thereby and its scope is to be determined by that of the appended claims.

Having thus described the invention, what is claimed is:

1. A method for collecting blood and separating the fluid portion from the cellular components of blood comprising the steps of drawing blood from a patient into a tube closed at one end and open at the other end and divided by a constriction into two chambers, the chamber at the open end having a volume between 10 percent and 80 percent of the total volume of the tube, said constriction having an inside diameter between 0.050 inches and 55 percent of the inside diameter of the tube to provide a fracture point and to permit an air lock to form; employing means for concentrating the cellular components in the chamber at the open end and the fluid portion in the other chamber; fracturing the tube at a score line at the constriction into a container holding the fluid portion and a container holding

the cellular components; and closing with a seal the fractured end of the container holding the fluid portion for handling.

2. The method of claim 1 in which the means for concentrating the fluid portion and the cellular components into the chambers comprises centrifuging the tube to separate the contents.

3. The method of claim 1 in which the means for concentrating the fluid portion and the cellular components in the chambers comprises allowing the cellular components to settle into the bottom chamber.

4. The method of claim 1 in which the blood is drawn into an evacuated tube having a penetrable stopper in the open end.

5. The method of claim 4 in which the tube is inverted before the fluid portion and the cellular components are concentrated in the respective chambers.

6. The method of claim 5 in which the means for concentrating the fluid portion and the cellular components in the respective chambers comprises centrifuging the tube to separate the contents.

7. The method of claim 5 in which the closed end of the tube is provided with a nipple, the nipple is broken off the sealed container holding the fluid portion and the seal is broken allowing such portion to escape through the nipple opening.

8. The method of claim 5 in which the closed end of the tube is provided with a nipple and the seal is a combination cap and bulb, the nipple is broken off the sealed container holding the fluid portion and such portion is dispensed through the nipple opening by means of the bulb.

9. The method of claim 5 in which the closed end of the tube is provided with a nipple and the seal is a cap extending down the side of the container holding the fluid portion, the nipple is broken and such portion is dispensed into the cap, which in turn can act as a sample vessel.

10. A method for collecting blood and separating plasma from the cellular components of blood comprising the steps of drawing blood from a patient into a tube containing an anticoagulant which tube is closed at one end and open at the other end and divided by a constriction into two chambers, the chamber at the open end having a volume between 10 percent and 80 percent of the total volume of the tube, said constriction having an inside diameter between 0.010 inches and 55 percent of the inside diameter of the tube to provide a fracture point and to permit an air lock to form; employing means for concentrating the cellular components in the chamber at the open end and the plasma in the other chamber; fracturing the tube at a score line at the constriction into a container holding the plasma and a container holding the cellular components; and closing with a seal the fractured end of the container holding the plasma for handling.

11. The method of claim 10 in which the blood is drawn into an evacuated tube having a penetrable stopper in the open end.

12. The method of claim 11 in which the tube is inverted before the plasma and the cellular components are concentrated in the respective chambers.

13. The method of claim 12 in which the means for concentrating the plasma and the cellular components in the respective chambers comprises centrifuging the tube to separate the contents.

14. The method of claim 12 in which the closed end of the tube is provided with a nipple, the nipple is broken off the sealed container holding the plasma and the seal is broken allowing such plasma to escape through the nipple opening.

* * * * *