Sept. 16, 1969 E. D. ROSS 3,467,095

BLOOD COLLECTION SET

Filed April 24, 1967 3 Sheets-Sheet 1

Fig. 1.

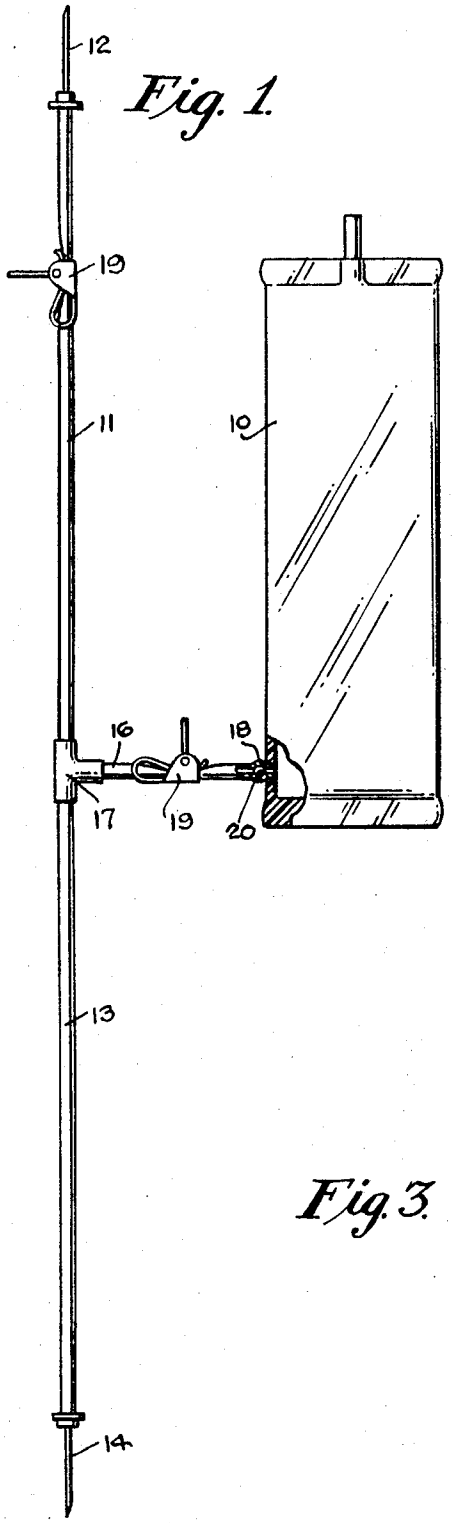


Fig. 2.

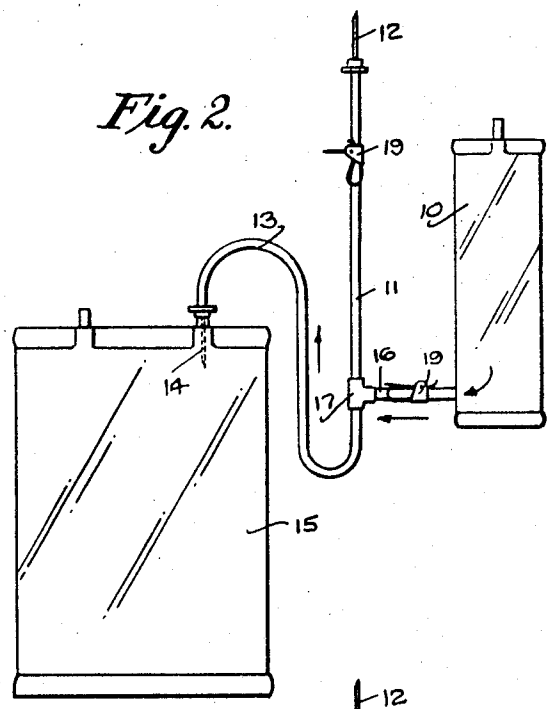
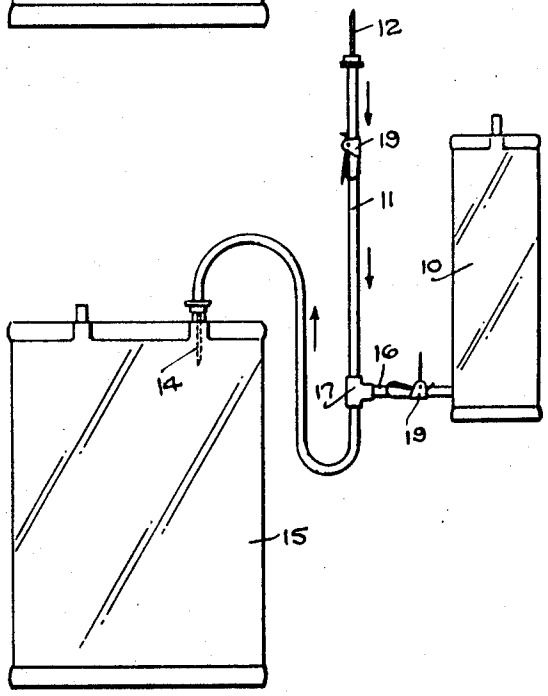


Fig. 3.



INVENTOR.

EUGENE D. ROSS

BY Edelsen and Udell

ATTORNEYS.

Sept. 16, 1969 E. D. ROSS 3,467,095

BLOOD COLLECTION SET

Filed April 24, 1967 3 Sheets-Sheet 2

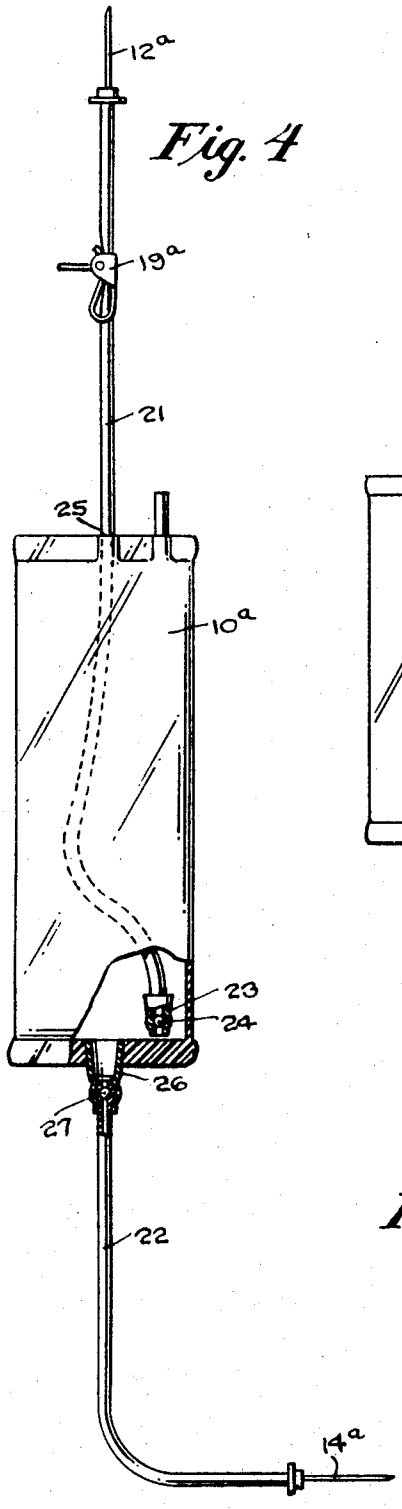


Fig. 4

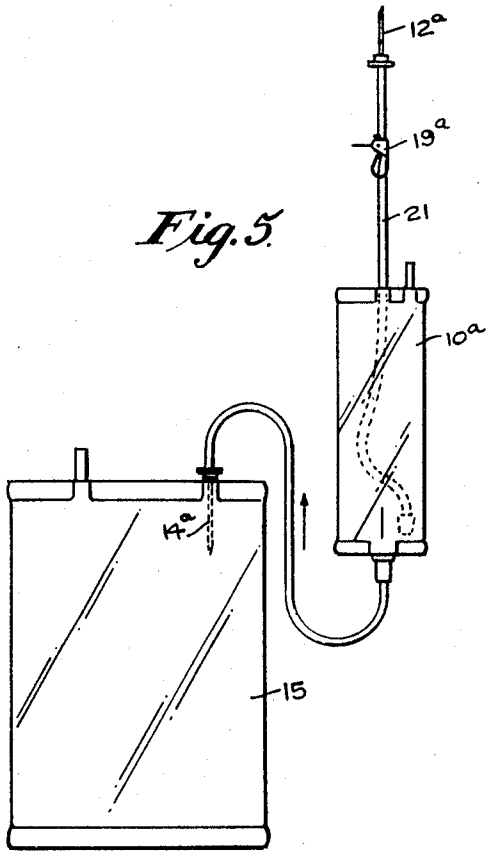


Fig. 5

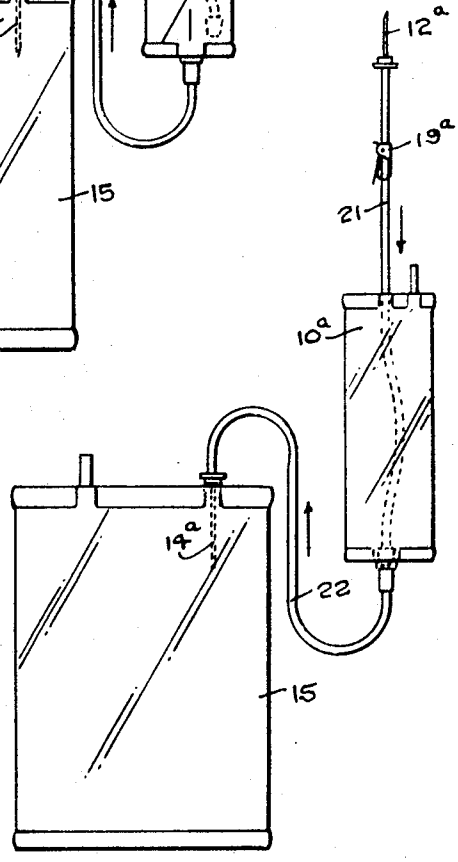


Fig. 6

INVENTOR.
EUGENE D. ROSS
BY Edelson and Udall
ATTORNEYS.

Sept. 16, 1969 E. D. ROSS 3,467,095

BLOOD COLLECTION SET

Filed April 24, 1967 3 Sheets-Sheet 3

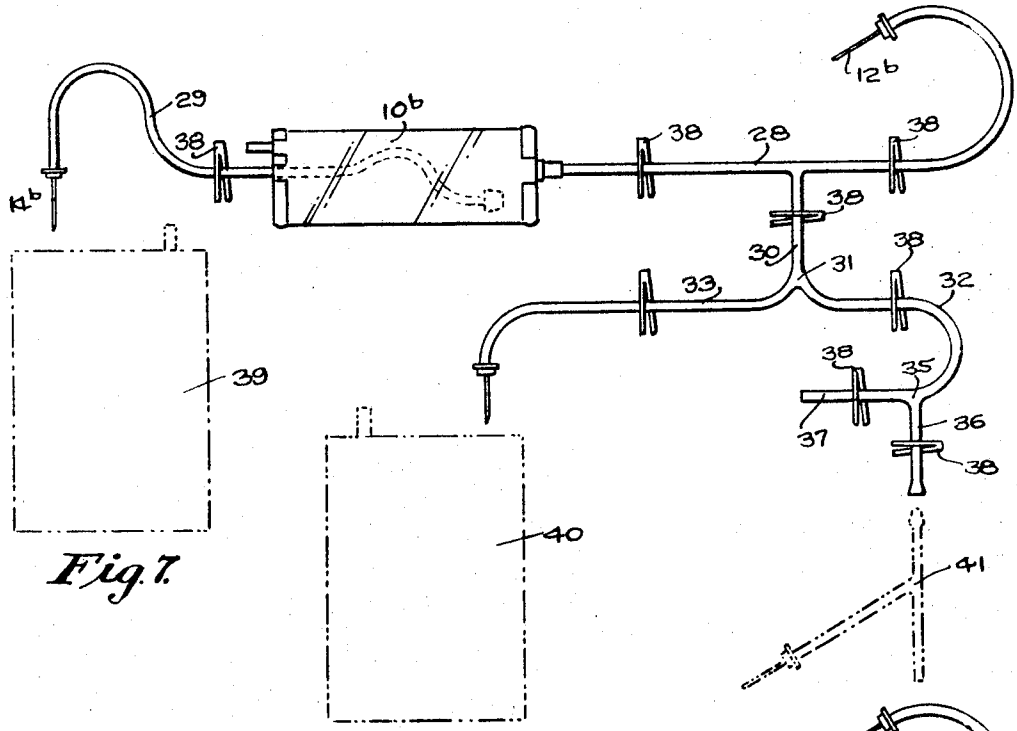


Fig. 7.

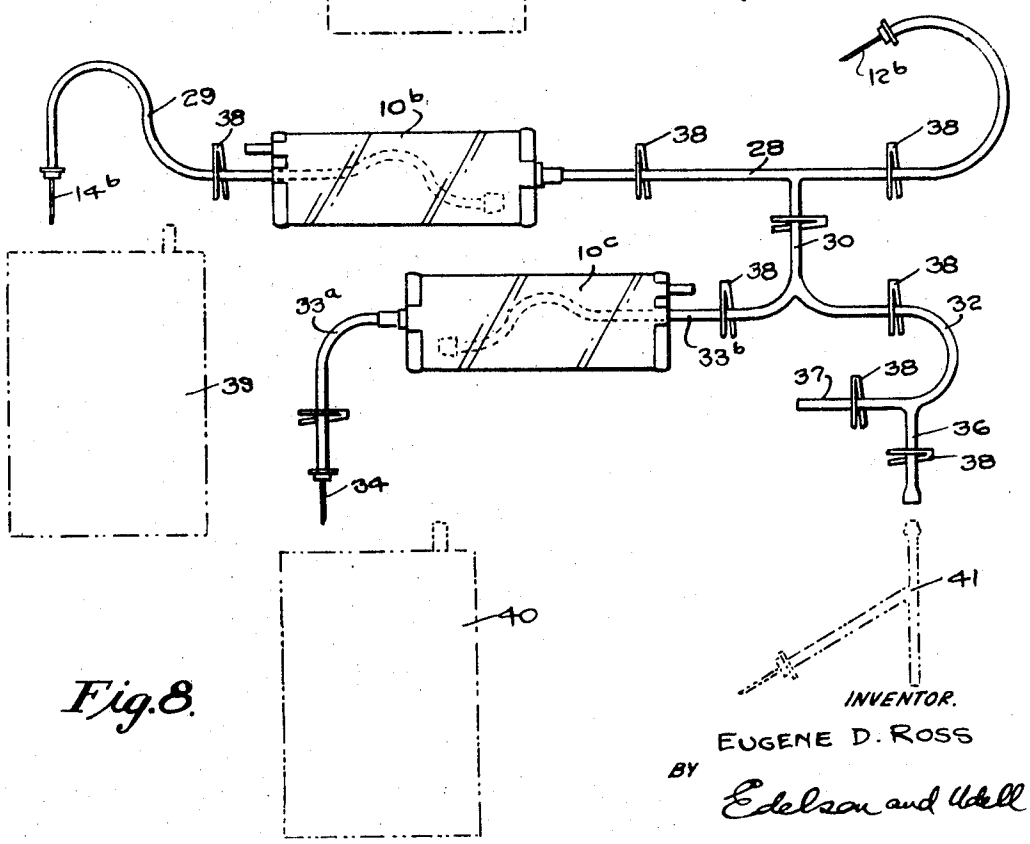


Fig. 8.

INVENTOR.
EUGENE D. ROSS
BY Edelson and Udell
ATTORNEYS.

United States Patent Office 3,467,095 Patented Sept. 16, 1969

3,467,095

BLOOD COLLECTION SET

Eugene D. Ross, Elkins Park, Pa., assignor to Eugene Ross Laboratories, Inc., Southampton, Pa., a corporation of Pennsylvania

Filed Apr. 24, 1967, Ser. No. 633,008
Int. Cl. A61m 5/14; A61n 5/18
U.S. Cl. 128—214.2 16 Claims

ABSTRACT OF THE DISCLOSURE

A blood collecting set having one or more vessels each containing a quantity of anti-coagulant in association with a flexible needle-equipped tubing system which is adapted for the collection of blood from a donor into one or more empty blood collecting vessels following introduction of the anti-coagulant into the empty vessel, as well as for plasmapheretic procedures, all of which may be effected by a single entry of a needle into the blood collecting vessel.

This invention relates to an apparatus for and method of receiving blood from a donor for collection in a hermetically sealed container and more particularly to improvements in blood collecting sets adapted for single and double plasmapheresis through single insertion into the blood collecting vessel of a needle in communication with the phlebotomy needle inserted into the vein of the blood donor.

It is well known that the container in which blood from a donor is collected and which contains an indicated quantity of anti-coagulant should be entered steriley by a needle or otherwise a minimal number of times (preferably only once) during the process of collecting the blood, since repeated entry into the blood container increases the risk of contamination of the blood and poses a serious problem. In addition, an empty container is preferable for the collection of blood provided that the anti-coagulant can be added at the time of the blood collection without necessitating repeated entry of a needle into the container. This increases greatly the versatility in use of the container and makes possible when collecting the blood to use any suitable anti-coagulant as needed.

In order to condition an empty container for acceptable collection of blood therein it has been necessary heretofore to make at least two needle entries into the container, one for introducing therein the indicated amount of anti-coagulant and the second for introducing the blood received from the donor. To avoid this double entry into the blood collecting vessel, the customary recognized procedure has been to initially include in the container a sealed-in quantity of the anti-coagulant.

It is among the principal objects of the present invention to provide an apparatus and a method by which blood collection may be performed with use of a completely empty container requiring but a single entry of a needle for introducing into the container not only the blood received from the donor but also the anti-coagulant required to prevent clotting of the collected blood.

A further object of the invention is to provide a means for and method of using an empty satellite container such as is provided with currently available multiple bag closed systems for collection of whole blood, whenever such satellite container is not required to be utilized for the separation or collection of specific components of the blood, as, for example, plasma, platelets, etc.

Still other objects, advantages and aspects of the present invention will appear more fully hereinafter, it being understood that the invention consists in the combination, location and relative arrangement of parts as described in the following specification, as shown in the accompanying drawings and as finally pointed out in the appended claims.

In the accompanying drawings:

FIGURE 1 is an elevational view of a blood collecting set constructed in accordance with and embodying the principles of the present invention;

FIGURE 2 is an elevational view of the set in conjunction with a blood collecting vessel showing the set conditioned for introduction of the anti-coagulant or other liquid into the blood collecting vessel preliminary to introducing into said vessel the blood collected from a donor;

FIGURE 3 is an elevational view showing the set conditioned for receiving blood from the donor and entering it into the blood collecting vessel;

FIGURES 4, 5 and 6 are views respectively corresponding to FIGURES 1, 2 and 3 but showing a modified construction of the blood collecting set;

FIGURE 7 is an elevational view of a further modification of the blood collecting set constructed in accordance with and embodying the principles of the present invention and designed particularly for use in carrying out a double plasmapheresis procedure by which a second donation of blood may be given safely by a blood donor without removing from his vein the needle which was inserted for obtaining the first donation of blood, the two donations of blood being respectively collected in one empty container and in another already containing anti-coagulant; and

FIGURE 8 is an elevational view showing a modification of the blood collecting set for obtaining two donations of blood from a donor while the needle is still inserted into the vein of the donor, the two collections in this instance being respectively made in two empty containers.

Referring now to the drawings and more particularly to FIGURES 1 to 3, it will be noted that the blood collecting set of the present invention essentially comprises a sterile vessel **10** having connected thereto a sterile system of flexible tubing consisting of a branch **11** terminating in a phlebotomy needle **12** for insertion into the vein of a blood donor, a branch **13** terminating in a needle **14** adapted for insertion into a completely empty blood collecting vessel **15** and a branch **16** having one end commonly in communication with the branches **11** and **13** of the tubing system, as by a T-connection **17**, and its opposite end connected to the vessel **10**, as at **18**. All of the tubing branches **11**, **13** and **16** are preferably formed of a compressible material, such as rubber or plastic, and the branches **11** and **16** each have a suitable closure clamp **19**, of any approved form, for opening or closing the branch with which it is associated to control the flow of fluid therethrough. The inner end of the branch **16** of tubing is interiorly fitted with a ball **20** which is normally frictionally retained in position within the end of the tube as shown to serve as a closure for sealing the vessel **10** against undesired flow therefrom of its liquid content, which ball is adapted to be dislodged from its sealing position by expressing it out of the open end of the tube branch **16** and into the vessel **10** when it is desired to effect flow of fluid **10** from the vessel into and through the tubing system.

The vessel **10** contains sterily sealed therewithin an anti-coagulant solution, such as acid citrate dextrose solution A, U.S.P., heparin or any suitable anti-coagulant solution, in an amount sufficient to prevent coagulation of the blood given at any one time by the donor for introduction into the blood collecting vessel **15**. Normally about 500 cc. of blood is so collected from the donor at any one time.

In use of the set as shown in FIGURES 1 to 3, with all of its tube clamps **19** closed and the ball valve **20** in its sealing position as shown in FIGURE 1, the needle **14** is inserted into the blood collecting vessel **15** preferably through a self-sealing port. Thereupon, the clamp **19** of the tube branch **16** is released or opened and the ball **20** expressed from its seat to permit the free flow of the anti-coagulant from its container **10** into the blood-collecting vessel **15** by way of the intercommunicating tube branches **16** and **13**. Having thus introduced the anti-coagulant into the empty blood-collecting vessel, the clamp **19** on the tube branch **16** is re-closed, the clamp **19** on the tube branch **11** is opened and the phlebotomy needle **12** is inserted into the vein of the blood donor, whereupon blood from the donor may flow into the blood-collecting vessel **15** through the branches **11** and **13** of the tubing system for admixture with the anti-coagulant previously introduced into the vessel **15**.

It will be noted that by use of the blood collecting set as above described, only one entry of a needle into a completely empty blood collecting vessel is required for introducing thereinto the blood collected from the donor and the requisite quantity of anti-coagulant for preventing coagulation of the collected blood, thereby reducing the risk of contamination of the blood as might result from multiple insertions of a needle or needles into the collecting vessel.

By the procedure described with use of the blood collecting set of the present invention for collecting blood in a hermetically sealed, completely empty vessel, the same sterile conditions which normally prevail when blood is collected in a blood bag already having sealed therein the requisite quantity of anti-coagulant are maintained and thus the present insertion makes possible hospital use of empty bags for conjointly collecting therein blood from a donor and the indicated quantity of anti-coagulant so that the collected blood may be banked for subsequent use without violating the regulations of the American Association of Blood Banks which mandatorily require use of the collected blood within twenty-four hours after the container in which it is collected has been entered more than once.

FIGURES 4 to 6 illustrate a modified form of the blood collecting set wherein the tubing system connected to the anti-coagulant container **10***a* consists of two flexible tubes **21** and **22** which are adapted to be interconnected interiorly of the container **10***a*, which in this instance is in the form of a flexible walled bag made of suitable plastic material. Thus, the tube **21** fitted at its outer free end with a phlebotomy needle **12***a* extends into the interior of the container with its inner end being fitted with a tapered sleeve **23** having frictionally seated therein a ball **24** which normally maintains the inner end of the tube sealed against flow of fluid therethrough. The tube **21** is, of course, sealed as at **25** to the bag **10***a* at the point of its entry into the bag. The container-enclosed portion of the tube is of a length such that by manipulation of the tube within the flexible bag **10***a* its tapered sleeve may be seated in the complementally shaped fitting **26** fitted upon the inner end of the second tube **22**. This fitting **26**, which is sealed into the end of the bag opposite that through which the tube **21** enters the bag, is also provided with a ball **27** which normally maintains the tube closed against flow of the anti-coagulant out of its container into and through the tube **21**, which latter is provided at its outer free end with a needle **14***a* for insertion into the empty blood-collecting vessel **15**. As in the previously described form of the blood-collecting set, the tube **21** fitted with the phlebotomy needle **12***a* is provided with a suitable closure clamp **19***a*.

In use of the modified set as shown in FIGURES 4 to 6, with the clamp **19***a* closed and the inner ends of the tubes **21** and **22** disconnected as in FIGURES 4 and 5, the needle of the tube **22** is first inserted into the empty blood-collecting vessel **15** and then the valve ball **27** is unseated by expressing it into the anti-coagulant container **10***a*, whereupon the anti-coagulant contained in the flexible bag **10***a* is introduced into the empty blood-collecting vessel by way of the tube **22**. Having expressed the anti-coagulant from its container into the blood-collecting vessel, the ball valve **24** is freed of the tube **21** and the two inner ends of the tubes **21** and **22** are then coupled together so that they provide in effect a continuous length of tubing leading from the phlebotomy needle **12***a* to the needle **14***a* inserted into the blood-collecting vessel. The phlebotomy needle **12***a* is then inserted into the vein of the blood donor and upon releasing the clamp **19***a*, the blood collected from the donor is passed through the coupled tubes **21** and **22** directly into the vessel **15** for admixture with the anti-coagulant previously introduced thereinto. Thus, as in the first described form of the blood-collecting out of the present invention, both the anti-coagulant and the collected blood are introduced into an empty blood-collecting vessel or bag by way of a single needle inserted only once into said vessel or bag.

While in the modified form of the set as shown in FIGURES 4 to 6 the anti-coagulant container **10***a* is preferably in the form of a flexible-walled bag to facilitate effective coupling together of the tubes **21** and **22** by manual manipulation thereof from outside of the bag, in the form of the set as shown in FIGURES 4 to 6 the anti-coagulant container **10** may be made of any suitable rigid or flexible material, such as glass, rubber, plastic or the like.

FIGURE 7 shows a blood-collecting set embodying the principles of the present invention adapted for double plasmapheresis use whereby two collections of blood are obtained from the same donor for introduction into two separate blood-collecting bags, one of which is completely empty and receives the anti-coagulant required for the first donation of blood as a part of the phlebotomy procedure and the other of which contains the requisite quantity of anti-coagulant for the second donation of blood. By this plasmapheresis procedure employing the blood collecting set of FIGURE 7, the first donation of blood may be centrifuged to separate out therefrom its red cell fraction for return of the same to the blood donor.

Thus, as shown in FIGURE 7, the blood-collecting set includes a vessel **10***b* containing an amount of anti-coagulant requisite for a single donation of blood, which vessel is provided, as in the form of the set shown in FIGURES 4 to 6, with two flexible tubes **28** and **29** respectively fitted at their free outer ends with needles **12***b* and **14***b*. These tubes **28** and **29** are adapted to be coupled together and uncoupled interiorly of the vessel **10***b* as previously described in connection with the tubes **21** and **22** of FIGURES 4 to 6.

In addition to these tubes **28** and **29**, the tubing system of the plasmapheresis set of FIGURE 7 includes a tube branch **30** leading from the tube **28** through a Y-connection **31** to a pair of tube branches **32** and **33**, the latter of which is end-fitted with a needle **34**. The outer end of the tube branch **32** is in turn connected by a Y-connection **35** to a pair of tube branches **36** and **37**. Both of the tubes **28** and **29** and all of the branch tubes leading from the tube **28** are each provided with a suitable clamp **38** for closing and opening each individual section of the tubing system.

For use of this set shown in FIGURE 7, two hermetically sealed blood-collecting bags are employed as shown in phantom. One of these bags, designated **39**, is completely empty, while the other bag, designated **40**, contains anti-coagulant in the amount necessary to prevent coagulation of blood entered into said bag.

The first step in use of this set is to insert the needle **14***b* into the empty bag **39** after which, upon opening only the clamp **38** of the tube **29** and with the tubes **28** and **29** uncoupled as shown, the anti-coagulant is expressed from its container **10***b* into the bag **39**. Follow-

ing this, the tubes **28** and **29** are coupled together interiorly of the container **10***b* to thereby provide a continuous length of tubing leading from the phlebotomy needle **12***b* to the needle **14***b* inserted in the blood collecting bag **39**. The phlebotomy needle **12***b* is then inserted in the vein of the blood donor, the clamps **29** on the tube **28** are released, and the first supply of the donor's blood is thus entered into the blood-collecting bag **39**.

Having thus entered the first donation of blood (containing plasma and red cells) into the bag **39**, the needle **14***b* is withdrawn from said bag which is then temporarily put aside for subsequent centrifugation to separate the red cells from the plasma fraction of the collected blood. The section of tube **28** between the vessel **10***b* and the tube branch **30** is now reclosed or occluded by its clamp **38**, following which there is attached to the free end of either one of the tube branches **36** and **37** a conventional saline infusion set (shown in phantom and designated **41**) for supplying a saline solution to the blood donor by way of the tube branches **36** (or **37**), **35**, **30**, **28** and the needle **12***b* which has remained inserted in the vein of the blood donor. Of course, for this purpose, those clamps which are associated with the several tube branches used for administering the saline solution to the donor will have been released or opened, while maintaining closed the clamps on the tube branches not so in use.

Following conventional centrifugation and separation of the red cells and plasma of the first donation of blood contained in the blood collecting bag **39** and injection of the saline solution into the vein of the blood donor, the red cells from that bag are returned to the donor by way of the needle-fitted tube portion of the infusion set in communication with that one of the tube branches **36** and **37** of the blood collecting set used for supplying the saline solution to the blood donor. Of course, for this purpose, the needle of the infusion set is projected into that section of the bag **39** which contains the red cells and upon withdrawal of said red cells, only the plasma fraction of the blood originally taken from the donor will be contained in the bag **39**.

Having so returned the red cells of the original blood donation to the donor, he is now ready to give a second donation of blood through use of the blood collecting set without having necessitated withdrawal of the phlebotomy needle **12***b* from his vein. For this second donation blood, all of the clamps **38** of the tube system are closed except for those providing direct communication between the phlebotomy needle **12***b* in the vein of the blood donor and the needle **34** inserted into the second bag **40** which as originally made, had sealed therein a predetermined quantity of anti-coagulant. There will now be collected in the second bag **40** the second donation of blood which will be processed as was the first donation and the red cells then will be returned to the donor using the same infusion set **41**.

FIGURE 8 shows a modified blood collecting set for use in carrying out a double plasmapheresis, which differs from that shown in FIGURE 7 only in that it includes a second vessel **10***c* containing anti-coagulant so that the two donations of blood successively obtained from a donor through the single insertion of a needle into his vein may each be collected in a completely empty bag which the anti-coagulant is introduced preliminarily to collection of blood in each bag. This second anti-coagulant vessel **10***c* is connected in the tube line leading from the Y-connection **31** to the needle **34**, which line includes a pair of tubes **33***a* and **33***b* adapted to be coupled and uncoupled within the vessel **10***c* in the same manner as are the tubes **28** and **29** associated with the anti-coagulant vessel **10***b*.

It will be apparent that the tubing system of FIGURES 1 to 3, in lieu of and as distinguished from that shown in the modified arrangement of FIGURES 4 to 6, may be employed in the double plasmapheresis set of either FIGURE 7 or FIGURE 8 and that other modifications and changes may be made from time to time without departing from the general principles or real spirit of the present invention. Accordingly, it will be understood that it is intended to claim the invention broadly, as well as specifically, as indicated in the appended claims.

What is claimed as new and useful is:

1. A blood collection set of the character described comprising a hermetically sealed vessel containing therein a liquid consisting of an anti-coagulant solution and a flexible tubing system connected to said vessel, said system having one section directly communicable with the interior of said vessel and other sections fitted at their terminal ends with hollow needles adapted respectively to be inserted into the vein of a blood donor and into an empty hermetically sealed blood collecting container, and means for selectively opening and closing said sections for sequentially delivering into said empty blood collecting container first the anti-coagulant contained in said vessel and then the blood taken from the donor while said needles are respectively inserted in the vein of the blood donor and in the blood collecting container.

2. A blood collection set of the character described comprising a hermetically sealed vessel containing therein a liquid consisting of an anti-coagulant solution and a flexible tubing system permanently connected to said vessel, said tubing system including a plurality of branches respectively leading into the interior of said anti-coagulant-containing vessel and to hollow needles insertable into the vein of a blood donor and into an empty hermetically sealed bag in which the donor's blood is collected, means effecting direct communication between the interior of said anti-coagulant vessel and the needle insertable into the blood collecting bag while maintaining occluded the tubing branch leading to the needle insertable into the donor's blood supplying vein, and means effecting direct communication between the two needles for direct delivery of blood from the donor into said blood collecting bag without any possible accumulation of blood in said anti-coagulant vessel.

3. A blood collection set of the character described comprising a hermetically sealed vessel containing therein a liquid consisting of an anti-coagulant solution and a flexible tubing system connected to said vessel, said system including separate fluid conduit branches each having a freely extending terminal end fitted with a hollow needle, said needles being respectively insertable into the vein of the blood donor and into a hermetically sealed empty blood collecting container, means for normally maintaining intact the hermetically sealed condition of the vessel containing the anti-coagulant, means for occluding the conduit branch connected to the vein-insertable needle and for opening the anti-coagulant vessel only to flow of the anti-coagulant solution therefrom into the blood-collecting container by way of the conduit branch connected to the needle insertable into said blood collecting container, said means being further operative to render said needle-connected branches effective as a direct conduit for the flow of blood from the donor to the blood collecting bag following transfer of the anti-coagulant solution from its vessel into the blood collecting bag.

4. In a blood collection set as defined in claim **3** wherein said needle-fitted conduit branches extend in by-passing relation to said anti-coagulant containing vessel and are commonly connected to the latter by auxiliary conduit branch having one end in communication with said needle-fitted branches by way of a T-connection and its opposite end connected to said vessel for communication with the interior thereof.

5. In a blood collection set as defined in claim **4** wherein the valve means for maintaining said anti-coagulant containing vessel hermetically sealed consists of a spherical element frictionally seated in the said end of said auxiliary conduit branch which is connected to said vessel,

said element being expressable out of its seat into the interior of said vessel to open the same to discharge of the anti-coagulant solution therefrom.

6. In a blood collection set as defined in claim 4 wherein said needle-fitted conduit branch insertable into the donor's vein and said auxiliary conduit branch are respectively fitted with clamp means operative to selectively open and close said branches to passage of fluid therethrough.

7. In a blood collection set as defined in claim 3 wherein said needle-fitted conduit branches are adapted to be connected together interiorly of the vessel containing the anti-coagulant to effectively provide a continuous conduit extending through said vessel, the connectable ends of said branches being each fitted with closure means for individually sealing said branches against flow of fluid therethrough, said being sequentially openable to permit sequential delivery into the blood collecting container of the anti-coagulant solution from said vessel and of the blood from the donor through said continuous conduit, both flows being by way of the same needle inserted into the blood-collecting container.

8. In a blood collection set as defined in claim 3 wherein said anti-coagulant containing vessel is formed of a substantially rigid, inflexible material.

9. In a blood collection set as defined in claim 3 wherein said anti-coagulant containing vessel as formed of flexible material and is provided with walls which may be pressed together to express therefrom the contained anti-coagulant solution.

10. In a blood collection set as defined in claim 3 wherein said tubing system is provided with an auxiliary conduit system for collecting a second donation of blood from the donor through a single insertion of a needle into the vein of the donor, said auxiliary conduit system having a branch connected at one end to said needle-fitted conduit branch insertable into the donor's vein and at its opposite end to a pair of freely extending branches one of which terminates in a hollow needle adapted for insertion into a second hermetically sealed blood collecting container and the other of which is adapted for connection to an infusion set for supplying an indicated solution into the vein of the blood donor.

11. In a blood collection set as defined in claim 10 wherein the needle-fitted branch of said auxiliary conduit system is connected to a second vessel containing an anti-coagulant solution and wherein means are provided for sequentially delivering into the second blood collecting container first the anti-coagulant contained in said second vessel and then the second donation of blood taken from the vein of the blood donor.

12. In a blood collection set as defined in claim 10 wherein each conduit branch of said auxiliary conduit system is provided with means for selectively opening and closing the same to flow of fluid therethrough.

13. A method of collecting blood from a donor for introduction into a hermetically sealed empty blood collecting container which consists in delivery of an anti-coagulant solution from a vessel in which said solution was initially sealed into the blood collecting container by way of a flexible delivery tube extending from said vessel to a-hollow needle fitted on the end of said tube and inserted into said container, in then re-sealing the anticoagulating vesesl by occluding the solution delivery tube against flow of fluid from the vessel therethrough, and thereafter inserting into the vein of a blood donor a hollow needle fitted on the end of a second tube in direct communication with the tube having its needle inserted into the blood collecting container to provide a conduit in by-passing relation to said re-sealed vessel for delivery of blood from the donor to the container.

14. A method of conducting plasmapheresis which consists of hermetically sealing a predetermined quantity of anti-coagulant solution in a vessel having a tube extending therefrom and terminating in a hollow needle, in inserting said needle into a hermetically sealed empty blood collecting container, in opening said vessel to free flow of the anti-coagulant solution therefrom into said container by way of the needle inserted into said container, in then closing off the interior of said vessel from said container, in then inserting into the vein of a blood donor a phlebotomy needle having direct tubular communication with the needle inserted in the blood collecting container for free flow of a first donation of blood from the donor into said container, in then removing the blood collecting container from its inserted needle and centrifuging the same to separate the red cell and plasma components of the collected blood while introducing into the donor's vein a saline solution by way of the phlebotomy needle initially inserted therein, in then returning to the donor's vein also by way of said phlebotomy needle the red cells recovered by said centrifugation of the first donation of blood, and thereafter delivering a second donation of blood through said phlebotomy needle in the vein of the donor to and into a second blood collecting cntainer.

15. A method of conducting plasmapheresis as defined in claim 14 wherein the second blood collecting container has already sealed therein a predetermined quantity of anti-coagulant solution.

16. A method of conducting plasmapheresis as defined in claim 14 wherein prior to introduction of the second donation of blood into said second container anti-coagulant solution from an external source of supply is introduced into said second container with both the anti-coagulant solution and the second donation of blood being successively introduced into said second container by way of a single entry of a needle into said second container.

References Cited

UNITED STATES PATENTS

1,517,849	12/1924	McLellan	128—214.2
1,610,622	12/1926	Shaweker	128—214.2
2,950,716	8/1960	Bellamy et al.	128—214
3,006,341	10/1961	Poitras	128—214
3,078,847	2/1963	Wandell et al.	23—258.5
3,064,647	11/1962	Earl	23—258.5

FOREIGN PATENTS

865,661	3/1941	France.
1,082,035	6/1954	France.

DALTON I. TRULUCK, Primary Examiner

U.S. Cl. X.R.

23—258.5