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(54) **COMPOSITIONS D'ERYTHROCYTES ET PROCEDES
PERMETTANT DE PRELEVER ET DE STOCKER LES
ERYTHROCYTES**

(54) **RED BLOOD CELL COMPOSITIONS AND METHODS FOR
COLLECTING AND STORING RED BLOOD CELLS**

(57) La présente invention concerne des procédés permettant de prélever des érythrocytes, procédés selon lesquels on associe le sang total à un anticoagulant, on sépare les érythrocytes du sang total et on associe les érythrocytes séparés à une solution de stockage. Les érythrocytes peuvent être stockés pendant une longue période de temps.

(57) Methods are disclosed for the collection of red blood cells whereby whole blood is combined with an anticoagulant, red cells are separated from the whole blood and the separated red cells are combined with a storage solution. The red cells may be stored for an extended period of time.

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(21) International Application Number: PCT/US98/03712 (22) International Filing Date: 25 February 1998 (25.02.98) (30) Priority Data: 08/819,106 17 March 1997 (17.03.97) US (71) Applicant: BAXTER INTERNATIONAL INC. [US/US]; One Baxter Parkway, Deerfield, IL 60015 (US). (72) Inventors: GUDINO, Maria, D.; 1001 Ambria Lane, Mundelein, IL 60060 (US). DENIEGA, Jose, C.; 20961 Eagles Glen, Lake Forest, CA 92630 (US). BUCHHOLZ, Donald, H.; 25910 Timberlake Road, Barrington, IL 60010 (US). (74) Agent: KOLOMAYETS Andrew G.; Cook, McFarron and Manzo, Suite 2850, 200 West Adams, Chicago, IL 60606 (US).		(81) Designated States: CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
(54) Title: RED BLOOD CELL COMPOSITIONS AND METHODS FOR COLLECTING AND STORING RED BLOOD CELLS (57) Abstract Methods are disclosed for the collection of red blood cells whereby whole blood is combined with an anticoagulant, red cells are separated from the whole blood and the separated red cells are combined with a storage solution. The red cells may be stored for an extended period of time.		

**RED BLOOD CELL COMPOSITIONS
AND METHODS FOR COLLECTING
AND STORING RED BLOOD CELLS**

TECHNICAL FIELD

The present invention relates generally to the separation of blood into its components such as red blood cells and plasma. More particularly, the present invention relates to the separation and collection of red blood cells whereby the red blood cells remain viable during extended storage.

BACKGROUND OF THE INVENTION

Blood may be separated into one or more of its components or fractions such as red cells, white cells, platelets and plasma, and one or more of the blood components or fractions may be collected. In typical blood collection procedures, whole blood is withdrawn from a donor or patient, anticoagulant is added to the withdrawn whole blood and one or more desired components or fractions are separated from the anticoagulated whole blood. A separated component may be administered, immediately or soon thereafter, to a patient in need of the particular component. Alternatively, the collected component may be stored for a period of time until it is required for transfusion.

Blood collection procedures and systems are often referred to as either "manual" or "automated." In "manual" blood collection procedures, whole blood is withdrawn from a donor and collected in a container that typically includes an amount of anticoagulant. After the collection, the donor is free to leave and the collected unit of whole blood is then subjected to the separation procedure generally described above.

In "automated" blood collection procedures, the donor is directly connected to a blood collection device and whole blood is withdrawn from the donor. A desired component is separated and collected while the remaining components may

be returned to the donor. Automated blood collection procedures have the advantage over manual blood collection procedures in that the initial collection of whole blood and the separation of the whole blood into the desired components or fractions can be achieved in a single procedure.

Instruments used to perform automated blood collection procedures, such as those described above, typically include a reusable hardware portion and a disposable tubing portion intended for one-time use only. The hardware portion may include pumps, such as peristaltic pumps for (1) withdrawing whole blood from a donor or patient, (2) introducing anticoagulant into the whole blood (3) introducing blood or blood components into a separation device for separating blood into its components and (4) withdrawing one or more blood components from the separation device for later use or for return to the donor or patient. Either the hardware portion or the disposable tubing portion may include the separation device which, for example, can be a rotating centrifuge as described in U.S. Patent No. 4,146,172 or a rotating membrane as described in U.S. Patent No. 4,753,729.

The disposable tubing portion typically includes, among other things, the venepuncture needle that is inserted into the donor and through which the whole blood is withdrawn, plastic tubing which transports the blood and/or blood components to and from the donor or patient and to and from the separation device. If a desired blood component is to be collected, the disposable tubing portion may also include plastic bags for collecting the desired blood component(s). Typically, the segments of the tubing are threaded over and engaged by the peristaltic pumps of the instrument. Peristaltic pumps include rotating members (rotors) driven by motors. Rotation of the pump rotors squeezes the tubing and consequently draws and pushes the blood or blood components through the tubing and through the system.

One example of a commercially available automated blood separation and collection system is the CS-3000® Plus, sold by Baxter Healthcare Corporation of Deerfield, Illinois. The CS-3000® Plus is an automated system for the separation and collection of blood components and/or fractions such as platelets, plasma, stem cells and the like. Another example of a commercially available automated blood separation and collection device is the Autopheresis-C®, also sold by Baxter Healthcare Corporation. The Autopheresis C® is an automated system for the collection of plasma.

Although, commercially available devices for the automated collection of platelets, plasma, stem cells and other components are known, automated red cell collection systems have only recently been introduced. One effort to provide a red blood cell collection system is described in detail in U.S. Patent Application Serial No. 08/512,807 entitled "Systems and Methods for Separating High Hematocrit Red Blood Cell Concentrations", filed in the name of Jose C. Deniega et al. and assigned to the assignee of the present application. U.S. Patent Application Serial No. 08/512,807 is incorporated by reference herein. Presently, the collection of red cells is performed using the manual procedures described above.

With respect to manually collected red cells, it is known that red cells can be stored for extended periods of time (e.g. beyond 24 hours) when combined with a suitable storage media. For example, in U.S. Patent No. 5,248,506, which is also incorporated by reference herein, manual collection of red cells from whole blood anticoagulated with a citrate-phosphate dextrose (CPD) anticoagulant and storage of the red blood cells in a red cell storage media is described. More specifically, U.S. Patent No. 5, 248,506 describes storage of red blood cells in a plasma-free storage medium that maintains the function and viability of the red cells for an extended period of time, e.g. (at least 42 days).

Factors that may affect the viability and function of stored red blood cells include ATP levels, 2,3 DPG levels, pH and the hemolysis of the red blood cells. For example, ATP (adenosine triphosphate) provides energy that is required to maintain the shape and volume of red blood cells. ATP is produced when the red blood cells metabolize glucose. Reduced ATP levels result in increased fragility of the red blood cells and, consequently, reduced viability. 2,3 diphosphoglycerate (DPG) plays a role in the red blood cell's ability to release oxygen. When 2,3 DPG levels decrease, the efficiency of oxygen release is impaired.

The pH of red blood cells must also be maintained. As the red cells break down glucose and form lactic acid, the pH of the red cells decreases and the red blood cells undesirably become more acidic. Finally, as red blood cells are stored, they undergo hemolysis. "Hemolysis" refers to the destruction of the red blood cell membrane.

Storage solutions for storing components such as red blood cells often contain nutrients and other preservatives intended to preserve the viability of red blood cells by helping maintain acceptable ATP, 2,3-DPG and pH levels and suppressing the hemolysis of red blood cells. Although there have been several reported attempts at providing methods for preserving the viability of red blood cells during storage, further improvement in ATP levels and further reduction in hemolysis (as well as other storage parameters) is, nonetheless, still desirable.

SUMMARY OF THE INVENTION

In one aspect, the present invention includes, but is not limited to, a method for collecting red blood cells which includes providing a quantity of whole blood and combining the whole blood with a quantity of an anticoagulant. The anticoagulant includes citric acid, trisodium citrate and dextrose. The anticoagulated whole blood is separated to provide a red blood cell concentrate. The red blood cell concentrate is combined with a quantity

of a solution that includes dextrose, sodium chloride, adenine and mannitol.

In another aspect, the present invention includes, but is not limited to, a red cell composition comprising between approximately 160-240 ml of red blood cells, 20-100 ml of plasma, 5-15 ml of an anticoagulant, which anticoagulant may include, among other things, citric acid, trisodium citrate and dextrose and 80-120 ml of a solution that may include, among other things, adenine, mannitol, dextrose and sodium chloride.

In another aspect, the present invention includes, but is not limited to, a red cell composition comprising a quantity of red cells, a quantity of a solution comprising dextrose, sodium chloride, adenine and mannitol. The red cell concentrate is derived from whole blood that has been anticoagulated with an anticoagulant comprising citric acid, sodium citrate, dextrose and is free of phosphate.

In another aspect, the present invention includes, but is not limited to, a method for suppressing the hemolysis of red blood cells providing a quantity of whole blood and combining the whole blood with a quantity of an anticoagulant. The anticoagulant may include citric acid, trisodium citrate and dextrose. The anticoagulated whole blood is separated to provide a red blood cell concentrate. The red blood cell concentrate is combined with a quantity of a solution that may include, among other things, dextrose, sodium chloride, adenine and mannitol. The combined red cell concentrate and solution are stored in a plastic container.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a top plan view of a disposable tubing set that may be used to separate and collect blood components in accordance with the present invention;

Fig. 2 is a perspective view of a blood separation and collection device with the tubing set of Fig. 1 installed thereon.

Fig. 3 is a perspective view of another disposable set that may be used to collect blood components in accordance with the present invention;

Fig. 3A is a perspective view of an integral closed disposable set that may be used to collect blood components in accordance with the present invention;

Fig. 4 is a graph comparing the pH levels of stored red blood cell compositions prepared in accordance with the present invention and red blood cell compositions prepared by a different method;

Fig. 5 is a graph comparing ATP levels of stored red blood cell compositions prepared in accordance with the present invention and red blood cell compositions prepared by a different method;

Fig. 6 is a graph comparing potassium levels of stored red blood cell compositions prepared in accordance with the present invention and red blood cell compositions prepared by a different method;

Fig. 7 is a graph comparing glucose levels of stored red blood cell compositions prepared in accordance with the present invention and red blood cell compositions prepared by a different method;

Fig. 8 is a graph showing the level of 2,3 DPG of stored red blood cell compositions prepared in accordance with the present invention;

Fig. 9 is a graph showing the level of lactate in stored red blood cell compositions prepared in accordance with the present invention; and

Fig. 10 is a graph comparing the levels of hemolysis in stored red blood cell compositions prepared in accordance with the present invention and red blood cell compositions prepared by a different method.

DETAILED DESCRIPTION OF THE DRAWINGS

Turning now to the figures, Figures 1 and 2 depict apparatus useful in the methods for collecting red blood cell compositions. As set forth above, the apparatus is described in detail in U.S. Patent Application Serial No.

08/512,807 entitled "Systems and Methods for Separating High Hematocrit Red Blood Cell Concentrations" which is incorporated by reference herein. Although a detailed discussion of the apparatus is, therefore, unnecessary, a general discussion of the apparatus is set forth below.

5 Fig. 1 shows a disposable tubing set 10 for use in collecting red cells and/or plasma separated from whole blood. Tubing set 10 of Fig. 1 includes a venepuncture needle 12, attached to whole blood inlet tubing line 13, and an anticoagulant spike 14 attached to anticoagulant tubing line 16. Disposable tubing set 10 includes a saline spike 18, saline line 20 and a separation device 22. As shown in 10 Fig. 1, separation device 22 includes a whole blood inlet port 24, packed red blood cell port 26 in communication with packed cell line 27 and platelet-poor plasma port 28 in communication with platelet-poor plasma line 30. As shown 15 in Fig. 1, lines 27 and 30 are attached to containers 32 and 34 respectively for collecting red blood cells (32) and plasma (34).

As shown in Fig. 2, disposable tubing set 10 is 20 installed on a blood separation and collection device 44. As seen, for example, in Figs. 2 a tubing organizer 36 with tubing segments is placed over peristaltic pump rotors 40. Placement of the tubing set 10 onto the hemapheresis device 44 is described in greater detail in U.S. Patent No. 25 5,460,493 and U.S. Patent Application Serial No. 08/779,094 entitled "Disposable Tubing Set and Organizer Frame for Holding Flexible Tubing," filed January 6, 1997 in the name of J. Kandler, M. Moubayed and M. Vandlik and assigned to the assignee of the present application. U.S. Patent No. 30 5,460,493 and U.S. Serial No. 08/779,094 are incorporated by reference herein.

Fig. 3 shows an accessory disposable tubing set 50 35 which may be used in combination with the disposable set 10 of Fig. 1. Disposable tubing set 50 includes spike 52 and a tubing segment 54, and may include a container 55 of storage solution. Disposable tubing set 50 also may include

a white cell removal filter 58 and a red blood cell collection container 60. Tubing set 50, including container 55, may be integral with tubing set 10 (as shown in Fig. 3A) to provide a unitary closed system or may be connected to tubing set 10 in a sterile manner.

5 The collection of a red cell concentrate utilizing the above-described tubing sets 10 (and, if necessary, tubing set 50) will now be generally described.

10 With reference to Fig. 1, whole blood is withdrawn from a donor by inserting venipuncture needle 12 into the vein of a donor (not shown). Whole blood is withdrawn through needle 12 and flows through inlet line 13. Anticoagulant spike 14 is inserted into anticoagulant container 15 (Fig. 2) to introduce anticoagulant into tubing set 10 through line 16. Whole blood flowing from the donor through inlet line 13 is combined with anticoagulant from line 16 by any known conventional means such as "Y" connector 19.

15 Anticoagulated whole blood is introduced into separation device 22 at whole blood inlet port 24. Once inside the separator, which in Figs. 1 and 2 includes a rotating spinning membrane as generally described in U.S. Patent Nos. 4,753,729 and 5,194,145, and incorporated by reference herein, the anticoagulated whole blood is separated into packed red cells and plasma. The rotating spinning membrane may be rotated at a speed of between approximately 3600-3900 with a preferred speed of approximately 3800 rpm. During the procedure, which typically takes between 20-40 minutes, anywhere between 1000-2000 ml of whole blood may be processed. Typically, however, the volume of whole blood processed is between 1200-1400 ml.

20 Separated plasma exits the separation device through port 28 and flows through line 30 to plasma container 34. Separated red cells exit the separation device through port 26 and, if they are to be collected, through line 27 to red cell collection container 32. It should be understood that it is not necessary that all of the separated red cells be

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collected in collection container 34. Some of the separated red cells may be returned to the donor.

Red cells in container 32 may be combined with a storage medium that assists in preserving the viability of the red blood cells. In one embodiment, red cells and the storage medium may be combined in red cell container 32. However, in a preferred embodiment, tubing set 50 shown in Fig. 3 may be used for transferring storage solution from container 55 of tubing set 50 to container 32 and, thereby, combining the red cell concentrate with the storage medium.

For example, turning briefly to Fig. 3, spike 52 may be inserted into container 55 of storage media and a selected quantity of the storage solution can be transferred to container 32 via tubing 54 which may be connected in a sterile manner to container 32. In addition, it may be desirable that the red cell concentrate in container 32 be filtered through a leukoreduction filter 58 (in Fig. 3) to remove white blood cells from the red cell concentrate. In that case, red cell concentrate and storage solution in container 32 may be transferred through line 54 and filter 58 to container 60. Filters, for filtering blood components are well known and are commercially available. Two filters suitable for use in the above-described method are the Pall WBF1 filter assembly available from the Pall Corporation of East Hills, New York and the Asahi RS2000 leukoreduction filter available from the Asahi Medical Co., Ltd. of Tokyo, Japan. Alternatively, as shown in Fig. 3A, tubing sets 10 and 50 (including solution container 55) may comprise one unitary closed system without the use of spikes and/or sterile connectors. Such a closed system may or may not include a filter as described above.

As set forth above, whole blood obtained from a donor is combined with anticoagulant. Several different anticoagulant formulations are known and may be used to collect red cells in accordance with the present invention. For example, the anticoagulant most commonly used for collection of red cells is citrate-phosphate-dextrose (CPD)

which includes trisodium citrate, citric acid, monobasic sodium phosphate and dextrose. Other available anticoagulants include the acid citrate dextrose (ACD) solutions A and B. In the preferred embodiment, whole blood is combined with ACD, Solution A (ACD-A). One (1) liter of ACD-A includes 22.0 g of trisodium citrate, 7.3 g citric acid, 24.50 g of dextrose and 1 l of water. Unlike CPD, ACD-A does not include phosphate.

The amount of anticoagulant combined with blood must be sufficient to prevent the clumping of blood cells or coagulation of plasma of the blood cells during processing. On the other hand, too much anticoagulant may result in excess citrate being reinfused to the donor or infused to the recipient, resulting in a "citrate reaction," the symptoms of which may include anxiety, chills, and tingling sensations around the mouth and fingers. Accordingly, the ratio of whole blood to anticoagulant should be between approximately 8:1 and 14:1 with a preferred ratio of approximately 12:1 (i.e. 8% ACD/Whole Blood).

The collected red cells, which may include plasma and some residual anticoagulant, are combined with a quantity of a storage solution which allows for extended storage of the red cell concentrate. Storage solutions for red cells are known. Storage solutions which may be useful in the method of the present invention are described, for example, in U.S. Patent No. 5,248,506. One such storage solution which is preferred for storage of red cells collected in accordance with the present invention is a solution that includes adenine, mannitol, dextrose and sodium chloride. Such a solution is commercially available under the name Adsol® and sold by Baxter Healthcare Corporation of Deerfield, Illinois. One liter of Adsol includes approximately 22.0g of dextrose, 0.27g adenine, 7.5 mannitol and 9.0g of sodium chloride. Of course, it should be understood that other solutions which may contain some, but not all, of the components of Adsol may also be used for storing red cell.

In one embodiment of the present invention, a red cell composition having a total volume of approximately 250ml (which includes plasma and anticoagulant) is combined with approximately 100ml of Adsol.

Collection of red cells in accordance with the above-described methods provides a viable red cell composition suitable for extended storage without compromising the viability of the red blood cells. As shown in Figs. 4-10, the ATP, 2, 3-DPG, potassium and pH levels were comparable to the levels obtained in manually collected red cells using CPD as the anticoagulant for the whole blood and stored in 100 ml of Adsol solution. With respect to hemolysis, red blood cells collected in accordance with the method described above showed results superior to hemolysis levels of manually collected red cells (using CPD as the anticoagulant and Adsol as the storage media) and superior to hemolysis levels in any other reported collections of red blood cells. A description of the procedure used to collect red cells in accordance with the above-described method is set forth below.

Example

Twenty one (21) units of red blood cells were collected from donors using the separation device generally described above. A total of approximately 1223 ml ($\pm$ 404 ml) was processed through a rotating membrane separation device of the type described above for approximately 25 minutes, ($\pm$ 8 min.) at a rotational speed of approximately 3800 rpm. The whole blood was anticoagulated with ACD-A solution in a ratio of approximately 12:1 whole blood to anticoagulant. Approximately 250ml of red blood cells having a hematocrit of approximately 70% were collected and combined with approximately 100ml of Adsol® solution added to the red blood cells immediately after collection. The red cells were leukoreduced at room temperature using a Pall WBF 1 or Asahi RS2000 leukoreduction filter and stored for 49 days at 4°C $\pm$ 2° C. In vitro red blood cell function assays were

performed at 0, 21, 35, 42 and 49 days of storage. The results (where n=12) are reported in Table 1 below.

TABLE 1

Days	Hemolysis %	ATP (umol/mL)	ATP (% of init.)	2,3-DPG (umol/mL)	K+ mEq/L
0	0.09(0.02)	66(7)	100	1.7 (0.2)	1.9(0.1)
21	0.14(0.03)	65(11)	98	*	22.2(3.0)
35	0.16(0.04)	60(8)	91	*	29.8(2.2)
42	0.19(0.08)	54 (7)	82	*	33.2(2.6)
49	0.23(0.09)	45(7)	69	*	36.5(2.8)

* Below detection limit; standard deviations are shown in parentheses

As shown in Table 1 and also in Figs. 4-10, collection of red blood cells using ACD-A as the anticoagulant for whole blood and Adsol® as the storage media resulted in a viable red cell product. As set forth in Table 1 (n=12) and Fig. 10 (n=21), the percent hemolysis levels at day 42 and day 49 were well below the 1.0 % maximum acceptable value required by the Food and Drug Administration and also below the 0.8% level suggested for Europe. Levels of ATP were also well preserved throughout the storage. On the basis of the above, whole blood collected using ACD as the anticoagulant and Adsol solution can be used to store the red blood cells collected by automated blood collection for at least 49 days.

The red cell compositions obtained in accordance with the above-described method wherein final hematocrit of the red cell composition is approximately 70% may include between 160-240 ml of red blood cells, 20-100 ml of plasma, 5-15 ml of anticoagulant and 80-120 ml of the storage solution. More specifically, the red cell composition may include approximately 175-185 ml of red blood cells, 60-70 ml of plasma, 6-10 ml of anticoagulant and 90-110 ml of storage solution. Stated as a percentage of the total

5 volume of the red cell composition, (which includes red cell concentrate, anticoagulant, plasma and storage solution), the red cell composition may include between about 40-79% red cell concentrate, between about 1-5% anticoagulant, 5-30% of the plasma and 20-40% storage solution. Of course, these volumes and/or percentages will vary depending on the donor hematocrit and donor weight.

10 While the invention has been described in connection with the foregoing, specific embodiments, it is to be understood that the invention is not limited thereto. The present invention is intended to cover various modifications within the spirit and the scope of the appended claims.

THAT WHICH IS CLAIMED:

1. A method for collecting red cells from whole blood comprising:

- a) providing a quantity of whole blood;
- b) combining said whole blood with a selected quantity of an anticoagulant, said anticoagulant comprising citric acid, trisodium citrate and dextrose;
- c) separating said anticoagulated whole blood to provide a red cell concentrate; and
- d) combining said red cell concentrate with a selected quantity of a solution comprising dextrose, sodium chloride, adenine and mannitol.

2. The method of Claim 1 further comprising filtering said red cell concentrate to remove white blood cells.

3. The method of Claim 1 further comprising storing said red cell concentrate and said solution for a period of at least 49 days.

4. The method of Claim 1 comprising withdrawing said whole blood from a donor and returning a portion of red cell concentrate to said donor.

5. The method of Claim 1 further comprising separating plasma from said whole blood.

6. The method of Claim 1 wherein the concentration of said anticoagulant comprises:

- a) approximately 7.3 g of citric acid;
- b) approximately 22.0 g of trisodium citrate;
- c) approximately 24.50 g of dextrose; and
- d) 1 L of water.

7. The method of Claim 1 wherein said anticoagulant is ACD-A.

8. The method of Claim 1 wherein the ratio of said whole blood to said anticoagulant is between 8:1 and 14:1.

9. The method of Claim 1 wherein said anticoagulant does not include phosphate.

10. The method of Claim 1 wherein the concentration of said solution comprises:

- a) 22.0 g of dextrose;

- b) 0.27 g of adenine;
- c) 7.5 g of mannitol;
- d) 9.0 g of sodium chloride; and
- e) 1 L of water.

11. A red blood cell composition comprising:

- a) between approximately 160-240 ml of red blood cells;
- b) between approximately 20-100 ml of plasma;
- c) between approximately 5-15 ml of an anticoagulant comprising citric acid, trisodium citrate and dextrose.

d) between approximately 80-120 ml of a solution comprising dextrose, adenine, mannitol and sodium chloride.

12. The red cell composition of Claim 11 comprising:

- a) approximately 185 ml of red blood cells;
- b) approximately 70 ml of plasma;
- c) approximately 10 ml of anticoagulant comprising citric acid, trisodium citrate, dextrose and does not include phosphate.

13. A red blood cell composition comprising:

- a) a selected quantity of red cell concentrate;
- b) a selected quantity of a solution comprising dextrose, sodium chloride, adenine and mannitol;

wherein said red cell concentrate is derived from whole blood that has been anticoagulated with an anticoagulant comprising citric acid, sodium citrate and dextrose and that is free of phosphate.

14. The red blood cell composition of Claim 13 comprising:

- a) between approximately 160-240 ml of red blood cells;
- b) between approximately 20-100 ml of plasma;
- c) between approximately 5-15 ml of and anticoagulant comprising citric acid, trisodium citrate and dextrose.

15. The red blood cell composition of Claim 13 wherein the ratio of whole blood to anticoagulant is between 8:1 and 12:1.

16. The red blood cell composition of Claim 11 or 13 wherein said composition is stored in a plastic container for at least 49 days.

17. The red blood cell composition of Claim 16 wherein the hemolysis of red blood cells is below 0.5 %.

18. The red blood cell composition of Claim 11 comprising:

- a) between approximately 40-70% red blood cells;
- b) between approximately 5-30% plasma;
- c) between approximately 1-5% of an anticoagulant comprising citric acid, trisodium citrate and dextrose;
- d) between approximately 20-40% of a solution comprising dextrose, adenine, mannitol and sodium chloride.

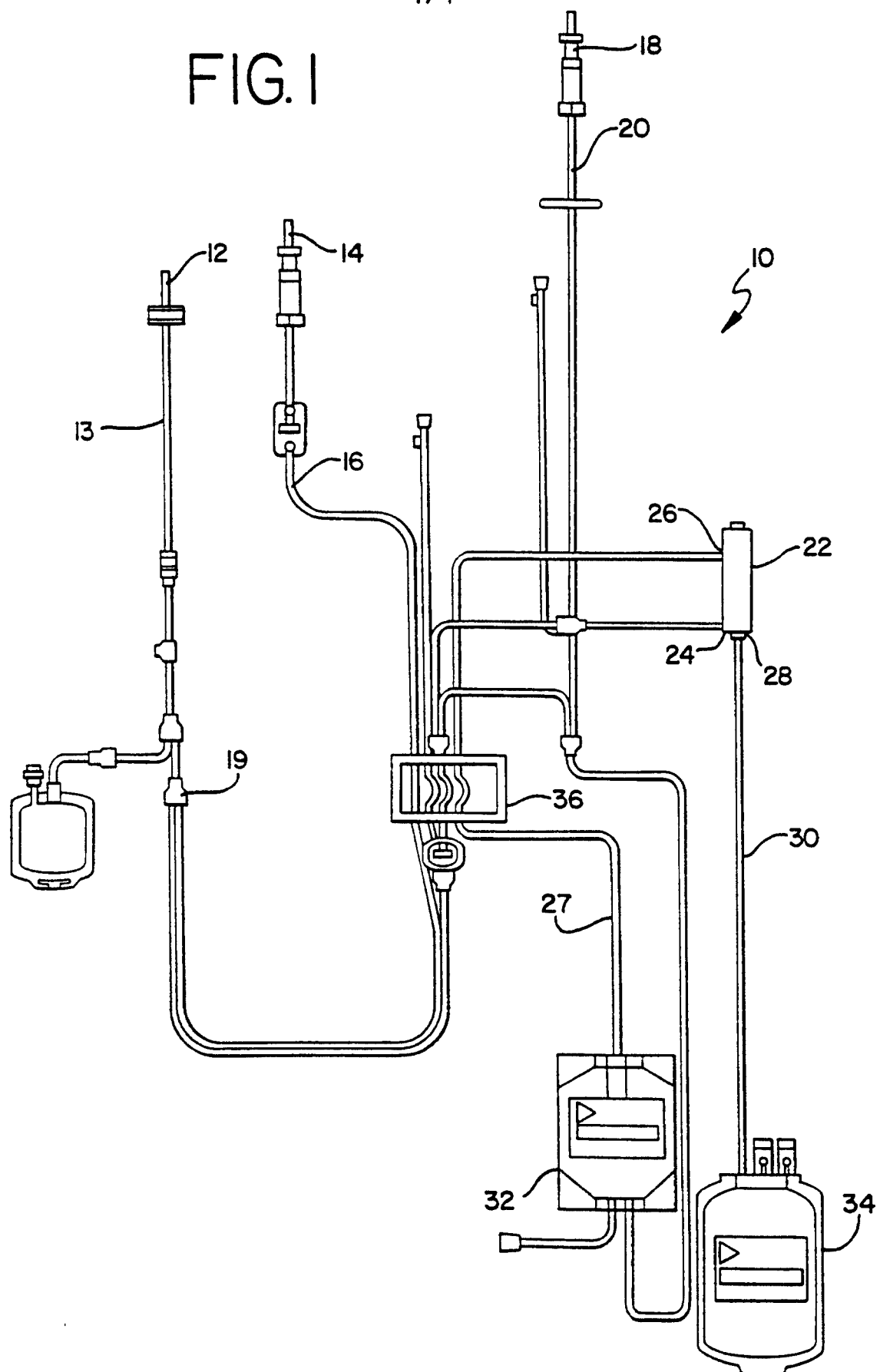
19. A method for suppressing the hemolysis in red blood cells comprising:

- a) providing a selected quantity of whole blood;
- b) combining said whole blood with a selected quantity of an anticoagulant, said anticoagulant comprising citric acid, sodium citrate and dextrose;
- c) separating said anticoagulated whole blood to provide a red cell concentrate;
- d) combining said red cell concentrate with a selected quantity of a solution comprising dextrose, sodium chloride, adenine and mannitol;
- e) storing said combined red cell concentrate and said solution in a plastic container.

20. The method of Claim 19 further comprising filtering said red cell concentrate to remove white blood cells.

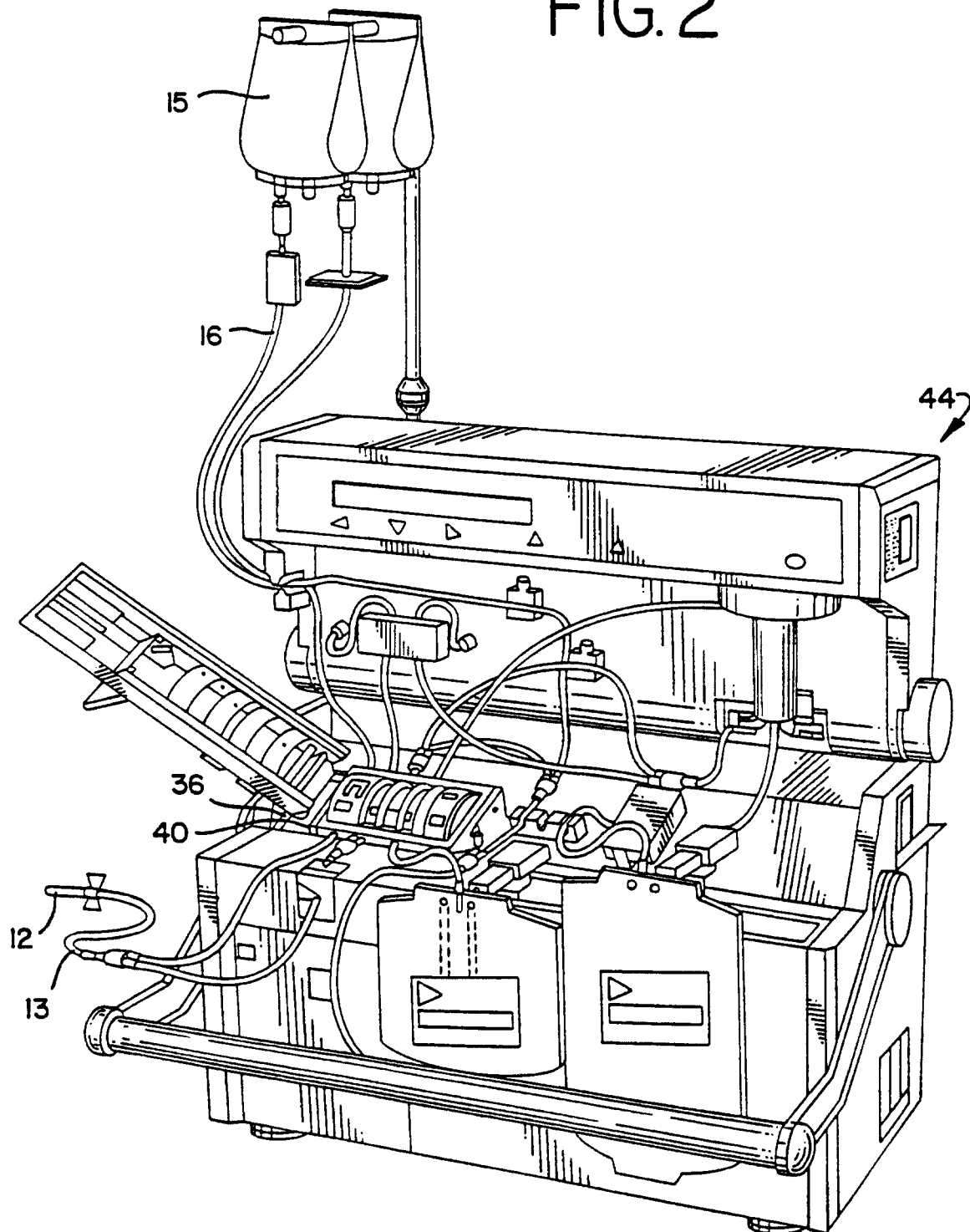
1/7

FIG. 1



2/7

FIG. 2



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FIG. 3

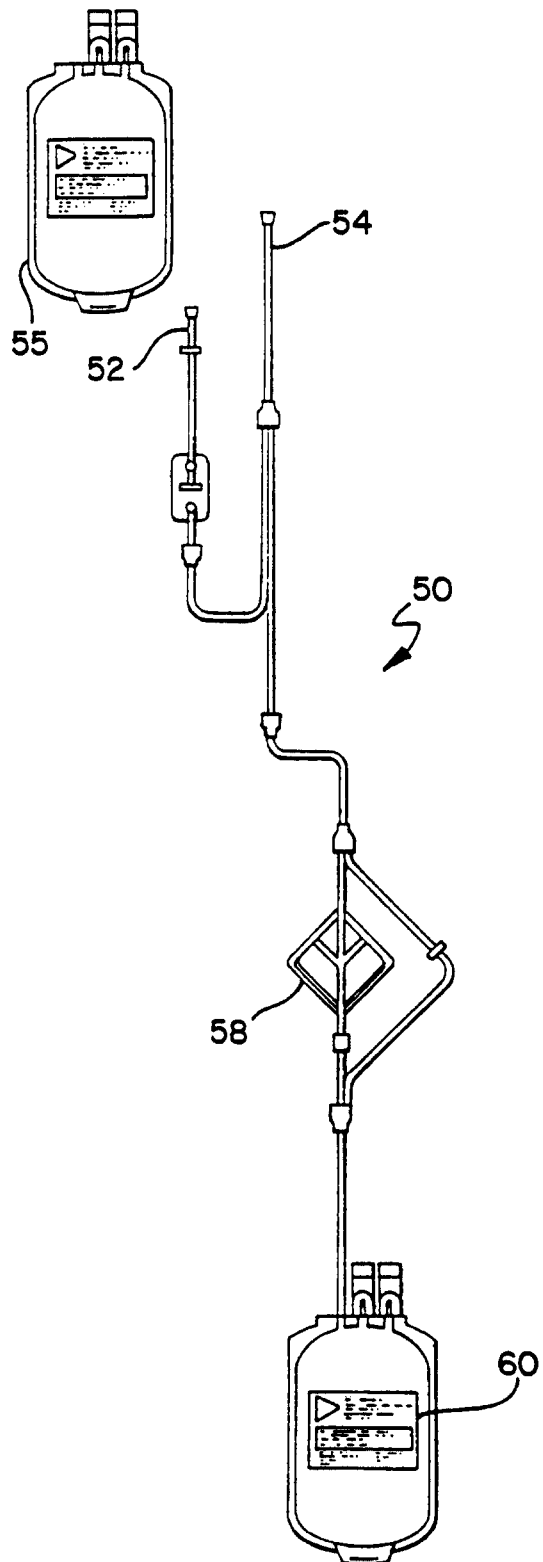
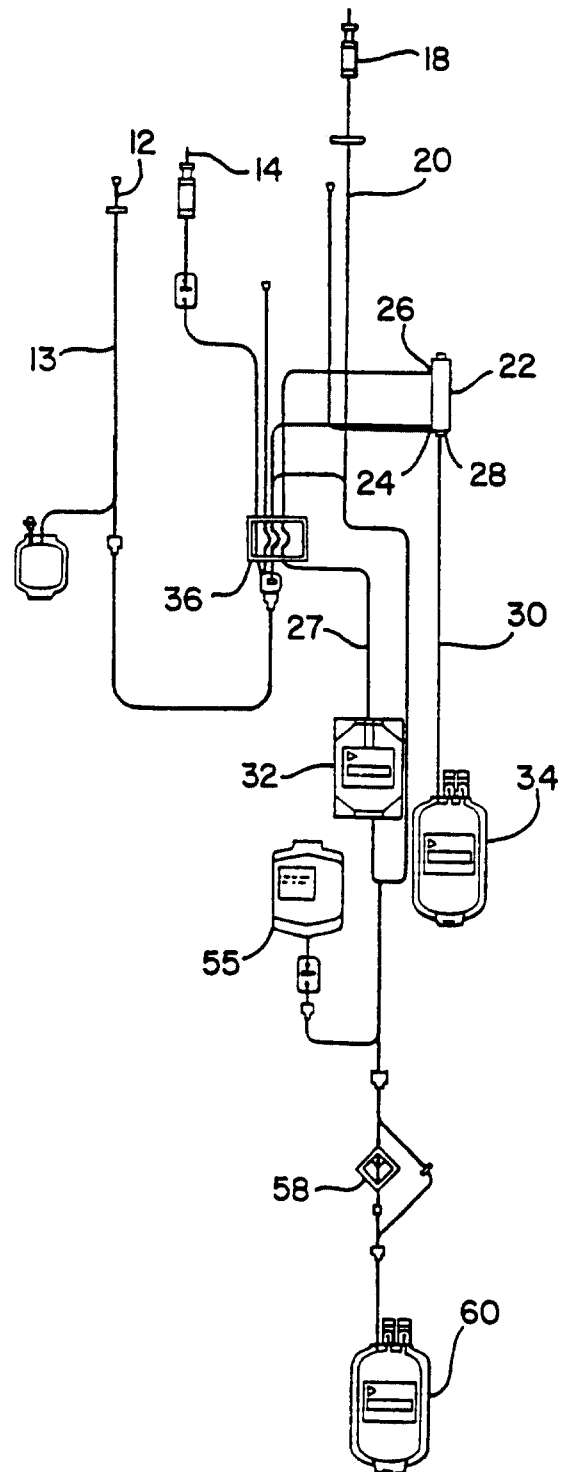


FIG. 3A



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FIG. 4

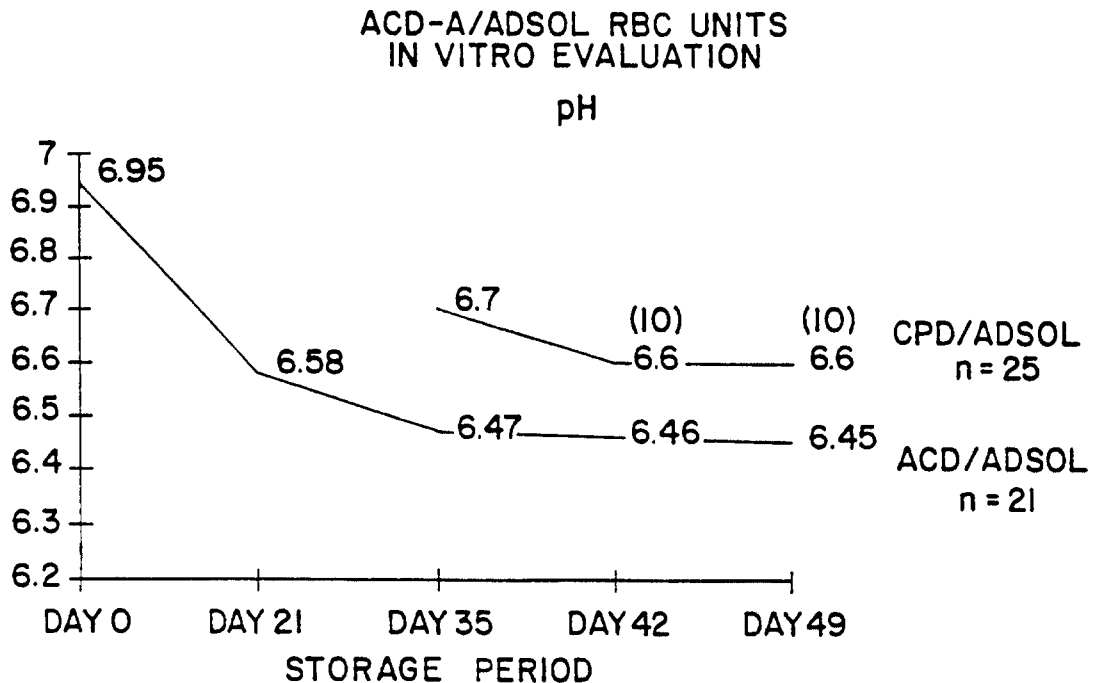
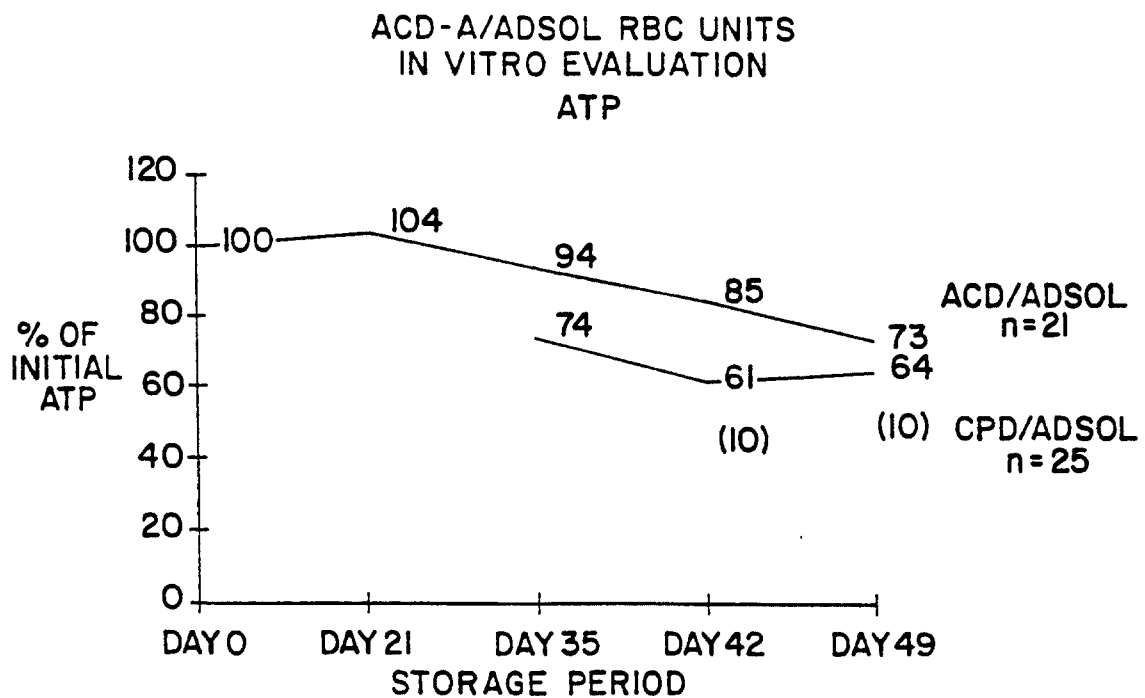


FIG. 5



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FIG. 6

ACD-A/ADSOL RBC UNITS
IN VITRO EVALUATION
POTASSIUM

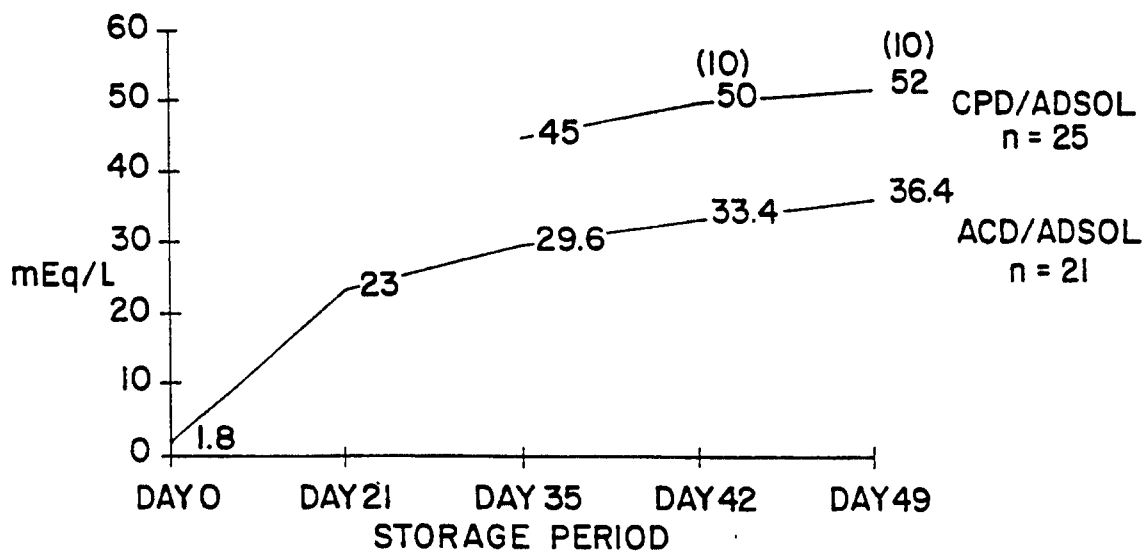
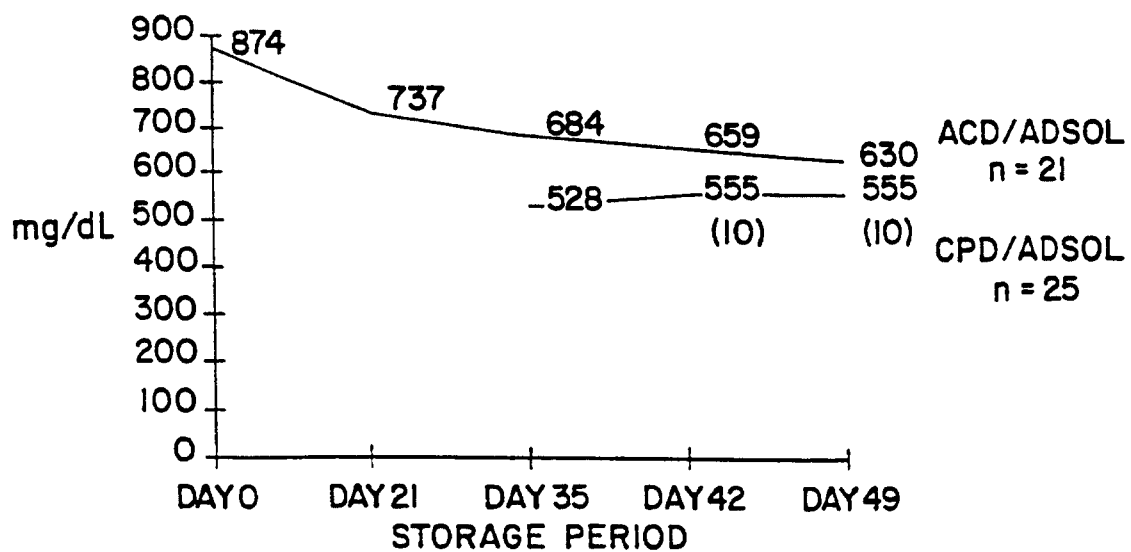


FIG. 7

ACD-A/ADSOL RBC UNITS
IN VITRO EVALUATION
GLUCOSE



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FIG. 8

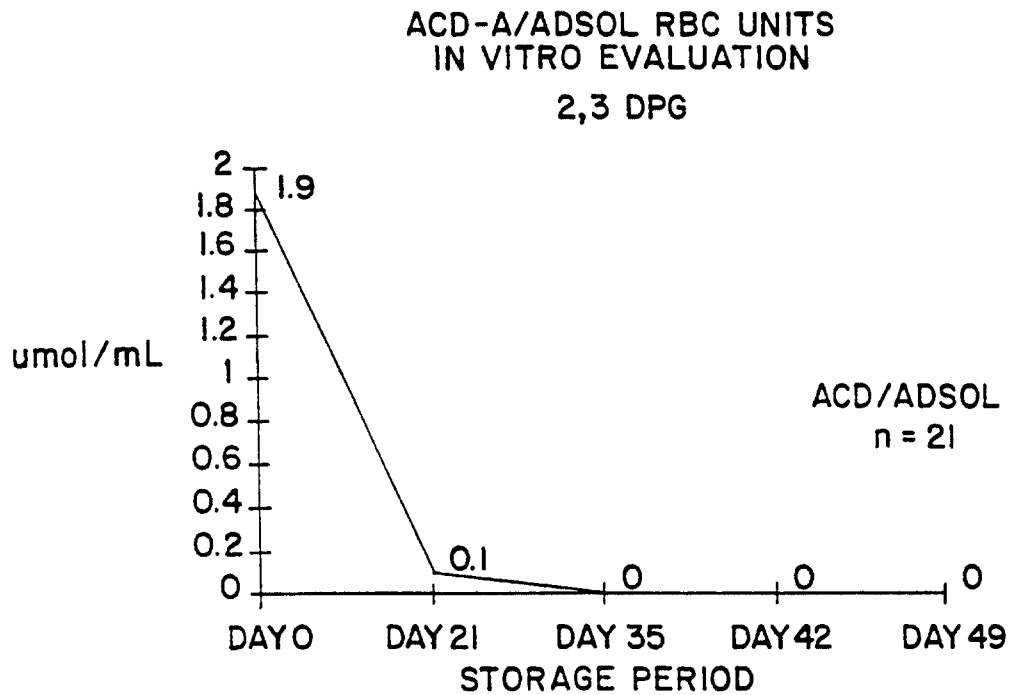
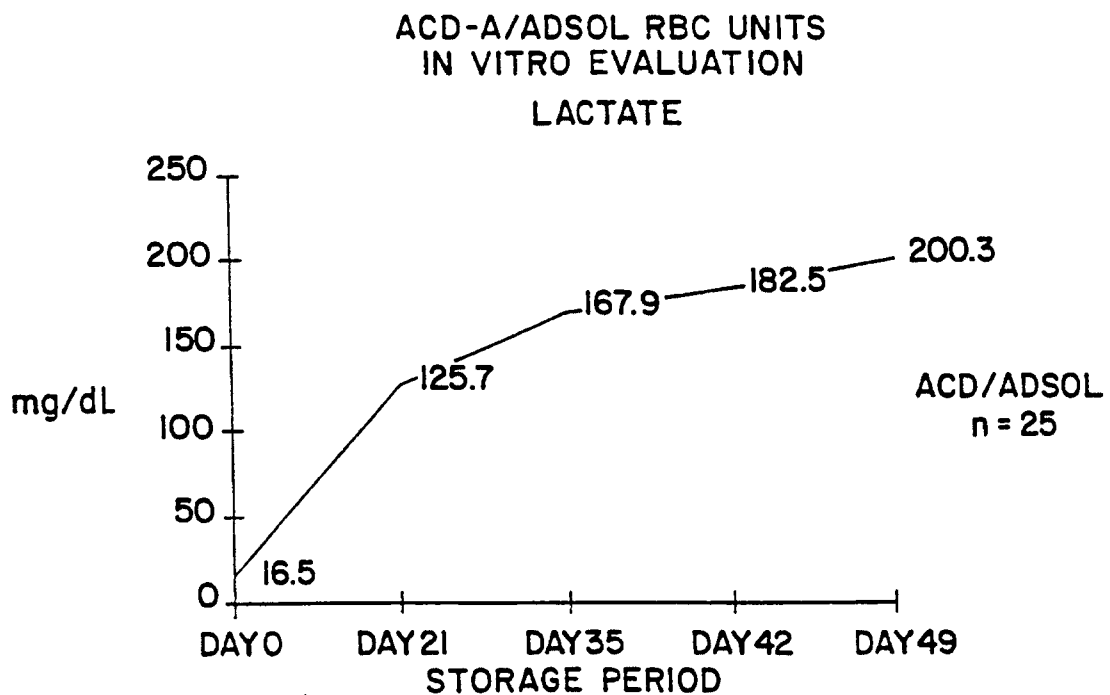


FIG. 9



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FIG. 10

ACD-A/ADSOL RBC UNITS
IN VITRO EVALUATION
HEMOLYSIS