

July 28, 1959

D. BELLAMY, JR

2,896,619

APPARATUS FOR HANDLING FLUID BLOOD

Filed Oct. 14, 1954

3 Sheets-Sheet 1

Fig. 1

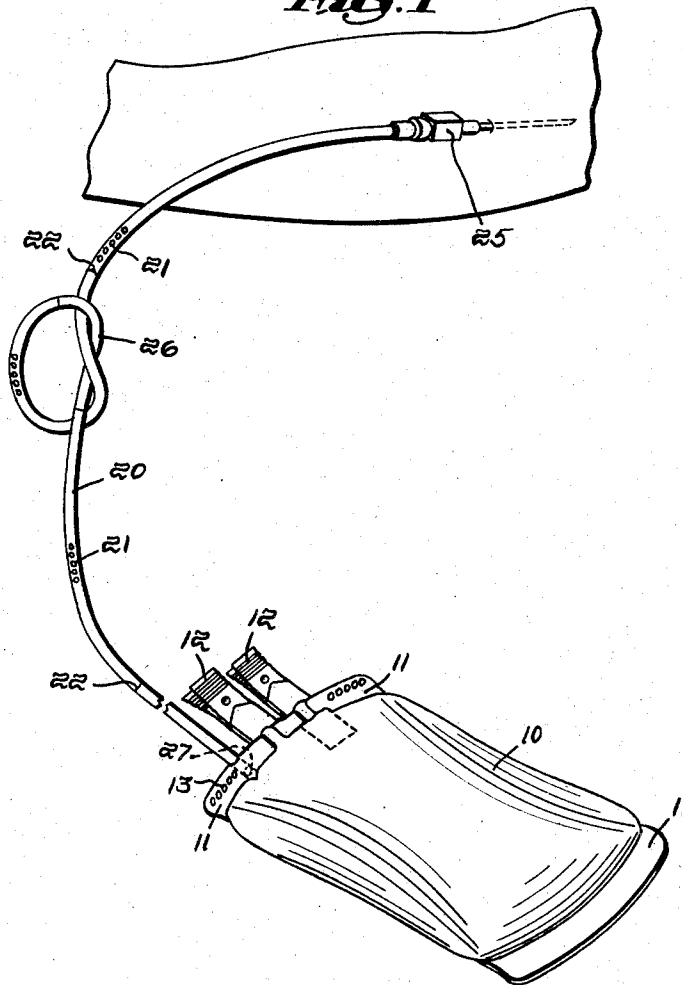
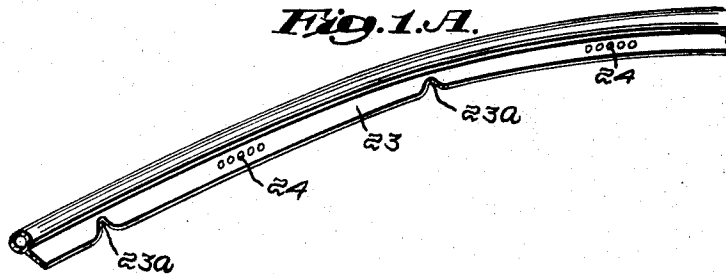


Fig. 1.A.



Inventor:
David Bellamy Jr.,
by *Emery, Booth, Townsend*
Miller & Whitmer, Attys

July 28, 1959

D. BELLAMY, JR

2,896,619

APPARATUS FOR HANDLING FLUID BLOOD

Filed Oct. 14, 1954

3 Sheets-Sheet 2

Fig. 2.

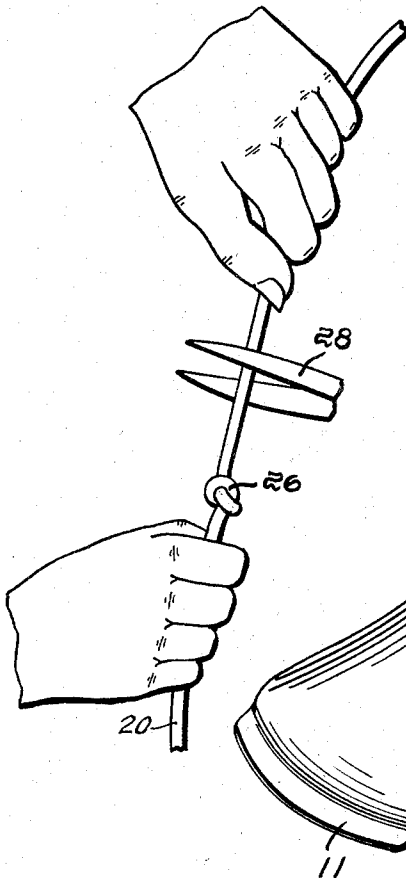


Fig. 3.

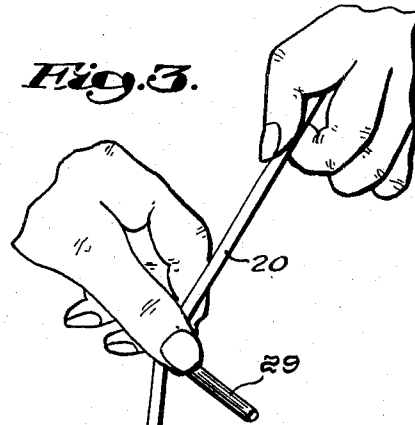
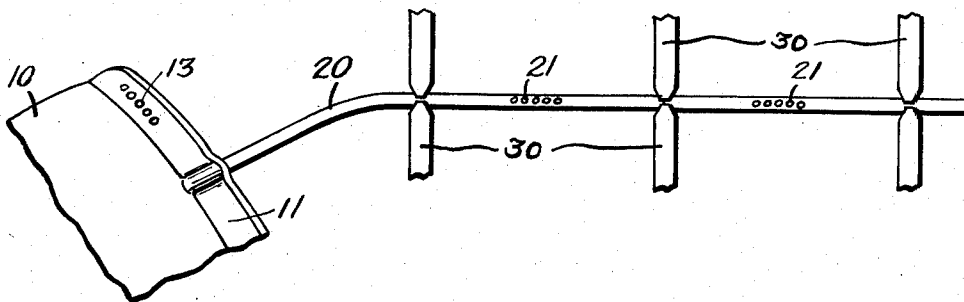


Fig. 4.



Inventor:
David Bellamy Jr.
by Emory, Booth, Townsend
Miller & Weidner **Attys**

July 28, 1959

D. BELLAMY, JR

2,896,619

APPARATUS FOR HANDLING FLUID BLOOD

Filed Oct. 14, 1954

3 Sheets-Sheet 3

Fig. 6.

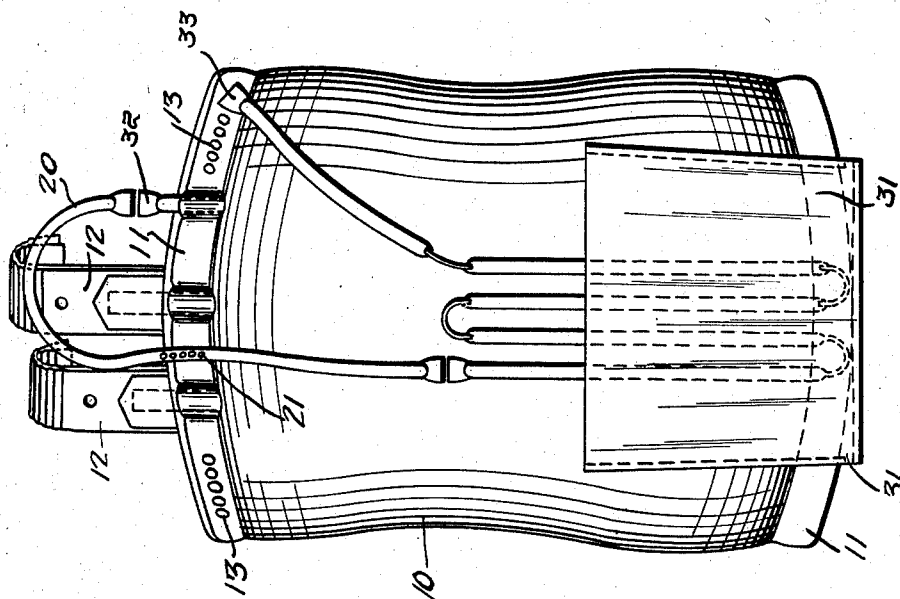


Fig. 5.

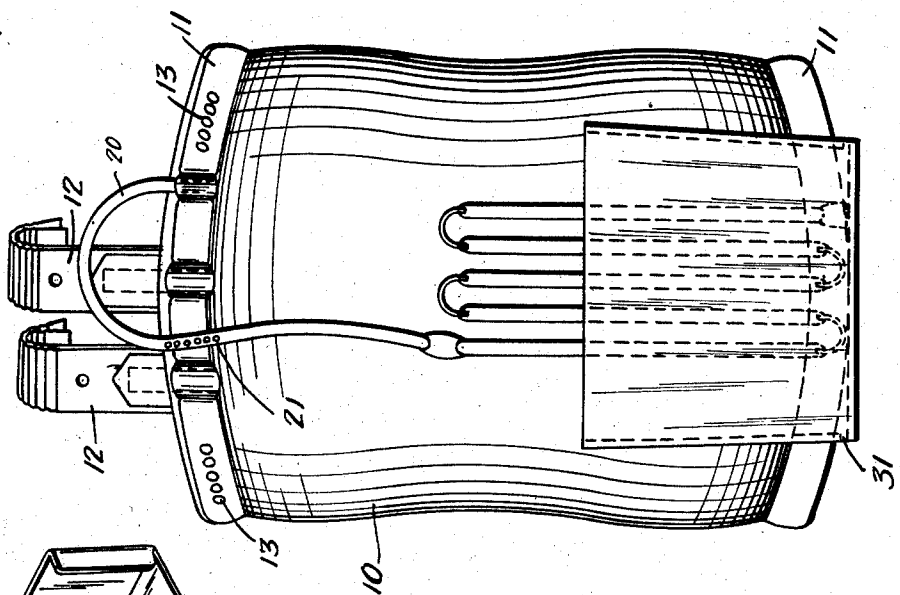
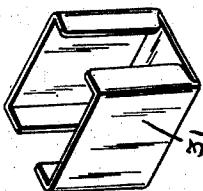


Fig. 2.



Inventor:
David Bellamy Jr.
by **Emory Booth, Townsend**
Miller & Heidner Attys

1

2

2,896,619

APPARATUS FOR HANDLING FLUID BLOOD

David Bellamy, Jr., Framingham, Mass., assignor to Fenwal Laboratories, Inc., Ashland, Mass., a corporation of Massachusetts

Application October 14, 1954, Serial No. 462,239

5 Claims. (Cl. 128—214)

This application relates generally to medical fluid handling and more particularly to blood collecting and storing method and apparatus. The invention aims generally to improve and adapt medical fluid-handling equipment and techniques for obtaining blood aliquots for sampling, typing, cross-matching and culturing purposes. The further object of the invention is the provision of novel, integral, segmented collection tube means and method for obtaining the aliquots as sterile-sealed, positive-identified parts or portions of and directly incident to the collection of a blood donation. The invention contemplates more particularly the isolating of donation portions or aliquots in a sterile, air-free system and with positive certainty of identification and relation.

In the conventional blood banking practice, the blood is collected into a bottle which is closed or stoppered, tagged or labeled, and then placed in refrigerated storage. After the bottle is filled a small amount of blood may be flowed or collected in pilot tubes as samples for typing, cross-matching and serology purposes. The pilot tubes are then physically coupled or joined to the bottle in order to tie or relate the samples to the particular donation. The tubes may be supported, for example, in or from a card or the like hung from the bottle and employed also as the blood labeling or identifying means.

It will be obvious that the prior practice as above described is subject to the possibility or hazard of confusion, loss or destruction of the blood identifying means. This is, of course, a serious risk; the misapplication of the blood may have fatal consequences. It will be understood further that under disaster conditions it would be impractical to use the separate pilot tubes for typing and cross-matching samples, in view of the human factor—the liability for error—and of the time consumed in making the necessary tests.

My present invention provides generally novel means and method whereby blood samples for serology, typing, cross-matching and the like purposes are obtained without any possibility of confusion or mistake in identity of the samples. It provides more particularly a technique and apparatus providing sterile, air-free collection and sure, lasting marking or labeling of the samples. The invention will be better understood from a consideration of the following specification, taken in conjunction with the accompanying drawing in which:

Fig. 1 shows the blood collecting and storing apparatus of the invention as applied to a donor;

Fig. 1A shows an alternative embodiment of the donor tube;

Figs. 2 and 3 illustrate the manipulation of the donor tube in the collection of the blood according to the invention;

Fig. 4 illustrates the treating of the donor tube to provide the sealed aliquots;

Fig. 5 illustrates the storage of the blood in the invention apparatus;

Fig. 6 illustrates the obtaining of a culture sample in accordance with the invention, and

Fig. 7 is a perspective view of an exemplary device for supporting the invention apparatus, as shown also in Figs. 5 and 6.

Referring now more particularly to Fig. 1, the blood-handling apparatus of the invention is there shown to comprise a flexible, collapsible storage container, bag or pack 10 and integral donor or collection tube 20. The unitary blood-collecting and storing container and tube 10, 20 are fashioned of an inert, non-toxic, glossy, hemo-repellent plastic, such as polyvinyl chloride, of medical quality. The blood bag 10 is shown more particularly to comprise a sleeve which is flatted and sealed at its ends 11, 11 and provided at one or both of said ends with one or more inlet-outlet port and port closing and sealing assemblies 12, 12 of the type shown and described in the co-pending application of David Bellamy, Jr., Serial No. 412,549, filed February 25, 1954. The medical fluid-handling means of Fig. 1 thus comprises a transparent and lightweight but durable apparatus providing a unitary, sterile-sealed, air-free, hemo-repellent system for the collection and storage of blood.

In accordance with the invention the bag 10 and tube 20 are novelly formed and conditioned to provide self-contained, positive-identified, blood aliquots for sampling, typing, cross-matching and culturing purposes. More particularly, the bag and tube are physically modified in manufacture or subsequently to provide suitable indicia or marking by which the aliquots and the donation may be positively and lastingly identified, and correctly related or matched one with the other and with the donor. The marking may take various forms, as lettering, numbering, or other symbols of which various combinations and arrangements may be used; and it may be affixed in various ways, as by raising, recessing, or impressing in the bag and tube surfaces. More particularly, it may be printed or imprinted on the invention apparatus, and is preferably hot-stamped, so that an indication will remain notwithstanding the lettering or numbering might become rubbed off. The marking may, of course, be affixed anywhere on the bag. It is herein shown by way of example as applied to a bag end seal as at 13, Fig. 1. In accordance with the invention the blood in the bag 10 and tube 20 is identified and related by a series of markings or numbers 21 identical with the serial number 13 on the bag 10 and applied to the tube 20 at uniform intervals.

The novel forming of the invention apparatus further comprises the physical demarking of the collection or donor tube at said intervals, and conditioning the tube for segmenting as a plurality of individually sealed sample quantities or aliquots. This is accomplished in the Fig. 1 embodiment by marking or raising or impressing suitable indicia, as for example a scribe 22 on the tube wall at such segmenting or aliquot-providing intervals, which may be three inches, more or less.

It will be understood that blood collecting and storing apparatus may be variously formed or modified in accordance with the invention to permit or promote the marking for identification. Referring now more particularly to Fig. 1A, an alternative embodiment of the flexible, plastic collecting or donor tube is therein shown to have an integral axial flange or rib 23, of a proportion and providing a flatted surface to which the desired indicia 24 may conveniently be applied. The rib 23 is seen to be interrupted or recessed as at 23a at the desired points or intervals of segment demarcation.

The unitary, hemo-repellent, air-free, blood collecting and storing apparatus of Fig. 1 is novelly utilized in accordance with the invention method for the provision of positive-identified, sterile-sealed blood aliquots for sampling, typing, cross-matching or culturing purposes. The blood is first collected in medically acceptable manner through and into a sterile tube 20 and bag 10.

Phlebotomy is accomplished more particularly by applying the coupled needle 25 to a prepared site, as shown, and flowing the blood with the tube 20 tied near the needle in a loose overhand knot 26. The blood is generally collected into an anti-coagulant solution with which the apparatus has been charged or partially filled after collapsing. A hemo-repellent bead 27 lodged, as shown, in the tube 20 at the entrance to the bag 10 prevents influx of air into the system at the instant of needle exposure, and is milked or squeezed down into the bag to permit the desired blood flow. Thorough mixing of the blood and anti-coagulant is accomplished during collection by manually working the bag, as by pressing or squeezing the bottom, or by turning the bag end to end.

When the blood bag is full, the integral donor tube 20 is sealed off as by pulling tight the knot 26, Fig. 2, before the needle 25 is removed from the vein, preserving the hermetic seal and preventing the contamination of the collected blood. The seal is effective when no blood can be seen in the turns of the knot.

The blood storing, sealing, and preserving assembly 10, 20 is next disengaged from the donor by severing the tube 20 above the knot 26 with a suitable cutting tool 28, Fig. 2, the tubing being pinched above the point of severance to prevent spillage of the blood.

When the collecting and storing apparatus of the invention is filled with blood as above described, the bag 10 will be observed to be firm but not taut, and the tube 20 to be charged with blood which is uncitrated. It will be appreciated that the typing and cross-matching samples are generally required to be uncitrated. Accordingly, the blood in the donor tube 20 is next citrated or made non-clotting by stripping the tube, and more particularly by grasping the tube at the free end and drawing it between the thumb and the back of a scissors, forceps handle, or other smooth instrument 29, Fig. 3, toward the bag 10 and under sufficient pressure to collapse the tube and force the blood ahead of the same and into the bag 10. When the tube 20 has thus been entirely freed of the unmixed blood, it is released and the citrated blood is allowed to flow back into and fill the same.

It should here be noted that samples of clotted blood may be desired, in which case the blood is not required to be stripped from the tube 20 and mixed with the anti-coagulant as just described.

Further in accordance with the invention, the sterile, air-free, hemo-repellent system in which the blood is collected as described is ordered as a unitary donation and an integral set of individually sealed samples. More particularly, the tube 20 is divided or sealed in any convenient manner at or opposite the segmenting or aliquot defining markings 22, 23a. The plastic tube 20 may for example be inserted in an apparatus providing one or more sets of clamping jaws such as schematically shown at 30, Fig. 4, and dielectrically heat sealed. It will be appreciated that by the invention means and method as thus far described, blood samples are obtained and preserved in an aseptic manner and with accuracy and permanency of identification and relation. More particularly, the aliquots are collected in sterile-sealed tube segments which are physically joined to each other and to the donation of which they are a sample, and are provided with an integral, lasting marking or indicia by which they may be positively, permanently and reliably identified and related.

The blood bag 10 and integral segmented donor tube 20 are conveniently and compactly stored as for blood banking purposes. The packs are mounted or suspended in a suitable support and refrigerated, preferably at $5^{\circ} \pm 1^{\circ}$ C. The support may be any convenient rack or the like, herein shown as a clip 31, Figs. 5, 6, 7, whereby the bag and tube may be ordered in desired vertical position, the tube segments herein being conveniently re-

versely folded and held between the side of the clip 31 and the wall of the bag 10.

When it is desired to use one of the donor tube segments for typing, cross-matching or serology purposes, the outer sedimented segment is merely separated or severed at the seal through which it is joined to the one adjacent, and opened at one or the other of its ends, according as it may be desired to use the cells or the plasma. The mere squeezing of the tubing will express one or more drops as desired.

A further feature of the invention is the provision for obtaining a sample for culture of the pack without entering the bag 10, and thus without danger of contaminating the stored blood. Blood supplies will be understood to be tested or sampled usually after two or three days of refrigerated storage. This is accomplished under the invention by stripping and refilling the innermost donor tube segment, which will have been originally citrated and left unsealed at its inner end. The culture aliquot is then sealed by closing the tube inner end, as shown at 32, Fig. 6. The free end of the segmented donor tube having been joined to the bag as at 33, Fig. 6, the innermost or culture aliquot housing tube segment is then separated from the bag, as by cutting at the seal 32, and similarly from the remainder of the tube 20.

From the foregoing it will be appreciated that this invention novelly provides for obtaining blood samples by sterile, air-free means and method, and for positively and accurately identifying and relating the samples. The invention has been shown further to provide improved integral, segmented, indicia-bearing blood collecting and storing apparatus, the apparatus incorporating more particularly and in one embodiment a novel rib-bearing donor tube. The invention will be understood to provide still further and novelly for the obtaining of a culture sample without exposure of the stored blood.

It will be understood that my invention, either as to means or method, is not limited to the exemplary embodiments or steps herein illustrated or described, and I set forth its scope in my following claims.

I claim:

1. Blood-handling apparatus comprising blood storing and preserving means, a collecting tube associated with said means, a segmented axial rib on said tube, and like indicia on said means and on the segments of said rib.

2. Blood-handling apparatus comprising a flexible, collapsible blood bag, a donor tube integral and communicating with the bag and formed with an integral, axial, segmented rib, and like blood-identifying indicia on the bag and on the segments of said rib.

3. Blood-handling apparatus comprising a flexible, collapsible blood bag, a collecting tube communicating with the bag and adapted to be closed off remote therefrom, said tube having a longitudinal rib interrupted to define tube segments, and duplicate blood-typing indicia on the bag and tube segments.

4. A blood handling apparatus comprising a flexible collapsible bag, the bag of a size to store a blood donation, a flexible collapsible collecting tube having one end opening through and integrally sealed into a wall of the bag, the tube of a length to present in line a plurality of individual sealed segments to store a like number of blood aliquots for sampling, typing, cross-matching, and culturing purposes, transverse demarcations integrally raised at segmenting intervals on the tube wall, said demarcations conditioning the tube for dividing by closing and sealing thereat into said individual aliquot-storing segments, and like symbol formations integrally raised on an external wall area of the bag and each segment, said formations positively and lastingly identifying and matching said aliquots with said donation.

5. A blood handling apparatus comprising a flexible collapsible bag, the bag of a size to store a blood donation, a flexible collapsible collecting tube having one end

5

opening through and integrally sealed into a wall of the bag, the tube of a length to present in line a plurality of individual sealed segments to store a like number of blood aliquots for sampling, typing, cross-matching, and culturing purposes, transverse demarcations integrally impressed at segmenting intervals on the tube wall, said demarcations conditioning the tube for dividing by closing and sealing thereat into said individual aliquot-storing segments, and like symbol formations integrally impressed on an external wall area of the bag and each segment, said formations positively and lastingly identifying and matching said aliquots with said donation.

References Cited in the file of this patent

UNITED STATES PATENTS

2,700,973 Ju ----- Feb. 1, 1955

15

2,702,034
2,780,225

5

88,138
105,038
189,127

10

6

Walter ----- Feb. 15, 1955
Barr et al. ----- Feb. 5, 1957

FOREIGN PATENTS

Germany ----- Aug. 21, 1896
Great Britain ----- Mar. 29, 1917
Great Britain ----- May 3, 1923

OTHER REFERENCES

Walter et al.: Surgery Gynecology and Obstetrics, vol. 94, No. 6, June 1952, pp. 687-692. (Available in Science Library.)

Alve Co. Catalogue, received Nov. 3, 1942, p. 22. (Copy in Div. 55.)