

[54] **BLOOD COLLECTING AND PROCESSING MEANS**

3,579,306 5/1971 Crane 356/36

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[57] **ABSTRACT**

[52] U.S. Cl. **356/39; 356/246; 128/2 F**

[51] Int. Cl. **G01n 33/16**

[58] Field of Search 356/246, 36, 39-42; 23/253, 259, 292

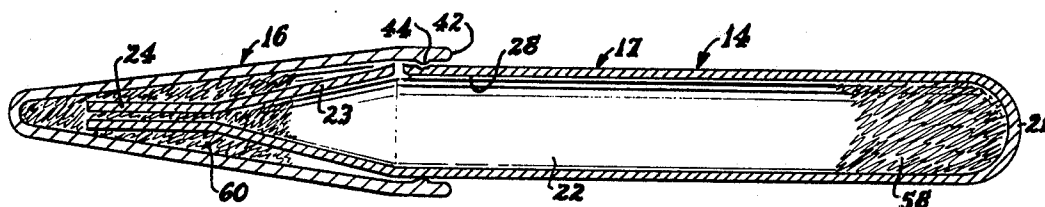
Blood collecting and processing container and a storage cap member assembly, by which blood specimens may be collected, stored, transferred, processed, and the blood constituents analyzed, without transfer to other containers, and providing other advantages of convenience, savings of time and effort, and attaining other advantages while avoiding certain disadvantages of prior art equipment for this use.

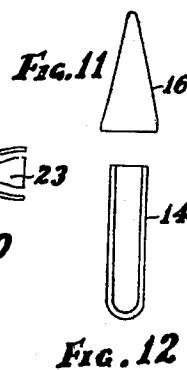
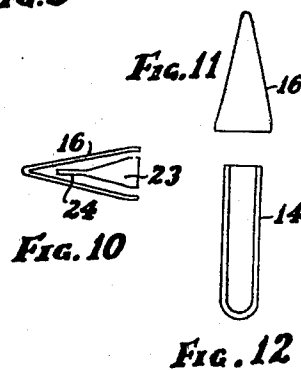
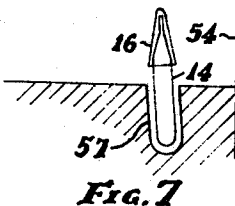
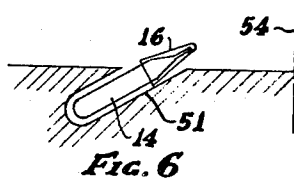
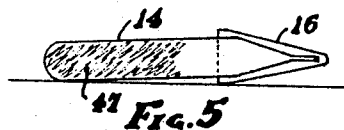
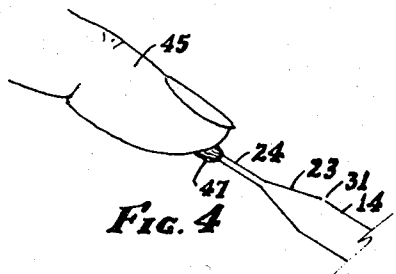
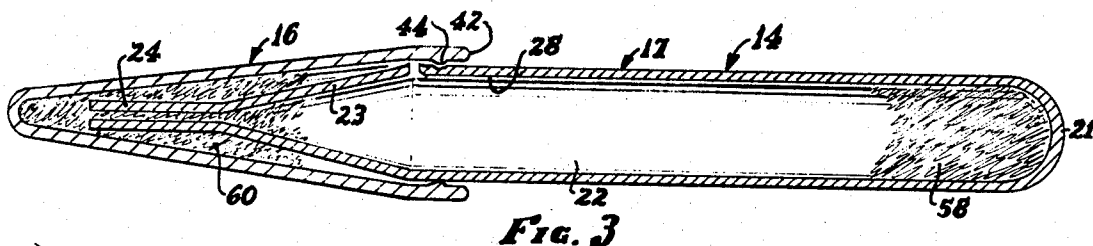
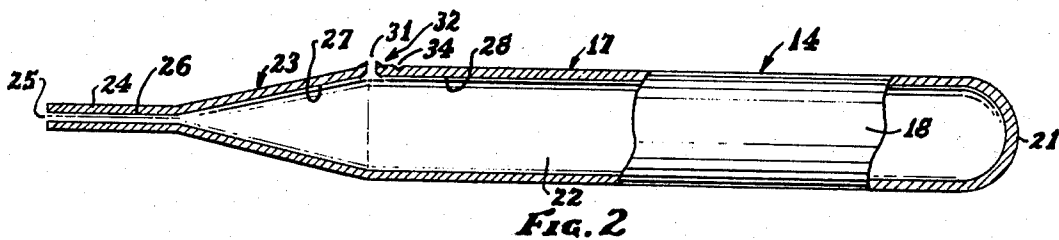
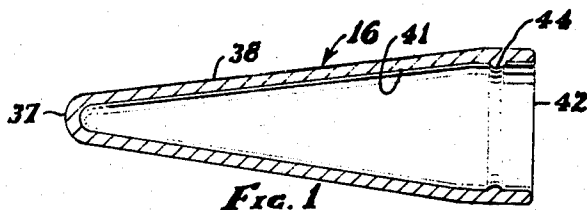
[56] **References Cited**

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8 Claims, 12 Drawing Figures





BLOOD COLLECTING AND PROCESSING MEANS

This invention relates to a novel and advantageous integrated container assembly for a procedural system for the collecting and processing of blood samples, as for clinical laboratory or specimen use in the running of various physiological tests.

The desirability of blood analysis itself is of course well known; and the present invention relates to advantageous equipment for that purpose, providing advantages of equipment and operation as detailed herein, and provides for an effective capillary-type blood-drawing technique which is less objectionable to many patients than the technique required by other equipment, because it requires only a "finger pricking" type of blood-drawing, and because its efficiency requires less blood to be drawn than with other equipment.

Also, the concepts provide that the two basic components themselves, that is, the blood-drawing capillary member and the closure cap therefor, are themselves used as the containers for either the whole blood or the separated blood constituents to be assayed, avoiding many disadvantages incidental to a transferring to other containers, subsequent labelling or re-labelling steps, etc.

Advantages of the inventive concepts thus provide, basically, a handy and convenient and effective container means for the withdrawing blood from a patient, and storing, processing, and assaying of blood and its constituents, with advantages of high sterility, low blood loss, etc., as detailed herein.

More particularly, the present invention provides an integrated container and a storage cap assembly which provides the several advantages: (a) ease of blood-drawing; (b) maintenance of sterilized conditions against outside contamination of the specimen during at least substantially all stages of the processing and assay procedures, including steps of handling, centrifuging to achieve desired separation of blood constituents, and assaying; (c) the achieving of a more thorough mixing than certain other equipment systems; (d) minimizing of spillage or other loss of contents, thus making for effectiveness of the test procedure and minimizing bother and discomfort to the patient; (e) permitting an adequate supply of blood for a thorough test to be less than required by other assay equipment; (f) provision of proper ratio of blood to chemical additive or reagent which is to react with the specimen to provide the assay measurement; (g) provision of a self-contained nature of the equipment for the collection, transfer, storage, and testing of blood and blood-constituent specimens; (h) a reliability of labelling by permitting a unitary nature of labelling even of separable-components and by permitting a single labelling to serve throughout most or all of any single overall assay, thus saving not only time and bother and expense but avoiding mix-ups and the consequent uncertainty or danger inherent in a mixed or false analysis; (i) provides an economical mechanical means of preventing contamination from all stages from the blood-collection to the final analysis or assay steps; and (j) provides containers for the assay specimens for either manual or automated techniques and equipment, without transferring to other containers, re-labelling, etc.

It is not here asserted that no single type of prior art is unable to achieve or approach the fullness of certain ones of these many advantages. However, none of the prior art devices or procedures is able to achieve all of

these advantages. That is, the various prior art equipment has been able to attain certain of these advantages only at the expense of other of these advantages; for the prior art, although it has attempted and used several different types of equipment for this purpose, has not had the particular combination of concepts here shown to be successful in attaining all of these desirable advantages.

For example, even a simple capillary tube device is certainly able to withdraw blood samples from a patient, and by merely a finger-pricking technique; but it provides no adequate concept or means for mixing or storing a specimen during centrifuging, and no means for adequate labelling, prevention of air locks in the capillary bore, etc.; and much of the collected blood sample is in effect wasted by adherence to the wall of the elongated small bore device.

The avoidance of blood spillage or loss by whatever defect of prior art devices is seen to be particularly significant not only because of the fact of discomfort of the patient in permitting the collection of the specimen, but because, even with the optimum collecting and handling equipment, the overall specimen quantity is going to be inherently reduced to about 50% due to the spinning of the blood specimen to the serum sample to be tested, in the widely-used assays which test blood constituents rather than the whole blood itself.

Thus, with merely the capillary tubes of the prior art, five or so of them would usually be needed and filled, although sometimes even more are needed; and even if the technician draws blood to fill many of them, they do not provide the advantages of this invention.

Probably most blood-sampling now being done is by some sort of vacuum or syringe-like method, involving a needle puncture with a vacuum or syringe technique. Although this has some advantage over the capillary tubes just mentioned, it has disadvantages such as an objectionable needle, requires extra labelling, requires more skill of the technician than finger puncture methods, etc.; these and other disadvantages of that type equipment being overcome or minimized by the device of the present invention.

Other type prior art devices range from aspiration operated (suction) devices, simple drip tubes, etc.; but without belaboring this description to particularize all of them and their various disadvantages, it should suffice for this introductory background summarization to point out that although the prior art has attempted several different types of equipment for this purpose, none provides the handiness and sterility and foolproofness and effectiveness of the present invention as set forth in the listing of advantages presented above.

Thus, although the present invention will be seen to be simple and relatively economical, formed desirably of merely two co-operating components, the invention nevertheless provides very useful and desirable equipment for the vital purpose of blood assay or analysis, providing a combination of advantages by concepts significantly different from prior art devices for blood collecting, handling, and processing.

The above description is of a generalized and introductory nature, to introductorily set forth the advantageous present invention against the background of the disadvantageous prior art. The present inventive concepts are more fully set forth in the following description of an illustrative embodiment, taken in conjunction with the accompanying somewhat schematic drawings, in which:

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FIG. 1 is an axial cross-sectional view of a dualfunction body member which serves as an end cap and a storage container;

FIG. 2 is an axial cross-sectional view of a body member which serves as a collection and storage tube or container;

FIG. 3 is an axial cross-sectional view of an assembly of the cap container of FIG. 1 and the collection tube of FIG. 2, the contents being shown after a centrifugation or other step which dis-associates, and separates from one another, the blood cells (at the closed or right-hand end of the collection tube), and the blood serum or plasma (in the cap member at the left or open end of the collection tube);

FIG. 4 is a diagrammatic view of a procedural step of a technician drawing a blood sample from the finger of a patient;

FIG. 5 is a diagrammatic side view of an assembly as in FIG. 3 lying on a supporting surface during an intermediate step, and with the assembly of container and storage cap intact, minimizing any chance of contamination;

FIGS. 6 and 7, respectively, are schematic views illustrating the assembly of FIGS. 3 and 5 in a centrifuge having, respectively, a tube-supporting hole or receiver at different slopes;

FIGS. 8 and 9 illustrate diagrammatically manual procedural steps in sequence, in which in FIG. 8 the technician is manually squeezing the end cap member, and in which in FIG. 9 he has relaxed that squeezing force;

FIG. 10 is a schematic view of the end cap member of FIG. 1 still in assembly with the adjacent portion of the container member, but with the container member having been broken into parts and with the closed (right-hand end of FIGS. 2 and 3) removed; and

FIGS. 11 and 12 are schematic views, respectively, of the end cap member and of the portion of the container member which had been broken off or away and thus not shown in FIG. 10.

As shown in the drawings, the invention provides a novel blood collecting and processing means providing advantages detailed herein. The components are merely two co-operating pieces or members, yet they provide the stated advantages. That is, the invention provides an integrated and co-operative novel combination of a hollow collecting tube 14 and a hollow storage cap member 16; and, by particular concepts, these two members achieve specific functions, advantageously, over equipment of other blood-collecting procedures.

Those particularized concepts are now set forth in detail, as shown in the illustrative embodiment which forms the invention disclosure of the accompanying drawings.

The collecting tube 14 is shown to have a main storage or body portion 17 in the general form of a "test tube," that is, a hollow cylindrical vial or ampule having a cylindrical side wall 18 and having one end (right in FIGS. 2 and 3) closed by an end wall 21, which define a chamber 22.

The open (left, FIGS. 2 and 3) end of the collection tube 14 is shown formed outwardly and axially (leftwardly) of the tube's side walls 18 of body portion 17 with conical tapering walls 23 which lead at their open (left) end to an outwardly extending capillary tube 24 open at its outer (left) end 25.

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The bore 26 of the capillary tube 24, inwardly of open end 25, opens smoothly to the inner wall 27 of the conical portion 23 which, in turn, open smoothly to the inner walls 28 of the collector tube side walls 18 of body portion 17, all that being one continuous chamber; and the bore or chamber 22 of substantially larger size than the bore 26 of capillary tube 24.

A small vent hole 31 is shown provided in the side wall-portion 32 of the container 14, adjacent the intersection of the conical neck 23 and the cylindrical body side-wall 18, as is shown best in FIGS. 2 and 3; and, as shown in those views, the sidewall 18 is provided with a score mark 34 in the region of side wall portion 32 adjacent the vent hole 31 for an optional breakage purpose mentioned below.

Continuing further with the description of the components themselves, the storage cap member 16 shown is formed of somewhat flexible material into a hollow tube having a closed end wall 37 from which extend side walls 38, having an inner face or wall 41 leading to an open cap end 42. Adjacent that open end 42, the inner cap face 41 is shown provided with an inwardly-projecting integral circumferential ring 44; and the relative diameter dimensions of the inner face of ring 44 and the outer diameter of portion 32 of side wall 18 of tube body portion 17, adjacent the intersection of the tube's side wall 18 and neck wall 23, are such that the former is slightly the lesser, providing that some resilient deformation must be imparted to achieve the engagement of the cap side wall 41 and ring 44 with the tube side wall portions 32 of tube wall 17.

Accordingly, the ring 44 serves as a sealing ring; and when the open end 42 of the cap 16 is pushed over outer components (capillary tube 24, neck 23, and body wallportion 32) of the collection tube 14, an effectively tight seal is achieved.

Both the container 14 and the storage cap 16 are desirably transparent.

The use of these components, that is, the collection tube 14 and the storage cap member 16, will now be detailed, illustrating the advantageous utility of the invention in the technical procedure of blood-sample collecting and subsequent processing.

FIG. 4 illustrates an initial step in which the open end 25 of the capillary tube 24 on collector tube 14 is held adjacent a patient's finger 45, which has been previously cut or lanced by an auxiliary lance or skin-puncturing tool. The bore 26 is small enough that capillary attraction draws blood 47 from the patient's finger; and, an advantage of the invention is that the conservation of blood-sample by the device components is that a relatively small amount of patient's blood need be drawn. There is relatively little serum loss due to blood adhering to the walls of the capillary tube bore 26.

The small hole 31 permits or provides the necessary venting, and the technician who is drawing the blood holds the capillary end 25 adjacent or against the patient's finger to get whatever amount of blood is desired, it running through the entirety of capillary bore 26 and into the tube neck 23 and body portion 17. (Those walls may, if desired, be pretreated or coated with suitable anti-coagulant. Moreover, mixing beads and/or density-gradient beads may be used for achieving a layering effect.)

Just as soon as the blood specimen or sample 47 is drawn, the technician withdraws the tube 14, and more specifically its capillary end 25 from the patient's finger and immediately applies the cap 16 over the capillary

tube 24 and neck 23 and onto the adjacent cylindrical sidewall portion 32 of tube body 17, sealing it and its contents as aforesaid.

In that sealed condition, as shown by FIG. 3, it will be noted that the sealing ring 44 is past the tube-vent 31, thus that vent hole 31 as well as the end hole 25 are operatively covered and sealed against outside contaminants.

Thus sealed, the technician transports the assembly of container body 14 and cap member 16 to the location of subsequent processing, without contamination.

The inventive concepts provide the provisions of any of a variety of subsequent processing steps or procedures, manual or automated or both, with advantages of handling, storing and other processing procedures, as illustratively set forth herein.

For example, it may be desired to be able to identify both tube 14 and cap 16 components of an assembly thereof during future process steps and even after subsequent disassembly or other disassociation thereof, as illustrated below. In such event, a two-part identification label having correspondingly identified portions continuously extending onto both the tube 14 and cap 16 may be applied to such an assembly while it is united, as in FIG. 5. (Alternatively, if the process was not going to utilize the cap 16 after some preliminary collecting and storage step, merely the tube 14 could have been pre-labelled.) Regardless of the stage or type of labelling, a label once affixed can stay with the tube 14 or cap 16 throughout subsequent procedural steps of the test, minimizing error of identification.

In a typical testing or assay procedure, the assembly (FIG. 5) of tube 14 and cap 16, with the whole blood 47 of the collected sample in the tube 14, would be placed by the technician in a selected support of an available centrifuge. For example, by supporting the assembly 14-16 in a support 51 such that the tube 14 is outermost from the centrifuge axis 54 (FIG. 6), or, alternatively or subsequently, in a centrifuge support 57 in which the cap 16 is outermost from the centrifuge axis, a selectively chosen placement of the blood cells 58 in contrast to the serum or plasma may be attained. But regardless, the sealed relationship of tube 14 and cap 16 retains the non-contaminated nature of the collected blood sample throughout and subsequent to the centrifuge step, a step desired to separate the blood constituents for assay purpose.

The storage cap 16 and its resilient flexibility are shown in FIGS. 8 and 9 as manually operable to get the separated blood serum or plasma 60 into the hollow bore 41 of the cap 16, when it is desired to utilize the cap 16 itself as a container thereof. This is easily achieved by an initial squeeze being applied to the cap sidewall 38 followed by a relaxing or releasing thereof.

The cap 16 is of an elongated nature, providing sufficient storage capacity of its bore 41 such that the cap 16 may be used as the serum or plasma container for subsequent assay procedures without changing the contents to another container. Thus the cap 16 serves the dual purpose of a cover cap and a storage container.

Either method of separation of blood serum or plasma from the blood cells may be achieved very quickly; and this is of great advantage, for otherwise the separation might not be fully maintained, and, for example, the amount of glucose in the serum would be lessened by the action of the cells metabolizing some of the glucose.

Further flexibility or optional character of use which is provided by the tube 14 and cap 16 is that the tube 14 itself may be utilized as the assay container, by conveniently breaking off the portion (capillary tube 24 and neck 23) outwardly of the tube-portion 32 by breaking the tube 14 at the score notch 34.

It is thus seen that blood collecting and assaying means according to the inventive concepts provides a desired and advantageous device, achieving the several advantages of convenience, effectiveness, and other advantages as mentioned in this specification, achieving the operativity advantages therein mentioned.

Accordingly, it will thus be seen from the foregoing description of the invention according to this illustrative embodiment, considered with the accompanying drawings, that the present invention provides new and useful blooddrawing and assaying means, having desired advantages and characteristics, and accomplishing its intended objects, including those hereinbefore pointed out and others which are inherent in the invention.

Modifications and variations may be effected without departing from the scope of the novel concepts of the invention; accordingly, the invention is not limited to the specific embodiment or form or arrangement of parts herein described or shown.

What is claimed is:

1. Blood collecting and processing means comprising:

a container member having a storage chamber and an open ended capillary tube; the bore of said storage chamber being of substantially greater size than the bore of said capillary tube;

said container means including a tapered hollow neck portion extending outwardly of said storage chamber and connecting said capillary tube to said storage chamber;

said container member being closed at the end thereof remote from said capillary tube;

means on said container member for providing easy separation of said capillary tube and neck portion from said storage chamber;

opening means in the side wall of said container member for forming a vent;

said opening means being located in said container member at a point farther remote from said closed end than is said separation means.

2. The invention as set forth in claim 2 in a combination in which the vent opening means is provided in the portion thereof adjacent the intersection of the storage chamber and the neck portion.

3. The invention as set forth in claim 2, and including an elongated cap member having sidewalls and a closed end;

said cap member being configured to provide an effective sealing engagement with said container member in covering relation with the open end of said capillary tube and also the said vent opening of said container member, whereby said cap member provides a storage container and a cover cap for said container member.

4. The invention as set forth in claim 1 in a combination in which the container separation means comprises a score providing for conveniently breaking said capillary tube and neck portion from said storage chamber.

5. The invention as set forth in claim 4, and including an elongated cap member having sidewalls and a closed end;

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said cap member being configured to provide an effective sealing engagement with said container member in covering relation with the open end of said capillary tube and also the said vent opening of said container member, whereby said cap member provides a storage container and a cover cap for said container member.

6. The invention as set forth in claim 1, and including an elongated cap member having sidewalls and a closed end;

said cap member being configured to provide an effective sealing engagement with said container member in covering relation with the open end of said capillary tube and also the said vent opening of said container member, whereby said cap member provides a storage container and a cover cap for said container member.

7. Blood collecting and processing means comprising:

a container member having a storage chamber and an open ended capillary tube; the bore of said storage chamber being of substantially greater size than the bore of said capillary tube;

said container member including a tapered hollow neck portion extending outwardly of said storage

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chamber and connecting said capillary tube to said storage chamber;

said container member being closed at the end thereof remote from said capillary tube;

there being also provided an elongated cap member having sidewalls and a closed end;

said cap member being configured to provide an effective sealing engagement with said container member in covering relation with the open end of said capillary tube and also the said vent opening of said container member, whereby said cap member provides a storage container and a cover cap for said container member;

in a combination in which said cap member is formed to include resiliently flexible material by which the cap member, by a sequence of force and a releasing thereof, provides an operative drawing of material outwardly of said neck and capillary tube and into the storage chamber of the cap member.

8. The invention as set forth in claim 7 in a combination in which the inner wall of the cap member adjacent its open end is provided with an inwardly-projecting circumferentially-extending ring which sealingly engages said container.

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UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,926,521 Dated December 16, 1975

Inventor(s) Byron E. Ginzel

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

Column 6, line 34, "means" should read -- member --.

Column 6, line 48, "2" should read -- 1 --.

Signed and Sealed this

Nineteenth Day of April 1977

[SEAL]

Attest:

RUTH C. MASON
Attesting Officer

C. MARSHALL DANN
Commissioner of Patents and Trademarks