

[54] **COMBINATION BLOOD SAMPLING
VACUUM SYRINGE CENTRIFUGE
CONTAINER AND SPECIMEN CUP**

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[56] **References Cited**

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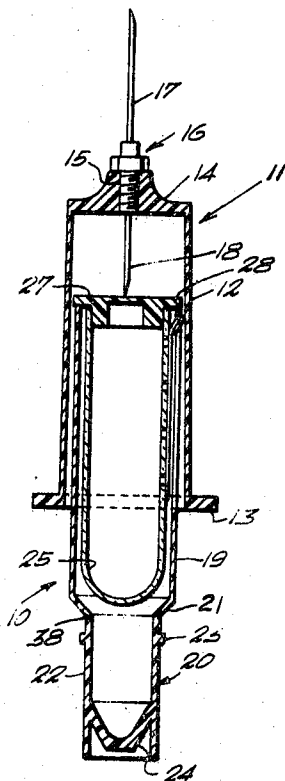
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[57] **ABSTRACT**

An elongated, unitary, blood sampling vacuum syringe, centrifuge container and specimen cup, for use with an ordinary tubular needle holder is described. The device includes an evacuated blood sample centrifuge container having a piercable diaphragm cap and being supported in spaced relation within one end of a housing member, the opposite end of which housing member is in the form of a separable specimen cup. After obtaining a blood sample in the usual fashion with use of an ordinary tubular needle holder, the device is centrifuged as a unit to separate the blood serum into the upper end of the centrifuge container. Vertically spaced openings provided in an upper side wall portion the centrifuge container and normally sealed off by means of a pressure-sensitive tear strip, are thereafter sequentially opened by manual removal of the tear strip to permit gravitation of the centrifuged blood serum down into the specimen cup, after which said serum-filled specimen cup can be separated for use in analysis.

7 Claims, 5 Drawing Figures



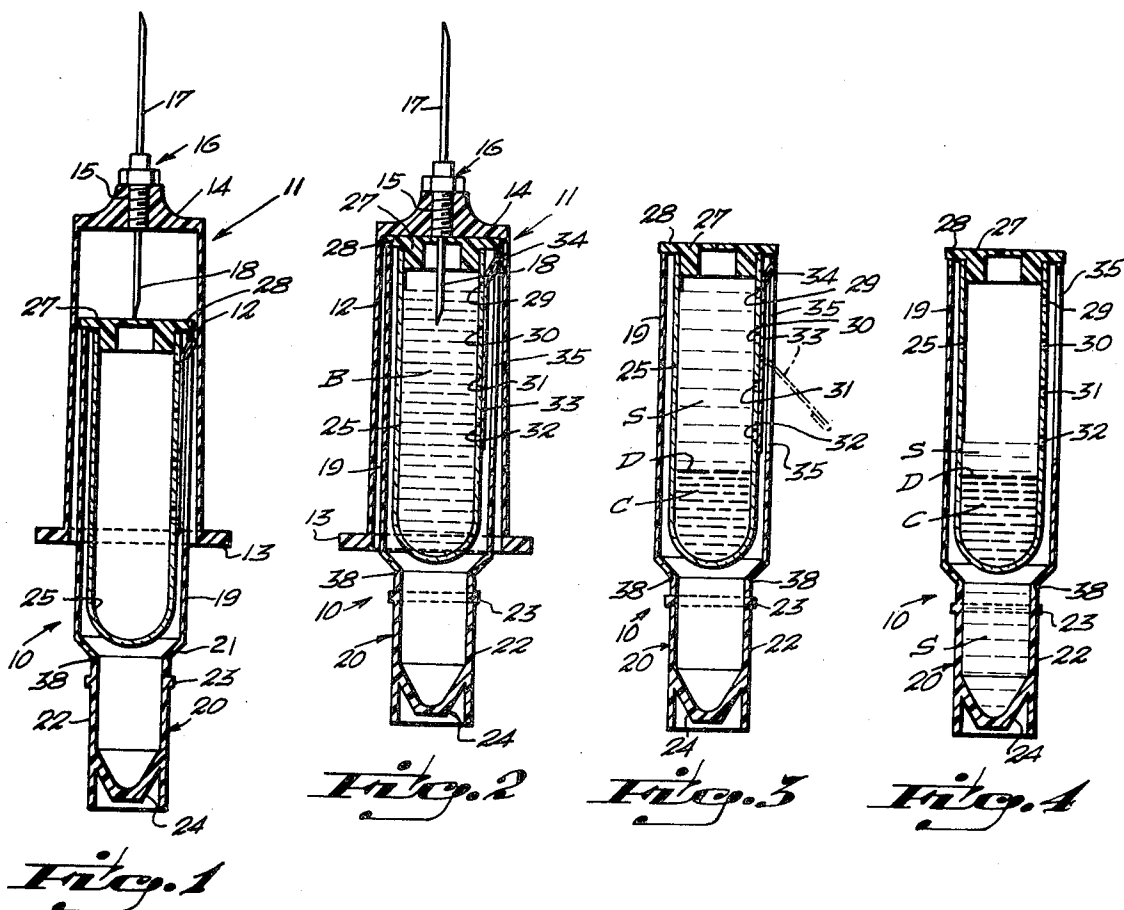


Fig. 2

Fig. 3

Fig. 4

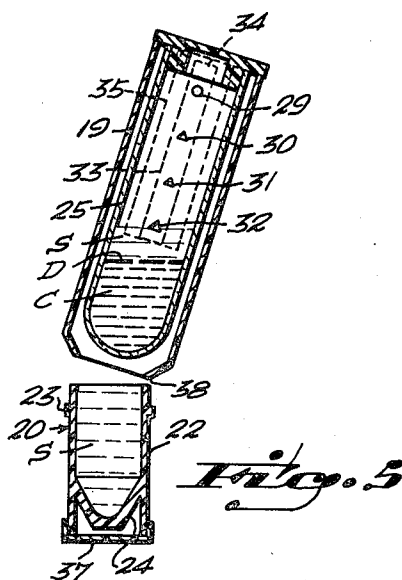


Fig. 5

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COMBINATION BLOOD SAMPLING VACUUM SYRINGE CENTRIFUGE CONTAINER AND SPECIMEN CUP

This invention relates to medical syringes and is directed particularly to improved vacuum syringe devices combining a blood sample centrifuge container and a serum receiving specimen cup in a unitary structure.

In blood analysis for medical diagnosis or research it is frequently necessary to separate the blood serum from the cellular blood matter for independent chemical analysis. This is usually done by centrifuging a blood sample or specimen taken from the patient or donor with the use of an ordinary pistoncontrolled or vacuum actuated medical syringe. Because freshly drawn blood has a tendency to change in character due to enzymatic action, it is essential that separation and removal of the blood serum be effected as soon as possible after collection to insure valid analysis. It is also important that the procedure undertaken in the centrifuging of the blood sample and removal of the serum specimen be such as to minimize any possibility of contamination. Since, in medical diagnosis, a substantial portion of the blood samples for analysis are taken in private clinics or physician's treatment facilities, and since such facilities vary over a wide range as to laboratory capability, availability and competence of technical personnel, the preparation for analysis of blood sample serum is not infrequently of less than optimum quality. It should also be noted that samples obtained in this manner are frequently shipped over long distances before being subjected to chemical analysis. If the cellular blood mass is not properly and totally separated from the serum, a faulty result will be obtained by the receiving laboratory. In such cases the specimen collection agency, and not the receiving laboratory, is at fault. The medical literature as well as the publications in the field of clinical chemistry have, in the past, expressed great concern over these deficiencies and stated that the following determinations are particularly affected. Thus, it is well known that a number of changes ensue when whole blood is allowed to stand without removal of the cellular fraction. The glucose concentration diminishes rapidly, electrolytes migrate across cell membranes to establish new equilibria; phosphatases cleave intracellular organic phosphate esters, increasing the inorganic phosphorous level, and cellular enzymes may leak out causing false serum levels. When hemolysis occurs these effects become exaggerated and, in addition, complications develop with the technical aspects of certain test procedures.

The removal of the centrifuged blood serum from the blood sample for analysis was heretofore accomplished either by manually pouring the serum from the top of the container or tube into the serum specimen cup, or by vacuum withdrawal by mouth with the use of a pipette tube lowered into the blood serum for subsequent release into separate specimen cups. It can readily be understood that either of these two commonly used serum removal methods are subject to sources of contamination. These methods of separation, moreover, are readily subject to contamination of the serum by migrating blood cells unless great care is taken in the separating process. For this reason, several spinnings in a centrifuge are generally necessary in

order to obtain a serum sample which lends itself to reliable and valid chemical analysis. This process of separation takes much of the technician's time and, in addition, necessitates the uneconomic use of glassware.

It is, accordingly, the principal object of this invention to provide a new and improved blood sampling vacuum syringe, centrifuge container and specimen cup that obviates the above described deficiencies of blood serum specimen preparation devices and procedures heretofore devised.

A more particular object of the invention is to provide a combination blood sampling vacuum syringe, centrifuge container and specimen cup of the character above described that will be of unitary structure including an enclosed blood sample centrifuge container and specimen cup for use with an ordinary tubular needle holder for vacuum drawing a blood sample into the centrifuge container, and which includes means for gravitationally removing a predetermined quantity of subsequently centrifuged blood serum in said container into the specimen cup for analysis upon the manual manipulation of the device in a simple and non-critical manner.

Still another object of the invention is to provide a vacuum syringe device of the above nature wherein the specimen cup forms a separable lower end portion of a housing member in the upper end of which the centrifuge container is disposed in coaxially-spaced relation, the centrifuge container being provided, in an upper side wall portion thereof, with vertically-spaced openings normally sealed off by means of a pressure sensitive tear strip adapted to be removed for sequentially unsealing said openings to permit gravitation of centrifuge blood serum down into the specimen cup.

And yet another object of the invention is to provide a vacuum syringe device in the above nature including means for readily transversely severing or breaking away the specimen cup end portion of the device housing to permit easy removal of the filled serum specimen cup for laboratory analysis. Quicker and more efficient separation of serum from cells is thus achieved with less labor and a higher degree of accuracy than heretofore possible.

Yet another object of the invention is to provide a vacuum syringe device of the above nature which will be of such simple and inexpensive construction as to be readily disposable or expendable after use, while at the same time providing under a clean environment a capped blood serum containing specimen cup for interchangeable use in automatic multiple test laboratory analyzers.

Other objects, features and advantages of the invention will be apparent from the following description when read with reference to the accompanying drawings. In the drawings, wherein like reference numerals denote corresponding parts throughout the several views:

FIG. 1 is a longitudinal cross-sectional view of a vacuum syringe device embodying the invention shown partially inserted in a tubular holder preparatory to the taking of a blood sample;

FIG. 2 is a vertical cross-sectional view similar to that of FIG. 1, but showing the vacuum syringe device fully depressed within the needle holder after a blood sample has been taken, and further showing the blood sam-

ple which has been withdrawn into the centrifuge chamber of the device;

FIG. 3 is a vertical cross-sectional view of the vacuum syringe device of FIG. 2, shown separately after centrifuging of the blood sample;

FIG. 4 is a longitudinal cross-sectional view similar to that of FIG. 3, but showing removal of the associated vent opening tear strip for gravity feed of the centrifuged blood serum into the specimen cup; and

FIG. 5 is a vertical cross-sectional view similar to that of FIG. 4, but showing how the upper portion of the cylindrical housing of the device can be broken away to separate the serum containing specimen cup.

Referring now in detail to the drawings, reference numeral 10 designates, generally, a combination blood sampling vacuum syringe, centrifuge container and specimen cup embodying the invention, the same being shown, in FIGS. 1 and 2, being used in association with a hollow needle holder 11. The needle holder 11 is of standard known construction, and may be of the type commonly used with ordinary vacuum syringes. As such, it comprises a tubular body portion 12 the lower end of which, as illustrated, is open to receive an evacuated blood collection tube and provided with an outwardly-extending peripheral flange 13 for manual grip and control. The opposite end of the tubular body portion 12 is closed with a bottom wall portion 14 provided with an internally-threaded axial opening 15 into which a disposable hollow needle assembly or cannula 16 may be removably fitted in known fashion. The needle assembly 16 comprises an outwardly-extending end 17 for insertion into the patient's vein upon the taking of a blood sample, and an inwardly-extending end 18 for piercing the centrifuge chamber of the vacuum syringe device, as is hereinbelow more particularly described.

The vacuum syringe device 10 embodying the invention comprises an elongated cylindrical housing member 19 coaxially jointed at its lower end with a reduced-diameter specimen cup 20 through a short, frusto-conical connector wall portion 21. The cylindrical housing member 19, connector wall portion 21 and specimen cup 20 are preferably integrally formed of a tough, transparent synthetic plastic material. The specimen cup 20 comprises a cylindrical outer wall 22 having an outwardly-extending, peripheral flange 23 near its upper or open end, and a substantially frusto-conical bottom wall 24 at its closed or lower end, as illustrated in the drawings. The specimen cup 20 is of a shape typical of those used in automatic blood chemistry analyzers, and therefore constitutes no part of the present invention in and of itself.

Coaxially disposed within the cylindrical housing member 19 is a cylindrical blood sample collecting tube 25 having a rounded bottom wall and being generally in the form of an ordinary test tube. The upper or open end of the collecting tube 25 is hermetically sealed with a diaphragm plug cap member 27 having a radially-extending peripheral upper end flange portion 28 an underside portion of which seats in abutting engagement against the upper edge or rim of said collecting tube. An outer marginal portion of the underside of the diaphragm plug cap flange portion 28 seats against the upper open edge of the cylindrical housing member 19 and is affixed thereto in any con-

venient manner, such as by the use of a suitable adhesive. Alternatively, an annular groove could be formed in the underside of the flange portion 28 to frictionally retain the upper end of the collecting tube in place. The outer diameter of the blood sample collecting tube 25 is of somewhat lesser diameter than the internal diameter of the cylindrical housing member 19 within which it is coaxially disposed to provide spacing therebetween for the purpose hereinafter appearing.

As is best illustrated in FIG. 5, the blood sample collecting tube 25 is provided in its side wall with a plurality of substantially equidistantly-spaced, vertically-aligned through openings 29, 30, 31, and 32. The uppermost opening 29 is located directly below the inner end of the diaphragm plug cap member 27, whereas the lowermost opening 32 is located a short distance below the longitudinal center of the collection tube 25. The upper through opening 29 may be round, while the remaining opening 30, 31 and 32 are preferably triangular with upwardly directed apices, for the purpose hereinafter appearing. Prior to use of the vacuum syringe device, the openings 29 through 32 are sealed off from the outside by means of a separable elongated seal strip 33 the upper end of which terminates in loose pull-tab portion 34. The seal strip 33 is retained in place in sealing engagement against the outside of the blood sample collection tube 25 and in sealing engagement with respect to the openings 29 through 32 by use, preferably, of a pressure-sensitive adhesive. To insure that the separable seal strip 33 be impervious to air leakage, it is preferably fabricated of aluminum foil, or the like dense, film-like material strong enough to permit pull away separation from the collecting tube 25 while at the same time being flexible or bendable enough to peel away for successive venting of the openings 29, 30, 31 and 32 one at a time, in a controlled manner. An elongated access opening 35, (see FIG. 5), is provided in the side wall of the cylindrical housing member 19, in register with the separable seal strip 33 of the collecting tube 35, to permit manual pulling away of said seal strip in the manner and for the purpose hereinbelow more particularly described.

Considering now the operation of the vacuum syringe device 10, the same will first be fitted loosely in a typical needle holder 11 as described above preparatory to insertion of the outwardly-extending end portion 17 of the needle assembly 16 in the distended vein of the patient giving the blood sample. As illustrated in FIG. 2, immediately upon insertion of the needle, the blood sample collecting tube 25 will become filled with blood, indicated at B in FIG. 2, drawn inwardly under the influence of the contained vacuum. The vacuum syringe device 10 will thereupon be withdrawn from the needle holder 11, and the diaphragm plug cap 37, being of a resilient material such as natural or synthetic rubber, will seal off the contained blood upon separation from the inwardly-extending needle portion 18. The blood containing vacuum syringe device 10 is now ready for centrifuging to separate the blood cell mass from the serum, such separation being illustrated in FIG. 3 by the cells C shown in the lower end portion of the collecting tube 25 and the blood serum, designated S, at the upper end portion of said collecting tube. As illustrated by reference character D in FIGS. 3, 4 and 5, after centrifuging there will be a rather sharp plane of

demarcation between the dense blood cell mass C and the now separated blood serum S.

The method and means by which the separated blood serum S in the collecting tube 25 is transferred to the specimen cup 20 will now be described with reference to FIGS. 3 and 4. As illustrated in FIG. 3, the vacuum syringe device 10 will be supported in an upright position and the loose pull-tab 34 at the upper end of the separable seal strip 33 will be grasped between thumb and forefinger and pulled upon gently so as first to open the top vent opening 29 of the collecting tube 25 and thereafter successively open the remaining serum drain openings 30, 31 and 32. As illustrated in FIG. 4, upon the above described openings 29, 30, 31 and 32, being opened, the centrifuged serum S will flow successively through the openings 30, 31 and 32 to trickle down into the specimen cup 20. In this connection, it is to be noted that the lowermost flow opening 32 will be well above the plane of separation D in any centrifuge blood sample to obviate any possibility of serum contamination by blood cells. It is also to be noted that if smaller quantities of centrifuged blood serum are required, the opening of only the first or the first two of the serum flow openings 30 and 31 will provide for such lesser amounts in the specimen cup 20.

As is best illustrated in FIG. 5, means is provided for quickly and easily separating the serum containing specimen cup 20 from the used vacuum syringe device. To this end, the zone of juncture between the upper end of the specimen cup 20 and the frusto-conical connector wall portion 21 is provided with an annular groove 38 defining a weakened wall zone permitting lateral breakaway upon the imposition of a slightly manually applied twisting and/or bending force upon said specimen tube with respect to the elongated cylindrical housing member 19.

While we have illustrated and described herein only one form in which our invention can conveniently be embodied in practice, it is to be understood that this form is given by way of example only and not in a limiting sense. The invention, in brief, comprises all the embodiments and modifications coming within the scope and spirit of the following claims.

What we claim as new and desire to secure by Letters

Patent is:

1. For use with a conventional tubular blood sampling needle holder, a combination holder, centrifuge container and specimen cup comprising, in combination, an elongated tubular housing member, and evacuated blood sample collecting tube, means supporting said collecting tube in spaced relation within one end of said housing member, the outer end of said collecting tube being fitted with a needle pierceable closure cap member, the other end of said housing member being closed, and normally-closed, manually-controlled aperture means in a side-wall portion of the outer end portion of said collecting tube for draining centrifuged blood serum from said collecting tube into the closed end of said housing member and means on said housing member allowing access to said manually-controlled aperture means.

2. The invention as defined in claim 1, wherein said other end of said housing member is in the form of a specimen cup having an open end facing the inner end of said collecting tube in longitudinally-space relation, and means for separating said specimen cup from the remainder of said tubular housing member.

3. The invention as defined in claim 2, wherein said aperture means comprises a plurality of vertically aligned openings in said collecting tube, and a pressure-sensitive tear strip normally adhered to said collecting tube in sealing relation with respect to said plurality of openings.

4. The invention as defined in claim 3, wherein said means allowing access comprises an elongated opening in said tubular housing member permitting access for manual tearing away of said tear strip.

5. The invention as defined in claim 4, wherein a lowermost sub-plurality of openings of said plurality of openings are of triangular shape.

6. The invention as defined in claim 5, wherein said tubular housing member is integrally formed of a transparent synthetic plastic material.

7. The invention as defined in claim 6, wherein said means for separating comprises a peripheral weakened wall zone at the upper end of said specimen cup to permit manual breakaway thereof after being supplied with a serum specimen.

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