

[54] **BLOOD SERUM COLLECTION TUBE AND METHOD**

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[22] Filed: **Aug. 7, 1972**

[21] Appl. No.: **278,227**

Related U.S. Application Data

[63] Continuation of Ser. No. 148,872, June 1, 1971, abandoned, which is a continuation-in-part of Ser. No. 854,982, Sept. 3, 1969, Pat. No. 3,586,064.

[52] **U.S. Cl.**..... **141/1**, 23/258.5, 23/259, 73/425.4, 141/327, 141/330, 210/540, 233/26

[51] **Int. Cl.**..... **B011 11/00**

[58] **Field of Search**..... 23/258.5, 259, 292; 73/425.4 R, 425.4 P; 128/218 M, 220, 272; 141/1, 2, 18, 22, 113, 250, 3.8, 325, 327, 329, 330; 210/540; 222/320; 233/26

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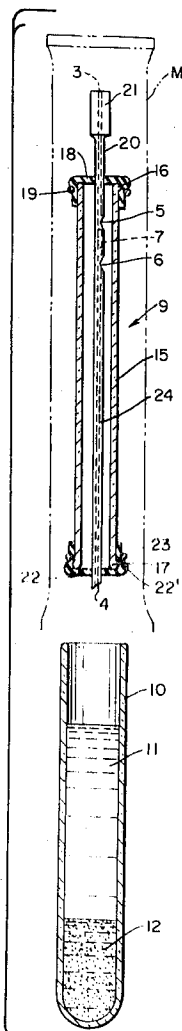
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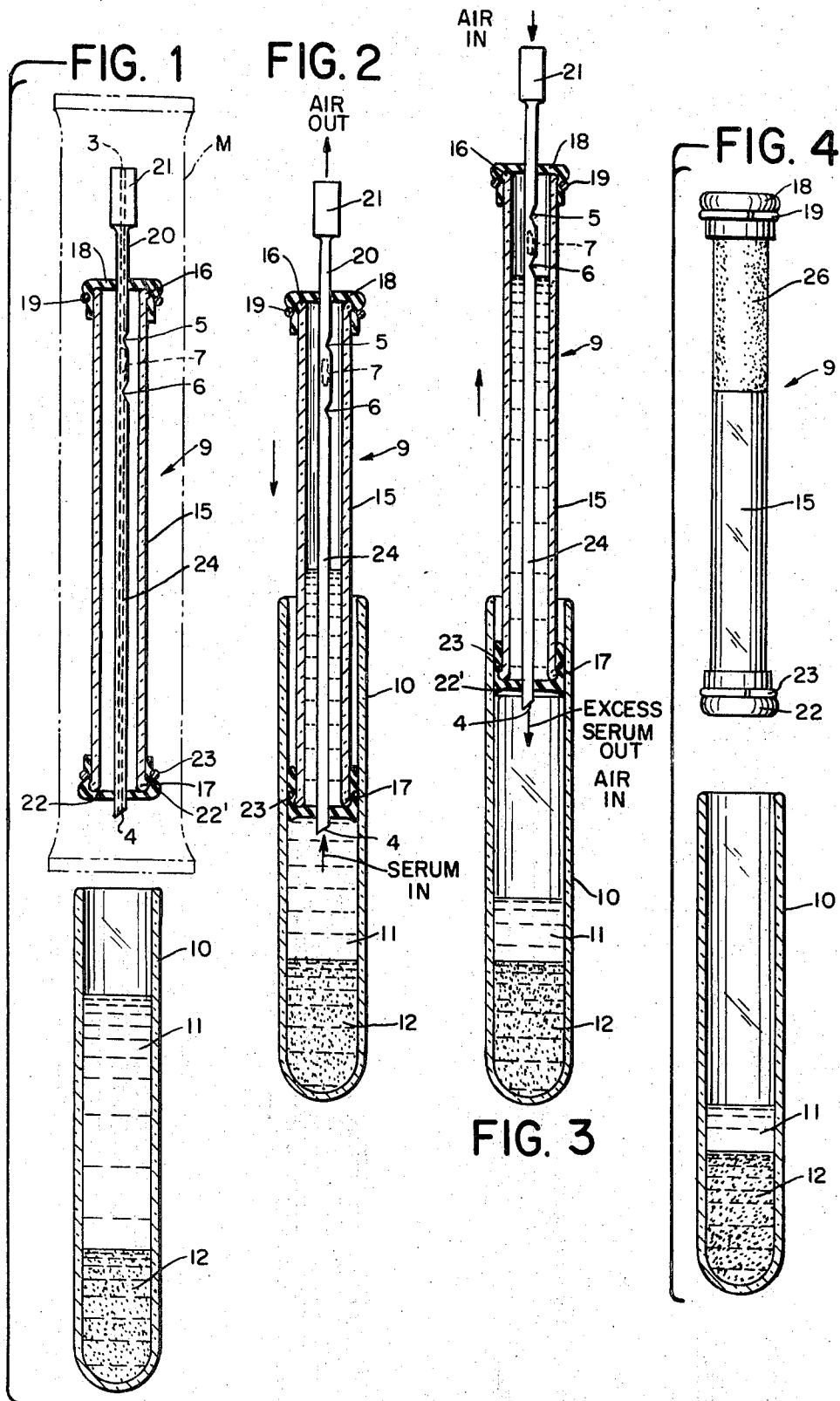
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ABSTRACT

The disclosure relates to an improved apparatus and an improved method for removing serum from the uppermost portions of a specimen tube of centrifuged blood, in which the blood serum is disposed in a liquid pool above settled-out cellular solid materials. More particularly, the invention is directed to an easily handleable, readily available, collection tube closed at both ends by "one shot" valve structures comprising self-sealing elastomeric elements pierced by a special one-piece hollow needle. Additionally, the lower elastomeric element includes an annular piston-like member which is adapted to engage the inner walls of the specimen tube to pump serum therefrom.

4 Claims, 4 Drawing Figures





BLOOD SERUM COLLECTION TUBE AND METHOD

CROSS REFERENCE TO RELATED APPLICATION

This is a continuation, of Ser. No. 148,872, filed June 1, 1971, now abandoned, which application is a continuation-in-part of copending application Ser. No. 854,982, filed Sept. 3, 1969, now U.S. Pat. No. 3,586,064.

BACKGROUND OF THE INVENTION

In the examination of blood samples in pathological laboratories, it is often necessary or desirable to examine blood serum after it has been separated from the suspended cellular material, and for this purpose it is customary to subject the specimen tubes, in which the blood samples are delivered to the laboratory, to centrifuging action to cause the settling of the cells to the bottom of the specimen tube. Since many laboratories process large numbers of blood samples every day, facility of handling specimens, accuracy of labeling of specimen, and the ease of drawing off and retaining serum specimens are important to successful and safe operation.

Quite often, laboratory workers have experienced difficulty in efficiently removing the clear serum from centrifuged blood specimen tube, without disturbing the settled out solid material. Additionally, there have been problems in maintaining with accuracy the identity of the source (patient) from which the serum was originally obtained throughout its travels from hospital to laboratory, etc.

Heretofore, the blood serum has been removed from the specimen tube, after the blood has been centrifuged to separate the serum from the clotted cells by drawing the serum off with a conventional syringe; by pouring the serum off through tilting of the specimen tube; by use of pipettes and the like; and or by use of plunger-like apparatus of the type disclosed in U.S. Pat. No. 3,355,098. The method and apparatus disclosed in our U.S. Pat. No. 3,586,064 represents an improvement over earlier work in this field, however, certain difficulties arose in the creation of vacuum forces which tended to separate the lower elastomeric element from the collection tube. In addition, two separate needles were required to be handled.

SUMMARY OF THE PRESENT INVENTION

The shortcomings of the prior art devices have been overcome by the method and apparatus of the present invention, which provide a new and improved method of collecting serum and a new and improved self-sealing, serum collection tube, which tube may be directly filled from centrifuged specimen tubes with collected blood serum. The new serum collection tube basically comprises a hollow cylinder whose ends are closed off by novel "one shot" valve structures, and whose lower end also carries a piston member. The valves themselves comprise self-sealing elastomeric end caps pierced by portions of an elongated one-piece removable hollow needle.

For a more complete understanding of the present invention and its attendant advantages, reference should be made to the following detailed description taken in conjunction with the accompanying drawings.

DESCRIPTION OF THE DRAWINGS

FIG. 1 is a cross-sectional view of the apparatus of the present invention with the elongated special needle in place and with the upper and lower "one shot" valves opened in preparation for collecting a serum sample from a specimen tube;

FIG. 2 is a cross-sectional view of the apparatus of FIG. 1 during the downward stroke of the collection tube during serum collection;

FIG. 3 is a cross-sectional view of the apparatus of the invention during the upward stroke of the collection tube and after serum collection;

FIG. 4 is a front elevational view of the collection tube with both ends self-sealed by withdrawal of the needle after removal of the collection tube from the specimen tube.

DETAILED DESCRIPTION OF THE INVENTION

Referring now to FIG. 1, there is shown a conventional centrifuged specimen collection tube 10 having a pool of serum 11 disposed above settled-out, clotted cellular material 12. The specimen tube advantageously may be of the so-called "Vacutainer" type sold by Becton-Dickinson Co. for use by medical personnel in withdrawing blood samples from patients for subsequent laboratory analysis. Such specimen tubes typically have inside diameters of approximately $\frac{5}{8}$ inch. Their lengths generally will vary depending upon the size of the volumetric samples of blood required. Once drawn, blood samples are centrifuged in accordance with well known procedures to separate within the specimen tube 10 the serum 11 and cellular matter 12, as shown in FIG. 1.

The new and improved serum collection apparatus 9 of the present invention, includes an elongated cylindrical, clear collection tube 15 which is open at its upper and lower ends. Integral annular beads or flanges 16, 17 are formed at the upper and lower ends respectively of the collection tube 15, as shown. Of course, the collection tubes may take other forms, such as tubes with enlarged upper cylindrical cross-sections and reduced lower cylindrical cross-sections, in order that they may be compatible with special test and analyzing apparatus.

In accordance with the principles of the invention, the upper end of the collection tube 15 is closed off by a generally cup-shaped, elastomeric, self-sealing element 18 which is mechanically connected to the collection tube by a friction fit, threads, or by other suitable means such as the illustrated resilient, split snap ring 19 (FIG. 1) to secure the element 18 of the flange 16. As an important aspect of the invention, the upper sealing element 18 is pierced by a narrow, elongated hollow needle 20, which is of overall length greater than the length of the tube 15. The needle 20 is made from a hardened steel syringe needle or a clear plastic needle, which is provided with openings or ports 5, 6 separated by a seal 7 formed by crimping or the like. The port 5 and the upper needle opening 3 provide communication between the inside of the tube 15 and the atmosphere, as will be understood. Advantageously, the needle 20 mounts a head or grippable portion 21 which is adapted to be grasped by a user to facilitate the subsequent removal of the needle 20 from the upper sealing element 18 and a lower sealing element 22 after serum collection. In accordance with the principles of the in-

vention, the sealing element 18 and the upper portions of the needle 20 (those portions above the seal 7) comprise an upper, selectively actuatable "one shot" valve.

The lower end of the collection tube, in a manner similar to the upper end, is closed off by a generally cup-shaped, elastomeric, self-sealing element 22. A friction fit, threads, the illustrated resilient split, snap ring 23 or other suitable means mechanically fastens the element 22 to the flanged, lower end of the tube, as shown. In accordance with the principles of the invention, the lower portion 24 (the portion below the seal 7) of the one-piece elongated, hollow needle 20 extends through the sealing element 22 to provide communication between the collection tube and the specimen tube through the lower needle opening 4 and the port 6.

As an important aspect of the present invention, the lower cup shaped element 22 together with the lower needle portion 24 also defines a "one shot" valve. Advantageously, the outer circumference 22' of the element 22 is slightly greater than the inner circumference of the tube 10 and, thereby, functions as a piston element when inserted in telescoping association with the specimen tube. That is to say, the cylindrical outer surfaces 22' of the elastomeric sealing element 22 are appropriately dimensioned (e.g. slightly greater than $\frac{5}{8}$ inch in diameter) so that the element 22 sealingly, slidingly engages the inner walls of the specimen tube when inserted therein, as shown in FIGS. 2 and 3.

In accordance with the present invention, blood serum may be removed from the centrifuged specimen tube 10 and securely trapped within the collection tube 15 in the following manner. The lower end of the collection tube 15 is inserted into the specimen tube, as shown in FIG. 2, and plunged downwardly therein, while the upper "one shot" valve is open to the atmosphere to vent air from uppermost portions of the tube 15 as the lowermost portions fill with serum entering through port 6. In accordance with well known principles of pumps, the serum will be driven by the "pump-like" action of the piston 22' up through the opening 4 and through the needle portion 24 and into the collection tube 15 through the port 6, without disturbing the clotted matter 12. When sufficient serum has been collected in this manner to cover the port 6, the height of which determines the final serum level in the tube 15, the collection tube 15 is withdrawn from the specimen tube 10, as shown in FIG. 3. In accordance with the principles of the invention, no "air lock" or objectionable vacuum lock interferes with withdrawal since excess serum (any serum above port 6) will drain through port 6 back into the specimen tube until port 6 is uncovered and exposed. No vacuum will form beneath the piston 22 since atmospheric air will be free to travel through the needle portion 24 and into the specimen tube. Thus, there will be no tendency to separate the lower cap-piston element 22 from the collection tube, as has heretofore been the case.

After withdrawal of tube 15 from tube 10, the collected serum 11 is permanently trapped in the collection tube 15 by removing the needle 20 by grasping and pulling outwardly on the gripping portion 21. This closes both the upper and lower "one shot" valves to provide a completely sealed collection tube 15. The needle 20 then may be discarded and the filled tube 15 may be readily mailed to pathology laboratories for

testing analysis, etc. in a suitable mailing envelope M (shown in phantom in FIG. 1).

In accordance with a more specific aspect of the invention, the sealing elements 18, 22 are advantageously made of rubber and the collection tube 15 is made from glass, plastic, or the like. Advantageously, the tube 15 has an etched labeling portion 26 integral therewith upon which suitable identifying indicia may be inscribed to ensure accurate handling.

It should be understood that the blood serum collection method and apparatus herein illustrated and described are intended to be representative only, as certain changes may be made therein without departing from the clear teachings of the disclosure. For example, the method of the invention may be practiced by dividing the needle 20 at the seal 7 into short and long needles or by using two separate needles, a short upper needle and a long lower needle. Accordingly, reference should be made to the following appended claims in determining the full scope of the invention.

We claim:

1. Apparatus for removing and trapping the upper portions of a pool of liquid contained in a specimen tube having a predetermined inner diameter, comprising

- a. a generally cylindrical tubular element of first predetermined length open at its upper and lower ends and having an outer diameter less than said predetermined inner diameter of the specimen tube;
- b. an elongated hollow needle of second predetermined length greater than said first predetermined length; said needle being open at its extremities and having spaced ports therebetween; means sealing said ports from one another and dividing said needle into upper and lower portions;
- c. selectively actuatable upper valve means closing off said upper end of said tubular element and being adapted to provide communication between interior upper portions of said tubular element and atmosphere;
- d. selectively actuatable lower valve means closing off the lower end of said tubular element and being adapted to communicate between said inner portions of said tubular element and the interior of said specimen tube;
- e. said lower valve means comprising a puncturable, first elastomeric sealing means secured to and closing off said lower end of said tubular element and said lower hollow needle portion extending there-through;
- f. said upper valve means comprising a puncturable, second elastomeric sealing means secured to and closing off said upper end of said tubular element and said upper hollow needle portion extending therethrough;
- g. said elastomeric material possessing sufficient resilience and said hollow needle being sufficiently narrow whereby on the removal of said needle from said elastomeric material, said ends of the tubular member will be completely self sealed;
- h. piston means including said lower end portions of said tubular element and said lower sealing means, said piston means having an outer diameter slightly greater than said predetermined inner diameter of said specimen tube, whereby said piston means is adapted to make sliding, sealing contact therewith.

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2. The apparatus of claim 1, in which
- a. the needle mounts a gripping means by which the needle may be removed from said first and second elastomeric sealing means.
3. A method of removing serum from a specimen tube comprising the steps of
- a. inserting a collection tube closed off at its lower end by a piston-like element pierced by a lower hollow needle portion into the specimen tube to drive serum upwardly therethrough and into said collection tube,
- b. maintaining the upper inner portions of said collection tube open to atmosphere by an upper hollow needle portion while said collection tube is driven downwardly into said serum;
- c. maintaining the upper inner portions of said collec-

6

- tion tube open to atmosphere during the upward stroke of said collection tube while removing said collection tube from said specimen tube;
- d. maintaining the space between the lower end of the collection tube and the interior lower portions of the specimen tube at atmospheric pressure;
- e. sealing off the upper and lower ends of said collection tube by removing said needle portions from the upper lower end thereof.
4. The method of claim 3, in which
- a. said upper and lower needle portions are supported and handled as a single unit, whereby said upper and lower ends may be sealed off substantially simultaneously by the removal of said single unit.

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