United States Patent [19]

Grams

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[54] **BIOLOGICAL FLUID SAMPLING AND TESTING APPARATUS**

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[52] **U.S. Cl.** ..... **73/421 R**, 73/425.4 R

[51] **Int. Cl.** **G01n 1/10**

[58] **Field of Search** ..... 210/96; 222/5, 83.5, 222/156, 159, 325–327, 386, 390, 88, 89; 73/421 R, 425.4 R

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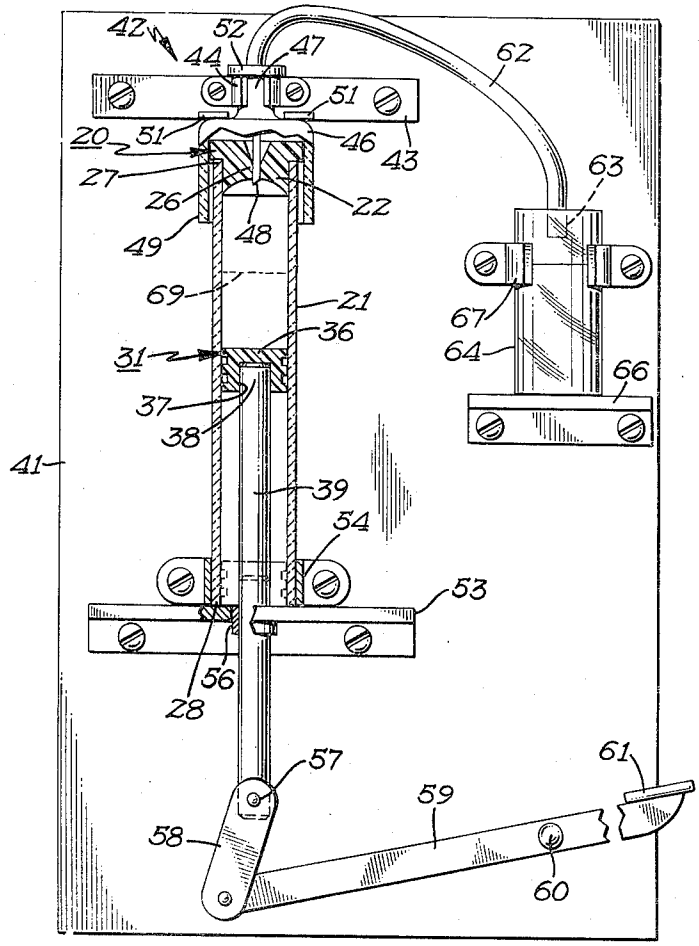
[57] **ABSTRACT**

Biological fluid sampling and testing apparatus includes a fluid sample container assembly of novel construction, and apparatus for transferring a selected portion of the fluid sample out of the container without the necessity of opening it. The container assembly has a puncturable wall portion through which a cannula needle may be inserted for removal of the sample. The container assembly also has a movable externally accessible delivery member, such as a piston, for urging the selected sample portion out of the container. The apparatus for removal of samples from the container includes a positioning means for a cannula needle, a supporting means for the container assembly, an actuator means for engagement with the delivery member of the container assembly, and moving means connected to at least one of the positioning means, supporting means and actuator means for causing relative movement of the delivery member in the container assembly to urge the selected sample portion out through the cannula needle. Preferred arrangements of delivery members and other closure members for such a container assembly and various control means for the transfer apparatus are also shown, such as control means for selective removal of sample portions of different volumes, monitoring or interuption of sample delivery in response to a predetermined characteristic of the sample, and both manual and automatic starting, stopping, and resetting or reversing means for the apparatus.

14 Claims, 8 Drawing Figures



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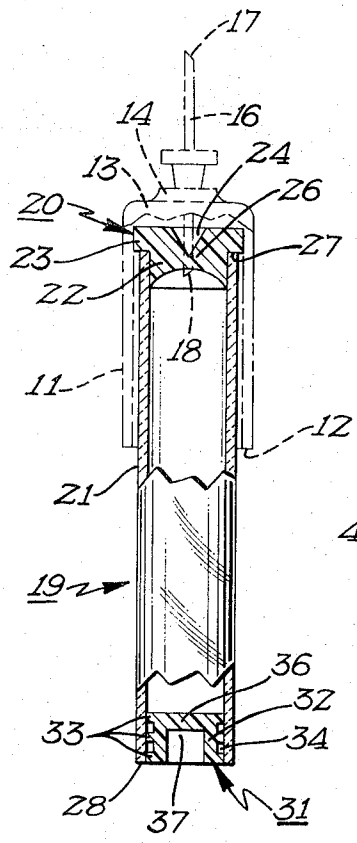

Fig 1

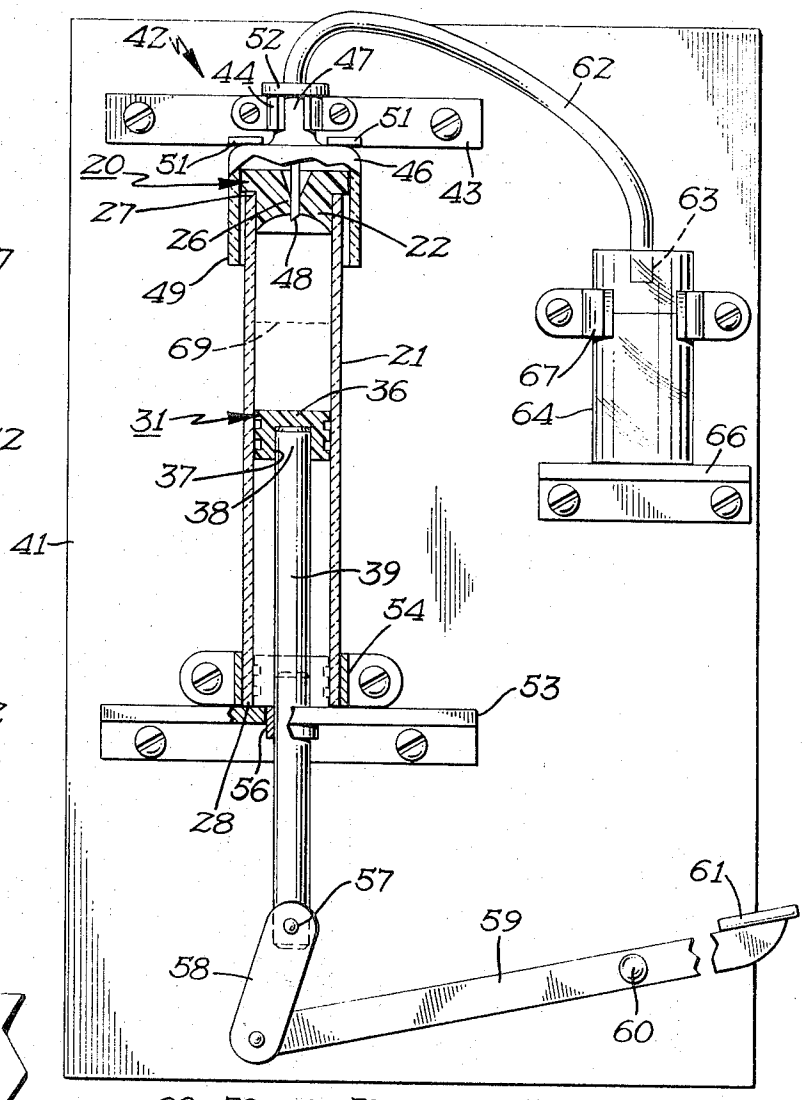

Fig 2

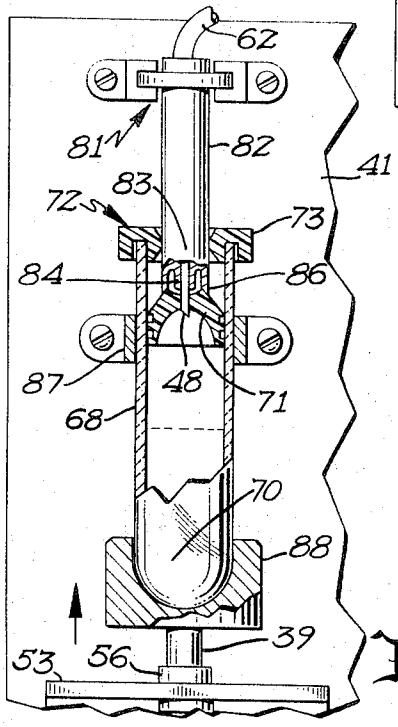

Fig 4

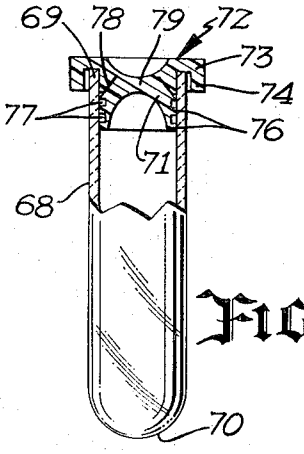

Fig 3

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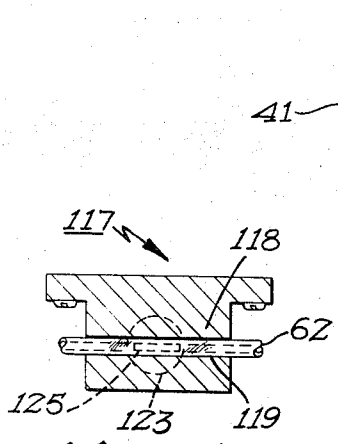

Fig 6

Fig 5

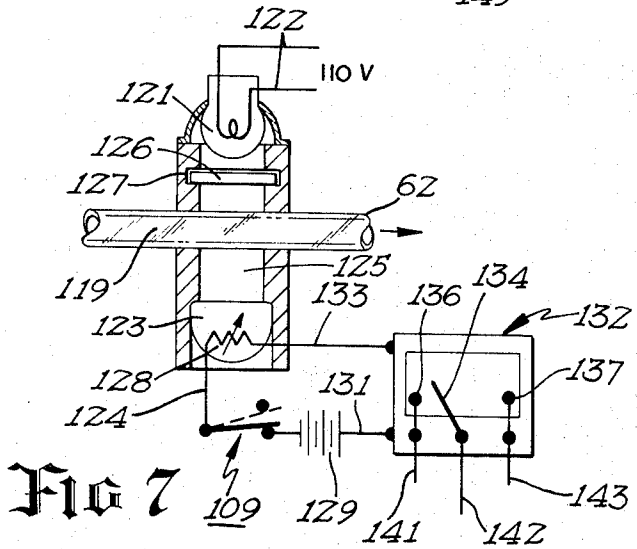

Fig 7

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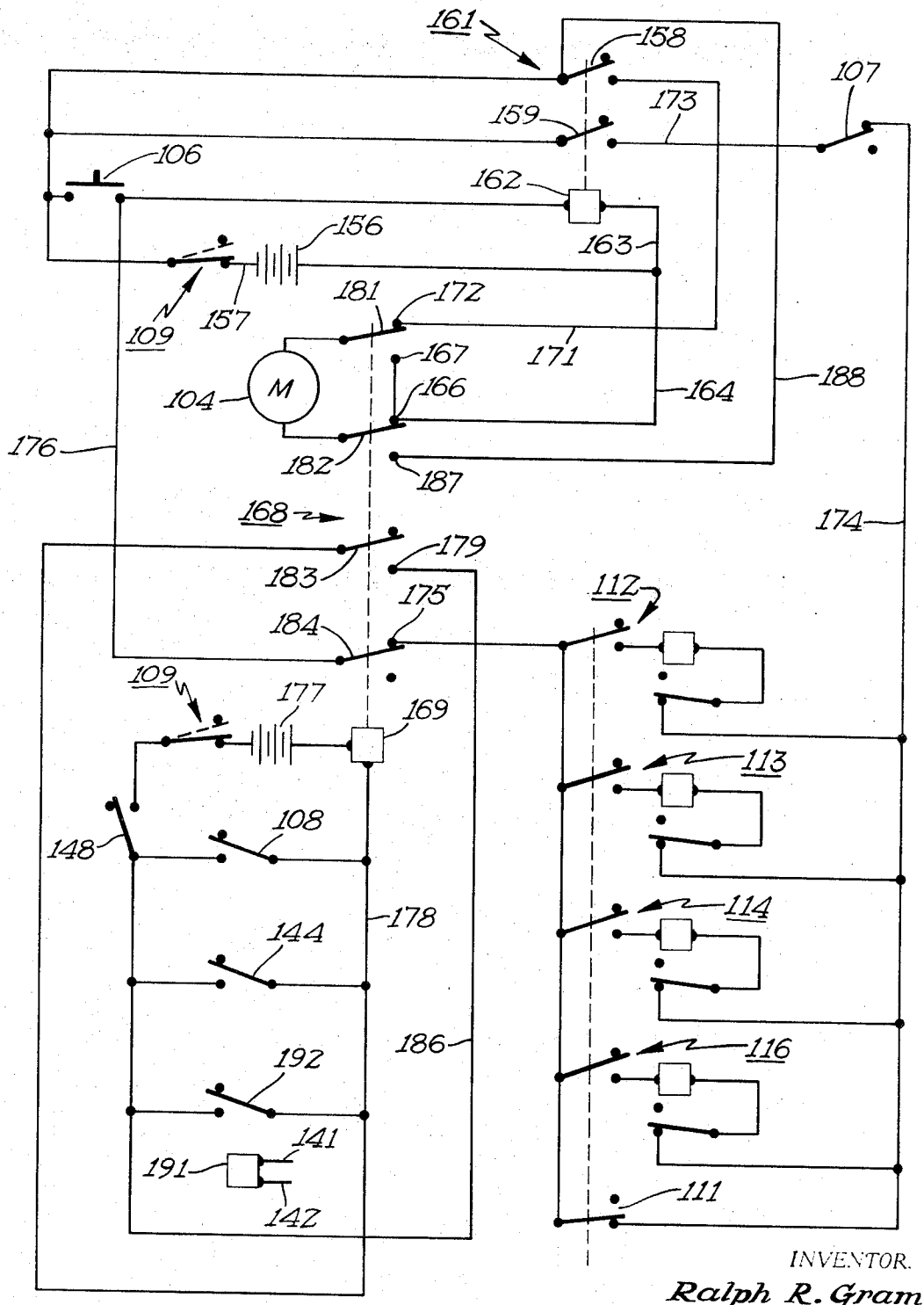

Fig 8

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BIOLOGICAL FLUID SAMPLING AND TESTING APPARATUS

BACKGROUND OF THE INVENTION

In presently known blood sample tubes, it is customary to have a sample holder provided with a needle or cannula which can be inserted into the blood vessel of a patient to obtain a blood sample or a series of such samples. The holder includes a needle portion extending away from the patient and is designed to penetrate the closure member at one end of a sample collection tube which is removably positioned within the holder. Thus when the sample tube is within the holder, the closure of the sample tube is penetrated by the holder needle for delivery of blood from the patient through the holder needle and through the pierced closure member of the sample tube into the interior of such tube. Some sample tubes have been vacuumized to expedite the drawing of the sample. When the desired sample has been collected, the sample tube is withdrawn from the holder, and turned over to laboratory personnel for desired testing.

In the prior art processing of such samples in the laboratory, it has been customary to place containers in a centrifuge for a centrifugal separation of the red cells into the bottom of the sample tube. Thus clear liquid of serum or plasma remains in the upper portion of such a tube after the centrifugal separation. At that point in the process it has been customary to remove the usual closure member from the top of the tube and to manually withdraw a desired portion of the clear liquid with a syringe or eye dropper type of device. The removed portion is then placed in another container for desired further testing. The opening of the sample tube, however, and the manual removal operation just described, provide increased opportunities for infection of laboratory workers. The increasing incidence of hepatitis, for example, and its presence in blood samples of patients who may not even be suspected of having this type of infection, have increased substantially the risk that laboratory testing personnel may suffer from this disease. Moreover, the manual withdrawal of sample portions from such a tube offers a substantial possibility of error. The operator, for example, may dip the removal device too far into the container and thus withdraw some of the red corpuscles or other denser material from the bottom of the tube, thus nullifying the efforts to separate such material by centrifuging.

SUMMARY OF THE INVENTION

The present invention provides an improved biological fluid sampling and testing apparatus in which both an improved fluid sample container assembly and a novel apparatus for transferring a selected portion of the fluid sample out of such a container assembly can be used to perform the desired removal accurately and safely without the necessity of opening the container.

The improved container assembly includes, in addition to a puncturable wall portion through which a cannula needle may be inserted for delivery of a fluid sample from the container assembly, a relatively movable and externally accessible delivery member which can be moved in a manner and direction for urging a selected portion of the fluid sample out of the container in response to movement of the delivery member. The container preferably includes a tubular container body section of uniform interior cross section open at least

at one end of the container, in combination with a movable piston member having a shape and construction fitting closely within the interior cross section of the body section and accessible through the open end of the section for a pushing engagement by external actuator means. The piston member serves as at least part of a closure member for the end of the body section in which it is initially supported and fits tightly within the section for sealing the container end both before and after the introduction or removal of a sample within the container.

In one form of the invention the other end of the container may be closed by an integral wall portion of the container body itself. Preferably, however, the container body is of tubular construction open at both ends, and another similar delivery member or a separate closure member may be positioned in the other end to provide a closure at that point. The puncturable wall portion through which a cannula needle is to be inserted for removal of the desired sample portion may be provided either in the delivery member, or in the separate closure member at the other end of the container, or at both points. The close fitting interengagement between the delivery and closure members on the one hand and the container body portion on the other is such as to provide both the desired sealing effect and a means releasably holding any such delivery member and closure member in their normal positions within the container throughout normal handling of the container, including the subjection of the container to a normal centrifuge operation.

The improved transfer apparatus of the present invention includes cannula positioning means for positioning a delivery cannula needle at one relative position, container supporting means for positioning a container assembly in a fluid delivery position at which a delivery cannula needle positioned by the positioning means penetrates the puncturable wall portion of the container assembly to receive the selected fluid sample portion, a delivery member actuator means located in the apparatus for engagement with the delivery member of the container assembly when the latter is in its fluid delivery position, and moving means connected to at least one of the aforesaid positioning means, supporting means and actuator means for causing relative movement of at least one of those means with respect to another. Such relative movement in turn causes relative movement of the delivery member in the container assembly in a direction and manner urging the desired portion of the fluid sample out of the container through the cannula needle. The moving means may be manually operable, but preferably involves motor means in combination with control means providing one or more additional features. Thus the preferred control means includes sensing means responsive to a predetermined characteristic of the portion of the sample which is being removed from the container. This sensing means is connected in such a way that the operation of the motor means to move the delivery member is interrupted in response to a predetermined or preselected change in characteristics of the fluid being transferred. A photo cell and filter combination responsive to appropriate light changes in the liquid sample is provided to terminate the delivery when the last of the relatively clear liquid of serum or plasma, for example, has been transferred out of the container assembly. Thus the sample portion to be further tested will not include the

red corpuscles or other particles which have been driven to the bottom of the sample container by a customary centrifuge operation. Additional manually operable controls are provided for starting, stopping, and reversing or resetting the motor means and delivery member actuator means. The preferred control system also includes manually operated means for selecting predetermined different volumes for different sample portions to be delivered from a particular container assembly.

Thus the fluid sample container assembly and apparatus for transferring selected portions from a container, according to the present invention, make it possible to obtain a biological fluid sample, to process that sample by centrifuging, and then to remove selected portions of this sample for a variety of different individual tests, all without opening the original sample container to expose its contents to laboratory personnel or to the atmosphere, and with a maximum of automatic control and processing of the sample which minimizes possibilities of human error.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is more fully described with reference to the accompanying drawings, in which like reference characters indicate like parts, and in which

FIG. 1 is a side elevation, partly in section, showing a biological fluid sample container according to the present invention assembled within a holder shown in phantom outline for initially receiving a fluid sample;

FIG. 2 is a side elevation, partly in section, showing details of a manually operable apparatus for transferring a selected portion of the fluid sample from the container assembly of FIG. 1 to an auxiliary container for further testing;

FIG. 3 is a view similar to FIG. 1 of a modified container assembly according to the invention;

FIG. 4 is a partial view similar to FIG. 2 of transfer apparatus adapted for use in connection with the container assembly of FIG. 3;

FIG. 5 is a view similar to FIG. 2 of a preferred form of apparatus in which a power unit is both automatically and manually controlled during a fluid transfer operation;

FIG. 6 is a sectional view, on the line 6 — 6 of FIG. 5 showing details of a light responsive sensing means;

FIG. 7 is an enlarged schematic view showing further details of the light responsive sensing means and associated portions of the control circuit; and

FIG. 8 is a wiring diagram showing further details of the control circuitry for the device of FIG. 5.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

A body fluid collecting apparatus embodying the invention is shown in FIG. 1. Here a suitable cylindrical holder 11, which may be of known construction, is open at its lower end 12 and is closed at its upper end by end wall 13 which, in turn, has a central supporting portion 14 for a cannula or needle 16. The upper end 17 of needle 16 is adapted for insertion into a blood vessel or other body portion of the patient to withdraw a biological fluid sample therefrom. Needle 16 has a lower end 18 through which the fluid sample is delivered to a sample tube assembly 19 through the closure member 20 at one end of the sample tube 21.

Closure member 20 has a main body portion 22 which fits resiliently within the upper end of tube 21 to provide a closure and seal for the tube. Flanges 23 on the upper end of member 20 provide a limiting means to determine the position at which the stopper or closure member fully seals the tube. These flanges 23 also extend circumferentially slightly outwardly beyond the margins of tube 21 to provide a guide or bearing portion for the tube 21 and stopper 20, as these portions of the sample collection tube assembly are positioned within the holder 11.

As is well known in the art, the end 17 of cannula 16 of holder 11 is first inserted in the appropriate portion of the patient's body. Then the holder can be used for collection of one or more fluid samples in individual sample tube assemblies 19, without the necessity of removal and reinsertion of the cannula with respect to the patient. An individual sample tube assembly 19 is pushed into the open end 12 of holder 11, until the closure member 20 is penetrated by the lower end 18 of the cannula or needle. This permits delivery of a fluid sample through the cannula to the interior of tube 21. To facilitate the insertion and removal of tube 21 and its cap 20 with respect to holder 11, the cap 20 has a central axial recess 24 at its upper end thereby providing a portion 26 of reduced thickness along the longitudinal axis of the stopper 20 and tube 21 at the area to be penetrated by the lower end 18 of needle 16. Stopper 20 is made of resilient material which is adapted to provide a self-sealing action and close the opening made by needle portion 18, as the tube 21 and closure member 20 are withdrawn from holder 11. Thus, the biological fluid sample will be retained in the individual sample tube assembly 19 in a sealed condition for further processing and/or testing.

The construction as described up to this point may be essentially similar to the known sample collecting devices presently available in the medical arts. Such sample tube assemblies, however, are customarily closed at their lower ends 28 by an integral end wall portion such as the spherical bottom of a standard glass tube open only at the top. Such prior art sample tube assemblies are customarily vacuumized, so that the relatively lower pressure within tube 21 will assist in drawing body fluid through needle 16 from a patient, and will permit the complete filling of tube 21 without having to provide for escape of air as the tube is filled.

According to the present invention, the improved sample tube assembly of FIG. 1 is provided at one end 28 with a relatively movable externally accessible delivery member 31. In this embodiment the delivery member is illustrated as a generally cylindrical piston member having a main body portion 32 with a plurality of circumferential flanges 33 separated by intermediate recesses 34. Delivery member 31 is made of resilient material, such as synthetic rubber, so that flanges 33 can act somewhat in the manner of piston rings to provide resilient sealing and retaining engagement between the delivery member and the inner surface of container 21. The container has a tubular body section, which in this embodiment extends throughout the length of the container, which has a uniform interior cross section extending along this longitudinal axis of the container. The cross section is normally circular, but other cross sections could be used. The external cross section of the piston or delivery member 31 cor-

responds to this interior cross section of the container body section 21.

The delivery member 31 is adapted for engagement through the open end 28 of the container by a suitable actuator means. For this purpose, the piston member 31 may have a recess 37 in its outwardly facing end surface as shown in FIGS. 1 and 2. This recess is adapted for pushing engagement by the upper end 38 of an actuator means 39 shown in FIG. 2 as a vertically movable rod or shaft.

The resilience of delivery member 31 and the close interfitting engagement between it and the interior of container body section 21 holds the delivery member 31 in its initial position as shown in FIG. 1 throughout initial storage and handling of the fluid sample tube assembly, including the taking of a sample from a patient with the aid of a holder 11 as illustrated in FIG. 1, and the subsequent contrifuging step (not shown) in which the assembly 19 is placed in a centrifuge in such a way that centrifugal forces due to rotation of the centrifuge effectively drive the heavier portions of the sample within the assembly down toward the lower end of FIG. 1 in the vicinity of delivery member 31. Thus delivery member 31 serves as a closure member for the end 28 of the container, and its resilient interfitting engagement with the interior of the container must be tight enough to hold the delivery member in its closure position during such centrifuging. This resilient engagement must also provide a sufficiently tight seal to maintain the normal vacuum within body section 21 during the period from its initial vacuumization by the manufacturer until the assembly is used, as in FIG. 1, to receive a fluid sample from a patient.

The fluid sample transfer apparatus shown in FIG. 2 includes a base or frame member 41 for supporting the various elements of the apparatus. One such element is a positioning means 42 for positioning a delivery cannula needle 48 at one desired relative position in the apparatus. Positioning means 42 includes a bracket 43 on which resilient spring clips 44 are adapted to receive and retain part of a delivery cannula needle holder 46. Holder 46 includes a central portion of reduced diameter at 47 which can be snapped into position between clips 4. Holder 46 also has a downwardly projecting cylindrical skirt 49 which is open at its lower end to receive the upper portion of the container assembly 19 in the same manner that such portion is received by the original holder 11 of FIG. 1. Thus, after the sample container assembly and its contents have been centrifuged in known manner, the container assembly 19, which will be kept in its centrifuged vertical position to avoid dispersion of the centrifugally separated contents, will be assembled with cannula needle holder 46 so that needle 48 penetrates the closure member 22 at the upper end 27 of the container assembly. The positioning means 42 may also include stop members 51 limiting the upward movement of the delivery cannula needle holder 46. A flange 52 at the upper end of the narrow neck 47 of member 46 serves as a stop preventing downward movement of the cannula needle 48. Thus the parts just described serve as cannula positioning means for positioning a delivery cannula needle at one relative position where it can penetrate the puncturable wall portion of the sample container assembly 19 to receive the selected fluid sample portion which is to be removed from that container assembly.

The apparatus also includes container supporting means for positioning the container assembly in a fluid delivery position, as shown in FIG. 2, in which the delivery cannula needle penetrates the puncturable wall portion 26 of the closure member 22 at the upper end of the container body section 21. This positioning means includes a shelf 53 for engagement by the lower end 28 of the container body section to prevent relative downward movement of the container assembly from its fluid delivery position. Side retaining clips 54 prevent lateral movement of the lower end of the container assembly out of its fluid delivery position.

The apparatus of FIG. 2 further includes a delivery member actuator means, one element of which is the vertically movable shaft 39 previously described. This shaft is guided in one or more bushings 56 which permit relative vertical sliding movement of the actuator means with respect to the relatively fixed container supporting means and cannula positioning means. In this embodiment, the apparatus includes manually operable moving means for causing relative movement of at least one of the previously described means, i.e., the cannula positioning means, the container supporting means, and the delivery member actuator means, with respect to another of said means. In the particular embodiment shown in FIG. 2, the moving means, i.e., lever 59, is pivoted to the frame at 60 and is manually operable at 61 for swinging movement of the lever around pivot 60. The opposite end of lever 59 is pivotally connected to a link 58, which in turn is pivoted at 57 to the lower end of the actuator means shaft 39. Thus downward manual pressure at 61 moves the lever 59 so that actuator means 39 is pushed upwardly. This relative upward movement, by engagement at 38 with delivery member 31, moves the delivery member upwardly within the container tube assembly from its original position at the bottom of the tube, as shown in dotted outline in FIG. 2 and heavy outline in FIG. 1, to one or more selected intermediate upper positions, one of which is shown in heavy lines in FIG. 2. During this upward movement of member 31, the fluid within the body section 21 of the container assembly is pushed upwardly so that the upper layers of such fluid are forced up and out of the container assembly through the delivery cannula needle 48. The desired portion of the fluid sample will be delivered from cannula needle 48 through any desired delivery conduit 62 which can discharge the sample portion through its outer end 63 into an auxiliary testing container 64. Container 64 is positioned in the apparatus by a supporting shelf 66 and retaining clips 67.

Although the auxiliary container 64 has been shown as an open-topped container into which the delivery end 63 of conduit 62 directs the fluid sample, a sealed or airtight connection could be provided by another cannula needle, if desired. In the embodiment of FIG. 2 it is understood that the fluid sample portion delivered into container 64 will be immediately subjected to some desired additional test procedure for which the fluid should be immediately accessible.

The desired volume of the fluid sample portion to be delivered into the auxiliary container 64 will be controlled by the operator by the extent of vertical movement of delivery member 31. During this vertical movement, the relative position of the contents within the container 21 will remain unchanged. Thus the heavier portions, such as the red corpuscles of a blood sample,

will remain in the lower most portion of the fluid which is retained in the container body section **21.** For example, such portions may remain below a separation line **69** which marks the boundary between such portions and the relatively clear liquid which remains above line **69** as a result of the centrifuge operation. If only the relatively clear fluid is desired for testing purposes, the upward movement of actuator means **39** would be terminated before that portion of the sample below the separation line **69** can be delivered to the outer end **63** of delivery conduit **62.**

The biological fluid sample container assembly shown in FIGS. **1** and **2** has been illustrated as a tubular section of uniform interior cross section originally open at both ends and provided with a movable delivery member which also serves as a closure for one end **28,** as well as a separate closure member **22** for closing the opposite end **27.** The puncturable wall portion of this container assembly has been provided in the separate closure member **22.**

In the modified embodiment of FIGS. **3** and **4,** however, the present invention is adapted for use with a container body portion which is permanently closed at one end by an integral wall portion such as the normal hemispherical bottom wall of a standard glass test tube construction. Thus the container body section **68** is of tubular construction with a uniform circular interior cross section substantially throughout its length. The tubular section **68** is open at its upper end **69** and closed at its lower end by an integral wall portion **70.** In this embodiment, the movable delivery member **71** constitutes at least a portion of a closure member **72** for the open end **69** of the container assembly. This closure member also includes an outer peripheral flange **73** which extends outwardly above the upper edge **69** of the tubular container body **68** and is provided with a downwardly directed annular skirt portion **74** to assist in retaining the closure member **72** at the outer end of the tube assembly. The relatively movable delivery member **71** includes circumferential flange portions **76** and intermediate annular spaces **77** similar to the corresponding portions of piston member **31** in FIG. **1.** A cut line **78** extending from the outer edge of the delivery member portion **71** inwardly provides part of a line of severance for separation of the delivery member portion **71** from the rest of the closure member **72,** when a selected portion of the fluid sample is to be removed from the container **68.** In this case, the puncturable wall portion of the container assembly is provided at **79** in the central area of the delivery member **71.**

The removal of such a selected sample portion can be accomplished with the apparatus of FIG. **4.** In this device the base of frame member **41** has a cannula positioning means **81** for positioning a delivery cannula needle **48** as shown, in a downwardly projecting direction. Positioning means **81** clamps the holder **82** of the cannula needle rigidly in position. The lower end **83** of holder **82** serves in this embodiment as the delivery member actuator means located for engagement with the delivery member **71** of the container assembly, when the assembly is in the fluid delivery position shown in FIG. **4.** Thus a central portion **84** at the lower end **83** of holder **82** engages the puncturable wall portion **79** of the delivery or piston member **71** and prevents relative upward movement thereof. A circumferential cutting edge **86** at the lower end **83** of holder **82** is provided to complete the severance of the delivery member **71** from the rest of closure member **72,** when the parts are moved with respect to each other as shown. The container supporting means of the apparatus of FIG. **4** includes fixed guide portions **87** for the container body **68** which prevent lateral movement of the container body but permit vertical movement thereof. The container supporting means also includes a base support member **88** which is recessed to receive the bottom **70** of the container assembly. Base member **88** is mounted at the upper end of a vertically movable member **39** which can be moved vertically by an operator by means of linkage similar to that shown in FIG. **2.**

In this embodiment, when a desired portion of the fluid sample is to be removed from container **68,** shaft **39** is moved upwardly, thereby causing relative movement of one of the cannula positioning means, container supporting means and delivery member actuator means with respect to another of such means. In this case the container supporting means moves upwardly with respect to the relatively fixed positions of the cannula positioning means **81** and the delivery member actuator **84,** thereby causing relative movement of the delivery member **71** downwardly with respect to the upwardly moving container **68.** This relative movement causes transfer of the desired portion of the fluid sample upwardly through needle **48** and out through conduit **62.**

In the devices of FIGS. **2** and **4,** the moving means for causing the desired relative movement of the parts to transfer a fluid sample portion is a manually operable moving means. A motorized or powered apparatus is shown in FIGS. **5** through **8** for accomplishing the desired transfers with the aid of a suitable motor in combination with various manual and automatic controls to provide a more efficient operation. In this device, the supporting frame **41** carries a cannula positioning means **42** for delivery cannula needle **48,** container supporting means **53, 54,** and delivery member actuator means **39** essentially similar to the corresponding elements in the apparatus of FIG. **2.** Similarly, a delivery conduit **62** delivers the selected portions of the fluid sample from cannula needle **48** to an outlet **63** which discharges into an auxiliary container **64.**

In this embodiment, however, the vertically movable actuator means **39** has a threaded lower section **92** which extends downwardly a substantial distance below the bushing **56** which slidably supports the upper portion of member **39.** At the lower end of threaded portion **92** a transverse guide member **93** is fixed to the shaft. Vertical guide members **94** on the frame are engaged by appropriate projections **96** on member **93** to prevent relative rotation of the threaded shaft **92** around its vertical axis and to guide the lower portion of this shaft for vertical movement within the guide members **94.** To provide the desired relative vertical movement of shaft **92,** an internally threaded gear member **97** is threaded on the shaft. Gear member **97** is retained in a predetermined vertical location between upper and lower retaining members **98** and **99.** Rotation of gear member **97** will therefore urge the threaded shaft portion **92** upwardly or downwardly along its axis depending upon the direction of relative rotation of gear **97.** This gear forms one element of the moving means for causing relative movement of shaft **39, 92.** For this purpose it includes external gear teeth **101** which are engaged by the teeth of a driving gear

102 secured to shaft 103 of a reversible electric motor 104. Since rotation of threaded shaft portion 92 on its axis is prevented by the interaction of guide members 93 and 94, operation of motor 104 to rotate gear member 97 will cause the desired vertical movement of shaft 92 and its actuator means 39.

The preferred apparatus of FIG. 5 includes both manual and automatic control means for the desired fluid delivery transfer operations. Thus a suitable control panel includes a manually operable starting switch member 106, a stopping switch member 107, a reversing switch means 108 and a suitable "on-off" switch 109. For automatic control of the transfer of any one of a plurality of preselected sample volumes, the control panel further includes a plurality of selective volume buttons, 111, 112, 113, 114, and 116. These are preferably interconnected in a manner so that only one of them may be depressed at a time and so that one of them will always be in an operated position.

The control means of this apparatus also includes sensing means indicated generally at 117 located at a position where it is responsive to a predetermined characteristic of the fluid sample portion which is being delivered through the delivery cannula needle 48 from the container 21. In this case the sensing means includes a suitable supporting portion 118 in which a transparent section 119 of delivery conduit 62 is supported. The particular sensing device illustrated is responsive to the light transmission characteristics of a fluid sample portion passing through the transparent conduit section 119. Thus the device includes a source of illumination 121 connected at 122 to the normal voltage supply. A photocell 123 receives that portion of the light transmitted from source 121 which passes through the fluid sample within transparent conduit portion 119. A color filter 126 is carried in a supporting slot 127 for determining the color of the light initially directed toward the sample. Thus, for the sensing of fluid from a blood sample, a blue filter 126 is preferred. The blue light transmitted by such filter passes readily through the relatively clear liquid of plasma or serum which is delivered from the upper portion of container 21. However, when the relative movement of the delivery member 31 reaches a stage where the darker portion including red corpuscles from the bottom of the centrifuged sample penetrates the delivery cannula needle 48 and reaches the conduit portion 119, this darker portion will block part of all of the transmission of light to a photocell 123, thereby producing a change in the output of such cell which can be measured and used for control of the motor 104 to stop the further delivery of such fluid. Moreover, by providing a visual indication of the output of photocell 123, for example by a suitable meter, an observer can reach certain diagnostic conclusions with respect to the characteristics of the sample passing through the delivery conduit. Thus in one embodiment of the apparatus, such a photocell was adjusted so that its output reached a level of almost 1 m.A. (milli-ampere) when the delivery conduit was completely removed. With red blood corpuscles in the tube blocking the light transmission, the photocell output dropped to less than 0.1 m.A. The maximum output just described as achieved when the photocell sensing unit is entirely empty, i.e., before the delivery conduit is inserted. When the tube is first inserted, and before the liquid sample is fed through the tube, the empty tube, with a hollow interior, substantially blocks some of the transmission so that the photocell output drops as low as 0.25 to 0.3 m.A. As delivery of the fluid sample starts, the clear liquid in the tube improves the light transmission characteristics so that the photocell output is again raised to a level somewhat above 0.75 m.A.

If, however, the supposedly clear fluid of serum of plasma involves a condition of hemolysis, in which the red cells have fractured and some red color in the liquid portion accordingly fails to go to the bottom of the sample with the red cells during centrifuging, the photocell output, with a blue filter, may drop to slightly below 0.25 m.A. although not quite so low as when the red blood corpuscles reach the conduit section. Similarly a lipemic condition, i.e., one in which the fat globules in the blood sample have failed to spin down to the bottom of the sample container, so that the fluid might look somewhat muddy in color, will be apparent from a meter reading, with blue filter, which drops part of the way down, e.g., to a level of substantially 0.5 m.A. in the example indicated. Thus the visual indication of the output of the sensing unit 117 can be used to some extent for visual diagnosis of the particular blood sample.

As emphasized in FIG. 6, it is desirable to control the transmitted light through the sample delivery conduit by appropriate slots 125 which have a lateral dimension substantially corresponding to the interior diameter of the conduit 62. Thus the variations in photocell output bear a more direct relationship to the changes in light transmission characteristics of the sample within that conduit, then would be the case if some of the transmitted light were permitted to pass through the curved outer walls of the conduit section 119.

FIG. 7 shows the manner in which such a light sensing unit can be connected to a 1 m.A. meter relay 132. Thus the photocell 123 has one connection 124 to a power supply 129. The other supply terminal is connected at 131 to one side of the meter coil which controls the movement of the meter pointer 134. Another connection 133 connects the remaining portion of the photocell output to the meter coil. The photocell output is normally adjustable at 128 to obtain the desired meter scale reading for a particular reference condition. The pointer 134 of such a meter relay 132 may engage lower and upper stops 136 and 137 which are visible at the face of the meter as shown in FIG. 5. The respective lower and upper stops or switch contacts may be respectively adjusted by manually operable members 138 and 139 to preset the lower and upper meter readings at which electrical contact will be made to actuate the desired relay for control purposes. Thus, as shown in FIG. 7, when meter pointer 134 engages adjustable lower limit 136 a circuit will be completed between meter relay contacts 141 and 142. Similarly, when pointer 134 reaches the upper limit contact 137 a circuit will be completed between meter relay contacts 142 and 143.

The apparatus of FIG. 5 also preferably includes one or more limit switches to prevent damage to the apparatus and insure reversal or stopping of the motor 104 at appropriate limit points. Thus upper limit switch 144 has an actuating arm 146 which is engaged by guide member 147 at the bottom of the actuator shaft 92 when the shaft reaches its maximum upward position, i.e., when delivery member 31 has been pushed all the way to the top of its container 21 or to a predetermined

upper position determined by the selected position of limit switch **144.**

A bottom limit switch **148** has an actuating arm **149** engaged by cross member **147** when the actuating shaft **39, 92** reaches its lower most position. These limit switches are connected, as shown in FIG. **8,** so that motor **104** is reversed when the upper limit switch is actuated, thereby returning the actuator means **39** to its lower or rest position. Similarly the lower limit switch **148** is connected to stop the operation of motor **104** entirely when the shaft **92** has reached its bottom or rest position.

Before describing the circuit of FIG. **8,** it should be noted that a visual indicator is provided by which the operator can observe the relative amount of the fluid sample being delivered from container **21** through delivery conduit **62.** For this purpose a suitable pointer **151** is carried by the cross member **93** at the bottom of shaft **39.** The pointer **151** cooperates with a fixed scale **152** on the apparatus, which may be calibrated to show the relative volume delivered from a sample container of known internal diameter, in response to the indicated vertical movement of the delivery member **31.** Thus an operator may, if desired, conveniently control the starting, stopping, restarting and ultimate reversal of the motor **104** to deliver one or more measured volumes of sample fluid by merely operating the manual control switch members **106, 107** and **108** at appropriate times as indicated by scale **152.**

FIG. **8** shows details of a control means according to the invention, with its various control switches and relays in the position they would occupy when the actuator means **39** is at rest in its lower most position causing normally closed limit switch **148** to be held open by member **93,** with the motor **104** de-energized. Switches **109** on FIGS. **7** and **8** are "on-off" controls for the power supply and are actuated simultaneously. They are turned to "on" position, as shown in FIG. **8** when the apparatus is to be used. Before operating the starting switch **106,** the operator will operate switch **111** so that it will be in closed position as shown in FIG. **8,** while the remaining switches **112, 113, 114** and **116** which are interconnected with it will necessarily be in open position. Operation of starting switch **106** will momentarily complete a switch operating circuit through wire **157,** switch **106,** energizing coil **162** of the two pole double throw switch relay **161,** and wire **163.** Energization of coil **162** will move switch arms **158** and **159** of relay **161** from the position shown in FIG. **8** to their closed positions. Thus a holding circuit for relay coil **162** will be completed from power supply **156** through wire **157,** switch arm **159,** wire **173,** normally closed stop switch **107,** wire **174,** closed selector switch **111,** switch contact **175** of a four pole double throw relay switch **168,** wire **176,** coil **162** and wire **163,** to hold relay switch arms **158** and **159** in their energized positions. At the same time a motor circuit will be completed from power supply **156** through wire **157,** switch arm **158,** wire **171,** contact **172** of relay **168,** motor **104,** contact **166,** and wire **164,** back to power supply **156.** Motor **104** will then drive the apparatus so that the actuator means **39** moves upwardly until the operator pushes the stop switch **107.** This will be done at the point at which the first part or leading edge of the fluid sample transferred through cannula needle **48** reaches the outlet **63** of the delivery conduit. Operation of stop switch **107** to its open position will interrupt the holding circuit through coil **162** and restore the various parts to the original position shown in FIG. **8,** with the motor de-energized.

At this time, the operator can select the desired volume for the first sample to be delivered from the container **21.** Thus he will push one of the selecting switches **112, 113, 114** or **116** depending on whether he wishes a relatively small or large sample. The control members **112** to **116** are illustrated as time delay reed relays which can be preset for different periods of time from one to forty seconds or more. As described earlier, only one of these relays can be operatively connected at a time. Thus, when the starting switch **106** is again operated, the holding circuit through wire **174** will be completed only for the particular period of time for which the preselected time delay reed relay has been set. This time will be coordinated with the relative speed of movement of delivery member **31** and the internal area of container **21** to deliver the preselected volume before the relay switch opens to break the circuit. After one such sample has been delivered, another of the reed relays can be actuated, the starting switch again operated, and another sample of the same or different volume delivered. As shown in FIG. **5,** relays **112, 113, 114** and **116** are set for times corresponding to delivery of 0.1 cc., 0.5 cc., 1.0 cc. and 2.0 cc. of fluid, respectively.

Whenever the operator desires to manually reverse the operation of motor **104** and reset the apparatus, he will operate reversing switch **108.** Operation of this switch will momentarily complete a circuit from power supply **177** through normally closed bottom limit switch **148,** reversing switch **108,** wire **178** and energizing coil **169** of the relay switch **168** to move the four switch arms **181, 182, 183** and **184** of relay **168** from the position shown in FIG. **8** to their alternate positions. Thus a holding circuit for relay coil **168** will be completed from power supply **177** through normally closed limit switch **148,** wire **186,** relay contact **179** and switch arm **183,** and wire **178** through relay coil **169** back to power supply **177.** The concurrent movement of relay switch arms **181** and **182** from their respective contacts **172** and **166** to their alternate contacts **167** and **187** will complete a motor circuit of opposite polarity through wires **188** and **157** to one side of power supply **156** and through wire **164** to the other side of battery **156.** Thus operation of motor **104** will take place in the opposite direction to lower the member **39** to its bottom position. Downward movement of the member **39** will ultimately energize the bottom limit switch **148** thus opening the circuit through switch relay coil **169** and restoring the circuit to its original condition.

Finally, if the operation of the motor in its normal direction to drive the actuator member **39** upwardly is not stopped manually or by the operation of one of the time delay reed relays, the ultimate movement of member **147** into engagement with arm **146** of upper limit switch **144** will momentarily close that switch **144** to energize relay coil **169** in the same manner that operation of the reversing switch **108** energizes that coil. Prior to the ultimate operation of upper limit switch **144,** there is also the possibility that the light-responsive sensing means **117** senses the arrival of darker material so that meter arm **134** engages adjustable lower limit contact **136.** Completion of the circuit between meter relay contacts **141** and **142** thus ener-

gizes relay coil **191** to close relay switch **192.** Thus relay coil **169** will be energized to operate relay switch arms **181** and **182,** thereby reversing the direction of operation of motor **104** in the same manner that operation of reversing switch **108,** as described above, achieves the same result.

The biological fluid sample container assembly, the apparatus for transferring a selected portion of a fluid sample out of such a container assembly, and the combination of these elements in a complete biological fluid sampling and testing apparatus, thus provide novel means for controlled and accurate collection and transfer of different desired volumes of fluid and various testing operations, without the necessity of opening the fluid sample container and with a minimum of manual handling by laboratory personnel. The invention is particularly useful for the collection, processing and delivery of contrifuged samples of blood serum or plasma, but may also be useful in other applications.

It will be understood by those skilled in the art that the shape, dimensions and other details of construction of the fluid sample tube assemblies and transfer apparatus shown in the drawings, as well as the circuit details for manual and automatic control of the apparatus, could be further modified in various ways within the scope and principles of the present invention. The foregoing specification, however, sets forth some of the ways in which the invention may be put into practice, including the best mode presently contemplated for carrying out the invention.

I claim:

1. Biological fluid sampling and testing apparatus comprising, in combination, a fluid sample container assembly including an initially vacuumized container into which a biological fluid sample can be initially introduced from a patient by a cannula needle with the help of such vacuum and subjected to desired centrifuging while the sample is in the container to separate a selected fluid portion of the sample at one end of the container, said container having a cannula-puncturable wall portion at said one end through which a cannula needle may be inserted for subsequent removal of at least part of the fluid sample from the container assembly after such centrifuging, all without opening the container, the container assembly having a relatively movable externally accessible delivery member for urging the selected portion of the fluid sample out of the container in response to relative movement of the delivery member within the container, said delivery member having a portion in interfitting sealing engagement with the container and maintaining vacuum during handling and storage prior to initial introduction of a fluid sample into the container, and said interfitting engagement of the delivery member and container preventing relative movement of said delivery member within the container in response to such vacuum as well as in response to centrifugal forces during such centrifuging, and apparatus for transferring the selected portion of the fluid sample out of the container, said apparatus comprising a supporting frame member holding the apparatus in an operating position, cannula positioning means for positioning a delivery cannula needle at one relative position, container supporting means for holding the container assembly in a fluid delivery position in which said one end of the container assembly is uppermost and a delivery cannula needle positioned by said cannula positioning means penetrates the puncturable wall portion to receive the selected fluid sample portion, a delivery member actuator means located for engagement with the delivery member of the container assembly when the assembly is in its fluid delivery position, and moving means connected to at least one of said positioning means, supporting means and actuator means for causing relative movement of at least one of said means with respect to another of said positioning means, supporting means and actuator means and thereby causing relative movement of the delivery member in the container assembly in a direction urging the selected portion of the fluid sample out of said one end of the container through the delivery cannula needle, while said container supporting means maintains the container assembly in the same relative fluid delivery position with said one end uppermost.

2. Apparatus according to claim **1** including a delivery conduit for receiving and conveying the selected fluid sample portion from the delivery cannula needle, sensing means responsive to a preselected change in a characteristic of the fluid sample portion urged through the delivery cannula needle, and control means for the moving means, said control means being connected to the sensing means and thereby automatically stopping operation of the moving means when the sensing means responds to the preselected change.

3. Apparatus according to claim **2** in which the delivery conduit has a transparent section and the sensing means is responsive to a preselected change in light transmission through the fluid sample portion in the transparent section.

4. Apparatus according to claim **3** having meter means connected to the sensing means and providing a visual indication of the changes in light transmission through the fluid sample portion.

5. Apparatus according to claim **4** in which said meter means includes manually adjustable relay means constituting at least part of the control means for automatically stopping operation of the moving means in response to a preselected decrease in light transmission through said fluid sample portion.

6. Biological fluid sampling and testing apparatus according to claim **1** in which the sample container assembly comprises a tubular container section of uniform interior cross section throughout its length and the relatively movable delivery member comprises a piston member of corresponding exterior cross section, said piston member being slidably supported within one end of the tubular container portion and constituting at least part of a closure member for said one end.

7. Biological fluid sampling and testing apparatus according to claim **6** in which said puncturable wall portion is a part of said piston member, said supporting means supports the container assembly with the tubular section in upright position and the piston member at the top of the tubular section, said positioning means positions the delivery cannula needle in downwardly projecting position with the needle penetrating the puncturable wall portion of the piston member, said apparatus including stop means engaging the upper end of the piston member and preventing relative upward movement thereof, and said moving means being connected for causing relative upward movement of the supporting means with respect to the positioning means and piston member.

8. Apparatus according to claim **7** in which the closure member for said one end includes an outer flange

portion projecting radially beyond the interior cross section of the tubular section and limiting the initial position of the piston member within the tube, one of said cannula positioning means and stop means having a circumferential cutting edge corresponding to the interior cross section of the tubular container section and severing the piston member from the outer flange portion during initial relative upward movement of the supporting means.

9. Apparatus according to claim **6** in which the supporting means positions the container assembly with the tubular section in upright position and with the piston member at the bottom of the tubular section, the container assembly includes a further closure member at the upper end of the tubular section, the puncturable wall portion is a part of said further closure member, the positioning means positions the delivery cannula needle in downwardly projecting position with the needle penetrating the puncturable wall portion of the further closure member, the positioning means and supporting means are in fixed positions with respect to each other, the actuator means comprises a piston-engaging member and means supporting the piston-engaging member for relative upward movement with respect to the positioning means and supporting means, and said moving means is connected to the piston engaging member for relative upward movement of the piston-engaging member and piston with respect to the positioning means and tubular container section in response to operation of the moving means.

10. Apparatus according to claim **1** in which said moving means includes a manually operable member.

11. Apparatus according to claim **1** in which said moving means includes motor means, and control means for said motor means, said control means including manually operable selecting means for operating the motor means for different selected movements of the piston member for delivery of selected fluid sample portions of correspondingly different volumes.

12. Apparatus according to claim **11** including sensing means for sensing preselected changes in a characteristic of the fluid sample, the sensing means being positioned in the apparatus at a location where the sensing means senses changes in the characteristic of that portion of the selected fluid sample which is urged through the delivery cannula needle, and said control means being connected to the sensing means and thereby automatically stopping operation of the motor means when the sensing means senses a preselected change.

13. Apparatus according to claim **1** in which said moving means includes reversible motor means and control means for said motor means, said control means including manually operable starting means, manually operable stopping means and manually operable reversing means all operatively connected to said motor means for respectively starting, stopping and reversing its operation.

14. Apparatus according to claim **13** in which said control means includes first limit switch means responsive to predetermined maximum movement of the delivery member actuator means in the direction urging the fluid sample out of the container for automatically reversing the operation of the motor means, and second limit switch means responsive to predetermined return movement of the actuator means to its starting position for automatically stopping the operation of the motor means.

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