

[54] **APPARATUS FOR CLINICAL
LABORATORY SAMPLE COLLECTION
AND AUTOMATIC SAMPLE PROCESSING**

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[21] Appl. No.: **395,214**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 108,118, Jan. 20,
1971, Pat. No. 3,774,762, and Ser. No. 157,942,
June 29, 1971, abandoned.

[52] **U.S. Cl.**..... **23/253 R; 23/259; 206/223;**
128/2 F

[51] **Int. Cl.²**..... **G01N 33/16**

[58] **Field of Search**..... **23/230 R, 253 R, 259, 592;**
206/47 A, 223; 128/2 F, 2 G

[56] **References Cited**

UNITED STATES PATENTS

3,476,515 11/1969 Johnson et al. 23/230

3,497,320 2/1970 Blackburn et al. 23/292 X
3,689,224 9/1972 Agnew et al. 23/253 TP

Primary Examiner—R. E. Serwin

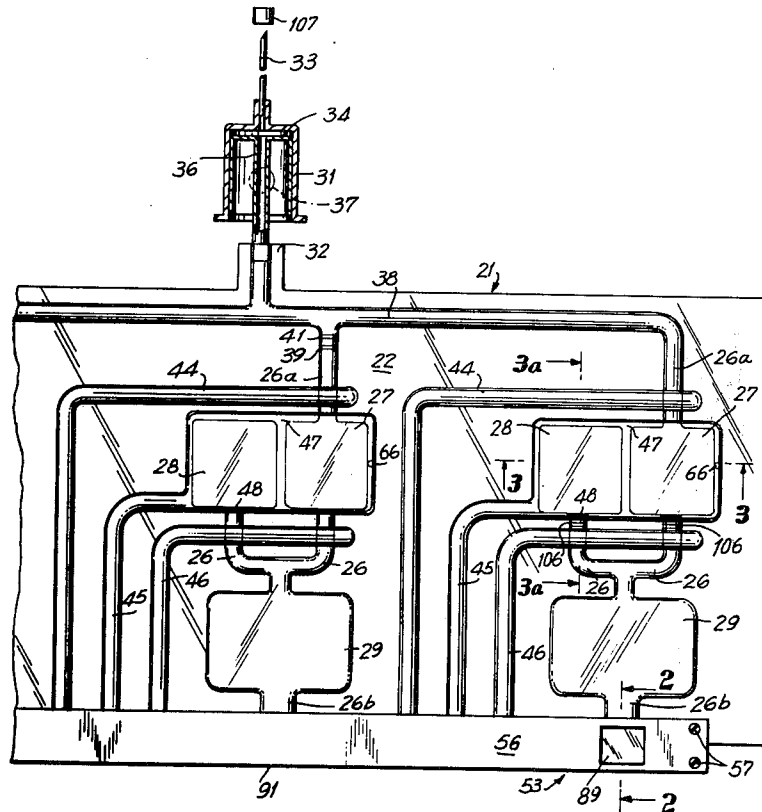
Attorney, Agent, or Firm—Blum, Moscovitz, Friedman
& Kaplan

[57]

ABSTRACT

A semi-automatic disposable device of flexible material for receiving a fluid sample and particularly a blood sample, subdividing it into aliquots for sequential processing in conjunction with contained active principles, or reagents, to perform multiple, predesignated analytic procedures. The necessary sequential manipulations are controlled by external means operating through pressurizable passages in said device.

26 Claims, 18 Drawing Figures



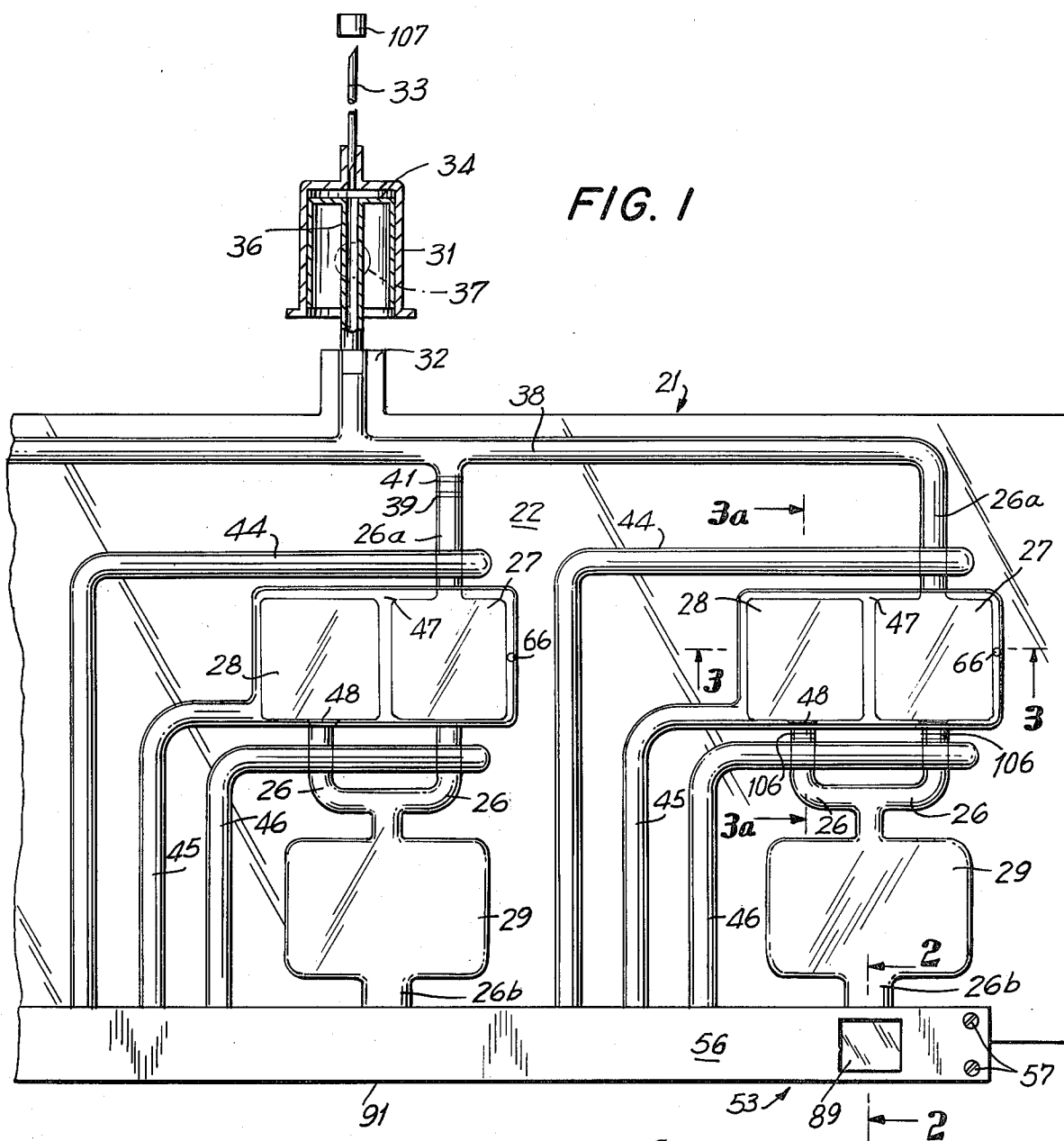


FIG. 2

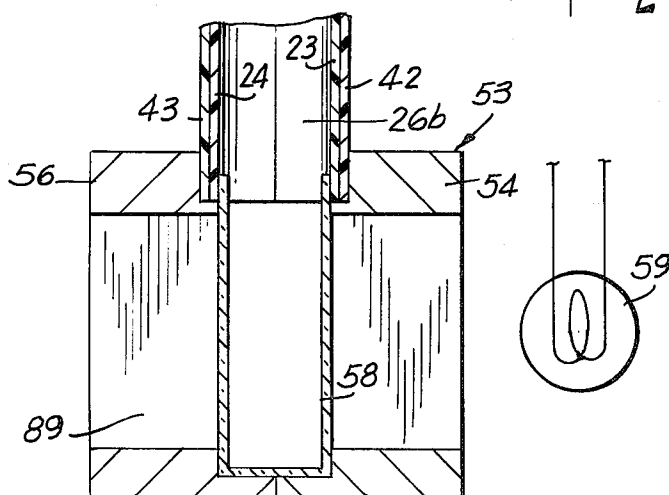


FIG. 3

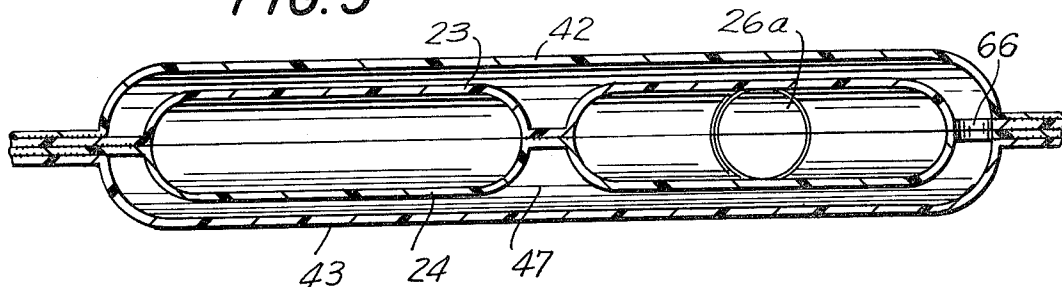


FIG. 3a

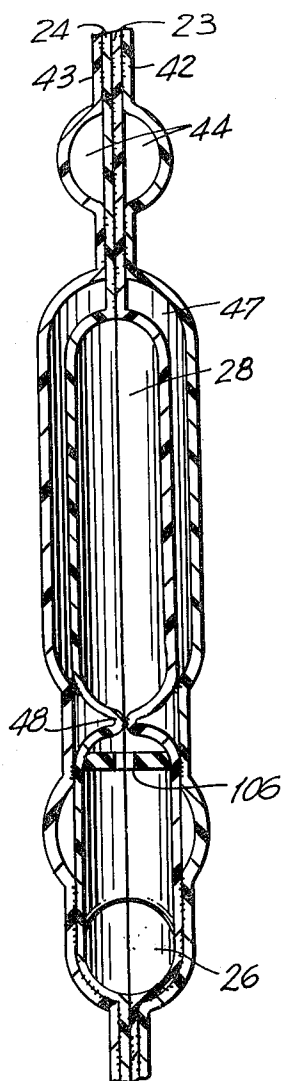


FIG. 4

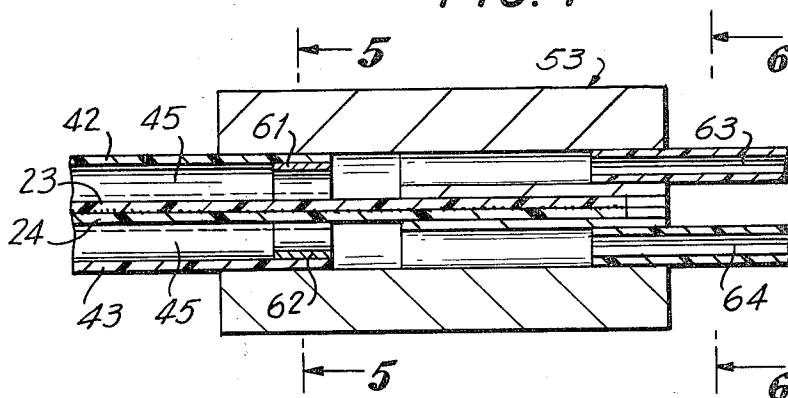


FIG. 5

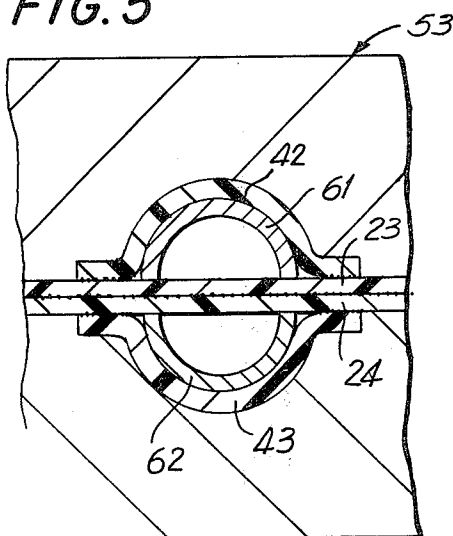
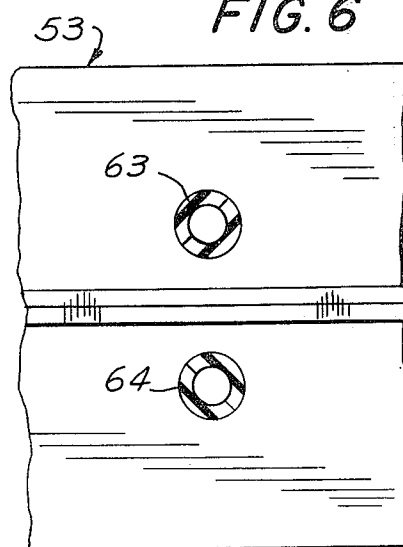


FIG. 6



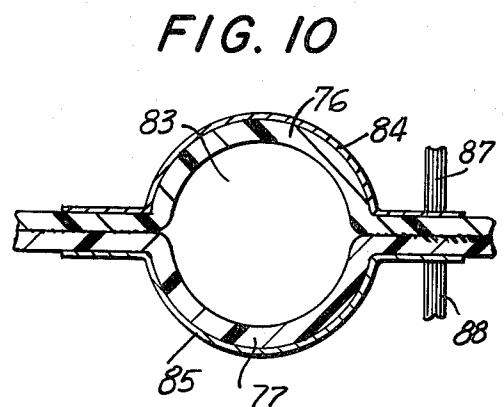
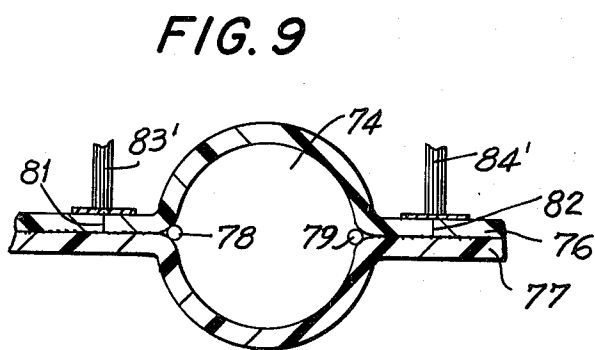
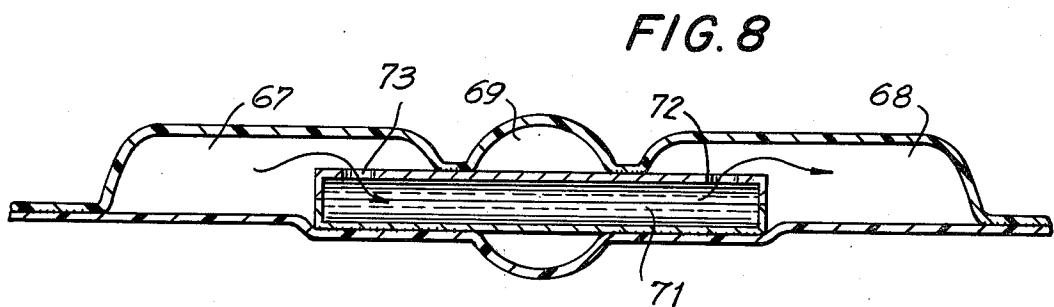
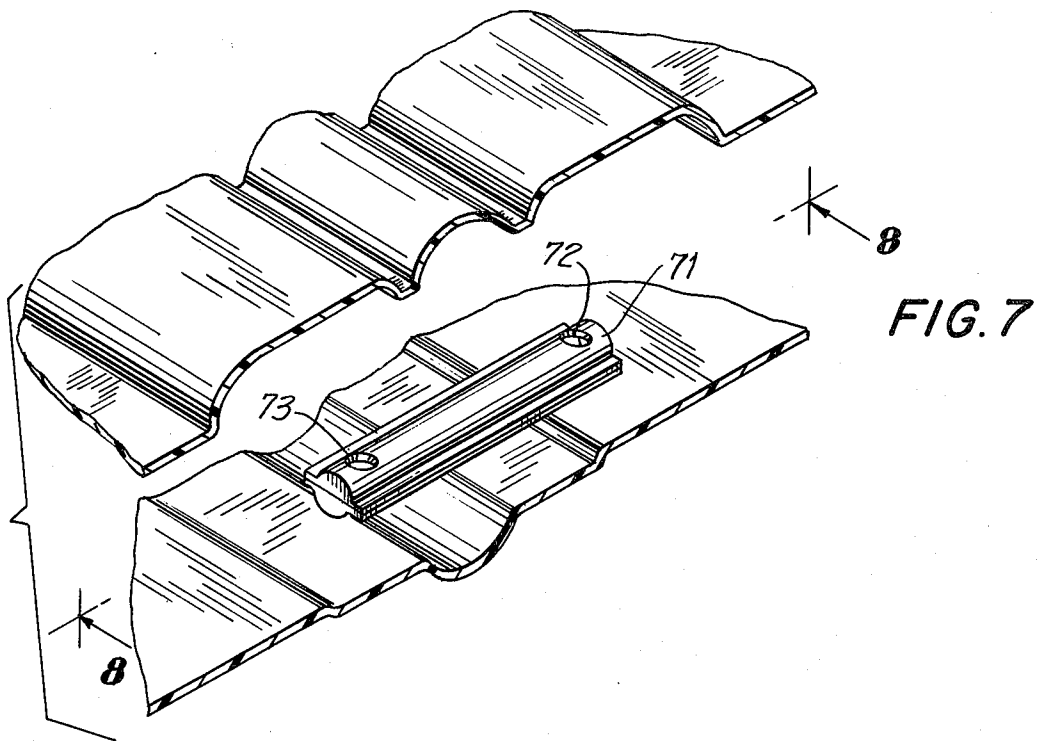


FIG. 11

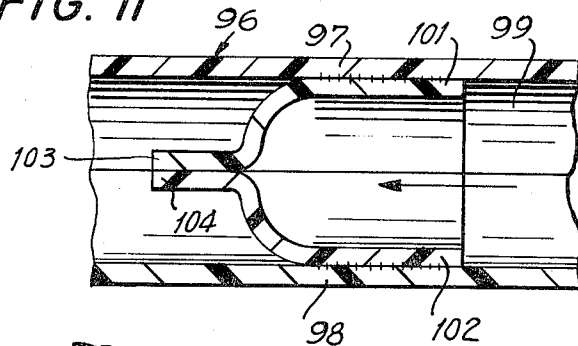


FIG. 12

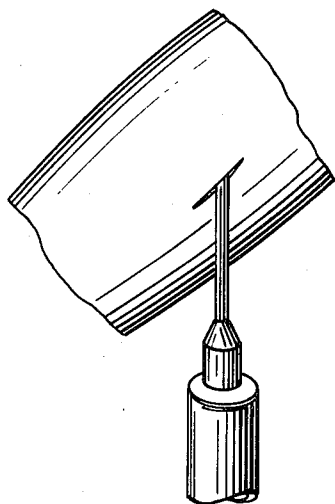


FIG. 17

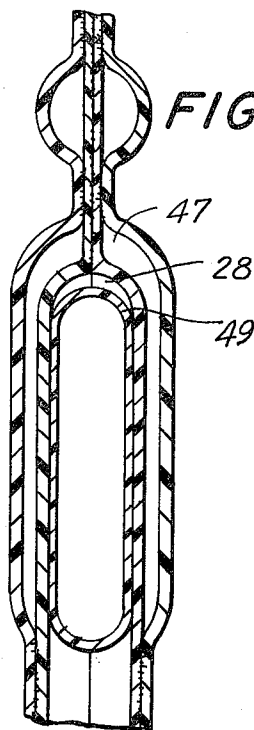


FIG. 13

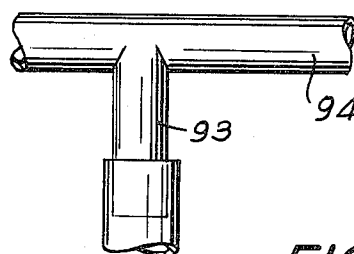


FIG. 14

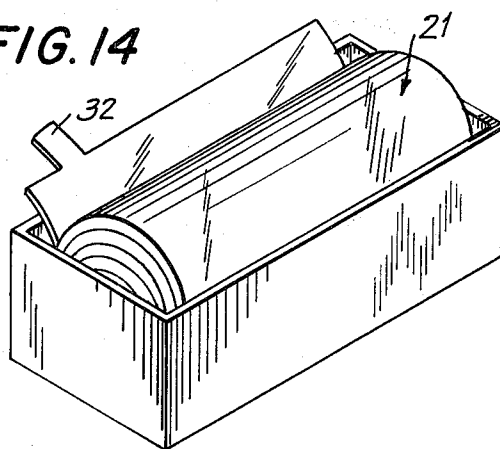


FIG. 15

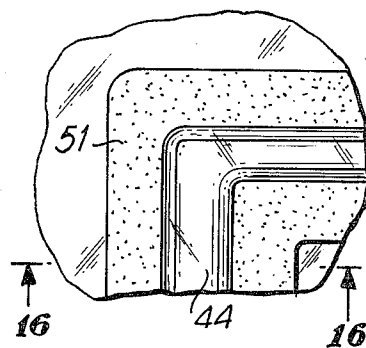
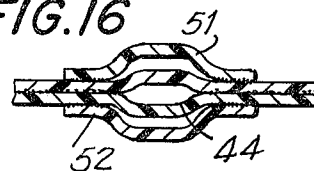


FIG. 16



APPARATUS FOR CLINICAL LABORATORY SAMPLE COLLECTION AND AUTOMATIC SAMPLE PROCESSING

CROSS REFERENCE TO RELATED APPLICATIONS

The present application is a continuation-in-part of my co-pending application Ser. No. 108,118, Filed: Jan. 20, 1971, now U.S. Pat. No. 3,774,762 and Ser. NO. 157,942, Filed: June 29, 1971, now abandoned.

BACKGROUND OF THE INVENTION

In a recent analysis of the efficiency of a highly automated clinical laboratory it was estimated that despite the automation, 40% of the cost of procedures was for labor associated with preparation of samples for automatic processing. This analysis included all steps subsequent to collection of a specimen, and did not include costs of supplies.

In addition to the costs incurred in the clinical laboratory itself, there are costs associated with transporting the specimen from whatever specimen-collecting means are used, to the clinical laboratory. Particularly, where the specimen is a blood sample, it is necessary that the sample be treated immediately to prevent deterioration. This involves further labor, frequently on the part of a physician or surgeon taking the specimen, so that the costs incurred may be very substantial even before the sample reaches the clinical laboratory.

In view of the above considerations, it would be highly desirable that a disposable device be available where the device could be operatively joined to a sample-taking means and where the device could then, either automatically or semi-automatically put the specimen into a stable form and then, preferably, carry out as many of the desired clinical tests as can be arranged for.

Above all, it would be desirable that the equipment used in conjunction with the sample-taking means be sufficiently inexpensive so that it is economical to use it only once, and be sufficiently compact so that it can readily and conveniently be used in combination with a sample-taking means and can be stored in a small volume such as a rectangular box.

Substantial progress toward these objectives has already been reported. For instance, Johnson et al., U.S. pat. No. 3,476,515 have described a pouch-like container consisting essentially of two sheets of flexible plastic bonded together so as to form compartments including reagent chambers in which reagent is stored and reaction chambers in which reaction with a reagent takes place. Fluids are transported through the Johnson et al device by means of pressure applied externally. The means of applying pressure are not specifically disclosed but apparently such means are primarily mechanical.

Blackburn et al., U.S. Pat. No. 3,497,320 disclose a system in which reagents for specific tests are prepackaged in individual disposable containers; the system need not be preprogrammed and a complex apparatus is required to bring into position the particular chemical reagent desired for the particular specimen.

Bednar et al., U.S. Pat. No. 3,504,376 have developed an automatic chemical analyzer which also uses packages of individual reagents which are brought to the specimen in accordance with the particular program of tests designed for the specimen. Again, com-

plex equipment is required, only the reagent packages being disposable.

Auphan et al., U.S. pat. No. 3,607,097 have developed an apparatus which automatically transports a plurality of liquid samples such as blood, through a series of program steps for colorimetric analysis of the samples. The equipment is complex, requiring a plurality of conveyors, and needles and tubes must be provided for taking samples from one set of containers and transferring them to another.

As can be seen from the above references, considerable effort in the direction of automatic or semi-automatic analysis of physiological specimens and in particular, blood specimens has been expended. Nevertheless, it is apparent that devices for carrying out a variety of biochemical tests which are essentially automatic and which are inexpensive enough so that they may be disposed of after one use remain to be developed, or at least, substantially improved.

SUMMARY OF THE INVENTION

A semi-automatic or automatic disposable device for receiving blood or other physiological fluid specimens and carrying out diagnostic tests on same is formed of two main sheets at least one of which is flexible sealed together in a pattern including a junction through which a sample is received and channels leading to compartments for temporary storage of samples, for storage of reagents and for reaction between samples and reagents. Samples are transported within the two main sheets by a combination of pumps and valves formed of at least a third sheet sealed to one of said two main sheets. Said third sheet is sealed to said one of said two main sheets in a pattern having compartments overlying said sample chambers and reagent chambers and also having passages which can be pressurized. Some of said passages overlie said channels so that pressurizing such passages closes off said channels thereby acting as valves. Other passages are connected to said compartments making it possible to pressurize said compartments and expel fluid or reagent from respective chambers between said two main sheets.

Filters may be inserted in channels leading to said fluid passages for the purpose of removing unwanted solid matter. Further, plugs containing reagents, such as for clotting blood, may be placed upstream of said filters so that the product emanating from said filters is serum.

One edge of said device may be enclosed in a block adapted for making connection with said pressurizable passages. Also, said block may be adapted for holding cuvettes into which fluid may be transferred for examination by spectrophotometric or other similar means. One face of said block may be of a self-sealing material such as rubber so that fluid samples may be withdrawn by means of a hypodermic needle.

The device may be fitted to any blood-taking means such as a syringe, a branch tube of a circulating system such as is used for dialysis or a catheter.

Accordingly, an object of the present invention is an improved disposable device suitable for semi-automatic or automatic operation for carrying out diagnostic tests on fluids.

Another object of the present invention is an improved disposable device suitable for semi-automatic or automatic operation for carrying out tests on blood or other physiological fluids.

A further object of the present invention is an improved disposable device suitable for semi-automatic or automatic operation which can be formed of thin flexible plastic and which can be rolled up into a small space for storage.

An important object of the present invention is an improved disposable device suitable for semi-automatic or automatic operation which can be coupled with a computer for a print-out of results.

Yet another object of the present invention is an improved disposable device suitable for semi-automatic or automatic operation which can be coupled to external equipment for programming a desired sequence of tests.

A significant object of the present invention is an improved disposable device suitable for semi-automatic or automatic operation in which a combination of pressurizable passages and compartments formed of flexible plastic can serve as valves and pumps.

Still other objects and advantages of the invention will in part be obvious and will in part be apparent from the specification.

The invention accordingly comprises the features of construction, combinations of elements, and arrangement of parts which will be exemplified in the constructions hereinafter set forth, and the scope of the invention will be indicated in the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

For a fuller understanding of the invention, reference is had to the following description taken in connection with the accompanying drawings, in which:

FIG. 1 is a plan view of a device in accordance with the present invention coupled to a syringe;

FIG. 2 is a view taken along the line 2—2 of FIG. 1;

FIG. 3 is a view taken along the line 3—3 of FIG. 1;

FIG. 3a is a view taken along line 3a—3a of FIG. 1;

FIG. 4 is a sectional view of a terminal block connecting pressurizable passages with a source of pressure;

FIG. 5 is a view taken along 5—5 of FIG. 4;

FIG. 6 is a view taken along the line 6—6 of FIG. 4;

FIG. 7 is an exploded view in perspective of a modification in which a connection is established between two passages lying on either side of a third passage;

FIG. 8 is a view taken along the line 8—8 of FIG. 7;

FIG. 9 is a sectional view of a fluid channel having electrodes therein for the measurement of electrical conductivity;

FIG. 10 is a sectional view of a fluid channel enclosed in conductive plates for the measurement of capacitance;

FIG. 11 is a sectional view of a one-way flap-valve;

FIG. 12 is a schematic view of a hypodermic needle in a vein in an arm for taking blood therefrom;

FIG. 13 shows schematically how the device of the present invention is connected for taking blood from tube through which blood is circulating;

FIG. 14 is a view of the device of the present invention rolled into a spiral and inserted into a rectangular box;

FIG. 15 is a plan view of a pressurizable passage using at least a third sheet of plastic in combination with two main sheets where the third sheet is not co-extensive with said main sheets;

FIG. 16 is a sectional view taken along the line 16—16 of FIG. 15; and

FIG. 17 is a sectional view of a reagent chamber containing an easily-rupturable bag holding said reagent.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

A portion of a device in accordance with the present invention is shown in plan in FIG. 1 and is indicated generally by the reference numeral 21. A principal portion of the device 21 is body 22 consisting principally of two main sheets 23 and 24 (FIG. 2) which are sealed together in a pattern including channels 26, fluid chambers 27, reagent chambers 28 and reaction chambers 29. In FIG. 1 main body 22 is shown connected to syringe 31 at junction 32. In order to take blood, for instance, from a subject, hollow needle 33 is inserted into a vein in the usual manner as shown in FIG. 12 and plunger 34 is withdrawn from the barrel of the syringe, drawing blood or other fluid into the syringe. In the syringe shown in FIG. 1 the plunger has a central tube 36 which connects with junction 32.

Device 21 is normally supplied in collapsed form but any residual air or other gas may be drawn into the plunger as the plunger is withdrawn from its seat in the barrel of the syringe. Optionally a one-way valve, indicated by the dashed circle 37 may be built into central tube 36 to prevent drawing any residual gas into the syringe.

After filling the syringe to the desired level, the plunger is once more forced toward its seat in the barrel of the syringe. As a result, the fluid in the syringe flows through the central tube, and the one-way valve if present, into the channels in the body 22 of the device. Conveniently, the channel arrangement is such that blood flows first into a manifold header 38 and thence into branch channels 26a.

In traversing branch channel 26a unwanted solid materials suspended in the fluid may be removed by positioning a filter 39 in branch channel 26a. Also, pretreatment of the fluid as by contact with a clotting agent may be carried out by positioning a porous plug 41 impregnated with a clotting agent upstream from filter 39. Another important technique is inclusion of anticoagulant such as EDTA or stabilized heparin in porous plug 41 or a fluid chamber 27. Main sheets 23 and 24 are preferably flexible and transparent, although one of said sheets may be rigid. The sheets must be sealable either by heat-sealing, ultrasonic welding or by adhesives. Suitable materials are polyolefins, polyvinyl acetate, polyvinyl chloride, polyvinylidene chloride and copolymers of such materials as well as ionomers, polyethylene terephthalate and any other polymers which are flexible, transparent and sealable by one means or another so that channels for fluid flow there-through may readily be formed in desirable selected patterns. Where one of the two main sheets 23 and 24 is rigid, it may be made of acrylic or any other material to which a flexible sheet can be sealed in a desired pattern. In general, however, the use of two flexible sheets is preferable to one sheet which is rigid and one sheet which is flexible.

Control of flow to the various fluid chambers 27 and reaction chambers 29 is achieved by means of at least one additional sheet of flexible plastic, sealed to a flexible main sheet. Preferably, where both main sheets 23 and 24 are flexible, two auxiliary sheets are used, one sealed to either face of the device. These auxiliary sheets 42 and 43 can be seen in FIGS. 3 and 3a. In the

process of sealing auxiliary or control sheets 42 and 43 to main sheets 23 and 24, pressurizable passages 44, 45 and 46 are formed on both sides of the device 22. Pressurization of passages 44 results in pinching off branch channel 26a, a step which would prevent entry of fluid into chambers 27. Depressurization of passages 44 allows fluid to pass from header 38 through branch channels 26a into chambers 27. Pressurization of passages 46 prevents flow of fluid from chambers 27 and 28 to reaction chambers 29. Depressurization of passages 46 allows flow of fluid from fluid chambers 27 and reagent chambers 28 to reaction chambers 29.

To induce flow of fluid into reaction chambers 29, a driving force is necessary. This force is supplied by pressurization of passages 45, which, in turn, pressurize compartments 47, each of which spans one or both of a fluid chamber and a reaction chamber. In the design shown in FIG. 1, each compartment 47 spans both chambers.

The method by which fluid is introduced into chambers 27 has already been presented. As for reagent chamber 28, this chamber, prior to use, is separated from passage 26 by means of a seal 48 which is weaker than the remainder of the periphery around the chamber. In preparation of reagent chamber 28, one of the main sheets is depressed as by vacuum-forming or the like, and the desired reagent is introduced, in liquid form, into the depression. The other main sheet is then sealed to the first main sheet using a technique such that the seal between the chamber 28 and passage 26 is weaker than around the remainder of the periphery. The weakening of the seal 48 relative to the remainder of the seal can be effected by such means as using a smaller quantity of adhesive, a weaker adhesive, or by using a lower pressure in this region during heat-sealing of the two sheets together. An alternative method of introducing and retaining reagent is shown in FIG. 17, in which an inner bag 49, introduced into reagent chamber 28 during the process of forming chamber 28, contains reagent. Bag 49 is deliberately made of a weak material which is readily rupturable or may have a weak spot in the bag which will break readily when compartment 47 is pressurized.

Auxiliary or control sheets 42 and 43 may be essentially coextensive with main sheets 23 and 24. This is the form as shown in FIG. 1. Alternatively, control sheets 51 and 52 (FIGS. 15 and 16) need be only wide enough for the formation of passages 44, 45 and 46 and compartments 47.

As is evident, by selective pressurization of passages 44 and 46 and compartments 47, it is possible to simulate the action of a pump which can operate in either direction.

In order to carry out the pressurization of the various passages in the control sheets and to make full use of the reactions which take place in chambers 29, a terminal block 53 is attached to one edge of the device. Outlet channels 26b leading from chambers 29 into terminal block 23 are clamped between portions 54 and 56 of terminal block 53 by clamping means such as screws 57. Conveniently, a cuvette is fitted into terminal block 53 to receive fluid transported through channel 26b. Cuvette 58 is preferably of glass and light from a source 59 can be passed therethrough for examination by a spectrophotometer or other optical instrument.

The way in which the pressurizable passages fit into terminal block 53 is shown in FIGS. 4 and 5. To hold

the control sheets 42 and 43 firmly against the block 53, semi-cylindrical, hollow inserts 61 and 62 are placed in the end portions of passages 44, 45 and 46.

Pressure or fluid can be introduced into the pressurizable passages by means of tubes 63 and 64 which lead to pressurizable passages on either side of main sheets 23 and 24. For most purposes, such as in driving or expelling the contents of chambers 27 and 28, pressure is introduced through tubes 63 and 64. Another use for these tubes is for thermostating the contents of chambers 27 and 28. For this purpose, compartment 47 is provided with an aperture 66 through main sheets 23 and 24. Then, water at a controlled temperature can be introduced through tube 63 into a passage 45 on one side of the main sheets to enter compartment 47 surrounding chambers 27 and 28, through aperture 66 to the other side of the main sheets and back through passage 45, also on the other side of the main sheets, and out through 64 to a sink (not shown).

The channels in main sheets 23 and 24 can be put to a variety of uses. For instance, it is possible to bridge a channel 69 lying between two channels 67 and 68 without leakage into channel 69. For example, as shown in exploded form in FIG. 7 and in section in FIG. 8, tube 71 having apertures 72 and 73 therein makes it possible to introduce fluid or gas into channel 67 and transport it to channel 68, passing through channel 69 in the process without leakage into channel 69.

Other uses are shown in FIGS. 9 and 10. In FIG. 9 is shown a channel 74 formed between sheets 76 and 77 by a sealing method, with electrodes 78 and 79 in channel 74. Electrodes 78 and 79 have leads 81 and 82 which penetrate sheet 76 and emerge at the exterior surface thereof so that contacts can be made with brushes 83' and 84'. By use of this arrangement, the conductivity of the fluid in channel 74 can be measured. Alternatively, either 78 or 79 could represent a thermocouple by which the temperature of the fluid in the channel is measured.

In the arrangement of FIG. 10, a channel 83 is formed by sealing sheets 76 and 77 together. Metal foil or conductive paint is then applied to sheets 76 and 77 in the form shown as indicated by the reference numerals 84 and 85. Using brushes 87 and 88 making contact with conductive members 84 and 85 the capacitance of the fluid in channel 83 can be measured.

That section of block 53 through which section 2—2 is taken has apertures or windows therein so that light may be shined through a cuvette 58. However, channel 26b may terminate in a recess in block 53. Where this is the case, it is desirable that block 53 be made of a self-sealing material such as rubber through which a hypodermic needle can be inserted as at 91, so that a sample of the material or fluid in chamber 29 can be withdrawn.

The form of the device as shown in FIG. 1 is particularly suitable for compact storage. The device can be rolled up around the block 53, leaving junction 32 exposed, and inserted into a rectangular box as shown in FIG. 14. This makes for economy in storage space and makes it possible to keep the device sterile until it is ready for use. As aforementioned, the device 21 can be joined to a syringe 31. Alternatively, it can be joined to a catheter (not shown) or to a branch tube 93 on a main tube 94 through which blood or other fluid is flowing.

Control of the direction of fluid flow can be achieved not only by the combination of pressurizable compartments and passages but by a one-way flap valve constructed as shown in FIG. 11. The flap valve 96 consists of two main sheets 97 and 98 which form a channel 99, to the interior of which are sealed two curved sheets 101 and 102. These sheets 101 and 102 end in flat sections 103 and 104 which make contact with each other but are not sealed together. Liquid flowing in the direction of the arrow forces the flat sections or flaps 103 and 104 apart so that flow is permitted. Any attempt to force liquid in the opposite direction forces flaps 103 and 104 together, cutting off or preventing flow.

A wide variety of measurements and tests are possible with the embodiments of the device shown. For instance, reference numeral 78 in FIG. 9 could represent an ion-specific electrode for determination of sodium, potassium, chloride, calcium, hydrogen or magnesium. Using cuvette 58 it is possible to determine colorimetrically bilirubin, cholesterol, uric acid, glucose, total protein and albumin and phosphate.

Studies of kinetics and reaction rates can also be carried out. Examples are the determination of enzyme levels, serum glutamic acid, oxaloacetic acid, transaminase, other transaminases, creatine-phosphokinase, lactic dehydrogenase, and phosphatase. Further, determination of enzyme activity with respect to the rate of reaction on a known concentration of substrate can be carried out.

Other enzymatic reactions which may be carried out are treatment of glucose with glucose oxidase and catalase in which hydrogen peroxide is formed which then decomposes to give oxygen, and decomposition of urea by urease to give gaseous ammonia, and treatment of lactate with lactic dehydrogenase to release detectable hydrogen ions.

Where reaction rates and kinetics are involved, it is desirable that the reagent and the fluid to be reacted enter the reaction chamber 29 at controlled rates. This can be effected by means of suitably located orifices 106 in channels 26 (FIG. 1).

From the above, it can be seen that the device of the present invention makes possible a sequentially-programmed series of diverse reactions in an apparatus which is sufficiently inexpensive so that it can be treated as disposable. Furthermore it can be used in combination with a variety of bloodtaking means such as the syringe of FIG. 1 in which blood flow from the syringe to the device can be effected by the simple expedient of placing a plug 107 of a soft material such as soft rubber on the point of needle 33 and pushing plunger 34 towards the seat of syringe 31. Also, as aforementioned, it can be used for tapping off samples of blood during the process of dialysis to determine the degree of progress of the process. Samples can easily be withdrawn for carrying out studies for which the particular device is not designed. Further, it can be coupled to equipment such as has already been described for carrying out studies of any degree of complexity. These advantages are gained largely by use of the combination of auxiliary sheets of flexible plastic sealed to main sheets of flexible plastic in a design which provides valves and pumps of a type not hitherto available. Provision of the terminal block 53 then makes it feasible to connect the pressurizable passages and compartments in the control sheets with external sources of pressure, vacuum and thermostatted fluid which are

programmed as desired. Thermostating is particularly important where kinetics are involved. Furthermore, the device is such that changes in pressure, conductivity, capacitance, etc. can readily be followed and recorded.

Most important, the device can be coupled with auxiliary equipment which supply test data, where such data is in the form of computer print-out.

It will thus be seen that the objects set forth above, among those made apparent from the preceding description, are efficiently attained and, since certain changes may be made in the above constructions without departing from the spirit and scope of the invention, it is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.

It is also to be understood that the following claims are intended to cover all of the generic and specific features of the invention herein described, and all statements of the scope of the invention which, as a matter of language, might be said to fall therebetween.

I claim:

1. A disposable device for receiving blood or other fluid and physiological samples and carrying out diagnostic tests on said samples, comprising two main sheets, at least one of which is of thin flexible plastic, said main sheets being sealed together in a distribution system pattern including junction means for joining said distribution system to blood-taking means for receiving blood therefrom, a first chamber for receiving and holding a blood sample or fluid derived from said blood, a first channel connecting said first chamber to said junction means, a second chamber for holding a diagnostic test reagent, said second chamber incorporating a breakable seal through which said test reagent may be released by application of pressure, pressure means for breaking the seal on said second chamber, a third chamber for receiving said blood sample and said reagent on breaking said seal, further channels connecting said first and said second chambers with said third chamber and first valve means for controlling the flow of blood or fluid from said first chamber to said third chamber, said valve means comprising at least a third sheet of flexible plastic sealed to one of said two main sheets to form a pressurizable valve passage crossing said channel connecting said first and third chambers, whereby pressurizing said pressurizable valve passage results in closure of said channel connecting said first and third chambers.

2. The disposable device as defined in claim 1 wherein said distribution system comprises pluralities of first, second and third chambers, where said pluralities are not necessarily equal in number, a manifold header connected to said junction and a branch channel leading from said header to each of said first chambers.

3. The disposable device as defined in claim 1 further comprising second valve means of structure similar to said first valve means, said second valve means being disposed so that it lies across the channel from said junction to said first chamber to control flow of blood to same and to prevent back flow of blood from said first chamber.

4. The disposable device as defined in claim 1 wherein said pressure means is a compartment and a pressurizable passage connected thereto, said compart-

ment overlying a first chamber, said compartment and pressurizable passage comprising a sheet of flexible plastic sealed to at least one of said two main sheets of said distribution system, said one sheet being flexible, whereby pressurizing said compartment while one of said valve means at a channel connected to said first chamber is unpressurized causes the blood in said first chamber to be essentially completely expelled in a corresponding direction, the combination of a valve in each of two channels connected to a first chamber and a pressurizable compartment having the characteristics of a two-way pump.

5. The disposable device as defined in claim 4, wherein said compartment spans and overlies corresponding first and second chambers, and said breakable seal in said second chamber is positioned at the junction of said second chamber with its connecting channel so that pressurizing said compartment while said valve in said channel leading to the corresponding third chamber is unpressurized results in breakage of said seal and simultaneous transfer of said blood and reagent to said third chamber where reaction can occur.

6. The disposable device as defined in claim 4 wherein said compartment spans and overlies said first and second chambers, and said device further comprises a bag of flexible plastic and test reagent therein, said bag having a seal breakable by application of pressure in said compartment so that pressurizing said compartment while said valve in said channel leading to the corresponding third chamber is unpressurized results in breakage of said seal and simultaneous transfer of said blood and reagent to said third chamber where reaction can occur.

7. The disposable device as defined in claim 5, wherein each of the channels leading from said first and second chambers to the corresponding third chamber has an orifice of selected size therein whereby the relative rates of flow of blood and reagent to said third chamber can be controlled.

8. The disposable device as defined in claim 1 wherein a branch channel leading to a first chamber has therein a filter of controlled porosity for removal of unwanted suspended solid matter.

9. The disposable device as defined in claim 8, wherein said branch channel has therein between said filter and said header a porous plug impregnated with a reagent for reacting with one or more components of blood passing therethrough to form solid matter, said solid matter being removed from the resultant fluid by said filter as said fluid passes therethrough.

10. The disposable device as defined in claim 1, wherein one of said main sheets is essentially rigid.

11. The disposable device as defined in claim 4 wherein both of said main sheets are flexible and at least one of said valves of said pressurizable compartments are formed of two additional sheets of flexible plastic, one of each being sealed to opposite sides of said main sheets, whereby a channel or a chamber may be subjected to pressure from both sides of said main sheets.

12. The disposable device as defined in claim 11, wherein at least one compartment spanning a chamber spans both faces of said chamber and a portion of said two main sheets exterior to said chamber by the use of two additional plastic sheets sealed to said main sheets, and that part of said two main sheets exterior to said

spanned chamber and interior to said compartment is apertured, whereby a fluid held at a predetermined temperature may be passed through a pressurizable passage into said compartment on one face of said distribution system, through said aperture and out through the corresponding pressurizable passage on the opposite face of said distribution system, as a means of bringing a blood sample or a reagent or both to a predetermined temperature.

13. The disposable device as defined in claim 1, further comprising a terminal block, and at least one channel leading from one of a first and third chamber to an edge of said distribution system, said terminal block being clampable to said edge of said distribution system and having a recess therein at a position corresponding to said one channel leading to said edge, whereby said terminal block provides a closure to said one channel and simultaneously a recess for receiving fluid from a first or a third channel.

14. The disposable device as defined in claim 13 wherein at least one portion of the wall of said recess is of a soft, self-sealing material so that it may be penetrated from the exterior of said block by a hollow needle for taking of fluid from said recess.

15. The disposable device as defined in claim 13 wherein a transparent vessel is held in said recess, said vessel being in a position to receive fluid from said distribution system and the wall of said recess is so apertured to make it possible to pass a light beam through said vessel and fluid contained therein.

16. The disposable device as defined in claim 1, further comprising a terminal block clampable to an edge of said distribution system, said distribution system having a pressurizable passage having an open end at said edge of said distribution system, said terminal block having an aperture therethrough in registry with said open end of said passage, said terminal block further having connecting means for making a fluid-tight connection between said passage and said aperture and between said aperture and an external source of fluid under pressure.

17. The disposable device as defined in claim 12, wherein both of a pair of compartment passages connected to one compartment have an open end proximate but not at an edge of said distribution system, said pair of compartment passages are in registry with each other on opposite faces of said main sheets, said distribution system further comprises a pair of hollow, resilient half-cylinders positioned in said open ends of said compartment passages to hold same open, and said device further comprises a terminal block adapted for clamping to said edge, said block having a matched pair of apertures therethrough, and a pair of first connecting means for connecting each of said apertures to one of said compartment passages and a pair of second connecting means for connecting one of said apertures to a pressurized source of fluid and the other of said apertures to a sink.

18. The disposable device as defined in claim 4 wherein said compartment spans and overlies said first and second chambers and said device further comprises a sealed bag containing reagent, said sealed bag being within said second chamber and having a region weak enough so that pressure exerted by said compartment can rupture said bag, thereby forcing said reagent toward said third chamber through a channel connecting said second and third chambers.

19. The disposable device as defined in claim 4 wherein said distribution system includes three channels two of which lie on either side of a central channel, and a tube connecting said two channels and crossing through said central channel, said tube having an aperture proximate either end and passing through said central channel without fluid interconnection therebetween, thereby making it possible to connect two channels across a central channel for sensing pressure or other characteristics of fluid in said central channel without changing the composition of said fluid.

20. The disposable device as defined in claim 1 further comprising a pair of electrodes sealed into at least one of a channel or chamber for measuring the electrical conductivity thereof.

21. The disposable device as defined in claim 1 further comprising conductive metal on either side of a channel for measuring the capacitance of the fluid therein.

22. The disposable device as defined in claim 1 further comprising at least one one-way valve means in a channel for preventing back-flow of blood or fluid.

23. The disposable device as defined in claim 11 wherein said main sheets and two additional sheets are sufficiently flexible to permit rolling said device into a cylinder for storage in a container.

24. The disposable device as defined in claim 1 wherein said third sheet is essentially coextensive with said main sheets.

25. The disposable device as defined in claim 4 wherein said third sheet is wide enough only to form

said passages and said compartment, said third sheet being sealed to one of said main sheets in the formation of said passages and compartment.

26. A disposable device for taking fluid from a patient and for carrying out diagnostic tests on said fluid, comprising valves, ducts, reservoirs and pumps, at least part of said valves, ducts, reservoirs and pumps being formed of a first pair of flexible plastic sheets joined together in a first pattern including interconnected ducts and chambers, and inlets and outlets for connecting said ducts and chambers with exterior sources of fluid and drains and at least a third flexible plastic sheet joined to said first pair in a second pattern such that at least one pressurizable channel between said third sheet and said first pair of sheets crosses a duct between said first pair of sheets, pressurization of said channel serving to close said duct at said crossing of said duct and said channel, the combination of duct and channel thereby functioning as a valve, said second pattern further being such that a pressurizable region between said third sheet and said first pair of sheets overlies a chamber between said first pair of sheets, said chamber having an input duct and an output duct connected therewith, pressurization of said region serving to expel liquid through one of said input and said output ducts when said one duct is functioning as a valve, whereby the combination of said pressurizable region with said chamber and said pressurizable channel with said duct functions as a pump.

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