19	Europäisches Patentamt European Patent Office Office européen des brevets	1	Publication number:	<b>0 348 116</b> A2
12	EUROPEAN PATENT APPLICATION			
21	Application number: 89306140.8	51	Int. Cl.4: G01N 1/10 , E	301L 3/02
2	Date of filing: 16.06.89			
3 3	Priority: 20.06.88 US 208447		Applicant: HELENA LABORATORIES CORPORATION 1530 Lindbergh Drive Beaumont Texas 77704(US)	
84	Designated Contracting States: DE FR GB IT		Inventor: Golias, Tipton Lee 1530 LIndbergh Drive P.O. Box 752 Beaumont Texas 77704(US)	
		74	Representative: Ranson, Art W.P. Thompson & Co. Coo Church Street Liverpool L1 3AB(GB)	

Method and apparatus for discharging contents of sealed container.

A method and apparatus is disclosed for discharging the contents of a sealed container (10), such as a test tube, having a resilient closure (18). A plurality of tubes or needles (32, 38) are mounted in a socket or holder (50). The tubes needles (32, 38) puncture the closure (18) to establish fluid flow paths between the interior and exterior of the container (10). A pump (66) is positioned at one end (34) of the first fluid flow path (32), and a discharge tube (70) extends through the second fluid flow path (38) such that upon activating the pump (66), air or the like is introduced into the interior of the container (10) creating a pressure therein, in response to which fluid from the container (10) is discharged through the discharge tube (70) onto a specimen plate (88) or the like.

Xerox Copy Centre

## METHOD AND APPARATUS FOR DISCHARGING CONTENTS OF SEALED CONTAINER

5

10

15

20

25

30

35

40

45

50

The present invention relates generally to a method and apparatus for discharging the contents of a sealed container and has a particular utility in discharging the contents of a test tube, blood collection tube or the like.

A test tube is frequently utilized as a collection container for blood specimens. The test tube, with the blood specimen container therein, is usually sealed with a resilient closure or stopper. The test tube and its contents are frequently subjected to a centrifugal operation. After centrifuging, it is typical to remove the stopper from the test tube so that some of the contents may be transferred to a specimen plate or the like for analysis.

There are several problems associated with the aforementioned technique, one of which is the potential for contamination of blood in the test tube once the stopper is removed. Another problem, of course, is that the laboratory technician is exposed to the blood, including any diseases carried by the blood, once the stopper is removed. Currently, there is, of course, substantial concern during the routine testing of blood insofar as exposure of laboratory technicians to the AIDS virus. A related problem which occurs initially upon removal of the stopper is known as aerosoling which refers to a mist or spray of minute quantities of the contents of the test ube which are expelled into the atmosphere by the forces created when the stopper is removed from the test tube.

Prior to the present invention, there were no known satisfactory solutions to these problems. It was customary and routine to remove the stopper or closure from the test tube and thereafter remove some of the contents (for testing or analyzing) by pipetting the contents from the test tube. An alternative technique was to remove the stopper and replace the stopper with a thin-walled flexible tip which would function as a pump such that upon inverting the test tube and alternately squeezing and releasing the resilient tip drops of blood or other contents would be dispensed onto a specimen plate. With both these procedures it was necessary to remove the stopper or closure in order to discharge the contents of the test tube.

The present invention overcomes this shortcoming by providing a method and apparatus for discharging the contents of the test tube without the need for removing the stopper by puncturing the stopper and establishing plural fluid flow paths. Air is introduced through one fluid flow path into the interior of the test tube under slight pressure, such as by a manual pump, in response to which contents of the test tube are discharged through the second fluid flow path. According to the present invention then, apparatus for transferring fluid from a sealed container such as a test tube or the like, the container having a resilient closure at one end, is characterised in that this comprises means for puncturing the resilient closure and for establishing first and second fluid flow paths through the closure, means for holding the puncturing means, and means for creating a pressure differential within the container and for discharging fluid therefrom through the second fluid flow path.

Also according to the present invention, a method is disclosed of discharging the contents from a container such as test tube or the like, the container being sealed with a resilient closure at one end the method being characterised by the steps of puncturing the resilient closure and establishing first and second fluid flow paths therethrough, introducing air through the first fluid flow path into the container, and transferring the contents from the interior of the container through the second fluid flow path in response to the introduction of air into the container through the first fluid flow path.

Furthermore, according to the present invention apparatus for transferring fluid from a container sealed by a resilient closure, is characterised in that the apparatus comprises a plurality of elongated hollow tubes for puncturing the resilient closure and establishing at least first and second fluid flow paths therethrough and a pump for introducing air through the first fluid path into the container causing a pressure increase therein, in response to which fluid in the container is dispensed through the second fluid flow path.

The invention will now be further described by way of example with reference to the accompanying drawings, in which:-

Fig. 1 is an exploded perspective illustration of a test tube, stopper and the apparatus of the present invention;

Fig. 2 is a partial elevational view, in crosssection and to a larger scale, of the apparatus of the present invention in engagement with a closed test tube; and

Fig. 3 is a diagrammatic illustration of discharging the contents of the test tube onto a specimen plate.

Referring to the drawings, a container 10 is illustrated in a form recognisable as a conventional test tube, blood collection tube, or the like. The container 10 is an elongated member with a hollow interior and having a thin wall 12 with the container open at a first end 14 and closed at a bottom or

5

second end 16. A conventional test tube may be formed of glass or other suitable materials having a degree of rigidity and imperviousness sufficient such that specimens collected therein may be conveniently stored, shipped, and even subjected to centrifuging.

The test tube may be provided with a stopper 18 having an enlarged head 20 and a stem or leg 22 such that the stopper is of generally "T" shape in cross-section. The stopper head 20 is frequently provided with a concave upper surface or recess 24. The stopper is made of a resilient material, such as a rubber, and is of a size to sealingly engage the test tube such that the leg 22 of the stopper frictionally fits within the test tube, in engagement with the wall 12, and such that the open first end of the test tube 14 will engage the underside of the head 20 of the stopper. Thus, upon insertion of the stopper into the open test tube, the stopper is urged toward the bottom 16 of the test tube until such time as the first end 14 of the test tube sealingly engages the underside of the head 20. The stopper, frequently called a closure, is made of the same material that functions as a stopper or closure for a vial of medicine and is thus not only resilient, but when punctured by a smalldiameter needle, once the needle is removed, the closure is re-sealed automatically. All of this is, of course, conventional.

Means are provided, according to the principles of the present invention, for discharging the contents of the sealed container without removing the closure 18. Specifically, means are provided for puncturing the closure and for establishing first and second fluid flow paths through the closure. The puncturing means 30 includes a first elongated tube or needle 32 having a first end 34 and a second, sharpened end 36. The needle (which may be a tube, cannula or the like) is preferably formed of stainless steel and may be a conventional number 21 needle having a 0.032 inch (0.0813 cms) outside diameter. The puncturing means also includes a second tube or needle 38 having a first end 40 and a second, sharpened end 42. The second needle 38 may be slightly larger than the first needle 32, such as a stainless steel number 16 needle having an outside diameter of 0.062 inches (0.1575 cms). It should be understood that the needle sizes are merely illustrative. For example, the needle diameters may be selected dependent upon the fluid being collected in the test tube such that they avoid picking up fibrin threads if blood is being collected. Thus, the needles may, in fact, selectively filter the fluid being discharged by virtue of the needle diameter.

The puncturing means is mounted in a holding means 50. The holding means is preferably made of impact styrene and is generally T-shaped in cross-section, including an enlarged head 52 and a leg or stem 54. Just as a test tube is circular in plan view, the holding means 50 is circular in plan view, and the bottom of the leg 54 may be curved

or rounded or convex as at 56 to seat within the concave recess 24 of the stopper. The holding means includes first and second apertures 58, 60 therethrough, in which the first and second needles are respectively inserted. As illustrated generally in

- Figures 1 and 2, for convenience the first needle 32 may extend slightly above and through the head of the holding means 50, for purposes to be described, and the second needle may optionally extend above the head 52 of the holding means 50.
- Discharge means 66 are provided for introduc-15 ing fluid, such as air, into the sealed test tube such that blood may be transferred out of the test tube. Specifically, a container 68 is mounted and secured to the first end 34 of the first needle 32. The container 68 is shaped as an enlarged bulbous 20 member, formed for example of low-density polyethylene, and as such is a resilient, flexible member. The discharging means further includes an elongated, thin hollow tube 70 dimensioned to slidably fit within the second needle 38 and having 25 a first end 72 and a second end 74. The tube 70 is preferably formed of an inert, low-friction material, such as polytetrafluoroethylene, and slides within the second fluid flow path (i.e. within the needle 38) as indicated diagrammatically by the double head-30 ed arrow 76.

The assembly of the apparatus of the present invention to a sealed test tube will now be explained. The holding means 50, which may be thought of as an insert or socket, containing the two needles, is forced downwardly (as illustrated in Figures 1 and 2) to puncture the closure or stopper 18, thus establishing first and second fluid flow paths through the closure. The elongated tube 70 is inserted through the second fluid flow path into the interior of the test tube and, more specifically, into the fluid contained within the test tube.

It may be appreciated that the fluid contained in the test tube may be homogenous, in which case the depth of penetration of the first end 72 of the tube 70 into the contents of the test tube is of lesser significance. However, if the contents of the test tube have been subjected to a centrifuge process, the contents of the test tube may be stratified into a plurality of layers 80, 82. In such a situation, the tube 70 should be inserted through the second needle 38 until the first end 72 of the tube reaches the desired depth, depending upon which layer of contents is to be discharged from the test tube.

In operation, once the closure has been punctured and the holding means pushed into seating contact with the closure, and the tube end 72 adjusted to its desired depth, the bulbous pump 68

3

55

35

40

45

5

5

10

15

20

is flexed or squeezed to force air from the bulbous pump 68 through the first fluid flow path or first needle 32 into the interior of the sealed test tube. This may be accomplished by squeezing opposite sides of the bulbous container or pump 68 as illustrated diagrammatically by two fingers 84 and 86, illustrated in Figure 3 as being on opposite sides of the bulbous pump 68. The introduction of air into the sealed test tube causes a pressure increase or pressure differential within the tube resulting in fluid within the test tube entering the first end 72 of the tube 70 and exiting from the second end 74 of the tube 70 onto a specimen collection plate or the like, diagrammatically identified by reference numeral 88. Figure 3 further illustrates, diagrammatically, a droplet 90 emerging from the second end 74 of the tube 70 and additional droplet 92 on the specimen plate 88.

•The foregoing is a detailed description and explanation of a preferred embodiment of the present invention. Numerous changes may be made without departing from the scope of the present invention as defined in the following claims.

## Claims

1. Apparatus for transferring fluid (80, 82) from a sealed container such as a test tube (10) or the like, the container having a resilient closure (18) at one end (14), characterised in that the apparatus comprises means (30) for puncturing the resilient closure (18) and for establishing first and second fluid flow paths through the closure, means (50) for holding the puncturing means, and means (66) for creating a pressure differential within the container and for discharging fluid (86, 82) therefrom through the second fluid flow path.

2. Apparatus as claimed in claim 1, characterised in that the puncturing means (30) includes two hollow tubes.

3. Apparatus as claimed in claim 1 or 2, characterised in that the puncturing means (30) includes, or the hollow tubes are in the form of, two hollow needles (32, 38).

4. Apparatus as claimed in claim 3, characterised in that the two hollow needles (32, 38) are laterally spaced apart.

5. Apparatus as claimed in any one of claims 1 to 4, characterised in that the holding means (50) is configured to seat on the closure (18).

6. Apparatus as claimed in any one of claims 1 to 5, characterised in that the closure (48) has a concave upper closure surface (24) and the holding means includes a convex portion (56) for seating on the concave closure surface (24). 7. Apparatus as claimed in any one of claims 1 to 6, characterised in that the holding means (50) includes first and second apertures therethrough.

8. Apparatus as claimed in any one of claims 1 to 6, characterised in that the holding means (50) includes first and second apertures therethrough for retaining the puncturing means (30) therein.

9. Apparatus as claimed in any one of claims 1 to 8, characterised in that the pressure differential creating means (66) includes a flexible chamber (68) for introducing air into the container.

10. Apparatus as claimed in any one of claims 1 to 9, characterised in that it includes an elongated hollow tube (70) extending through the second fluid flow path, one end (72) of the tube (70) being positioned interiorly of the container (10) and the other end (74) of said tube (70) being positioned exteriorly of the container (10).

11. Apparatus as claimed in claim 10, characterised in that the hollow tube (70) is mounted for slidable movement relative to the holding means (50).

12. Apparatus as claimed in any one of claims 1 to 11, characterised in that the fluid intended to be used in the container includes strands therein and the second fluid flow path has an inside diameter less than the size of the strands.

13. A method of discharging the contents from a container (10) such as test tube or the like, the container being sealed with a resilient closure (18) at one end (14) the method being characterised by the steps of puncturing the resilient closure (18) and establishing first and second fluid flow paths therethrough, introducing air through the first fluid flow path into the container, and transferring the contents from the interior of the container through the second fluid flow path in response to the introduction of air into the container through the first fluid flow path.

14. A method as claimed in claim 13, characterised in that the container contents are stratified into at least two layers (80, 28) and the step of transferring the contents through the second fluid flow path further includes selectively determining the layer from which fluid is transferred from the container (10).

15. A method as claimed in claim 13 or 14, characterised in that the step of transferring includes filtering a portion of the container contents.

16. Apparatus for transferring fluid from a container (10) sealed by a resilient closure (18) characterised in that the apparatus comprises a plurality of elongated hollow tubes (32, 38) for puncturing the resilient closure (18) and establishing at least first and second fluid flow paths therethrough and a pump (66) for introducing air through the first fluid path into the container (10) causing a pressure increase therein, in response to which fluid in the

55

25

30

35

40

45

container (10) is dispensed through the second fluid flow path.

•

