Express Mail Label No. EL 416966551US
Date of Deposit: May 2, 2001

UNITED STATES PATENT APPLICATION

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FOR: FLASHBACK BLOOD COLLECTION NEEDLE

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to a device for collecting blood samples by performing venipuncture on a patient. More particularly, the present invention relates to a needle assembly for multiple sample blood collection that allows a phlebotomist to determine whether vein entry has occurred when collecting a blood sample from a patient into an evacuated blood collection tube.

2. Description of Related Art

Venipuncture is the primary method used for acquiring blood samples for laboratory testing. In performing venipuncture procedures, a phlebotomist must follow several steps simultaneously. Such steps include assessing the patient's overall physical and psychological condition so as to properly select a venipuncture site and technique. The phlebotomist must also select the proper corresponding equipment and perform the technique so as to not only control bleeding, but also to properly collect and identify fluid specimens for testing. The phlebotomist must ascertain all of these coinciding factors, as such factors may adversely affect the distension of the vein and the length of the venipuncture procedure.

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Various venipuncture devices have been developed which address the above-described problems. These devices incorporate a needle assembly having a housing defining a chamber therewithin, wherein a single cannula pointed at both ends, is affixed to the housing. The intravenous end of the cannula is adapted for penetration of a patient's vein, and the non-patient end of the cannula has a sealable sleeve and adapted for penetration of a penetrable stop positioned within an evacuated container.

Upon vein entry with the intravenous end of the cannula, blood will flow through the cannula, into the sealable sleeve and into the housing chamber which is clear or translucent for visualization ("flashback"). Once air is vented from the housing chamber, the blood therewithin is pressurized each time the sealable sleeve is pushed toward the housing chamber upon activation of an evacuation container.

Due to the length of time between vein entry and flashback, the phlebotomist erroneously believes that satisfactory vein entry has not been achieved since there is no immediate indication thereof in the see-through chamber. Often the phlebotomist unnecessarily repeats the venipuncture procedure, requiring replacement of the evacuated container and/or the needle assembly itself. Such a repetitive process prolongs the physical and emotional discomfort endured by the patient.

It is therefore desirable to provide a fast, accurate and cost effective solution to conventional blood collection procedures upon which the phlebotomist may consistently rely on flashback to provide satisfactory venous entry. Moreover, it is particularly desirable to provide a blood collection device that permits blood flow through a relatively short needle

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directly into a flashback chamber, thereby providing immediate indication of successful vein entry.

SUMMARY OF THE INVENTION

The present invention provides a needle assembly for the extraction of at least one fluid sample into an evacuated container for laboratory testing, which needle assembly obviates the need for venting by providing a clear or translucent housing chamber with sufficient dead space for blood to flow into the chamber for visualization by the user to confirm successful vein entry.

A needle assembly is provided for collecting at least one fluid sample from a patient for subsequent discharge into at least one evacuated container. The needle assembly of the present invention includes a transparent or translucent housing having a fluid inlet end defined by a cylindrical exterior wall. The wall delineates an annular flashback chamber within the housing for retention of a blood sample therein. The housing further includes a fluid outlet end in communication with said fluid inlet end. A first cannula in fluid communication with the blood inlet end extends outwardly therefrom. The first cannula has an interior extremity positioned proximate the chamber and an exterior extremity opposed thereto that is adapted for puncture of a patient's vein. Similarly, a second cannula is provided in fluid communication with the fluid outlet end and extends outwardly therefrom. The second cannula has an interior extremity positioned proximate the first interior extremity and further includes an exterior extremity opposed to said second interior

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extremity. The second exterior extremity is adapted for puncture of a penetrable stopper in an evacuated container. The first and second cannulae are preferably in axial alignment with one another so as to provide an axial fluid flow path therebetween along a length of the housing. The second cannula further includes a sealable sleeve.

DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of the needle assembly of the present invention.

FIG. 2 is a side view of the needle assembly of FIG. 1.

FIG. 3 is a side cross-sectional view of the needle assembly of FIG. 2 taken along 3-3 thereof.

FIG. 4 illustrates the use of the needle assembly of FIG. 1 with a conventional needle holder.

FIG. 5 is a cross-sectional view of the needle assembly in use with a conventional needle holder and a container during venipuncture of a patient's arm.

FIG. 6 is a cross-sectional view of an alternate embodiment of the needle assembly of the present invention.

FIG. 7 illustrates the use of the needle assembly of FIG. 6 with a conventional needle holder.

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FIG. 8 is a cross-sectional view of the needle assembly in use with a conventional needle holder and a container during venipuncture of a patient's arm.

DETAILED DESCRIPTION

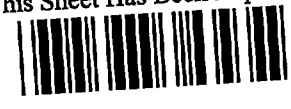
The present invention provides a needle assembly for blood collection that provides a visual indication of vein entry ("flashback") upon collection of a blood or other fluid sample from a patient into one or more evacuated blood collection tubes.

As illustrated in FIGS. 1-4, a needle assembly **10** of the present invention includes a transparent or translucent housing **12** which supports a fluid inlet needle (first cannula) on one side of the housing and a fluid outlet needle (second cannula) on an opposite side thereof. Fluid collected from the first cannula is immediately visualized through the housing to provide a timely indication of proper vein entry.

As shown in FIGS. 1-3, needle assembly **10** includes a housing **12** having a fluid inlet end **14** and a fluid outlet end **16** adjacent thereto. Fluid inlet end **14** is defined by a cylindrical exterior wall **18** having an annular shoulder **20** protruding from an extremity thereof proximate fluid outlet end **16**. Wall **18** circumscribes a flashback chamber **22** therein. Chamber **22** further includes an annular trench **26** defined within a frustoconical taper **28** depending outwardly from wall **18**.

Fluid inlet end **14** is further defined by an injection end **30** wherein a cylindrical

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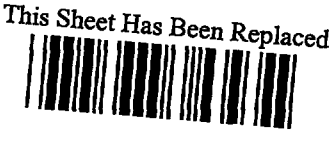
extension **32** is provided. Cylindrical extension **32**, having an outer diameter smaller than an inner diameter of wall **18**, protrudes outwardly from wall **18** with frustoconical taper **28** providing a bridge therebetween.

Cylindrical extension **32** has a large bore **34** extending therethrough which is sized to accommodate insertion and securement of a first fluid inlet cannula **36** therein. First cannula **36** has an exterior extremity **40** projecting outwardly from injection end **30** and further has a sharpened bevel **42**. A first interior extremity **44** is defined at an opposite end of cannula **36** having a blunt tip **46** for insertion of cannula **36** in injection end **30**. Bevel **42** and blunt tip **46** each include a correspondingly configured opening for uninterrupted passage of a fluid therethrough.

First cannula **36** is positioned in bore **34** such that first interior extremity **44** lies proximate annular trench **26** so as to remain in fluid communication therewith. Once cannula **36** is properly positioned, it may be frictionally engaged by bore **34** or affixed therein by means of an adhesive or the like.

Bore **34** spans an extent of cylindrical extension **32** and extends into taper **28** so as to be in communication with each of first cannula **36** and a second fluid outlet cannula **52**. Second cannula **52**, has a second interior extremity **54** with a blunt tip **56**. Blunt tip **56** circumscribes the opening within trench **26** so as to be adjacent first interior extremity **44** of first cannula **36**. Second cannula **52** further includes an exterior extremity **58** having a non-patient bevel end **60**. Second cannula **52** extends outwardly from fluid outlet end **16** so as to form an elongate fluid passageway through housing **12**. Non-patient bevel end **60** further

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includes a sealable sleeve **61** covering exterior extremity **58.**

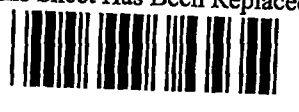
Fluid outlet end **16** of housing **12** includes a disc-like base **64** having a cylindrical protrusion **66** extending outwardly therefrom. Base **64** includes an annular flange **68** which is seated in cooperation with annular shoulder **20** of fluid inlet end **14** so as to form an interface **80** therebetween. The ends may be secured together along interface **80** by appropriate fastening means such as adhesives or the like.

As shown in FIG. 4, fluid outlet end **16** preferably includes means for securing needle assembly **10** to a holder **78** thereto. Such means includes a plurality of helical threads **82.** Although a system of mating threads is shown herein, it is understood that any attachment means conducive to the practice of the present invention may be utilized.

Housing **12** is constructed from a translucent or transparent material so that a user of the assembly can readily view the contents of chamber **22.** Although translucent rigid plastic is desirable, various sealed ports or windows such as window **100** shown in FIG. 2 may be used which enable the user to view the contents within chamber **22.**

As shown in FIG. 4, during a conventional venipuncture procedure, needle assembly **10** as connected to holder **78** punctures the patient's skin to make a vein entry. Flashback chamber **22** provides sufficient space in chamber **22** to allow blood to flow beyond the opening of interior extremity **44** into trench **26** for instantaneous flashback visualization in relation to venous entry. In this manner, the phlebotomist has an almost instant visual indication that vein entry has been satisfactorily achieved by first cannula **36.** Thus, upon satisfactory vein entry, air that is at atmospheric pressure within chamber **22** experiences

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compression due to the influence of venous pressure. Because the venous pressure exceeds the atmospheric pressure within chamber **22**, blood flows thereinto and covers the opening of second interior extremity **54**. Blood flow ceases once the pressure within chamber **22** and the venous pressure are equal.

Once venous entry is visually confirmed by the phlebotomist, container **70**, which is evacuated, is then inserted into holder **78** such that bevel **60** of second cannula **52** penetrates stopper **72** as shown in FIG. 5. Upon entrance into a vacuum portion **79** by second cannula **52**, a negative pressure gradient is transmitted to the needle assembly. A lower pressure within the container causes blood to flow from the vein and into the container. Because axially aligned cannulae **36** and **52** provide an unblocked path for blood flow into container **70**, under the influence of the negative pressure gradient. The blood present in trench **26** and chamber **22** is drawn into container **70** through the opening of second interior extremity **54** because of the negative pressure gradient in chamber **22**. When this occurs, the pressure within chamber **22** and trench **26** drops below the patient's venous pressure, whereby the higher venous pressure will pressurize trench **26** and chamber **26** back to venous pressure again. The net effect is that a small column of blood, pulsating within trench **26**, attempts to close the opening and minimizing air within chamber **22** from being drawn into container **70** by second interior extremity **54**. Blood may be collected into multiple evacuated containers so that corresponding multiple samples may be obtained using a single needle assembly **10**. The venipuncture procedure is terminated by removal of first cannula **36** from the patient's vein.

An additional embodiment of the present invention, as shown in FIGS. 6-8 includes

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many components which are substantially identical to the components of FIGS. 1-5. Accordingly, similar components performing similar functions will be numbered identically to those components of FIGS. 1-5, except that a suffix "a" will be used to identify those similar components of FIGS. 6-8.

FIG. 6 shows an alternate embodiment of the present invention, needle assembly **200** comprising an elongated flashback chamber **210** defined within housing **12a**. Chamber **210** includes an elongated area for retention of a fluid sample therewithin. Chamber **210** includes a substantially concave curvature that provides enhanced visual magnification during sample collection.

As illustrated in FIG. 7 during a conventional venipuncture, needle assembly **200** as connected to holder **78a**, punctures the patient's skin to make a vein entry. Chamber **210** indicates successful vein entry and reduces the draw of air present in housing **12a**. Thus, upon satisfactory vein entry, air that is at atmospheric pressure within chamber **210** experiences compression due to the influence of venous pressure. Because the venous pressure exceeds the atmospheric pressure within chamber **210**, blood flows thereinto. Blood flow ceases once the pressure within chamber **210** and the venous pressure are equal.

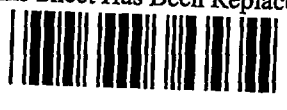
Once venous entry is visually confirmed by the phlebotomist, container **70a**, which is evacuated, is then inserted into holder **78a** such that bevel **60a** of second cannula **52a** penetrates stopper **72a** as shown in FIG. 8. Upon entrance into vacuum portion **79a** by second cannula **52a**, a negative pressure gradient is transmitted to chamber **210**. A lower pressure within the container causes blood to flow from chamber **210** into the container.

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Various other changes and modifications may be effected therein by one skilled in the art without departing from the scope or spirit of the invention, and it is intended to claim all such changes and modifications as fall within the scope of the invention.

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WHAT IS CLAIMED IS:

1. A needle assembly comprising:

a housing having a fluid inlet end and an opposed fluid outlet end in communication therewith, said housing defined by a cylindrical exterior wall that delineates an annular flashback chamber for retention of said sample therewithin and includes means for visualizing presence of a fluid in said chamber;

a first cannula in fluid communication with said fluid inlet end and extending outwardly therefrom, said first cannula having a first interior extremity with an opening positioned proximate said chamber and a first exterior extremity opposite thereto;

a second cannula in fluid communication with said fluid outlet end and extending outwardly therefrom, said second cannula having a second interior extremity with an opening positioned proximate said first interior extremity, said second cannula further having a second exterior extremity opposed to said second interior extremity;

wherein said first and second cannulae are in axial alignment with one another to provide an axial fluid flow path therebetween along a length of said housing.

2. The needle assembly of Claim 1, wherein said chamber includes an annular trench for retention of said sample.

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3. The needle assembly of Claim 1, wherein said visualizing means includes said wall being constructed of a material selected from the group of materials consisting of transparent and translucent rigid plastics.

4. The needle assembly of Claim 1, wherein said visualizing means includes a transparent window for viewing said fluid within said chamber.

5. The needle assembly of Claim 1, wherein an annular shoulder supports an integral cylindrical extension protruding from said said fluid inlet end toward said first exterior extremity.

6. The needle assembly of Claim 5, wherein a cylindrical bore is defined through said extension so as to simultaneously be in fluid communication with said chamber and accommodate insertion and securement of at least one of said first cannula and said second cannula therein.

7. 7. The needle assembly of Claim 5, wherein said blood outlet end includes an annular flange seated in cooperation with said shoulder so as to form an interface therebetween, said annular flange having a cylindrical protrusion extending therefrom toward said second exterior extremity.

8. The needle assembly of Claim 7, wherein said blood inlet end and said blood outlet end are secured to one another at said interface.



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9. The needle assembly of Claim 7, wherein said cylindrical protrusion includes means for connecting to a needle holder.

10. The needle assembly of Claim 9, wherein said connecting means includes a plurality of helical threads circumferentially defined on an exterior surface of said cylindrical protrusion.

11. A percutaneous access system for the collection of at least one fluid sample from a patient, comprising:

at least one evacuated container having a puncturable stopper for collection of said sample therein; and

a needle assembly for collecting at least one said sample from a patient for subsequent discharge into at least one evacuated container, said needle assembly comprising:

a housing having a fluid inlet end and an opposed fluid outlet end in communication therewith, said housing defined by a substantially cylindrical exterior wall that delineates an annular flashback chamber for retention of said sample therewithin and includes means for visualizing presence of a fluid in said chamber;

a first cannula in fluid communication with said fluid inlet end and extending outwardly therefrom, said first cannula having a first interior extremity with an opening



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positioned proximate said chamber and a first exterior extremity opposite thereto adapted for percutaneous insertion into a patient;

a second cannula in fluid communication with said fluid outlet end and extending outwardly therefrom, said second cannula having a second interior extremity with an opening positioned proximate said first interior extremity, said second cannula further having a second exterior extremity opposed to said second interior extremity and adapted for puncturable engagement with said evacuated container;

wherein said first and second cannulae are in axial alignment with one another to provide an axial fluid flow path therebetween along a length of said housing.

12. The needle assembly of Claim 11, wherein said chamber includes an annular trench for retention of said sample therewithin prior to evacuation of said sample into said evacuated container.

13. The needle assembly of Claim 11, wherein said visualizing means includes said wall being constructed of a material selected from the group of materials consisting of transparent and translucent rigid plastics.

14. The needle assembly of Claim 11, wherein said visualizing means includes a transparent window for viewing said fluid within said chamber.

15. The needle assembly of Claim 11, wherein an annular shoulder supports an



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integral cylindrical extension protruding from said fluid inlet end toward said first exterior extremity.

16. The needle assembly of Claim 15, wherein a cylindrical bore is defined through said extension so as to simultaneously be in fluid communication with said chamber and accommodate insertion and securement of at least one of said first cannula and said second cannula therein.

8. 17. The needle assembly of Claim 15, wherein said blood outlet end includes an annular flange seated in cooperation with said shoulder so as to form an interface therebetween, said annular flange having a cylindrical protrusion extending therefrom toward said second exterior extremity.

18. The needle assembly of Claim 17, wherein said blood inlet end and said blood outlet end are secured to one another at said interface.

19. The needle assembly of Claim 17, wherein said cylindrical protrusion includes means for connecting a holder for said evacuated container.

20. The needle assembly of Claim 19, wherein said connecting means includes a plurality of helical threads circumferentially defined on an exterior surface of said cylindrical protrusion.



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