FLASHBACK BLOOD COLLECTION NEEDLE

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0001] 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

[0002] 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, perform the technique so as to control bleeding, and 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.

[0003] Various venipuncture devices have been developed to address the above-described problems. These devices include a needle assembly with a housing that defines a chamber therein. 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. The non-patient end of the cannula has a sealable sleeve and is adapted for penetration of a penetrable stop positioned within an evacuated container.

[0004] 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 therein is pressurized each time the sealable sleeve is pushed toward the housing chamber upon activation of an evacuated container.

[0005] 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 of vein entry 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. In such cases, a phlebotomist may use a blood collection set to provide some entry indication, and will then incur the cost of the blood collection set, as well as the cost of a discard tube.

[0006] 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 directly into a flashback chamber, thereby providing immediate indication of successful vein entry.

SUMMARY OF THE INVENTION

[0007] The present invention provides a needle assembly for the extraction of at least one fluid sample into an evacuated container for laboratory testing. The needle assembly provides 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.

[0008] 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 extremity. The second exterior extremity is adapted for puncture of a penetrable stopper in an evacuated container. The first and second cannula are preferably in axial alignment with one another to provide an axial fluid flow path therebetween along a length of the housing. The second cannula further includes a sealable sleeve. The volumes defined by the lumens through the cannulas, the chamber and the sleeve are selected to achieve a very rapid indication of vein entry while avoiding the need for both a sealable vent or plug and a discard tube.

DESCRIPTION OF THE DRAWINGS

[0009] FIG. 1 is a perspective view of the needle assembly of the present invention.

[0010] FIG. 2 is a side view of the needle assembly of FIG. 1.

[0011] FIG. 3 is a side cross-sectional view of the needle assembly of FIG. 2 taken along 3-3 thereof.

[0012] FIG. 4 illustrates the use of the needle assembly of FIG. 1 with a conventional needle holder.

[0013] 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.

[0014] FIG. 6 is a cross-sectional view of an alternate embodiment of the needle assembly of the present invention.

[0015] FIG. 7 illustrates the use of the needle assembly of FIG. 6 with a conventional needle holder.

[0016] 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.

[0017] FIG. 9 is a schematic view of the needle assembly of FIG. 6 prior to use.

[0018] FIG. 10 is a schematic view similar to FIG. 9, but showing the first sign of venous entry.

[0019] FIG. 11 is a schematic view of a third embodiment.

DETAILED DESCRIPTION

[0020] 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.

[0021] As illustrated in FIGS. 1-4, a needle assembly **10** of the present invention includes a transparent or translucent housing **12** that 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.

[0022] 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**. 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**.

[0023] Fluid inlet end **14** is further defined by an injection end **30** wherein a cylindrical 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.

[0024] 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.

[0025] 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 positioned properly, it may be frictionally engaged by bore **34** or affixed therein by means of an adhesive or the like.

[0026] 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 includes a sealable sleeve **61** covering exterior extremity **58.**

[0027] 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.

[0028] As shown in FIG. 4, fluid outlet end **16** preferably includes means for securing needle assembly **10** to a holder **78**. 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.

[0029] 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**.

[0030] 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 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.

[0031] 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 cannula **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 **22** 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.

[0032] An additional embodiment of the present invention is shown in FIGS. 6-8, and includes many components which are substantially identical to the components of FIGS. 1-5.

[0033] With reference to FIG. 6, the alternate embodiment is directed to a needle assembly **210** with a housing **212** having a fluid inlet end **214**, a fluid outlet end **216** and a frustum-shaped exterior wall **218** extending between the ends. Exterior wall **218** defines an outer chamber **220**. Housing **212** further includes a cylindrical interior wall **224** that extends in outer chamber **220** from fluid inlet end **214** substantially concentrically with cylindrical exterior wall **218** for a major portion of the distance between fluid inlet end **214** and fluid outlet end **216**. The open end of cylindrical interior wall **224** is spaced from outlet end **216** of housing **212** by a distance "a" of only about 1.15mm. Cylindrical interior wall **224** defines a flashback chamber **226**. The elongate flashback chamber **226** behaves like a straw that draws residual blood in housing **212** from the previous draw into a new evacuated tube as explained herein.

[0034] Needle assembly **210** also includes a fluid inlet cannula **236** having an exterior end **240** that defines a sharpened bevel and an interior end **244** that is mounted fixedly in fluid inlet end **214** of housing **212**. Fluid inlet cannula **236** is characterized further by a

substantially cylindrical lumen **248** extending between the ends and communicating with the interior of housing **212**.

[0035] Needle assembly **210** further includes a fluid outlet cannula **252**. Outlet cannula **252** concludes a blunt interior end **254**, an exterior end **260** defining a sharpened bevel and a substantially cylindrical lumen **262** extending between the ends. Portions of outlet cannula **252** between the ends are securely affixed in outlet end **216** of housing **212**. Outlet cannula **252** is mounted so that interior end **254** passes substantially coaxially into interior wall **224** and so that interior end **254** of outlet cannula **252** substantially aligns axially with interior end **244** of inlet cannula **236**. Additionally, interior end **254** of outlet cannula **252** is spaced only a small distance from interior end **244** of inlet cannula **236**. This distance "b" between inlet and outlet cannulas **236** and **252** preferably is between 0.5mm and 1.2mm and most preferably about 1.0mm. An axial gap between interior end **254** of outlet cannula **252** and interior end **244** of inlet cannula **236** that is less than 0.5mm may result in a flashback that is inconsistent. On the other hand, a gap that is greater than 1.2mm may result in drawing more air from housing **212** into the evacuated tube.

[0036] Cylindrical interior wall **224** is dimensioned relative to outlet cannula **252** to achieve both desirable flow of blood through assembly **210** and to achieve effective flashback indication. In particular, cylindrical interior wall **224** preferably is dimensioned to provide a radial gap around outlet cannula **252** of about 0.2mm, as indicated by dimension "c" in FIG. 6. This gap achieves a substantially laminar blood flow within flashback chamber **226** and prevents blood hemolysis. Additionally, the small radial gap between cylindrical inner wall **224** and outlet cannula **252** enables a drop of blood to be spread thinly across the radial gap in flashback chamber **226** to provide a magnified flashback indication with a very small volume of blood. Thus, an easily

visualized flashback indication is achieved quickly at the first appearance of blood from interior end **244** of inlet cannula **236**. The small radial gap also has been found to increase surface adhesion between the blood and the inner surface of cylindrical interior wall **224** for further reducing the air draw from housing **212** into the evacuated tube **270** shown in FIG. 8.

[0037] Needle assembly **210** further includes a sealable sleeve **261** mounted to fluid outlet end **216** of housing **212** and covering exterior end **258** of outlet cannula **252** when sealable sleeve **261** is in an unbiased condition. However, sealable sleeve **261** can be collapsed in response to pressure exerted by stopper **272** of evacuated tube **270** for urging exterior end **260** of outlet cannula **252** through both sealable sleeve **261** and stopper of **272** evacuated tube **270**.

[0038] As illustrated in FIG. 7 during a conventional venipuncture, needle assembly **210** is connected to holder **278** and punctures the patient's skin to make a vein entry. Flashback chamber **226** indicates successful vein entry and reduces the draw of air present in housing **212**. Thus, upon satisfactory vein entry, air that is at atmospheric pressure within chamber **220** experiences compression due to the influence of venous pressure. Because the venous pressure exceeds the atmospheric pressure within chamber **220**, blood flows thereinto. Blood flow ceases once the pressure within chamber **220** and the venous pressure are equal.

[0039] Once venous entry is visually confirmed by the phlebotomist, container **270**, which is evacuated, is then inserted into holder **278** such that exterior end **260** of second cannula **252** penetrates stopper **272** as shown in FIG. 8. Upon entrance into vacuum portion **279** by second cannula **252**, a negative pressure gradient is transmitted to chambers **220** and **226**. A lower pressure within the container **270** causes blood to flow from chambers **220** and **226** into the container **270**.

[0040] The needle assemblies described above desirably should be small for convenient use, but should constructed to ensure reliable and rapid flashback. The occurrence of flashback in the needle assemblies described and illustrated above operate pursuant to the ideal gas law. In particular, at very low densities all gases and vapors approach ideal gas behavior and closely follow the Boyle's and Charles' laws given by:

$$P_1 V_1 = P_2 V_2$$

where:

P_1 denotes the pressure of air within the needle assembly before needle insertion,

P_2 denotes the pressure of air within the needle assembly after vein entry;

V_1 denotes the volume of air within the needle assembly before vein entry; and

V_2 denotes the volume of air within the needle assembly after vein entry.

[0041] Design parameters should keep the needle device as small as possible for easy use, while ensuring an appropriate volume as specified by the preceding equation. FIGS. 9 and 10 provide schematic representations of the needle assembly **210** of FIGS. 6-8 for purposes of depicting the application of the ideal gas law. In this regard, **A** identifies the volume of lumen **248** thought inlet cannula **236**. **B** denotes the total volume of outer chamber **220**, inner chamber **226**, lumen **242** through outlet cannula **252** and sealable sleeve **261**. Referring again to the preceding equation, P_1 is the pressure within needle assembly **210** before use, and hence substantially equals atmospheric pressure. Atmospheric pressure will vary slightly from time to time and from location to location. However, for purposes of this analysis, atmospheric pressure P_1 will be assumed to be 760mm Hg. P_2 in the preceding equation is the volume of the dead space in needle assembly **210** after vein entry. More particularly, after vein entry, blood will fill lumen

248 of inlet cannula **236**, thereby reducing the volume to be occupied by gas in remaining portions of needle assembly **210** and hence increasing the pressure of air in the remaining portion of needle assembly **210**. A needle assembly with dimensions approximately as shown in FIGS. 6-10 will have a pressure P_2 of about 790mm Hg at venous pressure (with tourniquet). V_1 in the preceding equation defines the volume of the total dead spaced in needle assembly **210** before use, and hence will equal **A** + **B** as shown in FIG. 9. V_2 defines the dead space in the device after vein entry, and with lumen **248** of inlet cannula **236** filled with blood, as shown in FIG. 10. Hence, V_2 in the preceding equation will equal **B**. These input parameters can be employed to define a minimum desired size for the respective components of needle assembly **200** as shown in the following application of the ideal gas law equation.

$$P_1 V_1 = P_2 V_2$$

$$P_1/P_2 = V_2/ V_1$$

$$760/790 = B/(A+B)$$

$$0.962 = B/(A+B)$$

$$0.962(A+B) = B$$

$$0.038B = 0.962A$$

$$B=25.3A$$

Therefore, dead space in housing **212**, outlet cannula **252** and sleeve **261** preferably is at least 25.3 times the volume defined by lumen **248** through inlet cannula **236**, and most preferably is about 26 times the volume of lumen **248**.

[0042] Upon satisfactory vein entry, air within housing **212** is compressed under the influence of venous pressure, thereby allowing blood to flow into inner chamber **220** for

visualization. Blood flow stops once pressure within housing **212** equals the venous pressure, covering inner end **254** of outlet cannula **252.**

[0043] The immediate response when an evacuated tube is placed in communication with outlet cannula **252** is to draw blood and air from the vein and housing **212** into tube **270**, as shown in FIG. 8. The highest pressure gradient is always maintained between the vein and the evacuated tube **270**. The axially aligned inlet cannula **236** and outlet cannula **252** provided an unobstructed path for blood flow from the vein into evacuated tube **270**. Conversely, air in housing **212** has tortuous path to outlet cannula **252** and the flow of air from housing **212** to outlet cannula **252** is detoured by the axially unobstructed blood flow between inlet and outlet cannula **236** and **252** respectively. The moment some air in housing **212** is drawn into the evacuated tube **270**, pressure within housing **212** drops below the venous pressure. Accordingly, more air loss is prevented until housing **212** is pressurized back venous pressure, and blood flows in flashback chamber **226** until the pressure in housing **212** equals the venous pressure. The above described pressurization and depressurization dynamics within housing **212** results in column of blood pulsating in flashback chamber **226**, and hence minimizing air draw into the evacuated tube **270**.

[0044] The preceding embodiments show structurally separate inlet and outlet cannulas that are axially aligned with one other and placed in close end-to-end relationship with one another. However, the principals of the invention described above also can be achieved with a single cannula formed with a transverse slot or aperture within the flashback chamber. For example, FIG. 11 schematically shows a needle assembly **310** with a housing **312** that is substantially identical to housing **212** described and illustrated above. Needle assembly **310** differs from needle assembly **210** in that a single double end needle cannula **336** is provided and passes entirely through housing **312**. More

particularly, needle cannula **336** includes a venous entry end **338**, a non-patient end **340** and a lumen **342** extending therebetween. Portions of cannula **336** within inner wall **324** include a slot or aperture **344** to provide communication between lumen **342** and flashback chamber **336** within inner wall **324**. Needle assembly **310** functions substantially in the same manner as needle assembly **210** described and illustrated above.

[0045] Although the relative dimensional calculations, volumes and pressures were carried out with respect to the second embodiment, the same theory applied to the first embodiment, and to other unillustrated needle assemblies with a flashback chamber. Accordingly, the scope of the as defined by the appending claims is not limited to the specific illustrated embodiments. 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.

WHAT IS CLAIMED IS:

1. A needle assembly comprising:

a housing having an inlet end, an outlet end and a chamber formed between said ends;

an inlet cannula having opposite external and internal ends and a lumen extending between said ends, said inlet cannula being mounted to said housing such that said external end of said inlet cannula is externally of said housing and such that said lumen through said inlet cannula communicates with said chamber;

an outlet cannula having opposite internal and external ends and a lumen extending between said ends, said outlet cannula being mounted to said housing such that said external end of said outlet cannula is externally of said housing and such that said lumen of said outlet cannula communicates with said chamber;

a sealable sleeve mounted over portions of said outlet cannula disposed externally of said housing; and

wherein said sealable sleeve, said lumen of said outlet cannula and said chamber of said housing define a combined volume sufficiently greater than a volume defined by said lumen of said inlet cannula for achieving a rapid indication of venous entry adjacent said external end of said inlet cannula.

2. The needle assembly of Claim 1, wherein said combined volume of said sealable sleeve, said lumen of said outlet cannula and said chamber is approximately 26 times said volume of said lumen of said inlet cannula.

3. The needle assembly of Claim 1, wherein said combined volume of said sealable sleeve, said lumen of said outlet cannula and said chamber is at least equal to a product of a pre-use volume of said needle assembly multiplied by a ratio of pressure in said needle assembly prior to use and pressure in said needle assembly when said lumen of said inlet cannula is filled with fluid.

4. The needle assembly of Claim 1, wherein said lumen of the said inlet cannula is substantially axially aligned with said lumen of said outlet cannula.

5. The needle assembly of Claim 4, wherein said inlet cannula is spaced from said outlet cannula by a distance of between approximately 0.5mm and 1.2mm.

6. The needle assembly of Claim 5, wherein said inlet cannula is spaced from said outlet cannula by a distance by approximately 1.0mm.

7. The needle assembly of Claim 4, further comprising a flashback chamber wall extending from said inlet end of said housing and disposed within said chamber, said flashback chamber wall surrounding said interior end of said inlet cannula and said interior end of said outlet cannula.

8. The needle assembly of Claim 7, wherein said flashback chamber wall is dimensioned to define a radial gap around said inlet cannula and said outlet cannula of approximately 0.2mm.

9. The needle assembly of Claim 8, wherein said flashback chamber wall extends a major portion of a distance between said inlet and outlet ends of said housing.

10. The needle assembly of Claim 9, wherein said flashback chamber wall is spaced from said outlet end of said housing by distance of about 1.15mm.

11. The needle assembly of Claim 10, wherein said inlet cannula is spaced from said outlet cannula by a distance of between approximately 0.5mm and 1.2mm.

12. The needle assembly of Claim 1, wherein said housing includes an inlet end wall at said inlet end of said housing, said inlet cannula being securely mounted in said inlet end wall, portions of said inlet end wall between said inlet cannula and said chamber defining a trench, said outlet cannula extending through said chamber such that said internal end of said outlet cannula is in said trench.

13. The needle assembly of Claim 12, wherein the trench is dimensioned to define an annular space surrounding portions of said outlet cannula extending into said trench.

14. The needle assembly of Claim 1, wherein said housing is free of air vents.