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SAMPLE COLLECTION SYSTEM

Abstract

Sample collection systems are provided. In one aspect, a sample collection system comprises a container, an adaptor and a securement. The adaptor receives a first end of the container into an interior of the adaptor. The securement holds the container at a first position, where the first end of the container is thereby held in a spaced relationship with a needle of the adaptor. The securement is operated or operates to permit the container to be advanced distally within the interior of the adaptor from the first position to a second position to engage the needle to receive a sample in the container. The securement further permits the container to be withdrawn proximally to remove the container from the interior of the adaptor, wherein, when the container is removed from the interior of the adaptor, the securing mechanism is removed by the container.

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Background/Summary

CROSS REFERENCE TO RELATED APPLICATIONS [0001] This application claims the priority of and benefit from U.S. Provisional Patent Application No. 63/359,373, filed Jul. 8, 2022, which is incorporated by reference herein.

TECHNICAL FIELD
[0002] The present technology relates to a sample collection system having an adaptor and a disposable sample collection container into which an initial portion of the patient sample is collected. Using venipuncture, the adaptor is fluidically coupled with the vein of patient. Initially, the patient sample is drawn through the adaptor and into the disposable collection system. Once the initial portion of the sample is collected, the disposable sample collection container and a mechanism that holds the disposable sample collection container in the adaptor is discarded and the adaptor is fluidically coupled to a sample collection vessel for collecting the remaining portion of the patient sample.
BACKGROUND
[0003] A blood culture test is presently the preferred method for identifying bacteremia and septicemia (sepsis). Sepsis is a body-wide response to a bacterial infection of the blood stream that can cause organ failure and death. Sepsis kills every one in six infected patients. Moreover, half of all in-hospital deaths involve sepsis. In fact, sepsis kills more people than AIDS, breast cancer and prostate cancer combined. Sepsis affects more hospital patients than any other diagnosis. Given the prevalence of sepsis, a patient's blood is frequently monitored to determine if there are bacteria in the patient's blood that indicates the onset of sepsis.
[0004] The need to accurately and reliably determine whether or not a patient has sepsis is apparent. Unfortunately, the United States healthcare system spends over $4 billion each year on unnecessary treatment associated with false positive blood culture results. See Oren Zwang & Richard K. Albert, *Analysis of Strategies to Improve Cost Effectiveness of Blood Cultures*, 1 J. Hosp. Med. 272 (September 2006). Moreover, “[i]t is currently accepted that most organisms identified as contaminants in blood cultures originate from the skin of the patient.” Robert A. Garcia et al., *Multidisciplinary Team Review of Best Practices for Collection and Handling of Blood Cultures to Determine Effective Interventions for Increasing the Yield of True-Positive Bacteremia, Reducing Contamination, and Eliminating False-Positive Central Line-Associated Bloodstream Infections,* 43 Am. J. Infect. Control 1222 (November 2015).
[0005] Thus, during a blood collection process, there is a need for a device capable of capturing an initial flow of blood from a patient that might contain contaminants from the skin of that patient in order to prevent that portion of the collected sample from entering the blood culture. Capturing the initial portion of the collected blood may reduce the number of collection positives. One such device is described in WO2019018324 to Milan Ivosevic, which was filed on Jul. 17, 2018 as PCT/US2018/042367 and is incorporated in its entirety by reference herein. Another such device is described in U.S. Provisional Application No. 62/883,941, which was filed on Aug. 7, 2019 and is

incorporated in its entirety by reference herein.

BRIEF SUMMARY

[0006] A sample collection system is described herein. The system includes a container for collecting a sample; an adaptor having a distal end, a proximal end, a needle, and an interior. The adaptor is configured to receive sample through a connector at the distal end. The sample may be collected via venipuncture or via a venous catheter. The needle extends from the connector into the interior of the adaptor, and the proximal end includes an opening to receive a first end of the container into the interior of the adaptor. The system also includes a securing mechanism configured to releasably secure the container at a first position, wherein, at the first position, the first end of the container is held in a spaced relationship with the needle in the interior of the adaptor. In one aspect, the securing mechanism is operated to allow the container to be advanced distally within the interior of the adaptor from the first position to a second position and thereby engage the needle to receive the sample into the container. In one aspect, the securing mechanism is further configured to enable the container to be withdrawn proximally to remove the container from the interior of the adaptor. In a further aspect, when the container is removed from the interior of the adaptor, the securing mechanism is configured to be removed by the container.

[0007] In one aspect, the securing mechanism comprises a collar fitted on the container. In a further aspect, the collar has an inner diameter that is larger than an outer diameter of the container an outer diameter that is smaller than an inner diameter of the adaptor. In a further aspect, the collar provides an interference fit when advanced into the adaptor. In yet a further aspect, the collar has a flange that prevents the collar from being advance completely into the adaptor.

[0008] In another aspect, the securing mechanism is a c-clamp. The securing mechanism may also have a resilient gasket that is received on the container and forms an interference fit for the container within the adaptor.

[0009] In another aspect, the container has a cap that may have a septum and a shield. The shield may extend from the septum and surrounding a perimeter of a portion of the container. In a further aspect, the above-described shield may have a first O-ring at a proximal end and a second O-ring at a distal end, each O-ring providing an interference fit when in the adaptor.

[0010] In another aspect, the securing mechanism is a collar on the container that forms a snap fit with a base of the shield, the securing mechanism providing an interference fit in the adaptor when advanced into the adaptor. In a further aspect, the collar has a flange at the proximal end thereof to prevent the collar from advancing completely into the adaptor.

[0011] In another aspect, the adaptor may have a spring on the interior thereof, which provides resistance with the container is advanced into the adaptor and into engagement with the needle, the spring biased to advance the container out of the adaptor after sample collection.

[0012] In another aspect of the sample collection system, the securing mechanism is a flanged foam rubber collar paced on the container that forms an interference fit with the adaptor when advanced into the adaptor, the flange having a diameter that is larger than an inner diameter of the adaptor to prevent the flanged collar from being completely advanced into the adaptor.

[0013] In another aspect of the sample collection system, the securing mechanism is a foam rubber collar placed on the container that seats within a flanged opening at the proximal end of the adaptor, the foam rubber collar forming an interference fit with the container but permits the container to be advanced and withdrawn through the collar.

[0014] In another aspect of the sample collection system, the securing mechanism is a foam rubber collar secured on the container forms interference fit when introduced into the adaptor. In a further aspect, the foam rubber collar is secured on the container with adhesive.

[0015] In another aspect of the sample collection system, the securing mechanism may be a flanged, O-ring collar on the container, wherein the O-ring forms a friction fit in the adaptor when the container is advanced in the adaptor and wherein the flange does not advance into the adaptor. In this aspect, the container is movably received in the flanged portion. In another aspect, a sticker

is provided to secure the container in its shipment position.
[0016] In another aspect, is an alternative mechanism that provides a friction fit for a flange/O-ring assembly that separates the container (i.e., discard tube) from the adaptor needle during shipment. In this aspect, the O-ring is positioned beneath a cap on the container and has a friction fit within the adaptor such that the container is slidably engaged in the adaptor. A sticker is provided to secure the container in its shipment position.

Description

BRIEF DESCRIPTION OF DRAWINGS
[0017] FIG. **1** is a side cross-sectional view of a sample collection system in accordance with the present technology.
[0018] FIG. **2**A is a side cross-sectional view of another sample collection system in accordance with the present technology.
[0019] FIG. **2**B is a side perspective view of a c-clamp of the system of FIG. **2**A.
[0020] FIG. **3**A is a side cross-sectional view of another sample collection system in accordance with the present technology.
[0021] FIG. **3**B is a close-up of a securing mechanism of the system of FIG. **3**A.
[0022] FIG. **4** is a side cross-sectional view of another sample collection system in accordance with the present technology.
[0023] FIG. **5**A-FIG. **5**D is another aspect of an assembly that keeps the collection/discard tube in spaced relation from the adaptor needle during shipping and storage and will allow the collection/discard tube to advance into engagement with the needle in the adaptor for sample collection. As illustrated, the side views of the sample collection system illustrate a foam rubber flange that provides the desired separation during shipping and storage and stays affixed to the discard tube when removed from the adaptor.
[0024] FIG. **6** is another aspect of an assembly that keeps the collection/discard tube in spaced relation from the adaptor needle during shipping and storage and will allow the collection/discard tube to advance into engagement with the needle in the adaptor for sample collection. As illustrated, the side view of the sample/collection discharge tube has a foam rubber flange with a friction fit on the discard tube which is pulled from the adaptor when the tube is removed therefrom. Tabs define a spaced relation between the discard tube and the cap thereon.
[0025] FIG. **7** is another aspect of an assembly that keeps the collection/discard tube in spaced relation from the adaptor needle during shipping and storage and will allow the collection/discard tube to advance into engagement with the needle in the adaptor for sample collection. Illustrated in FIG. **7** is an alternative foam flange friction fit to the tube.
[0026] FIG. **8**A is an alternative mechanism that provides a friction fit for a flange/O-ring assembly that separates the discard tube from the adaptor needle during shipment. In this aspect the O-ring is positioned beneath the cap and has a friction fit within the adaptor such that the discard tube is slidably engaged in the adaptor. A sticker is provided to secure the discard tube in its shipment position.
[0027] FIG. **8**B is a modified cap or stopper with O-rings disposed in a groove for slidable engagement of the cap in the adaptor. The O-rings provide the friction fit in the adaptor.
[0028] FIG. **8**C illustrates a sample collection system with the cap from FIG. **8**B and a sticker at the flange at the base of the adaptor that secures the collection/discard tube in its spaced relation from the adaptor needle.
[0029] FIG. **9**A-FIG. **91** illustrate the operation of a sample collection/discard tube in an adaptor. The sample collection/discard tube has fitted thereon a sleeve with flanges to accept an O-ring that secures the sample collection/discard tube from engagement with a needle in the adaptor during

shipment but allows for the collection/discard tube to be slid into engagement with the needle for sample collection and then removed from the adaptor after sample collection.
[0030] FIG. **10**A-FIG. **10**B is another aspect of an assembly that keeps the collection/discard tube in spaced relation from the adaptor needle during shipping and storage and will allow the collection/discard tube to advance into engagement with the needle in the adaptor for sample collection. FIG. **10**A-FIG. **10**B specifically illustrate a rubber ring that fits in the bottom of the adaptor and receives the collection tube snugly to ensure it remains spaced apart from the needle in the adaptor during shipment. The collection/discard tube may be advanced into engagement with the needle for sample collection. After sample collection, the rubber ring is pulled from engagement with the adaptor along with the collection/discard tube.
[0031] FIG. **11** is an alternative configuration of the rubber ring of FIG. **10**-FIG. **10**B. The rubber ring is fitted in the adaptor and the sample collection/discard tube has a flanged ring that engages the rubber ring in the adaptor. The rubber ring is pulled from the adaptor ring by the flanged ring when the collection/discard tube is removed from the adaptor.
[0032] FIG. **12** is another alternative configuration of a rubber ring disposed in the bottom the adaptor. In this aspect, the rubber ring has bearings that allow the collection/discard tube to be advanced into engagement with the needle in the adaptor. The rubber ring is prevented from advancing into the adaptor by a flange. The rubber ring is removed from the adaptor when the collection/discard tube cap is advanced out of the adaptor.
[0033] FIG. **13**A-FIG. **13**B is another aspect of an assembly that keeps the collection/discard tube in spaced relation from the adaptor needle during shipping and storage and will allow the collection/discard tube to advance into engagement with the needle in the adaptor for sample collection. FIG. **13**A-FIG. **13**B illustrate a collar with tabs that provide an interference fit in the adaptor. As illustrated in FIG. **13**B, the collar remains in place as the tube is advanced into engagement with the adaptor needle. The collar is removed from the adaptor when the collection/discard tube is pulled from the adaptor.
[0034] FIG. **14**A-FIG. **14**D is another aspect of an assembly that keeps the collection/discard tube in spaced relation from the adaptor needle during shipping and storage and will allow the collection/discard tube to advance into engagement with the needle in the adaptor for sample collection. FIG. **14**A-FIG. **14**D illustrate a one-way collar with internal grips that provide a friction force that permits the collection/discard tube to be advanced into the adaptor. As illustrated in FIG. **14**D, the collar grips the tube such that it is removed from engagement with the adaptor when the collection/discard tube is pulled from the adaptor. The collar has a catch that accepts the flange at the base of the adaptor. The catch is made of a soft material (TPE) so that the seal with the adaptor can be broken and detached from the adaptor.
[0035] FIG. **15**A-FIG. **15**D illustrate an alternative to the collar of FIG. **14**A-FIG. **14**D. The one-way collar in this aspect has a detent that engages with the base of the adaptor. The collar cannot advance upward into the adaptor. The collar grips the collection/discard tube such that it is removed from engagement with the adaptor when the detent mechanism is placed in the correct orientation to permit the collection/discard tube to be pulled from the adaptor. The grips are directed upwards to further secure the collar on the collection/discard tube.
[0036] FIG. **16**A-FIG. **16**D illustrate an alternative to the collar of FIG. **15**A-FIG. **15**D with a sticker added to secure the collar to the collection/discard tube.
[0037] FIG. **16**E-FIG. **16**K illustrate the operation of the assembly of FIG. **16**A-FIG. **16**D. The upward facing grips make it feasible to advance the collection/discard tub upwards into the adaptor but, when the collection/discard tube is advanced out of the adaptor, it carries the collar from the adaptor.
[0038] FIG. **17**A-FIG. **17**B is a two-piece alternative to the collar illustrated in FIG. **13**A-FIG. **13**B. A collar with barbs is affixed to the collection/discard tube by an interference fit. When advanced into the adaptor the barbs lock into holes in an adaptor collar. When the collection/discard tube is

advanced out of the adaptor, it carries the two-piece assembled collar from the adaptor.
[0039] FIG. **18**A-FIG. **18**C is another two-piece assembly for holding the collection/discard tube in spaced arrangement from the needle in the adaptor during shipment but allowing the collection/discard tube to be advanced into engagement with the needle for sample collection. The two-piece assembly is pulled from the adaptor when the collection/discard tube is removed therefrom. A snap ring with upward facing projections is fitted into the base of the adaptor. A sleeve with first and second flanges is fitted on the collection discard tube. When the first flange is advanced above the snap ring, the collection tube is held into place for shipment. When the second flange passes the snap ring, the collection tube is engaged with the needle for sample collection. The second flange on the sleeve pulls the snap ring from the adaptor when the collection/discard tube is removed therefrom.
[0040] FIG. **19**A-FIG. **19**C is an alternative aspect to the two-piece assembly in FIG. **18**A-FIG. **18**C for holding the collection/discard tube in spaced arrangement from the needle in the adaptor during shipment but allowing the collection/discard tube to be advanced into engagement with the needle for sample collection. The two-piece assembly is pulled from the adaptor when the collection/discard tube is removed therefrom. A snap ring with upward facing projections is fitted into the base of the adaptor. In this aspect the sleeve has first, second, and third flanges on the sleeve fitted on the collection/discard tube. When the first flange is advanced above the snap ring, the collection tube is held into place for shipment. The second flange pushes the snap ring outward when advanced therein, holding the collection/discard tube in place for shipment. When the third flange passes the snap ring, the collection tube is engaged with the needle for sample collection. The third flange on the sleeve pulls the snap ring from the adaptor when the collection/discard tube is removed therefrom.
[0041] FIG. **20** is a collection/discard tube with a flanged sleeve thereon for holding the collection/discard tube in spaced arrangement from the needle in the adaptor during shipment but allowing the collection/discard tube to be advanced into engagement with the needle for sample collection. The flanged sleeve prevents the sleeve from advancing beyond the open end of the adaptor when the collection/discard tube is placed therein. The flanged sleeve is flexible. When the collection/discard tube is advanced through the sleeve and into engagement with the needle in the adaptor for blood collection, the sleeve remains in position. Since the sleeve is flexible, it can assist with gripping the collection/discard tube when removed from the adaptor.
[0042] FIG. **21** is a two-part collar with a collar that fits in the bottom portion of the adaptor but does not advance therein. The first portion of the collar in the base of the adaptor cooperates with the collar on the collection/discard tube to hold the collection/discard tube in spaced relation to the needle in the adaptor. The second portion of the collar on the collection/discard tube has arms with notched engagement members that will advance past the first portion of the collar as the collection/discard tube is advanced into the adaptor. As such, the second portion of the collar is fashioned as an outside clip. When the collection/discard tube is removed from the adaptor after sample collection, the engagement members on the second portion of the collar pull the first portion of the collar from the base of the adaptor.
[0043] FIG. **22** is another flanged sleeve for the collection/discard tube. The flange locks to the flange at the base of the adaptor with a lip that fits over the adaptor base flange. The collection/discard tube is held in spaced arrangement from the needle in the adaptor during shipment by the sleeve. Advancing the collection/discard tube through the sleeve advances the collection/discard tube into connection with the adaptor needle. After the sample is collected, the flange fastener of the sleeve, which is flexible, is detached from the flange at the base of the adaptor and the collection/discard tube, with the sleeve attached, is removed from the adaptor.
[0044] FIG. **23**A-FIG. **23**C is another flanged sleeve that is detached by squeezing the elastomeric sleeve which causes the sleeve flange to separate from the flange at the base of the adaptor when the collection/discard tube is removed from the adaptor. In one aspect the sleeve is affixed to the

collection/discard tube by shrink wrap or tape during shipment, which shrink wrap or tape ensures that the collection/discard tube remains spaced apart from the needle during shipment.
[0045] FIG. **24**A-FIG. **24**B is an aspect of what is illustrated in FIG. **23**A-FIG. **23**C which shows how the sleeve flange seats on the flange at the base of the adaptor to retain the collection/discard tube in the spaced position from the adaptor needle during shipment.
[0046] FIG. **25**A-FIG. **25**B is an aspect of what is illustrated in FIG. **23**A-FIG. **23**C which shows how the sleeve can be affixed to the collection/discard tube to ensure that the discard collection tube is held in spaced arrangement from the adaptor flange needle during shipment.
[0047] FIG. **26** illustrates a collar for the collection/discard tube that has a collapsible section with a living hinge that allows the collar to keep the collection/discard tube in spaced relation to the needle in the adaptor during shipment but, for blood collection, as the collection/discard tube is advanced toward the needle, the living hinge collapses, allowing the collection/discard tube to be advanced into contact with the adaptor needle for blood collection. After collection, the collar is removed with the collection/discard tube as it is removed from the adaptor.
[0048] FIG. **27**A-FIG. **27**B is another aspect of the collection/discard tube assembly wherein the collection/discard tube has a sleeve affixed thereto with a twist-on, twist-off flange that attaches to the flange at the base of the adaptor. As illustrated, the line set is in fluid communication with the adaptor and blood is drawn into the collection/discard tube when the needle in the adaptor pierces the seal in the cap of the collection/discard tube when it is advanced into contact with the needle. The collection/discard tube is advanced in the sleeve, which remains fixed when locked on the flange of the adaptor. When the sleeve is twisted off the adaptor flange, the collection/discard tube is removed from the adaptor.
[0049] FIG. **28** is another aspect of the collection/discard tube assembly for holding the collection/discard tube in spaced relation from the needle in the adaptor during shipment but allowing the collection/discard tube to be advanced into engagement with the needle for sample collection In this aspect, the collection/discard tube has a sleeve that can be threaded into the adaptor. There is a flange at the base of the sleeve, which, as illustrated, has helical spines that provide a friction fit when advance into the adaptor. The flange limits how far the sleeve may advance. The sleeve holds the collection/discard tube in spaced relation from the needle during shipment and storage. The collection/discard tube is twisted to advance it within the sleeve. As illustrated, the line set is in fluid communication with the adaptor and blood is drawn into the collection/discard tube when the needle in the adaptor pierces the seal in the cap of the collection/discard tube when it is advanced into contact with the needle. After sample collection, the collection/discard tube is removed from the adaptor.
[0050] FIGS. **29**A-**29**C illustrate another aspect of the collection/discard tube assembly for holding the collection/discard tube in spaced relation from the needle in the adaptor during shipment but allowing the collection/discard tube to be advanced into engagement with the needle for sample collection. The collection/discard tube has a hinged spring ring that locks the collection/discard tube in spaced relation from the needle during shipment and storage. The spring flattens into the ring as the collection/discard tube is advanced in the adaptor. Blood is drawn into the collection/discard tube when the needle in the adaptor pierces the seal in the cap of the collection/discard tube when it is advanced into contact with the needle. After sample collection, the collection/discard tube is removed from the adaptor along with the hinged spring.
[0051] FIG. **30**A-FIG. **30**C is another aspect of a two-piece collar/sleeve assembly for holding the collection/discard tube in spaced relation to the needle in the adaptor during shipment and storage but allowing the collection/discard tube to be advanced into engagement with the needle for sample collection wherein the collar has notches. The sleeve has raised guides that travel through the notches in the adaptor collar. The sleeve is fitted onto the collection/discard tube. The sleeve has detents that keep the collection/discard tube in spaced relation from the needle during shipment and storage. Blood is drawn into the collection/discard tube when the needle in the adaptor pierces the

seal in the cap of the collection/discard tube when it is advanced into contact with the needle by bypassing the detents. After sample collection, the collection/discard tube is removed from the adaptor along with the collar and sleeve, the sleeve forcing the collar from the adaptor when the collection/discard tube is removed from the adaptor.

[0052] FIG. **31**A-FIG. **31**B is a modified aspect of what is illustrated in FIG. **30**A-FIG. **30**C. The two-piece collar/sleeve assembly in this aspect also has a collar has notches. The collar has clips that fasten to the flange at the base of the adaptor. The sleeve has raised guides that travel through the notches in the adaptor collar. The sleeve is fitted onto the collection/discard tube. The sleeve has raised portions at the base of the sleeve that keep the sleeve from advancing too far into the adaptor collar and ensures that the collection/discard tube is held in spaced relation from the needle during shipment and storage. Blood is drawn into the collection/discard tube when the needle in the adaptor pierces the seal in the cap of the collection/discard tube when it is advanced into contact with the needle by bypassing the detents. After sample collection, the collection/discard tube is removed from the adaptor along with the collar and sleeve, the sleeve forcing the collar from the adaptor when the collection/discard tube is removed from the adaptor.

[0053] FIG. **32**A-FIG. **32**B is a modified aspect of an assembly for holding the collection/discard tube in spaced arrangement from the needle in the adaptor during shipment but allowing the collection/discard tube to be advanced into engagement with the needle for sample collection. In this aspect, the collar that is disposed/secured on the collection/discard tube has posts that engage a slot in the adaptor housing. The side slot allows the collar to be rotated into a locked position that locks the collection/discard tube in spaced relation from the needle during shipment and storage. To advance the collection/discard tube into engagement with the adaptor needle, the collection/discard tube is rotated and the collar/collection/discard tube assembly can be advanced into engagement with the needle in the adaptor for blood collection because the collar pin can again advance along the slot in the adaptor housing. After sample collection, the collection/discard tube is removed from the adaptor along with the collar.

[0054] FIG. **33**A-FIG. **33**B is a modification of the aspect of FIG. **32**A-FIG. **32**B. The collar that is disposed on the collection/discard tube has posts that engage a slot in the adaptor housing. The side slot allows the collar to be rotated into a locked position that locks the collection/discard tube in spaced relation from the needle during shipment and storage. The side slot is angled downward, drawing the collection/discard tube slightly out of the adaptor as the pin advances in the detent slot. To advance the collection/discard tube into engagement with the adaptor needle, the collection/discard tube is rotated and the collar/collection/discard tube assembly can be advanced into engagement with the needle in the adaptor for blood collection because the collar pin can again advance along the slot in the adaptor housing. After sample collection, the collection/discard tube is removed from the adaptor along with the collar.

[0055] FIG. **34**A-FIG. **34**B is a modification of aspects of FIG. **32**A-FIG. **32**B. The collar that is disposed on the collection/discard tube has posts that engage a slot in the adaptor housing. The side slot allows the collar to be rotated into a locked position that locks the collection/discard tube in spaced relation from the needle during shipment and storage. To advance the collection/discard tube into engagement with the adaptor needle, the collection/discard tube is rotated and the collar/collection/discard tube assembly can be advanced into engagement with the needle in the adaptor for blood collection because the collar pin can again advance along the slot that is adjacent to the side slot in the adaptor housing. After sample collection, the collection/discard tube is again rotated and the collar pin travels down a discard slot, thereby removing the collection/discard tube from the adaptor along with the collar.

[0056] FIG. **35**A-FIG. **35**B is a modification of the aspects of FIG. **32**A-FIG. **32**B. In this aspect, the adaptor has a collar with the detent pin and the collection/discard tube has slots that engage the detent posts and control the motion of the collection/discard tube relative to the adaptor. The ribbed sleeve fits snugly on the collection/discard tube. When the collection/discard tube is rotated such

that the detent post is engaged in the side slot, this locks the collection/discard tube in spaced relation from the needle during shipment and storage. To advance the collection/discard tube into engagement with the adaptor needle, the collection/discard tube is rotated and the collar/collection/discard tube assembly may be advanced into engagement with the needle in the adaptor for blood collection because the collar pin can again advance along the slot in the sleeve. After sample collection, the collection/discard tube is again rotated and the sleeve travels downward because the collar pin is aligned with the slot in sleeve. When the collection discard tube is removed from the adaptor, it engages the adaptor collar, pulling it from the adaptor.

[0057] FIG. **36**A-FIG. **36**B is another aspect of an assembly that keeps the collection/discard tube in spaced relation from the adaptor needle during shipping and storage and will allow the collection/discard tube to advance into engagement with the needle in the adaptor for sample collection. In the illustrated aspect, the adaptor has a sleeve that latches into openings in the adaptor housing. The collection/discard tube has a collar with flexible projections that align with grooves in the adaptor sleeve. When the latch in the sleeve is depressed, the collection/discard tube may advance into engagement with the needle in the adaptor. At this point, the flexible projections engage openings in the sleeve, causing the collar and sleeve to engage. After sample collection, the collection/discard tube is removed from the adaptor along with the adaptor sleeve.

[0058] FIG. **37**A-FIG. **37**B is another aspect of an assembly that keeps the collection/discard tube in spaced relation from the adaptor needle during shipping and storage and will allow the collection/discard tube to advance into engagement with the needle in the adaptor for sample collection. In the illustrated aspect, the adaptor has a sleeve with a bump off that receive a latch on a collar that is press fit onto the collection/discard tube. When the latch in the collar is depressed, the collection/discard tube may advance into engagement with the needle in the adaptor. The collar also has projections that travel along guides in the adaptor sleeve. At this point, the latch on the collar engages the sleeve. After sample collection, the collection/discard tube is removed from the adaptor along with the adaptor sleeve, which is engaged with the collar.

[0059] FIG. **38** is the aspect of FIG. **37**A-FIG. **37**B but with tape instead of relying on the bump out to lock the collection/discard tube into position during shipping and storage.

[0060] FIG. **39**A-FIG. **39**B is another aspect of an assembly that keeps the collection/discard tube in spaced relation from the adaptor needle during shipping and storage and will allow the collection/discard tube to advance into engagement with the needle in the adaptor for sample collection. In the illustrated aspect, the adaptor has a sleeve with a resilient stop that will allow a projection on a collar press fit onto the collection/discard tube to pass by it when force is applied to advance the collection/discard tube in the adaptor. As such, tape is applied to ensure that the collection/discard tube is retained in the desired spaced relation with the adaptor needle. When the tape is removed, the collection/discard tube may advance into engagement with the needle in the adaptor. The collar also has projections that travel along guides in the adaptor sleeve. At this point, the projections on the collar and the resilient stop engages the projections on the collar. After sample collection, the collection/discard tube is removed from the adaptor along with the adaptor sleeve, which is engaged with the collar.

[0061] FIG. **40**A-FIG. **40**B is another aspect of an assembly that keeps the collection/discard tube in spaced relation from the adaptor needle during shipping and storage and will allow the collection/discard tube to advance into engagement with the needle in the adaptor for sample collection. In the illustrated aspect, the adaptor has sliding groove and locking grooves that cooperate with flexible fingers on the collar affixed to the collection/discard tube. Initially, the flexible fingers are disposed in the locking grooves to ensure that the collection/discard tube is retained in the desired spaced relation with the adaptor needle during shipment and storage. The collection/discard tube is rotated to place the fingers in the sliding grooves of the adaptor and the collection/discard tube may advance into engagement with the needle in the adaptor. After sample collection, the collection/discard tube is removed from the adaptor by sliding it out along the

sliding grooves.
[0062] FIG. **41** is another aspect of an assembly that keeps the collection/discard tube in spaced relation from the adaptor needle during shipping and storage and will allow the collection/discard tube to advance into engagement with the needle in the adaptor for sample collection. In the illustrated aspect, the collection/discard tube has a sleeve attached thereto with a portion of the sleeve having an enlarged diameter. The adaptor has windows that hold an O-ring in an elliptical configuration. The elliptical O-ring holds the collection/discard tube in spaced relation to the adaptor needle. When the collection/discard tube is forced past the O-ring, the tube can be advanced into contact with the adaptor needle for sample collection. In that position, the wider portion of the sleeve changes the O-ring configuration to circular, allowing the collection/discard container to backed out from the adaptor, carrying the O-ring with it.
[0063] FIG. **42**A-FIG. **42**B is another aspect of an assembly that keeps the collection/discard tube in spaced relation from the adaptor needle during shipping and storage and will allow the collection/discard tube to advance into engagement with the needle in the adaptor for sample collection. In the illustrated aspect, the collection/discard tube has a sleeve attached thereto with a portion of the sleeve having an enlarged diameter. The adaptor has windows above the flange at the base thereof that hold an elliptical ring. The elliptical ring holds the collection/discard tube in spaced relation to the needle adaptor. When the collection/discard tube is forced past the elliptical ring, the tube can be advanced into contact with the adaptor needle for sample collection. In that position, the wider portion of the sleeve changes the elliptical ring configuration to circular, allowing the collection/discard container to backed out from the adaptor, carrying the elliptical ring with it.
[0064] FIG. **43**A-FIG. **43**B is another aspect of an assembly that keeps the collection/discard tube in spaced relation from the adaptor needle during shipping and storage and will allow the collection/discard tube to advance into engagement with the needle in the adaptor for sample collection. In the illustrated aspect, the adaptor has a threaded inner collar with a flange that abuts the flange at the base of the adaptor. The collection/discard tube has a ring with posts. When the collection/discard tube is placed into the adaptor, the collection/discard tube is held away from the adaptor needle. When sample collection is desired, the collection/discard tube is rotated, which advances the ring, threading it such that the ring posts land in the detents in the threaded inner collar. When engaged, the sample is collected. After sample collection, the sample collection/discard tube is pulled from the adaptor with the ring and the threaded inner collar.
[0065] FIG. **44**A-**44**B is an alternative aspect of FIG. **43**A-FIG. **43**B, and is another aspect of an assembly that keeps the collection/discard tube in spaced relation from the adaptor needle during shipping and storage and will allow the collection/discard tube to advance into engagement with the needle in the adaptor for sample collection. In the illustrated aspect, the adaptor has a slotted inner collar with a flange that abuts the flange at the base of the adaptor. The slot has two detents. The collection/discard tube has a ring with posts. When the collection/discard tube is placed into the adaptor, the collection/discard tube is held away from the adaptor needle by the engagement of the post with the first detent. When sample collection is desired, the collection/discard tube is advanced, such that the ring posts land in the locking detents at the top of the adaptor sleeve. When engaged, the sample is collected into the collection/discard tube. After sample collection, the sample collection/discard tube is pulled from the adaptor with the ring and the slotted inner collar.
[0066] FIG. **45**A-FIG. **45**B is another aspect of an assembly that keeps the collection/discard tube in spaced relation from the adaptor needle during shipping and storage and will allow the collection/discard tube to advance into engagement with the needle in the adaptor for sample collection. The adaptor has two retention holes in its housing, proximal to the flange at the bottom of the adaptor. The collection/discard tube has a sleeve with a first larger diameter, a second smaller diameter and a flange distal to the cap of the collection/discard tube. Disposed in the sleeve are fingers that extend outward and will fit in the retention holes in the adaptor housing when aligned

therewith and holds the collection/discard tube away from the needle in the adaptor for storage and handling. Retracting the sleeve releases the fingers from the holes in the adaptor housing. The collection/discard tube is then advanced upward for sample collection. After sample collection, the sample collection/discard tube is pulled from the adaptor with the sleeve and fingers affixed thereto.

[0067] FIG. **46**A-FIG. **46**B is another aspect of an assembly that keeps the collection/discard tube in spaced relation from the adaptor needle during shipping and storage and will allow the collection/discard tube to advance into engagement with the needle in the adaptor for sample collection. The adaptor has two retention holes in its housing, proximal to the flange at the bottom the adaptor. The collection/discard tube has a flanged collar thereon and a holster with fingers that extend from the holster upward and outward into the adaptor. As the collar and the collection/discard tube are advanced into the adaptor, the holes in the collar align with the holes in the adaptor and the fingers extending from the holster on the collection/discard tube locks the collection/discard tube in a position away from the needle in the adaptor for storage and handling. Retracting the collar releases the fingers from the holes in the adaptor housing. The collection/discard tube is then advanced upward for sample collection. After sample collection, the sample collection/discard tube is pulled from the adaptor with the holster and fingers affixed thereto.

[0068] FIG. **47**A-**47**B illustrates a diversion adaptor that provide a first flow path for collecting a first portion of the collected sample and a second flow path that collects the portion of the sample to be used for testing. The adaptor has an inner sleeve that is retracted into the adaptor when shipped. The inner sleeve is drawn back and posts in the inner sleeve lock into a detent in the adaptor housing and the diversion portion of the sample is drawn through the first flow path in the adaptor into an upper chamber of the adaptor. After the diversion sample is collected, the inner sleeve is advanced upward and the adaptor engages the sample collection bottle, and the sample travels through the second flow path into the sample collection bottle.

[0069] FIG. **48**A-FIG. **48**B illustrate another aspect of an assembly that keeps the collection/discard tube in spaced relation from the adaptor needle during shipping and storage and will allow the collection/discard tube to advance into engagement with the needle in the adaptor for sample collection. In this aspect, the collection/discard tube is delivered into the adaptor within a sleeve that has a flange on the end of the sleeve distal from the adaptor needle. In the first position, when the collection/discard tube is held away from the adaptor needle for shipment and storage, tape secures the sleeve in a position where the sleeve flange is spaced apart from the adaptor flange at the adaptor opening. When the sticker is peeled away, the collection/discard tube and the sleeve are advanced further into the adaptor for sample collection. After sample collection, the sample collection/discard tube is pulled from the adaptor with the sleeve.

[0070] FIG. **49**A-FIG. **49**F illustrate different sticker configurations and placements to maintain the collection/discard tube in spaced relation from the adaptor needle during shipping and storage and will allow the collection/discard tube to advance into engagement with the needle in the adaptor for sample collection upon removal of the sticker.

[0071] FIG. **50** illustrates a different sticker configuration and placement to maintain the collection/discard tube in spaced relation from the adaptor needle during shipping and storage and will allow the collection/discard tube to advance into engagement with the needle in the adaptor for sample collection upon removal of the sticker. In this aspect, the collection/discard tube has a collar thereon and the sticker maintains separation of the collar from the adaptor. With the sticker severed, the collar may advance into the adaptor for sample collection. After sample collection, the collection/discard tube along with the sleeve is removed from the adaptor.

[0072] FIG. **51** illustrates the use of a heat shrink material to maintain the collection/discard tube in spaced relation from the adaptor needle during shipping and storage and will allow the collection/discard tube to advance into engagement with the needle in the adaptor for sample

collection upon removal of the heat shrink material. To advance the collection/discard tube into the adaptor, the heat shrink material is removed. After collection, the collection/discard tube is removed from the adaptor.

[0073] FIG. **52** illustrates another aspect of an assembly that keeps the collection/discard tube in spaced relation from the adaptor needle during shipping and storage and will allow the collection/discard tube to advance into engagement with the needle in the adaptor for sample collection. In this aspect, the collection/discard tube is delivered into the adaptor within a sleeve that has a bellows at the end thereof. The bellows operates to keep the collection/discard tube separated from the adaptor needle during shipment and storage. When sample collection is commenced, the collection/discard tube is forced upward, collapsing the bellows and allowing the adaptor needle to insert into the collection/discard tube for sample collection. When the desired amount of sample is collected, the collection/discard tube and sleeve are removed from the adaptor.

[0074] FIG. **53** illustrates another aspect of an assembly that keeps the collection/discard tube in spaced relation from the adaptor needle during shipping and storage and will allow the collection/discard tube to advance into engagement with the needle in the adaptor for sample collection. In this aspect, the collection/discard tube is delivered into the adaptor within a sleeve that has a collapsed, corrugated portion. The collapsed, corrugated portion operates to keep the collection/discard tube separated from the adaptor needle during shipment and storage. When sample collection is commenced the corrugated portion unfolds and the collection/discard tube is forced upward, allowing the adaptor needle to insert into the collection/discard tube for sample collection. When the desired amount of sample is collected, the collection/discard tube and sleeve are removed from the adaptor.

[0075] FIG. **54** is another aspect of the assembly described in FIG. **52**. FIG. **54** illustrates an assembly that keeps the collection/discard tube in spaced relation from the adaptor needle during shipping and storage and will allow the collection/discard tube to advance into engagement with the needle in the adaptor for sample collection. In this aspect, the collection/discard tube is disposed in a sleeve with a bellows at the end thereof, adjacent a flange that does not permit the bellows to enter the adaptor. The bellows operates to keep the collection/discard tube separated from the adaptor needle during shipment and storage. When sample collection is commenced the collection/discard tube is forced upward, collapsing the bellows and allowing the adaptor needle to insert into the collection/discard tube for sample collection. When the desired amount of sample is collected, the collection/discard tube is removed from the adaptor. The sleeve, having never entered the adaptor, remains on the collection/discard tube.

[0076] FIG. **55**A-FIG. **55**B is another aspect of an assembly that keeps the collection/discard tube in spaced relation from the adaptor needle during shipping and storage and will allow the collection/discard tube to advance into engagement with the needle in the adaptor for sample collection. In this aspect, the collection/discard tube is placed in a sleeve with netting disposed on the exterior of the collection/discard tube. Folds in the netting operate to keep the collection/discard tube separated from the adaptor needle during shipment and storage. When sample collection is commenced the collection/discard tube is forced upward, allowing the folds to unfold, thereby allowing the collection/discard tube to engage the adaptor needle, whereby the needle is inserted into the collection/discard tube for sample collection. When the desired amount of sample is collected, the collection/discard tube is removed from the adaptor along with the netting.

[0077] FIG. **56** is another aspect of an assembly that keeps the collection/discard tube in spaced relation from the adaptor needle during shipping and storage and will allow the collection/discard tube to advance into engagement with the needle in the adaptor for sample collection. In this aspect, a stopper is placed on top of the cap of the collection/discard tube. The stopper has a perimeter that forms a friction fit with the adaptor when the stopper/collection/discard tube assembly is placed within the adaptor. The friction fit allows the stopper to maintain the collection/discard tube in spaced relation with the adaptor needle.

[0078] FIG. **57** is another aspect of an assembly that keeps the collection/discard tube in spaced relation from the adaptor needle during shipping and storage and will allow the collection/discard tube to advance into engagement with the needle in the adaptor for sample collection. In this aspect, a removeable clip, tear-off strip or sticker is used to force a spaced relationship between a sleeve in which the collection/discard tube is disposed and the adaptor. The spaced relationship ensures that the collection/discard tube does not engage the adaptor needle during storage and shipping. When sample collection commences, the clip or sticker is removed and the sleeve in which the collection/discard tube is disposed can be advanced into contact with the adaptor needle for sample collection. After sample collection, the collection/discard tube (still disposed in the sleeve) is removed from the adaptor.

[0079] FIG. **58**A-FIG. **58**C is a three-piece assembly for holding the collection/discard tube in spaced relation from the needle in the adaptor during shipment but allowing the collection/discard tube to be advanced into engagement with the needle for sample collection. The three-piece assembly is pulled from the adaptor when the collection/discard tube is removed therefrom. A snap ring with upward facing projections is fitted into the base of the adaptor. A sleeve with first and second flanges is fitted on the collection/discard tube. A collar is placed adjacent the cap on the collection discard tube, the collar dimensioned to be advanced above the snap ring, which allows for the collection/discard tube to be held spaced apart from the adaptor needle during shipment and storage. When the first flange passes the snap ring, the collection tube is engaged with the needle for sample collection. The first flange on the sleeve and the collar cooperate to pull the snap ring from the adaptor when the collection/discard tube is removed therefrom.

[0080] FIG. **59** is a proof of concept illustration of using an elastomeric tube to hold the collection/discard tube in spaced relation from the needle in the adaptor during shipment but allowing the collection/discard tube to be advanced into engagement with the needle for sample collection. When the elastomer tube is removed, the collection/discard tube may be brought into engagement with adaptor needle for sample collection. When the desired amount of sample is collected, the collection/discard tube is removed from the adaptor.

[0081] FIG. **60** is a proof of concept illustration of using extensions from a sleeve on a collection/discard tube to hold the collection/discard tube in spaced relation from the needle in the adaptor during shipment but allowing the collection/discard tube to be advanced into engagement with the needle for sample collection. When the collection/discard tube is advanced into engagement with adaptor needle for sample collection, the extensions are carried into the adaptor. When the collection/discard tube is removed from the adaptor, the extensions are carried with it.

[0082] FIG. **61** is a further modification of the aspect illustrated in FIG. **60** and also is a proof of concept illustration that uses extensions from a sleeve on a collection/discard tube to hold the collection/discard tube in spaced relation from the needle in the adaptor during shipment but allowing the collection/discard tube to be advanced into engagement with the needle for sample collection. Tape is used to hold the sleeve together. In some aspects, the cardboard is corrugated for additional thickness and sturdiness. When the collection/discard tube is advanced into engagement with the adaptor needle for sample collection, the extensions are carried into the adaptor. When the collection/discard tube is removed from the adaptor, the extensions are carried with it.

[0083] FIG. **62** is a further modification of the aspect illustrated in FIG. **60** and also is a proof of concept illustration that uses extensions from a sleeve on a collection/discard tube to hold the collection/discard tube in spaced relation from the needle in the adaptor during shipment but allowing the collection/discard tube to be advanced into engagement with the needle for sample collection. Tape is used to hold the sleeve together and to hold the collection/discard tube in space relation to the adaptor needle. In some aspects, the cardboard is corrugated for additional thickness and sturdiness. When collection is commenced, the tape holding the collection/discard tube in place is removed, allowing the collection/discard tube to be advanced into engagement with the adaptor for sample collection, the extensions are carried into the adaptor. When the collection/discard tube

is removed from the adaptor, the extensions are carried with it.
[0084] FIG. **63** is a concept illustration of a sleeve structure for the collection/discard tube that is sufficiently wide so as not to enter the adaptor, thereby keeping the collection/discard tube in spaced relation from the needle in the adaptor during shipment but allowing the collection/discard tube to be advanced into engagement with the needle for sample collection. The collection/discard tube can be advanced in the sleeve structure. After sample collection, the structure is squeezed so that the collection/discard tube assembled to the sleeve may be backed out of the adaptor.
[0085] FIG. **64** is a concept illustration of a sleeve structure for the collection/discard tube that is sufficiently wide so as not to enter the adaptor, thereby keeping the collection/discard tube in spaced relation from the needle in the adaptor during shipment but allowing the collection/discard tube to be advanced into engagement with the needle for sample collection when the sleeve is squeezed. The collection/discard tube may then be advanced in the sleeve structure. After sample collection, the structure is squeezed for the collection/discard tube assembled to the sleeve to be backed out of the adaptor.
[0086] FIG. **65**A-FIG. **65**B is an assembly with a valve that has a first adaptor for receiving a collection/discard tube and at least one other adaptor for receiving a sample bottle. The assembly has an inlet that may be connected to a line set for collecting a sample from a patient. The valve may direct a first portion of the collected sample into the collection/discard tube. After the desired amount of sample is collected, the valve is rotated, and additional sample is directed to the one or more sample containers.
[0087] FIG. **66** is an alternative aspect of what is described in FIG. **65**A-FIG. **65**B. In this aspect, a pin is provided to prevent the valve from rotating beyond the position that will direct sample beyond the sample collection/discard tube adaptor unless the collection/discard tube is in engagement with the needle in the adaptor.
[0088] FIG. **67**A-FIG. **67**B illustrates an alternative aspect of the assembly described herein that deploys a collection/discard tube in communication with an adaptor for connection to a patient line set to collect sample from a patient into the container. In this aspect, the collection/discard tube is assembled with the adaptor but held in spaced relation from the adaptor needle during shipment and storage. The collection/discard tube may have one of the numerous examples of collars or sleeves or tape described herein for maintaining such spaced relation between the collection/discard tube and the needle. The adaptor has a valve on the end thereof that is placed in connection with the patient line set (not shown). The collection/discard tube is advanced into the adaptor to collect sample, after which the valve is opened. Once the initial portion of the patient sample is collected in the collection/discard tube, the collection/discard tube is removed from the adaptor and then the patient sample collection bottle is placed in fluid communication with adaptor needle for collecting the patient sample into the blood culture container.
[0089] FIG. **68**A-**68**B illustrates an alternative aspect of the assembly described herein that deploys a collection/discard tube in communication with an adaptor for connection to a patient line set to collect sample from a patient into the container. In this aspect, the collection/discard tube is assembled with the adaptor but held in spaced relation from the adaptor needle during shipment and storage by a rotating flap. The adaptor has a first port for receiving the collection/discard tube and a second port for receiving the blood culture bottle. The flap moves from a first position that is intermediate between the collection/discard tube and the adaptor needle, thereby preventing the collection/discard tube from coming into contact with the adaptor needle during shipment and storage, to a second position in which the flap is positioned alongside the collection/discard tube, and therefore no longer in the path between the collection/discard tube and the adaptor needle. Advancing the collection/discard tube in the adaptor moves the flap from the first position to the second position. The collection/discard tube is advanced into the adaptor to collect sample, after which the valve is opened. Once the initial portion of the patient sample is collected in the collection/discard tube, the collection/discard tube is removed from the adaptor and then the patient

sample collection bottle is placed in fluid communication with the adaptor needle in the larger port for collecting the patient sample into the blood culture container.

[0090] FIG. **69**A-FIG. **69**B illustrates an alternative aspect of the dual port adaptor described in FIG. **68**A-FIG. **68**B. The assembly described herein deploys a collection/discard tube in communication with a dual port adaptor for connection to a patient line set to collect sample from a patient into the container. The collection/discard tube will only fit in one of the dual ports. In this aspect, the collection/discard tube is assembled with the adaptor but held in spaced relation from the adaptor needle during shipment and storage by a ring or other mechanism described herein. The adaptor has the first port for receiving the collection/discard tube and a second port for receiving the blood culture bottle. The adaptor also has a lever/pin assembly with a first position and a second position. In the first position, the lever in the port that receives the collection/discard tube is positioned over a pin in the second port. In this position, the pin cannot move upward, the culture bottle cannot be brought into contact with the needle in the second port. When the collection/discard tube is advanced into fluid communication with the needle in the adaptor, the lever moves away from above the pin and the pin can be move upward, allowing the culture bottle to be placed in fluid communication with the needle in the second port for collection of the remainder of the sample. Once the initial portion of the patient sample is collected in the collection/discard tube, the collection/discard tube is removed from the adaptor and then the patient sample collection bottle is placed in fluid communication with adaptor needle in the larger port for collecting the patient sample into the blood culture container.

[0091] FIG. **70**A-FIG. **70**B illustrates an alternative aspect of the dual port adaptor described in FIG. **69**A-FIG. **69**B. The assembly described herein deploys a collection/discard tube in communication with a dual port adaptor for connection to a patient line set to collect sample from a patient into the container. The collection/discard tube will only fit in one of the dual ports. In this aspect, the collection/discard tube is assembled with the adaptor but held in spaced relation from the adaptor needle during shipment and storage by a ring or other mechanism described herein. The adaptor has the first port for receiving the collection/discard tube and a second port for receiving the blood culture bottle. The adaptor also has a needle shuttle that will move the needle from the first port to the second port. A lock out peg prevents the needle from being moved from the first port to the second port until sample is collected into the collection/discard tube in the first port. When the collection/discard tube is advanced into fluid communication with the needle in the adaptor, the lock out peg is moved upward, which allows the needle shuttle to be moved. Moving the needle shuttle moves the needle from the first port to the second port. The culture bottle can then be placed in fluid communication with the needle in the second port for collecting the remainder of the sample. Once the initial portion of the patient sample is collected in the collection/discard tube, the collection/discard tube is removed from the adaptor and then the patient sample collection bottle is placed in fluid communication with the adaptor needle in the larger port for collecting the patient sample into the blood culture container.

[0092] FIG. **71** illustrates an alternative aspect of the dual port adaptor described in FIG. **70**A-FIG. **70**B. The assembly described herein deploys a collection/discard tube in communication with a dual port adaptor for connection to a patient line set to collect sample from a patient into the container. The collection/discard tube will only fit in one of the dual ports. In this aspect, the collection/discard tube is assembled with the adaptor but held in spaced relation from the adaptor needle during shipment and storage by a ring or other mechanism described herein. The adaptor has the first port for receiving the collection/discard tube and a second port for receiving the blood culture bottle. The adaptor also has a needle shuttle that will move the needle from the first port to the second port. In this aspect, the assembly lacks the lock out peg. Once the initial portion of the patient sample is collected in the collection/discard tube, the collection/discard tube is removed from the adaptor, which allows the needle shuttle to be moved from the first port to the second port. and then the patient sample collection bottle is placed in fluid communication with the adaptor

needle in the larger port for collecting the patient sample into the blood culture container. Moving the needle shuttle moves the needle from the first port to the second port. The culture bottle can then be placed in fluid communication with the needle in the second port for collection the remainder of the sample.

[0093] FIG. **72**A-FIG. **72**B illustrates an alternative aspect of the dual port adaptor. The assembly described herein deploys a collection/discard tube in communication with a dual port adaptor for connection to a patient line set to collect sample from a patient into the container. The collection/discard tube will only fit in one of the dual ports. In this aspect, the collection/discard tube is assembled with the adaptor but held in spaced relation from the adaptor needle during shipment and storage by a ring or other mechanism described herein. The adaptor has the first port for receiving the collection/discard tube and a second port for receiving the blood culture bottle. The adaptor also has a rotary valve that will allow patient sample to flow into the collection/discard tube in one position, and into the blood culture bottle in a second position. Initially, before sample is collected, the rotary valve is in a third position (the “off” position). When the collection/discard tube is brought into fluid communication with the needle in the adaptor, the rotary valve is moved to the first position. Once the initial portion of the patient sample is collected in the collection/discard tube, the collection/discard tube is removed from the adaptor, and the valve is moved to the third position, which allows collecting the patient sample into the blood culture container when the blood culture bottle is brought into fluid communication with the adaptor needle.

[0094] FIG. **73** is an alternative aspect of FIG. **72**A-FIG. **72**B wherein the adaptor has a locking pin that requires the blood culture bottle to be inserted into the adaptor before the rotary valve is moved to the third position.

[0095] FIG. **74**A-FIG. **74**B illustrates an alternative aspect of the dual port adaptor. The assembly described herein deploys a collection/discard tube in communication with a dual port adaptor for connection to a patient line set to collect sample from a patient into the container. The collection/discard tube will only fit in one of the dual ports. In this aspect, the collection/discard tube is assembled with the adaptor but held in spaced relation from the adaptor needle during shipment and storage by a ring or other mechanism described herein. The adaptor has the first port for receiving the collection/discard tube and a second port for receiving the blood culture bottle. The ports are staggered so the collection/discard tube can be placed in one port and the culture bottle can be placed in the other port simultaneously and to provide a differential pressure between the flow path to the collection/discard tube and the flow path to the culture bottle. When the collection/discard tube is brought into fluid communication with the needle in the adaptor, sample is collected into the sample collection/discard tube. Once the initial portion of the patient sample is collected in the collection/discard tube, the blood culture bottle is placed in fluid communication with the needle in the second port. Because the second port is lower than the first port (or, more precisely, because the sample collection tube is held higher in the adaptor than the blood culture vessel) the sample flows preferentially to the blood culture vessel when both the collection/discard tube and the culture bottle are connected in the adaptor.

[0096] FIG. **75** is an aspect of a dual port adaptor wherein the sample collection/discard tube is held in spaced relation to the needle in the adaptor by variety of mechanisms described herein such as the rubber ring, the clutch, the sticker or other spacing mechanism. FIG. **75** illustrates a generic separation mechanism integrated with the sliding needle shuttle described in FIG. **71**.

[0097] FIG. **76** illustrates an adaptor in fluid communication with a sample collection/discard tube. The adaptor has a piezoelectric flow monitor that will indicate to a use when the sample collection discard tube is contains the target amount of sample.

[0098] FIG. **77** is an alternative aspect of two port adaptor. Each port is affixed to an end of a “Y” connector. The port that receives the sample collection/discard tube has a retention mechanism that keeps the collection/discard tube in spaced relation from the needle in the adaptor during shipment

and storage. When the sample collection/discard tube is brought into fluid communication with the needle in the adaptor port, the line from the line set to the “Y” connector is primed. The sleeve on the needle in the second port acts like a shut off valve when sample is being collected into the sample collection/discard tube. When the culture bottle is placed in fluid communication with the needle in the second port of the adaptor, sample flows preferentially into the culture bottle.

[0099] FIG. **78** is an alternative aspect of two port adaptor of FIG. **77** Each port is affixed to an end of a “Y” connector and the ports themselves are arranged in a “Y.” The port that receives the sample collection/discard tube may have a retention mechanism that keeps the collection/discard tube in spaced relation from the needle in the adaptor during shipment and storage. When the sample collection/discard tube is brought into fluid communication with a needle in the adaptor port, the line from the line set to the “Y” connector is primed. The sleeve on the needle in the second port acts like a shut off valve when sample is being collected into the sample collection/discard tube. When the culture bottle is placed in fluid communication with the needle in the second port of the adaptor, sample flows preferentially into the culture bottle since the collection/discard tube has the requisite amount of sample therein.

DETAILED DESCRIPTION

[0100] Embodiments of the present disclosure are described in detail with reference to the drawing figures wherein like reference numerals identify similar or identical elements. It is to be understood that the disclosed embodiments are merely examples of the disclosure, which may be embodied in various forms. Well-known functions or constructions are not described in detail to avoid obscuring the present disclosure in unnecessary detail. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a basis for the claims and as a representative basis for teaching one skilled in the art to variously employ the present disclosure in virtually any appropriately detailed structure.

[0101] Referring to FIG. **1**, a side cross-sectional view of a sample collection system **100** is shown in accordance with the present technology. The sample collected by the system of FIG. **1** may be a fluid, e.g., blood drawn from a patient. The system of FIG. **1** includes a container **102** (e.g., a bottle or tube) for collecting or storing the collected sample and an adaptor **150** configured to fluidically couple a collection container fluidically coupled to the adaptor (e.g., container **102**) to a line set (e.g., a venipuncture needle and tubing coupled to a patient) for receiving the sample therefrom. The container **102** is illustrated as a tube having an open end **104**A and a closed end **104**B. Container **102** further includes a cap or stopper **106** including a septum. The cap **106** is coupled to open end **104**A and seals the interior of the container **100** from fluid communication with the environment outside the container **100**. Container **102** may further include a shield **108** disposed around the cap **106** to protect the cap **106** from damage during use. Adaptor **150** includes distal end **154**A, proximal end **154**B, body **160** (e.g., configured in a substantially tubular shape), and needle **158**. Adaptor **150** has a connector **152** (illustrated as a luer connector) at the distal end **154**A of the adaptor **150**. Needle **158** is mounted to, and in fluid communication with, connector **152**. Needle **158** extends from connector **152** in a proximal direction into interior **156** of the adaptor **150**. Proximal end **154**B of adaptor **150** includes an opening providing access to interior **156** and configured to receive end **104**A of container **102**.

[0102] The sample collection is manufactured and shipped in the configuration illustrated in FIG. **1**. In this configuration, the container **102** is held separated from and unengaged with needle **158**. This is referred to as the first position herein. During the process of collecting a sample, such as blood, from the patient, end **104**A of container **102** is advanced further into the interior **156** from end **154**B of adaptor **150** from the first position to a second position. As stated above, in the first position, cap **106** is in a spaced relationship (e.g., at a predetermined distance) with the proximal end of needle **158** and not in engagement with needle **158**. At the second position, needle **158** engages (i.e., punctures) cap **106** of container **100** (e.g., where needle **158** pierces the septum of cap **106**). Furthermore, connector **152** is coupled to a corresponding connector for a line set and a

needle of the line set, wherein the line set needle is used for venipuncture to collect a blood sample from a patient. It is to be appreciated that, in some embodiments, connector **152** may be a male Luer-Lok® adaptor or connector connectable to a female Luer-Lok® adaptor of the line set, however other types of connectors for use with adaptors and containers, such as adaptor **150** and container **102**, are contemplated to be within the scope of the present disclosure, as are catheters in place of a line set.

[0103] Container **102** is a sealed container that has an internal pressure that is either a full or partial vacuum (i.e. sub-atmospheric pressure). When the needle **158** punctures the cap **106**, the sub-atmospheric pressure in the interior of container **102**, draws an initial portion of blood from the patient via the line set, connector **152**, and needle **158** into the interior of container **102**. After an initial portion of the patient sample is collected, container **102** is then withdrawn proximally from the interior **156** of adaptor **150** such that needle **158** disengages from fluidic communication with the interior of container **102**. Once the needle **158** is no longer in fluid communication with the interior of the container **102**, the flow of blood from the patient ceases. Container **102**, along with the initial portion of blood collected therein, is then discarded. At this point, a second container (e.g., a blood culture bottle) is advanced into the interior **156** of adaptor **150** to draw blood from the patient. The interior pressure of the second container is also sub-atmospheric. The blood drawn into the second container will serve as the blood that will be subjected to tests to determine if the patient's blood contains microbial contamination.

[0104] In some embodiments, the blood collection system of FIG. **1** may be implemented using one of Becton, Dickinson and Company's (“BD's”) Vacutainer® blood collection sets, such as BD's Vacutainer® push button blood collection set, BD's Vacutainer® Safety-Lok™ blood collection set, or BD's Vacutainer® UltraTouch™ push button blood collection set. Therefore, in some embodiments, adaptor **150** may be implemented using BD's Vacutainer® Multiple Sample Luer Adaptor. Moreover, in some embodiments, adaptor **150** may be implemented using BD's Vacutainer® One Use Holder.

[0105] As mentioned above, most organisms identified as contaminants in blood cultures originate from the skin of the patient. These contaminants are typically introduced into a patient's blood sample by the venipuncture and the initial flow of blood from the patient into a container or collection bottle, such as container **102**. In the sample collection system **100** described herein, the initial portion of the blood collected from a patient is contained in a first container **102** and then discarded. Then, a second portion of the blood collected from the patient is collected into a second container and stored for subsequent testing. As a result, the sample collection system **100** described herein potentially reduces the number of false positive blood cultures by discarding the first portion of the collected sample, which can yield false positives due to the presence of microbial contamination of the sample from the skin of the patient.

[0106] In accordance with the present technology, a securing mechanism is provided that is configured to releasably hold or secure a container, such as container **102**, to an adaptor, such as adaptor **150** in the first position (i.e., a spaced relationship where container **102** is not in engagement with the needle **158** of the adaptor **150**). In this way, the container **102** and adaptor **150** may be shipped to a user or technician as an assembled unit, with the container **102** held in the first position with respect to the adaptor **150** by the securing mechanism. After the technician connects the line set to the patient and the adaptor **150**, the securing mechanism is configured to permit the container **102** to be advanced from the first position to the second position. As explained above, in the second position, the needle **158** of the adaptor **150** pierces the seal of the container **102** and the sub-atmospheric pressure in the container **150** draws the patient sample through the line set, the connector/needle **158** and into the container **102**. After the blood is collected from the patient into the container **102**, the operator can remove the container **102** from the adaptor **150**. The securing mechanism is further configured to be removed with the container **102** when the container **102** is removed from the adaptor **150** by the operator.

[0107] For example, the system of FIG. **1** may include a securing mechanism **110** configured with the features described above. As shown in FIG. **1**, securing mechanism **110** includes a distal end or portion **112** and a proximal end or portion **114**. The securing mechanism **110** may be a made of rubber and configured in an annular shape. The securing mechanism **110** is disposed around the exterior of container **102**. Distal portion **112** has a predetermined thickness (between an outer diameter of portion **112** and an inner diameter shared by portions **112**, **114**) selected to enable portion **112** to fit between the exterior of container **102** and an inner wall **160** of the adaptor **150** defining an inner diameter. Furthermore, proximal portion **114** is configured as a rim or flange having a predetermined thickness (between an outer diameter of portion **114** and the inner diameter shared by portions **112**, **114**) that is selected to be greater than the predetermined thickness of portion **112** such that the outer diameter of portion **114** is greater than the inner diameter of the adaptor **150**. In this way, the predetermined thickness of portion **114** ensures that the securing mechanism **110** is retained at the proximal end of the adaptor **150** and does not advance distally into the interior **156** of the adaptor **150**.

[0108] The predetermined thickness of portion **112** is further configured to provide a sufficient amount of friction between the inner diameter of portion **112** of securing mechanism **110** and the outer diameter of container **102** such that container **102** is releasably secured or held in the first position (shown in FIG. **1**) and does not move relative to adaptor **150** absent a force applied to container **102** by a user. From the first position, a user may advance container **102** in a distal direction against the friction applied by securing mechanism **110** into the second position such that the septum seal of cap **106** of the container **102** is urged into engagement with and pierced by needle **158**. Since, as described above, the predetermined thickness of portion **114** prevents portion **114** from advancing distally into the interior **156** of adaptor **150**, as container **102** is advanced from the first position to the second position, the securing mechanism **110** is held at proximal end **154**B of the adaptor **150**. After the initial portion of the blood sample has been drawn from the patient user into container **102** (in the manner described above), container **102** is pulled proximally by an operator or user to remove container **102** from the adaptor interior **156**. When container **102** is withdrawn from interior **156**, securing mechanism **110** remains disposed around the exterior of body **102** and is also pulled from the adaptor **150** by the removal of the container **102** from the adaptor **150**.

[0109] It is to be appreciated that the securing mechanism of the present technology may take other forms in addition to the securing mechanism **110** described above. For example, referring to FIG. **2**A, a securing mechanism **210** is shown for use in a sample collection system **100** in accordance with the present technology. Securing mechanism **210** is configured as a c-clamp configured to be disposed around the outer diameter of body **102** of container **100**. A gasket, washer or O-ring, etc. **212** is provided in order to provide an interference fit between the adaptor **150** and the container **102**. The c-clamp **210** may be made of rubber and includes a predetermined thickness (between in an inner and outer diameter of c-clamp) configured to provide sufficient friction to hold or secure container **100** in the first position (as shown in FIG. **2**) so that container **100** does not move from the first position relative to adaptor **150** absent a force applied by a user or technician. As described above, the technician may advance the container **102** distally to the second position after venipuncture such that the line set is in fluid communication with the connector **152** and needle **158** of the adaptor **150**. In the second position, the needle **158** pierces the septum seal of the cap **106**. The sub-atmospheric pressure in the container **102** draws an initial portion of blood from the patient into the container **102**. Thereafter, when a sufficient volume of the initial portion is collected to ensure that microbial skin contamination is collected with the initial portion, the container **102** is pulled proximally by the technician to remove container **102** from interior **156** of adaptor **150**. When container **102** is removed from interior **156**, c-clamp **210** remains disposed around the outer diameter of container **102**, such that the removal of container **102** from interior **156** also removes c-clamp **210** from interior **156**. In one aspect, when the container **102** is removed

from the adapter, c-clamp **210** and gasket/washer/O-ring **212** are also removed. In accordance with this aspect, the outer diameter of shield **108** may be greater than the inner diameter of c-clamp **210**. In this way, when container **102** is withdrawn proximally to remove container **102** from interior **156**, a proximal end of shield **108** contacts c-clamp **210** and gasket/washer/O-ring **212** to pull c-clamp **210** and gasket/washer/O-ring **212** from interior **156** of the adaptor along with container **102**.
[0110] As another example, referring to FIGS. **3**A, **3**B, a securing mechanism **310** is shown for use in a sample collection system **100** in accordance with the present technology. As shown in FIG. **3**A, the securing mechanism **310** may form a snap fit with a shield **308** for container **102**. On a proximal end of shield **308**, a rim **309** projecting in a direction away from the exterior of container **102**. Furthermore, securing mechanism **310** is configured in an annular shape and is disposed around the exterior of container **102**. Securing mechanism **310** includes oppositely extending rims **312**, **314**. Rim **312** is disposed on a distal end of securing mechanism **310** and projects toward the exterior of container **102** (i.e., opposite the direction in which rim **309** projects). Rim **314** is disposed on a proximal end of securing mechanism **310** and projects away from the exterior of container **102**. The outer diameter of the securing mechanism **310** from the distal end to before the position of proximal rim **314** is selected to enable the distal portion of securing mechanism **310** to be inserted into interior **156**. Rim **314** extends beyond the inner diameter of the adaptor defined by inner surface **160** and functions as a stop or flange at proximal end **154**B. In this way, rim **314** prevents securing mechanism **310** from being advanced distally into container **150** beyond where rim **314** is adjacent to and in engagement with the proximal end of the adaptor and holds securing mechanism **310** at proximal end **154**B of adaptor **150**.
[0111] In use, end **104**A of container **102** is inserted into interior **156**, through an aperture of securing mechanism **310**, and advanced distally until rim **312** contacts rim **309** and rim **314** contacts the distal end **154**B of the adaptor **150**, as shown in FIG. **3**B. Rims **312** and **314** are disposed at a predetermined distance from each other, such that, in the arrangement shown in FIG. **3**B, container **100** is releasably secured or held in the first position with respect to adaptor **150** by the interlock of rims **309**, **312** (and rim **314** abutted against end **154**B) preventing container **102** from being advanced distally within interior **156**. Rim **312** and/or rim **309** are configured to deform slightly under a predetermined amount of force, such that a user applying a distal force to container **100** can force rim **309** distally beyond rim **312** (which is held stationary relative to adaptor **150** by the interaction of rim **314** with end **154**B) to advance container **100** from the first position to the second position such that needle **158** pierces the septum of cap **106**. The interaction between rim **314** and distal end **154**B retains securing mechanism **310** at the distal end **154**B of the adaptor **150** during the distal advancement of container **102**. When container **102** is removed from interior **156** by withdrawing container **100** proximally, rim **309** again contacts rim **312** and pulls securing mechanism **310** proximally to remove securing mechanism **310** from adaptor **150**. As the container **102** is advanced out of the adaptor **150** rim **314** is advanced away from the proximal end **154**B of the adaptor **150**.
[0112] As yet another example, referring to FIG. **4**, a securing mechanism **410** is shown for use in a sample collection system **100** in accordance with the present technology. In the system of FIG. **4**, securing mechanism **410** is configured as a compressible spring attached to the cap and/or shield **108** at end **104**A of container **102**. The spring **410** is releasably attached to the interior **156**, e.g., to distal surface **162** (shown in FIG. **4**), of adaptor **150** and disposed between distal surface **162** and cap **106**. Spring **410** is configured to bias container **102** at the first position such that needle **158** and cap **106** are in a spaced relationship and not in engagement. When the system of FIG. **4** is ready for use (i.e., the line set is connected to the patient and connector **152**), a technician may advance container **100** from the first position distally against the tension of the spring **410** to the second position, where the needle **158** engages cap **106** (i.e., needle **158** pierces the septum of cap **106**) and blood is drawn into container **1020**. It is to be appreciated that to maintain the second position and engagement between needle **158** and cap **106**, a user must actively hold container **102**

in the second position by applying a distal force against container **102** to overcome the tension of spring **410**. When the user removes the distal force from container **100**, the tension of spring **410** advances container **100** proximally to the second position to automatically disengage cap **106** and needle **158**. Thereafter, a user may remove container **100** from interior **156** and, since spring **410** is fixedly attached to cap **106** and/or shield **108**, spring **410** is also removed from interior **156** by the removal of container **100**.

[0113] FIG. **5**A-FIG. **5**D illustrate another aspect of an assembly with a securing mechanism **510** that keeps the collection/discard tube **102** in spaced relation from the adaptor needle **108** during shipping and storage and will allow the collection/discard tube **102** to advance into engagement with the needle **108** in the adaptor **150** for sample collection. As illustrated, the side views in FIGS. **5**A-**5**C of the sample collection system illustrate a foam rubber flange as the securing mechanism **510** that provides the desired separation during shipping and storage and stays affixed to the discard tube **102** when removed from the adaptor **150**. In one example, the securing mechanism **510** includes portions **512**, **514**, which may be configured with the same features described above in relation to portions **112**, **114** of securing mechanism **110**. In this way, portions **512**, **514** of securing mechanism **510** provide an interference fit between the collection/discard tube **102** and the foam **510** and the adaptor **150**. The interference fit holds the tube **102** in place relative to the adaptor **150** (e.g., in a spaced relationship in the first position), but allows easy movement of the tube **102** toward the needle **158** upon the application of an advancing force. Portion **514** has a predetermined thickness that is greater than the inner diameter of adaptor **150** to ensure that the securing mechanism **510** is retained at the proximal end of the adaptor **150** and does not advance distally into the interior **156** of the adaptor **150**. When the tube **102** is pulled out of adaptor **150**, the tube **102** and foam **510** come out of the adaptor **150** together. In one example, securing mechanism **510** includes one or more protrusions **516**, **518**. The protrusions **516** in the foam **510** are configured to protrude from the inner diameter of foam **510** (defined by the inner diameters of portions **512**, **514**) diametrically inward to control the interference force between tube **102** and foam **104**. The protrusions **518** may also be on the outer diameter of portion **512** on the adaptor side of the foam rubber flange **510**. The spot **520** on the collection/discard tube **102** illustrates an optional feature, where a drop of adhesive may be provided to snap into a receiving hole in the foam flange to affix it to the collection/discard tube **102**.

[0114] FIG. **6** is another aspect of an assembly with a securing mechanism **610** that keeps the collection/discard tube **102** in spaced relation from the adaptor needle **158** during shipping and storage and will allow the collection/discard tube **102** to advance into engagement with the needle **158** in the adaptor **150** for sample collection. As illustrated, the side view of the sample/collection discharge tube **102** has a foam rubber flange **610** with a friction fit on the discard tube **102**, which is pulled from the adaptor **150** when the tube **102** is removed therefrom. The foam rubber flange **610** has a low tack adhesive to affix the flange **610** in the base **154**B (e.g., a flange at an end) of the adaptor **150**. Tabs define a spaced relation between the discard tube **102** and the cap **106** thereon. In one aspect, the adhesive strength may be selected such that, when the tube **102** is pulled out of adaptor **150**, the cap **106** applies a pulling force to the securing mechanism **610** when the cap **106** contacts the securing mechanism **610**. The pulling force is sufficient to overcome the adhesion between the securing mechanism **610** and the base or flange **154**B to decouple the mechanism **610** from the base or flange **154**B. In this way, the securing mechanism **610** is carried away from the adaptor **150** with the removal of tube **102**.

[0115] FIG. **7** is another aspect of an assembly with a securing mechanism **710** in accordance with the present disclosure that keeps the collection/discard tube **102** in spaced relation from the adaptor needle **158** during shipping and storage and will allow the collection/discard tube **102** to advance into engagement with the needle **158** in the adaptor **150** for sample collection. Illustrated in FIG. **7** is an alternative foam friction fit collar **710** disposed around the collection/discard tube **102**. The collar **710** does not have the flange illustrated in FIG. **5**A-FIG. **5**D and FIG. **6**. The collar **710** is

configured with the friction fit features described above in relation to the securing mechanisms described above (e.g., securing mechanisms **110**, **510**, etc.) In one aspect, the collar **710** may be adhered (e.g., using a low tack adhesive or using one or more stickers, as will be described below) to the exterior of tube **102** to prevent accidental translation of tube **102** prior to a user pushing tube **102** into adapter **150**.

[0116] FIG. **8**A is an alternative mechanism that provides a friction fit for a flange/O-ring assembly that separates the discard tube from the adaptor needle during shipment. In this aspect, the O-ring is positioned beneath the cap and has a friction fit within the adaptor such that the discard tube is slidably engaged in the adaptor. A sticker is provided to secure the discard tube in its shipment position. The sticker is labeled as such.

[0117] FIG. **8**B is a modified cap or stopper with O-rings disposed in a groove for slidable engagement of the cap in the adaptor. The O-rings provide the friction fit in the adaptor.

[0118] FIG. **8**C illustrates a sample collection system with the cap from FIG. **8**B and a sticker at the flange at the base of the adaptor that secures the collection/discard tube in its spaced relation from the adaptor needle.

[0119] FIG. **9**A-FIG. **91** illustrate the operation of a sample collection/discard tube in an adaptor. The sample collection/discard tube has fitted thereon a sleeve with flanges to accept an O-ring that secures the sample collection/discard tube from engagement with a needle in the adaptor during shipment but allows for the collection/discard tube to be slid into engagement with the needle for sample collection and then removed from the adaptor after sample collection.

[0120] FIG. **10**A-FIG. **10**B is another aspect of an assembly with a securing mechanism **1010** that keeps the collection/discard tube **102** in spaced relation from the adaptor needle **158** during shipping and storage and will allow the collection/discard tube **102** to advance into engagement with the needle **158** in the adaptor **150** for sample collection. In this regard, the aspects illustrated in FIG. **10**A-FIG. **10**B are related to the aspects illustrated in FIG. **13**A-FIG. **13**B. FIG. **10**A-FIG. **10**B specifically illustrate a ring as the securing mechanism **1010**. The ring **1010** may be made of rubber. The rubber ring **1010** includes (annular) portions **1012**, **1014**. Portion **1014** has a predetermined outer diameter configured to provide an interference fit with the inner diameter of bottom end opening of the adaptor **150**. The inner diameter of portion **1012** (which defines the inner diameter of ring **1010**) is configured to receive the collection tube **102** snugly to ensure it remains spaced apart from the needle **158** in the adaptor **150** during shipment. In one aspect, portion **1012** projects from portion **1014** distally and has a distally tapering diameter. Portion **1012** is configured (via its inner diameter and shape) to permit the tube **102**, upon application of a pushing force, to be advanced easily only in a single direction into adaptor **150** as shown in FIG. **10**B such that the collection/discard tube **102** may be advanced into engagement with the needle **158** for sample collection. After sample collection, the rubber ring **1010** is pulled from engagement with the adaptor **150**. Upon application of a pulling force on tube **102** to remove tube **102** from adapter **150**, portion **1012** grabs or catches onto the exterior of tube **102** and causes the ring **1010** to disengage the adaptor **150** and the tube **102** and ring **1010** pulled together out of the adapter **150**. Ring **1010** is configured as a one-way ratchet mechanism.

[0121] FIG. **11** illustrates securing mechanism **1110**, which is an alternative configuration of the rubber ring **1010** of FIG. **10**A-FIG. **10**B. The rubber ring or securing mechanism **1110** includes portions **1114** and **1112**. The exterior diameter of ring **1110** is configured to provide an interference fit with the adapter **150** in the manner described above. Portions **1112** and **1114** each include an inner diameter. The inner diameter of portion **1112** is smaller than portion **1114** and is selected receive and grip the flange **1122** of sleeve **1120** that is disposed on tube **102** to hold tube **102** in a spaced relationship with needle **158** within adapter **150**. Tube **102** can be pushed into adapter **150** to engage needle **158**. When tube **102** is pulled out of adapter **150**, the flange **1122** engages the rubber ring **1110**. The rubber ring **1110** is pulled out from the adaptor **150** by the flanged ring **1120** when the collection/discard tube **102** is pulled and removed from the adaptor **150**.

[0122] FIG. **12** illustrates a securing mechanism **1210**, which is another alternative configuration of a rubber ring disposed in the bottom the adaptor **150** that is a variation of what is described in FIG. **10**A-FIG. **10**B and FIG. **11**. In this aspect, the rubber ring **1210** has bearings **1212** (e.g., ball bearings) that are embedded in an inner circumference of the rubber ring **1210**. The ring **1210** has outer and an inner diameters configured to hold the tube **102** in an interference fit with adapter **150**. In one aspect, the ring **1210** may include an inner ring **1214** that projects from the inner circumference of ring **1210** toward the center of the central opening of ring **1210**. The ring **1214** is configured to grip the exterior of tube **102** to hold tube **102** in place. Upon an application of the pushing force onto tube **102** into adapter **150**, the ring **1210** and the bearings **1212** are configured to easily allow the collection/discard tube **102** to be advanced into engagement with the needle **158** in the adaptor **150**. In one aspect, the rubber ring **1210** is prevented from advancing into the adaptor **150** by a flange or stepped end **1250** in the inner diameter of the open proximal end **154**B of the adapter **150**. The stepped end **1250** has an inner diameter that matches the outer diameter of ring **1210**. A surface **1216** of ring **1210** abuts against surface or ledge **1252** of stepped end **1250** to prevent ring **1210** from advancing into adapter **150**. The rubber ring **1210** is removed from the adaptor **150** when the tube **102** is pulled or advanced out of the adaptor **150**. In one aspect, when the tube **102** is pulled out of the adaptor **150**, the ring **1210** (e.g., due to the gripping ring **1214** and the surrounding material of ring **1212**) is configured to pinch the ball bearing **1212** such that the gripping force of ring **1210** on tube **102** is increased and the ring **1210** disengages the adaptor **150** and is pulled out of the adaptor **150** with the tube **102**.

[0123] FIG. **13**A-FIG. **13**B is another aspect of an assembly with a securing mechanism **1310** that keeps the collection/discard tube **102** in spaced relation from the adaptor needle **158** during shipping and storage and will allow the collection/discard tube **102** to advance into engagement with the needle **158** in the adaptor **150** for sample collection. FIG. **13**A-FIG. **13**B illustrate the securing mechanism as a ratcheting collar **1310** with tabs **1312** that extend from a flanged portion **1314**. The tabs **1312** are spaced around an inner circumference of the collar **1310** and extend distally from flanged portion **1314**. The central opening of collar **1310** receives the tube **102** and the tabs **1312** provide an interference fit for the collar **1310** in the adaptor **150** and with the tube **102** such that the collection/discard tube may be advanced through the collar **1310**. As shown in FIG. **13**A, at least a portion of each of the tabs **1312** extends in a direction toward the center of the central opening of collar **1310**. The flanged portion **1314** of the collar **1310** abuts against the open proximal end of adaptor **150** to hold adaptor **150** in place when tube **102** is pushed into adaptor **150**. As illustrated in FIG. **13**B, the collar **1310** remains in place as the tube **102** is advanced into engagement with the adaptor needle **158**. The collar **1310** permits the collection/discard tube **102** to freely advance toward the needle **158**, but tabs **1312** of the collar **1310** are configured to grip and bunch on the exterior of tube **102** when the collection/discard tube **102** is pulled away from the needle **158**. The collar **1310** is therefore removed from the adaptor **150** when the collection/discard tube **102** is pulled from the adaptor **150**. In one aspect, as shown in FIGS. **13**A-**13**B, tabs **1312** may be supported by ring or rim **1312** that extends distally from flanged portion **1314**. Alternatives to this configuration are described in FIG. **10**A-FIG. **10**B, FIG. **12**, FIG. **14**A-**14**D, FIG. **15**A-**15**D, and FIG. **16**A-**16**E. In this way, collar **1310** is like a one-way ratchet mechanism allowing easy advancement of the tube **102** into adaptor **150**, but catching and gripping the tube **102** when the tube **102** is pulled out.

[0124] FIG. **14**A-FIG. **14**D is another aspect of an assembly with a securing mechanism **1410** that keeps the collection/discard tube **102** in spaced relation from the adaptor needle **158** during shipping and storage and will allow the collection/discard tube **102** to advance into engagement with the needle **158** in the adaptor **150** for sample collection. FIG. **14**A-FIG. **14**D is another alternative to FIG. **13**A-FIG. **13**B. FIG. **14**A-FIG. **14**D illustrate securing mechanism as a one-way collar **1410**. The collar **1410** includes a tubular or barrel portion **1414** and a flanged portion. The collar **1410** includes internal grips **1416** disposed on and projecting from an inner surface of

portion **1414**. Grips **1416** provide a friction force for gripping the exterior of tube **102** when tube **102** is received into the interior of portion **1414**. Grips **1416** are configured to hold to tube **102** in place (e.g., in a spaced relationship with needle **158**) and permit the collection/discard tube **102** to be advanced into the adaptor **150** upon application of a pushing force onto tube **102**. As illustrated in FIG. **14**D, grips **1416** of the collar **1410** grip the tube **102** such that it is removed from engagement with the adaptor **150** when the collection/discard tube **102** is pulled from the adaptor **150**. The flanged portion **1412** of collar **1410** has a catch **1418** that accepts the flange at the base or open proximal end of the adaptor **150**. The catch **1418** may form all or part of the outer rim or circumference of the flanged portion **1412**. The grips **1416** grip the exterior of tube **102**, such that when tube **102** is pulled from the adapter **102**, seal/coupling of the catch **1418** to the base of adapter **150** is broken. The catch **1418** may be made of a soft material (TPE) so that the seal/coupling with flanged base of the adaptor **150** can be broken and detached from the adaptor **150** when the tube **102** is pulled out of adaptor **150**.

[0125] FIG. **15**A-FIG. **15**D illustrate an alternative securing mechanism **1510** to the collar **1310** of FIG. **13**A-FIG. **13**B and operates in a similar manner. The one-way collar **1510** in this aspect has portions **1512** and **1514**. Portion **1512** includes a detent or catch **1518** that engages with the base of the adaptor **150** in a similar manner as described above in relation to catch **1418**. As such, in this aspect, the collar **1510** does not have an interference fit with the adaptor **150**. Because of bump-offs **1520** in the detent **1518** on the collar **1510**, the collar **1510** cannot advance upward into the adaptor **150**. Collar **1510** includes grips **1516**, which extend upward (distally) and toward the center of the interior of portion **1514** from the interior wall of portion **1514**. The grips **1516** act as a one-way ratcheting mechanism on tube **102**. In use, the collar **1510** is disposed around tube **102** and grips **1516** hold to the exterior of tube **102** and detent **1518** engages with the base of the adapter **1510** to hold the tube **102** in a spaced relationship with needle **158**. The grips **1516** are configured to permit easy movement of the tube **102** toward the interior of adaptor **150** and into engagement with needle **158** with relatively low pushing force. Moreover, grips **1516** are configured to bunch and provide high resistance or friction force on the exterior of tube **102** when tube **102** is pulled toward the exterior of adaptor **150**. An example of the operation and bunching that occurs for grips **1516** is shown for the similarly configured grips **1616** in FIGS. **16**B, **16**C, and **16**E-**16**K. The grips **1516** hold to the collection/discard tube **102** such that detent **1518** is detected from the base of the adapter when tube **102** is removed or pulled from the adaptor **150**. Thus, the collar **1510** and the tube **102** are both removed from adapter **150** by the pulling of tube **102**.

[0126] FIG. **16**A-FIG. **16**D illustrate an alternative securing mechanism **1610** to the collar of FIG. **15** with a sticker **1650** added to secure the collar **1610** to the collection/discard tube **102** in the shipping/storage position. The collar **1610** includes portions **1612**, **1614**, which are configured with similar features as portions **1512**, **1514** described above. The bump-offs and detents **1618** are rotated ninety degrees relative to what is illustrated in FIG. **15**A-FIG. **15**D.

[0127] FIG. **16**E-FIG. **16**K illustrate the operation of the assembly of FIG. **16**A-FIG. **16**D. The upward facing grips **1618** make it feasible to advance the collection/discard tub **102** upwards into the adaptor **150** but, when the collection/discard tube **102** is advanced out of the adaptor **150**, it carries the collar **1610** with the tube **102** from the adaptor **150**. Grips **1616** act as a one-way grip so that the tube **102** may be advanced upward through the grips, but the tube **102** carries the collar **1610** when advanced outward from the adapter.

[0128] FIG. **17**A-FIG. **17**B is a two-piece securing mechanism. The securing mechanism **1710** illustrated in FIGS. **17**A-**17**B includes collars **1711** and **1721**. Variations of this aspect are illustrated in FIG. **18**A-FIG. **18**C and FIG. **19**A-FIG. **19**C. Collar **1721** includes a base portion **1722** and barbs **1724** that extend longitudinally (i.e., in the direction of insertion and extraction of the tube **102** into adaptor **150**) from base portion **1722**. The collar **1722** is affixed (e.g., adhered) to the exterior of the collection/discard tube **102** by an interference fit. Collar **1711** includes portions **1712**, **1714**, which are configured in a similar manner to portions **512**, **514** described above to form

an interference fit with the open base end of adaptor **150** and to prevent collar **1711** from being advanced further into adaptor **150**. The inner diameter of collar **1711** provides an interference grip onto the exterior of tube **102** to hold tube **102** in a stationary position relative to collar **1711** and adaptor **150** unless a sufficient force is applied to tube **102**. Collar **1711** includes holes **1716** configured to receives barbs **1724**. Tube **102** is held by collar **1711** in a spaced relationship with needle **158** during shipment and storage with the collar **1721** in a spaced relationship with collar **1711**. When tube **102** is pushed or advanced into the adaptor **105** and into engagement with needle **158**, the collar **1721** is advanced toward collar **1711** and the barbs **1724** lock into holes **1716** in a flanged adaptor collar **1711** which is in an interference fit with the adaptor base. The barbs **1724** of collar **1722** lock into openings **1716** in the flanged adaptor collar **1711**, forming a two-piece assembled collar. When the collection/discard tube **102** is advanced out of the adaptor **150**, tube **102** carries the two-piece assembled collar (comprising collars **1711**, **1721**) from the adaptor **150**.

[0129] FIG. **18**A-FIG. **18**C is another securing mechanism configured as a two-piece assembly for holding the collection/discard tube **102** in spaced arrangement from the needle **158** in the adaptor **150** during shipment but allowing the collection/discard tube **102** to be advanced into engagement with the needle **158** for sample collection. The two-piece assembly or securing mechanism is pulled from the adaptor **150** when the collection/discard tube **102** is removed therefrom. The securing mechanism comprises a snap ring **1811** with a ring portion **1814** and with upward facing projections or snap fins **1812** that project from ring portion **1814** and are biased to be angled toward the interior of snap ring **1811**. The snap ring **1811** is fitted into the open end base of the adaptor **150**. The adapter **150** includes a stepped end **1828** to receive the snap ring **1811**. The securing mechanism further comprises a sleeve **1821** and raised portions **1822** and **1823** configured to retain an O-ring **1825** between portions **1822** and **1823**. Sleeve **1821** further includes raised portion or flange **1824**. The sleeve **1821** is fitted on the collection discard tube **102** (e.g., sleeve **1821** may be adhered to the exterior and/or tube **102** or by grip the exterior of tube **102** with crush ribs **1826**). When the tube **102** is inserted into adaptor **150**, the projections **1812** permit the raised portions **1822**, **1823** and O-ring **1825** to pass through the snap ring **1811**. The O-ring **1825** provides friction against the interior of adaptor **150** to hold tube **102** in a spaced relationship with needed **158** during shipment and/or storage. The projections **1812** of the snap ring **1811** sign against the exterior of sleeve **1821** and abut against the raised portion **1823** and thus do not permit the tube **102** to be pulled out of the adaptor **150**. The tube **102** is pushed into adaptor **150** to engage needed **158** for sample collection. During this engagement, the projections **1812** permit the raised portion **1824** to pass through the snap ring **1811**. When the tube **102** is pulled out of the adaptor **150**, the flange or raised portion **1824** on the sleeve **1821** catches on the ends of projections **1812** and pulls the snap ring **1821** from the adaptor **150** when the collection/discard tube **102** is removed therefrom.

[0130] FIG. **19**A-FIG. **19**C is an alternative aspect to the two-piece assembly in FIG. **18**A-FIG. **18**C for holding the collection/discard tube **102** in spaced arrangement from the needle **158** in the adaptor **150** during shipment but allowing the collection/discard tube **102** to be advanced into engagement with the needle **158** for sample collection. The two-piece assembly or securing mechanism is pulled from the adaptor **150** when the collection/discard tube **102** is removed therefrom. The securing mechanism comprises a snap ring **1911** and a sleeve **1921**. The snap ring **1921** comprises upward facing projections or snap fins **1912** that project for a ring portion or base **1914** and are biased to be angled toward the interior of snap ring **1911**. The snap ring form an interference fit on the collection/discard tube **102**. The snap ring **1911** further comprises ribs **1916** for gripping the interior of adaptor **150** and a flange **1915** formed in the base **1914** for abutting against the rim of the open base end of adaptor **150**. The snap ring **1911** is fitted into the base of the adaptor **150** as shown with the ribs **1916** gripping the interior of adaptor **150** and the flange **1915** preventing the snap ring **1911** from being advanced further into the adaptor **150**. In this aspect the sleeve **1921** has first, second, and third flanges or raised portions **1921**, **1922**, **1924** projecting from the exterior of the sleeve **1921**. The sleeve **1921** further comprises ribs **1926** projecting from the

interior surface of sleeve **1921** for gripping the exterior of tube **102** when sleeve **1921** is fitted on the collection/discard tube **102** such that sleeve **1921** and tube **102** are stationary relative to each other. When the tube **102** is advanced into the adaptor **150** for shipment, the fins **1912** permit the first raised portion **1922** to advance past the fins **1912** such that the ends of the fins **1912** are inserted between raised portions **1922** and **1923** to lock the tube **102** and sleeve **1921** in place for shipment and storage with the tube **102** in a spaced relationship with the needle **158**. The inner surfaces of the fins **1912** lay against a portion of the second flange or raised portion **1923** in this position, holding the collection/discard tube **102** in place for shipment or storage. The ramped flange **1923** advance past the snap ring **1911** when the collection/discard tube in place in the second position. The fins **1912** permit the second and third raised portions **1923** and **1924** to pass through snap ring **1911** when the tube **102** is pushed into adaptor **150** to such that the collection tube **102** is engaged with the needle **158** for sample collection. When the tube **102** is pulled out of the adaptor **150**, the third flange or raised portion **1924** on the sleeve **1921** catches on the ends of projections **1912** and pulls the snap ring **1911** from the adaptor **150** when the collection/discard tube **102** is removed therefrom.

[0131] FIG. **20** is a collection/discard tube **102** with securing mechanism **2010** including a flanged sleeve disposed around the tube **102** for holding the collection/discard tube **102** in spaced arrangement from the needle **158** in the adaptor **150** during shipment but allowing the collection/discard tube **102** to be advanced into engagement with the needle **158** for sample collection. The securing mechanism **2010** includes a sleeve **2016** coupled to and extending from a flanged portion comprising portions **2012**, **2014**. Portions **2012**, **2014** may be configured with the same features described above in relation to portions **112**, **114** of securing mechanism **110** and portions **512**, **514** of securing mechanism **510**. In this way, portions **2012**, **2014** of securing mechanism **2010** provide an interference fit between the securing mechanism **2010** and the adaptor **150**. The flanged portion **2014** is engaged with the adaptor **150** through an interference fit. There is clearance between the outer diameter of the collection/discard tube **102** and the inner diameter of the sleeve portion **2016** that, upon application of a pushing/pulling force onto tube **102** permits easy (or free) movement of the collection/discard tube **102** in the securing mechanism **2010** and into the adaptor **150**. Portion **2014** has a larger diameter than the proximal end of adaptor **150** and prevents the securing mechanism **2010** from advancing into adaptor **150** beyond the open end of the adaptor **150** when the collection/discard tube **102** is placed therein. The flanged sleeve portion **2016** is flexible. When the collection/discard tube **102** is advanced through the securing mechanism **2010** and into engagement with the needle **158** in the adaptor **150** for blood collection, the securing mechanism **2010** remains in position. There is diametric clearance between the tube and the sleeve **2016** that allows free movement of the tube in the sleeve **2016**. The operator grips the collar adjacent the bottom of the adaptor **150** when advancing the collection/discard tube **102** into engagement with the needle **158** in the adaptor **150**. Since the sleeve **2016** is flexible, as indicated by arrows **2018**, the sleeve **2016** can assist with gripping (e.g., when gripped by an operator) the collection/discard tube **102** when removed from the adaptor **150**. Portion **2016** is dimensioned with a sufficient length such that when the tube **102** is advanced into adaptor **150** and engaged with needle **150**, the only way to grab the tube **102** is by grabbing the sleeve **2016** (as indicated by arrows **2018**). This forces the user to pull the securing mechanism **2010** out with the tube **102**. When the collection/discard tube **102** is pulled from the adapter **150**, the interference fit between portion **2012** and adaptor **150** is overcome and the flanged sleeve securing mechanism **2010** (which is being gripped by the user) is removed along with the collection/discard tube **102**.

[0132] FIG. **21** illustrates a securing mechanism **2110** including a two-part collar with a collar including portions **2112**, **2114** that fits in the bottom portion of the adaptor **150** but does not advance therein, e.g., in the same manner described in relation to the collars in FIGS. **5**A-**5**D and FIG. **20** above. The first portion of the collar **2112**, **2114** in the base of the adaptor **150** cooperates with the collar on the collection/discard tube **102** to hold the collection/discard tube **102** in spaced

relation to the needle **158** in the adaptor **102**. The second portion **2116** of the collar on the collection/discard tube **102** has arms **2108** with notched engagement members **2120** that will advance past the first portion **2114** of the collar as the collection/discard tube **102** is advanced into the adaptor **150**. As such, the second portion **2116** of the collar is fashioned as an outside clip. When the collection/discard tube **102** is removed from the adaptor **150** after sample collection, the engagement members **2120** on the second portion **2118** of the collar pull the first portion **2114** of the collar from the base of the adaptor **150**.

[0133] FIG. **22** is another securing mechanism **2210** configured as a flanged sleeve for the collection/discard tube **102** that is an alternative to what is illustrated in FIG. **20**. Securing mechanism **2210** includes flanged portion **2212** and sleeve portion **2214**. The flange **2212** locks to the flange at the base of the adaptor **150** with a lip/detent **2218** that fits over the adaptor base flange in the same manner described above in relation to flanged portion **4112** including catch **1418** in FIGS. **14**A-**14**D. As such, the securing mechanism **2210** is secured by a lock fit with adaptor **150** instead of an interference fit. The inner diameter of securing mechanism **2210** grips the outer diameter of tube **102** and collection/discard tube **102** is held in spaced arrangement from the needle **158** in the adaptor **150** during shipment by the securing mechanism **2210**. Advancing the collection/discard tube **102** through the securing mechanism **2210** advances the collection/discard tube **102** into connection with the adaptor needle **158**. After the sample is collected, the flanged portion **2212**, which is flexible, is detached from the flange at the base of the adaptor **150** and the collection/discard tube **102**, with the sleeve **2210** attached, is removed from the adaptor **150**. In one aspect, the flanged portion **2212**, when locked to the base of the adaptor **150** creates a sealed unit with the adaptor **150** for increased sterilization. In one aspect, the sleeved portion includes one or more opening(s) **2216** to enable the operator to view the contents (e.g., the sample collected) within tube **102**.

[0134] FIG. **23**A-FIG. **23**C is another securing mechanism **2310** configured as a flanged sleeve that is an alternative to what is illustrated in FIGS. **20** and **22**. The securing mechanism **2310** in this aspect includes portions flanged portion **2312** and sleeve portion **2314**. Flanged portion **2312** has a detent with bump-off for locking onto the base of the adaptor **150** as previously described and illustrated. The flanged sleeve **2310** is detached from the adaptor **150** by squeezing the (elastomeric) sleeve **2314** and applying a pulling force away from the adaptor **150**, which causes the sleeve flange **2312** to separate from the flange at the base of the adaptor **150** when the collection/discard tube **102** is removed from the adaptor **150**. The sleeve **2314** provides a gripping surface for removing the collection/discard tube **102**. There is diametric clearance between the sleeve **2314** and the collection/discard tube **102**. In one aspect, some or all of the sleeve portion **2314** may be made of a clear elastomeric material such that the contents of tube **102** are visible through the sleeve portion **2314**. In one aspect, the sleeve portion **2314** is affixed to the collection/discard tube **102** by shrink wrap or tape **2350** (shown in FIG. **23**C) during shipment. The shrink wrap or tape **2350** (in addition to the friction provided by the interior of the sleeve portion **2314**) helps ensure that the collection/discard tube **102** remains spaced apart from the needle **150** during shipment.

[0135] FIG. **24**A-FIG. **24**B is another securing mechanism **2410** and another aspect of what is illustrated in FIG. **20** and FIG. **23**A-FIG. **23**C. Securing mechanism **2410** includes flanged portion **2412** and sleeve portion **2410**, which includes similar features to the fanged portions **2212**, **2312** and sleeve portions **2214**, **2314**, described above. Sleeve portion **2414** includes opening(s) **2416** for enabling the user to view the contents of tube **102**. Each of the opening(s) **2416** may be formed as a closed loop (FIG. **24**A) or a slot (FIG. **24**B). In one aspect, the securing mechanism **2410** may include friction bead **2420** on the interior circumference of securing mechanism **2410** (e.g., inner circumference of portion **2412**) to add additional friction and aid in retaining tube **102** in a stationary position relative to securing mechanism **2410**. FIGS. **24**A and **24**B show how the sleeve flange securing mechanism **2410** seats on the flange at the base of the adaptor **150** to retain the

collection/discard tube **102** in the spaced position from the adaptor needle **150** during shipment. As described above, the tube **102** may be moved in relation to securing mechanism **2410** and adaptor **150** upon application of a pushing or pulling force into/out of the adaptor **150**.

[0136] FIG. **25**A-FIG. **25**C is another securing mechanism **2510** and another aspect of what is illustrated in FIG. **20**, FIG. **23**A-FIG. **23**C, and FIGS. **24**A-**24**B. Securing mechanism **2510** includes the same features (i.e., flanged portion and sleeve portion with opening(s)) as securing mechanism **2410**. In this aspect, as shown in FIG. **25**B, the securing mechanism **2510** may include a tape or adhesive strip **2550** (e.g., U-shaped, L-shaped, etc.) that is affixed over a portion of the securing mechanisms **2510** (e.g., over the sleeve portion) and over a portion of tube **102** to aid in retaining tube **102** in a stationary position relative to securing mechanism **2510** (and adaptor **150**). The strip **2550** may be positioned and configured to contact the tube **102** through one of the openings in the securing mechanism **2510**. The securing mechanism **2510** holds the tube **102** in a spaced relationship with needle **158** during shipment and allows the tube **102** to be moved relative to securing mechanism and adaptor **150** upon application of a pulling or pushing force into/out of adaptor **150**. It is to be appreciated that, after shipment and during use, the pulling and pushing forces on tube **102** will decouple the strip **2550** from tube **102**.

[0137] FIG. **26** illustrates a securing mechanism **2610** configured as a collar for the collection/discard tube **102** that has a collapsible section with a living hinge that allows the collar to keep the collection/discard tube in spaced relation to the needle in the adaptor during shipment but, for blood collection, as the collection/discard tube is advanced toward the needle, the living hinge collapses, allowing the collection/discard tube to be advanced into contact with the adaptor needle for blood collection. After collection, the collar is removed with the collection/discard tube as it is removed from the adaptor.

[0138] FIG. **27**A-FIG. **27**B is another securing mechanism **2710** and another aspect of the collection/discard tube assembly wherein the collection/discard tube has a sleeve affixed thereto with a twist-on, twist-off flange that attaches to the flange at the base of the adaptor. As illustrated, the line set is in fluid communication with the adaptor and blood is drawn into the collection/discard tube when the needle in the adaptor pierces the seal in the cap of the collection/discard tube when it is advanced into contact with the needle. The collection/discard tube is advanced in the sleeve, which remains fixed when locked on the flange of the adaptor. When the sleeve is twisted off the adaptor flange, the collection/discard tube is removed from the adaptor.

[0139] FIG. **28** is another securing mechanism **2810** and another aspect of the collection/discard tube assembly for holding the collection/discard tube in spaced relation from the needle in the adaptor during shipment but allowing the collection/discard tube to be advanced into engagement with the needle for sample collection. In this aspect, the collection/discard tube has a sleeve that can be threaded into the adaptor. There is a flange at the base of the sleeve, which, as illustrated, has helical spines that provide a friction fit when advance into the adaptor. The flange limits how far the sleeve may advance. The sleeve holds the collection/discard tube in spaced relation from the needle during shipment and storage. The collection/discard tube is twisted to advance it within the sleeve. As illustrated, the line set is in fluid communication with the adaptor and blood is drawn into the collection/discard tube when the needle in the adaptor pierces the seal in the cap of the collection/discard tube when it is advanced into contact with the needle. After sample collection, the collection/discard tube is removed from the adaptor.

[0140] FIGS. **29**A-**29**C illustrate another securing mechanism **2910** and another aspect of the collection/discard tube assembly for holding the collection/discard tube **102** in spaced relation from the needle **158** in the adaptor **150** during shipment but allowing the collection/discard tube **102** to be advanced into engagement with the needle **158** for sample collection. The securing mechanism **2910** has a collar **2912** and a flexible hinged spring ring **2914** attached to collar **2912** by hinge **2918**. The ring **2918** is biased by hinge **2918** to a slanted or angled position relative to collar **2912**. In one aspect, as shown in FIG. **29**A, the ring **2918** is biased to be slanted toward the interior of

collar **2912** and toward the interior of adaptor **150**. In another embodiment, as shown in FIG. **29**C, the ring **2918** is biased to be slanted toward the exterior of collar **2912** and exterior of adaptor **150**.
[0141] The collar **2912** includes an outer diameter selected to fit (e.g., snugly) within the inner circumference at the open end of the base of the adaptor **150** in an interference fit. The securing mechanism **2910** includes one or more tabs **2916** which extend away from the outer circumference of collar **2912**. Tabs **2916** are configured to abut against the circumference defining the opening at the end of the base of adaptor **150** to prevent the securing mechanism **2910** from being advanced further into the interior of adaptor **150** and to hold the securing mechanism **2910** in position at the base of adaptor **150**. The flexible hinged spring ring **2912** is configured to receive the tube **102** and to grip and hold the exterior of the collection/discard tube **102** in spaced relation from the needle **158** during shipment and storage. When the ring **2914** is at an angle relative to the base of the adaptor and/or the collar **2912**, the inner circumference of ring **2914** makes contact with the collection/discard tube and grips or locks against the exterior of tube **102**. The grip is such that, upon application of pulling or pushing force onto the tube **102**, the tube **102** is moveable in relation to the securing mechanism **2910** and adaptor **150** into and out of the adaptor **150**. The ring **2914** bends in the direction of the tube movement. When the tube **102** causes the ring **2914** to move toward the adaptor **150**, the ring **2914** reduces or releases contact with the collection/discard tube **102** and allows the collection/discard tube **102** to advance. Blood is drawn into the collection/discard tube **102** when the needle **158** in the adaptor **150** pierces the seal in the cap of the collection/discard tube **102** when it is advanced into contact with the needle **158**. After sample collection, the collection/discard tube **102** is removed from the adaptor **150** along with the securing mechanism **2910**. When the collection/discard tube **102** is pulled away from the needle **158** in the adaptor **150**, the ring **2914** bends away from the holder and grasps or pinches the collection/discard tube **102** more tightly. This locks the ring **2914** against the collection/discard tube **102** and the collection/discard tube **102** pulls the securing mechanism **2910** with it when the collection/discard tube **102** is removed from the adaptor **150**.
[0142] FIG. **30**A-FIG. **30**C illustrate another securing mechanism **3010** and another aspect of a two-piece collar/sleeve assembly for holding the collection/discard tube **102** in spaced relation to the needle **158** in the adaptor **150** during shipment and storage but allowing the collection/discard tube **102** to be advanced into engagement with the needle **158** for sample collection. The securing mechanism **3010** comprises a collar **3011** and a sleeve **3021**. The collar **3011** includes portions **3012** and **3014**, which are configured in the same manner described above in relation to portions **512**, **514** and portions to provide an interference fit with the open end at the base of the adaptor **150** and to prevent the collar **3011** from being advanced further into adaptor **150**. The collar **3011** includes notched channels **3016** in the interior of collar **3011**. Collar **3011** further includes detents or protrusions **3017** extending from an interior surface in each notched channel **3016**. The sleeve **3021** has raised guides **3023** that travel through the notches **3016** in the adaptor collar **3011**. The raised guides **3023** each include stepped or raised portions **3022**. Sleeve **3021** includes raised tabs **3024** which extend toward the exterior of sleeve **3021**. The sleeve **3021** is fitted onto the collection/discard tube **102**. In one aspect, the sleeve **3021** is mounted to tube **102** via friction or gripping between the interior of sleeve **3021** and the exterior of tube **102** or via adhesive applied between the interior of sleeve **3021** and the exterior of tube **102**. During shipment or storage, the raised portions **3022** sit behind detents **3017** such that the collection/discard tube **102** is kept in a stationary position and in spaced relation from the needle **158** and additional pushing force is required to advance tube **102** into the interior of adaptor **150**. In one aspect, the raised portions **3022** have an interference fit with the interior surface of notched channels **3016** to also aid in retaining the tube **102** in the stationary position unless a pulling or pushing force is applied to tube **102**. Blood is drawn into the collection/discard tube **102** when the needle in the adaptor **150** pierces the seal in the cap of the collection/discard tube **102** when it is advanced into contact with the needle **158** when the raised portions **3022** are forced to bypass the detents **3017** by the force on the

tube **102**. The channels **3016** and guides **3023** cooperate to provide smooth linear motion to tube **102**. When the cap of tube **102** is advanced into adaptor **150** to engage needle **158**, the tabs **3024** are configured to bend inward in a direction toward the interior of sleeve **3021** upon being compressed from the contact with the rim and interior surfaces of portions **3014** and **3012**. As tub **102** is pushed, the tabs **3024** advance beyond portion **3012** into the interior of adaptor **150**, where the tabs **3024** bend or deflect outwards to their original position due to the natural bias of tabs **3024**. After sample collection, the collection/discard tube **102** is pulled to remove the tube **102** from the adaptor **150**. When the tube **102** is pulled, the end of tabs **3024** abut against the rim defining the open end of portion **3012** of collar **3011** thus transferring the pulling force applied to tube **102** onto collar **3011** and forcing the collar **3011** to disengage from the adaptor **150** and be removed along with sleeve **3021** and tube **102** when the collection/discard tube **102** is removed from the adaptor **150**.

[0143] FIG. **31**A-FIG. **31**B illustrates a securing mechanism **3110** and is a modified aspect of what is illustrated in FIG. **30**A-FIG. **30**C. It is to be appreciated that components of FIG. **31**A that are similarly numbered to components of FIGS. **30**A-**30**C (i.e., **30**XX vs. **31**XX) are configured with the same features unless otherwise specified. The collar **3111** has clips **3115** that fasten to the flange at the base of the adaptor **150**, as described above in previous embodiments. The interior surface of collar **3111** includes inclined surface or raised portions **3019**, which converge toward the center of the collar **3111**. Clips **3115** and raised portions **3019** are configured as deflectable tabs, where deflection of a first tab **3119** toward the exterior of collar **3111** in an arc causes deflection of a first clip **3115** toward the interior of collar **3111** in an arced motion. The same relationship holds true for a second tab **3119** and a second clip **3115**, etc. The arced motion is shown by the arrows with dotted lines in FIGS. **31**A-**31**B. The sleeve **3021** has raised guides **3121** that travel through the notches **3116** in the adaptor collar **3111** and detents **3117** that cooperate with raised portions **3122**, as described above. The sleeve **3011** further includes raised portions **3125**, which correspond to respective pairs of clips **3115** and tabs **3119**, which as described below contact tabs **3119** to cause deflection of clips **3115**. The sleeve **3121** is fitted onto the collection/discard tube **102**. The sleeve has raised portions **3112** at the base of the sleeve **3112** that interact with detents **3117** ensure that the collection/discard tube **102** is held in spaced relation from the needle **158** during shipment and storage. Blood is drawn into the collection/discard tube **102** when the needle **158** in the adaptor **150** pierces the seal in the cap of the collection/discard tube **102** when it is advanced into contact with the needle **102** by bypassing the detents **3117**. When the tube **102** is advanced into adaptor **150** and into engagement with needle **158**, raised portions **3125** deflect raised portions **3119**, which cause deflection of clips **3115**, as indicated by the dotted lines and arrows in FIGS. **31**A-**31**B. When clips **3115** are deflected in this manner, the clips **3115** disengage the flange of the base of the adaptor **150**. When the raised portions **3125** deflect the raised portions **3119**, portions **3125** and **3119** may form an interference fit such that after sample collection, when the collection/discard tube **102** is pulled and removed from the adaptor **150**, the collar **3111** with disengaged clips **3115** and sleeve **2131** along with the tube **102** are also removed from adaptor **150**. The disengaged clips **3115** permit the withdrawal.

[0144] FIG. **32**A-FIG. **32**B is a modified aspect of an assembly for holding the collection/discard tube **102** in spaced arrangement from the needle **158** in the adaptor **150** during shipment but allowing the collection/discard tube **102** to be advanced into engagement with the needle **158** for sample collection. In this aspect, the securing mechanism **3210** comprises a ring or collar **3212** and a slot **3214** on the adaptor **150**. The collar **3212** is disposed on the collection/discard tube **102** and has posts **3212** that each engage a slot **3214** in the adaptor housing **150**. It is to be appreciated that although multiple slots and posts are shown, in some aspects, a single slot and post may be used. The side slot **3214** includes portions **3215** and **3216**. Portion **3215** extends along a longitudinal direction parallel to the insertion and extraction direction of the tube **102** into adaptor **150**. Portion **3216** branches off from portion **3215** in a direction that traverses the longitudinal direction. Portion

3215 of the slot is configured to receive a post **3213** and allows the collar and tube **102** to advance longitudinally within portion **3215** of the slot **3214**. Portion **3216** receives post **3213** to allow the collar **3212** (and tube **102**) to be rotated into a locked position (i.e., preventing longitudinal motion of collar **3212** and tube **102**) that locks the collection/discard tube **102** in spaced relation from the needle **158** during shipment and storage. In one aspect, portion **3216** of slot **3214** includes a detent or protrusion **3217** that extends into portion **3216** to lock the post **3213** in portion **3215**. A slot **3219** behind detent **3217** allows detent **3217** to move longitudinally when post **3213** is formed to traverse (e.g., by a torque force applied by the user to tube **102**) through portion **3216** of slot **3214**. To advance the collection/discard tube **102** into engagement with the adaptor needle **158**, the collection/discard tube **102** is rotated/twisted such that post **3213** travels through portion **3215** and into portion **3215** of slot **3214** and then tube **102** is pushed longitudinally to allow post **3213** to travel longitudinally through portion **3215** until tube **102** is advanced into engagement with the needle **158** in the adaptor **150** for blood collection because the collar pin/post **3213** can again advance along the slot portion **3215** in the adaptor housing **150**. After sample collection, the collection/discard tube **102** is removed from the adaptor **150** by pulling tube **102**, thereby pulling post **3213** through slot portion **3215** along with the collar **3212** until the tube **102** and collar **3212** are removed from adaptor **150**. It is to be appreciated that collar **3212** may be fixedly coupled to tube **102** or may have an interference or friction fit with tube **102** such that collar **3212** and tube **102** remain stationary with respect to each other.

[0145] FIG. **33**A-FIG. **33**B is a modification of the aspect of FIG. **32**A-FIG. **32**B. The securing mechanism in FIG. **33**A-**33**B comprises collar **3312** and slot **3314** in adaptor **150**. Collar **3312** includes posts **3313** which are slidable in slot **3314**, which includes slot portions **3316**, **3315**. Slot portion **3315** extends longitudinally and slot portion **3316** branches off in a direction traverse to the longitudinal direction. The collar **3312** that is disposed on the collection/discard tube **102** has posts **3313** that engage an angled slot **3316** in the adaptor housing **150**. The side slot **3316** receives the follower pin/post **3313** on the collar **3312** and holds the collection/discard tube **102** in spaced relation to the needle **158** in the adaptor **150**. The slot portion **3316** is angled such that the post **3313** when sitting at the closed end of portion **3316** prevents tube **102** from being pulled out of adaptor **150**. At the same time, slot portion **3316** is angled relative to portion **3315** such that when the operator advances the collection/discard tube **102** longitudinally, the follower pin/post **3313** is permitted to move through and past the detent into slot portion **3315**, which causes the collection/discard tube **102** to twist such that the follower pin/post **3313** is in the main vertical slot **3315**. Pin **3313** in slot **3315** allows tube **102** to be advanced longitudinally into adaptor **150** and into engagement with needle **158**. After sample collection, the collection/discard tube **102** is removed from the adaptor **150** by pulled tube **102**. Tube **102** is removed along with the collar **3312**. The follower pin/post **3313** moves down the vertical main slot **3315** for removal of the collection/discard tube **102** from the collection/discard device **150**.

[0146] FIG. **34**A-FIG. **34**B is a modification of aspects of FIG. **32**A-FIG. **32**B. The securing mechanism **3410** in FIGS. **34**A-**34**B include a collar **3412** with posts **3413** and a slot **3414** in the adaptor housing **150**. The slot **3414** is configured in a “U-turn” shaped path and forces the user to collect sample in the collection/discard tube **102** before the tube **102** is removed from the adaptor **150**. The slot may include a detent or protrusion **3417**. The configurations described herein that require the collection/discard tube **102** to engage the needle **158** in the adaptor **150** before the collection/discard tube **102** is removed therefrom are referred to herein as forced compliance configurations. The collar **3412** that is disposed on the collection/discard tube **102** has follower posts **3413** that engage a slot **3414** in the adaptor housing **150**. The side slot allows the collar **3414** to be rotated into a locked position that locks the collection/discard tube **102** in spaced relation from the needle during shipment and storage. A detent or protrusion **3417** may keep the post **3413** in the locked position. To advance the collection/discard tube **102** into engagement with the adaptor needle **158**, the collection/discard tube **102** is rotated such the post **3413** is also rotated past detent

3417 and the collar/collection/discard tube assembly can be advanced longitudinally (i.e., with post **3413** travelling along first longitudinal portion **3419** of slot **3414** to the end of portion **3419**) into engagement with the needle **158** in the adaptor **150** for blood collection because the collar follower pin **3413** can again advance along the slot **3419** that is adjacent to the side slot in the adaptor housing **150**. After sample collection, the collection/discard tube **102** is again rotated and the collar pin **3413** travels down a discard slot longitudinal portion **3421**, thereby removing the collection/discard tube **102** from the adaptor **150** along with the collar **3412**. To follow this path, the collection/discard tube **102** must be brought into engagement with the needle **158** in the adaptor **150**.

[0147] FIG. **35**A-FIG. **35**B is a modification of the aspects of FIG. **33**A-FIG. **33**B. The securing mechanism **3510** in FIGS. **35**A-**35**B comprises a collar **3511** and a sleeve **3521**. Collar **3511** includes portions **3512** and **3514**. Portion **3512** is configured to be received by the open base end of the adaptor **150**. Portion **3514** is configured to abut against the flanged base of adaptor **150** to stop the securing mechanism **3510** from being advanced further into the interior of adaptor **150**. Portion **3512** includes pins or posts **3516**, **3518**. Post **3516** extends toward the interior of portion **3511** and post **3518** extends toward the exterior of portion **3511**. Posts **3516**, **3518** are configured to be able to bend radially inward toward the center of collar **3511**. As will be described below, post **3516** controls the motion of the collection/discard tube **102** relative to the adaptor **150**.

[0148] Sleeve **3521** includes a ribbed interior (e.g., including ribs **3521** that extend from an internal surface of sleeve **3521** for gripping tube **102**). The ribbed sleeve **3521** fits snugly on the collection/discard tube **102**. When portion **3512** is inserted into adapter **150** and portion **3514** abuts against adaptor **150**, the locking detent pin **3518** locks into and extends into a slot **3522** in the adaptor **150** to hold the collar **3511** in a stationary position relative to adaptor **150**. Sleeve **3521** includes a relief or slot **3527** in the exterior surface of sleeve **3521**. Sleeve **3521** further includes a slot **3520** with a longitudinal portion **3523** and an angled portion **3525** that branches from portion **3523**. Pin **3516** is slidably disposed in slot **3520**. When the collection/discard tube **102** is rotated such that the post **3516** is engaged in end of the angled slot **3525**, this locks the collection/discard tube **102** in spaced relation from the needle **158** during shipment and storage and prevents (i.e., by pin **3516** abutting the closed end of portion **3525**) the tube **102** or collar **3511** from advancing further into adaptor **150**. As shown in FIG. **35**B, in this position, the relief slot **3527** on the exterior of sleeve **3521** is not aligned with post **3518** and thus it is not possible for the securing mechanism to escape adaptor **150**. To advance the collection/discard tube **102** into engagement with the adaptor needle **158**, the collection/discard tube **102** is pushed and rotated and guided by the travel of pin **3516** in portion **3525** and into portion **3523** of slot **3520** such that the collar/collection/discard tube assembly may be advanced into engagement with the needle **158** in the adaptor **150** for blood collection because the collar pin **3516** can again advance along portion **3523** in the slot **3520** in the sleeve **3521**. After sample collection, the collection/discard tube **102** is pulled and guided by pin **3516** in sleeve **3520** and the sleeve **3521** travels downward because the collar pin **3516** is aligned with the slot **3520** in sleeve **3521**. When the collection discard tube **102** is removed from the adaptor **150**, the pin **3516** engages the closed end (hard stop) of portion **3523** of slot **3520** and the relief slot **3527** is aligned with pin **3518** allowing pin **3518** to bend radially inward and exist slot **3522** in adaptor **150**. Thus, the collar **3511** is not locked with the adaptor **150** and is pulled out of the adaptor **150** with tube **102** when pin **3516** engages the hard stop at the closed end of portion **3523** of slot **3520**.

[0149] FIG. **36**A-FIG. **36**B is another aspect of an assembly with a securing mechanism that keeps the collection/discard tube **102** in spaced relation from the adaptor needle **158** during shipping and storage and will allow the collection/discard tube **102** to advance into engagement with the needle **158** in the adaptor **150** for sample collection. In this aspect, the securing mechanism comprises a collar **3612** and an insert **3614**. The collar **3612** is disposed around the tube **102** and includes flexible fingers or posts **3616** that extend toward the exterior of the tube **102**. The insert **3614**

includes a barrel or tubular portion **3620** that is received in the interior of adaptor **150**. Insert **3614** further includes a flanged end portion **3618** that has a larger diameter than the inner diameter of adaptor **150** and thus prevents the insert **3618** from being advanced further into adaptor **150**. Insert **3614** further includes slots **3622** in portion **3620**. In this aspect, adaptor **150** includes flexible or deflectable tabs **3624** that are biased to tilt toward the interior of adaptor **150** and are received by corresponding slots **3622** of the insert **3614** to lock the insert **3614** in a stationary position with respect to the adaptor **150**. When the assembly is shipped or stored, the tube **102** and collar **3612** is held in a spaced relationship with needle **158**. In one aspect, the finger **3616** press into the interior surface of insert **3614** such that the tube **102** is held in the spaced relationship unless a force is applied. In one aspect, insert **3614** includes longitudinal grooves **3613** that the posts **3616** travel or slide in longitudinally when the tube **102** is pushed into adaptor **150**. The collection/discard tube **102** may advance into engagement with the needle **158** in the adaptor **150**. When the tube **102** is pressed into adaptor **150**, the fingers **3616** enter the slots **3622** and force the tabs **3624** out of the slots **3622** to release the insert **3614** from the locked arrangement with the adaptor **150**. After sample collection, the collection/discard tube **102** is pulled and removed from the adaptor **150** and the fingers **3616** in slots **3622** pull the insert **3614** along with the tube **102** and the collar **3612** out of adaptor **150**.

[0150] FIG. **37**A-FIG. **37**B is another aspect of an assembly illustrated in FIG. **36**A-**36**B including a securing mechanism that that keeps the collection/discard tube **102** in spaced relation from the adaptor needle **158** during shipping and storage and will allow the collection/discard tube **102** to advance into engagement with the needle **158** in the adaptor **150** for sample collection. In the illustrated aspect, the securing mechanism has a sleeve **3714** with a bump off **3717**, slots **3715**, and slots **3716**. The securing mechanism further comprises a collar **3731** including raised portions **3732** and flexible projections or fins **3734** that are biased to project at an angle toward the exterior of collar **3731**. The collar **3731** includes ribs **3733** to grip the exterior of tube **102** as shown. The sleeve **3714** is received into adaptor **150** as shown and includes a flanged end to prevent the sleeve **3731** from advancing further into adaptor **150** than what is shown. The adaptor includes flexible projections or fins **3724** that are biased to project toward the interior of adaptor **150**. When the sleeve **3714** is inserted into adaptor **150**, the projections **3724** extend into and catch and end of respective slots **3716** to retain sleeve **3714** in a locked position in adaptor **150**. The collar **3731** grips the tube **102** as shown and tube **102** is inserted into sleeve **3714** such that projections **3734** project into and catch slots **3717** to retain tube **102** and collar **3731** in a locked position such that tube **102** is in a spaced relationship with needle **158** of adaptor **150**. When tube **102** is advanced into adaptor **150**, the raised portions **3716** are guided along slots **3716** and the projections **3734** deflect inward to release collar **3731** from the locked position. In this way, the collection/discard tube **102** may advance into engagement with the needle **158** in the adaptor **150**. When the tube **102** engages the needle **158**, the raised portions **3732** press projections **3724** outward and out of slots **3716**, thus unlocking sleeve **3714** from adaptor **150**. Furthermore, projections **3734** extend into slots **3715** and catch the closed end of slots **3715**, thus locking collar **3731** to the sleeve **3714**. After sample collection, the collection/discard tube **102** is removed from the adaptor **150** along with the sleeve **3714** and the collar **3731**, which are now engaged.

[0151] FIG. **38** is the aspect of FIG. **37**A-FIG. **37**B but with tape or sticker **3850** instead of relying on the bump out to lock the collection/discard tube into distanced position from the needle in the adaptor during shipping and storage.

[0152] FIG. **39**A-FIG. **39**B is another aspect of an assembly illustrated in FIG. **36**A-**36**B including a securing mechanism that keeps the collection/discard tube **102** in spaced relation from the adaptor needle **158** during shipping and storage and will allow the collection/discard tube **102** to advance into engagement with the needle **158** in the adaptor **150** for sample collection. In the illustrated aspect, the adaptor has a sleeve with a resilient stop that will allow a projection on a collar that is press fit onto the collection/discard tube to pass by it when force is applied to advance the

collection/discard tube in the adaptor. As such, tape is applied to ensure that the collection/discard tube is retained in the desired spaced relation with the adaptor needle. When the tape is removed, the collection/discard tube may advance into engagement with the needle in the adaptor. The collar also has detent projections that travel along guides in the adaptor sleeve. At this point, the projections on the collar and the resilient stop engages the projections on the collar. After sample collection, the collection/discard tube is removed from the adaptor along with the adaptor sleeve, which is engaged with the collar.

[0153] FIG. **40**A-FIG. **40**B is another aspect of an assembly with a securing mechanism that keeps the collection/discard tube **102** in spaced relation from the adaptor needle **158** during shipping and storage and will allow the collection/discard tube **102** to advance into engagement with the needle **158** in the adaptor **150** for sample collection. In the illustrated aspect, the adaptor has longitudinal sliding grooves **4022** and locking grooves or slots **4020** disposed in the interior surface of the adaptor **150**. Moreover, the securing mechanism comprises a collar **4011** fixed or coupled to the exterior of the tube **102**. The collar **4011** includes flexible fingers or projections **4012** extending from a ring portion of the collar **4012**. The flexible fingers **4012** on the collar **4012** extend into the respective locking grooves **4020**, where tube **102** is in a spaced relationship with the needle **158** (i.e., not engaged therewith) for storage and/or shipment and the grooves **4020** and flexible fingers **4012** prevent insertion/removal of the tube **102** into or out of the adaptor **150**. The flexible fingers **4012** are configured to be depressed when the collar **4012** and tube **102** is rotated. Thus, the fingers **4012** allow rotation of the tube **102** such that rotation of tube **102** causes the fingers **4012** to exit the locking grooves **4020** and to enter the sliding grooves **4022**. When collection/discard tube **102** is rotated to place the fingers **4012** in the sliding grooves **4020** of the adaptor **150**, the collection/discard tube **102** may be advance into engagement with the needle **158** in the adaptor **150** with the fingers **4012** sliding longitudinally in the sliding grooves **4022** to permit the advancement. After sample collection, the collection/discard tube **102** is removed from the adaptor **150** by sliding it out with the flexible fingers **4012** sliding along the sliding grooves **4022**.

[0154] FIG. **41** is another aspect of an assembly with a securing mechanism that keeps the collection/discard tube **102** in spaced relation from the adaptor needle **158** during shipping and storage and will allow the collection/discard tube **102** to advance into engagement with the needle **158** in the adaptor **150** for sample collection. In this aspect, the securing mechanism is configured such that the collection/discard tube **102** must be placed into engagement with the needle **158** in the adaptor **150** before it is removed from the adaptor **150**. As such, this aspect is also a forced compliance configuration. In the illustrated aspect, the collection/discard tube **102** has a sleeve **4111** attached thereto with a portion **4112** of the sleeve **4111** having an enlarged diameter relative to a portion **4113**. The sleeve **4111** has a flange at the proximal end that prevents the sleeve from being advanced entirely into the adaptor **150**. The adaptor **150** has windows **4122** cut into the sides of the housing that hold a molded, flexible component **4124** (e.g., an oval locking ring that is free floating) in an oval configuration. The component **4124** is in the oval shape when in a resting state. The oval component **4124** holds the collection/discard tube **102** in spaced relation to the adaptor needle **158**. In this regard, in one aspect, the inner circumference of the ring **4124** along the minor axis (i.e., the vertices of the minor axis) grip the outer surface of the sleeve **4111** at portion **4113** to hold (via friction) the tube **102** in the spaced relationship. The larger diameter portions of the oval component **4124** protrude into/from windows **4122** in the base of the adaptor **150** and this oval component **4124** locks the collection/discard tube **102** in place such that it is maintained in spaced relation from the needle **158** during shipping and storage. When the collection/discard tube **102** is forced past the oval component **4124**, the tube **102** can be advanced into contact with the adaptor needle **158** for sample collection. In that position, the wider portion **4112** of the sleeve **4111** changes the oval component **4124** configuration to circular (i.e., the outer surface of portion **4112** contacts and pushes out against the inner circumference at the minor axis or shorter diameter of the oval component **4124** to change the shape to circular), which pulls those portions of the oval

component **4124** that were extending out of the windows **4122** at the base of the adaptor **150** inside the adaptor **150**. In this position, the component **4124** is retained snugly by friction on the outer diameter of portion **4112**. This change in shape allows the collection/discard container **102** to be backed out from the adaptor **150**, carrying the component **4112** with the tube **102** and the sleeve **4111**.

[0155] FIG. **42**A-FIG. **42**B is another aspect of the assembly of FIG. **41** including a securing mechanism that keeps the collection/discard tube **102** in spaced relation from the adaptor needle **158** during shipping and storage and will allow the collection/discard tube **102** to advance into engagement with the needle **158** in the adaptor **150** for sample collection. In this aspect, the collection/discard tube **102** must be placed into engagement with the needle **158** in the adaptor **150** before it is removed from the adaptor **150**. As such, this aspect is also a forced compliance configuration. In the illustrated aspect, the collection/discard tube **102** has a sleeve **4211** attached thereto with a portion **4212** of the sleeve **4211** having an enlarged diameter relative to a portion **4213**. The adaptor **150** has windows **4222** above the flange at the base thereof that hold a flexible oval ring **4224**. The oval ring **4224** includes tabs or projections **4226** at the vertices of the major axis (largest diameter) of the oval ring **4224**. The tabs or projections **4226** are shaped to be received into windows **4222**. The larger diameter portions (i.e., tabs **4226**) of the oval component **4224** protrude from windows **4222** in the base of the adaptor **150** and the inner circumference portions of the ring **4224** along the minor axis (i.e., the vertices of the minor axis) extend into windows **4215** of sleeve **4211**. In this way. the oval component **4224** locks the collection/discard tube **102** in place such that it is maintained in spaced relation from the needle **158** during shipping and storage. The oval ring **4224** holds the collection/discard tube **102** (by engaging both windows **4222** and **4215**) in spaced relation to the needle **158** in adaptor **150**. When the collection/discard tube **102** is forced through the oval ring **4224** into the interior of adaptor **150**, the tube **102** can be advanced into contact with the adaptor needle **158** for sample collection. In that position, in the same manner described above in relation to FIG. **41**, the wider portion **4212** of the sleeve **4211** changes the oval ring **4224** configuration to circular, which pulls the tabs **4226** that were extending into the windows **4222** at the base of the adaptor **150** inside the adaptor **150** and the portions of the inner circumference of ring **4224** that were extending into windows **4215** out of windows **4215**. This change in shape allows the collection/discard container **102** to be backed out from the adaptor **150**, carrying the ring component **4224** and sleeve **4211** with it.

[0156] FIG. **43**A-FIG. **43**B is another aspect of an assembly with a securing mechanism that keeps the collection/discard tube in spaced relation from the adaptor needle during shipping and storage and will allow the collection/discard tube to advance into engagement with the needle in the adaptor for sample collection. In the illustrated aspect, the adaptor has a threaded inner collar with a flange that abuts the flange at the base of the adaptor. The collection/discard tube has a ring with posts. When the collection/discard tube is placed into the adaptor, the collection/discard tube is held away from the adaptor needle. When sample collection is desired, the collection/discard tube is rotated, which advances the ring, threading it such that the ring posts land in the detents in the threaded inner collar. When engaged, the sample is collected. After sample collection, the sample collection/discard tube is pulled from the adaptor with the ring and the threaded inner collar.

[0157] FIG. **44**A-**44**B is an alternative aspect of FIG. **43**A-FIG. **43**B, and is another aspect of an assembly with a securing mechanism that keeps the collection/discard tube **102** in spaced relation from the adaptor needle **158** during shipping and storage and will allow the collection/discard tube **102** to advance into engagement with the needle **158** in the adaptor **150** for sample collection. In the illustrated aspect, the securing mechanism comprises a slotted inner collar **4111** with a flanged end that abuts the flange at the base of the adaptor **150** and prevents the collar **4111** from being inserted further into the adaptor **150**. The barrel portion of the collar **4111** is inserted into adaptor **150**. The slot **4413** of the collar **4111** has two detents **4415**, **4415**. The collection/discard tube has a ring **4431** affixed thereon with posts **4433** that extend from a ring base. When the collection/discard

tube **102** is placed into the adaptor **150**, the collection/discard tube **102** is held away from the adaptor needle **158** by the engagement of each post **4433** with each first detent **4414**. When sample collection is desired, the collection/discard tube **102** is advanced into adapter **150**, such that the ring posts **4433** land in the locking detents **4415** at the top of slot **4413**. When engaged, the sample is collected into the collection/discard tube **102**. After sample collection, the sample collection/discard tube **102** is pulled from the adaptor **150** with the ring **4431** and the slotted inner collar **4411**.

[0158] FIG. **45**A-FIG. **45**B is another aspect of an assembly with a securing mechanism that keeps the collection/discard tube in spaced relation from the adaptor needle during shipping and storage and will allow the collection/discard tube to advance into engagement with the needle in the adaptor for sample collection. The adaptor has two retention holes in its housing, proximal to the flange at the bottom of the adaptor. The collection/discard tube has an inner sleeve thereon. A collar is disposed on the sleeve. The collar has a first larger diameter, a second smaller diameter and a flange distal to the cap of the collection/discard tube. Disposed in the sleeve are fingers that extend outward and will fit in the retention holes in the collar when aligned therewith and holds the collection/discard tube away from the needle in the adaptor for storage and handling. Retracting the collar releases the fingers from the holes. The collection/discard tube may then be advanced upward for sample collection or downward to remove the collection/discard tube from the adaptor. After sample collection, the sample collection/discard tube is pulled from the adaptor with the sleeve and fingers affixed thereto.

[0159] FIG. **46**A-FIG. **46**B is another aspect of an assembly with a securing mechanism that keeps the collection/discard tube in spaced relation from the adaptor needle during shipping and storage and will allow the collection/discard tube to advance into engagement with the needle in the adaptor for sample collection. The adaptor has two retention holes in its housing, proximal to the flange at the bottom the adaptor. The collection/discard tube has a flanged collar thereon and a holster with fingers that extend from the holster upward and outward into the adaptor. As the collar and the collection/discard tube are advanced into the adaptor, the holes in the collar align with the holes in the adaptor and the fingers extending from the holster on the collection/discard tube locks the collection/discard tube in a position away from the needle in the adaptor for storage and handling. Retracting the collar releases the fingers from the holes in the adaptor housing. The collection/discard tube is then advanced upward for sample collection. After sample collection, the sample collection/discard tube is pulled from the adaptor with the holster and fingers affixed thereto.

[0160] FIG. **47**A-**47**B illustrates a diversion adaptor that provide a first flow path for collecting a first portion of the collected sample and a second flow path that collects the portion of the sample to be used for testing. The adaptor has an inner sleeve that is retracted into the adaptor when shipped. The inner sleeve is drawn back and posts in the inner sleeve lock into a detent in the adaptor housing and the diversion portion of the sample is drawn through the first flow path in the adaptor into an upper chamber of the adaptor. After the diversion sample is collected, the inner sleeve is advanced upward and the adaptor engages the sample collection bottle, and the sample travels through the second flow path into the sample collection bottle.

[0161] FIG. **48**A-FIG. **48**B illustrate another aspect of an assembly with a securing mechanism that keeps the collection/discard tube in spaced relation from the adaptor needle during shipping and storage and will allow the collection/discard tube to advance into engagement with the needle in the adaptor for sample collection. In this aspect, the collection/discard tube is delivered into the adaptor within a sleeve that has a flange on the end of the sleeve distal from the adaptor needle. In the first position, when the collection/discard tube is held away from the adaptor needle for shipment and storage, tape secures the sleeve in a position where the sleeve flange is spaced apart from the adaptor flange at the adaptor opening. When the sticker is peeled away, the collection/discard tube and the sleeve are advanced further into the adaptor for sample collection.

After sample collection, the sample collection/discard tube is pulled from the adaptor with the sleeve.

[0162] FIG. **49**A-FIG. **49**F illustrate different sticker configurations and placements to maintain the collection/discard tube **102** in spaced relation from the adaptor needle **158** during shipping and storage and will allow the collection/discard tube **102** to advance into engagement with the needle **158** in the adaptor **150** for sample collection upon removal of the sticker **4960**. As shown, one or more stickers **4960** may be disposed over the base end of the adaptor **150** and over a portion of the exterior of the tube **102**. The sticker placement and configuration are selected such that the tube **102** cannot be pulled from or pushed into the adaptor **150** inadvertently. Sticker **4960** holds the tube **102** in place prior to use. Moreover, the sticker placement and configuration are such that when the tube **102** is pushed into the adaptor **150**, the portion of the sticker **4960** that is adhered to the exterior of tube **102** is peeled away, or torn or otherwise decoupled from tube **102** (as shown in FIG. **49**E) to allow the collection/discard tube to advance to the second position. In one aspect, as the tube **102** is pushed into the adaptor **150**, perforations **4962** (or thinned sections **4964**) in the sticker are configured to tear to sever the sticker **4960** and allow the tube **102** to be pushed into engagement with the needle **158**. As shown, the stickers **4960** may come in a variety of shapes (e.g., capital I, rectangle, U, Y shaped, etc.). The sticker may include perforations **4962** or thinner sections **4964** to help the sticker tear consistently. The sticker **4960** may be configured with suitable properties, such as, sticker size, orientation, peroration(s) **4962** (quantity of perforations, location of perforations, depth of perforations, etc.) such that the sticker(s) **4960** maintains the spaced relationship and peel away from the tube **102** and when the tube **102** is pushed into adaptor **150** into engagement with the needle **158**. In one aspect, including one sticker on either side of the tube **102** and adaptor **150** maintains alignment of the tube **102** within the adaptor **105** with the needle **150** for engagement with the tube **102** during insertion of the tube **102** into adaptor **150**.

[0163] FIG. **50** illustrates a different sticker configuration and placement to maintain the collection/discard tube **102** in spaced relation from the adaptor needle **158** during shipping and storage and will allow the collection/discard tube **102** to advance into engagement with the needle **158** in the adaptor **150** for sample collection upon removal of the sticker(s) **4960**. In this aspect, the securing mechanism of the collection/discard tube **102** has a collar **5011** (e.g., including the same features as collar **510** and other similar collars described above) thereon and the sticker(s) **4960** maintains separation of the collar **5011** from the adaptor **150** and of the tube **102** from the needle **158**. The collar **5011** includes cutting blade(s) **5012** configured to cut or sever the sticker(s) **4960** (e.g., in a central, perforated or thinner section thereof) into two separate pieces. With the sticker(s) **4960** severed, the collar **5011** may advance into the adaptor **150** for sample collection. After sample collection, the collection/discard tube **102** along with the collar **5011** is removed from the adaptor **150**.

[0164] FIG. **51** illustrates the use of a heat shrink material or wrap **5170** to maintain the collection/discard tube **102** in spaced relation from the adaptor needle **158** during shipping and storage and will allow the collection/discard tube **102** to advance into engagement with the needle **158** in the adaptor **150** for sample collection upon removal of the heat shrink material **5170**. To advance the collection/discard tube **102** into the adaptor **150**, the heat shrink material **5170** is removed. The shrink wrap **5170** may include perforations (as described below in relation to wrap **5770**) to facilitate easy tear-off/splitting the wrap **5170** and removal of the wrap **5170** to allow insertion of the tube **102** into adaptor **150**. The wrap **5170** has the advantage of conforming to different geometries of the adaptor **150**, tube **102**, securing mechanisms, etc. that may be present in the assembly. After collection, the collection/discard tube **102** is removed from the adaptor **150**.

[0165] FIG. **52** illustrates another aspect of an assembly with a securing mechanism that keeps the collection/discard tube in spaced relation from the adaptor needle during shipping and storage and will allow the collection/discard tube to advance into engagement with the needle in the adaptor for sample collection. In this aspect, the collection/discard tube is delivered into the adaptor within a

sleeve that has a bellows at the end thereof. The bellows operates to keep the collection/discard tube separated from the adaptor needle during shipment and storage. When sample collection is commenced, the collection/discard tube is forced upward, collapsing the bellows and allowing the adaptor needle to insert into the collection/discard tube for sample collection. When the desired amount of sample is collected, the collection/discard tube and sleeve are removed from the adaptor.

[0166] FIG. **53** illustrates another aspect of an assembly with a securing mechanism that keeps the collection/discard tube in spaced relation from the adaptor needle during shipping and storage and will allow the collection/discard tube to advance into engagement with the needle in the adaptor for sample collection. In this aspect, the collection/discard tube is delivered into the adaptor within a sleeve that has a collapsed, corrugated portion. The collapsed, corrugated portion operates to keep the collection/discard tube separated from the adaptor needle during shipment and storage. When sample collection is commenced the corrugated portion unfolds and the collection/discard tube is forced upward, allowing the adaptor needle to insert into the collection/discard tube for sample collection. When the desired amount of sample is collected, the collection/discard tube and sleeve are removed from the adaptor.

[0167] FIG. **54** is another aspect of the assembly described in FIG. **52**. FIG. **54** illustrates an assembly with a securing mechanism that keeps the collection/discard tube in spaced relation from the adaptor needle during shipping and storage and will allow the collection/discard tube to advance into engagement with the needle in the adaptor for sample collection. In this aspect, the collection/discard tube is disposed in a sleeve with a bellows at the end thereof, adjacent a flange that does not permit the bellows to enter the adaptor. The bellows operates to keep the collection/discard tube separated from the adaptor needle during shipment and storage. When sample collection is commenced the collection/discard tube is forced upward, collapsing the bellows and allowing the adaptor needle to insert into the collection/discard tube for sample collection. When the desired amount of sample is collected, the collection/discard tube is removed from the adaptor. The sleeve, having never entered the adaptor, remains on the collection/discard tube.

[0168] FIG. **55**A-FIG. **55**B is another aspect of an assembly with a securing mechanism that keeps the collection/discard tube in spaced relation from the adaptor needle during shipping and storage and will allow the collection/discard tube to advance into engagement with the needle in the adaptor for sample collection. In this aspect, the collection/discard tube is placed in a sleeve with netting disposed on the exterior of the collection/discard tube. Folds in the netting operate to keep the collection/discard tube separated from the adaptor needle during shipment and storage. When sample collection is commenced the collection/discard tube is forced upward, allowing the folds to unfold, thereby allowing the collection/discard tube to engage the adaptor needle, whereby the needle is inserted into the collection/discard tube for sample collection. When the desired amount of sample is collected, the collection/discard tube is removed from the adaptor along with the netting.

[0169] FIG. **56** is another aspect of an assembly with a securing mechanism that keeps the collection/discard tube in spaced relation from the adaptor needle during shipping and storage and will allow the collection/discard tube to advance into engagement with the needle in the adaptor for sample collection. In this aspect, a stopper is placed on top of the cap of the collection/discard tube. The stopper has a perimeter that forms a friction fit with the adaptor when the stopper/collection/discard tube assembly is placed within the adaptor. The friction fit allows the stopper to maintain the collection/discard tube in spaced relation with the adaptor needle.

[0170] FIG. **57** is another aspect of an assembly with a clamp-like or shrink wrap securing mechanism that keeps the collection/discard tube **102** in spaced relation from the adaptor needle **158** during shipping and storage and will allow the collection/discard tube **102** to advance into engagement with the needle **158** in the adaptor **150** for sample collection. In this aspect, a removeable clip **5750**, tear-off strip or sticker **5760**, or a shrink wrap **5770** (disposed over the base

end of adaptor **150** and over tube **102** and at least a portion of sleeve **5721**) is used to force a spaced relationship between a sleeve **5721** (configured with the same features as sleeve **5821** described below) in which the collection/discard tube **102** is disposed and the adaptor **150**. The shrink wrap **5770** may include a tear handle **5772** and perforations (indicated by dotted lines) for tearing the shrink wrap **5770** off of the assembly. It is to be appreciated that the assembly may include any of the securing mechanisms described herein and the clip, sticker, or shrink wrap may be used in addition to or instead of the securing mechanism to maintain the spaced relationship. The spaced relationship ensures that the collection/discard tube **102** does not engage the adaptor needle **158** during storage and shipping. When sample collection commences, the clip **5750** or sticker **5760** is removed and the sleeve in which the collection/discard tube is disposed can be advanced into contact with the adaptor needle **158** for sample collection. After sample collection, the collection/discard tube **102** (still disposed in the sleeve) is removed from the adaptor.

[0171] FIGS. **58**A-**58**C is an alternative aspect of FIG. **17**A-FIG. **17**B, FIG. **18**A-FIG. **18**C, and FIG. **19**A-FIG. **19**C. Illustrated is a securing mechanism comprising a three-piece assembly for holding the collection/discard tube **102** in spaced relation from the needle **158** in the adaptor **150** during shipment but allowing the collection/discard tube **102** to be advanced into engagement with the needle **158** for sample collection. The three-piece assembly is pulled from the adaptor **150** when the collection/discard tube **102** is removed therefrom. The securing mechanism comprises snap ring **5811**, sleeve **5821**, and ring **5831**. The snap ring **5821** includes upward facing projections **5812** extending for a ring base **5814** and biased to be angled toward the interior of snap ring **5811**. The outer diameter of ring base **5814** is fitted to be snugly retained in the base open base end of the adaptor **150**. The sleeve **5821** in this aspect is configured in tubular shape with an open end that receives a portion of tube **102** and a closed end **5825**. In one aspect, sleeve **5821** is fixed (e.g., via adhesive) to the tube **102**. The sleeve **5821** includes first and second flanges or raised portions **5822** and **5824**. The collar or ring **5831** is placed adjacent the cap **5831** on the collection discard tube **102**. The collar **5831** is dimensioned to be advanced through and above the snap ring **5811** and permitted to pass the projections **5812**. The outer diameter of the collar **5831** may be configured to grip the interior of adaptor **150** to hold the collection/discard tube **102** spaced apart from the adaptor needle **158** during shipment and storage. Additionally and/or alternatively, the projections **5812** may grip the exterior of the tube **102** to hold the tube **102**. In one aspect, the adaptor **150** includes a stepped end in the base to receive the snap ring **5811**. The collar **5831** abuts against the ends of projections **5812** and thus tube **102** is prevented from being pulled out of adaptor **150** easily and is held in the spaced relationship with needle **158**. The tube **102** may be pushed into the adaptor **150** further with the projections **5812** permitting raised portion **5822** to pass through snap ring **5811** and the projections snap to the exterior of sleeve **5821** to the area between raised portions **5822** and **5824**. In this position, the snap ring **5811** and the sleeve **5831** are locked to each other and projections **5812** prevent the tube **102** from being pulled easily out of the adaptor **150**. Moreover, in this position, the collection tube **102** is engaged with the needle **158** for sample collection. The first flange **5822** on the sleeve **5821** and catches on the ends of projections **5812** when the tube **102** is pulled out of the adaptor **150** to pull the snap ring **5811** from the adaptor **150** when the collection/discard tube **102** and sleeve **5821** are removed therefrom. In one aspect, as shown in FIG. **58**C, when the assembly is stored or shipped, a removable clip **5850** (e.g., configured with the same features as clip **5750**) is disposed around tube **102** between the open end of sleeve **5821** and the collar **5831** that abuts against the base of adaptor **150** and the sleeve **5831**. The clip **5850** prevents the tube **102** from being pushed prematurely into adaptor **150** and the ring **5831** that abuts against the snap ring **5811** prevents the tube **102** from being pulled from adaptor **150**. Thus, the tube **102** is held in the spaced relationship from needle **158**.

[0172] FIG. **59** is a proof of concept illustration of using an elastomeric tube to hold the collection/discard tube in spaced relation from the needle in the adaptor during shipment but allowing the collection/discard tube to be advanced into engagement with the needle for sample

collection. When the elastomer tube is removed, the collection/discard tube may be brought into engagement with adaptor needle for sample collection. When the desired amount of sample is collected, the collection/discard tube is removed from the adaptor.
[0173] FIG. **60** illustrates extensions (e.g., made of any suitable material) from a sleeve on a collection/discard tube to hold the collection/discard tube in spaced relation from the needle in the adaptor during shipment but allowing the collection/discard tube to be advanced into engagement with the needle for sample collection. When the collection/discard tube is advanced into engagement with adaptor needle for sample collection, the extensions are carried into the adaptor. When the collection/discard tube is removed from the adaptor, the extensions are carried with it.
[0174] FIG. **61** is a further modification of the aspect illustrated in FIG. **60** and also is a proof of concept illustration that uses extensions from a sleeve on a collection/discard tube to hold the collection/discard tube in spaced relation from the needle in the adaptor during shipment but allowing the collection/discard tube to be advanced into engagement with the needle for sample collection. Tape is used to hold the sleeve together. In some aspects, the cardboard is corrugated for additional thickness and sturdiness. When the collection/discard tube is advanced into engagement with the adaptor needle for sample collection, the extensions are carried into the adaptor. When the collection/discard tube is removed from the adaptor, the extensions are carried with it.
[0175] FIG. **62** is a further modification of the aspect illustrated in FIG. **60** and also is a proof of concept illustration that uses extensions from a sleeve on a collection/discard tube to hold the collection/discard tube in spaced relation from the needle in the adaptor during shipment but allowing the collection/discard tube to be advanced into engagement with the needle for sample collection. Tape is used to hold the sleeve together and to hold the collection/discard tube in space relation to the adaptor needle. In some aspects, the cardboard is corrugated for additional thickness and sturdiness. When collection is commenced, the tape holding the collection/discard tube in place is removed, allowing the collection/discard tube to be advanced into engagement with the adaptor for sample collection, the extensions are carried into the adaptor. When the collection/discard tube is removed from the adaptor, the extensions are carried with it.
[0176] FIG. **63** is a concept illustration of a sleeve structure for the collection/discard tube that is sufficiently wide so as not to enter the adaptor, thereby keeping the collection/discard tube in spaced relation from the needle in the adaptor during shipment but allowing the collection/discard tube to be advanced into engagement with the needle for sample collection. The collection/discard tube can be advanced in the sleeve structure. After sample collection, the structure is squeezed so that the collection/discard tube assembled to the sleeve may be backed out of the adaptor.
[0177] FIG. **64** is a concept illustration of a sleeve structure for the collection/discard tube that is sufficiently wide so as not to enter the adaptor, thereby keeping the collection/discard tube in spaced relation from the needle in the adaptor during shipment but allowing the collection/discard tube to be advanced into engagement with the needle for sample collection when the sleeve is squeezed. The collection/discard tube may then be advanced in the sleeve structure. After sample collection, the structure is squeezed for the collection/discard tube assembled to the sleeve to be backed out of the adaptor.
[0178] FIG. **65**A-FIG. **65**B is an assembly with a valve that has a first adaptor for receiving a collection/discard tube and at least one other adaptor for receiving a sample bottle. The assembly has an inlet that may be connected to a line set for collecting a sample from a patient. The valve may direct a first portion of the collected sample into the collection/discard tube. After the desired amount of sample is collected, the valve is rotated, and additional sample is directed to the one or more sample containers.
[0179] FIG. **66** is an alternative aspect of what is described in FIG. **65**A-FIG. **65**B. In this aspect, a pin is provided to prevent the valve from rotating beyond the position that will direct sample beyond the sample collection/discard tube adaptor unless the collection/discard tube is in engagement with the needle in the adaptor.

[0180] FIG. **67**A-FIG. **67**B illustrates an alternative aspect of the assembly described herein that deploys a collection/discard tube in communication with an adaptor for connection to a patient line set to collect sample from a patient into the container. In this aspect, the collection/discard tube is assembled with the adaptor but held in spaced relation from the adaptor needle during shipment and storage. The collection/discard tube may have one of the numerous examples of collars or sleeves or tape described herein for maintaining such spaced relation between the collection/discard tube and the needle. The adaptor has a valve on the end thereof that is placed in connection with the patient line set (not shown). The collection/discard tube is advanced into the adaptor to collect sample, after which the valve is opened. Once the initial portion of the patient sample is collected in the collection/discard tube, the collection/discard tube is removed from the adaptor and then the patient sample collection bottle is placed in fluid communication with adaptor needle for collecting the patient sample into the blood culture container.

[0181] FIG. **68**A-**68**B illustrates an alternative aspect of the assembly described herein that deploys a collection/discard tube in communication with an adaptor for connection to a patient line set to collect sample from a patient into the container. In this aspect, the collection/discard tube is assembled with the adaptor but held in spaced relation from the adaptor needle during shipment and storage by a rotating flap. The adaptor has a first port for receiving the collection/discard tube and a second port for receiving the blood culture bottle. The flap moves from a first position that is intermediate between the collection/discard tube and the adaptor needle, thereby preventing the collection/discard tube from coming into contact with the adaptor needle during shipment and storage, to a second position in which the flap is positioned alongside the collection/discard tube, and therefore no longer in the path between the collection/discard tube and the adaptor needle. Advancing the collection/discard tube in the adaptor moves the flap from the first position to the second position. The collection/discard tube is advanced into the adaptor to collect sample, after which the valve is opened. Once the initial portion of the patient sample is collected in the collection/discard tube, the collection/discard tube is removed from the adaptor and then the patient sample collection bottle is placed in fluid communication with the adaptor needle in the larger port for collecting the patient sample into the blood culture container.

[0182] FIG. **69**A-FIG. **69**B illustrates an alternative aspect of the dual port adaptor described in FIG. **68**A-FIG. **68**B. The assembly described herein deploys a collection/discard tube in communication with a dual port adaptor for connection to a patient line set to collect sample from a patient into the container. The collection/discard tube will only fit in one of the dual ports. In this aspect, the collection/discard tube is assembled with the adaptor but held in spaced relation from the adaptor needle during shipment and storage by a ring or other mechanism described herein. The adaptor has the first port for receiving the collection/discard tube and a second port for receiving the blood culture bottle. The adaptor also has a lever/pin assembly with a first position and a second position. In the first position, the lever in the port that receives the collection/discard tube is positioned over a pin in the second port. In this position, the pin cannot move upward, the culture bottle cannot be brought into contact with the needle in the second port. When the collection/discard tube is advanced into fluid communication with the needle in the adaptor, the lever moves away from above the pin and the pin can be move upward, allowing the culture bottle to be placed in fluid communication with the needle in the second port for collection of the remainder of the sample. Once the initial portion of the patient sample is collected in the collection/discard tube, the collection/discard tube is removed from the adaptor and then the patient sample collection bottle is placed in fluid communication with adaptor needle in the larger port for collecting the patient sample into the blood culture container.

[0183] FIG. **70**A-FIG. **70**B illustrates an alternative aspect of the dual port adaptor described in FIG. **69**A-FIG. **69**B. The assembly described herein deploys a collection/discard tube in communication with a dual port adaptor for connection to a patient line set to collect sample from a patient into the container. The collection/discard tube will only fit in one of the dual ports. In this

aspect, the collection/discard tube is assembled with the adaptor but held in spaced relation from the adaptor needle during shipment and storage by a ring or other mechanism described herein. The adaptor has the first port for receiving the collection/discard tube and a second port for receiving the blood culture bottle. The adaptor also has a needle shuttle that will move the needle from the first port to the second port. A lock out peg prevents the needle from being moved from the first port to the second port until sample is collected into the collection/discard tube in the first port. When the collection/discard tube is advanced into fluid communication with the needle in the adaptor, the lock out peg is moved upward, which allows the needle shuttle to be moved. Moving the needle shuttle moves the needle from the first port to the second port. The culture bottle can then be placed in fluid communication with the needle in the second port for collecting the remainder of the sample. Once the initial portion of the patient sample is collected in the collection/discard tube, the collection/discard tube is removed from the adaptor and then the patient sample collection bottle is placed in fluid communication with the adaptor needle in the larger port for collecting the patient sample into the blood culture container.

[0184] FIG. **71** illustrates an alternative aspect of the dual port adaptor described in FIG. **70**A-FIG. **70**B. The assembly described herein deploys a collection/discard tube in communication with a dual port adaptor for connection to a patient line set to collect sample from a patient into the container. The collection/discard tube will only fit in one of the dual ports. In this aspect, the collection/discard tube is assembled with the adaptor but held in spaced relation from the adaptor needle during shipment and storage by a ring or other mechanism described herein. The adaptor has the first port for receiving the collection/discard tube and a second port for receiving the blood culture bottle. The adaptor also has a needle shuttle that will move the needle from the first port to the second port. In this aspect, the assembly lacks the lock out peg. Once the initial portion of the patient sample is collected in the collection/discard tube, the collection/discard tube is removed from the adaptor, which allows the needle shuttle to be moved from the first port to the second port. and then the patient sample collection bottle is placed in fluid communication with the adaptor needle in the larger port for collecting the patient sample into the blood culture container. Moving the needle shuttle moves the needle from the first port to the second port. The culture bottle can then be placed in fluid communication with the needle in the second port for collection the remainder of the sample.

[0185] FIG. **72**A-FIG. **72**B illustrates an alternative aspect of the dual port adaptor. The assembly described herein deploys a collection/discard tube in communication with a dual port adaptor for connection to a patient line set to collect sample from a patient into the container. The collection/discard tube will only fit in one of the dual ports. In this aspect, the collection/discard tube is assembled with the adaptor but held in spaced relation from the adaptor needle during shipment and storage by a ring or other mechanism described herein. The adaptor has the first port for receiving the collection/discard tube and a second port for receiving the blood culture bottle. The adaptor also has a rotary valve that will allow patient sample to flow into the collection/discard tube in one position, and into the blood culture bottle in a second position. Initially, before sample is collected, the rotary valve is in a third position (the “off” position). When the collection/discard tube is brought into fluid communication with the needle in the adaptor, the rotary valve is moved to the first position. Once the initial portion of the patient sample is collected in the collection/discard tube, the collection/discard tube is removed from the adaptor, and the valve is moved to the third position, which allows collecting the patient sample into the blood culture container when the blood culture bottle is brought into fluid communication with the adaptor needle.

[0186] FIG. **73** is an alternative aspect of FIG. **72**A-FIG. **72**B wherein the adaptor has a locking pin that requires the blood culture bottle to be inserted into the adaptor before the rotary valve is moved to the third position.

[0187] FIG. **74**A-FIG. **74**B illustrates an alternative aspect of the dual port adaptor. The assembly

described herein deploys a collection/discard tube in communication with a dual port adaptor for connection to a patient line set to collect sample from a patient into the container. The collection/discard tube will only fit in one of the dual ports. In this aspect, the collection/discard tube is assembled with the adaptor but held in spaced relation from the adaptor needle during shipment and storage by a ring or other mechanism described herein. The adaptor has the first port for receiving the collection/discard tube and a second port for receiving the blood culture bottle. The ports are staggered so the collection/discard tube can be placed in one port and the culture bottle can be placed in the other port simultaneously and to provide a differential pressure between the flow path to the collection/discard tube and the flow path to the culture bottle. When the collection/discard tube is brought into fluid communication with the needle in the adaptor, sample is collected into the sample collection/discard tube. Once the initial portion of the patient sample is collected in the collection/discard tube, the blood culture bottle is placed in fluid communication with the needle in the second port. Because the second port is lower than the first port (or, more precisely, because the sample collection tube is held higher in the adaptor than the blood culture vessel) the sample flows preferentially to the blood culture vessel when both the collection/discard tube and the culture bottle are connected in the adaptor.

[0188] FIG. **75** is an aspect of a dual port adaptor wherein the sample collection/discard tube is held in spaced relation to the needle in the adaptor by variety of mechanisms described herein such as the rubber ring, the clutch, the sticker or other spacing mechanism. FIG. **75** illustrates a generic separation mechanism integrated with the sliding needle shuttle described in FIG. **71**.

[0189] FIG. **76** illustrates an adaptor in fluid communication with a sample collection/discard tube. The adaptor has a piezoelectric flow monitor that will indicate to a use when the sample collection discard tube is contains the target amount of sample.

[0190] FIG. **77** is an alternative aspect of two port adaptor. Each port is affixed to an end of a “Y” connector. The port that receives the sample collection/discard tube has a retention mechanism that keeps the collection/discard tube in spaced relation from the needle in the adaptor during shipment and storage. When the sample collection/discard tube is brought into fluid communication with the needle in the adaptor port, the line from the line set to the “Y” connector is primed. The sleeve on the needle in the second port acts like a shut off valve when sample is being collected into the sample collection/discard tube. When the culture bottle is placed in fluid communication with the needle in the second port of the adaptor, sample flows preferentially into the culture bottle.

[0191] FIG. **78** is an alternative aspect of two port adaptor of FIG. **77** Each port is affixed to an end of a “Y” connector and the ports themselves are arranged in a “Y.” The port that receives the sample collection/discard tube may have a retention mechanism that keeps the collection/discard tube in spaced relation from the needle in the adaptor during shipment and storage. When the sample collection/discard tube is brought into fluid communication with a needle in the adaptor port, the line from the line set to the “Y” connector is primed. The sleeve on the needle in the second port acts like a shut off valve when sample is being collected into the sample collection/discard tube. When the culture bottle is placed in fluid communication with the needle in the second port of the adaptor, sample flows preferentially into the culture bottle since the collection/discard tube has the requisite amount of sample therein.

[0192] Sample collection systems are described herein. In one aspect, a sample collection system includes a container for collecting a sample, an adaptor having a distal end, a proximal end, a needle, and an interior. The adaptor is configured to receive a sample through a connector at the distal end. The needle extends from the connector into the interior of the adaptor, and the proximal end includes an opening to receive a first end of the container into the interior of the adaptor. The system also includes a securing mechanism configured to releasably secure the container at a first position, wherein, at the first position, the first end of the container is held in a spaced relationship with the needle in the interior of the adaptor. In one aspect, the securing mechanism is operated to allow the container to be advanced distally within the interior of the adaptor from the first position

to a second position and thereby engage the needle to receive the sample into the container. In one aspect, the securing mechanism is further configured to enable the container to be withdrawn proximally to remove the container from the interior of the adaptor. In a further aspect, when the container is removed from the interior of the adaptor, the securing mechanism is configured to be removed by the container.

[0193] In one aspect, the securing mechanism comprises a collar fitted on the container. In a further aspect, the collar has an inner diameter that is larger than an outer diameter of the container an outer diameter that is smaller than an inner diameter of the adaptor. In a further aspect, the collar provides an interference fit when advanced into the adaptor. In yet a further aspect, the collar has a flange that prevents the collar from being advance completely into the adaptor.

[0194] In another aspect, the securing mechanism is a c-clamp. The securing mechanism may also have a resilient gasket that is received on the container and forms an interference fit for the container within the adaptor.

[0195] In another aspect, the container has a cap that may have a septum and a shield. The shield may extend from the septum and surrounding a perimeter of a portion of the container. In a further aspect, the above-described shield may have a first O-ring at a proximal end and a second O-ring at a distal end, each O-ring providing an interference fit when in the adaptor.

[0196] In another aspect, the securing mechanism is a collar on the container that forms a snap fit with a base of the shield, the securing mechanism providing an interference fit in the adaptor when advanced into the adaptor. In a further aspect, the collar has a flange at the proximal end thereof to prevent the collar from advancing completely into the adaptor.

[0197] In another aspect, the adaptor may have a spring on the interior thereof, which provides resistance when the container is advanced into the adaptor and into engagement with the needle, the spring biased to advance the container out of the adaptor after sample collection.

[0198] In another aspect of the sample collection system, the securing mechanism is a flanged foam rubber collar placed on the container that forms an interference fit with the adaptor when advanced into the adaptor, the flange having a diameter that is larger than an inner diameter of the adaptor to prevent the flanged collar from being completely advanced into the adaptor.

[0199] In another aspect of the sample collection system, the securing mechanism is a foam rubber collar placed on the container that seats within a flanged opening at the proximal end of the adaptor, the foam rubber collar forming an interference fit with the container but permits the container to be advanced and withdrawn through the collar.

[0200] In another aspect of the sample collection system, the securing mechanism is a foam rubber collar secured on the container and forms interference fit when introduced into the adaptor. In a further aspect, the foam rubber collar is secured on the container with adhesive.

[0201] In another aspect of the sample collection system, the securing mechanism may be a flanged, O-ring collar on the container, wherein the O-ring forms a friction fit in the adaptor when the container is advanced in the adaptor and wherein the flange does not advance into the adaptor. In this aspect, the container is movably received in the flanged portion.

[0202] In another aspect, described herein is a method for collecting a sample from a patient, the method comprising providing a sample collection system as described above, manipulating the securing mechanism of the sample collection system to permit the container to be advanced into fluid communication with the needle in the adaptor, collecting sample into the container and removing the container from the adaptor.

[0203] In another aspect, a sample collection system is described that includes a container for collecting a sample, an adaptor comprising a distal end, a proximal end, a needle, and an interior, the adaptor configured to receive a sample through a connector at the distal end, the needle extending from the connector into the interior of the adaptor, and the proximal end including an opening to receive a first end of the container into the interior of the adaptor, and a securing mechanism configured to hold the container at a first position, wherein, at the first position, the

first end of the container is held in a spaced relationship with the needle in the interior of the adaptor. In the above aspect, the securing mechanism is configured to allow the container to be advanced distally within the interior of the adaptor from the first position to a second position and thereby engage the needle to receive the sample into the container, wherein the securing mechanism is further configured to enable the container to be withdrawn proximally to remove the container from the interior of the adaptor. Optionally, when the container is removed from the interior of the adaptor, the securing mechanism is configured to be withdrawn by the container.

[0204] In another aspect, the securing mechanism is made of rubber and has an annular shape, wherein the securing mechanism is disposed around an exterior of the container, and wherein the securing mechanism has a distal portion comprising a thickness that will fit between the container and the adaptor and a proximal portion comprising a flange having a diameter that exceeds an inner diameter of the adaptor.

[0205] In another aspect, the securing mechanism provides a snap fit with a shield for the container, the securing mechanism comprising a rim that extends away from the container and provides a stop that prevents the securing mechanism from being advanced further into the adaptor.

[0206] In another aspect, the securing mechanism comprises a compressible spring attached to a distal end of the container, the compressible spring configured to be inserted between the container and the adaptor, wherein the compressible spring holds the container in the first position, but permits the container to be advanced into the second position when a tension provided by the spring is overcome.

[0207] In another aspect, the securing mechanism comprises a foam rubber flange that provides an interference fit on the container wherein the container can be advanced in the foam rubber flange with application of a force from the first position to the second position, and wherein a first portion of the foam rubber flange may be advanced into the adaptor and a second portion of the foam rubber flange is too large to be advanced in to the adaptor.

[0208] In another aspect, the securing mechanism is a foam rubber flange that is adhesively fixed to a corresponding flange at a base of the adaptor.

[0209] In another aspect, the securing mechanism is a collar that forms a friction fit with the container such that the collar cannot be advanced into the adaptor but the container may be advanced through the collar from the first position to the second position.

[0210] In another aspect, the securing mechanism is an O-ring secured on the container by a flange formed on the container.

[0211] In another aspect, a removable sticker is applied to the adaptor and container to secure the container in the first position.

[0212] In another aspect, the securing mechanism is a collar that retains an o-ring that forms and interference fit between the container and the adaptor, wherein the collar is positioned adjacent to a cap on the container.

[0213] In another aspect, the securing mechanism comprises a collar that forms an interference fit with both an outer diameter of the container and an inner diameter of the adaptor.

[0214] In another aspect, the securing mechanism further comprises a second portion that is a sleeve that fits on the container, wherein the sleeve comprises a flange that engages the collar such that the flange pulls the collar from the adaptor when the container is removed therefrom.

[0215] In another aspect, the securing mechanism comprises a collar that forms an interference fit on the container, wherein the securing mechanism has bearings therein.

[0216] In another aspect, the securing mechanism comprises a ratcheting collar, wherein the ratcheting collar comprises tabs that grip the container when the container is removed from the adaptor.

[0217] In another aspect, the securing mechanism is a one-way collar that fits on the container, the one-way collar comprising a tubular portion and a flange portion, wherein the tubular portion comprises grips on a surface in contact with the container.

[0218] In another aspect, the securing mechanism comprises a collar and a detent that engages with a base of the adaptor and a flange that prevents the collar from advancing into the adaptor.
[0219] In another aspect, the securing mechanism comprises a collar comprising one-way grips extending upward into the collar that fits on the container, such that the container can only be advanced through the collar in one direction, wherein the securing mechanism further comprises tape adhered to the container and the collar to secure the container in the first position, wherein the tape is removed or torn when the container is advanced to the second position.
[0220] In another aspect, the securing mechanism comprises a first collar portion and a second collar portion, each of which form an interference fit with the container, wherein the first collar portion comprises receptacles for barbs on the second collar portion, wherein the first and second collar portions are joined together when the container is advanced into the second position such that first and second collar portions are carried with the container when the container is removed from the adaptor.
[0221] In another aspect, the securing mechanism comprises a snap ring comprising projections that extend upward into the adaptor when the snap ring is received by the adaptor, the container carrying a sleeve thereover, the sleeve carrying an O-ring that forms an interference fit between the container and the adaptor when the O-ring is advanced into the adaptor, the sleeve comprising a raised portion that catches on the projections as the container is advanced into the adaptor.
[0222] In another aspect, the securing mechanism comprises a flanged sleeve, wherein the sleeve is flexible and wherein there is diametric clearance between the sleeve and the container.
[0223] In another aspect, the securing mechanism has a first portion of the two part collar comprising a clip and a second portion comprising a collar that also provides an interference fit on the container, wherein the clip advances past the second portion of the collar when the container is advance to the second position, and the clip pulls the second portion of the collar from the adaptor when the container is removed from the adaptor.
[0224] In another aspect, the securing mechanism is a flanged sleeve comprising detents that engage with a base of the adaptor wherein the detents can be rotated out of engagement with the base of the adaptor to remove the container and the securing mechanism from the adaptor.
[0225] In another aspect, the container is secured in the first position with removable adhesive tape.
[0226] In another aspect, the securing mechanism is a threaded sleeve, wherein the threaded sleeve forms an interference fit with the container and is advanced upward into the adaptor by screwing the sleeve into the adaptor, wherein the container is backed out of the adaptor by unscrewing the sleeve therefrom.
[0227] In another aspect, the securing mechanism comprises a collar and a sleeve, wherein the collar comprises guide notches that receive raised guides on the sleeve, the guide notches having detents therein, the detents holding the raised guides in place when the container is in the first position, wherein the sleeve further comprises tabs that are biased outward such that the tabs carry the collar from the adaptor when the container is removed therefrom.
[0228] In another aspect, the securing mechanism comprises a collar and a sleeve, wherein the collar comprises clips configured to attach to a base of the adaptor and a tapered inner portion that receives the sleeve, wherein the sleeve has first raised portions that cooperate with detents on an interior of the sleeve to hold the container in the first position and second raised portion that deflects that sleeve whereby the clips disengage from the base, allowing the container to be removed from the adaptor.
[0229] In another aspect, the securing mechanism is a collar with posts that cooperates with first lateral and second linear slots that intersect and that are provided in the adaptor, wherein the slots receive the posts to allow the container to be locked in the first position by rotating the container so that the posts on the collar are received in the lateral slot, and, if the container is rotated such that the posts are in the linear slot, then the container can be advanced into the second position or removed from the adaptor.

[0230] In another aspect, the securing mechanism is a collar with posts that cooperates with first slanted and second linear slots that intersect and that are provided in the adaptor, wherein the slanted slots receive the posts to allow the container to be locked in the first position, and, to advance the container to the second position, the container is rotated so that the post is in the linear slot, which allows the container to be advanced into the second position or removed from the adaptor.

[0231] In another aspect, the securing mechanism comprises a collar with posts that cooperates with a slotted track in the adaptor, wherein the slot track engages the posts at a first end where the track holds the post such that the container is heled in the first position in the adaptor, wherein rotating the container moves the post into a portion f the track that allows the container to be advanced to the second position, wherein rotating the container again advance the post into the portion of the track that allows the container to be removed from the adaptor, the container carrying the collar out of the adaptor.

[0232] In a further aspect, the portion of the slot track that holds the container in the first position comprises a detent to hold the post in place.

[0233] In another aspect, the securing mechanism comprises a collar and sleeve assembly, the collar comprising a first portion that is received into the adaptor and a flange portion that will not advance into the adaptor, the collar further comprising a biased detent pin comprising a locking detent and a follower detent that locks into a slot provided in the adaptor, the sleeve comprising a slot having an angled portion and a longitudinal portion, wherein the container is locked in the first position by the locking detent when the detent pin is aligned with the angled portion of the slot and wherein the container can be advanced into the second position or removed from the adaptor when the detent pin is aligned with the longitudinal portion of the slot such that the locking detent is no longer held the adaptor slot.

[0234] In another aspect, the securing mechanism comprises a collar and sleeve assembly, the collar comprising flexible posts and the sleeve comprising a flange that will not advance into the adaptor, wherein the adaptor comprises deflectable tabs that are positioned to be received by slots in the sleeve to lock the container in the first position in the adaptor, wherein advancing the collar into the container causes the flexible posts to move the deflectable tabs from engagement with the slots in the sleeve, allowing the container to be advanced to the second position or out of the adaptor.

[0235] In another aspect, the securing mechanism comprises a sleeve comprising a bump off, first slots, second slots, and a flange that stops the sleeve from advancing completely into the adaptor, and a collar comprising raised portions and flexible projections biased toward an interior of the adaptor into which the container is received, and ribs, wherein the ribs engage the container on which the sleeve is placed, wherein the adaptor comprises projections that are biased inward, wherein the projections engage the sleeve slots to hold the container in the first position and wherein the raised portions of the collar move the projections out of engagement with the sleeve slots to allow the container to advance to the second position and to lock the collar to the sleeve allowing the sleeve and collar to be removed with the container.

[0236] From the foregoing and with reference to the various figure drawings, those skilled in the art will appreciate that certain modifications can also be made to the present disclosure without departing from the scope of the same. While several embodiments of the disclosure have been shown in the drawings, it is not intended that the disclosure be limited thereto, as it is intended that the disclosure be as broad in scope as the art will allow and that the specification be read likewise. Therefore, the above description should not be construed as limiting, but merely as exemplifications of particular embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

Claims

1. A sample collection system comprising: a container for collecting a sample; an adaptor comprising a distal end, a proximal end, a needle, and an interior, the adaptor configured to receive a sample through a connector at the distal end, the needle extending from the connector into the interior of the adaptor, and the proximal end including an opening to receive a first end of the container into the interior of the adaptor; and a securing mechanism configured to releasably secure the container at a first position, wherein, at the first position, the first end of the container is held in a spaced relationship with the needle in the interior of the adaptor, wherein the securing mechanism is operated to allow the container to be advanced distally within the interior of the adaptor from the first position to a second position and thereby engage the needle to receive the sample into the container, wherein the securing mechanism is further configured to enable the container to be withdrawn proximally to remove the container from the interior of the adaptor, wherein, when the container is removed from the interior of the adaptor, the securing mechanism is configured to be removed by the container.
2. The sample collection system of claim 1, wherein the securing mechanism comprises a collar fitted on the container.
3. The sample collection system of claim 2, wherein the collar has an inner diameter that is larger than an outer diameter of the container an outer diameter that is smaller than an inner diameter of the adaptor.
4. The sample collection system of claim 2, wherein the collar provides an interference fit when advanced into the adaptor.
5. The sample collection system of claim 2, wherein the collar has a flange that prevents the collar from being advance completely into the adaptor.
6. The sample collection system of claim 1, wherein the securing mechanism is a c-clamp.
7. The sample collection system of claim 6, wherein the securing mechanism further comprises a resilient gasket that is received on the container and forms an interference fit for the container within the adaptor.
8. The sample collection system of claim 1, wherein the container comprises a cap, the cap comprising a septum and a shield, the shield extending from the septum and surrounding a perimeter of a portion of the container.
9. The sample collection system of claim 8, wherein the securing mechanism is a collar on the container that forms a snap fit with a base of the shield, the securing mechanism providing an interference fit in the adaptor when advanced into the adaptor.
10. The sample collection system of claim 9, wherein the collar has a flange at the proximal end thereof to prevent the collar from advancing completely into the adaptor.
11. The sample collection system of claim 1, wherein the adaptor has a spring on the interior thereof, which provides resistance when the container is advanced into the adaptor and into engagement with the needle, the spring biased to advance the container out of the adaptor after sample collection.
12. The sample collection system of claim 1, wherein the securing mechanism is a flanged foam rubber collar placed on the container that forms an interference fit with the adaptor when advanced into the adaptor, the flange having a diameter that is larger than an inner diameter of the adaptor to prevent the flanged collar from being completely advanced into the adaptor.
13. The sample collection system of claim 1, wherein the securing mechanism is a foam rubber collar placed on the container that seats within a flanged opening at the proximal end of the adaptor, the foam rubber collar forming an interference fit with the container, but permits the container to be advanced and withdrawn through the collar.
14. The sample collection system of claim 1, wherein the securing mechanism is a foam rubber

collar secured on the container and forms interference fit when introduced into the adaptor.
15. The sample collection system of claim 14, wherein the foam rubber collar is secured on the container with adhesive.
16. The sample collection system of claim 1, wherein the securing mechanism is a flanged and O-ring collar on the container, wherein the O-ring forms a friction fit in the adaptor when the container is advanced in the adaptor and wherein the flange does not advance into the adaptor, wherein the container is movably received in the flange.
17. The sample collection system of claim 8, wherein the shield has a first O-ring at a proximal end and a second O-ring at a distal end, each O-ring providing an interference fit when in the adaptor.
18. A sample collection system comprising: a container for collecting a sample; an adaptor comprising a distal end, a proximal end, a needle, and an interior, the adaptor configured to receive a sample through a connector at the distal end, the needle extending from the connector into the interior of the adaptor, and the proximal end including an opening to receive a first end of the container into the interior of the adaptor; and a securing mechanism configured to hold the container at a first position, wherein, at the first position, the first end of the container is held in a spaced relationship with the needle in the interior of the adaptor, wherein the securing mechanism is configured to allow the container to be advanced distally within the interior of the adaptor from the first position to a second position and thereby engage the needle to receive the sample into the container, wherein the securing mechanism is further configured to enable the container to be withdrawn proximally to remove the container from the interior of the adaptor, wherein, when the container is removed from the interior of the adaptor, the securing mechanism is configured to be withdrawn by the container.
19. The sample collection system of claim 18, wherein the securing mechanism is made of rubber and has an annular shape, wherein the securing mechanism is disposed around an exterior of the container, and wherein the securing mechanism has a distal portion comprising a thickness that will fit between the container and the adaptor and a proximal portion comprising a flange having a diameter that exceeds an inner diameter of the adaptor.
20. The sample collection system of claim 18, wherein the securing mechanism provides a snap fit with a shield for the container, the securing mechanism comprising a rim that extends away from the container and provides a stop that prevents the securing mechanism from being advanced further into the adaptor.
21. The sample collection system of claim 18, wherein the securing mechanism comprises a compressible spring attached to a distal end of the container, the compressible spring configured to be inserted between the container and the adaptor, wherein the compressible spring holds the container in the first position, but permits the container to be advanced into the second position when a tension provided by the spring is overcome.
22. The sample collection system of claim 18, wherein the securing mechanism comprises a foam rubber flange that provides an interference fit on the container wherein the container can be advanced in the foam rubber flange with application of a force from the first position to the second position, and wherein a first portion of the foam rubber flange may be advanced into the adaptor and a second portion of the foam rubber flange is too large to be advanced in to the adaptor.
23. The sample collection system of claim 18, wherein the securing mechanism is a foam rubber flange that is adhesively fixed to a corresponding flange at a base of the adaptor.
24. The sample collection system of claim 18, wherein the securing mechanism is a collar that forms a friction fit with the container such that the collar cannot be advanced into the adaptor but the container may be advanced through the collar from the first position to the second position.
25. The sample collection system of claim 18, wherein the securing mechanism is an O-ring secured on the container by a flange formed on the container.
26. The sample collection system of claim 25, wherein a removable sticker is applied to the adaptor and container to secure the container in the first position.

27. The sample collection system of claim 18, wherein the securing mechanism is a collar that retains an o-ring that forms and interference fit between the container and the adaptor, wherein the collar is positioned adjacent to a cap on the container.
28. The sample collection system of claim 18, wherein the securing mechanism comprises a collar that forms an interference fit with both an outer diameter of the container and an inner diameter of the adaptor.
29. The sample collection system of claim 28, wherein the securing mechanism further comprises a second portion that is a sleeve that fits on the container, wherein the sleeve comprises a flange that engages the collar such that the flange pulls the collar from the adaptor when the container is removed therefrom.
30. The sample collection system of claim 18, wherein securing mechanism comprises a collar that forms an interference fit on the container, wherein the securing mechanism has bearings therein.
31. The sample collection system of claim 18, wherein the securing mechanism comprises a ratcheting collar, wherein the ratcheting collar comprises tabs that grip the container when the container is removed from the adaptor.
32. The sample collection system of claim 18, wherein the securing mechanism is a one-way collar that fits on the container, the one-way collar comprising a tubular portion and a flange portion, wherein the tubular portion comprises grips on a surface in contact with the container.
33. The sample collection system of claim 18, wherein the securing mechanism comprises a collar and a detent that engages with a base of the adaptor and a flange that prevents the collar from advancing into the adaptor.
34. The sample collection system of claim 18, wherein the securing mechanism comprises a collar comprising one-way grips extending upward into the collar that fits on the container, such that the container can only be advanced through the collar in one direction, wherein the securing mechanism further comprises tape adhered to the container and the collar to secure the container in the first position, wherein the tape is removed or torn when the container is advanced to the second position.
35. The sample collection system of claim 18, wherein the securing mechanism comprises a first collar portion and a second collar portion, each of which form an interference fit with the container, wherein the first collar portion comprises receptacles for barbs on the second collar portion, wherein the first and second collar portions are joined together when the container is advanced into the second position such that first and second collar portions are carried with the container when the container is removed from the adaptor.
36. The sample collection system of claim 18, wherein the securing mechanism comprises a snap ring comprising projections that extend upward into the adaptor when the snap ring is received by the adaptor, the container carrying a sleeve thereover, the sleeve carrying an O-ring that forms an interference fit between the container and the adaptor when the O-ring is advanced into the adaptor, the sleeve comprising a raised portion that catches on the projections as the container is advanced into the adaptor.
37. The sample collection system of claim 18, wherein the securing mechanism comprises a flanged sleeve, wherein the sleeve is flexible and wherein there is diametric clearance between the sleeve and the container.
38. The sample collection system of claim 18, wherein the securing mechanism comprises a two-part collar, a first portion of the two part collar comprising a clip and a second portion comprising a collar that also provides an interference fit on the container, wherein the clip advances past the second portion of the collar when the container is advance to the second position, and the clip pulls the second portion of the collar from the adaptor when the container is removed from the adaptor.
39. The sample collection system of claim 18, wherein the securing mechanism is a flanged sleeve comprising detents that engage with a base of the adaptor wherein the detents can be rotated out of engagement with the base of the adaptor to remove the container and the securing mechanism from

the adaptor.
40. The sample collection system of claim 39, wherein the container is secured in the first position with removable adhesive tape.
41. The sample collection system of claim 18, wherein the securing mechanism is a threaded sleeve, wherein the threaded sleeve forms an interference fit with the container and is advanced upward into the adaptor by screwing the sleeve into the adaptor, wherein the container is backed out of the adaptor by unscrewing the sleeve therefrom.
42. The sample collection system of claim 18, wherein the securing mechanism comprises a collar and a sleeve, wherein the collar comprises guide notches that receive raised guides on the sleeve, the guide notches having detents therein, the detents holding the raised guides in place when the container is in the first position, wherein the sleeve further comprises tabs that are biased outward such that the tabs carry the collar from the adaptor when the container is removed therefrom.
43. The sample collection system of claim 18, wherein the securing mechanism comprises a collar and a sleeve, wherein the collar comprises clips configured to attach to a base of the adaptor and a tapered inner portion that receives the sleeve, wherein the sleeve has first raised portions that cooperate with detents on an interior of the sleeve to hold the container in the first position and second raised portion that deflects that sleeve whereby the clips disengage from the base, allowing the container to be removed from the adaptor.
44. The sample collection system of claim 18, wherein the securing mechanism is a collar with posts that cooperates with first lateral and second linear slots that intersect and that are provided in the adaptor, wherein the slots receive the posts to allow the container to be locked in the first position by rotating the container so that the posts on the collar are received in the lateral slot, and, if the container is rotated such that the posts are in the linear slot, then the container can be advanced into the second position or removed from the adaptor.
45. The sample collection system of claim 18, wherein the securing mechanism is a collar with posts that cooperates with first slanted and second linear slots that intersect and that are provided in the adaptor, wherein the slanted slots receive the posts to allow the container to be locked in the first position, and, to advance the container to the second position, the container is rotated so that the post is in the linear slot, which allows the container to be advanced into the second position or removed from the adaptor.
46. The sample collection system of claim 18, wherein the securing mechanism is a collar with posts that cooperates with a slotted track in the adaptor, wherein the slot track engages the posts at a first end where the track holds the post such that the container is heled in the first position in the adaptor, wherein rotating the container moves the post into a portion f the track that allows the container to be advanced to the second position, wherein rotating the container again advance the post into the portion of the track that allows the container to be removed from the adaptor, the container carrying the collar out of the adaptor.
47. The sample collection system of claim 46, wherein the portion of the slot track that holds the container in the first position comprises a detent to hold the post in place.
48. The sample collection system of claim 18, wherein the securing mechanism comprises a collar and sleeve assembly, the collar comprising a first portion that is received into the adaptor and a flange portion that will not advance into the adaptor, the collar further comprising a biased detent pin comprising a locking detent and a follower detent that locks into a slot provided in the adaptor, the sleeve comprising a slot having an angled portion and a longitudinal portion, wherein the container is locked in the first position by the locking detent when the detent pin is aligned with the angled portion of the slot and wherein the container can be advanced into the second position or removed from the adaptor when the detent pin is aligned with the longitudinal portion of the slot such that the locking detent is no longer held the adaptor slot.
49. The sample collection system of claim 18, wherein the securing mechanism comprises a collar and sleeve assembly, the collar comprising flexible posts and the sleeve comprising a flange that

will not advance into the adaptor, wherein the adaptor comprises deflectable tabs that are positioned to be received by slots in the sleeve to lock the container in the first position in the adaptor, wherein advancing the collar into the container causes the flexible posts to move the deflectable tabs from engagement with the slots in the sleeve, allowing the container to be advanced to the second position or out of the adaptor.

50. The sample collection system of claim 18, wherein the securing mechanism comprises a sleeve comprising a bump off, first slots, second slots, and a flange that stops the sleeve from advancing completely into the adaptor, and a collar comprising raised portions and flexible projections biased toward an interior of the adaptor into which the container is received, and ribs, wherein the ribs engage the container on which the sleeve is placed, wherein the adaptor comprises projections that are biased inward, wherein the projections engage the first slots of the sleeve to hold the container in the first position and wherein the raised portions of the collar move the projections out of engagement with the first sleeve slots to allow the container to advance to the second position and to lock the collar to the sleeve allowing the sleeve and collar to be removed with the container.

51. The sample collection system of claim 18, wherein the securing mechanism comprises a sleeve that is attached to the container, the sleeve having a larger diameter portion, wherein the adaptor comprises a base portion with windows that receive tabs on a locking oval ring that holds the container with the sleeve thereon in the first position in its relaxed state, as the larger diameter portion of the sleeve is advanced into the locking oval ring, the oval ring expands causing the tabs to withdraw from the windows of the adaptor and attach to the sleeve.