METHODS AND DEVICES FOR SAMPLE COLLECTION AND SAMPLE SEPARATION

BACKGROUND

[0001] A blood sample for use in laboratory testing is often obtained by way of venipuncture, which typically involves inserting a hypodermic needle into a vein on the subject. Blood extracted by the hypodermic needle may be drawn directly into a syringe or into one or more sealed vials for subsequent processing. When a venipuncture may be difficult or impractical such as on a newborn infant, a non-venous puncture such as a heel stick or other alternate site puncture may be used to extract a blood sample for testing. After the blood sample is collected, the extracted sample is typically packaged and transferred to a processing center for analysis.

[0002] Unfortunately, conventional sample collection and testing techniques of bodily fluid samples have drawbacks. For instance, except for the most basic tests, blood tests that are currently available typically require a substantially high volume of blood to be extracted from the subject. Because of the high volume of blood, extraction of blood from alternate sample sites on a subject, which may be less painful and/or less invasive, are often disfavored as they do not yield the blood volumes needed for conventional testing methodologies. In some cases, patient apprehension associated with venipuncture may reduce patient compliance with testing protocol. Furthermore, the traditional collection technique adds unnecessary complexity when trying to separate a single blood sample into different containers for different pre-analytical processing.

SUMMARY

[0003] At least some of the disadvantages associated with the prior art ~~are~~may be overcome by one or more embodiments of the devices, systems, or methods described herein.

[0004] In ~~one embodiment~~ an aspect described herein, a device is provided for use with a formed component liquid sample, the device comprising at least one sample inlet for receiving said sample; at least a first outlet for outputting only a liquid portion of the formed component liquid sample; at least a second outlet for outputting the formed component liquid sample at least a first material mixed therein.

[0005] It should be understood that one or more of the following features may be adapted for use with any of the embodiments described herein. By way of non-limiting example, the body may a first pathway fluidically couples the sample inlet with the first outlet. Optionally, a

having surface pores at the minimum surface of a mean diameter of at least about 1 micron and having a flow rate of greater than about 4 cm/min/psi. Optionally, the flow rate of the material, unassisted, is between 1 cm/min/psi and 4.3 2 cm/min/psi.

[0006] In one ~~embodiment~~ aspect described herein, a device for collecting and separating a bodily fluid sample from a subject is provided comprising: at least two sample collection pathways configured to draw the bodily fluid sample into the device from a single end of the device in contact with the subject, thereby separating the fluid sample into two separate samples; a second portion comprising a plurality of sample containers for receiving the bodily fluid sample collected in the sample collection pathways, the sample containers operably engagable to be in fluid communication with the sample collection pathways, whereupon when fluid communication is established, the containers provide a motive force to move a majority of the two separate samples from the pathways into the containers. ~~Optionally, the~~ The device also includes a separation material along one of the sample collection pathways, the material configured to remove formed components from the sample when outputting to at least one of the sample containers.

[0007] In another ~~embodiment~~ aspect described herein, a device for collecting a bodily fluid sample is provided comprising: a first portion comprising at least one fluid collection location leading to at least two sample collection pathways configured to draw the fluid sample therein via a first type of motive force; a second portion comprising a plurality of sample containers for receiving the bodily fluid sample collected in the sample collection pathways, the sample containers operably engagable to be in fluid communication with the sample collection pathways, whereupon when fluid communication is established, the containers provide a second motive force different from the first motive force to move a majority of the bodily fluid sample from the pathways into the containers; wherein at least one of the sample collection pathways comprises a fill indicator to indicate when a minimum fill level has been reached and that at least one of the sample containers can be engaged to be in fluid communication with at least one of the sample collection pathways. ~~Optionally, the~~ The device also includes a separation material along one of the sample collection pathways, the material configured to remove formed components from the sample when outputting to at least one of the sample containers.

[0008] In another ~~embodiment~~aspect described herein, a device for collecting a bodily fluid sample is provided comprising a first portion comprising at least two sample collection channels configured to draw the fluid sample into the sample collection channels via a first type of motive force, wherein one of the sample collection channels has an interior coating designed to mix with the fluid sample and another of the sample collection channels has another interior coating chemically different from said interior coating; a second portion comprising a plurality of

sample containers for receiving the bodily fluid sample collected in the sample collection channels, the sample containers operably engagable to be in fluid communication with the collection channels, whereupon when fluid communication is established, the containers provide a second motive force different from the first motive force to move a majority of the bodily fluid sample from the channels into the containers.; ~~wherein containers are arranged such that mixing of the fluid sample between the containers does not occur. Optionally, the~~ The device also includes a separator along one of the sample collection channels, the separator configured to remove formed component from the sample when outputting to at least one of the sample containers.

[0009] In another ~~embodiment~~aspect described herein, a device for collecting a bodily fluid sample is provided comprising: a first portion comprising a plurality of sample collection channels, wherein at least two of the channels are configured to simultaneously draw the fluid sample into each of the at least two sample collection channels via a first type of motive force; a second portion comprising a plurality of sample containers for receiving the bodily fluid sample collected in the sample collection channels, wherein the sample containers have a first condition where the sample containers are not in fluid communication with the sample collection channels, and a second condition where the sample containers are operably engagable to be in fluid communication with the collection channels, whereupon when fluid communication is established, the containers provide a second motive force different from the first motive force to move bodily fluid sample from the channels into the containers. ~~Optionally, the~~ The device also includes a separator along one of the sample collection channels, the separator configured to remove formed component from the sample when outputting to at least one of the sample containers.

[0010] In another ~~embodiment~~aspect described herein, a sample collection device is provided comprising: (a) a collection channel comprising a first opening and a second opening, and being configured to draw a bodily fluid sample via capillary action from the first opening towards the second opening; and (b) a sample container for receiving the bodily fluid sample, the container being engagable with the collection channel, having an interior with a vacuum therein, and having a cap configured to receive a channel; wherein the second opening is defined by a portion the collection channel configured to penetrate the cap of the sample container, and to provide a fluid flow path between the collection channel and the sample container, and the sample container has an interior volume no greater than ten times larger than the interior volume of the collection channel. ~~Optionally, the~~ The device also comprises a separator along ~~one of~~ the ~~sample~~ collection channel, the separator configured to remove formed components from the sample prior to and when outputting to the sample container.

[0011] In another ~~embodiment~~aspect described herein, a sample collection device is provided comprising: (a) a collection channel comprising a first opening and a second opening, and being configured to draw a bodily fluid sample via capillary action from the first opening towards the second opening; (b) a sample container for receiving the bodily fluid sample, the container being engagable with the collection channel, having an interior with a vacuum therein, and having a cap configured to receive a channel; and (c) an adaptor channel configured to provide a fluid flow path between the collection channel and the sample container, having a first opening and a second opening, the first opening being configured to contact the second opening of the collection channel, the second opening being configured to penetrate the cap of the sample container. ~~Optionally, the~~ The device also comprises a separator along ~~one of~~ the sample collection channel, the separator configured to remove formed components from the sample prior to and when outputting to the sample container.

[0012] In another ~~embodiment~~ aspect described herein, a sample collection device is provided comprising: (a) a body, containing a collection channel , the collection channel comprising a first opening and a second opening, and being configured to draw a bodily fluid via capillary action from the first opening towards the second opening; (b) a base, containing a sample container for receiving the bodily fluid sample, the sample container being engagable with the collection channel, having an interior with a vacuum therein, and having a cap configured to receive a channel; and (c) a support, wherein, the body and the base are connected to opposite ends of the support, and are configured to be movable relative to each other, such that sample collection device is configured to have an extended state and a compressed state, wherein at least a portion of the base is closer to the body in the extended state of the device than in the compressed state, the second opening of the collection channel is configured to penetrate the cap of the sample container, in the extended state of the device, the second opening of the collection channel is not in contact with the interior of the sample container, and in the compressed state of the device, the second opening of the collection channel extends into the interior of the sample container through the cap of the container, thereby providing fluidic communication between the collection channel and the sample container. ~~Optionally, the~~ The device also comprises a separator along ~~one of~~ the sample collection channel, the separator configured to remove formed component from the sample prior to and when outputting to the sample container.

[0013] In another ~~embodiment~~ aspectdescribed herein, a sample collection device is provided comprising: (a) a body, containing a collection channel , the collection channel comprising a first opening and a second opening, and being configured to draw a bodily fluid via capillary action from the first opening towards the second opening; (b) a base, containing a sample container for

receiving the bodily fluid sample, the sample container being engagable with the collection channel, having an interior with a vacuum therein and having a cap configured to receive a channel; (c) a support, and (d) an adaptor channel, having a first opening and a second opening, the first opening being configured to contact the second opening of the collection channel, and the second opening being configured to penetrate the cap of the sample container, wherein, the body and the base are connected to opposite ends of the support, and are configured to be movable relative to each other, such that sample collection device is configured to have an extended state and a compressed state, wherein at least a portion of the base is closer to the body in the extended state of the device than in the compressed state, in the extended state of the device, the adaptor channel is not in contact with one or both of the collection channel and the interior of the sample container, and in the compressed state of the device, the first opening of the adaptor channel is in contact with the second opening of the collection channel, and the second opening of the adaptor channel extends into the interior of the sample container through the cap of the container, thereby providing fluidic communication between the collection channel and the sample container. ~~Optionally, the~~ The device also comprises a separator along ~~one of~~ the sample collection channel, the separator configured to remove formed component from the sample prior to and when outputting to the sample container.

[0014] In another ~~embodiment~~ aspect described herein, a device for collecting a fluid sample from a subject is provided comprising: (a) a body containing a collection channel, the collection channel comprising a first opening and a second opening, and being configured to draw a bodily fluid via capillary action from the first opening towards the second opening; (b) a base, engagable with the body, wherein the base supports a sample container, the container being engagable with the collection channel, having an interior with a vacuum therein, and having a cap configured to receive a channel; wherein the second opening of the collection channel is configured to penetrate the cap of the sample container, and to provide a fluid flow path between the collection channel and the sample container. ~~Optionally, the~~ The device also comprises a separator along ~~one of~~ the sample collection channel, the separator configured to remove formed component from the sample prior to and when outputting to the sample container.

[0015] ~~In another embodiment described~~ As disclosed herein, a device for collecting a fluid sample from a subject is provided comprising: (a) a body containing a collection channel, the collection channel comprising a first opening and a second opening, and being configured to draw a bodily fluid via capillary action from the first opening towards the second opening; (b) a base, engagable with the body, wherein the base supports a sample container, the sample container being engagable with the collection channel, having an interior with a vacuum therein and

[0018] ~~In another embodiment described~~ As disclosed herein, a method is provided comprising contacting one end of a sample collection device to a bodily fluid sample to split the sample into at least two portions by drawing the sample into at least two collection channels of the sample collection device by way of a first type of motive force; establishing fluid communication between the sample collection channels and the sample containers after a desired amount of sample fluid has been confirmed to be in at least one of the collection channels, whereupon the containers provide a second motive force different from the first motive force to move each of the portions of bodily fluid sample into their respective containers.

[0019] ~~In another embodiment described~~ As disclosed herein, a method is provided comprising metering a minimum amount of sample into at least two channels by using a sample collection device with at least two of the sample collection channels configured to simultaneously draw the fluid sample into each of the at least two sample collection channels via a first type of motive force; after a desired amount of sample fluid has been confirmed to be in the collection channels, fluid communication is established between the sample collection channels and the sample containers, whereupon the containers provide a second motive force different from the first motive force use to collect the samples to move bodily fluid sample from the channels into the containers.

[0020] ~~In another embodiment described~~ As disclosed herein, a method of collecting a bodily fluid sample is provided comprising (a) contacting a bodily fluid sample with a device comprising a collection channel, the collection channel comprising a first opening and a second opening, and being configured to draw a bodily fluid via capillary action from the first opening towards the second opening, such that the bodily fluid sample fills the collection channel from the first opening through the second opening; (b) establishing a fluid flow path between the collection channel and the interior of a sample container , said sample container having an interior volume no greater than ten times larger than the interior volume of the collection channel and having a vacuum prior to establishment of the fluid flow path between the collection channel and the interior of the sample container, such that establishment of the fluid flow path between the collection channel and the interior of the sample container generates a negative pressure at the second opening of the collection channel, and the fluidic sample is transferred from the collection channel to the interior of the sample container.

[0021] ~~In another embodiment described~~ As disclosed herein, a method of collecting a bodily fluid sample is provided comprising (a) contacting a bodily fluid sample with any collection device as described herein, such that the bodily fluid sample fills the collection channel from the first opening through the second opening of at least one of the collection channel(s) in the device; and

(b) establishing a fluid flow path between the collection channel and the interior of the sample container , such that establishing a fluid flow path between the collection channel and the interior of the sample container generates a negative pressure at the second opening of the collection channel, and the fluidic sample is transferred from the collection channel to the interior of the sample container.

[0022] It should be understood that one or more of the following features may be adapted for use with any of the embodiments described herein. Optionally, the collection channel and the interior of the sample container are not brought into fluid communication until the bodily fluid reaches the second opening of the collection channel. Optionally, the device comprises two collection channels, and the collection channels and the interior of the sample containers are not brought into fluidic communication until the bodily fluid reaches the second opening of both collection channels. Optionally, the second opening of the collection channel in the device is configured to penetrate the cap of the sample container, and wherein a fluidic flow path between the second opening of the collection channel and the sample container is established by providing relative movement between the second opening of the collection channel and the sample container, such that the second opening of the collection channel penetrates the cap of the sample container. Optionally, the device comprises an adaptor channel for each collection channel in the device, the adaptor channel having a first opening and a second opening, the first opening being configured to contact the second opening of the collection channel, and the second opening being configured to penetrate the cap of the sample container, and wherein a fluidic flow path between the collection channel and the sample container is established by providing relative movement between two or more of: (a) the second opening of the collection channel, (b) the adaptor channel, and (c) the sample container, such that the second opening of the adaptor channel penetrates the cap of the sample container.

[0023] ~~In another embodiment described~~ As disclosed herein, a method for collecting a bodily fluid sample from a subject is provided comprising: (a) bringing a device comprising a first channel and a second channel into fluidic communication with a bodily fluid from the subject, each channel having an input opening configured for fluidic communication with said bodily fluid, each channel having an output opening downstream of the input opening of each channel, and each channel being configured to draw a bodily fluid via capillary action from the input opening towards the output opening; (b) bringing, through the output opening of each of the first channel and the second channel, said first channel and said second channel into fluidic communication with a first container and a second container, respectively; and (c) directing said bodily fluid within each of said first channel and second channel to each of said first container and second

container with the aid of: (i) negative pressure relative to ambient pressure in said first container or said second container, wherein said negative pressure is sufficient to effect flow of said bodily fluid through said first channel or said second channel into its corresponding container, or (ii) positive pressure relative to ambient pressure upstream of said first channel or said second channel, wherein said positive pressure is sufficient to effect flow of said whole blood sample through said first channel or said second channel into its corresponding container.

[0024] ~~In another embodiment described~~ As disclosed herein, a method of manufacturing a sample collection device is provided comprising forming one portion of a sample collection device having at least two channels configured to simultaneously draw the fluid sample into each of the at least two sample collection channels via a first type of motive force; forming sample containers, whereupon the containers are configured to be coupled to the sample collection device to the provide a second motive force different from the first motive force use to collect the samples to move bodily fluid sample from the channels into the containers.

[0025] ~~In another embodiment described~~ As disclosed herein, computer executable instructions are provided for performing a method comprising: forming one portion of a sample collection device having at least two channels configured to simultaneously draw the fluid sample into each of the at least two sample collection channels via a first type of motive force.

[0026] ~~In another embodiment described herein,~~ There is also disclosed computer executable instructions for performing a method comprising: forming sample containers, whereupon the containers are configured to be coupled to the sample collection device to provide a second motive force different from the first motive force use to collect the samples to move bodily fluid sample from the channels into the containers.

[0027] ~~In yet another embodiment described herein,~~ There is also disclosed a device for collecting a bodily fluid sample from a subject, the device comprising: means for drawing the bodily fluid sample into the device from a single end of the device in contact with the subject, thereby separating the fluid sample into two separate samples; means for transferring the fluid sample into a plurality of sample containers, wherein the containers provide a motive force to move a majority of the two separate samples from the pathways into the containers.

[0028] ~~In one embodiment~~As disclosed, the desired range of channel surface area relative to the surface area of the separator on that side of the separator is in the range of about 35% to 70%. Optionally, the desired range of channel surface area relative to the surface area of the separator on that side of the separator is in the range of about 40% to 70%. Optionally, the desired range of channel surface area relative to the surface area of the separator on that side of the separator is in the range of about 50% to 60%.

[0029] In yet another ~~embodiment~~aspect, a method is provided comprising collecting a bodily fluid sample into a collection channel, the collection channel comprising a first opening and a second opening, and being configured to draw the bodily fluid via capillary action from the first opening towards the second opening; and using a separator along the sample collection channel to remove formed component from the sample prior to and when outputting to the sample container.

[0030] In yet another ~~embodiment~~aspect, a method is provided comprising collecting a bodily fluid sample into device having a first collection channel and a second collection channel, the collection channel comprising a first opening and a second opening, and being configured to draw the bodily fluid via capillary action from the first opening towards the second opening; using a separator along the first sample collection channel to remove formed component from the sample prior to and when outputting to the sample container; wherein when the bodily fluid sample is blood, the device outputs both blood and plasma, each from separate outlets, from the one sample collected into the device.

[0031] ~~In one embodiment described~~As disclosed herein, it is desirable to use separation materials on a bodily fluid to allow for plasma-based assays. The desired list of assays includes not only large molecules such as proteins and lipids, but also smaller metabolites such as those that are part of the complete metabolic panel and examples include but are not limited to glucose, calcium, magnesium, etc.... Since the plasma separation materials were not primarily designed for these assays but for use in select types of test-strip based assays, the hemolysis-preventing agent used in these materials can interfere with other assay chemistries.

[0032] In the case of at least some bodily fluid separation materials described herein, the separation material may have a coating of a protective material such as but not limited to an anti-hemolytic material like single and/or double alkyl chain N-oxides of tertiary amines (NTA). Alternatively, separation material coating can constitute a combination of an anti-hemolytic (such as surfactant, protein, sugar, or a combination of these), alongside an anti-coagulant (such as EDTA and its derivatives or Heparin). NTA generally does not interfere with several large molecule assays. NTA, however, is a chelating agent that strongly binds to di-valent cations such as calcium and magnesium ions. Unfortunately, this results in a very strong interference in certain assays used to measure, for example and not limitation, calcium and magnesium concentrations and also for assays where Ca and Mg are co-factors for enzymes which are part of the reaction. This can result in significant errors for such assays.

[0033] One or more of the embodiments described herein may provide the benefits of the anti-hemolytic material but also may provide a much reduced downside effect of the anti-hemolytic

[0045] In ~~one non-limiting example~~an aspect described herein, a device is provided for collecting a sample from a subject and outputting a filtrate from the sample.

[0046] In ~~one non-limiting example~~an aspect described herein, a device is provided device for collecting a sample from a subject and forming a filtrate from at least a portion of the sample.

[0047] In ~~one non-limiting example~~an aspect described herein, a method is provided of using a device for collecting a sample from a subject and outputting a filtrate from the sample.

[0048] In ~~one non-limiting example~~an aspect described herein, a method is provided of processing a formed component separation membrane.

[0049] In ~~one non-limiting example~~an aspect described herein, a method is provided of processing a formed component separation material.

[0050] This Summary is provided to introduce a selection of concepts in a simplified form that are further described below in the Detailed Description. This Summary is not intended to identify key features or essential features of the claimed subject matter, nor is it intended to be used to limit the scope of the claimed subject matter.

INCORPORATION BY REFERENCE

[0051] All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference. However, in the event of a conflict between the content of the present express disclosure and the content of a document incorporated by reference herein, the content of the present express disclosure controls.

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BRIEF DESCRIPTION OF THE DRAWINGS

[0053] Figure 1 shows a schematic view of a device according to one embodiment described herein.