SYSTEMS, DEVICES, AND METHODS FOR BODILY FLUID SAMPLE COLLECTION

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 disadvantages associated with the prior art are overcome by at least some or all of the embodiments described in this disclosure. Although the embodiments herein are typically described in the context of obtaining a blood sample, it should be understood that the embodiments herein are not limited to blood samples and can also be adapted to acquire other fluid(s) or bodily sample(s) for analysis.

[0003a] According to an aspect of the present invention, there is provided a device for collecting a bodily fluid sample from a subject, the device 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, wherein a second

motive force associated with the container is used to move a majority of the two separate samples from the pathways into the containers.

[0003b] According to an aspect of the present invention, there is provided a device for collecting a bodily fluid sample, the device 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, wherein 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.

[0003c] According to an aspect of the present invention, there is provided a sample collection device, comprising: 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 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.

[0003d] According to an aspect of the present invention, there is provided a sample collection device, comprising: 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; a sample container for receiving the bodily fluid sample, the container being engageable with the collection channel, having an interior with a vacuum therein, and having a cap configured to receive a channel; and 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.

[0003e] According to an aspect of the present invention, there is provided a sample collection device, comprising: 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; a base, containing a sample container for receiving the bodily fluid sample, the sample container being engageable with the collection channel, having an interior with a vacuum therein, and having a cap configured to receive a channel; and 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.

[0003f] According to an aspect of the present invention, there is provided a sample collection device, comprising: 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; a base, containing a sample container for receiving the bodily fluid sample, the sample container being engageable with the collection channel, having an interior with a vacuum therein and having a cap configured to receive a channel; a support, and 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.

[0003g] According to an aspect of the present invention, there is provided a device for collecting a fluid sample from a subject, comprising: 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; a base, engageable with the body, wherein the base supports a sample container, the container being engageable 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.

[0003h] According to an aspect of the present invention, there is provided a device for collecting a fluid sample from a subject, comprising: 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; a base, engagable with the body, wherein the base supports a sample container, the sample container being engageable with the collection channel, having an interior with a vacuum therein and having a cap configured to receive a channel; and 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.

[0004] In one embodiment described herein, a device is provided for collecting a bodily fluid sample. This embodiment may be useful for accurately collecting small volumes of bodily fluid sample that are often associated with non-venous blood draws. In one non-limiting example, the sample volume is about 1 mL or less. Optionally, the sample volume is about 900 uL or less. Optionally, the sample volume is about 800 uL or less. Optionally, the sample

volume is about 700 uL or less. Optionally, the sample volume is about 600 uL or less. Optionally, the sample volume is about 500 uL or less. Optionally, the sample volume is about 400 uL or less. Optionally, the sample volume is about 300 uL or less. Optionally, the sample volume is about 200 uL or less. Optionally, the sample volume is about 100 uL or less. Optionally, the sample volume is about 90 uL or less. Optionally, the sample volume is about 80 uL or less. Optionally, the sample volume is about 70 uL or less. Optionally, the sample volume is about 60 uL or less. Optionally, the sample volume is about 50 uL or less.

[0005] In one non-limiting example, this device can be used to split the bodily fluid sample directly into two or more different portions that are then deposited into their respective containers. ~~In one non-limiting example~~According to an aspect of the present invention, ~~the~~there is provided a device for collecting a bodily fluid sample, the device ~~comprises~~comprising a first portion having 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. The sample collection device includes 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~~ wherein 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.

[0005a] The containers may be arranged such that mixing of the fluid sample between the containers does not occur. Because this device may be used with non-venous draws, it may take a longer period of time to obtain a desired volume of sample and the early introduction of a material such as an anti-coagulant which may coat the channels, can prevent premature clogging of the channels during collection.

[0006] ~~In another embodiment described herein~~According to an aspect of the present invention, a device is provided for collecting a bodily fluid sample. The device comprises 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. The device may also include 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~~ wherein a second motive

force different from the first motive force to move bodily fluid sample from the channels into the containers.

[0006a] According to an aspect of the present invention, there is provided a method 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.

[0006b] According to an aspect of the present invention, there is provided a method of collecting a bodily fluid sample, comprising: 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; 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.

[0006c] According to an aspect of the present invention, there is provided a method of collecting a bodily fluid sample, comprising: contacting a bodily fluid sample with a device according to aspects of the present invention, 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 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.

[0007] ~~In a still further embodiment described herein~~According to an aspect of the present invention, 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.

[0007a] ~~In some alternative embodiments~~As disclosed, devices that use only a single channel to collect the body fluid or devices that have a plurality of channels but do not collect them simultaneously are not excluded. Optionally, the collection of sample fluid is performed without the use of a wicking material.

[0008] ~~In one embodiment~~As disclosed herein, there is a discrete amount of time between sample collection and introduction of the sample into a sample pre-processing device. In one non-limiting example, the process is a non-continuous process. The sample collection occurs in one processing station and then the sample is taken to a second station. This second station may be in the sample building. Optionally, the second station may be located at another location where the sample needs to be walked, driven, flown, conveyor-ed, placed in a transport device, or placed in a transport container to reach the second location. In this manner, there is a discrete break in the processing to allow for time associated with sample transport.

[0009] ~~In another embodiment~~ As disclosed herein, separator gel(s) can also be included in the sample containers such that the gels will separate cell-free fractions of whole blood from the cellular or other solid or semi-solid portions of the sample. Such a gel or other similar separator material may be included in the sample container prior to, during, or after sample has been introduced into the sample container. The separator material may have a density between that of the cells and solution components, so that the material separates the sample components by flowing to a position between the solution and non-solution sample layers during separation such as by centrifugation. Following centrifugation, the separator material stops flowing and remain as a soft barrier between the layers. In some embodiments, the separator material can be further processed to harden into a more rigid barrier. In on non-limiting example, the separator material may be a UV-curable material such as but not limited to thixotropic gel of sorbitol-based gelator in a diacrylate oligomer. The sample container may have the entire vessel or optionally, on that

portion with the UV-curable material exposed to UV light for a period of time such as but not limited to 10 to 30 seconds to harden the material. Such hardening may involve cross-linking of material in the UV-curable material. Optionally, the UV curable material may be used in conjunction with traditional separator gel material such that only one side (the solution side or the solid side) is in contact with the UV cured material. Optionally, the UV cured material may be used with a third material such that the UV cured material is between two separator materials and is not in direct contact with the solution and non-solution portions of the sample.

[0009a] According to an aspect of the present invention, there is provided a method for collecting a bodily fluid sample from a subject, comprising: 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; 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 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: 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 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.

[0009b] According to an aspect of the present invention, there is provided a method of manufacturing a sample collection device 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.

[0009c] According to an aspect of the present invention, there is provided computer executable instructions 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.

[0009d] According to an aspect of the present invention, there is provided 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 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.

[0009e] According to an aspect of the present invention, there is provided 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.

[0009f] According to an aspect of the present invention, there is provided a device comprising a sample collection device.

[0009g] According to an aspect of the present invention, there is provided a device for collecting a sample from a subject.

[0009h] According to an aspect of the present invention, there is provided a device for collecting a capillary blood sample from a subject.

[0010] ~~In one non-limiting example~~According to an aspect of the present invention, a device is provided for collecting a sample from a non-venous wound on a subject.

[0011] ~~In one non-limiting example~~According to an aspect of the present invention, a method is provided for using a device for collecting a sample from a subject and outputting at least one aliquot into a first sample container.

[0012] ~~In one non-limiting example~~According to an aspect of the present invention, a method is provided for using a device for collecting a sample from a subject and outputting at least one aliquot into a first sample container and at least a second aliquot into a second sample container.

[0013] ~~In one non-limiting example~~According to an aspect of the present invention, a method is provided for using a device for collecting a sample from a subject and outputting at least one aliquot into a first sample container and at least a second aliquot into a second sample container, wherein the sample is obtained from a single point of contact with the subject.

[0014] ~~In one non-limiting example~~According to an aspect of the present invention, a method is provided for using a device for collecting a sample from a subject and outputting at least one aliquot into a first sample container and at least a second aliquot into a second sample container, wherein the sample is obtained from a single collection event.

[0014a] According to an aspect of the present invention, there is provided a system comprising a processor programmed to determine at least a desired sample dilution for a sample and at least a desired number of aliquot(s).

[0015] 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

[0016] 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