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 may be overcome by one or more embodiments of the devices, systems, or methods described herein.

[0004] In 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; and a separation material along the first pathway configured to remove said formed component from the sample prior to outputting at the first outlet.

[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

second pathway fluidically couples the sample inlet with the second outlet. ~~Optionally, a separation material along the first pathway configured to remove said formed component from the sample prior to outputting at the first outlet.~~ Optionally, the separation material and a distributor are configured to have an interface that provides a multi-mode sample propagation pattern wherein at least a first portion is propagating laterally within the separator and a second portion is propagating through the channels of the distributor over the separator. Optionally, there is at least 50 mm^2 surface area of separator per 30 uL of sample to filter. Optionally, there is at least 60 mm^2 surface area of separator per 30 uL of sample to filter. Optionally, there is at least 70 mm^2 surface area of separator per 30 uL of sample to filter. Optionally, the inlet directs the sample to primarily contact a planar portion of separator surface, and not a lateral edge of the separator. Optionally, the amount of time for sample to fill the first pathway and reach the first outlet is substantially equal to the time for sample to fill the second pathway and reach the second outlet. Optionally, the first pathway comprises a portion configured in a distributed pattern of channels over the filtration material to preferentially direct the sample over the surface of the separation material in a pre-determined configuration. Optionally, at least a portion of the separation material is coupled to a vent which contacts the membrane in a manner that the vent is only accessible fluidically by passing through the separation material. Optionally, containers have interiors under vacuum pressure that draw sample therein. Optionally, the separation material is held in the device under compression. Optionally, the separation material comprises an asymmetric porous membrane. Optionally, the separation material is a mesh. Optionally, the separation material comprises polyethylene (coated by ethylene vinyl alcohol copolymer). Optionally, at least a portion of the separation material comprises a polyethersulfone. Optionally, at least a portion of the separation material comprises an asymmetric polyethersulfone. Optionally, at least a portion of the separation material comprises polyarylethersulfone. Optionally, at least a portion of the separation material comprises an asymmetric polyarylethersulfone. Optionally, at least a portion of the separation material comprises a polysulfone. Optionally, the separation material comprises an asymmetric polysulfone. Optionally, the separation material comprises a cellulose or cellulose derivative material. . Optionally, the separation material comprises polypropylene (PP). Optionally, the separation material comprises polymethylmethacrylate (PMMA). In one non-limiting example, the separation material comprises a polymer membrane wherein filtrate exit surface of the membrane comprises a relatively open pore structure and the opposite surface comprises a more open pore structure and wherein the supporting structure comprises asymmetry through at least 50% of the supporting structure but no more than 95% of the supporting structure, the membrane

WHAT IS CLAIMED IS:

1. A device 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; and

a separation material along the first pathway configured to remove said formed component from the sample prior to outputting at the first outlet.

2. The device of any one of the foregoing claims wherein a first pathway fluidically couples the sample inlet with the first outlet.

3. The device of any one of the foregoing claims wherein a second pathway fluidically couples the sample inlet with the second outlet.

~~4. The device of any one of the foregoing claims further comprising a separation material along the first pathway configured to remove said formed component from the sample prior to outputting at the first outlet.~~

~~5~~4. The device of any one of the foregoing claims wherein the separation material and a distributor are configured to have an interface that provides a multi-mode sample propagation pattern wherein at least a first portion is propagating laterally within the separator and a second portion is propagating through the channels of the distributor over the separator.

~~6.~~5 The device of any one of the foregoing claims wherein there is at least 50 mm^2 surface area of separator per 30 uL of sample to filter.

76. The device of any one of the foregoing claims wherein there is at least 60 mm^2 surface area of separator per 30 uL of sample to filter.

87. The device of any one of the foregoing claims wherein there is at least 70 mm^2 surface area of separator per 30 uL of sample to filter.

98. The device of any one of the foregoing claims wherein the inlet directs the sample to primarily contact a planar portion of separator surface, and not a lateral edge of the separator.

109. The device of any one of the foregoing claims wherein the amount of time for sample to fill the first pathway and reach the first outlet is substantially equal to the time for sample to fill the second pathway and reach the second outlet.

1110. The device of any one of the foregoing claims wherein the first pathway comprises a portion configured in a distributed pattern of channels over the ~~filtration~~ separation material to preferentially direct the sample over the surface of the separation material in a pre-determined configuration.

1211. The device of any one of the foregoing claims wherein at least a portion of the separation material is coupled to a vent which contacts the membrane in a manner that the vent is only accessible fluidically by passing through the separation material.

1312. The device of any one of the foregoing claims further comprising containers with interiors under vacuum pressure that draw sample therein.

1413. The device of any one of the foregoing claims wherein the separation material is held in the device under compression.

1514. The device of any one of the foregoing claims wherein the separation material comprises an asymmetric porous membrane.

1615. The device of any one of the foregoing claims wherein separation material is a mesh.

1716. The device of any one of the foregoing claims wherein at least a portion of the separation material comprises a polyethersulfone.

1817. The device of any one of the foregoing claims wherein at least a portion of the separation material comprises an asymmetric polyethersulfone.

1918. The device of any one of the foregoing claims wherein at least a portion of the separation material comprises polyarylethersulfone.

2019. The device of any one of the foregoing claims wherein at least a portion of the separation material comprises an asymmetric polyarylethersulfone.

2120. The device of any one of the foregoing claims wherein at least a portion of the separation material comprises a polysulfone.

2221. The device of any one of the foregoing claims wherein the separation material comprises an asymmetric polysulfone.

2322. The device of any one of the foregoing claims wherein the separation material comprises a polysulfone membrane.

2423. A device for collecting and separating 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, 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;

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.

2524. 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, 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;

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;

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.

~~26~~25. A device for collecting a bodily fluid sample, the device 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;

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;

wherein containers are arranged such that mixing of the fluid sample between the containers does not occur.

~~27~~26. A device for collecting a bodily fluid sample, the device 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;

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.

~~28~~27. A sample collection device, 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;

a separator along the collection channel, the separator configured to remove formed components from the sample prior to and when outputting to the sample container.

~~29~~28. A sample collection device, 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;

a separator along the sample collection channel, the separator configured to remove formed components from the sample prior to and when outputting to the sample container.

~~30~~29. A sample collection device, 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;

a separator along the sample collection channel, the separator configured to remove formed component from the sample prior to and when outputting to the sample container.

~~31~~30. A sample collection device, 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;

a separator along the sample collection channel, the separator configured to remove formed component from the sample prior to and when outputting to the sample container.

~~3231~~. A device for collecting a fluid sample from a subject, 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;

a separator along the sample collection channel, the separator configured to remove formed component from the sample prior to and when outputting to the sample container.

~~33~~32. A method 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.

~~34~~33. A method 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; and

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.

~~35. A device for collecting a sample from a subject and outputting a filtrate from the sample.~~

~~36. A device for collecting a sample from a subject and forming a filtrate from at least a portion of the sample.~~

~~37. A method of using a device for collecting a sample from a subject and outputting a filtrate from the sample.~~

~~38. A method of processing a formed component separation membrane.~~

~~39. A method of processing a formed component separation material.~~