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| United States Patent | 12383174 |
| Kind Code | B2 |
| Date of Patent | August 12, 2025 |
| Inventor(s) | Rogers; Bobby E. et al. |


# Non-venting bodily fluid sample optimization device and system


## Abstract

A fluid sample optimization device for optimizing a fluid sample includes an inlet, an outlet, a sample path connected between the inlet and the outlet, and a contaminant containment reservoir connected between the inlet and the outlet. The contaminant containment reservoir includes an air permeable fluid resistor proximate the outlet, and is arranged to receive, when a pressure differential is applied between the inlet and the outlet, a first portion of the fluid sample to displace air therein through the air permeable fluid resistor and the outlet, such that upon receipt of the first portion of the fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the fluid sample can be conveyed by the sample path from the inlet to the outlet when subsequent pressure differentials are applied between the inlet and the outlet.



**Inventors:** **Rogers; Bobby E. (San Diego, CA), Nason; Kevin (Chandler, AZ), Stroup; David Karl (San Diego, CA), Matsuura; David G. (Solana Beach, CA), Matsuura; Belinko K. (Encinitas, CA)**

**Applicant:** **Kurin, Inc.** (San Diego, CA)



**Family ID:** **1000008750327**

**Assignee:** **Kurin, Inc. (San Diego, CA)**

**Appl. No.:** **16/838017**

**Filed:** **April 01, 2020**

## Prior Publication Data

| Document Identifier | Publication Date |
|---|---|
| US 20200305780 A1 | Oct. 01, 2020 |

## Related U.S. Application Data

us-provisional-application US 62827783 20190401

## Publication Classification

**Int. Cl.:** **A61B5/15** (20060101)

**U.S. Cl.:**

CPC **A61B5/150213** (20130101); **A61B5/150099** (20130101); **A61B5/150351** (20130101); **A61B5/150992** (20130101);

## Field of Classification Search

**USPC:** None

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*Primary Examiner:* Cheng; Jacqueline

*Assistant Examiner:* Portillo; Jairo H

## Background/Summary

CROSS-REFERENCE TO RELATED APPLICATIONS (1) This application claims the benefit of U.S. Provisional Application No. 62/827,783, filed Apr. 1, 2019. This application is incorporated herein by reference in its entirety.

BACKGROUND
(1) Bacteraemia is the presence of microorganisms in the blood. Sepsis, on the other hand, is bacteraemia in the presence of clinical symptoms and signs such as fever, tachycardia, tachypnea and hypotension. Bacteraemia and sepsis are associated with a high mortality and an increased incidence and duration of hospital stay and associated costs. Many bacteraemias, sepsis, fungaemias and other pathogens actually occur within a hospital or other healthcare settings with catheters and venipunctures being a source of contamination as potential carriers of these pathogens.
(2) Blood cultures are the standard test used to detect microbial pathogens related to bacteraemia and sepsis in a patient's blood. The term blood culture refers to a single venipuncture, either from a peripheral site or central or arterial line, with the blood inoculated into one or more blood culture bottles or containers. One bottle is considered a blood culture where two or more are considered a set. Multiple sets may be obtained from multiple venipunctures and are associated with different sites on the patient.
(3) These methods allow for microbial identification and susceptibility testing to be performed, which is a critical component to managing sepsis, however the lack of rapid results and decreased sensitivity for fastidious pathogens has led to the development of improved systems and adjunctive molecular or proteomic testing.
(4) Collection of blood samples for conducting blood cultures is a critical component of modern patient care and can either positively affect the patient outcome by providing an accurate diagnosis, or can adversely affect the outcome by providing a false positive result of an infection, prolonging unnecessary antimicrobial therapy, the length of hospital stays, and increasing costs.
(5) One outcome of collection of blood cultures is contamination. Blood culture contamination can lead to a false positive culture result and/or significant increase in healthcare related costs. Sources of blood culture contamination include improper skin antisepsis, improper collection tube disinfection, and contamination of an initial amount of blood of a blood draw, which may then skew results.
(6) Blood culture collection kits generally consist of a “butterfly” set, infusion set, or other type of venipuncture device as offered by companies like BD, Smiths, B. Braun and others, and aerobic and anaerobic blood culture bottles. Various different bottles are also available depending on the test requirements. These bottles are specifically designed to optimize recovery of both aerobic and anaerobic organisms. In conventional kits, a bottle used is known generally as a “Vacutainer,” which is a blood collection tube formed of a sterile glass or plastic tube with a closure that is evacuated to create a vacuum inside the tube to facilitate the draw of a predetermined volume of liquid such as blood.
(7) False positive blood cultures are typically a result of poor sampling techniques. They cause the use of antibiotics when not needed, increasing hospital costs and patient anxiety. Blood cultures are drawn from a needlestick into the skin, and then a Vacutainer is attached to capture a sample of blood. Contamination may occur from improper or incomplete disinfection of the skin area in and around the puncture site. It may also occur from the coring of the skin by the needle during insertion, with the cored skin cells and any associated contamination being pulled into the sample.

(8) Blood flow through a hypodermic needle is laminar, and as such, a velocity gradient can be developed across the flow tube as a pressure drop is applied to the hypodermic needle. Either forceful aspiration of blood, or using a very small hypodermic needle, can cause lysis and a release of potassium from the red blood cells, thereby potentially rendering the blood samples abnormal.
(9) Various strategies have been implemented to decrease blood culture contamination rates, e.g. training staff with regard to aseptic collection technique, feedback with regard to contamination rates and implementation of blood culture collection kits. Although skin antisepsis can reduce the burden of contamination, 20% or more of skin organisms are located deep within the dermis and are unaffected by antisepsis. Changing needles before bottle inoculation is not advisable as it increases the risk to acquire needle stick injuries without decreasing contamination rates.
(10) Some conventional systems and techniques for reducing blood culture contamination include discarding the initial aliquot of blood taken from central venous catheters, venipunctures, and other vascular access systems. However, these systems require the user to mechanically manipulate an intravascular device or require a complex series of steps that are difficult and reduce the chances they are consistently followed.

SUMMARY

(11) This document describes a non-venting bodily fluid sample optimization device and system, for use in a blood sampling or blood culture collection system. In accordance with implementations described herein, a device has no moving parts, valves, state-transitioning switches or diverters, or other mechanisms that move, shift or transition from one operating mode to another operating mode, or from one state to another state.
(12) In some implementations, a fluid sample optimization device includes an inlet port, an outlet port, and a contaminant containment reservoir having a proximal end coupled with the inlet port and a distal end coupled with the outlet port. The fluid sample optimization device further includes an air permeable fluid resistor positioned and secured within the contaminant containment reservoir, the air permeable fluid resistor having a front surface toward the proximal end of the contaminant containment reservoir and a rear surface toward the distal end of the contaminant containment reservoir. The fluid sample optimization device further includes a sample path having a proximal end connected with the inlet port near the proximal end of the contaminant containment reservoir, and a distal end coupled with the outlet port.
(13) A drawing or pulling force applied to the outlet port, such as a vacuum pressure or the pulling of a plunger of a syringe, draws a first amount fluid such as venous blood into the inlet port and first into the contaminant containment reservoir, where air therein is pulled through the air permeable fluid resistor. Eventually, the fluid fills the contaminant containment reservoir and eventually encounters the air permeable fluid resistor, where it is at least partially trapped for at least a known period of time. Before the fluid can traverse and exit the air permeable fluid resistor, the force (such as a vacuum) draws a second amount of fluid into a parallel or co-existent sample path fluidically connected between the inlet port and the outlet port, to cause the second amount of fluid to bypass the contaminant containment reservoir and the fluid at least temporarily resistively maintained therein. Subsequent amounts of fluid to the second amount of fluid can also bypass the first amount of fluid and the contaminant containment reservoir, to be drawn into the inlet port through the sample path, and out the outlet port.
(14) In some aspects, a fluid sample optimization device includes an inlet configured to connect with the fluid source, an outlet configured to connect with the fluid collection device, and a sample path connected between the inlet and the outlet. The fluid sample optimization device further includes a contaminant containment reservoir connected between the inlet and the outlet. One or more of the inlet, outlet, contaminant containment reservoir and sample path, and possibly other components of the fluid sample optimization device can be housed in and/or defined by a housing.
(15) The contaminant containment reservoir further includes an air permeable fluid resistor connected with the sample path, preferably proximate the outlet. The contaminant containment

reservoir is arranged to receive, when a pressure differential is applied between the inlet and the outlet, a first portion of the fluid sample from the fluid source to displace air therein through the air permeable fluid resistor and the outlet. The air permeable fluid resistor can be self-sealing upon contact with non-air fluid such as blood or other bodily fluids.
(16) Upon receipt of the first portion of the fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the fluid sample can be received and conveyed by the sample path from the inlet to the outlet when subsequent pressure differentials are applied between the inlet and the outlet. In some implementations, the fluid sample optimization device includes a resistive plug that initially substantially plugs the sample path from the inlet while, and until, the first portion of the fluid is received in the contaminant containment reservoir.
(17) In other aspects, a fluid sample optimization device for optimizing a fluid sample collected by a fluid collection device from a fluid source, where a first portion of the fluid sample potentially having contaminants, includes an inlet configured to connect with the fluid source and an outlet configured to connect with the fluid collection device. The fluid sample optimization device further includes a sample path connected between the inlet and the outlet. The sample path has a resistive plug that is configured to inhibit at least a part of the first portion of the fluid sample and the contaminants from entering the sample path.
(18) The fluid sample optimization device further includes a contaminant containment reservoir connected between the inlet and the outlet. The contaminant containment reservoir has an air permeable fluid resistor proximate the outlet. The contaminant containment reservoir is arranged to receive, when a pressure differential is applied between the inlet and the outlet, the first portion of the fluid sample from the fluid source to displace air therein through the air permeable fluid resistor and the outlet, such that upon receipt of the first portion of the fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the fluid sample can be forced through the resistive plug of the sample path and conveyed by the sample path from the inlet to the outlet when subsequent pressure differentials are applied between the inlet and the outlet.
(19) The details of one or more embodiments are set forth in the accompanying drawings and the description below. Other features and advantages will be apparent from the description and drawings, and from the claims.

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## Description

BRIEF DESCRIPTION OF THE DRAWINGS
(1) These and other aspects will now be described in detail with reference to the following drawings.
(2) FIGS. **1**A and **1**B illustrate non-venting fluid contaminant sample optimization devices, in accordance with implementations described herein;
(3) FIG. **2** shows a non-venting fluid contaminant sample optimization device, in accordance with implementations described herein;
(4) FIG. **3** shows a fluid sampling system using a fluid sample optimization device, in accordance with implementations described herein;
(5) FIGS. **4**A-**4**D illustrate a process for withdrawing a first amount of bodily fluid from a patient, and bypassing it to collect a second and/or subsequent amounts of bodily fluid;
(6) FIG. **5** shows a fluid sample optimization device without a housing;
(7) FIGS. **6**A-**61** shows an implementation of a non-venting fluid sample optimization device, as well as various implementations of a resistor;
(8) FIGS. **7**A and **7**B illustrate still other implementations of a resistor having a dissolvable material;

(9) FIGS. **8**A and **8**B illustrate yet other implementations of a resistor having both a dissolvable material and a non-dissolvable material that is highly viscous;
(10) FIGS. **9**A-**9**C illustrate yet other implementations of a resistor having pierceable member;
(11) FIGS. **10**A and **10**B show a specific configuration of a non-venting fluid sample optimization device formed in a housing, using an elongated air permeable fluid resistor;
(12) FIGS. **11**A and **11**B show another specific configuration of a non-venting fluid sample optimization device formed in a housing;
(13) FIGS. **12**A-**12**C show various configurations of an air permeable fluid resistor for use in implementations described herein;
(14) FIGS. **13**A-**13**C show various configurations of a resistive plug for use in implementations described herein; and
(15) FIGS. **14**A-**14**C illustrate a resistive plug having an iris or aperture that widens to open up upon certain pressure conditions.
(16) Like reference symbols in the various drawings indicate like elements.

DETAILED DESCRIPTION

(17) This document describes a fluid sample optimization device, for use in fluid sampling or fluid collection systems, such as for blood cultures or blood testing, or the like, and for containing contaminants that are likely in a first portion of a sampled or collected fluid. The fluid sample optimization device is configured for sequential fluid flows, i.e., to receive a first amount of bodily fluid from a patient, maintain at least a portion of the bodily fluid in a contaminant containment reservoir, and receive a second amount of bodily fluid from the patient via a sample path and automatically bypass the bodily fluid that is maintained in the contaminant containment reservoir. In some implementations, the bodily fluid is blood, and the first amount of blood can contain contaminants that might be picked up and mixed in with the first amount of blood by a venipuncture or other vascular access process, as an example.
(18) As illustrated in FIG. **1**A, a fluid sample optimization device **10** includes an inlet **12** and an outlet **14**. The inlet **12** can include an inlet port, connector or interface, for connecting to an external device such as tubing or interface thereof. The inlet **12** can be connected with a patient or a patient's fluid source, such as via a venipuncture needle, in which fluid is provided at pressure P**1** and which can be the patient's own blood pressure. The outlet **14** can include an outlet port, connector or interface, for connecting to an external device such as tubing or an interface thereof. For instance, the outlet **14** can be connected with a fluid collection device, such as an evacuated tube like a Vacutainer® or a syringe, in which fluid is drawn by the fluid collection device from the fluid source by a pressure P**2** that is lower than pressure P**1**. The differential pressure between P**1** and P**2** can allow the fluid sample optimization device **10** to be closed to atmosphere and atmospheric pressure, i.e. where the fluid sample optimization device **10** need not include any vent or pathway to outside atmosphere at least when in use.
(19) The fluid sample optimization device **10** further includes a contaminant containment reservoir **16** connected with the inlet **12** and with the outlet **14**, and having an air permeable fluid resistor **17** between a distal end of the contaminant containment reservoir **16** and the outlet **14**. As further described herein, the contaminant containment reservoir **16** can be sized for holding a desired amount of fluid, and may contain an absorbent material that at least partially fills the contaminant containment reservoir **16**. Also as further described herein, the contaminant containment reservoir **16** can be configured as a tortuous path, a series of chambers of differing cross sections and volumes, and/or contain rifling or baffles extending from an inner surface therein to minimize backflow, i.e. a flow toward the inlet **12**.
(20) The air permeable blood resistor **17** allows air to pass through and be displaced by a first portion or amount of fluid in the inlet **12** and sequestration chamber **16** when a pressure differential is applied between the inlet **12** and outlet **14**, i.e. a negative pressure at the outlet **14** exceeds the pressure at the inlet **12**. Once the fluid contacts the air permeable fluid resistor **17** the flow of fluid

into the contaminant containment reservoir **16** is at least partially stopped, maintaining at least a portion of the fluid in the contaminant containment reservoir **16**.

(21) The fluid sample optimization device **10** further includes a sample path **18** also connected with the inlet **12** and the outlet **14**. The sample path includes **18** a resistor **19** provided proximate the inlet **12**. At the same time the pressure P**2** is drawing the first portion or amount of fluid into the contaminant containment reservoir **16**, the resistor **19** is configured to resist, inhibit, limit or prohibit a flow of the fluid into the sample path **18** until the first portion or amount of fluid has entered into the contaminant containment reservoir **16**. As described further herein, the resistor **19** is configured such that after the first portion or amount of fluid has entered into the contaminant containment reservoir **16**, the resistor **19** will allow a second and/or subsequent portions or amounts of fluid to flow from the inlet **12** through the sample path **18** to the outlet **14**, still under force of the pressure differential between P**2** and P**1**. Also as further described herein, the resistor **19** can be recessed in the sample path **18** away from the inlet **12**, to allow for vacuum pressure to build up, and can also include a pilot hole or small capillary, aperture, iris, or the like, to allow the dissolvable material to initiate being dissolved by fluid that continues to be drawn toward the outlet **14**.

(22) As further described herein, the resistor **19** can be formed of a composition that includes at least portion of a dissolvable material. In specific implementations, the dissolvable material is dissolvable by contact with blood. Suitable materials for the dissolvable material can include, without limitation, any number of synthetic soluble polymers such as: polyvinal alcohol (PVA); polyvinylpyrrolidone (PVP), which is also commonly called polyvidone or povidone and is a water-soluble polymer made from the monomer N-vinylpyrrolidone; polyethylene glycol (PEG); polyethylene oxide (PEO); and/or other synthetic soluble polymers. Materials for the dissolvable material can also include, without limitation, any number of natural soluble polymers such as: hydroxypropelmethyl cellulose (HPMC), cellulose, corn starch or other starches, salt, and/or rice paper.

(23) A key to the material used for the dissolvable material is that it must be inert or non-reactive to lab tests of sampled or collected fluid specimens, which are often provided with cultures to test for specific bacteria or viruses, or antibodies thereof, or other pathogens existing in the fluid sample. Stated another way, the dissolvable material should not include any substance or material that might materially affect a fluid sample test or determination. Further, such dissolvable material must be harmless to the patient in a very unlikely case of infusion by back-pressure or exposure to the patient's venous system.

(24) Consistent with FIG. **1**A, FIG. **1**B illustrates an implementation of a fluid sample optimization device **20** that includes an inlet **22** and an outlet **24**. As described above, the inlet **22** can be connected with a patient or a patient's fluid source, such as via a venipuncture needle, in which fluid is provided at pressure P**1** and which can be the patient's own blood pressure. The outlet **24** can be connected with a fluid collection device, such as an evacuated tube like a Vacutainer® or a syringe, in which fluid is drawn by the fluid collection device from the fluid source by a pressure P**2** that is lower than pressure P**1**.

(25) The fluid sample optimization device **20** further includes a contaminant containment reservoir **26** connected with the inlet **22** and with the outlet **24**, and having an air permeable fluid resistor **27** between a distal end of the contaminant containment reservoir **26** and the outlet **24**. The fluid sample optimization device **20** further includes a sample path **28** also connected with the inlet **22** and the outlet **24**. The sample path includes **28** a resistor **29** provided proximate the inlet **22**.

(26) In some implementations, as illustrated in FIG. **1**B, the fluid sample optimization device **20** can include an acceleration portion **30** to reduce fluid pressure of a fluid moving through it, and thereby increase a velocity of the fluid, such as from the inlet **22** to the contaminant containment reservoir **26**. This can further help in preferentially directing the first portion or amount of fluid from the inlet **22** to the contaminant containment reservoir **26**, before subsequent portions or

amounts of fluid penetrate and traverse the resistor **29**, to be output through the outlet **24** for collection. The acceleration portion can include a smaller cross sectional area, or constriction region, choke point or the like, such as in a Venturi path. The acceleration portion **30** can be followed by a larger cross-sectional area of the contaminant containment reservoir **26**, which again, can be configured to hold a predetermined volume of fluid. In some implementations, the acceleration portion **30** can be positioned proximate to the connection point from the inlet **22** to the sample path **28**, whereby once the contaminant containment reservoir **26** is filled, subsequent portions or amounts of blood will build up a pressure within the acceleration portion **30** in order to overcome resistor **29** to allow the subsequent portions or amounts to flow through the sample path **28** to the outlet **24**.

(27) FIG. **2** shows a fluid sample optimization device **100** that includes an inlet port **102** and an outlet port **104**. The inlet port **102** can be fluidically coupled with a bodily fluid sample access device such as a patient needle, tubing, access port, catheter port or the like. The outlet port **104** can be fluidically coupled with a fluid collection device, such as a Vacutainer® set, which can include a sealed sampling needle on which a vacuum-sealed collection tube can be placed to break the seal and provide vacuum-based motive force through the fluid sample optimization device **100** from the inlet port **102** to the outlet port **104**. The outlet port **104** can also be connected with any other collection device, such as a syringe, which may or may not use a plunger to create a pressure differential to "pull" fluid from a patient through the fluid sample optimization device **100**.

(28) The fluid sample optimization device **100** further includes a contaminant containment reservoir **106** having a proximal end **107** coupled with the inlet port **102** and a distal end **109** coupled, at least fluidically such as with air, with, or toward the outlet port **104**. The contaminant containment reservoir **106** can have any shape and/or cross-sectional dimensions. Further, the transition from the inlet port **102** to the contaminant containment reservoir **106** can be straight or curved. In some implementations, the contaminant containment reservoir **106** is cylindrical or otherwise has a rounded cross-section, as smooth transitions with no sharp edges or corners can avoid hemolysis if the fluid traversing or bypassing the contaminant containment reservoir **106**, is blood.

(29) The fluid sample optimization device **100** further includes an air permeable fluid resistor **108** positioned and secured within the contaminant containment reservoir **106**, and which is also referred to herein as a "plug." The air permeable fluid resistor **108** can be a complete or partial resistor to the passage of fluid therethrough, depending on time and pressure provided to the fluid. In accordance with some preferred implementations, the air permeable fluid resistor **108** has a front surface facing or toward the proximal end **107** of the contaminant containment reservoir **106**, and a rear surface facing or toward the distal end **109** of the contaminant containment reservoir **106**. The air permeable fluid resistor **108** allows passage of air from the contaminant containment reservoir **106**, when a vacuum is applied to the outlet port **104** and as pushed by a first amount of bodily fluid, such as blood, through the air permeable fluid resistor **108** and toward and out the outlet port **104** of the fluid sample optimization device **100**.

(30) As with implementations described herein, the air permeable fluid resistor **108** can have a thickness or length of between less than 0.05 mm to up to 5 cm or more, and can be of a uniform or varying density. For instance, the air permeable fluid resistor **108** can be less dense and more porous on the side facing the proximal end **107** of the contaminant containment reservoir **106**, and more dense and less porous toward the distal end **109** of the contaminant containment reservoir **106**. The diameter of the air permeable fluid resistor **108** will match the internal dimensions of contaminant containment reservoir **106** in a manner that prevents blood from passing between the outer portion of air permeable fluid resistor **108** and the inner walls of contaminant containment reservoir **106**. The air permeable fluid resistor **108** may also be in the form of multiple components constructed of diverse materials.

(31) In some implementations, the air permeable fluid resistor **108** can be impregnated with a

material that expands upon contact with a fluid such as blood. While shown in FIG. **2** as being positioned toward the distal end **109** of the contaminant containment reservoir **106**, the air permeable fluid resistor **108** can be positioned anywhere along the length of the contaminant containment reservoir, and can extend from the proximal end **107** to the distal end **109**, depending on how absorptive the material is that forms the air permeable fluid resistor **108**. Filtration media that forms the air permeable fluid resistor **108** may be surface-modified, or additives may be incorporated into the porous matrix to enhance functionality depending on specific performance requirements, such as timing and/or fluid volumes, for example.

(32) In some implementations, the air permeable fluid resistor **108** is formed of a material, or combination of materials, that are configured to allow air to pass, but which can get saturated with a portion of the first amount of bodily fluid. The air permeable fluid resistor **108** can be formed at least in part by a porous polymer or plastic, and/or a natural fiber material such as cotton, hemp, or the like. In some implementations, the air permeable fluid resistor **108** can be formed of two portions: a first portion that is permeable to air and mostly impermeable to fluid at the distal end (toward the outlet **104**); and a second portion that contains an additive that seals upon contact with blood at the proximal end (toward the contaminant containment reservoir **106**). This configuration can keep the additive from mixing with the fluid flowing through the sample path and out to a collection bottle or the like. The air permeable fluid resistor **108** can receive and trap at least a part of the first portion of fluid, to thereby trap any contaminants therein.

(33) The fluid sample optimization device **100** further includes a sample path **110** having a proximal end **111** connected with the inlet port near the proximal end **107** of the contaminant containment reservoir **106**, and a distal end **113** coupled with the outlet port **104**. The sample path **110** can be formed as a channel, tubing, track, passage, portion, cavity, housing, encasement, or the like. The air permeable fluid resistor **108** is configured to hold the part of the first portion of fluid for a time period sufficient to allow a second portion of bodily fluid to bypass the contaminant containment reservoir **106** via the sample path **110**. As shown in FIG. **2**, the sample path **110** can traverse the fluid sample optimization device **100** substantially parallel to an orientation of the contaminant containment reservoir **106**. In some implementations, a cross-sectional area of the contaminant containment reservoir **106** can be larger than a cross-sectional area of the sample path **110**, which can aid in preferentially directing a first amount of fluid from the inlet port **102** into the contaminant containment reservoir **106**.

(34) The inlet port **102**, the proximal end of the contaminant containment reservoir **106**, and the proximal end of the sample path **110** together form a junction **112**. The junction **112** can include a number of curved passageways, such as leading to the proximal end of the sample path, and which can be configured to facilitate a fluid flow first into the contaminant containment reservoir **106** and then to bypass the contaminant containment reservoir **106** and into and through the sample path **110**. Importantly, as distinct from various prior art blood diversion or blood sample optimization devices, the junction **112** relies on passive fluidic control and includes no active switches, valves or other mechanically movable device to divert or switch a fluid flow.

(35) In terms of fluid dynamics, the resistance to flow in the initial path (R**1**) must be less than the resistance to flow in the sample path (R**2**). As the contaminant containment reservoir fills resistance is increased as blood is prevented from moving through the air permeable resistor. Air flows easily through it but not blood. As R**1** increases as some point the scales tip and R**1** becomes greater than R**2**. At that point blood will flow into the sample path. R**2** can be increased with variations applied to the length, diameter and to some extent geometry. R**1** can be reduced by the same means or variations, and by managing air permeability of the plug, as described in further detail herein.

(36) In some implementations, the fluid sample optimization device **100** includes a housing **120** that forms and provides one or more of the inlet port **102**, outlet port **104**, contaminant containment reservoir **106**, and sample path **110**. For instance, the housing **120** can be formed of a top member mated with a bottom member, where one or both of the top member and bottom member are

formed with grooves, channels, pathways, areas, or other features to define and provide the one or more of the inlet port **102**, outlet port **104**, contaminant containment reservoir **106**, and sample path **110**. The housing **120** can be made of a sturdy, resilient material such as plastic (i.e. polycarbonateacrylic, PVC, ABS, etc.), a metal, or the like, and which can be sanitized before use so as to be used in a clean, sanitized state, free of microbes. The inlet port **102** and/or the outlet port **104** can further include or be outfitted with connectors, such as a Luer connector or threaded connection.

(37) FIG. **3** illustrates a fluid sampling system **200**, which includes a fluid sample optimization device **201** connected with a blood sampling pathway having a patient needle **203** and a sample collection device **205**, which in some implementations includes an adapter with a sealed sample collection needle that receives one or more vacuum sample bottles. The patient needle **203** can be a safety-type vascular access needle, such as described in U.S. patent application Ser. No. 16/045,321, entitled “Needle Assembly with Needle Safety Shield,” the contents of which are incorporated by reference herein for all purposes.

(38) The fluid sample optimization device **201** includes an inlet port **202** connected with the patient needle **203**, an outlet port **204** connected with the sample collection device **205**, a contaminant containment reservoir **206** having an air permeable fluid resistor **208**, and a sample path **210** having a proximal end fluidically coupled with the inlet port **202** and a distal end fluidically connected with the outlet port **204**. The fluid sample optimization device **201** can further include a housing **220** that houses and defines one or more of the inlet port **202**, the outlet port **204**, the contaminant containment reservoir **206**, and the sample path **210**. The housing **220** can be formed of any rigid material that is susceptible to sterilization, or possibly having antimicrobial properties, but which can also shield the inlet port **202**, outlet port **204**, contaminant containment reservoir **206** and sample path **210**, and any components therein, from external contamination.

(39) Each of the contaminant containment reservoir **206** and the sample path **210** can be connected with the inlet port **202** via a junction **212** that is sized and configured to allow a first portion of fluid, such as blood, to be drawn, pulled, or otherwise flow, into the contaminant containment reservoir **206** to displace air therein through the air permeable fluid resistor **208**, and for at least a portion to be maintained, at least temporarily, in the contaminant containment reservoir **206**, and to allow a second portion of blood to bypass the contaminant containment reservoir **206** and flow into the sample path **210** toward the outlet port **204** and the sample collection device **205**.

(40) The sample collection device **205** can be a Vacutainer® type device, with a collection adapter having a collection needle that is sealed by an elastomeric seal that can be pierced by a vacuum-sealed collection bottle to expose the collection needle and allow insertion of the collection needle into a septum of the collection bottle. The vacuum in the collection bottle can be the force that helps draw the bodily fluid from a patient, through the fluid sample optimization device **201**.

(41) FIGS. **4**A-**4**D illustrate an operation of the fluid sample optimization device **100**/**201**, and described specifically in the context of blood sampling, although other types of bodily fluids can be collected or sampled. With reference to FIG. **3**, and as illustrated in FIG. **4**A, when fluid collection device creates a low pressure at the outlet of the fluid sample optimization device, such as when a collection bottle or tube is inserted into a collection adapter, the pressure difference between the outlet and in inlet, such as by venipuncture of a patient (or more particularly, the patient's vascular blood pressure) will force the air out of the fluid sample optimization device and into the collection bottle, and blood will fill in behind it.

(42) In the implementation shown, the air can flow through two parallel paths—through the plug in the contaminant containment reservoir and through the sample path. A volume of flow through each can be proportional to a resistance within each path. Accordingly, an optimal configuration for the fluid sample optimization device includes consideration of: volume of the contaminant containment reservoir, an arrangement of the junction connecting the inlet with the contaminant containment reservoir and the sample path, relative cross sectional dimensions of the inlet,

contaminant containment reservoir, and sample path, a resistivity of the plug, a location and size of the plug, a curvature of various transitions or interfaces between the inlet, contaminant containment reservoir, and sample path, etc., and the like.

(43) FIG. **4**B shows blood filling the contaminant containment reservoir. If the air does not pass through the plug quickly enough, i.e. if the resistance through the plug is not lower than the resistance though the sample path, pressure will build up in the contaminant containment reservoir and force the fluid down the sample path prior to the contaminant containment reservoir filling with fluid. FIG. **4**C shows a filled contaminant containment reservoir. Once all the air is pushed out of the contaminant containment reservoir (through the plug and sample path), fluid will hit the plug, and its progress through the plug is slowed and will possibly stop. This can force the fluid to flow down the sample path, leaving the initial volume of blood trapped in the contaminant containment reservoir. There might not be fluid flow through the plug at this point. FIG. **6** shows the fluid flow once the air is flushed from the device, an in particular from the contaminant containment reservoir. Subsequent blood volume will flow into and through the sample path, following the path of least resistance (lower pressure gradient) toward the distal end of the sample path and toward and out the outlet port.

(44) Fluid flow can be completely stopped or allowed to flow slowly into the plug—it just cannot reach the other side and mix with the sample path during use.

(45) Making the resistance of the air flow through the plug lower than through the sample path can be achieved by: 1) Cross sectional area—if the area of the plug is much larger than the area of the sample path, the resistance will be lower; and 2) Lengthening the sample path will increase the resistance, but the effect is much lower with air flow than with fluid flow.

(46) The first amount of fluid can fill the contaminant containment reservoir first based on geometry—as shown in FIGS. **4**A-**4**D, the inertia of the fluid will urge the fluid to keep it traveling straight into the contaminant containment reservoir rather than turning the corner into the sample path. In some implementations, the contaminant containment reservoir and the sample path, or any inlets and outlets thereof, can be coated differently to provide more or less resistance to fluid flow. For instance, coating the walls of the contaminant containment reservoir with a hydrophilic coating and the walls (or at least the entrance) of the sample path with a hydrophobic coating can help fill the contaminant containment reservoir first. The hydrophilic coating can include one or more of Polyurethane (PU), Polyvinylpyrolidone (PVP), Polyacrylic acid (PAA), and/or Polyethylene oxide (PEO). The hydrophobic coating can include Polytetrafluoroethylene (PTFE). Resistance in the sampling path may also be increased by inserting a dissolvable bio-compatible material in the path that dissolves upon contact with blood or a fluid, reducing the resistance to flow through the sample path once the contaminant containment reservoir is filled with fluid.

(47) In another implementation, a benign, inert or non-reactive bio-compatible material, i.e., one that does not affect blood test results, can be placed in the device, or at least the junction to the contaminant containment reservoir, to block the sampling path. This material can be configured to dissolve when blood or fluid makes contact. Such material can be sized and configured to inhibit blood flow for a fraction of a second as the contaminant containment reservoir will fill almost instantaneously.

(48) FIG. **5** illustrates a housing-less implementation of a fluid sample optimization device **300** having a contaminant containment reservoir **302** and sample path **304** that are formed of tubing or other type of fluidic conveyance mechanism, and which form parallel or similar-directional paths via Y-site connectors **306**A and **306**B on opposite ends of the device. The Y-site connectors **306**A and **306***b* can be provided in any orientation or alignment, and can be spaced apart sufficient to provide the contaminant containment reservoir **302**, if implemented as tubing with a known cross-sectional diameter and length, with a predetermined volume. The contaminant containment reservoir **302** includes an air permeable fluid resistor **308** that is resistant to fluid flow but allows passage of air, so that, after a first amount or aliquot of fluid fills the contaminant containment

reservoir **302**, subsequent amounts of fluid bypass the contaminant containment reservoir **302** and flow through the sample path **304** for eventual collection by a fluid collection device.
(49) A system employing the fluid sample optimization device **300** can include a patient needle **301** connected with the Y-site connector **306**A, and a sample collection device **303** having a sealed sampling needle connected with the Y-site connector **306**B. The tubing of the fluid sample optimization device **300** can be flexible or rigid. At least parts of the tubing can be made of a translucent material, so that a clinician can view a flow of blood therein. The fluid sample optimization device **300** can include a filter **308**, which can be formed at least in part from air permeable blood resistor material. The filter **308** allows air in the contaminant containment reservoir **302** to be displaced therefrom through the filter **308** upon a vacuum force, or other mechanism creating a negative pressure differential between the sample collection device **303** and the
(50) In some implementations, a fluid sample optimization device **300** may function as a flash chamber, in which, upon venipuncture of a patient, blood may “flash” or be suddenly present in at least a portion of the contaminant containment reservoir **302**, based at least in part on a vacuum force at an outlet junction of the fluid sample optimization device **300**. Vacuum pressure draws the contaminated blood preferentially across the resistor (not capturing contaminated blood) into the contaminant chamber.
(51) FIG. **6**A shows a fluid sample optimization device **400** that includes an inlet **402** and an outlet **404**. The inlet **402** can include an inlet port, connector or interface, for connecting to an external device such as tubing or interface thereof. The inlet **402** can be connected with a patient or a patient's fluid source, such as via a venipuncture needle, in which fluid is provided at pressure P**1** and which can be the patient's own blood pressure. The outlet **404** can include an outlet port, connector or interface, for connecting to an external device such as tubing or an interface thereof. As discussed above, for instance, the outlet **404** can be connected with a fluid collection device, such as an evacuated tube like a Vacutainer® or a syringe, in which fluid is drawn by the fluid collection device from the fluid source by a pressure P**2** that is lower than pressure P**1**. The pressure differential can allow the fluid sample optimization device **400** to be closed to atmosphere and atmospheric pressure, i.e. where the fluid sample optimization device **400** need not include any vent or pathway to outside atmosphere at least when in use.
(52) The fluid sample optimization device **400** further includes a contaminant containment reservoir **406** connected with the inlet **402** and with the outlet **404**, and having an air permeable fluid resistor **407** between a distal end of the contaminant containment reservoir **406** and the outlet **404**. As further described herein, the contaminant containment reservoir **406** can be sized for holding a desired amount of fluid, and may contain an absorbent material that at least partially fills the contaminant containment reservoir **406**. Also as further described herein, the contaminant containment reservoir **406** can be configured as a tortuous path, a series of chambers of differing cross sections and volumes, and/or contain rifling or baffles extending from an inner surface therein to minimize backflow, i.e. a flow toward the inlet **402**. For instance, the contaminant containment reservoir **406** can include one or more channels **406**A and one or more chambers **406**B, all of which can be interconnected to receive, convey or contain a predetermined volume of fluid, as well as contain any contaminants therein.
(53) The air permeable blood resistor **407** allows a first portion or amount of fluid to be drawn from the fluid source by a pressure differential applied between the inlet **402** and the outlet **404** to enter into the inlet **402** and into the contaminant containment reservoir **406**, displacing air therein, until the fluid contacts the air permeable fluid resistor **407** where the flow fluid into the contaminant containment reservoir **406** is at least partially stopped.
(54) The fluid sample optimization device **400** further includes a sample path **408** also connected with the inlet **402** and the outlet **404**. The sample path **408** includes a resistive plug **409** provided proximate the inlet **402**. At the same time a pressure differential between the inlet **402** and the

outlet **404** can draw the first portion or amount of fluid into the contaminant containment reservoir **406**, the resistive plug **409** is configured to resist, inhibit, limit or prohibit a flow of the fluid into the sample path **408** until the first portion or amount of fluid has entered into the contaminant containment reservoir **406**.

(55) The fluid sample optimization device **400** can further include a housing **401**, which can define one or more of the inlet **402**, the outlet **404**, the contaminant containment reservoir **406**, the sample path **408**, or possibly other components such as the air permeable fluid resistor **407** and the resistive plug **409**. The housing **401** can be formed in one or more parts. For instance, as shown in the example in FIG. **6**A, the housing **401** can include a top housing portion **422** mated with a bottom housing portion **424**, and which can be mated and sealed together by sonic welding, thermal bonding, gluing, or the like.

(56) As described herein, the resistive plug **409** is configured such that after the first portion or amount of fluid has entered into the contaminant containment reservoir **406**, the resistive plug **409** will allow a second and/or subsequent portions or amounts of fluid to flow from the inlet **402** through the sample path **408** to the outlet **404**, still under force of a pressure differential between inlet **402** and the outlet **404**. The resistive plug **409** can be recessed in the sample path **408** away from the inlet **402**, to allow for vacuum pressure to build up, and can also include a pilot hole or small capillary, aperture, iris, or the like, to allow the dissolvable material to initiate being dissolved by fluid that continues to be drawn toward the outlet **404**. Accordingly, a portion of the sample path **408** the inlet **402**, and/or contaminant containment reservoir **406** can form a junction **411** proximate the resistive plug **409** and opposite a main portion of the sample path **408**, to allow vacuum pressure to build up for better fluid access through the resistive plug **409** after the contaminant containment reservoir **406** is filled.

(57) Once the fluid fills the contaminant containment reservoir **406**, a volume of air can be trapped in the junction **411** between the fluid and the resistive plug **409**. Without a way for air to escape, the fluid will not reach the dissolvable material that forms at least part of the resistive plug **409** to be able to flow down the sample path **406**. Thus, as shown in FIGS. **6**B-**61**, an air path through or around the resistive plug **409** can be provided that will only allow air to flow once it is exposed to the full vacuum pressure of the collection device, as fluid fills the contaminant containment reservoir **406** and plugs the air-permeable fluid resistor **407**, such that fluid does not come in contact with the dissolvable material in the resistive plug **409** until after the contaminant containment reservoir **406** is completely filled and/or the contaminants are contained therein.

(58) FIG. **6**B shows a variation of resistive plug **409** as a film **431**, which can be formed as a thin film of material. In some implementations, the film **431** can be formed at least in part by a dissolvable or easily-torn material. The film **431** has a small orifice **432** or pilot hole as a mechanism to start the dissolving or tearing process. FIG. **6**C shows a film **431** having a slit **433** that is closed in a static, steady state, but which can open and allow fluid flow when a pressure is applied to one or both opposite sides or surface of the resistor. In some implementations, as shown in FIG. **6**D, the slit **433** can be formed as an “X” or other configuration, such as a linear slit, curved slit, star slit or the like. As shown in FIG. **6**E, the film **431** can be formed as a porous membrane that allows air to flow through, but not bodily fluids such as blood. As shown in FIG. **6**F, the film **431** can be positioned between the top housing portion **422** and the bottom housing portion **424** at the entrance to the sample path **408**, so as to allow air to “leak” around the film **431** when a predetermined pressure is applied to it.

(59) FIGS. **6**G-**61** illustrate a resistive plug **409** as a cylindrical plug member **435**, although the resistive plug **409** can be formed in other shapes such as squared, rectangular, or other shape. The cylindrical plug member **435** can be provided with a small pilot hole, as shown in FIG. **6**G, or be porous to air, as shown in FIG. **6**H. The resistive plug **409**, whether implemented as a cylindrical plug member **435** or other shape, can be positioned between the top housing portion **422** and the bottom housing portion **424** at the entrance to the sample path **408**, so as to allow air to “leak”

around the cylindrical plug member **435** when a predetermined pressure is applied to it.
(60) As further described herein and as shown in FIG. **7**, a resistive plug **500** for an opening to the sample path can be formed of a composition that includes at least portion of a mesh **502** impregnated with a dissolvable material **504**. In some specific implementations, the resistive plug **500** can include a mesh material that supports a dissolvable material **502**. The mesh material can be, for example, a mesh of plastic or nylon, such as a mesh of 50-100 μm nylon or plastic thread. The dissolvable material **504**, which may not be formable as a rigid plug or film, can be impregnated into the mesh **502** or other porous material. The dissolvable material **504** is dissolvable by contact with fluid, such as blood. The dissolvable material **504** is formulated to be inert or non-reactive to lab tests of sampled or collected fluid specimens, which are often provided with cultures to test for specific bacteria or viruses, or antibodies thereof, or other pathogens existing in the fluid sample.
(61) As shown in FIG. **8**, a resistive plug **600** can also be formed of a mesh **602** as described above, but which is overlaid with, or integrates, a non-dissolvable viscous material **604**, such as silicone grease. The viscous material **604** can be spread on the mesh **602** or other porous material. Once the pressure differential across the resistive plug **600** is high enough, the viscous material **604** is pulled through openings in the mesh **602** to create openings for the fluid sample to flow through, as shown in FIG. **8**B. At most, only trace amounts of the viscous material **604** would ever exit the outlet, and therefore should not interfere with any testing or culturing of the fluid sample.
(62) As shown in FIGS. **9**A-**9**C, a resistive plug **700** can be formed of a membrane **702** stretched or positioned over and spaced apart from a piercing member **704** in an initial state. The piercing member **704** can include a spike, pin, blade, shard, or the like, and can be held substantially in the center of the opening to the sampling path, as shown in FIG. **9**A, by a holding mechanism as shown in FIG. **9**B. The membrane **702** can be an elastic sheet of material, such as a rubber or other elastomeric material. As shown in FIG. **9**C, once the contaminant containment reservoir fills with fluid, an amount of pressure is exerted against the membrane **702** to stretch it further to contact the piercing member **704**. Once contact is made between the membrane **702** and the piercing member **704**, the membrane **702** is punctured or otherwise broken by the piercing member **704** to open a larger area for subsequent amounts or portions of fluid to flow into the sample path.
(63) FIGS. **10**A-**11**B show various views of a fluid sample optimization device **800** and **900** for optimizing a fluid sample collected by a fluid collection device from a fluid source, and where a first portion of the fluid sample potentially has contaminants. As shown in FIGS. **10**A and **10**B, a fluid sample optimization device **800** includes an inlet **802** configured to connect with the fluid source, an outlet **804** configured to connect with the fluid collection device, and a sample path **808** connected between the inlet **802** and the outlet **804**. The fluid sample optimization device **800** further includes a contaminant containment reservoir **806** connected between the inlet **802** and the outlet **804**. One or more of the inlet **802**, outlet **804**, contaminant containment reservoir **806** and sample path **808**, and possibly other components of the fluid sample optimization device **800** can be housed in and/or defined by a housing **820**.
(64) The contaminant containment reservoir **806** further includes an air permeable fluid resistor **812** connected with the sample path **808**, preferably proximate the outlet **804**. The contaminant containment reservoir **806** is arranged to receive, when a pressure differential is applied between the inlet **802** and the outlet **804**, a first portion of the fluid sample from the fluid source to displace air therein through the air permeable fluid resistor **812** and the outlet **804**. The air permeable fluid resistor **812** can be elongated and configured for a particular air flow range, as shown in FIG. **12**A, and can be self-sealing upon contact with non-air fluid such as blood or other bodily fluids.
(65) Upon receipt of the first portion of the fluid sample and containment of the contaminants in the contaminant containment reservoir **806**, subsequent portions of the fluid sample can be received and conveyed by the sample path **808** from the inlet **802** to the outlet **804** when subsequent pressure differentials are applied between the inlet **802** and the outlet **804**. In some

implementations, the fluid sample optimization device **800** includes a resistive plug **810** that initially substantially plugs the sample path **808** from the inlet **802** while, and until, the first portion of the fluid is received in the contaminant containment reservoir **806**.
(66) As shown in FIGS. **11**A and **11**B, a fluid sample optimization device **900** includes an inlet **902** configured to connect with the fluid source, an outlet **904** configured to connect with the fluid collection device, and a sample path **908** connected between the inlet **902** and the outlet **904**. The fluid sample optimization device **900** further includes a contaminant containment reservoir **906** connected between the inlet **902** and the outlet **904**. One or more of the inlet **902**, outlet **904**, contaminant containment reservoir **906** and sample path **908**, and possibly other components of the fluid sample optimization device **900** can be housed in and/or defined by a housing **920**.
(67) The contaminant containment reservoir **906** further includes an air permeable fluid resistor **912** connected with the sample path **908**, preferably proximate the outlet **904**. The contaminant containment reservoir **906** is arranged to receive, when a pressure differential is applied between the inlet **902** and the outlet **904**, a first portion of the fluid sample from the fluid source to displace air therein through the air permeable fluid resistor **912** and the outlet **904**. The air permeable fluid resistor **912** can be cylindrical and configured for a particular air flow range, and can be multi-layered to include a self-sealing layer that seals upon contact with non-air fluid such as blood or other bodily fluids, as shown in FIGS. **12**B and **12**C, respectively.
(68) Upon receipt of the first portion of the fluid sample and containment of the contaminants in the contaminant containment reservoir **906**, subsequent portions of the fluid sample can be received and conveyed by the sample path **908** from the inlet **902** to the outlet **904** when subsequent pressure differentials are applied between the inlet **902** and the outlet **904**. In some implementations, the fluid sample optimization device **900** includes a resistive plug **910** that initially substantially plugs the sample path **908** from the inlet **902** while, and until, the first portion of the fluid is received in the contaminant containment reservoir **906**.
(69) FIGS. **13**A-**13**C show various implementations and configurations of a resistive plug, such as a cylindrical plug (FIG. **13**A), a film or membrane (FIG. **13**B), or a flexible cap (FIG. **13**C).
(70) FIGS. **14**A-**14**C illustrate a resistive plug with an aperture **1000** or iris that is selectively actuated/disrupted manually or automatically to allow or prevent flow through at different times and based on different pressures exerted on the resistive plug \. In some implementations, the resistive plug is an elastomeric membrane, with a small aperture **1000** substantially in the center. When a differential pressure is applied to one side of the membrane that forms the resistive plug, it will deflect and increase the size of the aperture **1000**, allowing fluid to flow through to the output. Alternatively, the resistive plug can include a rigid or semi-rigid plug member **1002** that would cover the aperture **1000** and then fall out of the way once the aperture **1000** is activated.
(71) Although a few embodiments have been described in detail above, other modifications are possible. Other embodiments may be within the scope of the following claims.

## Claims

1. A device for optimizing a fluid sample collected by a fluid collection device from a fluid source, the device comprising: an inlet configured to connect with the fluid source; an outlet configured to connect with the fluid collection device; a sample path connected between the inlet and the outlet, the sample path further having a resistive plug; and a chamber connected between the inlet and the outlet, the chamber having an air permeable fluid resistor proximate the outlet, the chamber being arranged to receive, when a pressure differential is applied between the inlet and the outlet, a first portion of the fluid sample from the fluid source to displace air therein through the air permeable fluid resistor and the outlet, such that upon receipt of the first portion of the fluid sample in the chamber, subsequent portions of the fluid sample can be conveyed by the sample path from the inlet to the outlet, the resistive plug including a membrane that is pierceable; and a piercing

member configured to pierce the membrane, wherein the resistive plug and the piercing member are spaced apart from the chamber, wherein the device is configured such that, once the chamber fills with the first portion of the fluid sample, pressure is exerted against the membrane causing the membrane to stretch and contact the piercing member.

2. The device in accordance with claim 1, further comprising a housing that houses and/or defines one or more of the inlet, the outlet, the sample path, and the chamber.

3. The device in accordance with claim 1, wherein the air permeable fluid resistor includes a material that seals upon contact with the first portion of the fluid sample.

4. The device in accordance with claim 1, wherein the chamber includes a tortuous path.

5. A device for optimizing a fluid sample collected by a fluid collection device from a fluid source, the device comprising: an inlet configured to connect with the fluid source; an outlet configured to connect with the fluid collection device; a sample path connected between the inlet and the outlet, the sample path further having a resistive plug that is configured to inhibit at least a part of a first portion of the fluid sample from entering the sample path; and a chamber connected between the inlet and the outlet, the chamber further having an air permeable fluid resistor proximate the outlet, the chamber being arranged to receive, when a pressure differential is applied between the inlet and the outlet, the first portion of the fluid sample from the fluid source to displace air therein through the air permeable fluid resistor and the outlet, such that upon receipt of the first portion of the fluid sample in the chamber, subsequent portions of the fluid sample can be forced through the resistive plug and conveyed by the sample path from the inlet to the outlet, the resistive plug including a membrane that is pierceable; and a piercing member configured to pierce the membrane, wherein the resistive plug and the piercing member are spaced apart from the chamber, wherein the device is configured such that, once the chamber fills with the first portion of the fluid sample, pressure is exerted against the membrane causing the membrane to stretch and contact the piercing member.

6. The device in accordance with claim 5, further comprising a housing that houses and/or defines one or more of the inlet, the outlet, the sample path, and the chamber.

7. The device in accordance with claim 5, wherein the air permeable fluid resistor includes a material that seals upon contact with the first portion of the fluid sample.

8. The device in accordance with claim 5, wherein the chamber includes a tortuous path.

9. A device for optimizing a fluid sample, the device comprising: an inlet; an outlet; a sample path connected between the inlet and the outlet; and a chamber connected between the inlet and the outlet, the chamber having an air permeable fluid resistor proximate the outlet, the chamber being arranged to receive, when a pressure differential is applied between the inlet and the outlet, a first portion of the fluid sample to displace air therein through the air permeable fluid resistor and the outlet, such that upon receipt of the first portion of the fluid sample in the chamber, subsequent portions of the fluid sample can be conveyed by the sample path from the inlet to the outlet, wherein the sample path further includes a resistive plug that is configured to inhibit at least a part of the first portion of the fluid sample from entering the sample path during receipt of the first portion of the fluid sample in the chamber, the resistive plug including a membrane that is pierceable; and a piercing member configured to pierce the membrane, wherein the resistive plug and the piercing member are spaced apart from the chamber, wherein the device is configured such that, once the chamber fills with the first portion of the fluid sample, pressure is exerted against the membrane causing the membrane to stretch and contact the piercing member.

10. The device in accordance with claim 9, further comprising a housing that houses and/or defines one or more of the inlet, the outlet, the sample path, and the chamber.

11. The device in accordance with claim 9, wherein the air permeable fluid resistor includes a material that seals upon contact with the first portion of the fluid sample.

12. The device in accordance with claim 9, wherein the chamber includes a tortuous path.