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United States Patent Application Publication

20250264453

Kind Code

A1

Publication Date

August 21, 2025

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DEVICE WITH A FLUID COMPONENT ASSESSMENT FEATURE

Abstract

A device including a housing, a zone and a means for testing a fluid sample within the housing is disclosed. The housing is constructed of a fluid impermeable material, and defines a first fluid port, and a second fluid port. The first fluid port is configured to connect to a fluid collection device to receive a fluid sample from the fluid collection device into the housing. The second port is configured to pass the fluid sample from the housing into a testing instrument. The zone is formed in the housing. The zone is constructed of a material that allows an analysis of the fluid sample positioned within the housing, and located adjacent to the zone.

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Appl. No.: 19/204098

Filed: May 09, 2025

Related U.S. Application Data

parent US continuation 17299821 20210604 parent-grant-document US 12326442 US continuation PCT/US2019/064627 20191205 child US 19204098
us-provisional-application US 62776825 20181207

Publication Classification

Int. Cl.: G01N33/49 (20060101); B01L3/00 (20060101); G01N21/25 (20060101); G01N21/77 (20060101)

CPC **G01N33/491** (20130101); **B01L3/508** (20130101); **G01N21/251** (20130101);
G01N21/77 (20130101); **G01N33/4915** (20130101); **G01N33/4925** (20130101);
B01L2200/0689 (20130101); B01L2200/16 (20130101); B01L2300/0663 (20130101);
B01L2300/0681 (20130101); B01L2400/0478 (20130101); G01N2021/7763 (20130101);
G01N2201/0221 (20130101)

Background/Summary

REFERENCE TO RELATED APPLICATIONS [0001] This application is a continuation of U.S. Ser. No. 17/299,821, filed Jun. 4, 2021; which is a U.S. National Stage application filed under 35 USC § 371 of International Application No. PCT/US 2019/064627, filed Dec. 5, 2019; which claims benefit under 35 USC § 119 (e) of U.S. Provisional Application No. 62/776,825, filed Dec. 7, 2018. The entire contents of each of the above-referenced patent applications are hereby expressly incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] Point-of-care testing refers generally to medical testing at or near the site of patient care, such as in an emergency room. A desired outcome of such tests is often rapid and accurate lab results to determine a next course of action in the patient care. A number of such point of care tests involve analysis of a blood sample from the patient. Prior to testing the sample, it may be necessary or beneficial to treat the sample by for instance separating a whole blood sample into components, adding a reagent, or removing a component. In some cases, pure plasma is separated from the source whole blood sample. However, even in such plasma samples, there are often residual broken blood cells as a result of hemolysis due to imperfections in obtaining the sample from the subject, pre-analytical blood sample handling, and the whole blood separation process. Hemolyzed cells can interfere with the integrity of analytical test results, whether in whole blood or plasma.

[0003] For example, if hemolysis occurs, resulting free hemoglobin in the sample may cause interference in a number of tests, thereby leading to a signal reduction, reduced measurement accuracy and precision, or to false positive results at the other end of the spectrum. For one, it has been found that the potassium concentration in a corresponding sample with lysis of red blood cells may increase significantly and cause a high risk of misdiagnosis in a diagnostic test for potassium levels.

[0004] To determine whether hemolysis has occurred, a number of tests have been developed to determine hemoglobin (Hb) levels in a blood sample. One common reagent used for determining Hb levels or hemolysis in a blood sample is referred to as Drabkin's Reagent. Drabkin's Reagent comprises a mixture that works by lysing red blood cells and quantitatively converting all Hb in a sample into one form, cyanomethaemoglobin, which is then be measured on a spectrometer using a single wavelength. As such, Drabkin's Reagent measures intracellular hemoglobin as well as free hemoglobin. For at least this reason, Drabkin's Reagent does not provide a realistic picture of the extent of free Hb present at a particular point in time in a sample, which is indicative of hemolysis. The most common way to determine hemolysis is to use a centrifuge to spin down a blood sample, therein producing a method of qualitative assessment for the resulting plasma layer. This is generally sufficient in the laboratory setting.

[0005] Sampler caps exist that are used in a point of care environment for de-aerating blood samples while sealing a sampler to prevent inadvertent leakage of the blood sample. See for example U.S. Pat. No. 7,896,818. Such sampler caps have an inlet for connecting to a syringe, and an outlet that allows an analyzer probe to be extended through the sampler cap for obtaining a

blood sample from the sampler. These sampler caps, however, do not have any mechanism for testing the blood sample prior to the introduction of the blood sample into the analyzer. [0006] A need exists, therefore, for rapid testing of a fluid sample while also making the fluid sample seamlessly available for further testing within a testing instrument, such as an analyzer. It is to such an improved device and method that facilitates rapid and accurate multi-testing of the fluid sample that the present disclosure is directed.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate one or more implementations described herein and, together with the description, explain these implementations. In the drawings:

[0008] FIG. 1 illustrates an exploded view of a fluid testing device removably attachable to a fluid housing such as a syringe constructed in accordance with one embodiment of the present disclosure.

[0009] FIG. 2 illustrates a perspective view of the fluid testing device of FIG. 1, and constructed in accordance with one embodiment of the present disclosure.

[0010] FIG. 2A is a perspective view of another embodiment of a fluid testing device connected to a fluid collection device such as a vacutainer in accordance with embodiments of the present disclosure.

[0011] FIG. 3 illustrates a top plan view of the fluid testing device of FIG. 1, and constructed in accordance with one embodiment of the present disclosure.

[0012] FIG. 4 illustrates an exploded view of a fluid testing device removably attachable to a fluid housing, such as a syringe, and constructed in accordance with one embodiment of the present disclosure.

[0013] FIG. 4A is a diagrammatic view of a lateral flow membrane being a multi-layer structure in accordance with embodiments of the present disclosure.

[0014] FIG. 5 illustrates a perspective view of another embodiment of a fluid testing device constructed in accordance with the present disclosure.

[0015] FIG. 6 illustrates a perspective view of a fluid testing device having a moveable gate constructed in accordance with one embodiment of the present disclosure.

[0016] FIG. 7 illustrates the fluid testing device of FIG. 6 having the moveable gate in a first position.

[0017] FIG. 8 illustrates the fluid testing device of FIG. 6 having the moveable gate in a second position.

[0018] FIGS. 9A and 9B illustrate a fluid housing of FIG. 6 being inserted into an analysis unit for fluid analysis in accordance with embodiments of the present disclosure.

[0019] FIG. 10 illustrates an exploded view of a fluid testing device removably attachable to a fluid housing, such as a syringe, and constructed in accordance with one embodiment of the present disclosure.

[0020] FIG. 11 illustrates a perspective view of another embodiment of a fluid testing device constructed in accordance with the present disclosure.

[0021] FIG. 12 is a cross sectional view of a portion of a blood testing device constructed in accordance with one embodiment of the present disclosure.

[0022] FIG. 13 is a cross sectional view of a portion of the blood testing device of FIG. 12 showing a sample of actively separated blood in accordance with one embodiment of the present disclosure.

[0023] FIG. 14 is an orthogonal view of a fluid collection device having an integrated blood testing device constructed in accordance with the present disclosure.

[0024] FIGS. **15A-15C** illustrate views of portions of another fluid collection device constructed in accordance with the present disclosure.

[0025] FIGS. **16A** and **16B** illustrate a fluid housing of FIG. **15A** being inserted into an analysis unit for active separation in accordance with one embodiment of the present disclosure.

[0026] FIG. **17** illustrates a perspective view of a blood testing device having a closeable gate constructed in accordance with one embodiment of the present disclosure.

[0027] FIG. **18** illustrates the blood testing device of FIG. **11** having the closeable gate in a first position.

[0028] FIG. **19** illustrates the blood testing device of FIG. **11** having the closeable gate in a second position.

[0029] FIG. **20** illustrates a perspective view of a blood testing device having a moveable gate constructed in accordance with one embodiment of the present disclosure.

[0030] FIG. **21** illustrates the blood testing device of FIG. **14** having the moveable gate in a first position.

[0031] FIG. **22** illustrates the blood testing device of FIG. **14** having the moveable gate in a second position.

[0032] FIG. **23** illustrates a side, perspective cut away view of a fluid testing device having an air vent constructed in accordance with one embodiment of the present disclosure.

[0033] FIG. **24** illustrates a partial cut away top view of the fluid testing device of FIG. **23**.

[0034] FIG. **25** is a cross-sectional view of the fluid testing device of FIG. **24**, taken along the lines **25-25**.

[0035] FIG. **26** illustrates an exploded view of a fluid testing device having an air vent constructed in accordance with one embodiment of the present disclosure.

[0036] FIG. **27** illustrates an orthogonal cut away view of the fluid testing device of FIG. **26**.

[0037] FIG. **28** illustrates a perspective cut away view of the fluid testing device of FIG. **27** taken along the lines **28-28** depicted in FIG. **27**.

[0038] FIG. **29** illustrates an exploded view of a fluid testing device having an air vent constructed in accordance with one embodiment of the present disclosure.

[0039] FIG. **30** illustrates a perspective view of the fluid testing device of FIG. **29**.

[0040] FIG. **31** illustrates an orthogonal cut away view of the fluid testing device of FIG. **29**.

[0041] FIG. **32** illustrates a perspective cut away view of the fluid testing device of FIG. **29**.

[0042] FIG. **33** illustrates an orthogonal cut away view of a fluid testing device having a pierceable membrane constructed in accordance with one embodiment of the present disclosure.

DETAILED DESCRIPTION

[0043] The following detailed description refers to the accompanying drawings. The same reference numbers in different drawings may identify the same or similar elements.

[0044] As used herein, the terms “comprises,” “comprising,” “includes,” “including,” “has,” “having” or any other variation thereof, are intended to cover a non-exclusive inclusion. For example, a process, method, article, or apparatus that comprises a list of elements is not necessarily limited to only those elements, but may include other elements not expressly listed or inherent to such process, method, article, or apparatus. Further, unless expressly stated to the contrary, “or” refers to an inclusive or and not to an exclusive or. For example, a condition A or B is satisfied by any one of the following: A is true (or present) and B is false (or not present), A is false (or not present) and B is true (or present), and both A and B are true (or present).

[0045] In addition, use of the “a” or “an” are employed to describe elements and components of the embodiments herein. This is done merely for convenience and to give a general sense of the inventive concept. This description should be read to include one or more and the singular also includes the plural unless it is obvious that it is meant otherwise.

[0046] Further, use of the term “plurality” is meant to convey “more than one” unless expressly stated to the contrary.

[0047] As used herein any reference to “one embodiment” or “an embodiment” means that a particular element, feature, structure, or characteristic described in connection with the embodiment is included in at least one embodiment. The appearances of the phrase “in one embodiment” in various places in the specification are not necessarily all referring to the same embodiment.

[0048] Circuitry, as used herein, may be analog and/or digital, components, or one or more suitably programmed microprocessors and associated hardware and software, or hardwired logic. Also, “components” may perform one or more functions. The term “component,” may include hardware, such as a processor, an application specific integrated circuit (ASIC), or a field programmable gate array (FPGA), or a combination of hardware and software. Software includes one or more computer executable instructions that when executed by one or more component cause the component to perform a specified function. It should be understood that the algorithms described herein are stored on one or more non-transitory memory. Exemplary non-transitory memory includes random access memory, read only memory, flash memory or the like. Such non-transitory memory may be electrically based or optically based.

[0049] The term “sample” as used herein refers to any fluid that can be removed from a source of fluid, and that may be subject to multiple tests. In one embodiment, the term sample refers to a bodily fluid from a mammal, such as blood, saliva or urine. Other types of samples include water from a source such as a river, pool or the like.

[0050] The term “matrix” as used herein refers to a material in which something can be enclosed or embedded. An example of a “matrix” includes a lateral flow membrane designed as a filter to separate a first constituent part such as red blood cells from a second constituent part such as plasma. A matrix can also be constructed of a backing material having spaced apart microposts to form a filter capable of separating the first constituent part from the second constituent part.

[0051] In accordance with one aspect, there are provided devices, systems, and processes for determining a presence of hemolysis in a sample. Advantageously, devices, systems, and processes described herein that test a fluid sample that has been collected from a source via a fluid collection device having a fluid housing, such as a syringe, and present the fluid sample for further assessment to a testing instrument, such as an analyzer. In some embodiments, the device may determine whether hemolysis has occurred in the fluid sample based upon a colorimetry assessment of a portion of the sample.

[0052] In accordance with another aspect, there are provided devices, systems, and processes for testing a fluid sample obtained by a fluid collection container.

[0053] In accordance with another aspect, there are provided fluid collection devices, systems, accessories and processes having a plasma separating feature.

[0054] In accordance with another aspect, there are provided fluid collection devices, systems, accessories, and processes having a hemolysis indicating feature.

[0055] In accordance with another aspect, there are provided fluid collection devices, systems, accessories and processes that can determine the presence and/or a concentration of one or more analyte within a sample, such as blood or urine or other fluid. These fluid devices, systems, accessories and processes can be used for a variety of purposes, such as to determine blood type, pathological analysis, glucose levels, determine pregnancy, or the like.

[0056] Referring now to the Figures and in particular to FIG. 1, shown therein is a lateral flow testing device **100** constructed in accordance with the present disclosure having a fluid collection device **101** having a fluid housing **102**, a first fluid reservoir **104** encompassed at least partially by the fluid housing **102**, and a fluid treatment module **106**. As will be explained below, the fluid treatment module **106** of the lateral flow testing device **100** includes a means for testing a fluid sample within the fluid treatment module **106**. The means for testing may be implemented in a variety of manners discussed herein that conducts a test upon the fluid sample. Exemplary means for testing include lateral flow strips (that are treated with a reagent or devoid of a reagent) filters, matrix materials or the like, sensors (e.g., electrochemical sensors) or the like. The means for

testing may be read by a suitable reader, such as a camera, electrical circuit or the like. The construction of the reader will depend upon the type of data generated by the means for testing. In some embodiments, the means for testing includes a means for adding a constituent to the fluid sample; and/or a means for removing a constituent from the fluid sample. The means for adding the constituent to the fluid sample includes a substance or mixture, e.g., a reagent, for use in chemical analysis or other reactions. When the fluid sample is blood, the constituent can be plasma devoid of red blood cells. The means for removing may include a device for the active or passive separation of the constituent. Active separation devices include one or more transducer generating a medium applied to the fluid sample to separate the constituents of the fluid sample. The transducer can work on the principle of magnetics; acoustics; or dielectrophoretics. See Optofluidic sensor for inline hemolysis detection on whole blood, ACS Sens. 2018, 3, 4, 784-791. Publication Date Feb. 23, 2018.

[0057] Passive separation devices include lateral flow strips, paper filters, matrices, micro capillaries and the like that physically separate at least one of the constituents from the fluid sample.

[0058] In the example shown in FIG. 1, the fluid treatment module **106** is provided with a lower portion **108**, an upper portion **110**, a second fluid reservoir **111**, a testing device, such as a lateral flow strip **112**, a fluid channel **114**, a first fluid port **116**, a second fluid port **118**, an optical zone **120**, and a bar code **122**. Although one testing device, such as the lateral flow strip **112** is shown in FIG. 1, it should be understood that the fluid treatment module **106** can be provided with multiple testing devices within a volume encompassed by the lower portion **108** and/or the upper portion **110**. In this embodiment, each of the testing devices may be configured to conduct a predetermined test for a different analyte/condition.

[0059] The fluid housing **102** is constructed so that the fluid housing **102** can hold and contain a fluid sample such as blood containing blood cells suspended within plasma. The fluid collection device **101** can be a syringe having a piston **102a** within the fluid housing **102** so as to define the first fluid reservoir **104** or a vacutainer, for example. The fluid housing **102** can be a part of the syringe or the vacutainer, for example. The fluid collection device **101** can be used to obtain the fluid sample from a fluid source, such as an animal or other liquid source (add a urine example and a blood example test for heart attack, drug use, pre-MRI testing (determine pregnancy or a heart attack) and stored within the fluid housing **102**. For example, blood may be collected from an animal, such as a human, or a non-human (such as a cat, dog, cow, horse, fish, or the like).

[0060] The lower portion **108** and the upper portion **110** of the fluid treatment module **106** can be tubular devices that are sealably connected to form a housing that encompasses the second fluid reservoir **111**. The lower portion **108** has the first fluid port **116** formed in an upper wall of the lower portion **108**. The lower portion **108** and the upper portion **110** can be constructed of fluid impermeable materials, such as plastic using any suitable manufacturing process, such as 3D printing or injection molding. When the fluid treatment module **106** is connected to the fluid housing **102**, a fluid sample may be transferred from the first fluid reservoir **104** to the second fluid reservoir **111**. Once in the second fluid reservoir **111**, a portion of the fluid sample may be directed through the second fluid port **118** into the fluid channel **114** containing the lateral flow strip **112**. The second fluid port **118** may be formed in the lower portion **108**. Once in the fluid channel **114**, the fluid sample passes through the lateral flow strip **112** or other type of membrane or filter paper to enter an analysis portion **123** of the lateral flow strip **112** or membrane or filter paper. The lateral flow strip **112** or membrane or filter paper or the like can add a constituent to the fluid sample, can remove a constituent from the fluid sample or add a first constituent to the fluid sample and remove a second constituent from the fluid sample. For example, the lateral flow strip **112** can be untreated with a reagent and remove a constituent, such as red blood cells, from the fluid sample. Or, the lateral flow strip or membrane or filter paper can be treated with a reagent that is then added to the fluid sample as the fluid sample passes through the lateral flow strip **112**. As another example, the

lateral flow strip **112** may be a filter adapted to separate red blood cells from plasma and be treated with a reagent. In this case, the reagent is added to the plasma as the plasma is passed to the analysis portion **123**. The lateral flow strip **112** can also be treated with the reagent so that the reagent mixes with the plasma as the plasma passes through the lateral flow strip **112** to the analysis portion **123**. In some embodiments, the lateral flow strip **112** may use capillary action (which may also be referred to as capillary flow) and/or size exclusion techniques, such as filter paper, to cause the separation of constituents in the fluid sample such as blood cells and plasma if the fluid sample is a blood sample as described more fully in U.S. patent application Ser. No. 15/317,748, the entirety of which is incorporated herein by reference. The analysis portion **123** of the lateral flow strip **112** may be placed adjacent to the optical zone **120**. The optical zone **120** is a portion of the lower portion **108** that is transparent to light of a predetermined spectrum so that the analysis portion **123** can be read through the optical zone **120**. In some embodiments, the predetermined spectrum is visible light. When the action caused by the lateral flow strip or the like is separation of the blood into plasma, the plasma that has passed through the lateral flow strip **112** may then be analyzed colorimetrically in the optical zone **120** to determine a degree of hemolysis using an optical reader or human eyes. Exemplary degrees of hemolysis include none (plasma has a yellowish color and generally less than 25 milligram/deciliter of hemolysis) slight (plasma has an orangish color and has hemolysis generally between 25 milligram/deciliter to 150 milligram/deciliter), moderate (plasma has a reddish color and hemolysis is generally between 150 milligram/deciliter to 300 milligram/deciliter) and gross (generally above 300 milligram/deciliter). The optical reader may be a part of a point of care analyzer, or a camera and software of a smart phone, or the like. In some embodiments, the lateral flow strip **112** or membrane or filter paper or the like may have one or more reagent in a path from the second fluid port **118** to the analysis portion **123**. In these embodiments, the reagent(s) may react with the sample so as to cause a predetermined change (e.g., color) that may be detected in the analysis portion of the lateral flow strip **112**. For instance, it may be important to pre-analyze a sample for certain drugs or diseases. [0061] There are many advantages of using the embodiments of the inventive concepts disclosed herein, such as the fluid collection device **101** and the fluid treatment module **106**, such as improved sanitation, timing, and consistency due to the enclosed nature and predetermined fluid paths. For example, the lateral flow strip **112** can be treated with a reagent suitable for conducting a pregnancy test. The reagent may be configured to detect a hormone named human chorionic gonadotropin (HCG) in urine. The patient may collect a urine sample in a cup, and then draw a sample of the urine with the fluid collection device **101**. After the sample of urine is drawn, the patient may then connect the fluid treatment module **106** to the fluid collection device **101** to form a fluid tight assembly such that urine will not be spilled. As the urine passes into the fluid treatment module **106**, the urine will mix with the reagent thereby causing a reaction that may be monitored to determine whether the patient is pregnant. This avoids having to apply a wand treated with the reagent into a urine stream, or sloshing the wand within the cup as accomplished in conventional pregnancy tests.

[0062] In another example, a patient may present with symptoms indicative of a stroke. Prior to providing a contrast MRI for the patient, the health care provider may ask the patient if the patient is pregnant or has kidney problems, but the patient may not be able to answer these questions in a reliable manner. The health care provider will then likely obtain a sample from the patient to test for an analyte, such as creatinine, that is indicative of the patient's kidneys not functioning properly or hCG to determine pregnancy. The sample can be blood or urine. In this case, the lateral flow strip **112** may be treated with a reagent configured to test for pregnancy. After the health care provider obtains the sample with the fluid collection device **101**, the health care provider will connect the fluid treatment module **106** to the fluid collection device **101** to form a fluid tight assembly. As the sample passes into the fluid treatment module **106**, the sample will mix with the reagent on the lateral flow strip **112**, for example, thereby causing a reaction that may be monitored

to determine whether the patient is pregnant. A portion of the sample may then be drawn from the fluid treatment module **106** by an analyzer to test for creatinine, for example, by inserting a probe or pipette from the analyzer through the third connector portion **130**. In this manner, the health care provider can test/verify that the patient is not pregnant and that the patient's kidneys are functioning properly in a sanitary manner by conducting the pregnancy test as a part of the work flow for testing for creatinine.

[0063] In other embodiments, one or more analyte sensors **124** may be positioned within the fluid channel **114** and positioned to interact with the fluid sample passing through the fluid channel **14**. The analyte sensors **124** can be electrochemical sensors, such as potentiometric sensors, amperometric sensors and combinations thereof.

[0064] To facilitate directing the fluid sample into the second fluid port **118**, the lower portion **108** and/or the upper portion **110** may have a removable cap or gas permeable/fluid impermeable membrane sealing the first fluid port **116** (not shown), for instance, that temporarily prevents movement of the fluid sample through the first fluid port **116**. When the fluid sample has been analyzed using the lateral flow testing device **100**, the cap may be removed and the fluid sample may be allowed to pass through the first fluid port **116** to be used for further testing, for instance, as desired. The gas permeable/fluid impermeable membrane covering the first fluid port **116** may pass air out of the fluid sample to de-aerate the fluid sample.

[0065] As described above, the bar code **122** may be positioned on an exterior surface of the upper portion **110**, and used to identify the fluid sample, the patient that the fluid sample belongs too, the geographic area the fluid sample was collected from (e.g. river), the test to be performed, and the like.

[0066] In one use, the fluid collection device **101** can be used to obtain a fluid sample from an animal and to deposit the fluid sample within the fluid housing **102**. When the fluid housing **102** is a syringe having a needle, the needle can then be removed to expose a first connector portion **126** of the fluid housing **102**. The first connector portion **126** can be any suitable type of connector, such as a Luer connector, a male port, or a female port. Then, a second connector portion **128** of the lower portion **108** can be connected to the first connector portion **126**, and a portion of the fluid sample directed from the first fluid reservoir **104** to the second fluid reservoir **111**. Once in the second fluid reservoir **111**, the removable cap, or gas permeable/fluid impermeable membrane may prevent the flow of the fluid sample through the first fluid port **116**. As pressure builds within the second fluid reservoir **111**, a portion of the fluid sample may be directed through the second fluid port **118** into the fluid channel **114** containing the lateral flow strip **112**. The second fluid reservoir **111** and the fluid channel **114** are separated by a fluid impermeable wall **129** having the second fluid port **118**. The second fluid port **118** may be spaced a distance from the optical zone **120** so that the fluid sample passes through a substantial amount of the lateral flow strip **112** prior to reaching the analysis portion **123**, or the optical zone **120**. The analyte sensors **124** are positioned between the second fluid port **118** and the optical zone **120**. Readings can then be taken in the optical zone **120**, or from the analyte sensors **124**. For example, if the lateral flow strip **112** or membrane or filter paper is configured to separate red blood cells from plasma, the red blood cells may be separated from the plasma prior to the plasma entering the analysis portion **123** and be read to determine an extent of hemolysis. The extent of hemolysis can be determined by the color of the plasma. That is, plasma that is pink or red may be determined to have hemolyzed, and plasma that is colorless, yellow or light orange (none to slight hemolysis) may be determined to have not hemolyzed to an extent to prevent further analysis. A color reference chart may be provided on the exterior surface of the fluid treatment module **106**. In any event, if the testing occurring within the lower portion **108** indicates that further testing may be accomplished, then the fluid sample may be transferred through a third connector portion **130** of the upper portion **110** to a blood gas analyzer or other suitable testing instrument for additional testing. Suitable testing instruments may include urine analyzers, blood analyzers, or the like. In certain cases, a pipette (also known as a “probe”)

(not shown) may be introduced through the third connector portion **130** to obtain a portion of the sample from within the first fluid reservoir **104** or the second fluid reservoir **111**. The third connector portion **130** can be a luer connector, a male port, a female port of the like. The bar code **122** can be read by an optical reader and entered into a medical software program to track the results of one or more tests occurring within the lower portion **108** or by the blood gas analyzer or other suitable testing instrument.

[0067] In some embodiments, the housing has a longitudinal axis **132** extending between the upper portion **110** and the lower portion **108**, and the lateral flow strip **112** has a major axis **134** extending in a non-parallel relationship with the longitudinal axis **132**. In the example shown in FIG. **1**, the major axis **134** of the lateral flow strip **112** can be substantially perpendicular to the longitudinal axis **132**. The lateral flow strip **112** can be constructed in a variety of manners. For example, the lateral flow strip **112** can be a lateral flow membrane or matrix that filters the first constituent (e.g., red blood cells) of the sample from a second constituent (e.g., plasma). The lateral flow strip **112** may have a distal end **136** in the optical zone **120** and a proximal end **138** away from the optical zone **120**. The distal end **136** and/or the proximal end **138** may be treated with a reagent.

[0068] FIG. **2** illustrates a lateral flow testing device **140** including a fluid collection device **141** having a fluid housing **142**, a fluid treatment module **144** encompassed by the fluid housing **142**, a first fluid reservoir **146**, and a second fluid reservoir **148**. The lateral flow testing device **140** is similar to the lateral flow testing device **100** described above, therefore, in the interest of brevity only the differences will be described herein. The fluid collection device **141** and the fluid treatment module **144** are integrated into a unitary structure in which the fluid housing **142** encompasses the first fluid reservoir **146** and the second fluid reservoir **148**. Further, the third connector portion **130** is used for the inflow of the fluid sample into the fluid collection device **141** and also used to draw the fluid sample from the first fluid reservoir **146** and/or the second fluid reservoir **148**.

[0069] FIG. **2A** illustrates a lateral flow testing device **140a** including a fluid collection device **141a** having a fluid housing **142a**, a fluid treatment module **144a** connected to the fluid housing **142a**, a first fluid reservoir **146a**, and a second fluid reservoir **148a**. The lateral flow testing device **140** is similar to the lateral flow testing device **100** described above, therefore, in the interest of brevity only the differences will be described herein. In the embodiment shown in FIG. **2A**, the fluid collection device **141** is a vacutainer, and the fluid treatment module **144** has a second connector portion **128a** in the form of a needle **150** extending through a septum **152** of the fluid collection device **141**. To draw the fluid sample into the second fluid reservoir **148** from the first fluid reservoir **146**, the fluid treatment module **144** may include a negative pressure device **154** in fluid communication with the second fluid reservoir **148**. The negative pressure device can be a bellows used to create the negative pressure, or a vacuum port that is connectable to a vacuum source.

[0070] FIG. **3** illustrates a top plan view of a fluid treatment module **160** similar to fluid treatment modules **106** and **144**. In this embodiment, the fluid treatment module **160** is provided with a fluid channel **162** that connects a first fluid port **164** with a second fluid port **166** to direct a flow of a fluid sample into a fluid channel **168** for separation of the fluid sample into at least two constituent parts, for testing by way of one or more analyte sensors as described above. For instance, when the fluid sample is blood, the lateral flow strip **112** housed in the fluid channel **168** functions to separate the blood cells from the plasma so that the plasma is visible in the optical zone **120**. The fluid impermeable wall **129** may fluidly isolate the fluid channel **168** from the first fluid port **164**, with the exception of the fluid channel **162**.

[0071] Referring now to FIG. **4**, shown therein is another embodiment of a lateral flow testing device **180** having a fluid housing **182**, a fluid reservoir **184**, and a fluid treatment module **186**. The fluid housing **182** can be identical in construction and function as the fluid housing **102** discussed above. The fluid treatment module **186** of the lateral flow testing device **180** is provided with a

lower portion **188**, an upper portion **190**, a second fluid reservoir **192** defined by the lower portion **188**, a third fluid reservoir **193** defined by at least a portion of the upper portion **190**, and a lateral flow membrane **194**. The lateral flow membrane can be similar in construction and function as the lateral flow strip **112** discussed above.

[0072] The lower portion **188** and the upper portion **190** of the fluid treatment module **186** are sealably connected to form the second fluid reservoir **192** and the third fluid reservoir **193** separated by the lateral flow membrane **194**. When the fluid treatment module **186** is connected to the fluid housing **182**, a fluid sample may be transferred from the first fluid reservoir **184** to the second fluid reservoir **192** and through the lateral flow membrane **194** into the third fluid reservoir **193**. As the fluid sample is transferred from the second fluid reservoir **192** to the third fluid reservoir **193**, the fluid sample passes through the lateral flow membrane **194** and the fluid sample is separated into at least two constituent parts, e.g., blood cells remain in the second fluid reservoir **192** or are captured within the lateral flow membrane **194**, and plasma passes through the lateral flow membrane **194** and into the third fluid reservoir **193**.

[0073] As shown in FIG. 4A, the lateral flow membrane **194** may be a multi-layer structure, with each layer performing a separate function to the sample as the sample passes sequentially through the layers. For example, as shown in FIG. 4A, the lateral flow membrane **194** may have three layers **195a**, **195b**, and **195c**. The layer **195a** may be a mesh configured to divert bubbles within the sample into a hollow chamber. For instance, layer **195a** may be an asymmetric membrane which diverts gas within the sample into the hollow chamber, and allows liquid within the sample to pass through. The layer **195b** may be a material suitable to separate red blood cells from plasma as well as separating any clots or particulate matter from the plasma. Any one or more of the layers **195a**, **195b**, or **195c** can be provided with one or more analyte regions that receive the sample and mixes an analyte with a portion of the sample to provide an indication of the presence and/or concentration of certain analytes within the sample. The liquid portion of the sample can pass sequentially through the layers **195a**, **195b** and **195c** as indicated by arrow **197**. In some embodiments, the layer **195c** may also be provided with one or more electrochemical sensor (not shown) to provide further analysis of the sample.

[0074] Referring again to FIG. 4, at least the upper portion **190** of the fluid treatment module **186** may be constructed of an optically clear material which allows the fluid that has passed through the lateral flow membrane **194** to be colorimetrically analyzed in the third fluid reservoir **193** using an optical reader, as described above or human eyes. Because the fluid can be analyzed with human eyes, the fluid treatment module **186** allows a fluid sample to be analyzed at a point-of-care without the need for additional devices and is non-disruptive to standard fluid collection workflow. This point-of-care review prevents or reduces pre-analytical errors, such as hemolyzed blood for instance, due to sample handling.

[0075] Also shown in FIG. 4 is a probe **196** which may be attached to or part of a testing instrument or fluid analysis machine (not shown) such as a blood gas analyzer when the sample is blood. Where whole blood is needed for analysis, the probe **196** may be passed through a fluid port **198** in the fluid treatment module **186**, through the third fluid reservoir **193**, and through the lateral flow membrane **194** into the second fluid reservoir **192** where the fluid sample has not been separated. It should be noted that in some embodiments the fluid treatment module **204** is sized such that the probe **196** does not pass through the second fluid reservoir **192** and thus draws a sample of fluid from the second fluid reservoir **192**, rather than the first fluid reservoir **184**.

[0076] FIG. 5 illustrates another version of a lateral flow fluid testing device **200** having a fluid collection device **201** having a fluid housing **202**, a fluid treatment module **204**, a first fluid reservoir **206**, a second fluid reservoir **208**, a third fluid reservoir **209**, a lateral flow membrane **210**, and a fluid port **214**. The lateral flow fluid testing device **200** is similar to the lateral flow fluid testing device **180** described above, therefore, in the interest of brevity only the differences will be described herein. In the embodiment shown in FIG. 2A, the fluid collection device **201** is a

vacutainer, and the fluid treatment module **204** has a connector portion **216** in the form of a needle extending through a stopper **218** of the fluid collection device **141**. To draw the fluid sample into the second fluid reservoir **208** from the first fluid reservoir **206**, the fluid treatment module **204** may include a negative pressure device **220** in fluid communication with the third fluid reservoir **209**. The negative pressure device **220** can be a bellows used to create the negative pressure, or a vacuum port that is connectable to a vacuum source (not shown).

[0077] A probe **212** is also shown which may be attached to or part of a testing instrument or fluid analysis machine (not shown) such as a blood gas analyzer. Where whole blood is needed for analysis, the probe **212** may be passed through the fluid port **214** in the fluid treatment module **204**, through the third fluid reservoir **209**, and through the lateral flow membrane **210** into the second fluid reservoir **208** where the blood sample has not been separated. The fluid treatment module **204** may be sized such that the probe **212** does not pass through the second fluid reservoir **208** but draws a fluid sample from fluid in the second fluid reservoir **208**, rather than the first fluid reservoir **206**. In some embodiments, the probe **212** may be passed into and used to draw the fluid sample from the third fluid reservoir **209**.

[0078] Referring now to FIGS. 6-9B, shown therein is another embodiment of a fluid testing device **280** that can be read by a reader **80** and/or utilized to separate the fluid sample into at least two constituent parts. When the fluid sample is blood, the fluid testing device **280** can separate the blood into a first constituent part having plasma having a concentration of red blood cells higher than a concentration of red blood cells in the blood; and a second constituent part having plasma that is substantially devoid of red blood cells. The fluid testing device **280** is provided with a fluid housing **282**, a fluid reservoir **284**, a fluid treatment reservoir **285**, an optical zone **286** on an exterior wall **286a** of the fluid housing **282**, a treatment window **288** on the exterior wall **286a** of the fluid housing **282**, a first flow path **292**, a lateral flow membrane **293** within the first flow path **292**, a second flow path **294** separate from the first flow path **292**, a gate **296** having a port **298**, and a gate guide channel **300**. The gate **296** is positioned within the gate guide channel **300** and can be moved in any suitable direction (such as laterally), as described below to guide the fluid sample into the first flow path **292** or the second flow path **294**.

[0079] When the gate **296** is in a first position (shown in FIG. 7), a fluid sample is directed into the first flow path **292** and through the lateral flow membrane **293** such that the fluid sample is separated into at least two constituent parts and a separated fluid sample is directed into the optical zone **286** where the separated fluid sample may be read with the reader **80**. The lateral flow membrane **293** can be similar in construction and function as the lateral flow strip **112**. When the reader **80** is an optical reader and the fluid sample is a blood sample, a degree of hemolysis can be determined by a control unit **84** based upon a colorimetric analysis of the separated fluid sample. That is, when the separated fluid sample (plasma in the case of a blood sample) is devoid of hemolysis, the plasma will be substantially devoid of any color, i.e., the sample will be transparent. When hemolysis has occurred within the separated fluid sample, the plasma will be pink. By correlating the color of the plasma with predetermined colors indicative of an extent of hemolysis occurring within other samples, the extent of hemolysis within the separated fluid sample can be determined. The fluid sample, including but not limited to blood, can be tested for one or more analytes as discussed above with respect to the discussion regarding the lateral flow strip **112**.

[0080] The reader **80** may be provided with an optical reader (not shown). When the fluid testing device **280** is inserted into the reader **80**, the optical reader of the reader **80** has a field of view directed to the optical zone **286** where the fluid sample may be read. The lateral flow membrane **293** separates the fluid sample such that only the separated fluid sample is visible in the optical zone **286**. Then the optical reader captures an image of the separated fluid sample and any backdrop and sends the image to the analysis unit **84** for colorimetric analysis as discussed above. The analysis unit **84** may be provided with further fluid analysis features (not shown) such as gas analysis which may further analyze the fluid sample after it passes through the second flow path

294.

[0081] The reader **80** may be portable and have a housing **88** that includes a slot **90** sized and dimensioned to receive the fluid testing device **280** such that the optical zone **286** is in the field of view of the optical reader. The housing **88** can be provided in a variety of shapes such as a hot dog bun, for instance. The analysis unit **84** can be supported in the housing **88** or be separate therefrom. For example, the reader **80** can be provided with a wireless transceiver to communicate with the analysis unit **84**.

[0082] Once the fluid sample has been analyzed, the gate **296** may be moved to a second position (shown in FIG. **8**), which moves the port **298** into the second flow path **294** allowing the fluid sample to pass into the second flow path **294**.

[0083] FIG. **10** illustrates a lateral flow fluid testing device **350** having a fluid housing **352**, a first fluid reservoir **354**, and a fluid treatment module **356**. The fluid treatment module **356** of the lateral flow testing device **350** is provided with a lower portion **358**, an upper portion **360**, a second fluid reservoir **362**, a third fluid reservoir **363**, and a lateral flow membrane **364** inset in a third fluid port **365** of a fluid impermeable divider **366**.

[0084] The lower portion **358** and the upper portion **360** of the fluid treatment module **356** are sealably connected to form the second fluid reservoir **362** and the third fluid reservoir **363** separated by the fluid impermeable divider **366**. When the fluid treatment module **356** is connected to the fluid housing **352**, a fluid sample may be transferred from the first fluid reservoir **354** to the second fluid reservoir **362** and through the lateral flow membrane **364** into the third fluid reservoir **363**. As the fluid sample is transferred from the second fluid reservoir **362** to the third fluid reservoir **363**, the fluid sample passes through the lateral flow membrane **364** and the fluid sample is separated into at least two constituent parts, e.g., blood cells remain in the second fluid reservoir **362** and plasma passes through the lateral flow membrane **364** and into the third fluid reservoir **363**.

[0085] At least the upper portion **360** of the fluid treatment module **356** is constructed of an optically clear material which allows the fluid that has passed through the lateral flow membrane **364** to be colorimetrically analyzed in the third fluid reservoir **363** using an optical reader as described above or human eyes.

[0086] Also shown in FIG. **10** is a probe **367** which may be attached to or part of a testing instrument or fluid analysis machine (not shown) such as a blood gas analyzer. Where whole blood is needed for analysis, the probe **367** may be passed through a fluid port **368** in the fluid treatment module **356**, through the third fluid reservoir **193**, and through the lateral flow membrane **364** into the second fluid reservoir **362** where the blood sample has not been separated. It should be noted that the fluid treatment module **356** may be sized such that the probe **367** does not pass through the second fluid reservoir **362** and thus draws a sample of fluid from the second fluid reservoir **362**.

[0087] The fluid impermeable divider **366** may further be provided with at least one reagent **370** (only one of which is designated in FIG. **10**) that allow further testing of a fluid sample. For instance, reagents **370** may be used to determine blood type, pathological analysis, glucose levels, determine pregnancy, etc. While reagents **370** are illustrated only on one side of the fluid impermeable divider **366**, it should be noted that reagents **370** may be placed on one side or both sides of the fluid impermeable divider **366**. For instance, some reagents may be placed on the side of the second fluid reservoir **362** to test the fluid sample before separation into constituent parts through the lateral flow membrane **364** while others may be placed on the side of the third fluid reservoir **363** to test the separated fluid sample. In some embodiments, reagents **370** may be placed on both sides of the fluid impermeable divider **366** to test the fluid sample and the separated fluid sample. Reaction with the reagents may be read by an optical reader as described above or human eyes.

[0088] FIG. **11** illustrates another version of a lateral flow fluid testing device **400** having a fluid collection device **401** having a fluid housing **402**, a fluid treatment module **404** connected to the

fluid housing **402**, a first fluid reservoir **406** within the fluid housing **402**, a second fluid reservoir **408** within the fluid treatment module **404**, a third fluid reservoir **409** within the fluid treatment module **404**, a lateral flow membrane **410** separating the second fluid reservoir **408** and the third fluid reservoir **409**, and a first fluid port **414**. The lateral flow fluid testing device **400** is similar to the lateral flow fluid testing device **350** described above, therefore, in the interest of brevity only the differences will be described herein. In the embodiment shown in FIG. **11**, the fluid collection device **401** is a vacutainer, and the fluid treatment module **404** has a second fluid port **415a** in the form of a needle **416** extending through a septum **418** of the fluid collection device **401**. To draw the fluid sample into the second and third fluid reservoirs **408** and **409** from the first fluid reservoir **406**, the fluid treatment module **404** may include a negative pressure device **420** in fluid communication with the third fluid reservoir **409**. The negative pressure device **420** can be a bellows used to create the negative pressure, or a vacuum port that is connectable to a vacuum source.

[0089] Also shown in FIG. **11** is a probe **412** which may be attached to or part of a testing instrument or fluid analysis machine (not shown) such as a blood gas analyzer. Where whole blood is needed for analysis, the probe **412** may be passed through the fluid port **414** in the fluid treatment module **404**, through the third fluid reservoir **409**, and through the lateral flow membrane **410** into the second fluid reservoir **408** where the blood sample has not been separated. It should be noted that the fluid treatment module **404** may be sized such that the probe **412** does not pass through the second fluid reservoir **408** and thus draws a sample of fluid from the second fluid reservoir **408**. In some embodiments, the fluid treatment module **404** and/or the probe **412** may be sized so as to draw a fluid sample from the first fluid reservoir **406**.

[0090] Referring now to FIG. **12**, shown therein is a diagrammatic view of a testing device **450** (this is a means for separating, removing a component, exemplary, etc.) constructed in accordance with the present disclosure. The testing device **450** can be used for testing blood, or other sample(s) that would benefit from separating two constituent components in the sample. The testing device **450** will be described hereinafter by way of example as a blood testing device. In general, the blood testing device **450** includes a fluid collection device, such as a housing **452**, a transducer **456**, a reader **458**, and a control unit **460** connected to the transducer **456** and the reader **458**. The transducer **456** will be described herein by way of example as being an acoustic transducer generating acoustic waves. It should be understood, however, that the transducer **456** can be implemented in other manners to actively separate a sample into a first constituent part (e.g., enhanced red blood cells and plasma) and a second constituent part (e.g., plasma substantially devoid of red blood cells). For example, the transducer **456** can be a magnetic transducer, or a dielectrophoretic transducer. See Optofluidic sensor for inline hemolysis detection on whole blood, ACS Sens. **2018**, **3**, **4**, **784-791**. Publication Date Feb. 23, 2018. The power level for the transducer **456** is preferably set at a level that the medium generated by the transducer **456** separates the sample into the first constituent part and the second constituent part without destroying cells or other matter within the sample. The housing **452** is constructed of a fluid impermeable material so that the housing **452** can hold and contain a sample of blood containing blood cells suspended within plasma. The housing **452** can be a syringe or a vacutainer, for example, used for collecting blood and transporting the blood for purposes of testing. The blood may be collected from an animal, such as a human, or a non-human (such as a cat, dog, cow, horse, fish, or the like). The acoustic transducer **456**, the reader **458**, and the control unit **460** may be located outside of the housing **452** as shown in FIG. **12** or inside the housing **452** (not shown). The acoustic transducer **456** selectively generates acoustic forces that are directed to the housing **452**. In some embodiments, the acoustic transducer **456** can be tuned so as to provide a magnitude and/or frequency of acoustic forces so as to facilitate separation of the undamaged blood cells from the plasma and damaged blood cells. The magnitude and/or frequency of the acoustic forces generated by the acoustic transducer **456** can be selected depending upon a size and/or construction of the

housing **452**, or composition of the blood sample within the housing **452**. In one embodiment, the acoustic transducer **456** can be a piezoelectric element. Piezoelectric elements are known to separate plasma from red blood cells. See Optofluidic sensor for inline hemolysis detection on whole blood, ACS Sens. **2018**, **3**, **4**, **784-791**. Publication Date Feb. 23, 2018. At least a portion of the housing **452**, adjacent to the transducer **456**, is constructed of a material that functions to pass the acoustic forces generated by the acoustic transducer **456** into the sample contained within the housing **452**. Exemplary materials that can be used to form the housing **452** include glass, crystal, and the like. Parts of the housing **452** away from the transducer **456** can be made of other materials such as plastic. The application of the acoustic forces into the sample by the acoustic transducer **456** causes the blood cells within the blood to move within the plasma to form a first zone **462** having an increased density or concentration of the blood cells than the blood contained prior to the application of the acoustic forces, and at least one second zone **464** being substantially only plasma, i.e., substantially devoid of any undamaged blood cells. The reader **458** is positioned adjacent to the second zone **464** and functions to read at least one parameter of the plasma. In one embodiment, the reader **458** is an optical reader, such as a camera or photospectrometer having a field of view overlapping with the housing **452** such that the plasma within the second zone **464** is visible to the reader **458**. In some embodiments, the reader **458** may also include a light source, such as a light emitting diode providing light through the housing **452**, a mixer and/or a bar code reader.

[0091] The housing **452** may define a first port **465a** fluidly connected with the first zone **462** to receive the blood having the increased density or concentration of the red blood cells in the plasma, and a second port **465b** to receive the plasma that is substantially devoid of any red blood cells. The first port **465a** and/or the second port **465b** can be connected to a testing instrument or a collection receptacle. The first port **465a** and the second port **465b** can be combined within a bifurcated port. One or more testing devices, such as the lateral flow strip **112** can be placed within the first zone **462** or the second zone **464** for separately testing the constituent parts of the blood sample. The testing device(s) may be surrounded with fluid impermeable material so as to isolate the testing device(s) from the blood until a test is desired. At that time, a moveable gate, pierceable membrane or the like can be used to expose the blood sample within the first zone **462** to a first testing device(s), or the blood sample within the second zone **464** to a second testing device(s).

[0092] The optical reader **458** is positioned such that the second zone **464** is within the field of view. The control unit **460** selectively actuates/deactuates the acoustic transducer **456** to cause separation of the blood cells and plasma into the first zone **462** and the second zone **464**. Then, in some embodiments, the control unit **460** actuates the reader **458** to capture information indicative of at least one parameter of the plasma. The information captured by the reader **458** is then transferred to the control unit **460** to analyze the parameter to conduct at least one predetermined test. Exemplary test(s) include a degree of hemolysis within the sample of blood. Other exemplary tests include HIL (hemolysis, icterus and lipemia) detection, troponin detection, drug detection, pregnancy detection, microclot detection and the like. The control unit **460** can be constructed of circuitry and/or a combination of circuitry and software.

[0093] When the reader **458** is the optical reader, the degree of hemolysis can be determined by the control unit **460** based upon a colorimetric analysis of the sample. That is, when the sample is devoid of hemolysis and is illuminated with white light, the plasma will be substantially devoid of any color, i.e., the sample will be transparent. When hemolysis has occurred within the sample, the plasma will be pink when the plasma is illuminated with white light. By correlating the color of the plasma with predetermined colors indicative of an extent of hemolysis occurring within other samples, the extent of hemolysis within the sample can be determined. Depending upon a color of a backdrop, and/or color of illumination of the plasma, colors detected by the reader **18** indicative of an extent of hemolysis may differ.

[0094] Information indicative of an extent of hemolysis within the sample can be used to determine

whether the blood has hemolysis. As discussed above, other tests may also be conducted by the control unit **460**.

[0095] FIG. **14** illustrates a testing device **480** constructed in accordance with one embodiment of the present disclosure. The testing device **480** can be used for testing blood, or other sample(s) that would benefit from separating two constituent components in the sample. The testing device **480** will be described hereinafter by way of example as a blood testing device. The blood testing device **480** is provided with a fluid container such as a syringe **482** or vacutainer having a fluid reservoir **484** for containing blood. The blood testing device **480** may also be provided with an acoustic transducer **486**, an optical zone **488**, and a bar code **490** which identifies the contents of the syringe **482** and can be correlated to specific patients. The acoustic transducer **486** may be provided with any suitable shape, such as planar, arcuate, or the like. In some embodiments, the acoustic transducer **486** may be provided with a shape to match a shape of the optical zone **488**, or other section of the blood testing device **480** to be stimulated by the acoustic transducer **486**. In such an embodiment, the blood testing device **480** allows the blood to be acoustically treated using the acoustic transducer **486** after which the blood may be analyzed using an optical reader or the human eye through the optical zone **488** to conduct one or more predetermined test, such as a degree of hemolysis, HIL detection, troponin detection, drug detection, pregnancy detection, microclot detection or the like. Once a degree of hemolysis within the sample of blood has been determined, for example, a decision can be made whether or not to continue with further testing of the sample of blood.

[0096] Referring now to FIGS. **15A-15C**, shown therein is an embodiment of a testing device **500** and reader **501**. The testing device **500** can be used for testing blood, or other sample(s) that would benefit from separating two constituent components in the sample. The testing device **500** will be described hereinafter by way of example as a blood testing device. The blood testing device **500** has a fluid housing **502**, a fluid treatment module **503**, a fluid reservoir **504** fluidly connected to the fluid treatment module **503**. The fluid treatment module **503** includes a fluid treatment housing **505**, an optical zone **506**, a treatment window **508**, and a flow port **512** within the fluid treatment housing **505**. When the fluid treatment housing **505** of the fluid treatment module **503** is connected to the fluid housing **502**, the fluid reservoir **504** is in fluid communication with the flow port **512** such that a sample within the fluid reservoir **504** can be directed to a treatment area **513** via the flow port **512**. In one embodiment, the fluid housing **502** includes a syringe having a fluid fitting connected to the fluid treatment housing **505** of the fluid treatment module **503**.

[0097] The reader **501** has a reading device **510** adjacent to the flow path **512** when the fluid treatment module **503** and the fluid housing **502** are positioned within a bay **531a**, and an analysis unit **514**. In this embodiment of the blood testing device **500**, a blood sample is contained in the fluid housing **502** and directed along the flow path **512** into the fluid treatment area **513** where the blood sample is directed to flow past the treatment window **508**. The treatment window **508** is constructed of a material that functions to pass acoustic forces generated by an acoustic transducer into the blood sample contained within the fluid housing **502**.

[0098] The reading device **510** is part of the analysis unit **514** and is provided with an acoustic transducer (not shown) and an optical reader (not shown) which operate as described above to acoustically treat the blood sample. The acoustic transducer may be provided with a planar shape so as to mate with the treatment window **508** of the blood testing device **500**. The optical reader of the reading device **510** has a field of view directed to the optical zone **506** where the acoustically treated blood sample may be read. The analysis unit **514** actuates the acoustic transducer to acoustically treat the blood sample and move the blood cells away from the optical zone **506** such that only the plasma is visible in the optical zone **506**. Then the optical reader captures an image of the plasma and any backdrop and sends the image to the analysis unit **514** for colorimetric analysis as discussed above. The analysis unit **514** may be provided with further blood analysis features (not shown) such as blood gas analysis which may further analyze the blood sample after it passes

through the flow path **512**. The reader **501** may be portable and have a housing **518** that includes a slot **520** sized and dimensioned to receive the blood testing device **500** such that the optical zone **506** is in the field of view of the optical reader and the treatment window overlaps with the acoustic transducer. The housing **518** can be provided in a variety of shapes such as in a shape of a hot dog bun, for instance. The analysis unit **514** can be supported in the housing **518** or be separate therefrom. For example, the reading device **510** can be provided with a wireless transceiver to communicate with the analysis unit **514**. The analysis unit **514** may be constructed and function in a similar manner as the control unit **460** discussed above.

[0099] FIGS. **16A** and **16B** illustrate another variation of the reader **501** having a portion **519** in which the fluid treatment module **503** of FIG. **15A** may be inserted into the housing **518** so that the blood sample, for example, may be acoustically treated and read by the reading device **510** within the housing **518** as described above. The portion **519** may be sized and adapted to mating receive the fluid treatment module **503** when the fluid treatment module **503** is connected to the fluid housing **502**.

[0100] Referring now to FIGS. **17-19**, shown therein is yet another version of a testing device **600** similar to the testing device **500** shown in FIG. **15A** that can be read by the reader **501**. The testing device **600** can be used for testing blood, or other sample(s) that would benefit from separating two constituent components in the sample. The testing device **600** will be described hereinafter by way of example as a blood testing device. In the interest of brevity, only the differences will be described in detail herein. The blood testing device **600** is provided with a fluid housing **602**, a fluid treatment module **603**, a fluid reservoir **604**, and a fluid treatment housing **605**. The fluid treatment housing **605** includes an optical zone **606**, a treatment window **608**, a flow path **612**, a gate **614** having a port **616**, and a gate guide channel **618**.

[0101] When the gate **614** is in a first position (shown in FIG. **18**), the flow path **612** is restricted such that a blood sample in the flow path **612** stops in the optical zone **606** where the sample may be acoustically treated to move undamaged blood cells away from the plasma adjacent to the optical zone **606** and read with the reader **501** as described above.

[0102] Once the blood sample has been analyzed the gate **614** may be moved to a second position (shown in FIG. **19**), which moves the port **616** into the flow path **612** allowing the blood sample to pass.

[0103] Referring now to FIGS. **20-22**, shown therein is yet another version of a testing device **650** similar to the testing devices **500** and **600** shown in FIGS. **15A** and **17-19**, respectively, that can be read by the reader **501**. In the interest of brevity, only the differences will be described in detail herein. The testing device **650** can be used for testing blood, or other sample(s) that would benefit from separating two constituent components in the sample. The testing device **650** will be described hereinafter by way of example as a blood testing device. The blood testing device **650** is provided with a fluid housing **652**, a fluid treatment module **653**, a fluid reservoir **654**, and a fluid treatment module **655** connected to the fluid housing **652**. The fluid treatment module **655** includes a fluid treatment housing **656**. The fluid treatment housing **656** includes an optical zone **657**, a treatment window **658**, a first flow path **662**, a second flow path **664**. The fluid treatment module **655** includes a gate **666** having a port **668** positioned within a gate guide channel **699** of the fluid treatment housing **656**.

[0104] When the gate **666** is in a first position (shown in FIG. **21**), a blood sample is directed from the fluid housing **652** into the first flow path **662** such that the blood sample stops in the optical zone **657** where the blood sample may be acoustically treated with acoustic transducer **670** and read with the reading device **672** as described above.

[0105] Once the blood sample has been analyzed the gate **666** may be moved to a second position (shown in FIG. **22**), which moves the port **668** into the second flow path **664** allowing the blood sample to pass through the second flow path **664**.

[0106] Referring now to FIGS. **23-25**, shown therein is a fluid testing device **700** which may be

removably attachable to a fluid collection device or a fluid housing such as a syringe, for example. The fluid testing device **700** may be provided with a tubular housing **701** having a first end **701a**, a second end **701b**, a bore **701c** extending between the first end **701a** and the second end **701b**, and an interior surface **701d**. The fluid testing device **700** is also provided with a connector **702** which may be located at the first end **701a**. The fluid testing device **700** may also be provided with a first wall **703a**, a second wall **703b**, and a third wall **703c** positioned within and extending across the bore **701c** of the tubular housing **701**. The first wall **703a**, the second wall **703b**, and the third wall **703c** are spatially disposed between the first end **701a** and the second end **701b** of the tubular housing **701**. As shown in FIG. 23, an aperture **703** extends through the first wall **703a** so as to permit the sample to travel from the connector **702** past the first wall **703a**. The first wall **703a**, the second wall **703b**, and the interior surface **701d** of the tubular housing **701** between the first wall **703a** and the second wall **703b** define a first fluid chamber **704**. The second wall **703b**, the third wall **703c** and the interior surface **701d** between the second wall **703b** and the third wall **703c** define a second fluid chamber **706**. A clot catcher **708** extends through the second wall **703b** and connects the first fluid chamber **704** to the second fluid chamber **706**. The third wall **703c** and the interior surface **701d** of the tubular housing **701** adjacent to the second end **701b** define an outlet portion **710** of the tubular housing **701**. As shown in FIG. 23, the fluid testing device **700** is also provided with a sensing housing **711** which may be connected to an exterior surface of the tubular housing **701**. The sensing housing **711** encompasses and supports one or more lateral flow strip **712**. A single lateral flow strip **712** is shown in FIG. 23 for purposes of brevity. The lateral flow strip **712** can be similar in construction and function as the lateral flow strip **112** discussed above. The sensing housing **711** also defines a vent portion **714**, and an optical zone **716**. In one embodiment, the lateral flow strip **712** is located outside of the tubular housing **701** and is positioned between the sensing housing **711** and the tubular housing **701**.

[0107] The connector **702** may be provided with means for connecting the fluid testing device **700** to a syringe, for example, such as a screw coupling, a bayonet joint, or a snap lock coupling on the inside or the outside of the connector **702**. For example, in one embodiment, the connector **702** may form a standard syringe luer for creating a leak-free connection between the fluid testing device **700** and a syringe (not shown). It should be understood, however, that the connector **702** may be any type of connector known in the industry for creating a leak-free connection between the blood testing device and a fluid sample container such as a syringe or fluid collection tube (commonly referred to as a vacutainer), for example.

[0108] The vent portion **714** allows equilibration of any pressure differences created during collection of test samples (e.g., air collected in a syringe), and thus allows gas to escape from the first fluid chamber **704**. Gases may pass around the lateral flow strip **712** through at least one aperture **720a** and **720b** (see FIG. 24) formed in the tubular housing **701** into a separation chamber **722** defined by one or more walls **723** in the sensing housing **711**. The apertures **720a** and **720b** may communicate with the first fluid chamber **704** and the separation chamber **722**. The separation chamber **722** may also be defined by a portion of the lateral flow strip **712**. As shown in FIG. 23, the separation chamber **722** is above the lateral flow strip **712**.

[0109] In use, the connector **702** is attached to the syringe to form a fluid tight seal, and a sample is introduced into the first fluid chamber **704** from the syringe thereby forming a contained system where the sample is unlikely to leak from the fluid testing device **700**. The third wall **703c** may be a fluid impermeable/gas permeable membrane. In this instance, the sample also flows through the clot catcher **708** and into the second chamber **706**. Any gas within the first chamber **704** is displaced by the sample into the aperture **720a** and **720b** and is vented through the vent portion **714**. Any gas within the second chamber **706** is also displaced by the sample and vented through the third wall **703c**. As the gas is displaced, pressure builds within the first chamber **704** and the second chamber **706** causing the sample to flow through the first and second apertures **720a** and **720b** into the separation chamber **722**. Because the separation chamber **722** is bounded by the

lateral flow strip **712**, at least a portion of the sample is introduced into the lateral flow strip **712**. Once the sample is introduced into the lateral flow strip **712**, capillary action causes the sample to move within the lateral flow strip **712** toward the optical zone **716**. When the sample is blood, as the sample moves through the lateral flow strip **712**, the lateral flow strip may separate any blood cells from plasma prior to the plasma reaching the optical zone **716**. The optical zone **716** can be a portion of the sensing housing **711** that can pass light within a visible part of the electromagnetic spectrum, thus permitting viewing of the plasma within the optical zone **716** to determine the results of one or more tests being conducted by the lateral flow strip **712**. If the tests indicate that the sample should be subject to further testing, then the fluid sample may be transferred through the outlet portion **710** into a testing instrument, such as a blood gas analyzer or other suitable testing instrument for additional testing. Suitable testing instruments may include urine analyzers, blood analyzers, or the like. In certain cases, a pipette (also known as a “probe”) (not shown) may be introduced through the outlet portion **710** and through the membrane **760** to draw a de-aerated sample from within the second fluid chamber **706**. Once the testing instrument has the sample, then one or more further tests can be conducted on the sample by the testing instrument.

[0110] The gases may then pass through a first vent aperture **724** formed within the wall **723**, and into a gas chamber **726** also defined by one or more walls **727** of the vent portion **714**. The gases may then pass through the gas chamber **726** of the vent portion **714** and out through an optional second vent aperture **728** formed within the wall **727**. The wall **727** can be cup shaped so as to define the gas chamber **726**. The gas chamber **726** of the vent portion **714** may be filled with an absorbent material **729** that allows gas to pass through the absorbent material **729** while absorbing any fluid of the sample that may have entered the gas chamber **726** and passed through the first vent aperture **724**.

[0111] The sensing housing **711** may also include a plurality of ribs **730a-f** forming a tortuous path for the sample to flow between the first fluid chamber **704** and an optical chamber **732** to be viewed through the optical zone **716**. The optical chamber **732** can be defined between the sensing housing **711** and the lateral flow strip **712**. The ribs **730a-f** engage the lateral flow strip **712** and define voids between the sensing housing **711** and the lateral flow strip **712**. Any excess fluid of the sample flowing through the lateral flow strip **712** may be displaced into the voids so as to prevent oversaturation of the lateral flow strip **712** prior to the optical zone **716**.

[0112] The ribs **730a-f** help prevent leaking as well as assisting in the separation of fluid constituents such as red blood cells and plasma, for instance. Thus, when a fluid such as blood containing blood cells suspended within plasma is introduced into the fluid testing device **700**, the red blood cells and plasma will be separated by the lateral flow strip **712** and the plasma will be visible in the optical chamber **732** through the optical zone **716** while the red blood cells remain in the first fluid chamber **704**, the second fluid chamber **706**, the separation chamber **722**, the adsorbent material **729**, and a portion of the lateral flow strip **712** used to separate the red blood cells from the plasma.

[0113] Under a predetermined amount of pressure, fluid may pass from the first fluid chamber **704** to the second fluid chamber **706** through the clot catcher **708**. The clot catcher **708** may be provided with a plurality of apertures **740** (only one of which is numbered) which have a geometry and size designed to allow certain fluid constituents to pass through the second wall **703b** while trapping larger constituents. For instance, when the fluid is blood containing red blood cells, plasma, and clotted blood, the clot catcher **708** will allow the plasma and the red blood cells to pass through into the second fluid chamber **706** while trapping the clotted blood in the first fluid chamber **704**.

[0114] The outlet portion **710** is bounded by the third wall **703c**, which may be in the form of a membrane **760** that closes the second fluid chamber **706** and keeps fluid from passing into the outlet portion **710** unless the membrane **760** is pierced. The membrane **760** may be formed of a fluid impermeable material. In some embodiments, the membrane **760** may be formed of a gas

permeable but fluid impermeable material to allow any air that has entered the second fluid chamber **706** to pass through the membrane **760** and out through the outlet **710**.

[0115] The outlet portion **710** may be sized and shaped to allow the fluid testing device **700** to be attached to a testing instrument such as a blood gas analyzer, for example. For instance, the outlet portion **710** of the fluid testing device **700** may form a standard syringe luer which provides a fluid tight seal with the testing instrument. Or, a probe or pipette from the testing instrument may be inserted through the outlet portion **710**, through the membrane **760** to draw a sample from within the second fluid chamber **706**.

[0116] In some embodiments of the fluid testing device **700**, the tubular housing **701** may be constructed of a body **770** having a first piece **772** and a second piece **774** sealably connected along line **776**. The sensing housing **711** may be formed of a separate component which is attached to the body **770**. Likewise the wall **727** of the vent portion **714** may be constructed as a separate component that is then attached to the wall **723** of the sensing housing **711**.

[0117] In some instances, the fluid testing device **700** can be made by forming the first piece **772**, the second piece **774**, the wall **723** and the wall **727**. Then, the first piece **772** is connected to the second piece **774** to form the body **770**. The lateral flow strip **712** is placed on a predetermined portion of the body **770**, and then the wall **723** is connected to the body **770** to encapsulate the lateral flow strip **712**. The absorbent material **729** is placed within the wall **727**, and then the wall **727** is connected to the wall **723** as shown in FIG. **23** to encapsulate the absorbent material **729**.

[0118] The tubular housing **701**, the sensing housing **711**, and the vent portion **714** may be formed of any appropriate material such as plastic, for instance. The tubular housing **701**, the sensing housing **711**, and the vent portion **714** may be formed using techniques such as injection molding, extrusion molding, vacuum casting, 3D printing, and the like. The tubular housing **701**, the sensing housing **711**, and the vent portion **714** may be joined using techniques and materials known in the art such as solvent bonding, heat, vibration welding, mechanical fastening, and the like.

[0119] In some embodiments of the fluid testing device **700**, the first aperture **724** may include a gas permeable filter (not shown) designed to allow gas to pass through while keeping fluid in the separation chamber **722**.

[0120] Referring now to FIGS. **26-28**, a fluid testing device **800** is illustrated having an inlet portion **802**, a container portion **804**, and an outlet portion **806**.

[0121] The inlet portion **802** may be sealably connected to the container portion **804** and the container portion **804** may be sealably connected to the outlet portion **806** using any known method in the industry. By way of example, the inlet portion **802**, container portion **804**, and outlet portion **806** may be connected using bonding agents such as glue or ultra-sonically welded, for instance.

[0122] The inlet portion **802** may be provided with a tubular housing **814** having a first end **816a**, a second end **816b**, a bore **818** extending from the first end **816a** to the second end **816b**, an interior surface **819**, and a connector **820** located at the first end **816a**. The inlet portion may also be provided with a first wall **822** positioned within and extending across the bore **818**. As shown in FIG. **27**, an aperture **824** extends through the first wall **822** so as to allow a sample to travel from the connector **820** through the first wall **822**. The connector **820** may be any suitable type of connector, such as a Luer connector for connecting the fluid testing device **800** to a syringe, for instance, or other fluid containers.

[0123] The container portion **804** may be provided with a tubular housing **826** having a first end **828a**, a second end **828b**, a bore **829** extending from the first end **828a** to the second end **828b**, and an interior surface **830**. The container portion **804** may also be provided with a second wall **831** positioned within and extending across the bore **818** and spatially disposed between the first end **828a** and the second end **828b** of the container portion **804**. The second wall **831** and the interior surface **830** of the tubular housing **826** between the first end **828a** and the second wall **831** define a first fluid chamber **833**. A clot catcher **832** may extend through the second wall **831** and connects the inlet portion **802** to the first fluid chamber **833**. The clot catcher **832** may operate as described

above with regard to element **740**. The interior surface **830** extending from the second wall **831** to the second end **828b** define a second fluid chamber **834** of the container portion **804**.

[0124] The fluid testing device **800** may also be provided with a sensing housing **845** having an optical zone **846**. The sensing housing **845** may be connected to an exterior surface of the tubular housing **826** of the container portion **804**. The sensing housing **845** encompasses and supports a test strip **844**. In the illustrated embodiment, the test strip **844** is located outside of the tubular housing **826** and is positioned between the sensing housing **845** and the tubular housing **826**.

[0125] A fluid channel **842** is formed in the tubular housing **826** between the interior surface **830** and a test chamber **843** defined between an exterior surface of the tubular housing **826** and an interior surface of the sensing housing **845**. The test strip **844** may be positioned within the test chamber **843**. When a fluid sample is introduced into the second fluid chamber **834**, capillary action causes the sample to move through the fluid channel **842** and onto the test strip **844**. The sample being on the test strip **844** can be observed through the optical zone **846**. The test strip **844** may include one or more reagent which can react with the sample and be used to determine any number of conditions, such as blood type, pathological analysis, glucose levels, pregnancy, etc.

[0126] The outlet portion **806** may be provided with a tubular housing **847** having a first end **847a**, a second end **847b**, a bore **848** extending from the first end **847a** to the second end **847b**, an interior surface **849**, a third wall **850**, a connector **852**, an outlet aperture **853** that passes through the third wall **850**, at least one channel **854** formed in the interior surface **849**, a shroud **855** extending circumferentially around the connector **852** and at least one air outlet aperture **856** that passes through the third wall **850**. The third wall **850** is connected to and extends from the connector **852**. In the example shown, the third wall **850** has a ring shape and extends around the connector **852**. The shroud **855** is connected to the third wall **850** and extends around at least a portion of the connector **852**. The shroud **855** is spaced a distance from the connector **852** to form a recess **858**. The air outlet aperture **856** communicates with the recess **858** so that air passing through the air outlet aperture **856** from the channel **854** is exhausted into the recess **858**.

[0127] A septum **860** and a filter **862** may be positioned within the outlet portion **806**, generally at the first end **847a** thereof. The septum **860** extends across the bore **848** so as to prevent gas or fluid from flowing through the bore **848**. As shown in FIG. 27, the filter **862** is located downstream from the septum **860**. The septum **860** may be located at the intersection of the second end **828b** of the container portion **804** and the first end **847a** of the outlet portion **806**. The filter **862** extends across and covers the at least one air channel **854**. The at least one air channel **854** (only one of which is numbered in FIG. 26) allows air to pass around the septum **860**, through the filter **862**, and out the air outlet aperture **856** without the air passing through the bore **848** defined by the connector **852**. The filter **862** is constructed of a gas permeable, fluid impermeable material that allows passage of air, but prevents passage of fluid. Thus, any air in a fluid in the second fluid cavity **840** may pass through the air channel **854**, around the septum **860**, through the filter **862** and out of the outlet portion **806** through the air outlet **876**. With respect to fluids, however, the septum **860** blocks the bore **848** to prevent fluids to pass into the bore **848**, and the filter **862** blocks fluids from passing into the air channel **854**.

[0128] The connector **852** of the outlet portion **806** may be sized and shaped to allow the fluid testing device **800** to be attached to testing instrument, such as a blood gas analyzer (not shown). For instance, the connector **852** of the outlet portion **806** may form a standard syringe Luer having an aperture **853** that allows a probe **874** of the testing instrument, such as a blood gas analyzer to pass through the bore **848** and into the second fluid cavity **840** by piercing the septum **860**. The outlet portion **806** and the container portion **804** of the fluid testing device **800** may be sized such that the probe **874** of the testing instrument does not pass through the container portion **804** but draws fluid to be tested from the second fluid cavity **840**.

[0129] In use, when the fluid container is attached to the fluid testing device **800** and a sample is introduced into the first fluid cavity **833**, any gas within the fluid container and the first fluid cavity

are displaced by the sample through the clot catcher **832** and into the second fluid cavity **840** in the container portion **804**. The clot catcher **832** may operate as described above with regard to element **740**. Any gas within the second chamber is also displaced by the sample and vented through the air outlet **856** of the third wall **850** into the recess **858**. The sample may pass by capillary action from the second fluid cavity **840** through fluid channel **842** onto the test strip **844**. The test strip **844** may be observed through optical zone **846**.

[0130] Referring now to FIGS. **29-32**, a fluid testing device **900** is shown. The fluid testing device **900** may be provided with an inlet portion **902**, a body portion **904**, a fluid director **906**, a filter **908**, a cap **910**, a test strip **912**, and an optical zone **914**.

[0131] The inlet portion **902** may be provided with a housing **915** having a first end **915a**, a second end **915b**, a bore **916** extending between the first end **915a** and the second end **915b**, an interior surface **917a**, and an exterior surface **917b**. The inlet portion **902** may also be provided with a connector **918** located at the first end **915a** and extending into the bore **916**. The connector **918** may be any suitable type of connector, such as a Luer connector for connecting the fluid testing device **900** to a syringe (not shown), for instance, or other fluid containers or testing devices.

[0132] The inlet portion **902** may further be provided with a first wall **919** positioned within and extending across the bore **916**. The first wall **919** connects the housing **915** to the connector **918**. As shown, the first wall **919** may have a ring shape. An aperture **921** extends through the connector **918** and the first wall **919**. The inlet portion **902** may further be provided with a clot catcher **920** disposed within the bore **916** of the inlet portion **902**. The clot catcher **920** may be downstream of the connector **918**, and extend across the bore **916** so as to form a first fluid cavity **923** downstream of the connector **918**. The first fluid cavity **923** is defined by the clot catcher **920**, the first wall **919**, and the housing **915**. The clot catcher **920** may be provided with a plurality of apertures **922** (only one of which is numbered in FIG. **29**) which are sized and shaped as has been described herein to allow fluid to pass through but catch fluid constituents that are larger than a predetermined size.

[0133] The body portion **904** may be provided with a housing **924** having a first end **924a**, a second end **924b**, a bore **925** extending between the first end **924a** and the second end **924b**, an interior surface **926a**, an exterior surface **926b**, and an aperture **927** extending between the interior surface **926a** and the exterior surface **926b**.

[0134] The body portion **904** may be connected to the inlet portion **902** with a portion of the bore **925** of the body portion **904** and a portion of the bore **916** of the inlet portion **902** forming a second fluid cavity **930**. The body portion **904** may be further provided with an outlet **932** extending between the interior surface **926a** and the second end **924b** and a plurality of air channels **934** (only one of which is numbered in FIG. **29**) formed in the exterior surface **926b** that direct fluid and air from the second fluid cavity **930** to the filter **908** as will be explained in further detail herein. The filter **908** may be a gas permeable/fluid impermeable material that allows the air to pass through while preventing the fluid from passing thus venting any air in the fluid. In some embodiments, an air channel **936** may be formed in a shoulder **968** of the cap **910** which supports and engages a portion of the filter **908** and allows air to pass through the filter **908** into the air channel **936** as will be explained in further detail herein.

[0135] The fluid director **906** may be provided with a conical body **940** having an interior surface **940a** and an exterior surface **940b** and an aperture **941** extending between the interior surface **940a** and the exterior surface **940b**. The conical body **940** may be provided with a frusto-conical shape. The fluid director **906** may be sized and shaped such that at least a portion of the interior surface **940a** of the fluid director **906** engages at least a portion of the exterior surface **926b** of the body portion **904**. When the fluid director **906** and the body portion **904** are connected, the aperture **941** of the fluid director **906** and the aperture **927** of the body portion **904** are aligned.

[0136] The cap **910** may be provided with a housing **951** having a first end **952**, a second end **954**, an interior surface **955a**, an exterior surface **955b**, a frusto-conically shaped center portion **956**, the shoulder portion **958**, a testing portion **960** sized and shaped to encompass and support the test strip

912, and an aperture **962** extending between the interior surface **955a** and the testing portion **960**. [0137] The conically shaped center portion **956** may be sized and shaped such that at least a portion of the interior surface **955a** of the cap **910** engages at least a portion of the exterior surface **940b** of the fluid director **906**. When the cap **910** is connected to the body portion **904** and the fluid director **906**, apertures **927**, **941**, and **962** are aligned to form a passage **950**.

[0138] In use, the connector **918** of the fluid testing device **900** may be connected to the syringe and a sample is introduced through the aperture **921** into the first fluid cavity **923**. Fluid and any gas introduced into the first fluid cavity **923** of the fluid testing device **900** pass through the clot catcher **920** and enter the second fluid cavity **930** where the fluid may be tested. Any gas within the second fluid cavity **930** and any air introduced into the second fluid cavity **930** from the syringe are displaced and pass through channels **934** and are vented through filter **908**. As the gas is displaced, pressure builds in the second fluid cavity **930** and at least a portion of the sample may travel through passage **950** and flow onto the test strip **912** which can be viewed through the optical zone **914**. The fluid may move through the passage **950** under pressure, or, the fluid may move through the passage **950** by capillary action. The test strip **912** may be any type of test strip for testing fluid.

[0139] Referring now to FIG. **33**, a fluid testing device **960** is shown. The fluid testing device **960** is similar to the fluid testing device **900** described above, therefore, in the interest of brevity only the differences will be described herein. The fluid testing device may be provided with a membrane **962** that seals an aperture **964** that is formed between an interior surface **965a** and an exterior surface **965b** of a cap **966** and an interior surface **967a** and an exterior surface **967b** of a fluid director **968** allowing access to a fluid cavity **970**. For instance, the membrane **962** of the fluid testing device **960** may be penetrated by a probe **972** to withdraw fluid from the fluid cavity **970**. As described above, the probe **972** may be part of a testing instrument such as a blood gas analyzer (not shown), and the fluid testing device **960** may be sized to ensure that the probe **972** stays in the fluid cavity **970** when fully inserted such that fluid is drawn from the fluid cavity **970** by the blood gas analyzer.

[0140] The following is a number list of non-limiting illustrative embodiments of the inventive concept disclosed herein: [0141] 1. A device, comprising: [0142] a housing constructed of a fluid impermeable material, and defining a first fluid port, and a second fluid port, the first fluid port configured to connect to a fluid collection device to receive a fluid sample from the fluid collection device into the housing, and the second port configured to pass the fluid sample from the housing into a testing instrument; [0143] a zone formed in the housing, the zone constructed of a material that allows an analysis of the fluid sample positioned within the housing, and located adjacent to the zone; and [0144] means for testing the fluid sample within the housing. [0145] 2. The device of illustrative embodiment 1, wherein the means for testing the fluid sample within the housing includes a matrix supported by the housing and positioned adjacent to the zone such that the fluid sample passed from the first fluid port to the matrix is treated prior to entering the zone. [0146] 3. The device of any one of illustrative embodiments 1 or 2, wherein the housing is separate from the fluid collection device, and wherein the fluid collection device is a syringe. [0147] 4. The device of any one of illustrative embodiments 1-3, wherein the fluid collection device is a syringe, and the testing instrument is an analyzer. [0148] 5. The device of illustrative embodiment 4, wherein the analyzer is a blood gas analyzer. [0149] 6. The device of illustrative embodiment 2, wherein the fluid sample is blood having red blood cells and plasma, and wherein the matrix is configured to separate the red blood cells from the plasma to present plasma substantially devoid of red blood cells within the zone. [0150] 7. The device of any one of illustrative embodiments 1-6, wherein the zone is an optical zone and wherein the optical zone is constructed of a material that is transparent to visible light. [0151] 8. The device of illustrative embodiment 2, wherein the matrix is a lateral flow membrane. [0152] 9. The device of illustrative embodiment 8, wherein the matrix is devoid of treatment with a reagent. [0153] 10. The device of illustrative embodiment 8, wherein the housing has an upper portion, a lower portion and a side, and wherein the lateral flow membrane is situated

on the side of the housing. [0154] 11. The device of illustrative embodiment 8, wherein the housing has an upper portion, a lower portion, and a longitudinal axis extending between the upper portion and the lower portion, and wherein the lateral flow membrane has a major axis extending in a non-parallel relationship with the longitudinal axis. [0155] 12. The device of illustrative embodiment 11, wherein the major axis extends side to side relative to the longitudinal axis. [0156] 13. The device of any one of illustrative embodiments 1-12, wherein the housing defines a first fluid reservoir, and wherein the housing defines a second fluid reservoir separated from the first fluid reservoir with a fluid impermeable divider, the housing having a fluid channel through the fluid impermeable divider connecting the first fluid reservoir and the second fluid reservoir, and wherein the matrix is positioned in the second fluid reservoir. [0157] 14. The device of illustrative embodiment 13, wherein the fluid channel is spaced a distance from the zone. [0158] 15. The device of any one of illustrative embodiments 1-14, further comprising a gas permeable/liquid impermeable membrane covering a third fluid port positioned between the first fluid port and the second fluid port. [0159] 16. The device of illustrative embodiment 2, wherein the matrix is a flow membrane configured to separate red blood cells from plasma. [0160] 17. The device of any one of illustrative embodiments 2 or 16, wherein the matrix is treated with a reagent. [0161] 18. The device of illustrative embodiment 2, wherein the fluid sample is blood having red blood cells and plasma, and wherein the matrix is configured to separate the red blood cells from the plasma to present plasma substantially devoid of red blood cells within the zone. [0162] 19. The device of illustrative embodiment 1, wherein the zone is an optical zone and wherein the optical zone is constructed of a material that is transparent to visible light. [0163] 20. The device of illustrative embodiment 2, wherein the matrix has a distal end in the zone, and wherein the distal end is treated with a reagent. [0164] 21. The device of illustrative embodiment 2, wherein the matrix has a proximal end away from the zone, and wherein the proximal end is treated with the reagent. [0165] 22. The device of any one of illustrative embodiments 1-21, wherein the first fluid port includes a needle. [0166] 23. The device of any one of illustrative embodiments 1-21, wherein the second fluid port is a luer connector. [0167] 24. The device of any one of illustrative embodiments 1-21, wherein the second fluid port is a male port. [0168] 25. The device of any one of illustrative embodiments 1-21, wherein the second fluid port is a female port. [0169] 26. A method comprising: [0170] extracting a fluid sample from a fluid source with a fluid collection device having a first fluid housing such that the fluid sample is positioned within a first fluid reservoir defined by the first fluid housing; [0171] connecting a first fluid housing to a second fluid housing; [0172] passing a portion of the fluid sample from the first fluid reservoir in the first fluid housing into a second fluid reservoir in the second fluid housing, at least a portion of the fluid sample interacting with at least one of a matrix and a sensor in the second fluid housing; [0173] analyzing the fluid sample in the second fluid housing to conduct a first test of the fluid sample; [0174] passing a portion of the fluid sample from the second fluid reservoir into an analyzer; and [0175] analyzing the fluid sample in the analyzer to conduct a second test of the fluid sample. [0176] 27. The method of illustrative embodiment 26, wherein the second fluid housing has a third fluid reservoir separated from the second fluid reservoir by a fluid impermeable divider, and wherein at least a portion of the fluid sample passes from the second fluid reservoir into the third fluid reservoir via a fluid channel through the fluid impermeable divider, the portion of the fluid sample interacting with the at least one sensor or matrix in the third fluid reservoir. [0177] 28. The method of illustrative embodiment 27, wherein the matrix is a flow membrane in the third fluid reservoir, and wherein the method comprises the flow membrane separating the portion of the fluid sample into at least two constituent parts. [0178] 29. The method of illustrative embodiment 28, wherein the fluid sample is blood, and wherein the at least two constituent parts includes red blood cells, and plasma. [0179] 30. The method of illustrative embodiment 28, wherein the sensor includes a reagent. [0180] 31. The method of any one of illustrative embodiments 26-29, wherein the sensor includes a reagent. [0181] 32. The method of illustrative embodiment 26, wherein the sensor is an

electrochemical sensor. [0182] 33. The method of any one of illustrative embodiments 26-32, wherein the fluid collection device is a syringe, and the fluid sample is a bodily fluid. [0183] 34. The method of any one of illustrative embodiments 26-32, wherein the fluid collection device is a vacutainer, and the fluid sample is a bodily fluid. [0184] 35. A method, comprising: [0185] passing a fluid sample of blood containing blood cells and plasma from a syringe having a first fluid reservoir in a first fluid housing into a second fluid reservoir in a second fluid housing, [0186] separating the blood cells from the plasma within the second fluid reservoir into a first zone containing plasma and blood cells, and a second zone containing plasma and being substantially devoid of blood cells; [0187] analyzing the plasma within the second zone to determine a degree of hemolysis within the blood sample; and [0188] passing a portion of the fluid sample containing red blood cells and plasma into an analyzer subsequent to analyzing the plasma within the second zone. [0189] 36. The method of illustrative embodiment 35, wherein the analyzer is a blood gas analyzer. [0190] 37. The method of any one of illustrative embodiments 35-36, wherein analyzing the plasma includes a colorimetric analysis of the plasma. [0191] 38. The method of any one of illustrative embodiments 35-36, wherein analyzing the plasma includes analyzing the plasma with a sensor. [0192] 39. The method of illustrative embodiment 38, wherein the sensor includes a reagent. [0193] 40. The method of illustrative embodiment 38, wherein the sensor is an electrochemical sensor. [0194] 41. The method of any one of illustrative embodiments 35-40, wherein separating the blood cells from the plasma within the second fluid reservoir into the first zone containing plasma and blood cells, and the second zone containing plasma and being substantially devoid of blood cells is defined further as separating the blood cells from the plasma by actuating a transducer to generate forces applied to the plasma and blood cells within the second fluid reservoir. [0195] 42. The method of illustrative embodiment 41, wherein the transducer is an acoustic transducer. [0196] 43. The method of illustrative embodiment 41, wherein the transducer is a magnetic transducer. [0197] 44. The method of illustrative embodiment 41, wherein the transducer is a dielectrophoretic transducer. [0198] 45. The method of any one of illustrative embodiments 41-44, wherein the transducer is located outside of the second fluid housing. [0199] 46. The method of any one of illustrative embodiments 41-45, wherein the second fluid housing has a port in communication with the second fluid reservoir, and further comprising passing at least a portion of the plasma that is substantially devoid of blood cells out of the second fluid reservoir through the port. [0200] 47. A fluid testing device, comprising: [0201] a housing constructed of a fluid impermeable material and having a first fluid port configured to receive a fluid sample from a fluid collection device and a second fluid port configured to pass a portion of the fluid sample to an analyzer; [0202] an optical zone formed in the housing, the optical zone constructed of a material that allows a colorimetric analysis of the fluid sample positioned within the housing, and located adjacent to the optical zone; and [0203] a lateral flow membrane positioned between the housing and the optical zone such that a portion of the fluid sample to be received by the first fluid port from the fluid collection device passes through the lateral flow membrane to direct a portion of the fluid sample to enter the optical zone. [0204] 48. The fluid testing device of illustrative embodiment 47, further comprising a piston positioned within the housing. [0205] 49. An assembly, comprising: [0206] a fluid collection device having a first fluid reservoir containing a fluid sample, the fluid sample being a bodily fluid; [0207] a fluid treatment module comprising a housing having a first fluid port and a second fluid port, the first fluid port connected to the fluid collection device, the fluid treatment module defining a second fluid reservoir and a testing device within the housing, the testing device receiving a portion of the fluid sample and conducting a first test of the portion of the fluid sample; and [0208] an analyzer connected to the second fluid port of the fluid treatment module when the first fluid port of the fluid treatment module is connected to the fluid collection device, the analyzer receiving a portion of the fluid sample from at least one of the fluid collection device and the fluid treatment module, the analyzer configured to conduct a second test of the portion of the fluid sample. [0209] 50. The assembly of illustrative embodiment

49, wherein the fluid collection device is a syringe. [0210] 51. The assembly of illustrative embodiment 49 or 50, wherein the testing device is a lateral flow membrane. [0211] 52. The assembly of illustrative embodiment 51, wherein the housing of the fluid treatment module has an upper portion, a lower portion and a side, and wherein the lateral flow membrane is situated on the side of the housing. [0212] 53. The assembly of illustrative embodiment 51, wherein the housing has an upper portion, a lower portion, and a longitudinal axis extending between the upper portion and the lower portion, and wherein the lateral flow membrane has a major axis extending in a non-parallel relationship with the longitudinal axis. [0213] 54. The assembly of illustrative embodiment 53, wherein the major axis extends side to side relative to the longitudinal axis. [0214] 55. The assembly of illustrative embodiment 49, wherein the housing of the fluid treatment module defines a third fluid reservoir separated from the second fluid reservoir with a fluid impermeable divider, the housing having a fluid channel through the fluid impermeable divider connecting the second fluid reservoir and the third fluid reservoir, and wherein the testing device is positioned in the third fluid reservoir. [0215] 56. The assembly of illustrative embodiment 55, wherein the fluid channel is spaced a distance from the zone. [0216] 57. The assembly of any one of illustrative embodiments 49-56, further comprising a gas permeable membrane positioned within the housing of the fluid treatment module, and wherein the analyzer includes a probe extending through the gas permeable membrane. [0217] 58. The assembly of illustrative embodiment 49, wherein the testing device is a flow membrane configured to separate red blood cells from plasma. [0218] 59. The assembly of illustrative embodiment 49, wherein the testing device includes a matrix treated with a reagent. [0219] 60. The assembly of any one of illustrative embodiments 49-59, wherein the first fluid port includes a needle. [0220] 61. The assembly of any one of illustrative embodiments 49-60, wherein [0221] the second fluid port is a luer connector. [0222] 62. The assembly of any one of illustrative embodiments 49-59, wherein the second fluid port is a male port. [0223] 63. The assembly of any one of illustrative embodiments 49-59, wherein the second fluid port is a female port. [0224] 64. A method, comprising: [0225] receiving a bodily sample from a patient into a fluid collection device; [0226] passing a first portion of the bodily sample from the fluid collection device into a fluid treatment module; [0227] conducting a test on the bodily sample within the fluid treatment module; and [0228] passing a second portion of the bodily sample through at least a portion of the fluid treatment module into an analyzer. [0229] 65. The method of illustrative embodiment 64, wherein the test is a first test, and further comprising conducting a second test on the second portion of the bodily sample within the analyzer. [0230] 66. The method of illustrative embodiment 65, wherein the first test is conducted prior to passing the second portion of the bodily sample into the analyzer. [0231] 67. The method of illustrative embodiment 64, wherein passing the second portion of the bodily sample into the analyzer is defined further as passing the second portion of the bodily sample through at least a portion of the fluid treatment module into the analyzer when the fluid treatment module is connected to the fluid collection device. [0232] 68. The method of any one of illustrative embodiments 64-67, wherein the fluid collection device is a syringe. [0233] 69. The method of any one of illustrative embodiments 64-67, wherein the fluid collection device is a vacutainer. [0234] 70. The method of any one of illustrative embodiments 64-67, wherein the fluid treatment module includes a housing defining a first fluid reservoir separated from a second fluid reservoir by a fluid impermeable divider, and wherein at least a portion of the bodily sample passes from the first fluid reservoir into the second fluid reservoir via a fluid channel through the fluid impermeable divider, the portion of the bodily sample interacting with at least one sensor or matrix in the second fluid reservoir. [0235] 71. The method of illustrative embodiment 70, wherein the matrix is a flow membrane in the second fluid reservoir, and wherein the method comprises the flow membrane separating the portion of the bodily sample into at least two constituent parts. [0236] 72. The method of illustrative embodiment 71, wherein the bodily sample is blood, and wherein the at least two constituent parts includes red blood cells and plasma. [0237] 73. The method of illustrative embodiment 70, wherein the sensor includes a reagent. [0238] 74. The

method of illustrative embodiment 70, wherein the sensor is an electrochemical sensor. [0239] 75. The method of any one of Illustrative embodiments 64-74, wherein passing the second portion of the bodily sample through at least a portion of the fluid treatment module into the analyzer includes inserting a probe from the analyzer into a fluid port of the fluid treatment module. [0240] 76. The method of illustrative embodiment 75, wherein the probe includes an end, and wherein inserting the probe from the analyzer into the fluid port of the fluid treatment module includes inserting the end of the probe through the fluid treatment module and into the fluid collection device. [0241] 77. The method of illustrative embodiment 75, wherein the probe includes an end, and wherein inserting the probe from the analyzer into the fluid port of the fluid treatment module includes inserting the end of the probe into the fluid treatment module without the end of the probe entering into the fluid collection device. [0242] 78. A fluid testing assembly, comprising: [0243] a fluid testing device, comprising: [0244] a housing constructed of a fluid impermeable material; [0245] a treatment window formed in the housing, the treatment window constructed of a material capable of passing forces into the housing; [0246] an optical zone formed in the treatment window of the housing, the optical zone constructed of a material that allows a colorimetric analysis of a fluid sample positioned within the housing, and located adjacent to the optical zone; and [0247] a reader, comprising: [0248] a bay for receiving at least a portion of the fluid testing device; [0249] a transducer positioned adjacent to the bay such that when the fluid testing device is positioned within the bay, the transducer is configured to selectively generate forces directed through the treatment window of the housing and into the fluid sample; and [0250] a control unit for selectively actuating and deactivating the transducer; and [0251] a sensor positioned adjacent to the optical zone for obtaining colorimetric information from the optical zone. [0252] 79. The fluid testing assembly of illustrative embodiment 78, wherein the transducer is an acoustic transducer. [0253] 80. The fluid testing assembly of illustrative embodiment 78, wherein the transducer is a magnetic transducer. [0254] 81. The fluid testing assembly of illustrative embodiment 78, wherein the transducer is a dielectrophoretic transducer. [0255] 82. The fluid testing assembly of any one of illustrative embodiments 78-81, wherein the fluid sample has a first constituent part and a second constituent part, the housing defining a first channel and a second channel adjacent to the treatment window such that the first channel is positioned to receive the first constituent part and the second channel is positioned to receive the second constituent part. [0256] 83. The fluid testing assembly of any one of illustrative embodiments 78-82, wherein the housing includes an optical zone formed in the treatment window of the housing, the optical zone constructed of a material that allows the colorimetric analysis of the fluid sample, the fluid sample positioned within the housing and located adjacent to the optical zone. [0257] 84. The fluid testing assembly of any one of illustrative embodiments 78-83, wherein the fluid testing device is integrated with a fluid collection device. [0258] 85. The fluid testing assembly of illustrative embodiment 84, wherein the fluid collection device is a syringe. [0259] 86. The fluid testing assembly of illustrative embodiment 84, wherein the fluid collection device is a vacutainer. [0260] 87. The fluid testing assembly of illustrative embodiment 86, wherein the vacutainer includes a housing sealed with a stopper, and wherein the fluid testing device includes a needle positioned through the stopper. [0261] 88. A fluid testing assembly, comprising: [0262] a fluid testing device, comprising: [0263] a housing constructed of a fluid impermeable material; [0264] a treatment window formed in the housing, the treatment window constructed of a material capable of passing forces into the housing; and [0265] a transducer positioned adjacent to the treatment window, the transducer being configured to selectively generate forces directed through the treatment window of the housing and into a fluid sample to separate the fluid sample into a first constituent part and a second constituent part. [0266] 89. The fluid testing assembly of illustrative embodiment 88, wherein the transducer is an acoustic transducer. [0267] 90. The fluid testing assembly of illustrative embodiment 88, wherein the transducer is a magnetic transducer. [0268] 91. The fluid testing assembly of illustrative embodiment 88, wherein the transducer is a dielectrophoretic transducer. [0269] 92. The fluid

testing assembly of any one of illustrative embodiments 88-91, wherein the housing defines a first channel and a second channel, adjacent to the treatment window such that the first channel is positioned to receive the first constituent part and the second channel is positioned to receive the second constituent part. [0270] 93. The fluid testing assembly of any one of illustrative embodiments 88-92, wherein the housing includes an optical zone formed in the treatment window of the housing, the optical zone constructed of a material that allows a colorimetric analysis of the fluid sample positioned within the housing, and located adjacent to the optical zone. [0271] 94. The fluid testing assembly of any one of illustrative embodiments 88-93, wherein the fluid testing device is integrated with a fluid collection device. [0272] 95. The fluid testing assembly of illustrative embodiment 94, wherein the fluid collection device is a syringe. [0273] 96. The fluid testing assembly of illustrative embodiment 94, wherein the fluid collection device is a vacutainer. [0274] 97. The fluid testing assembly of illustrative embodiment 96, wherein the vacutainer includes a housing sealed with a stopper, and wherein the fluid testing device includes a needle positioned through the stopper. [0275] 98. A blood testing assembly, comprising: [0276] a blood testing device, comprising: [0277] a housing constructed of a fluid impermeable material; [0278] a treatment window formed in the housing, the treatment window constructed of a material capable of passing acoustic forces into the housing; [0279] an optical zone formed in the treatment window of the housing, the optical zone constructed of a material that allows a colorimetric analysis of a blood sample positioned within the housing, and located adjacent to the optical zone; and [0280] a reader, comprising: [0281] an acoustic transducer position to selectively generate acoustic forces directed through the treatment window of the housing and into the blood sample; and [0282] a control unit for selectively actuating and deactuating the acoustic transducer. [0283] 99. A method, comprising: [0284] within a fluid treatment module, separating blood cells from plasma within a blood sample into a first zone containing plasma and blood cells, and a second zone containing plasma and being substantially devoid of blood cells; and [0285] colorimetrically analyzing the plasma within the second zone to determine a degree of hemolysis within the blood sample. [0286] 100. The method of illustrative embodiment 99, wherein the fluid treatment module includes a housing constructed of a fluid impermeable material, and defining a first fluid port, and a second fluid port, the first fluid port configured to connect to a fluid collection device to receive a fluid sample from the fluid collection device into the housing, and the second port configured to pass the fluid sample from the housing into a testing instrument. [0287] 101. The method of illustrative embodiment 99, further comprising connecting a first fluid port of the fluid treatment module to a second fluid port of a syringe containing the blood sample; and passing a portion of the blood sample into the fluid treatment module. [0288] 102. A method, comprising: [0289] within a blood testing device having a plunger positioned within a housing in which the plunger and an interior surface of the housing define a fluid reservoir, separating blood cells from plasma within a blood sample into a first zone containing plasma and blood cells, and a second zone containing plasma and being substantially devoid of blood cells; and [0290] colorimetrically analyzing the plasma within the second zone to determine a degree of hemolysis within the blood sample. [0291] 103. A syringe, comprising: [0292] a housing having a first fluid reservoir; [0293] a plunger positioned within the housing and bordering the first fluid reservoir; and [0294] means for testing a fluid sample when the fluid sample is positioned within the housing. [0295] From the above description, it is clear that the inventive concepts disclosed herein is well adapted to carry out the objects and to attain the advantages mentioned herein as well as those inherent in the inventive concepts disclosed herein. While presently preferred embodiments of the inventive concepts disclosed herein have been described for purposes of this disclosure, it will be understood that numerous changes may be made which will readily suggest themselves to those skilled in the art and which are accomplished within the scope and coverage of the inventive concepts disclosed and claimed herein.

Claims

1. A device, comprising: a housing constructed of a fluid impermeable material and defining a first fluid port and a second fluid port, the first fluid port configured to connect to a fluid collection device, the first fluid port configured to receive a fluid sample from the fluid collection device into the housing, and the second fluid port configured to pass the fluid sample from the housing into an external testing instrument; a zone formed in the housing, the zone constructed of a material that allows an analysis of the fluid sample positioned within the housing and located adjacent to the zone; and means for testing the fluid sample within the housing.
2. The device of claim 1, wherein the means for testing the fluid sample within the housing includes a matrix supported by the housing and positioned adjacent to the zone such that the fluid sample passed from the first fluid port to the matrix is treated prior to entering the zone.
3. The device of claim 1, wherein the housing is separate from the fluid collection device, and wherein the fluid collection device is a syringe.
4. The device of claim 1, wherein the fluid collection device is a syringe, and the external testing instrument is an analyzer.
5. The device of claim 4, wherein the analyzer is a blood gas analyzer.
6. The device of claim 2, wherein the fluid sample is blood having red blood cells and plasma, and wherein the matrix is a lateral flow membrane configured to separate the red blood cells from the plasma to present plasma substantially devoid of red blood cells within the zone.
7. The device of claim 1, wherein the zone is constructed of a material that allows analysis of the plasma substantially devoid of red blood cells within the zone to determine a degree of hemolysis.
8. The device of claim 1, wherein the zone is an optical zone and wherein the optical zone is constructed of a material that is transparent to visible light.
9. The device of claim 8, wherein the optical zone is constructed of a material that is transparent to visible light to allow an analysis of the fluid sample positioned within the housing and located adjacent to the zone by a human eye through the optical zone.
10. The device of claim 1, wherein the fluid sample is blood comprising red blood cells and plasma, and wherein the means for testing the fluid sample within the housing comprises: an optical reader configured to capture information indicative of at least one parameter of the fluid sample; and a control unit comprising circuitry configured to receive the information captured by the optical reader and to analyze the information to determine a degree of hemolysis of the blood.
11. The device of claim 10 wherein the circuitry is configured to receive the information captured by the optical reader and to colorimetrically analyze the information to determine the degree of hemolysis of the blood.
12. The device of claim 10 wherein the optical reader and the control unit are components of a point of care analyzer.
13. The device of claim 2, wherein the matrix is a lateral flow membrane.
14. The device of claim 13, wherein the matrix is devoid of treatment with a reagent.
15. The device of claim 13, wherein the housing has an upper portion, a lower portion and a side, and wherein the lateral flow membrane is situated on the side of the housing.
16. The device of claim 13, wherein the housing has an upper portion, a lower portion, and a longitudinal axis extending between the upper portion and the lower portion, and wherein the lateral flow membrane has a major axis extending in a nonparallel relationship with the longitudinal axis.
17. The device of claim 16, wherein the major axis extends side to side relative to the longitudinal axis.
18. The device of claim 1, wherein the housing defines a third fluid port positioned between the first fluid port and the second fluid port, and further comprising a gas permeable/liquid

impermeable membrane covering the third fluid port.

19. The device of claim 2, wherein the matrix is a flow membrane configured to separate red blood cells from plasma.
 20. The device of claim 2, wherein the matrix is treated with a reagent.
 21. The device of claim 20, wherein the reagent changes color when reacting with the fluid sample to pre-analyze the fluid sample for a certain analyte.
 22. The device of claim 20, wherein the fluid sample is urine, and wherein the reagent changes color when reacting with the urine to pre-analyze the fluid sample for a certain analyte.
 23. The device of claim 22, wherein the reagent is configured to conduct a pregnancy test.
 24. The device of claim 22, wherein the reagent is configured to test for creatinine.
 25. The device of claim 20, wherein the fluid sample is blood containing red blood cells and plasma, and wherein the reagent is configured to change color when reacting with the plasma of the blood to pre-analyze the blood for hemolysis.
 26. The device of claim 2, wherein the fluid sample is blood having red blood cells and plasma, and wherein the matrix is configured to separate the red blood cells from the plasma to present plasma substantially devoid of red blood cells within the zone.
 27. The device of claim 2, wherein the matrix has a distal end in the zone, and wherein the distal end is treated with a reagent.
 28. The device of claim 27, wherein the reagent is configured to change color when reacting with the fluid sample to pre-analyze the fluid sample for a certain analyte.
 29. The device of claim 27, wherein the fluid sample is urine, and wherein the reagent changes color when reacting with the urine to pre-analyze the fluid sample for a certain analyte.
 30. The device of claim 29, wherein the reagent is configured to conduct a pregnancy test.
 31. The device of claim 29, wherein the reagent is configured to test for creatinine.
 32. The device of claim 27, wherein the fluid sample is blood containing red blood cells and plasma, and wherein the reagent is configured to change color when reacting with the plasma of the blood to pre-analyze the blood for hemolysis.
 33. The device of claim 2, wherein the matrix has a proximal end away from the zone, and wherein the proximal end is treated with a reagent.
 34. The device of claim 33, wherein the reagent is configured to change color when reacting with the fluid sample to pre-analyze the fluid sample for a certain analyte.
 35. The device of claim 1, wherein the first fluid port includes a needle.
 36. The device of claim 1, wherein the second fluid port is a luer connector.
 37. The device of claim 1, wherein the second fluid port is a male port.
 38. The device of claim 1, wherein the second fluid port is a female port.
 39. The device of claim 1, wherein the housing defines a fluid channel within the housing and configured to receive a portion of the fluid sample, and further comprising one or more analyte sensors positioned within the fluid channel and positioned to interact with the fluid sample passing through the fluid channel.
 40. The device of claim 39, wherein the one or more analyte sensors include an electrochemical sensor.
 41. The device of claim 40, wherein the electrochemical sensor is selected from a group consisting of a potentiometric sensor, and an amperometric sensor.
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