

BIOFLUID DISPENSING AND ASSAY APPARATUSES

Cross Reference to Related Application(s)

- 5 The present disclosure claims the benefit of Greece Patent Application No. 20190100403 filed on 18 September 2019, which is incorporated in its entirety by reference herein.

Technical Field

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The present disclosure generally relates to biofluid dispensing and assay apparatuses. More particularly, the present disclosure describes various embodiments of a dispensing apparatus for dispensing biofluid samples and an assay apparatus for assaying the biofluid samples.

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Background

An assay is an investigative or analytic procedure in medicine and/or biology contexts for qualitatively assessing or quantitatively measuring the presence or amount or the functional activity of analytes in biofluid samples. A subject or patient may provide the biofluid sample to detect the presence or extent of a certain disease. The biofluid sample may come in the form as excretion or secretion from a living individual which would include from serum, interstitial fluid, urine, blood, saliva, intravascular fluid, cytosol, and intracellular fluid.

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As an example, urinalysis is a type of assay performed on biofluid samples, particularly urine samples, from individuals that provides a source of information about the anatomy and function of an individual's kidneys and urinary tract. It provides insights into the status of systemic diseases such as chronic kidney disease and/or diabetes mellitus. Urinary albumin is one of the key markers tested on the urine samples so that to gather information to establish the individual's present state of function of the kidney and urinary tract. It is widely adopted that urinary albumin is used as the gold standard to diagnose chronic kidney disease. Creatinine is another key marker that is tested on

the urine samples. PCT publication WO 2015/130225 describes tests for diagnosing chronic kidney disease by determining urine albumin and creatinine concentrations and the corresponding albumin-to-creatinine ratio.

- 5 Albumin and creatinine concentrations can be measured at different times or in different steps, however this takes a longer time and needs more manual operation steps, so concurrent analysis is desirable to reduce measurement time. However, manual operation steps are prone to human errors that contribute to inconsistent, less reliable results. Measurement of albumin and creatinine requires chemical reactions
10 of urine with reagents and a suitable reaction time is required to obtain accurate and consistent results. Manual operation steps may result in measuring for albumin and creatinine too early or too late, i.e. the reaction time is inconsistent or incorrect. Trained personnel and supporting lab equipment may be required for improving the urinalysis assay process. However, trained personnel and/or proper equipment is uncommon in
15 remote locations where there is limited access to healthcare.

- PCT publication WO 2017/078630 describes a point-of-care assay system for home or clinical use. The assay system uses a dispensing apparatus to dispense biofluid samples into cuvettes and an assay apparatus then analyses the biofluid samples. A
20 separate actuator is used to actuate a piston assembly to thereby dispense the biofluid samples into the cuvettes. The cuvettes containing the biofluid samples are then placed into the assay apparatus for analysis. There may be some delay between dispensing of the biofluid samples into the cuvettes and placing of the cuvettes into the assay apparatus. This in turn affects the reaction time between the biofluid
25 samples and reagents in the cuvettes, potentially compromising the analysis results and even false diagnoses.

- Therefore, in order to address or alleviate at least one of the aforementioned problems and/or disadvantages, there is a need to provide improved apparatuses for dispensing
30 and assaying biofluid samples.

Summary

According to a first aspect of the present disclosure, there is a dispensing apparatus for dispensing biofluid, the dispensing apparatus comprising a cartridge. The cartridge comprises: a receiving chamber for receiving a bulk sample of biofluid; a set of metering chambers fluidically communicative with the receiving chamber, each
5 metering chamber configured for holding a predefined volume of biofluid sample apportioned from the biofluid bulk sample; and each metering chamber comprising an outlet for dispensing the respective biofluid sample and a dispensing filter for filtering the respective biofluid sample during dispensing, wherein the biofluid samples in the metering chambers are dispensable through the outlets by applying vacuum pressure
10 in the cartridge, the dispensing filters preventing dispensing of the biofluid samples in absence of the vacuum pressure.

According to a second aspect of the present disclosure, there is an assay apparatus for assaying biofluid. The assay apparatus comprises: a vacuum chamber for
15 removably housing a dispensing apparatus comprising a set of cuvettes and a set of biofluid samples, the cuvettes comprising a set of reagents; a vacuum cover for sealing the dispensing apparatus in the vacuum chamber; a vacuum device for applying vacuum pressure in the vacuum chamber, the vacuum pressure for dispensing the biofluid samples into the cuvettes, such that the biofluid samples react with the
20 reagents to form assay samples; and a set of assay control systems for controlling the vacuum device and performing an assay process, the assay process comprising applying the vacuum pressure to dispense the biofluid samples and assaying the assay samples in the cuvettes.

25 According to a third aspect of the present disclosure, there is a method for assaying biofluid. The method comprises: providing an assay apparatus comprising a vacuum chamber, a vacuum cover, and a vacuum device; loading a dispensing apparatus into the vacuum chamber, the dispensing apparatus comprising a set of cuvettes and a set of biofluid samples, the cuvettes comprising a set of reagents; sealing the dispensing
30 apparatus in the vacuum chamber with the vacuum cover; operating the vacuum device to apply vacuum pressure in the vacuum chamber, the vacuum pressure for dispensing the biofluid samples into the cuvettes, such that the biofluid samples react with the reagents to form assay samples; and operating a set of assay control systems

to control the vacuum device and perform an assay process, the assay process comprising applying the vacuum pressure to dispense the biofluid samples and assaying the assay samples in the cuvettes.

5 According to a fourth aspect of the present disclosure, there is an assay system for assaying biofluid. The assay system comprises: a base station; a number of test stations communicatively connected to the base station, each test station comprising an assay apparatus. The assay apparatus comprises: a vacuum chamber for removably housing a dispensing apparatus comprising a set of cuvettes and a set of
10 biofluid samples, the cuvettes comprising a set of reagents; a vacuum cover for sealing the dispensing apparatus in the vacuum chamber; and a set of assay control systems for performing an assay process. The assay system further comprising a set of vacuum devices for applying vacuum pressure in the vacuum chambers of the test stations, the vacuum pressure for dispensing the biofluid samples into the cuvettes,
15 such that the biofluid samples react with the reagents to form assay samples, wherein the respective assay process comprises applying the vacuum pressure to dispense the biofluid samples and assaying the assay samples in the cuvettes; and wherein the base station is configured for controlling the test stations to perform the assay processes.

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According to a fifth aspect of the present disclosure, there is an identification system for supporting an assay process performed on biofluid samples of a patient. The identification system comprises: a first identification label permanently disposed on a dispensing apparatus for collecting and dispensing biofluid for assaying, the first
25 identification label comprising encoded first identification data associated with the dispensing apparatus; a second identification label permanently disposed on the dispensing apparatus, the second identification label comprising encoded second identification data associated with reagents contained in cuvettes of the dispensing apparatus; and a third identification label detachably attached to the dispensing
30 apparatus, the third identification label comprising encoded third identification data for the patient to access the assay results, wherein the first identification data and/or second identification data are verifiable against reference identification data for verifying the dispensing apparatus and/or the reagents; and wherein the third

identification data enable the patient to access the assay results using an electronic device of the patient.

According to a sixth aspect of the present disclosure, there is a computerized method
5 for availing assay results from an assay process performed on biofluid samples of a patient. The computerized method comprises: receiving, from a first electronic device, a request from the patient to access an online interface and initiate the assay process, the patient request comprising a device identifier of the first electronic device and identification data associated with a dispensing apparatus for collecting the biofluid
10 samples; associating the identification data with the device identifier; receiving, from a second electronic device, a request from an operator performing the assay process to access the online interface and input the assay results, the operator request comprising the identification data and the assay results; associating the assay results with the identification data; and sending a results message to the first electronic device,
15 the results message indicating the assay results are available on the online interface accessed by the first electronic device.

Apparatuses for dispensing and assaying biofluid samples according to the present disclosure are thus disclosed herein. Various features, aspects, and advantages of the
20 present disclosure will become more apparent from the following detailed description of the embodiments of the present disclosure, by way of non-limiting examples only, along with the accompanying drawings.

Brief Description of the Drawings

25 Figure 1A to Figure 1D are various illustrations of a dispensing apparatus for dispensing biofluid.

Figure 2A is a cross-sectional illustration of the dispensing apparatus including a set
30 of cuvettes.

Figure 2B is an exploded illustration of the dispensing apparatus including the cuvettes.

Figure 3A and Figure 3B are cross-sectional illustrations of the dispensing apparatus during dispensing of biofluid samples.

Figure 4A and Figure 4B are various other illustrations of the dispensing apparatus.

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Figure 5A and Figure 5B are various other illustrations of the dispensing apparatus.

Figure 6A to Figure 6D are various illustrations of a metering chamber of the dispensing apparatus.

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Figure 7A to Figure 7C are various illustrations of a piston assembly of the dispensing apparatus.

Figure 7D is an illustration of a cartridge lid of the dispensing apparatus.

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Figure 8A and Figure 8B are various illustrations of the cuvettes and a cuvette casing for holding the cuvettes.

Figure 9A to Figure 9C are various illustrations of an assay apparatus for assaying biofluid.

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Figure 10 is a flowchart illustration of a method for assaying biofluid using the assay apparatus.

Figure 11A and Figure 11B are various illustrations of a vacuum cover of the assay apparatus.

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Figure 12A and Figure 12B are illustrations of a vacuum device of the assay apparatus and a vacuum control system for controlling the vacuum device.

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Figure 13A and Figure 13B are various illustrations of a vacuum actuator of the assay apparatus.

Figure 14 is an illustration of an electromagnetic mixing system of the assay apparatus.

Figure 15A to Figure 15C are various illustrations of an optical measurement system of the assay apparatus.

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Figure 16 is an illustration of a time schedule for operating the optical measurement system.

Figure 17A and Figure 17B are various illustrations of an assay system for assaying
10 biofluid.

Figure 18A to Figure 18C are various arrangements of test stations of the assay system.

15 Figure 19 is an illustration of an identification system used in the dispensing apparatus for supporting the assay process.

Figure 20 is a flowchart illustration of a computerized method for availing assay results from the assay process.

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Detailed Description

For purposes of brevity and clarity, descriptions of embodiments of the present disclosure are directed to apparatuses for dispensing and assaying biofluid samples,
25 in accordance with the drawings. While aspects of the present disclosure will be described in conjunction with the embodiments provided herein, it will be understood that they are not intended to limit the present disclosure to these embodiments. On the contrary, the present disclosure is intended to cover alternatives, modifications and equivalents to the embodiments described herein, which are included within the scope
30 of the present disclosure as defined by the appended claims. Furthermore, in the following detailed description, specific details are set forth in order to provide a thorough understanding of the present disclosure. However, it will be recognised by an individual having ordinary skill in the art, i.e. a skilled person, that the present

disclosure may be practiced without specific details, and/or with multiple details arising from combinations of aspects of particular embodiments. In a number of instances, well-known systems, methods, procedures, and components have not been described in detail so as to not unnecessarily obscure aspects of the embodiments of the present disclosure.

In embodiments of the present disclosure, depiction of a given element or consideration or use of a particular element number in a particular figure or a reference thereto in corresponding descriptive material can encompass the same, an equivalent, or an analogous element or element number identified in another figure or descriptive material associated therewith.

References to “an embodiment / example”, “another embodiment / example”, “some embodiments / examples”, “some other embodiments / examples”, and so on, indicate that the embodiment(s) / example(s) so described may include a particular feature, structure, characteristic, property, element, or limitation, but that not every embodiment / example necessarily includes that particular feature, structure, characteristic, property, element or limitation. Furthermore, repeated use of the phrase “in an embodiment / example” or “in another embodiment / example” does not necessarily refer to the same embodiment / example.

The terms “comprising”, “including”, “having”, and the like do not exclude the presence of other features / elements / steps than those listed in an embodiment. Recitation of certain features / elements / steps in mutually different embodiments does not indicate that a combination of these features / elements / steps cannot be used in an embodiment.

As used herein, the terms “a” and “an” are defined as one or more than one. The use of “/” in a figure or associated text is understood to mean “and/or” unless otherwise indicated. The term “set” is defined as a non-empty finite organisation of elements that mathematically exhibits a cardinality of at least one (e.g. a set as defined herein can correspond to a unit, singlet, or single-element set, or a multiple-element set), in accordance with known mathematical definitions. The recitation of a particular

numerical value or value range herein is understood to include or be a recitation of an approximate numerical value or value range. The terms “first”, “second”, “third”, etc. are used merely as labels or identifiers and are not intended to impose numerical requirements on their associated terms. The term “each other” represents a reciprocal
5 relation between two or more elements.

Dispensing Apparatus 100

In representative or exemplary embodiments of the present disclosure with reference
10 to Figure 1A to Figure 1D, there is a dispensing apparatus 100 for dispensing biofluid samples 110. A biofluid can be defined as a biological or bio-organic fluid produced by organisms. The biofluid samples 110 may include samples of urine excreted from a living person (i.e. a subject or patient) for screening, monitoring, and/or diagnosing kidney-related diseases such as early stage diabetes including its evolving stages,
15 chronic kidney disease, acute kidney disease, or any other disease capable of using urine samples. A bulk sample of biofluid is transferred to the dispensing apparatus 100 from a collection device, such as a cup, pipette, or other types of vessels. The dispensing apparatus 100 includes a cartridge 102 having a receiving chamber 104 and a set of one or more metering chambers 106 fluidically communicative with the
20 receiving chamber 104. The receiving chamber 104 is configured for receiving the biofluid bulk sample and apportioning the biofluid bulk sample into the metering chambers 106.

Each metering chamber 106 is configured for holding a predefined volume of biofluid
25 sample 110 apportioned from the biofluid bulk sample. Depending on the configuration / dimensions of the metering chambers 106, the predefined volumes in the metering chambers 106 may be equal or different to each other. Further with reference to Figure 2A, each metering chamber 106 includes an outlet 108 for dispensing the respective biofluid sample 110 and a dispensing filter 112 for filtering the respective biofluid
30 sample 110 during dispensing. Preferably, the dispensing filter 112 is disposed at one end of the respective metering chamber 106 just before the respective outlet 108. The outlets 108 may be in the form of nozzles and the dispensing filters 112 are configured

for filtering out particulate matter of certain sizes so that the particulate matter is not dispensed through the outlets 108.

As shown in Figure 2A, the filtered biofluid samples 110 are dispensed from the cartridge 102 to a set of one or more cuvettes 200. In some embodiments, the dispensing apparatus 100 includes a cuvette casing 202 for removably receiving the set of cuvettes 200 and to protect the cuvettes 200. The cartridge 102 and cuvette casing 202 are removably coupleable to each other such that each cuvette 200 is joined to a respective one of the metering chambers 106 for receiving the respective filtered biofluid sample 110. For example, a bottom portion of the cartridge 102 includes fastening mechanisms 114 that removably couple to the cuvettes 200. Non-limiting examples of fastening mechanisms 114 include latches, snap clips, screw threads, and step clips. The middle portion of the cartridge 102 may include a set of aligners 105, a distance away from the fastening mechanisms 114, configured to align with the cuvette casing 202 for coupling such that the cuvettes 200 are properly positioned for assaying. The bottom portion may include structural elements, such as reinforcement ribs, to strengthen the metering chambers 106. Figure 2B illustrates an exploded view of how the various parts of the dispensing apparatus 100 including the cuvettes 200 and cuvette casing 202 are assembled together.

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The biofluid samples 110 in the metering chambers 106 are dispensable through the outlets 108 into the cuvettes 200 by applying vacuum pressure in the cartridge 102, i.e. by depressurizing the cartridge 102. As shown in Figure 3A, the biofluid samples 110 are apportioned into the metering chambers 106 prior to dispensing. As shown in Figure 3B, the biofluid samples 110 are dispensed into the cuvettes 200. As described further below, the cuvettes 200 contain reagents 210 and the biofluid samples 110 which will be mixed together for assaying.

Additionally, the dispensing filters 112 prevent dispensing of the biofluid samples 110 in absence of the vacuum pressure. The cartridge 102 may include a cartridge lid 116 at a top portion thereof for sealing the cartridge 102 and facilitate depressurization of or creation of a vacuum environment for the cartridge 102. It will be appreciated that any suitable method may be used to achieve said sealing, such as ultrasonic welding

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to prevent leakage of air. The cartridge lid 116 may include a filling port 118 for transferring the biofluid bulk sample from the collection device to the receiving chamber 104.

- 5 The receiving chamber 104 may include a set of intermediate fluidic conduits or channels 117 that facilitate communication of the biofluid bulk sample to the metering chambers 106. The intermediate fluidic conduits or channels 117 are fluidically communicative with the receiving chamber 104 and metering chambers 106 and are arranged to facilitate even apportioning or distribution of the biofluid bulk sample from
- 10 the receiving chamber 104 into the metering chambers 106. The intermediate fluidic conduits or channels 117 may have multiple holes distributed evenly throughout and corresponding to the metering chambers 106 for communicating the biofluid samples 110 into the metering chambers 106. The cartridge lid 116 may include an intermediate containment fluidically communicative with the filling port 118. The intermediate
- 15 containment may have multiple holes distributed evenly throughout and corresponding to the metering chambers 106 for communicating the biofluid bulk sample received via the filling port 118 into the receiving chamber 104 and subsequently into the metering chambers 106.
- 20 The cartridge lid 116 may include a cap 120 for reclosing the filling port 118 after transferring the biofluid bulk sample. Figure 4A and Figure 4B show an embodiment of the cartridge 102 wherein the filling port 118 is closed after transferring the biofluid bulk sample into the cartridge 102. Figure 5A and Figure 5B show another embodiment of the cartridge 102. The cap 120 may be flexibly joined or hinged to the
- 25 cartridge lid 116 or separately screwed onto the filling port 118. The cartridge lid 116 may include a vacuum port 122 for receiving an external actuator that is actuatable by application of the vacuum pressure. This external actuator is operated by the vacuum pressure and may be referred to as a vacuum actuator. The cartridge lid 116 may include a set of air vents 124 that allow air to be vented during application of the
- 30 vacuum pressure, thus preventing pressure from building up inside the cartridge 102. The air vents 124 may include filters or hydrophobic membranes that vent air and prevent leakage of liquids. In absence of the vacuum pressure, the air vents 124

prevent air in the cartridge 102 from escaping and prevent ambient air from entering into the cartridge 102.

Each dispensing filter 112 may include a set of frit filters and/or a set of semipermeable
5 membranes. For example, the frit filters may include fritted glass and/or sintered frit
and the semipermeable membranes may be made of a hydrophobic material. The frit
filters / semipermeable membranes have pores that are sized to allow the respective
biofluid sample 110 to flow through the respective outlet 108 during application of
vacuum pressure, while preventing dispensing of the biofluid sample 110 and sealing
10 it in the respective metering chamber 106 in absence of the vacuum pressure. The
pores may be sized to withhold or filter out particulate matter ranging from
approximately 1 μm to 5 μm . The pores are preferably sized to withhold particulate
matter of at least 2 μm , and particulate matter below 2 μm would still be contained in
the biofluid samples 110 and pass through the dispensing filters 112. The dispensing
15 filters 112 can also serve to prevent reagents 210 in the cuvettes 200, which may be
displaced during mixing with the biofluid samples 110, from entering the metering
chambers 106.

The cartridge lid 116 may include a filling filter engageable with the filling port 118. The
20 filling filter is detachable from the filling port 118 so it can be removed, especially after
the filling filter is becoming clogged with particulate matter. In this instance, where
insufficient biofluid sample 110 passes through the filling port 118 into the receiving
chamber 104, a new filling filter may then be placed on the filling port 118 such that
sufficient biofluid sample 110 be dispensed into the receiving chamber 104 before the
25 dispensing apparatus 100 is reused. Similar to the dispensing filters 112, the filling
filter may include a set of frit filters and/or semipermeable membranes that may be
formed of a hydrophobic material. The filling filter performs pre-filtration of the biofluid
bulk sample during transfer into the receiving chamber 104, the pre-filtration removing
some particulate matter before the biofluid samples 110 flow into the metering
30 chambers 106. The dispensing filters 112 then perform a second filtration of the
biofluid samples 110 during dispensing. The filling filter and dispensing filters 112 are
cooperative for two-stage filtration of the biofluid samples 110. The filling filter and
dispensing filters 112 may have suitably sized pores to control the two-stage filtration.

For example, the filling filter may have larger pores to remove larger particulate matter from the biofluid bulk sample, and the dispensing filters 112 may have finer pores to filter and refine the biofluid samples 110 during dispensing into the cuvettes 200. The filling filter thus provides a user of the dispensing apparatus 100 with the flexibility of pre-filtering the biofluid bulk sample. The user may be a patient attempting to fill the cartridge 102 with his/her biofluid, or an operator (e.g. a clinician) helping the patient to fill the cartridge 102 such as with a collection device containing the biofluid.

In some embodiments, each metering chamber 106 includes at least one set of ribs or raised supports 126 for supporting and/or proper placement of the respective dispensing filter 112. Additionally, the ribs 126 prevent the dispensing filter 112 from collapsing or deforming under pressure from the biofluid sample 110 when it is being dispensed through the dispensing filter 112 and outlet 108, thus allowing the biofluid sample 110 to be properly filtered and dispensed into the cuvette 200.

In some embodiments, each metering chamber 106 includes a plurality of sets of the ribs 126 that may be positioned concentrically to each other. For example, a first set ribs 126 may be positioned furthest from the centre of the outlet 108, a third set of ribs 126 may be positioned nearest to the centre of the outlet 108, and a second set of ribs 126 may be positioned between the first and third sets of ribs 126. The ribs 126 in one set may have the same or different depth as the ribs 126 in another set. For example, the first set of ribs 126 may be shorter than the second set of ribs 126 which may in turn be shorter than the third set of ribs 126. In this arrangement, angled or gradient spaces are formed across the ribs 126. The gradient spaces are profiled and angled towards the centre of the outlet 108 to facilitate communication of the biofluid sample 110 in the metering chamber 106 to the centre of the outlet 108 during dispensing. The gradient spaces thus allow the biofluid samples 110 to flow seamlessly towards the outlets 108 which are gravitationally non-obstructive. Various examples of arrangements of the ribs 126 are shown in Figure 6A to Figure 6D, but it will be appreciated that other arrangements are possible and/or the metering chamber 106 may include any number of sets of ribs 126.

In some embodiments, a peripheral edge of the dispensing filter 112 resides within at least one of the sets of ribs 126. The peripheral edge of the dispensing filter 112 or a portion thereof engages with the outermost ribs 126 to form a sealing portion that prevents flow of the biofluid sample 110 around the peripheral edge of the dispensing filter 112, thereby allowing the biofluid sample 110 to be properly filtered through the dispensing filter 112. The peripheral edge may be shaped or folded / bent to an inward perpendicular shape to reside between the ribs 126. Alternatively, the peripheral edge can be adhesively and/or ultrasonically bonded to an inner surface of the metering chamber 106 so that the biofluid sample 110 does not backflow into the metering chamber 106. The engagement between the dispensing filters 112 and ribs 126 adds rigidity to the dispensing filters 112 and prevents the dispensing filters 112 from displacement during application of the vacuum pressure. Yet alternatively, the metering chamber 106 may include a retainer ring 128 disposed on the dispensing filter 112. Specifically, the retainer ring 128 is force fitted onto the dispensing filter 112 to secure the dispensing filter 112 onto the ribs 126 and to prevent backflow of the biofluid sample 110.

As described above, vacuum pressure is applied to the cartridge 102 to dispense the biofluid samples 110 through the outlets 108 into the cuvettes 200 by a combination of the vacuum pressure and gravity. During dispensing upon application of the vacuum pressure, the biofluid samples 110 are filtered through the dispensing filters 112 to remove particulate matter of certain sizes, such as at least 2 μm . Each outlet 108 may be configured to allow a predefined amount of filtered biofluid sample 110 to flow through depending on the vacuum pressure.

In some embodiments, the dispensing apparatus 100 includes a cover 130 covering the cartridge 102 and cuvette casing 202 when they are coupled together. The cover 130 may include a window or viewable portion 132 disposed on its surface to permit viewing of the receiving chamber 104. The window 132 permits viewing of the level of the volume of biofluid samples 110 in the cartridge 102 to check that the metering chambers 106 contain the desired predefined volumes of biofluid samples 110. The window 132 includes indicators that inform the user on how much to fill the cartridge 102 with the bulk sample of biofluid from the collection device. As shown in Figure 5B,

the window 132 includes a lower indicator 134 and an upper indicator 135. If the volume level of biofluid samples 110 as seen through the window 132 is below the lower indicator 134, this means that insufficient biofluid samples 110 are contained in the metering chambers 106. If the volume level is above the upper indicator 135, this means that the volume of biofluid samples 110 is too high. Thus, the lower indicator 134 and upper indicator 135 can be relied upon to increase the amount of biofluid bulk sample filling the cartridge 102 to an appropriate level to achieve the desired volumes of biofluid samples 110 in the metering chambers 106. Visual baffles may be disposed behind the window 132 where the visual baffles can interact with the biofluid samples 110 to provide a visual backdrop. The window 132 is thus configured to provide visual feedback to the user to determine whether the desired predefined volumes of biofluid samples 110 are reached. The user can rely on the visual feedback to increase the volumes of the biofluid samples 110 accordingly.

In some embodiments, the cover 130 may include two or more of the windows 132 disposed on its surface to permit viewing of the receiving chamber 104. For example, a first window 132 is disposed on one side of the cartridge 102 and a second window 132 is disposed on an opposing side of the cartridge 102, wherein both windows 132 are horizontally aligned to each other. Both windows 132 allow the user to view the level of the volume of biofluid samples 110 in the cartridge 102 from both sides of the cartridge 102 to visually check on whether the biofluid samples 110 have been distributed evenly in the metering chambers 106. If one window 132 shows the volume level at the lower indicator 134 while the other window 132 shows the volume level at the upper indicator 135, this means that the biofluid samples 110 are not evenly distributed in the metering chambers 106. This may happen because the filling port 118 is disposed near one side of the cartridge 102 and the biofluid may not flow smoothly to the furthest metering chamber 106. The user may then make appropriate adjustments, such as to add more biofluid, to ensure the biofluid samples 110 are evenly distributed. If both windows 132 show approximately the same volume level between the lower indicator 134 and upper indicator 135, this means that the biofluid samples 110 are evenly distributed in the metering chambers 106. This in turn ensures that accurate volumes of the biofluid samples 110 are dispensed into the cuvettes 200

and react with the reagents 210 for assaying and yielding useful assay results for diagnosing medical conditions.

In some embodiments as shown in Figure 2A and Figure 2B, the dispensing apparatus 100 includes a set of gaskets or retaining seals 136 disposed between the cartridge 102 and cuvette casing 202. The gaskets 136 create a biasing effect to secure the coupling between the cartridge 102 and cuvette casing 202, thus retaining a tight fit between them and providing sealing engagement between the cartridge 102 and the cuvettes 200. The number of gaskets 136 may correspond to the number of cuvettes 200 such that each gasket 136 is configured to engage with a respective one of the cuvettes 200. The skilled person will readily understand the arrangement of the gaskets 136 can be configured to match with the cuvettes 200. The gaskets 136 may include a set of holes, suitably sized and shaped and accordingly positioned, to facilitate dispensing of the filtered biofluid samples 110 from the outlets 108 and into the cuvettes 200.

Piston Assembly 150

The biofluid samples 110 are dispensed from the cartridge 102 to the cuvettes 200 by applying the vacuum pressure. In some embodiments, the vacuum pressure acts directly on the biofluid samples 110 contained in the metering chambers 106 and pushes out the biofluid samples 110 through the outlets 108 and dispensing filters 112. In some embodiments, the dispensing apparatus 100 includes a piston assembly 150 disposed in the cartridge 102 and the vacuum pressure actuates the piston assembly 150 to dispense the biofluid samples.

As shown in Figure 7A to Figure 7C, the piston assembly 150 includes a set of pistons / plungers / rods 152 for actuation into the metering chambers 106 to dispense the biofluid samples 110. The piston assembly 150 further includes a main shaft 153 joined to the pistons 152, wherein the main shaft 153 is received in the vacuum port 122 of the cartridge lid 116, as shown in Figure 7D. Each piston 152 corresponds to one of the metering chambers 106 for dispensing the respective biofluid sample 110 therein. Specifically, the pistons 152 can be actuated or displaced from a first position

to a second position to force out or purge the biofluid samples 110 through the dispensing filters 112 and into the cuvettes 200. Further, in order to allow positive displacement of the piston assembly 150, air vents are disposed in appropriate locations on the dispensing apparatus 100 for air flow transfer beyond the confines of the dispensing apparatus 100. For example, the cartridge lid 116 includes the air vents 124 that can vent air, enabling displacement of pressure within cartridge 102 and preventing pressure build-up. Thus, in this way, the pistons 152 can stroke downwards into the metering chambers 106.

The piston assembly 150 is disposed in the cartridge 102 and upon application of the vacuum pressure, the piston assembly 150 is displaced downwards to thereby dispense the biofluid samples 110 through the dispensing filters 112 and outlets 108. In some embodiments, the application of the vacuum pressure actuates an external actuator or vacuum actuator that in turn displaces the piston assembly 150. Vacuum operation of the vacuum actuator may be bypassed to allow manual operation and to manually displace the piston assembly 150, such as in situations where application of the vacuum pressure malfunctions.

In some embodiments, the dispensing apparatus 100 includes the set of intermediate fluidic conduits or channels 117 for communicating the biofluid bulk sample from the receiving chamber 104 to the metering chambers 106. Before the piston assembly 150 is displaced into the metering chambers 106, the intermediate fluidic conduits or channels 117 may hold a first portion of the biofluid bulk sample. As the piston assembly 150 is displacing into the metering chambers 106, a second portion of the biofluid bulk sample or excess biofluid may be displaced away from the metering chambers 106. When the piston assembly 150 is fully displaced into the metering chambers 106, the second portion of the biofluid bulk sample may reside at the intermediate fluidic conduits or channels 117, leaving behind the biofluid samples 110 in the metering chambers 106.

The piston assembly 150 may include suitable structural elements, such as ribs and trusses, to align and guide the pistons 152 during displacement along the height of the metering chambers 106 and to reinforce the pistons 152 to maintain structural integrity

when the vacuum pressure is applied. An example of a truss structure 158 in the piston assembly 150 is shown in Figure 7A and Figure 7B. Similarly as shown in Figure 7D, the vacuum port 122 may include a main structural element 137 and a set of supporting structural elements 138 such as retaining ribs that align the piston assembly 150 and constrain the piston assembly 150 from torsion or rotation during application of the vacuum pressure. The structural elements 137, 138 further add strength and maintain structural integrity under vacuum pressure. The truss structure 158 may include at least one raised portion 155 for perpendicular engagement with the end of the main structural element 137. Additionally, the piston assembly 150 may include an orientation aligner 157, such as a poka-yoke mechanism, to prevent incorrect orientation of the piston assembly 150 during assembly into the vacuum port 122.

Each metering chamber 106 may include a set of piston stoppers 154 disposed at a height above the outlet 108. The piston stoppers 154 cooperate with the respective piston 152 to prevent it from overrunning and to accurately dispense the predefined volume of biofluid sample 110 into the respective cuvette 200. The piston stoppers 154 can be sized differently to hold or contain a different predefined volume of biofluid sample 110 in the metering chamber 106. The piston stoppers 154 may be further configured to channel away volumes of biofluid above the desired predefined volume for the respective metering chamber 106.

In one embodiment, the piston assembly 150 includes first, second, and third pistons 152. In one example, the first and third pistons 152 have the same length that is longer than that of the second piston 152. In another example, the first and third pistons 152 have the same length that is shorter than that of the second piston 152. It will be appreciated that the first, second, and third pistons 152 can have varying lengths. By varying the lengths, the volume accuracy of the biofluid samples 110 dispensed from the metering chambers 106 can be controlled. For example, a first piston 152 having a shorter length can dispense a smaller volume than a second piston 152 having a longer length, because the first piston 152 can displace along a longer distance.

Each piston 152 further includes a resilient piston seal 156, such as a rubber or silicone toric joint, disposed at one end thereof for engaging with the respective metering

chamber 106, such that the piston seal 156 is coaxial with the metering chamber 106. The outer diameter of the piston seal 156 is concentric to the inner diameter of the metering chamber 106 such that, during operation, the vacuum pressure displaces the pistons 152 and the piston seals 156 remains tightly fitted to the metering chambers 106.

Each metering chamber 106 may include structural elements, such as reinforcement ribs, that cooperate with the pistons 152 and prevent undesirable collapse or deforming when the vacuum pressure is applied. Each metering chamber 106 may be suitably sized to control the predefined volume of biofluid sample 110 and to reduce formation of air bubbles in the biofluid sample 110, thus ensuring accuracy of the dispensed volume. The applied vacuum pressure also facilitates evacuation of air in the cartridge 102 including the metering chambers 106, mitigating formation of air bubbles in the biofluid samples 110 and ensuring that accurate volumes of the biofluid samples 110 are dispensed. Preferably, the biofluid samples 110 contained within each of the metering chambers 106 can be dispensed through the outlets 108 in approximately the same duration of time. Depending on the desired duration and lengths of the pistons 152, each cuvette 200 may receive the dispensed biofluid sample 110 in approximately similar durations or in different durations.

Cuvette 200

As described above, the filtered biofluid samples 110 are dispensed from the cartridge 102 to a set of one or more cuvettes 200. In some embodiments as shown in Figure 2A, the dispensing apparatus 100 includes the cuvette casing 202 removably coupled to the cartridge 102 and further includes the cuvettes 200 joined to the metering chambers 106 for receiving the filtered biofluid samples 110. The cartridge 102 and cuvette casing 202 are removably coupled to each other and the cartridge 102 can be removed to view the cuvettes 200 received in the cuvette casing 202. As shown in Figure 8A, each cuvette 200 may include fastening mechanisms 204 that removably couple to the corresponding fastening mechanisms 114 at the bottom portion of the cartridge 102. Non-limiting examples of fastening mechanisms 204 include latches, snap clips, screw threads, and step clips.

As shown in Figure 8B, the cuvette casing 202 may include a set of cuvette aligners 205 to align the cuvettes 200 such that the cuvettes 200 are properly positioned for assaying. As shown in Figure 8C, the cuvette aligners 205 may include one or more
5 stepped sections 207 disposed at a bottom portion of the cuvette casing 202. The cuvette casing 202 may further include a set of cartridge aligners 209 to align the cuvette casing 202 for coupling to the cartridge 102. The bottom portion of the cuvette casing 202 may include a space or gap 206 such that when the cuvettes 200 are received into the cuvette casing 202, the bottom of the cuvettes 200 does not
10 physically contact the cuvette casing 202.

Each cuvette 200 may contain a reagent 210, such as a dry or wet reagent, for reacting with the biofluid sample 110 dispensed therein. The reagents 210 may include bromocresol green (BCG) for detecting albumin and/or 3,5-Dinitrobenzoic acid (DNBA)
15 (or picric acid) for detecting creatinine. As shown in Figure 1D, the cartridge 102 / cuvette casing 202 may include a set of indicators 208 to identify the reagents 210 and/or purpose of the respective cuvettes 200. In many embodiments, three cuvettes 200 are used in the dispensing apparatus 100 – a BCG reference cuvette 200, a DNBA cuvette 200, and a BCG sample cuvette 200. The skilled person would readily
20 understand the indicators 208 can be arranged in any desired order. Additionally, the indicators 208 inform the operator to correctly arrange the cuvettes 200 in the cuvette casing 202 before coupling to the cartridge 102. The indicators 208 can be embossed or attached (such as by using representative stickers) onto a surface of the cartridge 102 / cuvette casing 202.

25

As shown in Figure 2A, each cuvette 200 may contain at least one magnetic object 212, which may be in the form of a bead or a spherical object. The magnetic object 212 may be made of a neodymium or ferrite material such that it can be moved by effects of the magnetic fields. More specifically, the cores of the magnetic object 212
30 may be made of the neodymium / ferrite material and the magnetic object 212 is externally coated with an inert material. This inert material is non-reactive with the biofluid samples 110 / reagents 210 and seeks to prevent contamination of the biofluid samples 110 which could affect the assay results. The magnetic object 212 should be

small to fit inside the cuvettes 200 with sufficient space to move about for stirring and mixing the biofluid samples 110 with the reagents 210. Each cuvette 200 may have a cuboid space to facilitate agitation or mixing of the biofluid sample 110 and reagent 210. For example, the top portion and bottom portion of the cuvette 200 may be
5 rectangular shaped, and the top portion can be dimensionally equal or larger than the bottom portion.

As shown in Figure 2B, the dispensing apparatus 100 may include the gaskets 136 that provide sealing engagement between the cartridge 102 and the top portion of the
10 cuvettes 200. The gaskets 136 include a set of holes, suitably sized and shaped, to facilitate dispensing of the filtered biofluid samples 110 from the outlets 108 and into the cuvettes 200. The holes also facilitate de-bubbling of the cuvettes 200, especially after the mixing process which can cause air bubbles to form, depending on at least the type of reagents 210 and mixing speed. When the vacuum pressure is applied, the
15 air bubbles are evacuated via the holes in the gaskets 136. The holes may be arranged in the gaskets 136 in any suitable arrangement, such as to de-bubble only certain cuvettes 200. For example, the holes may be positioned only at the DNBA cuvette 200 for de-bubbling this cuvette 200 only. Optionally, each cuvette 200 may include at least one vent hole 214 to facilitate evacuation of air bubbles when the vacuum pressure is
20 applied. The vent hole 214 may include a hydrophobic membrane that vent air and prevent leakage of the biofluid sample 110.

When the cuvettes 200 are received into the cuvette casing 202, the cuvettes 200 are properly aligned for assaying, such as by using a light beam. Each cuvette 200 may
25 be made of a substantially transparent material to enable the light beams to pass through efficiently for assaying the mixture of biofluid sample 110 and reagent 210. The transparent cuvettes 200 also provide viewability of the reagents 210 in the cuvettes 200 during manufacturing, thus ensuring the correct reagents 210 are present in the correct cuvettes 200. The cuvette casing 202 may include a set of windows 216
30 that enable the light beams to propagate through the cuvettes 200 for assaying the biofluid samples 110. More specifically, the windows 216 are disposed on at least two sides of the cuvette casing 202 and positioned at appropriate heights so that the light beams do not intersect or interfere with each other. This allows the mixed biofluid

samples 110 (or assay samples 310) to be assayed by the light beams without interference. The windows 216 may be of various shapes and sizes, such as circular (as shown in Figure 4A and Figure 4B) or elongated / oblong (as shown in Figure 5A and Figure 5B).

5

Assay Apparatus 300

In representative or exemplary embodiments of the present disclosure with reference to Figure 9A to Figure 9C, there is an assay apparatus 300 for assaying biofluid.

10 Particularly, the assay apparatus 300 is configured for assaying or analysing biofluid samples 110 that are mixed with reagents 210 in the cuvettes 200. The mixture of the biofluid samples 110 and reagents 210 may be referred to as assay samples 310. The assay results of the assay samples 310 can be used to screen, monitor, and/or diagnose diseases or conditions such as diabetes or chronic kidney disease.

15

The assay apparatus 300 includes a vacuum chamber 400 for removably housing the dispensing apparatus 100 as described above. Particularly, the dispensing apparatus 100 includes a set of cuvettes 200 and a set of biofluid samples 110, the cuvettes 200 containing a set of reagents 210. The cuvettes 200 are housed in a cuvette casing 202 and the base of the cuvette casing 202 may be structured such that there is a space or gap 206 that prevents the cuvettes 200 from physically contacting the base. The gap 206 may reduce vibrations during agitation or mixing of the biofluid samples 110 and reagents 210, and the reduced vibrations in turn minimize movement of the cuvettes 200 such that a light beam may focus through the windows 216 accurately.

20 The cuvette casing 202 may have a base aligner 218 disposed a distance away from the base of the cuvette casing 202 and can additionally align with the vacuum chamber 400 to facilitate housing of the dispensing apparatus 100 in the vacuum chamber 400, such as to allow insertion of the dispensing apparatus 100 into the vacuum chamber 400 in only one orientation.

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30 The assay apparatus 300 further includes a vacuum cover 450 for sealing the dispensing apparatus 100 in the vacuum chamber 400. Preferably, the vacuum cover 450 is moveably coupled to the vacuum chamber 400, such as by hinging, to facilitate

opening and closing of the vacuum cover 450. Figure 9B shows the vacuum cover 450 in hinged to the vacuum chamber 400 and in the open state. However, it will be appreciated that the vacuum cover 450 may be detachably attached to the vacuum chamber 400 such that the vacuum cover 450 can be physically removed / replaced.

5 The vacuum cover 450 may include a bottom mating portion 452 and the vacuum chamber 400 may include a top mating portion 402, wherein the bottom and top mating portions 452,402 are engageable with each other and creates a sealing engagement between the vacuum cover 450 and the vacuum chamber 400.

10 The assay apparatus 300 includes a vacuum device 500 for applying vacuum pressure in the vacuum chamber 400, the vacuum pressure for dispensing the biofluid samples 110 into the cuvettes 200. In other words, the vacuum device 500 depressurizes the vacuum chamber 400 and the dispensing apparatus 100 sealed inside the vacuum chamber 400 and closed vacuum cover 450, including the metering chambers 106
15 that contain the biofluid samples 110, the depressurization causing the biofluid samples 110 to dispense from the metering chambers 106 into the cuvettes 200. The assay apparatus 300 may include a vacuum actuator 550 that is actuatable, as a result of the vacuum pressure, against the piston assembly 150 of the dispensing apparatus 100 to thereby dispense the biofluid samples 110 from the metering chambers 106.

20

The assay apparatus 300 includes a set of assay control systems 320 for controlling the vacuum device 500 and performing an assay process including applying the vacuum pressure to dispense the biofluid samples 110, mixing the biofluid samples 110 and the reagents 210 to form the assay samples 310, and assaying the assay
25 samples 310 in the cuvettes 200. Specifically, the assay control systems 320 include a vacuum control system 330 configured for controlling the vacuum device 500 to apply the vacuum pressure and depressurize the vacuum chamber 400, as well as a number of other assay control systems 320 that perform and control parts of the assay process. Non-limiting examples of such assay control systems 320 include an
30 electromagnetic mixing system 600 configured for performing a mixing process using electromagnetism to mix the biofluid samples 110 with the reagents 210 in the cuvettes 200 to yield the assay samples 310, an optical measurement system 700 configured for performing spectroscopy on the assay samples 310, and a temperature control

system 800 configured for monitoring and/or controlling the temperature in the assay apparatus 300. The set of assay control systems 320 may further include a main control system 350 configured for controlling the assay control systems 320 and automating the assay process.

5

The assay apparatus 300 is operated by an operator to perform the assay process. The operator may be a clinician, laboratory assistant, or skilled technician (collectively referred to as "operator") who is able to conduct the assay process.

- 10 The assay apparatus 300 may include a number of mounting portions for mounting the various components, such as and including any one or more of the assay control systems 320 or parts thereof. The mounting portions are arranged such that these components can be mounted in a prearranged manner to ensure alignment with other components. For example, the optical measurement system 700 must be properly
- 15 aligned with the vacuum chamber 400 for accurate assaying of the assay samples 310 in the dispensing apparatus 100 housed in the vacuum chamber 400. Some of the mounting portions may be suitable for mounting fans or similar cooling units for air ventilation of the assay apparatus 300 to facilitate heat dissipation. The body of the assay apparatus 300 may be formed with a network of fluidic conduits, e.g. flow
- 20 channels, fluidically communicative with the fans to direct conductive and/or convectional heat flow.

- By using prearranged mounting portions for mounting the various components in the assay apparatus 300, there is ease of assembly control as the components can be
- 25 easily rearranged to other mounting portions. The components can be rearranged to optimize the space in the assay apparatus 300 and to optimize air flow for better air circulation which in turn results in better heat dissipation. Rearranging the components also helps to redistribute the overall weight of the assay apparatus 300 more evenly, stabilizing the assay apparatus 300 during the assay process. The assay apparatus
- 30 300 may include a tilt sensor to feedback positional information about the assay apparatus so the operator can check whether the assay apparatus 300 is in an appropriate position and orientation, such as on a flat surface position. Particularly,

the tilt sensor checks whether the assay apparatus 300 is maintained in a flat position during the assay process so as not to compromise the assay results.

When the dispensing apparatus 100 is initially housed or loaded in the vacuum chamber 400, such as shown in Figure 9C, the vacuum cover 450 is open, i.e. separated from the vacuum chamber 400, and the vacuum chamber 400 is exposed to ambient atmospheric pressure. The closing of the vacuum cover 450 creates the sealing engagement and allows a vacuum environment to be created for the dispensing apparatus 100 sealed inside. Additionally, the vacuum cover 450 and vacuum chamber 400 may include a set of interlocking members and/or interlocking detectors configured for checking the sealing engagement between the vacuum cover and vacuum chamber. This ensures that the vacuum chamber 400 is properly sealed by the closed vacuum cover 450 so that the vacuum chamber 400 can be depressurized by the vacuum device 500 for dispensing the biofluid samples 110.

The assay process includes applying the vacuum pressure to dispense the biofluid samples 110 and assaying the assay samples 310, such as by use of the optical measurement system 700. The assay process may further include mixing the biofluid samples 110 with the reagents 210 using the electromagnetic mixing system 600 before assaying the assay samples 310. The assay results can then be used to derive information about the assay samples 310, such as for screening, monitoring, and/or diagnosing diseases or conditions. After the assay process has been completed, the vacuum cover 450 is opened and the dispensing apparatus 100 is removed from the vacuum chamber 400. Notably, the vacuum chamber 400 may be pressurized, i.e. returned to ambient atmospheric pressure, before opening the vacuum cover 450.

Assay Method 900

In representative or exemplary embodiments of the present disclosure with reference to Figure 10, there is a method 900 for assaying biofluid, particularly by using the assay apparatus 300. The method 900 includes a step 902 of providing the assay apparatus 300 including a vacuum chamber 400, a vacuum cover 450, and a vacuum device 500. The method 900 includes a step 904 of loading a dispensing apparatus

100 into the vacuum chamber 400, the dispensing apparatus 100 including a set of cuvettes 200 and a set of biofluid samples 110, the cuvettes 200 containing a set of reagents 210. The method 900 includes a step 906 of sealing the dispensing apparatus 100 in the vacuum chamber 400 with the vacuum cover 450. The method
5 900 includes a step 908 of operating the vacuum device 500 to apply vacuum pressure in the vacuum chamber 400, the vacuum pressure for dispensing the biofluid samples 110 into the cuvettes 200, such that the biofluid samples 110 react with the reagents 210 to form the assay samples 310. The method 900 includes a step 910 of operating a set of assay control systems 320 to control the vacuum device 500 and perform an
10 assay process including applying the vacuum pressure to dispense the biofluid samples 110 and assaying the assay samples 310 in the cuvettes 200.

In some embodiments, the assay control systems 320 include an electromagnetic mixing system 600. The assay process may include a mixing process to mix the
15 biofluid samples 110 with the reagents 210 in the cuvettes 200 using the electromagnetic mixing system 600. In some embodiments, the assay control systems 320 include an optical measurement system 700. The assay process may include a spectroscopy on the assay samples 310 in the cuvettes 200. In some embodiments, the assay control systems 320 include a temperature control system 800. The assay
20 process may include monitoring and/or controlling the temperature in the assay apparatus 300.

After the assay process has been completed and the assay results have been obtained, the vacuum cover 450 is opened and the used dispensing apparatus 100 is
25 unloaded from the vacuum chamber 400. A fresh or previously unused dispensing apparatus 100 containing a new batch of biofluid samples 110 and reagents 210 may be loaded into the vacuum chamber 400 for performing another assay process. Preferably, the dispensing apparatus 100 is of the disposable type for hygiene purposes and the used dispensing apparatus 100 is disposed, such as how
30 biohazardous waste is disposed, after the assay process has been completed. However, it will be appreciated that the dispensing apparatus 100 may be manufactured to be reusable after cleaning and sterilization.

Various embodiments of the present disclosure provide improved apparatuses 100,300 for dispensing and assaying biofluid samples 110. The dispensing of the biofluid samples 110 also include filtering the biofluid samples 110 to remove particulate matter, yielding filtered biofluid samples 110 that are less contaminated and allowing for more accurate assay results to be obtained. For example, the biofluid samples 110 are urine samples and the reagents 210 used are BCG and DNBA. The assay results can be used to diagnose diseases or conditions such as chronic kidney disease by determining urine albumin and creatinine concentrations and the corresponding albumin-to-creatinine ratio.

10

By automating the assay process with the assay control systems 320, the assay process can be performed with higher accuracy and greater reliability, as compared to conventional measurements through the human eye. Conventional or manual measurements are prone to human errors that contribute to inconsistent, less reliable results, as measurements of the albumin and creatinine may be too early or too late, i.e. the reaction time between the biofluid samples 110 and reagents 210 is inconsistent or incorrect. The automated assay process ensures consistency in the reaction time and in the steps from dispensing of the biofluid samples 110 to mixing of the biofluid samples 110 with the reagents 210 and to assaying of the assay samples 310. Particularly, the dispensing and reactions only occur after the dispensing apparatus 100 has been loaded into the assay apparatus 300, eliminating the risk of any delay that would otherwise occur if reactions had begun before loading. Skilled or trained personnel may not be required to evaluate the assay results. The dispensing and assay apparatuses 100,300 can be used to more quickly obtain accurate assay results and medical diagnoses, especially in remote locations where there is limited access to trained personnel and healthcare.

25

Although various embodiments herein are described in relation to urinalysis, such as using BCG and DNBA as exemplary reagents 210 for diagnosis of medical conditions like chronic kidney disease, it will be appreciated that other reagents 210 can be used for diagnosis of other medical conditions. It will also be appreciated that other forms of biofluid samples 110, such as saliva and blood samples, can be similarly used in

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the apparatuses 100,300 described herein for assaying and consequently for diagnosis of medical conditions.

Vacuum Chamber 400

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As shown in Figure 9C, the vacuum chamber 400 is configured to removably house the dispensing apparatus 100 including the set of cuvettes 200 and the set of biofluid samples 110. The vacuum chamber 400 may include suitable alignment / guiding elements for receiving and placement of the dispensing apparatus 100. Additionally,
10 the vacuum chamber 400 may be configured such that the dispensing apparatus 100 can be inserted into the vacuum chamber 400 in only one orientation. For example, the dispensing apparatus 100 and vacuum chamber 400 may have corresponding alignment / guiding elements, such as the base aligner 218 of the cuvette casing 202, which prevent the vacuum chamber 400 from receiving the dispensing apparatus 100
15 in other orientations.

Alignment of the cuvette casing 202 in the vacuum chamber 400 ensures accuracy and unblocked channelling of the light beams from the optical measurement system 700 for assaying. The vacuum chamber 400 may include a set of windows or space
20 408 (as shown in Figure 15A) that enable the light beams to propagate through the cuvette casing 202 and cuvettes 200 for assaying. More specifically, the windows or spaces 408 are disposed on at least two sides or opposite sides of the vacuum chamber 400 and aligned to the windows 216 of the cuvette casing 202 so that the light beams do not intersect or interfere with each other.

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In one embodiment, the vacuum chamber 400 is integrally formed within the body of the assay apparatus 300. In another embodiment, the vacuum chamber 400 is separately formed and coupled to the body of the assay apparatus 300 by suitable coupling mechanisms. For example, the vacuum chamber 400 may have a set of
30 coupling holes and the body of the assay apparatus 300 may have a corresponding set of coupling holes. The vacuum chamber 400 can be coupled to the assay apparatus 300 via the coupling holes, such as by using fasteners like screws and bolts.

The vacuum chamber 400 may be supported on its base by a number of structural elements. The structural elements are arranged to maintain the vacuum chamber 400 in the desired position to minimize alignment error due to vibrations caused by the depressurization. The structural elements are further arranged to structurally support the vacuum chamber 400 during loading on the dispensing apparatus 100 by the vacuum actuator 550 so that the vacuum chamber 400 maintains its desired position. The vacuum chamber 400 may be supported by a set of anti-vibration isolators for controlling the amount of vibration translation or resonance. The anti-vibration isolators may be disposed on a base of the vacuum chamber 400 and may be lined with a non-slip material to prevent slippage. Additional anti-vibration isolators may be disposed on a base of the assay apparatus 300 and may be cooperative with a set of adjustable fasteners to adjust the orientation of the assay apparatus 300 and to minimize tilting of the assay apparatus 300.

The vacuum chamber 400 includes the top mating portion 402 engageable with the bottom mating portion 452 of the vacuum cover 450. The top mating portion 402 may include a groove 404 for holding a set of sealing elements for creating the sealing engagement with the vacuum cover 450. The sealing elements may include an O-ring, a toric joint, a gasket, and/or a radial seal. The groove 404 may have a cross-section in the form of a dovetail or partial dovetail and may include pinches at one or more sections of the groove 404.

The vacuum chamber 400 may include a set of vacuum chamber interlocking members 406 configured to lock the engagement between the vacuum cover 450 and vacuum chamber 400. The vacuum chamber interlocking members 406 may include one or more locking receptacles 406 for receiving corresponding vacuum cover interlocking members 456, such as retractable locking pins 456, of the vacuum cover 450. The locking pins 456 are engageable with the locking receptacles 406 to ensure that the closed vacuum cover 450 is properly locked in place against the vacuum chamber 400. The engaged locking pins 456 also prevent the operator from accidentally opening the vacuum cover 450 during the assay process which could compromise the assay results.

The vacuum chamber 400 may include a set of vacuum chamber interlocking detectors configured to detect that the vacuum cover 450 is closed to seal the vacuum chamber 400. The assay process may commence after or in response to the vacuum chamber interlocking detectors detecting that the vacuum cover 450 is properly closed.

- 5 The vacuum chamber interlocking detectors may include a magnetic sensor, such as a Hall effect sensor, configured to detect a magnetic element of the vacuum cover 450. Specifically, when the vacuum cover 450 is closed, the magnetic element is close enough to interact with and be detected by the magnetic sensor. The magnetic sensor may optionally produce a visual and/or sound alert to inform the operator that the
- 10 vacuum cover 450 is properly closed.

- Proper closure of the vacuum cover 450 ensures the sealing engagement is intact and the vacuum chamber 400 is ready for depressurization. Additionally, the sealed vacuum chamber 400 is not influenced by external ambient light which could interfere
- 15 with the optical measurement system 700 and compromise the assay results. In some situations such as due to misalignment of components of the optical measurement system 700, light from the optical measurement system 700 such as laser light, which should normally be contained in the vacuum chamber 400, may instead be scattered away from the vacuum chamber 400. By ensuring the sealing engagement is intact,
- 20 the laser light will remain contained in the sealed vacuum chamber 400, preventing the operator from becoming directly exposed to the laser light which can be harmful to the operator's eyes. Another way to mitigate this risk is to include a shield in the vacuum chamber 400 to block out the laser light from exposure to the operator during the assay process. This shield may be made of a dark / light-absorbent material such
- 25 as black acetal.

- After the assay process has been completed, the vacuum device 500 pressurizes and returns the vacuum chamber 400 to ambient atmospheric pressure. The vacuum chamber 400 may include a set of vent holes for neutralizing it to ambient atmospheric
- 30 pressure. Notably, the vent holes are closed during depressurization and opened after completing the assay process.

Vacuum Cover 450

With reference to Figure 9A, Figure 11A, and Figure 11B, the vacuum cover 450 is configured to seal the dispensing apparatus 100 in the vacuum chamber 400. As described above for the vacuum chamber 400, the vacuum cover 450 includes the bottom mating portion 452 engageable with the top mating portion 402 of the vacuum chamber 400 to create the sealing engagement therebetween. The vacuum cover 450 may include a set of vacuum cover interlocking members 456 configured to lock the engagement between the vacuum cover 450 and vacuum chamber 400. The vacuum cover interlocking members 456 may include one or more retractable locking pins 456 engageable with the locking receptacles 406 of the vacuum chamber 400 to lock the vacuum cover 450 and prevent the operator from accidentally opening it. The locking pins 456 may be snap-fitted when the vacuum cover 450 is closed to provide tactile and/or sound feedback to the operator. The vacuum cover 450 and/or locking pins 456 may be configured, such as with suitable resilient areas, to guard against sudden slamming of the vacuum cover 450 and mitigate risk of damage to the assay apparatus 300. To open the vacuum cover 450 after the assay process has been completed, the locking pins 456 are retracted or disengaged.

The vacuum cover 450 may include a set of vacuum cover interlocking detectors configured to detect that the vacuum cover 450 is closed to seal the vacuum chamber 400. The vacuum cover interlocking detectors may include a magnetic element arranged to be detected by a magnetic sensor of the vacuum chamber 400 when the vacuum cover 450 is closed. The vacuum cover interlocking detectors may further include a photo-interrupter 454 to detect that the vacuum cover 450 is closed. The photo-interrupter 454 operates such that a light source emits a light beam directly to a light detector and the light detector detects the light beam when it is uninterrupted. The photo-interrupter 454 is normally positioned such that it does not intersect the light beam when the vacuum cover 450 is open. Closing of the vacuum cover 450 moves the photo-interrupter to a position that interrupts the light beam so that the interrupted light beam would not be detected by the light detector. Failure to detect the interrupted light beam means that the vacuum cover 450 is properly closed.

The vacuum cover 450 may include either one or both types of vacuum cover interlocking detectors – magnetic-based and photo-based – to detect that the vacuum cover 450 is properly closed. Implementing both types is a redundancy measure to avoid a single point of failure or a single fault tolerant safety system. This fail-safe approach further adds safety for the operator, especially for untrained operators and/or for operators who are deployed to remote locations where the assay apparatus 300 is used. For example, if the magnetic sensor fails to detect the magnetic element, the photo-interrupter can still work to ensure that the vacuum cover 450 is closed. If one or both fails, the optical measurement system 700 may be deactivated and prevented from performing the assay process. The assay process may involve laser light which can be harmful to the operator's eyes if exposed to the operator, particularly if the vacuum cover 450 is not properly closed which resulted in failure of either one or both types of vacuum cover interlocking detectors.

The vacuum cover 450 may be moveably coupled to the vacuum chamber 400, such as by a hinge mechanism 404. The hinge mechanism 404 may include a set of torsion springs 458 configured to move the vacuum cover 450 between an open state and a closed state. The torsion springs 458 may be configured to bias the vacuum cover 450 towards the closed state. The torsion springs 458 may be disposed on both sides of the vacuum cover 450 to prevent the vacuum cover 450 from becoming deformed or damaged when opening and closing the vacuum cover 450.

The torque applied by the torsion spring 458 reinforces the sealing engagement between the vacuum cover 450 and vacuum chamber 400. The torsion spring 458 may be configured such that the amount of force required to overcome the torsion spring torque and move the vacuum cover 450 to the open state is manageable by the operator. This allows the operator to comfortably open the vacuum cover 450 and make suitable adjustments to the vacuum cover 450 and/or vacuum chamber 400 where necessary.

The torsion springs 458 may be configured to dampen the movement of the vacuum cover 450, especially when closing the vacuum cover 450. For example, the hinge mechanism 404 may include a set of dampening elements cooperative with the torsion

springs 458. The dampening elements guard against accidental forceful closure of the vacuum cover 450 and mitigates risk of damage to the assay apparatus 300. Additionally, the dampening elements reduce or prevent external forces from causing misalignment and/or vibrations on the vacuum cover 450, so that the sealing engagement is not affected by the external forces and remains intact.

The vacuum cover 450 may include a vacuum cover handle 460 for handling by the operator to open and close the vacuum cover 450. The vacuum cover handle 460 is moveable between a closed state and an open state. The vacuum cover 450 can be opened when the vacuum cover handle 460 is in the open state. For example, as the operator moves the vacuum cover handle 460 to the open state, the locking pins 456 of the vacuum cover 450 are released from the locking receptacles 406 of the vacuum chamber 400. This unlocks the vacuum cover 450 from the vacuum chamber 400 and allows the vacuum cover 450 to be opened by the operator. The vacuum cover handle 460 may be connected to the vacuum cover 450 by a set of springs that biases the vacuum cover handle 460 towards the closed state.

The vacuum cover 450 may include a vacuum cover actuator, such as a solenoid actuator or latch, engageable with the vacuum cover handle 460. The solenoid actuator may be activated in response or after the assay process has begun. Specifically, when the assay process begins, the vacuum cover 450 is already closed, and the solenoid actuator is activated to engage with the vacuum cover handle 460. The activated solenoid actuator locks the vacuum cover handle 460 in the closed state. The activated solenoid actuator creates additional locking forces against the vacuum chamber 400 that restrict motion of the closed vacuum cover 450 and prevent the vacuum cover 450 from being opened accidentally by the operator. After the assay process has been completed, the solenoid actuator is deactivated to disengage from the vacuum cover handle 460. The deactivated solenoid actuator frees the vacuum cover handle 460 to be moved to the open state by the operator, thereby allowing the vacuum cover 450 to be opened. The solenoid actuator may be spring-loaded such that it is biased towards the deactivated state.

To open the vacuum cover 450, the operator first opens the vacuum cover handle 460 partially by tilting or lifting it to an intermediate state or partially open state. The vacuum cover interlocking members 456 may be configured to retract from the vacuum chamber interlocking members 406 in tandem with the lifting of the vacuum cover handle 460. The operator continues to open the vacuum cover handle 460 by tilting or lifting it to from the intermediary state to the open state. At the open state, the interlocking detectors, such as the Hall effect sensor and photo-interrupter 454, will be triggered to deactivate the optical measurement system 700. This disables the light beams and prevents any unwanted or stray laser light beam from escaping or scattering out from the assay apparatus 300. The vacuum cover handle 460 in the open state unlocks the vacuum cover 450 and enables it to be opened.

Vacuum Device 500

With reference to Figure 12A and Figure 12B, the vacuum device 500 is controlled by the vacuum control system 330 for depressurizing the vacuum chamber 400 to dispense the biofluid samples 110 into the cuvettes 200. The vacuum device 500 may be or include a vacuum pump to apply the vacuum pressure, thus depressurizing the vacuum chamber 400 from ambient atmospheric pressure which is normally around 1 bar. The vacuum pump may rotate at approximately 2000 RPM to 3000 RPM, and preferably at 2400 RPM, to apply the vacuum pressure. The vacuum pressure or negative pressure applied to the vacuum chamber 400 generally ranges from -20 kPa to -160 kPa relative to ambient atmospheric pressure. The vacuum pressure preferably ranges from -70 kPa to -100 kPa relative to 1 bar atmospheric pressure, or alternatively from -11 kPa to -15 kPa in absolute terms. In some embodiments, a number of predefined settings may be provided for selection of predefined ranges of vacuum pressure. The predefined ranges may be -45 kPa to -50 kPa, -75 kPa to -85 kPa, -86 kPa to -95 kPa, -65 kPa to -74 kPa, -96 kPa to -105 kPa, and -106 kPa to -115 kPa. The predefined ranges advantageously allow the assay apparatus 300 to account for varying atmospheric conditions, especially when the assay apparatus 300 is deployed in different locations where the pressure differs from low altitude to high altitude environments. It will be appreciated that the increments between respective

predefined ranges may vary differently to account for usage lifecycle of the vacuum device 500.

5 The vacuum device 500 may be supported on a vacuum mounting in the assay apparatus 300. The vacuum mounting is configured to transfer or transmit vibration forces from the vacuum device 500 towards the base of the assay apparatus 300. The vacuum device 500 may be mounted to the vacuum mounting such that the centre of mass of the vacuum device 500 is close to the bottom of the assay apparatus 300 to improve vibration dampening. For example, the vacuum pump or motor is heavier and
10 should be disposed close to the bottom.

As shown in Figure 12B, the vacuum device 500 may be fluidically connected to a set of valves 502, such as solenoid valves, to facilitate depressurization and pressurization of the vacuum chamber 400. The valves 502 may include a check valve
15 to prevent backflow of air to the vacuum chamber 400 after the vacuum chamber 400 has been depressurized to the desired vacuum pressure or when the vacuum device 500 is inactive. The check valve may be configured to allow air to flow back to the vacuum chamber 400 to pressurize the vacuum chamber 400 after completing the assay process. It will be appreciated that any number of valves 502 may be used and
20 the configuration and connection of the valves 502 to the vacuum device 500 will be readily known to the skilled person. The vacuum device 500 may additionally be fluidically connected to a carbon filter 504 for cleaning of the air exchange between the vacuum device 500 and the vacuum chamber 400. This prevents leakage of any odour to the ambient environment. The carbon filter 504 uses activated carbon to
25 remove impurities in the air using adsorption. However, it will be appreciated that other types of filters, such as non-carbon filters, may be used to remove impurities.

After the vacuum chamber 400 has been depressurized and the biofluid samples 110 have been dispensed into the cuvettes 200, the biofluid samples 110 can mix with the
30 reagents 210 into the assay samples 310. The vacuum pressure may be reduced in magnitude to facilitate de-bubbling of the assay samples 310 in the cuvettes 200. The de-bubbling removes any residual air bubbles in the assay samples 310 to improve accuracy of the assaying by the optical measurement system 700 and consequently

improve the assay results. A pressure sensor 506 may be disposed in or connected to the vacuum chamber 400 to feedback the current pressure to the vacuum device 500 so that the vacuum device 500 can control application of the vacuum pressure accordingly.

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Vacuum Actuator 550

As shown in Figure 11B, the vacuum cover 450 may include a housing 470 for the vacuum actuator 550 configured to actuate on the dispensing apparatus 100 to
10 thereby cause dispensation of the biofluid samples 110 into the cuvettes 200. The vacuum device 500 applies the vacuum pressure to cause actuation of the vacuum actuator 550 housed in the vacuum cover 450. The vacuum actuator housing 470 is fluidically communicative with the vacuum chamber 400 such that the vacuum actuator housing 470 is depressurized to actuate the vacuum actuator 550 when the vacuum
15 pressure is applied to the vacuum chamber 400. Alternatively, the vacuum device 500 may apply the vacuum pressure directly to both the vacuum actuator housing 470 and vacuum chamber 400.

With reference to Figure 13A and Figure 13B, when the vacuum device 500 applies
20 the vacuum pressure, a lower part 552 of the vacuum actuator 550 is subjected to the vacuum pressure and an upper part 554 of the vacuum actuator 550 is exposed to ambient atmospheric pressure. The pressure differential between the ambient atmospheric pressure and the vacuum pressure actuates the vacuum actuator 550 from a disengaged position downwards and towards the dispensing apparatus 100. In
25 the disengaged position as shown in Figure 13A, the vacuum actuator 550 may be housed entirely in the vacuum actuator housing 470. The vacuum actuator 550 is actuated until it is in a first engaged position where it engages the piston assembly 150 of the dispensing apparatus 100. In the first engaged position, the vacuum actuator 550 continues actuating to a second engaged position as shown in Figure
30 13B to displace the piston assembly 150 downwards. In the second engaged position, the piston assembly 150 is displaced into the metering chambers 106 and the biofluid samples 110, which the biofluid samples 110 were contained in receiving chamber 104 and the metering chambers 106, are dispensed into the cuvettes 200. The vacuum

actuator 550 may be configured such that, in the second engaged position, the vacuum actuator 550 activates a limit switch to stop further actuation of the vacuum actuator 550. Accordingly, the pressure differential causes the vacuum actuator 550 to actuate and to eventually dispense the biofluid samples 110.

5

The vacuum actuator 550 may include a spring 556 or other biasing element arranged to bias the vacuum actuator 550 to the disengaged position as shown in Figure 13A. The spring 556 is designed such that the pressure differential is sufficient to compress the spring 556 to actuate the vacuum actuator 550. After the assay process has been completed, the vacuum device 500 pressurizes and returns the vacuum chamber 400 and vacuum actuator housing 470 to ambient atmospheric pressure. The pressure differential is eliminated and the spring 556 returns the vacuum actuator 550 to the disengaged position. The vacuum actuator housing 470 may include a set of vent holes 472 for neutralizing it to ambient atmospheric pressure. Notably, the vent holes 472 are closed during depressurization and opened after completing the assay process.

The vacuum actuator 550 is housed in the vacuum actuator housing 470 in a similar manner to a piston seal that is able to achieve good sealing properties and low frictional forces because the pressure differential needed to actuate the vacuum actuator is low. The vacuum actuator 550 may include a peripheral groove 558 for holding an O-ring, toric joint, or gasket for reducing or minimizing the frictional forces during actuation. The vacuum actuator 550 may be cushioned in the vacuum actuator housing 470 with a resilient material such as foam to protect it from external forces.

25

Electromagnetic Mixing System 600

With reference to Figure 14, the electromagnetic mixing system 600 is configured for performing a mixing process in or as part of the assay process. The magnetic mixing system 600 includes a set of electromagnetic units 602 for generating magnetic fields within the vacuum chamber 400, or more specifically, within the cuvettes 200 received into the vacuum chamber 400. Each cuvette 200 may be paired with a respective set of electromagnetic units 602. The electromagnetic units 602 may be arranged in a

30

quadrangle layout around each cuvette 200, such that the generated magnetic fields are targeted towards the cuvette 200. Each electromagnetic unit 602 includes at least one electromagnetic element or electromagnet that generates the magnetic field.

- 5 The magnetic fields facilitate mixing of the biofluid samples 110 with the reagents 210 in the cuvettes 200 by causing movement of the magnetic object 212 in each cuvette 200. The movement of the magnetic objects 212 in the cuvettes 200 physically stirs and mixes the biofluid samples 110 with the reagents 210. The metering chambers 106 are configured, such as by cooperation of the dispensing filters 112 and ribs 126,
10 to prevent the assay samples 310, which are in the cuvettes 200 and which may be displaced during the mixing, from backflowing or seeping into the metering chambers 106.

- The power input to the electromagnetic units 602 can be controlled to control the
15 generation of the magnetic fields. The controlled generation of the magnetic fields can constrain the magnetic objects 212 in the cuvettes 200 to move along predefined pathways. For example, the magnetic objects 212 may move according to a predefined pattern or variable patterns as defined or selected by the operator. The predefined patterns may be in the form of a u-shaped pattern or an n-shaped pattern,
20 but it will be appreciated that there can be other patterns or pathways which the magnetic objects 212 can move in the cuvettes 200. The generation of the magnetic fields may be time-controlled to ensure that the biofluid samples 110 and reagents 210 are homogenously mixed within a certain duration to form the assay samples 310 that are viable for assaying. Notably, homogenous mixing or agitation means that there is
25 minimal to no remaining or unmixed biofluid samples 110 or reagents 210 in the cuvettes 200.

- During the mixing process, the vacuum pressure is continuously applied to maintain a vacuum environment in the cuvettes 200, which in turn reduces the tendency for air
30 bubbles to form in the cuvettes 200. After mixing by the magnetic objects 212, the vacuum pressure is maintained or reduced to facilitate de-bubbling of the assay samples 310, thus removing any residual air bubbles in the assay samples 310.

Therefore, by operating the electromagnetic mixing system 600 to generate magnetic fields in the vacuum chamber 400 and cuvettes 200 therein, the biofluid samples 110 and reagents 210 in the cuvettes 200 can be physically mixed by the magnetic objects 212. The magnetic objects 212 can be controlled by the magnetic fields to move at
5 desired timings, speed, and direction to physically mix the biofluid samples 110 and reagents 210 together. This allows the biofluid samples 110 and reagents 210 to be consistently mixed, avoiding overmixing or undermixing which could result in non-viable assay samples 310 and compromise the assay results. Moreover, mixing occurs without any contact with an outside component, e.g. a glass stirrer, or by a continuous
10 inversion method. Without needing to use the glass stirrer to mix the biofluid samples 110, the assay apparatus 300 can be used for safely assaying the assay samples 310 that might be biohazardous in some cases.

Optical Measurement System 700

15 With reference to Figure 15A, the optical measurement system 700 is configured for performing spectroscopy or photochemistry inspection in or as part of the assay process. After the biofluid samples 110 and reagents 210 have been mixed using the electromagnetic mixing system 600, the spectroscopy analyses or studies the
20 interactions between the biofluid samples 110 and reagents 210 using electromagnetic radiation, such as by using light beams. For example, the spectroscopy can determine the presence of albumin in the biofluid samples 110 using the BCG reagent 210 and the presence of creatinine using the DNBA reagent 210. The spectroscopy may be performed in response to completion of the mixing process performed by the
25 electromagnetic mixing system 600, or after a predefined duration of time has lapsed after completing the mixing process. The mixing of the biofluid samples 110 with the reagents 210 and the spectroscopy on the resulting assay samples 310 can thus be performed in an automated manner with reduced or minimal manual operator intervention.

30 The optical measurement system 700 may include at least one light source 702 and at least one light detector 704. Each cuvette 200 may be paired with a respective set of light source 702 and light detector 704 arranged collinearly. Specifically, as shown

in Figure 15A, the light source 702 is arranged on one side of the cuvette 200 and the light detector 704 is arranged on an opposing side of the cuvette 200. The light sources 702 and light detectors 704 are arranged such that the light beams do not intersect or interfere with each other, allowing the assay samples 310 to be assayed without interference. The cuvette casing 202 align and hold the cuvette 200 such that each cuvette 200 is properly aligned in the path of the respective light beam between the respective light source 702 and light detector 704. The cuvette 200 may be made of a substantially transparent material to enable the light beam to pass through efficiently. The optically clear windows or spaces 408 of the vacuum chamber 400 and the optically clear windows 216 of the cuvette casing 202 are aligned with each other and enable the light beam to pass through the assay samples 310 for assaying. The cuvette 200 is preferably shaped like a cuboid to reduce reflection / refraction effects, thus mitigating loss of laser information.

The optical measurement system 700 may include a set of optical elements 706 arranged between a light source 702 and a light detector 704 for adjusting the light beam to improve the assay results. For example, the optical elements 706 may include convergent lens, divergent lens, and/or Fresnel lens arranged for collimation / redirection of the light beam and to focus the light beam at the cuvette 200. The optical elements 706 may include a light guide for guiding the emitted light beams from the light source 702 through the cuvette 200 to the light detector 704. The optical elements 706 may include a light filter, such as a light blocker, to allow positive light emittance through the cuvette 200 towards the light detector 704. Other optical elements 706 that may be used are mirrors and prisms or other reflective / refractive elements, but are not limited to such.

In one embodiment, the light beam diverges from the light source 702 and the divergent light beam propagates through the cuvette 200 towards the light detector 704. In one embodiment, the light beam diverges from the light source 702 and the optical elements 706 adjust and collimate or focus the light beam. The collimated light beam then propagates through the cuvette 200 towards the light detector 704. In one embodiment, the light beam diverges from the light source 702 and the optical elements 706 converge the light beam towards the cuvette 200. In one embodiment

as shown in Figure 15B, the light beam diverges from the light source 702 and a collimating lens 706 collimates the divergent light beam. The collimated light beam propagates through the cuvette 200 towards the light detector 704. A focussing lens converges the collimated light beam at the light detector 704.

5

The optical measurement system 700 may include a number of baffles 708 surrounding each light source 702 and/or each light detector 704. The baffles 708 are arranged to prevent light scattered from the light sources 702 from leaking to the vacuum chamber 400, constraining the light beams to the assay samples 310. For example as shown in Figure 15A, an aperture or opening 718 may be positioned between the collimating lens 706 and the window or space 408. A baffle 708 may be arranged with the aperture 718 to reduce stray light from the light beam and allows substantially all of the light beam to propagate towards the window or space 408. The baffles 708 are also arranged to prevent external ambient light from reaching the light detectors 704 which could compromise the assay results. The baffles 708 may be made of a dark / light-absorbent material, such as black acetal, to contain the light scattered from the light sources 702 as well as the ambient light. Additionally, black acetal material is able to operate at a high temperature of at least 80 °C, allowing the optical measurement system 700 to continue functioning despite the thermal radiation from the light sources 702.

The optical measurement system 700 may include a set of heat sinks 710 for the light sources 702. As shown in Figure 15C, each light source 702 may be disposed on a respective one of the heat sinks 710 to facilitate absorption / dissipation of heat generated by the light source 702 during emission of light. For example, the light source 702 may have a set of source leads 712 attached, such as by soldering, to the heat sink 710 and an adhesive / bonding material 714 may be applied in between to stabilize the attachment. The adhesive / bonding material 714 may be a thermal paste or any other similar thermal compound for optimal thermal conductivity. The heat sink 710 may be made of a heat conductive material, such as metallic materials including aluminium and copper. It will be appreciated that the structure of the heat sink 710 may include heat dissipative elements such as fins to increase the overall surface area for heat dissipation. Dissipating heat away from the light sources 702 helps to prevent

damage to the light sources 702. The heat sinks 710 also reduce transfer of unwanted heat to the cuvettes 200, mitigating thermal factors that could compromise the assay results.

5 The light source 702 may be a light emitting diode (LED) or a laser diode that emits a laser. The laser diode achieves higher optical efficiency than the LED, consuming less power while emitting a more powerful laser. The laser diode is able to deliver high power conversion efficiency, high spectral resolution, and high optical coupling. The laser beam is better collimated and focused, allowing it to travel some distance
10 unguided. In this way, the vacuum chamber 400 for the dispensing apparatus 100 including the cuvettes 200 can be larger for easier access for maintenance, such as for cleaning. The laser diode may have an integrated sensor for measuring the intensity of the emitted laser beams. The narrower spectral bandwidth of the laser diode gives greater specificity to a single absorption coefficient than an LED.

15

The light detector 704 may be a photodiode for detecting the light beam and measuring changes in light absorption by the assay sample 310 in the cuvette 200. The photodiode may be made of a silicon or silicon-based material for measuring light beams in the 400 to 900 nm wavelength range, for example. The optical measurement
20 system 700 may include a set of transimpedance amplifiers and a set of analogue to digital converters, such as 20-bit delta-sigma converters, connected to the photodiodes and configured to suppress noise and improve performance of the photodiodes. The improve performance can extend the linear dynamic measurement range and increase attenuated optical measurement by a factor of around 1000 (or 3
25 absorbance units), allowing for more precise measurements of compounds in the assay samples 310.

In some embodiments, the optical measurement system 700 is configured to perform a calibration process to improve accuracy of the assay results. For example, the
30 calibration can compensate for laser intensity drifts that may be influenced by high temperatures. In one embodiment, a light source 702 emits a first light beam and a second light beam. The first light beam is propagated to be detected by a first light detector 704 and the second light beam is propagated to be detected by a second light

detector 704. In another embodiment, a light source 702 emits a light beam and the optical elements 706, such as a mirror / prism, separate the light beam into a first light beam and second light beam. Specifically, the first light beam is reflected by the mirror / prism to a first light detector 704 and the second light beam is propagated through the mirror / prism to a second light detector 704. The first light detector 704 may be referred to as a feedback light detector because the first light beam is largely unattenuated.

In the calibration process, a base optical attenuation of the optical elements 706 of the optical measurement system 700 is first calculated before loading the vacuum chamber 400 with the dispensing apparatus 100. The base optical attenuation represents the rate at which the light intensity decreases through the optical elements 706 when the vacuum chamber 400 is unloaded. The power produced by the light beam emitted from the light source 702 is denoted as P_L . The first light beam is reflected by the optical elements 706 to the first light detector 704 and is largely unattenuated by the optical elements 706. The second light beam is propagated through the optical elements 706 to the second light detector 704 and is attenuated by the optical elements 706. The power of the first light beam detected by the first light detector 704 is denoted as P_{1b} . The power of the second light beam detected by the second light detector 704 is denoted as P_{2b} . The responsivity of the first light detector 704 is denoted as r_1 . The responsivity of the second light detector 704 is denoted as r_2 . The base optical attenuation is denoted as a_b and can be calculated using Equation [1] and Equation [2].

Equation [1]

$$P_{1b} = r_1 P_L$$

Equation [2]

$$P_{2b} = a_b r_2 P_L$$

30

The vacuum chamber 400 is then loaded with the dispensing apparatus 100 including the cuvettes 200 containing the reagents 210. The biofluid samples 110 are dispensed into the cuvettes 200 and mixed with the reagents 210. The mixed biofluid samples

110 or assay samples 310 in the cuvettes 200 are tested to obtain the assay results. An assay optical attenuation, which represents the rate at which the light intensity decreases through the cuvettes 200 including the assay samples 310, is calculated to measure the light absorbance of the cuvettes 200 and assay samples 310. The light
 5 beam is emitted in the same manner as the calibration process described above. The first light beam is reflected by the optical elements 706 to the first light detector 704 and is largely unattenuated because it does not propagate through the cuvettes 200. The second light beam is propagated through the optical elements 706 and cuvettes 200 to the second light detector 704 and is attenuated by them. The power of the first
 10 light beam detected by the first light detector 704 is denoted as P_{1a} . The power of the second light beam detected by the second light detector 704 is denoted as P_{2a} . The assay optical attenuation is denoted as a_a and can be calculated using Equation [3] and Equation [4].

15 Equation [3]

$$P_{1a} = r_1 P_L$$

Equation [4]

$$P_{2a} = a_a a_b r_2 P_L$$

20

To further improve accuracy of the assay results, the optical attenuation through the material of the cuvettes 200 should be accounted for in the light absorbance measurements, even if the cuvettes 200 are substantially transparent. The assay optical attenuation is a combination of a cuvette optical attenuation (denoted as a_c)
 25 and a sample optical attenuation (denoted as a_s), as shown in Equation [5]. The cuvette optical attenuation represents the rate at which the light intensity decreases through empty cuvettes 200. In other words, it is the transparent material of the cuvettes 200 that causes the cuvette optical attenuation. The sample optical attenuation represents the rate at which the light intensity decreases through the assay
 30 samples 310 themselves, without influence by the transparent material of the cuvettes 200.

Equation [5]

$$a_a = a_c a_s$$

To calculate the cuvette optical attenuation, the vacuum chamber 400 is loaded with the dispensing apparatus 100 including the cuvettes 200 but without the biofluid samples 110 nor reagents 210, i.e. the cuvettes 200 are empty. The light beam is emitted in the same manner as the calibration process described above. The first light beam is reflected by the optical elements 706 to the first light detector 704 and is largely unattenuated because it does not propagate through the empty cuvettes 200. The second light beam is propagated through the optical elements 706 and empty cuvettes 200 to the second light detector 704 and is attenuated by them. The power of the first light beam detected by the first light detector 704 is denoted as P_{1c} . The power of the second light beam detected by the second light detector 704 is denoted as P_{2c} . The cuvette optical attenuation can be calculated using Equation [6] and Equation [7].

15

Equation [6]

$$P_{1c} = r_1 P_L$$

Equation [7]

20

$$P_{2c} = a_c a_b r_2 P_L$$

With the values of the base optical attenuation, assay optical attenuation, and cuvette optical attenuation known, the sample optical attenuation can be calculated to determine to measure the light absorbance of the assay samples 310. This measured light absorbance is more accurate as it is not influenced by the cuvette material. Therefore, calibrating the optical measurement system 700 to account and compensate for noise influences by the optical elements 706 and cuvette material and isolate the optical attenuation caused by solely the assay samples 310. This yields more accurate and more consistent assay results that are useful for diagnosis of medical conditions.

30

In many embodiments, there are three cuvettes 200 containing three assay samples 310 being assayed – a BCG reference cuvette 200, a DNBA cuvette 200, and a BCG

sample cuvette 200. For the BCG cuvettes 200, the light detector 704 is configured to measure absorbance of an albumin BCG target and deactivated BCG reactions for estimating albumin concentration in the biofluid samples 110 mixed with the BCG reagents 210. For the DNBA cuvette 200, the light detector 704 is configured to measure the kinetic measurement of a creatinine reaction for estimating creatinine concentration in the biofluid sample 110 mixed with the DNBA reagent 210. In one embodiment, all three assay samples 310 are assayed at the same time. In one embodiment, the assay samples 310 are assayed in sequence, and the time gap between each assay may be the same or different.

For example as shown in a time schedule 716 in Figure 16 for operating the optical measurement system 700, the light detectors 704 may measure the light absorbance of the assay samples 310 sequentially in respective time periods. Specifically, a first light detector 704 may measure the light absorbance of the assay sample 310 in the BCG sample cuvette 200 in a first time period, a second light detector 704 may measure the light absorbance of the assay sample 310 in the DNBA cuvette 200 in a second time period, and a third light detector 704 may measure the light absorbance of the assay sample 310 in the BCG reference cuvette 200 in a third time period. In this configuration, only the light source 702 for one cuvette 200 is active in any time period, reducing overall heat generation by the optical measurement system 700 and improving performance of the light detectors 704.

When the biofluid sample 110 reacts with the reagent 210, such as BCG or DNBA, a colorimetric chemical reaction occurs and this causes absorption change. Different coloured light or light of different wavelengths is preconfigured to match the absorption wavelength of the reacted biofluid sample 110 which is the assay sample 310. In one example, the light source 702 paired with the DNBA cuvette 200 is configured to emit green light in the 495 to 570 nm wavelength range, and preferably a wavelength range of 510 to 530 nm. If creatinine is present in the biofluid sample 110, it will react with DNBA reagent 210 to form a purple-red complex in the assay sample 310. The rate of formation of the complex is directly proportional to the concentration of creatinine. The concentration of creatinine can be determined by measuring the change of the absorbance, under effects of the green light, of the complex over a period of time,

calculating the rate of the absorbance change of the complex over the period of time, and comparing the calculated rate to a predetermined calibration curve of creatinine concentration.

- 5 In another example, the light sources 702 for the BCG cuvettes 200 are configured to emit red light in the 620 to 750 nm wavelength range, and preferably a wavelength range of around 630 to 640 nm. The BCG sample cuvette 200 contains the biofluid sample 110 mixed with the BCG reagent 210. The BCG reference cuvette 200 contains the biofluid sample 110 mixed with the BCG reagent 210 and another reagent
- 10 210 for denaturing the biofluid sample 110. The BCG reference cuvette 200 used as a control or reference for the BCG sample cuvette 200 to compare against. If albumin is present in the biofluid samples 110, the albumin would react with BCG reagent 210 to form a coloured complex in the assay sample 310. The coloured complex is formed in the BCG sample cuvette 200 but this formation is blocked in the BCG reference
- 15 cuvette 200 because the biofluid sample 110 has been denatured. The colour intensity of the complex is directly proportional to the concentration of albumin in the urine. The concentration of albumin can be determined by measuring the absorbance spectra, under effects of the red light, of the assay samples 310 in the BCG cuvettes 200, calculating the difference between the absorbance spectra of the both assay samples
- 20 310, and comparing the calculated difference absorbance to a predetermined calibration curve of albumin concentration.

Although the optical measurement system 700 is described to perform spectroscopy wherein the assay samples 310 absorb electromagnetic radiation, such as visible light,

25 of predefined wavelengths, other forms of spectroscopic measurements may be performed on the assay samples 310, such as transmission spectroscopy, reflectance spectroscopy, and scattering spectroscopy. In order to perform other forms of spectroscopy, other optical elements 706, such as mirrors for reflectance spectroscopy, may be used and the arrangements of the light sources 702, light

30 detectors 704, and optical elements 706 may vary, as will be readily understood by the skilled person.

Temperature Control System 800

The temperature control system 800 is configured for monitoring and/or controlling the temperature in the assay apparatus 300 in or as part of the assay process. The chemical reactions between the biofluid samples 110 and reagents 210 are usually
5 affected by the environment or ambient temperature. Particularly, a higher ambient temperature may accelerate the rate of reaction, and this may sometimes be unwanted. In one embodiment, the temperature control system 800 is configured to monitor the temperature variations of the assay apparatus 300 before start of assaying or during the period of usage for the day to provide feedback whether to continue or allow the
10 assay apparatus 300 to cool down to prevent any unnecessary heat impact on the assay samples 310. Monitoring the temperature prior to any start of assaying will eliminate error results and return reliable assay results. In another embodiment, the temperature control system 800 is configured to compensate for temperature variations for the chemical reactions in the cuvettes 200. Specifically, the reaction
15 results provide feedback to compensate for a higher reaction rate at a higher temperature. For example, for creatinine reactions, the feedback can compensate for a higher reaction rate at a higher temperature in the creatinine reaction where a kinetic measurement is used. Controlling the temperature for the chemical reactions can increase the reliability of the assay results. This provides a consistent environment in
20 the cuvettes 200 and ensure that the assay samples 310 are assayed at around the same temperature.

The temperature control system 800 may include a set of HVAC (heating, ventilation, and air conditioning) components disposed on or integrated with the assay apparatus
25 300. The HVAC components are configured to control the temperature of the assay apparatus 300 such that it is within the desired operating temperature range. In some cases, the assay apparatus 300 is deployed in an air-conditioned environment where there is reduced need for such temperature control. However, in some other cases, the assay apparatus 300 may be deployed in harsher environments, such as remote
30 or rural locations, where the assay apparatus 300 is exposed to the weather elements.

The HVAC components may include one or more ventilation outlets and/or one or more fans for exchange of air between the assay apparatus and the external

environment. The HVAC components may include a set of heating and/or cooling units, such as heat sinks and cooling coils, for heating and/or cooling the assay apparatus 300 to within a predefined desired operating temperature range, which may be from 30 °C to 80 °C and preferably below 50 °C. If the operating temperature exceeds the
5 desired range, the efficiency of the light sources 702 may decrease, potentially resulting in inaccurate assay results.

The temperature control system 800 may include a set of temperature sensors for measuring the temperature of various components of the assay apparatus 300 and to
10 provide temperature feedback. The temperature control system 800 may send the temperature feedback to thereby adjust various conditions of the assay apparatus 300 based on the temperature feedback. Some of these conditions include cooling time before assaying the assay samples 310 or proceeding with the next assaying of the next batch of assay samples 310, settling time for the lasers, temperature of the lasers,
15 laser driving current, operating temperature of the assay apparatus 300, and temperature of the vacuum chamber 400. For example, one or more temperature sensors are configured to measure a set of laser calibration temperature for determining the operating temperature condition. Each laser diode 702 is activated to emit a laser through the respective cuvette 200 to the respective laser detector 704
20 and feedback the respective calibration temperature. If the laser calibration temperatures exceed a temperature range from 15 °C to 40 °C, such as above 40 °C, an error message may be sent for the operator to determine whether to void current and previous assay results as they might have been compromised.

25 The temperature sensors may include a thermistor sensor configured to measure ambient temperature for providing feedback on the present ambient temperature. The thermistor sensor may be exposed on the exterior of the assay apparatus 300. Alternatively, the thermistor sensor may be enclosed in a casing to prevent any accidental mishandling or tampering. The ambient temperature may be measured
30 continuously or at regular intervals. The ambient temperature measured by the thermistor sensor may further constrain the desired operating temperature range of the assay apparatus 300, such as between 20 °C and 40 °C. Preferably, the desired operating temperature range may be from 20 °C to 30 °C. With the thermistor sensor,

the assay apparatus 300 can account for any deviation at any given time to provide an accurate assessment of the operating conditions before proceeding with the assay process. When the thermistor sensor measures the ambient temperature to exceed the desired operating temperature range, the operator can be alerted and prompted to consider terminating the assay process.

Main Control System 350

The main control system 350 is configured for global control of the assay control systems 320, including the vacuum device 500, electromagnetic mixing system 600, optical measurement system 700, and temperature control system 800. The main control system 350 includes a processor or central processing unit (CPU) configured to perform various steps of the assay process. The processor may be in the form of a printed circuit board and may include suitable algorithm, logic, circuitry, and/or interfaces to execute such steps, as will be readily understood by the skilled person. The main control system 350 includes a set of memory devices or modules containing information stored therein relevant to performance of the assay process. This information is pre-stored in the memory devices at the manufacturing level and may not be manipulated at the operator level.

The main control system 350 includes an operator control interface 352 for the operator to provide inputs to control the assay process and view dynamic information, such as progress and updates, about the assay process. The operator may be required to enter login details, such as a username and password, before the main control system 350 allows the operator to control the assay process. This prevents unauthorized operators from accessing the main control system 350. After accessing the main control system 350, the operator may initiate the assay process through interaction with the operator control interface 352.

The operator control interface 352 may include a set of input devices for the operator to provide the inputs, such as to make appropriate adjustments for the assay process. Some of these adjustments include, but are not limited to, the operating temperature, vacuum power, pathways for the magnetic objects 212 in the cuvettes 200 to follow,

and alignment of the light sources 702 / light detectors 704 of the optical measurement system 700. These adjustments ensure that the assay process can be performed within acceptable or parameters. The input devices may include, but are not limited to, a keyboard (physical and/or virtual), buttons, switches, knobs, joysticks, mouse, 5 trackball, etc.

The operator control interface 352 may include a display panel for displaying information to the operator, such as in response to the operator inputs. For example, the displayed information may include temperature feedback to inform the operator of 10 the current operating temperature, keeping the operator informed as to whether it is within the desired operating temperature range. This temperature feedback helps to prevent invalid assay results that could be compromised because of overheating.

The display panel may optionally include a graphical user interface (GUI) to display 15 information and to receive operator inputs. For example, the display panel may include a touchscreen panel for receiving capacitive inputs which may be contact-based or non-contact-based. The main control system 350 may include illumination and/or audio devices that are configured to produce visual / sound alerts. These alerts may be related to the information displayed on the GUI or about any errors during the assay 20 process. For example, the GUI may show symbols that to accordingly reflect whether the vacuum cover 450 is in the locked or unlocked state. This provides a visual feedback to the operator and prevents the operator from forcefully opening the vacuum cover 450.

25 The main control system 350 includes a set of communication ports, such as USB ports, where a number of other electronic devices can be removably connected to. These other electronic devices may include a printer, a scanner, a data storage device, and an adaptor for connecting to an information system of a facility. For example, the adaptor may be based on the RS-232 communication protocol and is configured for 30 connecting to a hospital information system (HIS) or a laboratory information system (LIS). The main control system 350 may include a communications device for wireless communications, such as based on Wi-Fi, Bluetooth, and/or cellular network communication protocols. The communications device may communicate with an

external electronic device, such as a computer, laptop, tablet device, or mobile phone, to provide access to the assay results on-the-fly. This further adds flexibility for the operator to coordinate and conduct other tests for patients. The main control system 350 further includes a power switch 354 such as a rocker switch for switching on and
5 off the assay apparatus 300, and a power input socket such as a 24 V DC socket for wired connection to a power source.

The main control system 350 may be programmed with a power management system configured to switch the assay apparatus 300 to a sleep or hibernation mode after a
10 predefined period of inactivity. The power management system is also configured to safely power off the assay apparatus 300 in the event of an emergency power failure so that data integrity can be preserved, especially for recent assay results that have not been backed up elsewhere. As a power redundancy measure, the main control system 350 may include or may be connected to a backup power source, such as an
15 uninterruptible power source (UPS). The main control system 350 may be programmed with a schedule management programme to periodically prompt the operator to perform cleaning and inspection steps for maintenance of the assay apparatus 300, thus ensuring the quality and validity of the future assay results.

20 Assay System 1000

In representative or exemplary embodiments of the present disclosure with reference to Figure 17A and Figure 17B, there is an assay system 1000 for assaying or analysing assay samples 310 created from biofluid samples 110 mixed with reagents 210. The
25 assay system 1000 includes a base station 1010 and a number of test stations 1020 communicatively connected to the base station 1010. The base station 1010 is configured for controlling the test stations 1020 to perform a respective assay process on each respective test station 1020. The base station 1010 may be integrated with one of the test stations 1020. Alternatively, the base station 1010 is communicatively
30 connected with the test stations 1020 but is not integrated with any test station 1020.

The base station 1010 includes a main control system 350 (base control system 1012) configured for global control of the test stations 1020 to perform the assay processes.

Each test station 1020 includes a respective assay apparatus 300 that includes at least the vacuum chamber 400, vacuum cover 450, and a set of assay control systems 320 for performing the respective assay process. Each assay apparatus 300 may optionally include a respective vacuum device 500, or alternatively, the assay system
5 1000 may include a set of vacuum devices 500 for applying vacuum pressure in the vacuum chambers 400 of all the test stations 1020. The vacuum pressures applied in the respective vacuum chambers 400 may be substantially equal to or different from each other. The vacuum pressure applied in any one of the vacuum chambers 400 may be substantially equal to or different from any one of the other vacuum chambers
10 400. It will be appreciated that various aspects of the assay apparatus 300 described herein apply similarly or analogously to the test stations 1020 and are not further elaborated for purpose of brevity.

The respective assay apparatus 300 of each test station 1020 includes the main
15 control system 350 (test control system 1022) configured for local control of the respective set of assay control systems 320. In some cases, the operator may operate the respective test control systems 1022 of the test stations 1020 to perform the assay processes on the respective test stations 1020. For example, each of the test control systems 1022 may include an operator control interface 352 or GUI. In some other
20 cases, the operator may operate the base control system 1012 of the base station 1010 to exercise global control over the test stations 1020. The base control system 1010 may similarly include the operator control interface 352 or GUI which may be absent in the test control systems 1022.

25 The base control system 1012 may include a set of base control programs for administration / management of the global control. Similarly, each test control system 1022 may include a set of test control programs for administration / management of the respective local control. These control programs enable various administration / management functions to be performed. Some non-limiting examples of these
30 functions relate to operator access management, operator control interface management, power management, memory management, data storage management, external devices management, data communications management, as well as maintenance and quality check schedules management. It will be appreciated that

other programs to facilitate administration / management of the stations 1010,1020 can be installed.

In some embodiments as shown in Figure 17A and Figure 17B, the test stations 1020
5 are physically connected to the base station 1010 in a series arrangement, such as in a daisy chain network topology. Figure 18A and Figure 18B show various examples of such series arrangements. In one example as shown in Figure 18A, the base station 1010 and test stations 1020 are connected to each other using communication cables 1016 such as USB cables. In another example as shown in Figure 17B and Figure
10 18B, the base station 1010 and test stations 1020 are integrally connected to each other in a monolithic arrangement. Specifically, each station 1010,1020 includes at least one connection interface or port 1014,1024 (as shown in Figure 9A and Figure 17A) for direct coupling to at least one other station 1010,1020. The couplings in this monolithic arrangement may be temporary or permanent and may be performed at a
15 manufacturing facility or by a qualified service technician.

In some embodiments, the test stations 1020 are physically connected to the base station 1010 in a parallel arrangement, such as in a star network topology. In one example, the base station 1010 and test stations 1020 are connected to each other
20 using communication cables 1016. In another example, the base station 1010 and test stations 1020 are connected to a common network device that routes network traffic across the stations 1010,1020. The network device may provide network security features such as firewalls to protect the assay system 1000 against malicious exploits. Notably, each station 1010,1020 may include similar network security features that
25 collectively protect the assay system 1000.

In some embodiments, the test stations 1020 are wirelessly connected to the base station 1010 using various wireless communication protocols such as Wi-Fi. The base station 1010 and test stations 1020 may be connected to a common network device
30 that implements the wireless communications. The network device may likewise provide the network security features described above.

Although only some examples of network topologies for connecting the base station 1010 and test stations 1020 are described, it will be appreciated that they may be connected in other arrangements / topologies, such that the base station 1010 can communicate with the test stations 1020. Additionally, each station 1010,1020 may be
5 powered from separate or independent power sources. Alternatively, the base station 1010 may be powered from a power source and the test stations 1020 receive power from the base station 1010.

In some embodiments, the test stations 1020 are physically connected to the base
10 station 1010 in a monolithic daisy chain network topology. Specifically, a first test station 1020 is integrated with the base station 1010, a second test station 1020 is connected to the base station 1010, a third test station 1020 is connected to the second test station 1020, a fourth test station 1020 is connected to the third test station 1020, and so forth according to the number of test stations 1020.

15 The base station 1010 includes a communications device for transmitting instructions to the test stations 1020. Specifically, the base station 1010 may transmit a first set of instructions to the first test station 1020 containing a first batch of biofluid samples 110 mixed with a first batch of reagents 210 (i.e. a first batch of assay samples 310), a
20 second set of instructions to the second test station 1020 containing a second batch of biofluid samples 110 mixed with a second batch of reagents 210 (i.e. a second batch of assay samples 310), a third set of instructions to the third test station 1020 containing a third batch of biofluid samples 110 mixed with a third batch of reagents 210 (i.e. a third batch of assay samples 310), a fourth set of instructions to the fourth
25 test station 1020 containing a fourth batch of biofluid samples 110 mixed with a fourth batch of reagents 210 (i.e. a fourth batch of assay samples 310), and so forth. The batches of reagents 210 may be the same or different from each other across batches or within each respective batch, allowing for different reagent tests in the assay processes to be performed for diagnosis of different medical conditions, thereby
30 establishing comprehensive medical records for patients. For example, the first batch of reagents 210 is different from the second batch of reagents 210 to allow for different assaying tests and to establish a broader set of diagnoses of the patients. Additionally,

the first test station 1020 may configured differently from the second test station 1020 to cater for the different batches of reagents 210.

For each test station 1010, the respective set of instructions may include a request to
5 perform a preliminary test on the respective test station 1020, such as to calibrate the optical measurement system 700 according to the respective batch of reagents 210 or to check the operational status of the respective assay apparatus 300. Each set of instructions may include a request to perform a live test, i.e. the assay process, on the respective batch of assay samples 310. The base station 1010 may determine the
10 number of iterations of the preliminary tests to be performed on the test stations 1020 before performing the live tests. The sets of instructions may be sent in any sequence so that the test stations 1020 are able to perform the assay processes independently of each other. Alternatively, the base station 1010 may transmit a common set of instructions to all the test stations 1020 to simultaneously perform the assay processes
15 on the respective batches of assay samples 310.

After the first assay process has been completed, the first assay results are returned from the first test station 1020 to the base station 1010 for storage and communication to the operator. Similarly, after the second and third assay processes have been
20 completed, the second and third assay results are returned from the second and third test stations 1020, respectively, to the base station 1010. The assay results may further include event logs and/or error records. The event logs may contain data related to the respective assay process, such as date / time stamp and identification data of the respective batch of reagents 210. The error records may contain data
25 related to any errors or problems that may have occurred during the respective assay process.

The combination of the base station 1010 and first test station 1020 may be referred to as a first test system 1030. The second test station 1020 may be referred to as the
30 second test system 1032, the third test station 1020 may be referred to as the third test system 1034, the fourth test station 1020 may be referred to as the fourth test system 1036, and so forth. As shown in Figure 17B and Figure 18C, the first test system 1030 may be integrally housed in a common body or first housing 1040, the

second test system 1032 may be housed in a second housing 1042, the third test system 1034 may be housed in a third housing 1044, the fourth test system 1036 may be housed in a fourth housing 1046, and so forth. It will be appreciated that the operator may accordingly rely on any one or more of the test systems 1030,1032,1034,1036.

In one embodiment of this arrangement of test systems 1030,1032,1034,1036, each test station 1020 includes the respective vacuum device 500 for depressurizing the respective vacuum chamber 400. The vacuum devices 500 are not fluidically connected to each other, and each vacuum device 500 may be operated independently from the others. In another embodiment, there is a common vacuum device 500 in the first test station 1020 configured for depressurizing the vacuum chamber in the first test station 1020. The common vacuum device 500 is fluidically connected to the vacuum chambers 400 in all the test stations 1020 and is further configured for depressurizing all the vacuum chambers 400. All the vacuum chambers 400 can thus be collectively depressurized by the common vacuum device 500.

In this arrangement of test systems 1030,1032,1034,1036, each test station 1020 is capable of receiving at least one dispensing apparatus 100 for the respective assay process. Each test station 1020 is capable of performing the assay process independently from the others. Additional test stations 1020 may be connected and installed in a plug and play approach to expand the assay system 1000. The operator may connect additional test stations 1020 on demand to increase overall throughput, specifically to increase the number of assay processes performed by the assay system 1000. For example, the assay system 1000 may be deployed at a remote location where there is limited access to healthcare. The assay system 1000 allows for assaying of biofluid samples 110 taken from local patients at that remote location for quick screening, monitoring, and/or diagnosis of medical conditions. By installing more test stations 1020 in the assay system 1000, more assay processes can be performed at the same time and better healthcare support can be provided to the local patients.

This assay system 1000 is capable of conducting multiple tests for many patients at a central location in a quick and efficient manner. Ease of expansion of the assay system

1000 advantageously allows more patients to be quickly screened, monitored, and/or diagnosed of any medical conditions. With an increasing human population, there is greater demand for such tests for people to better understand their physical health as early as possible, especially even as the number of people with medical conditions
5 like diabetes or chronic kidney disease is on the rise. Medical expenses are also increasing for individuals and this directly impacts the economy as the push for government to dip into their reserves becomes higher if these medical conditions are not screened, monitored, and/or diagnosed early.

10 Identification System 1100

In representative or exemplary embodiments of the present disclosure with reference to Figure 19, there is an identification system 1100 for supporting the assay process performed on the biofluid samples 110 of a patient. Particularly, the identification
15 system 1100 helps the patient to identify and obtain his/her assay results after the assay process has been completed. The identification system 1100 includes at least three identification labels 1110, i.e. a first identification label 1112, a second identification label 1114, and a third identification label 1116. The first and second identification labels 1112, 1114 are permanently disposed on the dispensing apparatus
20 100 configured for dispensing biofluid samples 110 collected from the patient. The first and second identification labels 1112, 1114 may be directly formed on the dispensing apparatus 100, such as by printing / scribing / embossing on a surface thereof, or formed separately and later attached to a surface thereof, such as by fasteners, adhesive, or other bonding means. It will be appreciated that the first and second
25 identification labels 1112, 1114 may be positioned differently, such as by reversing their positions, from that as shown in Figure 19.

The third identification label 1116 is detachably attached to the dispensing apparatus 100. The third identification label 1116 is detached or removed, either by the patient
30 or the operator such as a clinician assisting the patient, and used to subsequently identify and obtain the assay results after the assay process on the patient's biofluid samples 110 has been completed. The third identification label 1116 may be attached such that it cannot be reattached after it has been removed. The attachment for the

third identification label 1116 may include anti-tamper / tamperproof features as will be readily known to the skilled person. The identification labels 1110 may be disposed on or attached to any surface or part of the dispensing apparatus 100 such as the cartridge 102. For example, the first and second identification labels 1112,1114 are
5 disposed on opposing sides of the cartridge 102, and the third identification label 1116 is disposed on the window 132 of the cartridge 102.

The assay apparatus 300 is configured to receive the dispensing apparatus 100. The assay apparatus 300 further includes a set of reader devices configured to read or
10 scan at least the first and second identification labels 1112,1114. In one embodiment, a common reader device is arranged to read both the first and second identification labels 1112,1114. In another embodiment, a first reader device is arranged to read the first identification label 1112 and a second reader device is arranged to read the second identification label 1114. The reader devices may be disposed in the vacuum
15 chamber 400 and the dispensing apparatus 100 is preferably inserted into the vacuum chamber 400 in only one orientation to facilitate reading of the first and second identification labels 1112,1114. The first and second identification labels 1112,1114 may be read after the vacuum cover 450 has been closed.

20 In another embodiment, the first identification label 1112 and/or second identification label 1114 may be disposed on the cartridge lid 116 such that the operator may utilise an external reader device, e.g. a barcode reader, not connected to the assay apparatus 300, to scan the first identification label 1112 and/or second identification label 1114. This external scanning provides a secondary safety approach in the event
25 of the reader devices of the assay apparatus 300 failing to read the first identification label 1112 and/or second identification label 1114.

The vacuum chamber 400 may include a reader mounting portion for mounting the reader devices and may include a window to cover the reader devices. The window
30 may be sealed over the reader devices, such as by adhesive or fasteners, while allowing the reader devices to be able to read the first and second identification labels 1112,1114. When the dispensing apparatus 100 is housed in the vacuum chamber 400, the reader devices may be positioned at a distance away from the first and

second identification labels 1112,1114 for fast and reliable reading. A reflective element may be disposed on an inner surface of the reader mounting portion to provide off-axis illumination through the window and onto the first and second identification labels 1112,1114, without reflecting back to the reader devices. The reflective element
5 may be a thin piece of aluminium foil.

The reader devices may employ any suitable technology to read the first and second identification labels 1112,1114. For example, each of the first and second identification labels 1112,1114 may be in the form of a barcode or other optical code, and the reader
10 devices may include laser scanners and/or camera-based readers to read or scan the barcodes. The barcodes may be linear barcodes such as GS1-128 or GS1 DataBar. The barcodes may be matrix barcodes such as GS1 QR Code or GS1 DataMatrix. Using barcodes based on the GS1 standard allows products such as the dispensing
15 apparatus 100 and information associated therewith to move smoothly, efficiently, and safely for the proper interoperative use from the manufacturing facility to the deployment location. For example, the GS1 barcodes may encode information such as product numbers, serial numbers, and batch numbers.

In some embodiments, the dispensing apparatus 100 is of the disposable type and is
20 manufactured with the cartridge 102 and cuvettes 200 pre-coupled together at the manufacturing facility. The cuvettes 200 are also pre-loaded with the reagents 210. The disposable dispensing apparatus 100 may include a BCG sample cuvette 200, a BCG reference cuvette 200, and a DNBA cuvette 200 that contains BCG or DNBA reagents 210 accordingly. The reader devices read the first and second identification
25 labels 1112,1114 to retrieve identification data about the dispensing apparatus 100 and reagents 210, wherein the identification data is used to calibrate the assay apparatus 300 to perform the assay process.

The reader devices read the first identification label 1112 to detect presence of the
30 dispensing apparatus 100 and to retrieve first identification data about or associated with the dispensing apparatus 100. The first identification data may be encoded in the GS1 barcodes of the first identification label 1112 and may be stored on a memory or storage device of the assay apparatus 300 upon retrieval. The first identification data

may include the identifiers of the dispensing apparatus 100 or parts thereof such as the cartridge 102, batch identifiers, lot identifiers, serial identifiers, product codes, etc. and the like.

- 5 The reader devices read the second identification label 1114 to retrieve second identification data about or associated with the reagents 210 contained in the cuvettes 200 of the dispensing apparatus 100. The second identification data may be encoded in the GS1 barcodes of the second identification label 1114 and may be stored on the memory or storage device of the assay apparatus 300 upon retrieval. The second
- 10 identification data may include the identifiers of the reagents 210, manufacturing dates, expiry dates, batch identifiers, lot identifiers, serial identifiers, product codes, etc. and the like.

After retrieving and storing the first and second identification data, reference

15 identification data is retrieved from a pre-established library or database and compared with the first and second identification data.

In one embodiment, the database resides locally in the assay apparatus 300, such as on the memory or storage device. The local database may be part of a closed intranet

20 system that does not interface with the internet. The intranet system can receive the reference identification data and store it on the local database only from licensed manufacturers of the dispensing apparatus 100 and reagents 210. The local database may be pre-loaded with the reference identification data during scheduled upgrades or maintenance activities that are permitted by the licensed manufacturers to reduce

25 risk of tampering.

In another embodiment, the assay apparatus 300 is communicatively connected to an integrated system of the facility where the assay apparatus 300 is deployed, such as the HIS or LIS, and the database resides on the facility integrated system. While assay

30 apparatus 300 can retrieve the reference identification data from the facility database, the assay apparatus 300 may not share the first and second identification data, as well as the assay results, with the facility database due to data privacy issues. The first and second identification data and the assay results remain stored on the local memory or

storage device of the assay apparatus 300. This configuration adds a layer of security to protect the identity of the patient.

5 In yet another embodiment, the assay apparatus 300 is communicatively connected to a remote server, such as a cloud server, where the database resides. A verification process between the assay apparatus 300 and the cloud server may be required before the assay apparatus 300 can receive the reference identification data from the cloud server. The verification process may include verifying identifiers of the assay apparatus 300 and cloud server with each other before they can be paired and bonded
10 together to open at least one communication channel for communicating the reference identification data. The reference identification data may be encrypted by the cloud server to add another layer of security, and the encrypted reference identification data is later decrypted by the assay apparatus 300 using a predetermined security key. It will be appreciated that these security features, specifically pairing / bonding and
15 encryption / decryption, in data communications will be readily understood by the skilled person and are not further elaborated for purpose of brevity.

When a fresh or updated version of the reference identification data is installed or loaded in the database, the installation may at the same time delete older versions of
20 the reference identification data still stored in the database. In other words, the fresh or updated version overwrites all older versions in the database. These older versions may have become obsolete or invalid over time and are no longer applicable for future assays. This prevents the assay apparatus 300 from assaying an older / obsolete / invalid dispensing apparatus 100.

25 By comparing against the reference identification data, the retrieved first and second identification data can be verified as to its authenticity, i.e. whether the dispensing apparatus 100 and reagents 210 are genuine or valid products from the licensed manufacturers. Failed verification can indicate a possibility that the dispensing
30 apparatus 100 and/or reagents 210 contained therein are counterfeit products from unlicensed or unauthorized suppliers. It can also indicate a possibility that the dispensing apparatus 100 and/or reagents 210 are genuine but later found to be defective or contaminated during quality checks and the manufacturers have already

rejected or recalled the products. This verification process can be used to identify fraudulent or invalid products and further adds integrity to the assay results.

5 The comparison against the reference identification data can be used for other checks and validations as well. For example, the first / second identification data may indicate that the dispensing apparatus 100 / reagents 210 are intended for use in a particular country or geographical location. If the dispensing apparatus 100 is loaded into the assay apparatus 300 that is located in a different country or geographical location, then the assay apparatus 300 will generate an error alert to reject the dispensing
10 apparatus 100 and the assay process will not commence. The error alert may be in the form of a displayed message, a visual indication, a sound alert, or any combination thereof. This check may offer some protection against use of dispensing apparatuses 100 that are parallel imported from other territories. In another example, the reference identification data may indicate that the assay apparatus 300 can only be used for a
15 predetermined set of dispensing apparatuses 100 and/or reagents 210. If the first / second identification data of a dispensing apparatus 100 does that match those of the predetermined set, then the assay apparatus 300 will generate an error alert to reject the dispensing apparatus 100 and the assay process will not commence.

20 After verifying the first and second identification data against the reference identification data, the assay apparatus 300 retrieves one or more algorithms or programs for calibration before commencing the assay process. The algorithms or programs may be stored on the local database of the assay apparatus 300 or remotely, such as on the cloud server. The algorithms or programs are customized for the
25 particular batch of reagents 210 in the dispensing apparatus 100 and are used to calibrate the assay apparatus 300, especially the optical measurement system 700, so as to optimize the assay process. In this way, appropriate algorithms or programs can be retrieved securely for assaying the assay samples 310 without needing to know the patient's identity.

30

The third identification label may similarly be in the form of a barcode or other optical code that contains third identification data encoded therein. The third identification data is unique to the dispensing apparatus 100 and suitable for single use only. An

external electronic device or reader device can be used to read the third identification data to access the assay results after the assay process on the patient's biofluid samples 110 has been completed. The external electronic device or reader device may be connectable to the assay apparatus 300 or to an external computer system.

5 In some embodiments with reference to Figure 20, there is a computerized method 1150 for availing assay results from the assay process performed on biofluid samples 110 of the patient. The computerized method 1150 is implemented on a computer system such as the remote server or cloud server where the database resides. It will be appreciated that the computer system includes a processor and various modules /
10 components for performing various steps of the method 1150, and such steps are performed in response to non-transitory instructions operative or executed by the processor that includes suitable logic, circuitry, and/or interfaces to execute such steps.

The operator first removes or detaches the third identification label 1116 from the
15 dispensing apparatus 100 prior to providing the dispensing apparatus 100 to the patient. The detached third identification label 1116 is placed on a medical record document of the patient which contains sensitive patient data avail only to a select group of people including the operator. The patient takes the dispensing apparatus 100 without the third identification label 1116 and proceeds to transfer the biofluid bulk
20 sample through a collection device. The patient then returns the dispensing apparatus 100, which now contains the biofluid samples 110, to the operator.

After returning the dispensing apparatus 100, the patient uses a first electronic device, such as mobile phone with an integrated camera, to read the third identification label
25 1116 on the medical record document. In an alternative embodiment, the patient may take the dispensing apparatus 100 with the third identification label 1116 still intact and collect the biofluid samples 110. The dispensing apparatus 100 is returned to the operator and the third identification label 1116 is detached and placed on the medical record document. The patient may use the first electronic device to read the third
30 identification label 1116 before or after it has been detached. In yet another embodiment, the dispensing apparatus 100 may further include a fourth identification label detachably attached to the dispensing apparatus 100. The fourth identification label contains the third identification data encoded therein. One of the third and fourth

identification labels can be detached and placed on the medical record document while the other remains on the dispensing apparatus 100. It will be appreciated that additional identification labels may be detachably attached to the dispensing apparatus 100.

5

To minimize the time spent inside the facility where the assay apparatus 300 is deployed, such as a clinic or hospital, the patient may later access the assay results remotely through an online interface, such as via an app or website. The method 1150 includes a step 1152 of receiving, from the first electronic device, a request from the
10 patient to access the online interface and initiate the assay process. The patient request includes the third identification data and further includes a device identifier of the first electronic device. In one example, the first electronic device reads the third identification label 1116 (or fourth identification label) and retrieves the third identification data which contains an address or URL to the online interface. In another
15 example, the first electronic device executes an app to access the online interface. The first electronic device captures an image of the third identification label 1116 (or fourth identification label) to obtain the third identification data and sends the patient request.

20 The step 1152 thus activates the third identification data which remains in the activated state until the assay results are received. Optionally, the method 1150 may include a step of verifying the third identification data against the reference identification data. By comparing against the reference identification data, the third identification data can be verified as to whether it is detached from a genuine product (dispensing apparatus
25 100) and/or whether it is valid. For example, failed verification can indicate that the dispensing apparatus 100 is faulty or that the third identification data has already been deactivated, such as because it has already been used in an earlier assay process for another patient and the dispensing apparatus 100 is intended for single use only. A verification message may be sent to the first electronic device to inform the patient of
30 the verification status.

The device identifier may be a network address such as a media access control (MAC) address of the first electronic device. The method 1150 includes a step 1154 of

associating the third identification data with the device identifier. This makes the third identification data unique to the first electronic device and thus the patient. This also prevents other patients from accessing the assay results of the patient.

- 5 After the operator has received the dispensing apparatus 100 containing the biofluid samples 110, the operator loads the dispensing apparatus 100 into the assay apparatus 300 and performs the assay process. After the assay process has been completed, the operator prepares to input the assay results into the computer system. Specifically, the operator uses a second electronic device, such as a computer
- 10 integrated with or connected to a camera, returning the dispensing apparatus 100, the patient uses a first electronic device, to read the third identification label 1116 (or fourth identification label). The method 1150 includes a step 1156 of receiving, from the second electronic device, a request from the operator to access the online interface and input the assay results. The operator request includes the third identification data
- 15 and the assay results. In one example, the second electronic device reads the third identification label 1116 (or fourth identification label) and retrieves the third identification data which contains an address or URL to the online interface. In another example, the second electronic device executes an app to access the online interface. The first electronic device captures an image of the third identification label 1116 (or
- 20 fourth identification label) to obtain the third identification data and sends the operator request along with the assay results.

Optionally, the method 1150 may include a step of verifying the third identification data against the reference identification data, as described above. A verification message

25 may be sent to the second electronic device to inform the operator of the verification status.

The method 1150 includes a step 1158 of associating the assay results with the third identification data. This makes the assay results unique to the third identification data

30 which is in turn unique to the first electronic device and thus the patient. Thus, other patients would not be able to gain access to the assay results. The method 1150 includes a step 1160 of sending a results message to the first electronic device. The results message indicate that the assay results are available on the online interface

accessed by the first electronic device. The patient then uses the first electronic device and continues on the online interface, such as via the app or website, to access the assay results.

5 In an exemplary situation, there is a first dispensing apparatus 100 having a first "third identification data" and a second dispensing apparatus 100 having a second "third identification data". The patient may use the first dispensing apparatus 100 to collect the biofluid samples 110 but the step of verifying the first "third identification data" may indicate that the first dispensing apparatus 100 is invalid. Nevertheless, the patient
10 can still return the first dispensing apparatus 100 to the operator who will transfer the biofluid samples 110 to the second dispensing apparatus 100. The step of verifying the second "third identification data" indicates that the second dispensing apparatus 100 is valid and the operator proceeds with the assay process. The assay results are associated with the second "third identification data" but a further association may be
15 made between the second "third identification data" and the first "third identification data". This allows the patient to access the assay results using the first "third identification data". Alternatively, the operator may require the patient to activate the second "third identification data" after the operator transfers the biofluid samples 110 from the first dispensing apparatus 100 to the second dispensing apparatus 100, so
20 that the patient can assay results using the second "third identification data" normally as described above.

In another exemplary situation, the patient collects his/her biofluid in the collection device and transfers the biofluid from the collection device into a first dispensing
25 apparatus 100. The patient thereafter passes the first dispensing apparatus 100 and the collection device with leftover biofluid to the operator. Thereafter, the operator conducts the assay process. In an unlikely scenario whereby insufficient biofluid samples 110 are dispensed into the cuvettes 200, the assay results may become invalid. In order to prevent the patient from dispensing another batch of biofluid, the
30 operator may use the collection device with leftover biofluid of the patient and dispense into a second dispensing apparatus 100. Prior to performing the assay process with the second dispensing apparatus 100, the operator may use an external device or reader device to scan both the third identification labels 1116 of the first and second

dispensing apparatuses 100 for traceability of the number of used dispensing apparatuses 100. Alternatively, the reader device of the assay apparatus 300 may read the first dispensing apparatus 100 and consecutively the second dispensing apparatus 100 to reflect the same patient usage of the first and second dispensing apparatuses 100.

Optionally, the method 1150 may include a step of deactivating the third identification data in response to the first electronic device accessing the assay results on the online interface. This prevents the dispensing apparatus 100, from which the third identification label 1116 (or fourth identification label) was detached, from being used in subsequently assay processes, especially if the dispensing apparatus 100 is of the disposable type and intended for single use only. The method 1150 may include a step of deactivating the third identification data if the assay results are not accessed after a predefined expiry period has lapsed. This reduces wastage of computing resources as the assay results would not be hosted on the computer system for an indefinite period while waiting for the patient to access the assay results.

Optionally, the method 1150 may include a step of starting a predefined waiting period for the third identification data in response to receiving the patient request. This predefined waiting period may be, but is not limited to, between 10 minutes to 30 minutes. The method 1150 may further include a step of sending, to the first electronic device, a waiting message in response to starting of the predefined waiting period. This waiting message informs the patient of the estimated time to wait before the patient can expect to receive the assay results. From the perspective of the operator performing the assay process, this predefined waiting period also encourages the operator to input the assay results within that period. The method 1150 may further include a step of deactivating the third identification data if the assay results are not received after the predefined waiting period has lapsed. The assay results may not be accurate if the assay process is not completed within that period, as the biological / chemical profile of the biofluid samples 110 may have altered over that period. Deactivating the third identification data can inform the patient not to expect the assay results as they would not be accurate anyway.

Throughout the patient's journey from receiving the dispensing apparatus 100 to collecting the biofluid samples 110 and to accessing the assay results, the patient relies on the third identification data to initiate the assay process on the online interface and later access the assay results. The patient does not need to reveal his/her
5 personal identity, allowing the patient to test the biofluid samples and receive the assay results anonymously. The identification system 1100 and computerized method 1150 thus help to protect the patient's privacy throughout the assay process.

Based on the assay results, the patient may then consider whether to continue
10 visitation at the clinic or hospital. For example, the assay results may reveal to the patient of quantitative numbers of compounds or substances in the biofluid samples 110 that demonstrate little to no risk to the patient, such that there may not be any necessity to arrange follow-up visits at least in the short term. However, even so, as the pathogens such as viruses become more prominent and widespread, screening
15 and monitoring at off site or non-centric hospitals or clinics will become even more important for the patients to check on their medical profile.

In some embodiments, there is an assay system 1000 including a base station 1010 and a plurality of test stations 1020, each test station including the assay apparatus
20 300. Using two test stations 1020 as an example, the first test station 1020 with a first assay apparatus 300 receives a first dispensing apparatus 100 containing a first batch of reagents 210, and the second test station 1020 with a second assay apparatus 300 receives a second dispensing apparatus 100 containing a second batch of reagents 210. In one embodiment, each test station 1020 compares the respective first and
25 second identification data against the respective reference identification data. In another embodiment, both sets of first and second identification data are sent from the test stations 1020 to the base station 1010. The base station then compares both sets of first and second identification data against the respective reference identification data. The comparison results are returned from the base station 1010 to the test
30 stations 1020. The comparison results may be sent together with the appropriate algorithms or programs for the assay processes to be performed by the test stations 1020. Alternatively, the test stations 1020 may retrieve the appropriate algorithms or programs from the local assay apparatuses 300.

- An identification label 1110 can be in the form of a GS1 QR Code and the identification data is encoded in the GS1 QR Code. However, the GS1 QR Code has a limited data capacity which may not be sufficient to encode all the necessary identification data. It
- 5 will be appreciated that additional identification labels 1110 may be included in the identification system, such that all the identification labels 1110 can enable retrieval of all necessary identification data relevant to the dispensing apparatus 100 and reagents 210. Alternatively, instead of encoding the identification data in the identification label 1110, the identification label 1110 may encode an address or URL to an online location.
- 10 The reader devices read the identification label 1110 and access the address to retrieve the identification data stored remotely at the online location. This may be achieved when the assay apparatus 300 is connected to an intranet system or the internet.
- 15 In an embodiment, the identification labels 1110 may be disposed on a set of print sticker labels. The set of print sticker labels may be disposed on one or more surface portions of the dispensing apparatus 100, such as on the cartridge 102 and/or cuvette casing 202. Each of the print sticker label may include any one or more of the identification labels 1110 in any combination. For example, smaller labels 1110 may
- 20 be consolidated and printed together in a single print sticker label, while larger labels 1110 may be printed individually.

Materials and Manufacturing

- 25 Various components of the dispensing apparatus 100 / assay apparatus 300 may be made of any of, but not limited to, the following materials – polypropylene / polypropene (PP), high-density polyethylene (HDPE), silicone, butyl rubber, nitrile rubber, and poly(methyl methacrylate) (PMMA), or a combination of materials – styrene acrylonitrile resin (SAN). The material PMMA may alternatively be known as
- 30 acrylic or acrylic glass, as well as by the trade names Plexiglas®, Acrylite®, Lucite®, and Perspex®. Where appropriate, various components of the dispensing apparatus 100 / assay apparatus 300 are assembled together with sealing elements to prevent or at least mitigate leakage of biofluid. Such sealing elements may include, but are not

limited to, O-rings, toric joints, or gaskets made of resilient materials, rubber / silicone tight fitting connections, ultraviolet bonding, ultrasonic bonding, adhesive glue, latching, cantilever, etc.

- 5 The dispensing apparatus 100 / assay apparatus 300 or various components thereof may be fabricated by moulding or other known manufacturing methods. Particularly, they may be formed by a manufacturing process that includes an additive manufacturing process. A common example of additive manufacturing is three-dimensional (3D) printing; however, other methods of additive manufacturing are
10 available. Rapid prototyping or rapid manufacturing are also terms which may be used to describe additive manufacturing processes.

As used herein, “additive manufacturing” refers generally to manufacturing processes wherein successive layers of material(s) are provided on each other to “build-up” layer-
15 by-layer or “additively fabricate”, a 3D component. This is compared to some subtractive manufacturing methods (such as milling or drilling), wherein material is successively removed to fabricate the part. The successive layers generally fuse together to form a monolithic component which may have a variety of integral sub-components. In particular, the manufacturing process may allow an example of the
20 disclosure to be integrally formed and include a variety of features not possible when using prior manufacturing methods.

Additive manufacturing methods described herein enable manufacture to any suitable size and shape with various features which may not have been possible using prior
25 manufacturing methods. Additive manufacturing can create complex geometries without the use of any sort of tools, moulds, or fixtures, and with little or no waste material. Instead of machining components from solid billets of plastic or metal, much of which is cut away and discarded, the only material used in additive manufacturing is what is required to shape the part.

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Suitable additive manufacturing techniques in accordance with the present disclosure include, for example, Fused Deposition Modelling (FDM), Selective Laser Sintering (SLS), 3D printing such as by inkjets and laserjets, Stereolithography (SLA), Direct

Selective Laser Sintering (DSLS), Electron Beam Sintering (EBS), Electron Beam Melting (EBM), Laser Engineered Net Shaping (LENS), Electron Beam Additive Manufacturing (EBAM), Laser Net Shape Manufacturing (LNSM), Direct Metal Deposition (DMD), Digital Light Processing (DLP), Continuous Digital Light Processing (CDLP), Direct Selective Laser Melting (DSLM), Selective Laser Melting (SLM), Direct Metal Laser Melting (DMLM), Direct Metal Laser Sintering (DMLS), Material Jetting (MJ), NanoParticle Jetting (NPJ), Drop On Demand (DOD), Binder Jetting (BJ), Multi Jet Fusion (MJF), Laminated Object Manufacturing (LOM), and other known processes.

The additive manufacturing processes described herein may be used for forming components using any suitable material. For example, the material may be metal, plastic, polymer, composite, or any other suitable material that may be in solid, liquid, powder, sheet material, wire, or any other suitable form or combinations thereof. More specifically, according to exemplary embodiments of the present disclosure, the additively manufactured components described herein may be formed in part, in whole, or in some combination of materials suitable for use in additive manufacturing processes and which may be suitable for the fabrication of examples described herein.

As noted above, the additive manufacturing process disclosed herein allows a single component to be formed from multiple materials. Thus, the examples described herein may be formed from any suitable mixtures of the above materials. For example, a component may include multiple layers, segments, or parts that are formed using different materials, processes, and/or on different additive manufacturing machines.

In this manner, components may be constructed which have different materials and material properties for meeting the demands of any particular application. In addition, although the components described herein are constructed entirely by additive manufacturing processes, it should be appreciated that in alternate embodiments, all or a portion of these components may be formed via casting, machining, and/or any other suitable manufacturing process. Indeed, any suitable combination of materials and manufacturing methods may be used to form these components.

Additive manufacturing processes typically fabricate components based on 3D information, for example a 3D computer model (or design file), of the component. Accordingly, examples described herein not only include products or components as described herein, but also methods of manufacturing such products or components
5 via additive manufacturing and computer software, firmware or hardware for controlling the manufacture of such products via additive manufacturing.

The structure of the product may be represented digitally in the form of a design file. A design file, or computer aided design (CAD) file, is a configuration file that encodes
10 one or more of the surface or volumetric configuration of the shape of the product. That is, a design file represents the geometrical arrangement or shape of the product.

Design files can take any now known or later developed file format. For example, design files may be in the Stereolithography or "Standard Tessellation Language" (.stl)
15 format which was created for Stereolithography CAD programs of 3D Systems, or the Additive Manufacturing File (.amf) format, which is an American Society of Mechanical Engineers (ASME) standard that is an extensible markup-language (XML) based format designed to allow any CAD software to describe the shape and composition of any 3D object to be fabricated on any additive manufacturing printer. Further examples
20 of design file formats include AutoCAD (.dwg) files, Blender (.blend) files, Parasolid (.x_t) files, 3D Manufacturing Format (.3mf) files, Autodesk (3ds) files, Collada (.dae) files and Wavefront (.obj) files, although many other file formats exist.

Design files can be produced using modelling (e.g. CAD modelling) software and/or
25 through scanning the surface of a product to measure the surface configuration of the product. Once obtained, a design file may be converted into a set of computer executable instructions that, once executed by a processor, cause the processor to control an additive manufacturing apparatus to produce a product according to the geometrical arrangement specified in the design file. The conversion may convert the
30 design file into slices or layers that are to be formed sequentially by the additive manufacturing apparatus. The instructions (otherwise known as geometric code or "G-code") may be calibrated to the specific additive manufacturing apparatus and may specify the precise location and amount of material that is to be formed at each stage

in the manufacturing process. As discussed above, the formation may be through deposition, through sintering, or through any other form of additive manufacturing method.

- 5 The code or instructions may be translated between different formats, converted into a set of data signals and transmitted, received as a set of data signals and converted to code, stored, etc., as necessary. The instructions may be an input to the additive manufacturing system and may come from a part designer, an intellectual property (IP) provider, a design company, the operator or owner of the additive manufacturing
10 system, or from other sources. An additive manufacturing system may execute the instructions to fabricate the product using any of the technologies or methods disclosed herein.

Design files or computer executable instructions may be stored in a (transitory or non-
15 transitory) computer readable storage medium (e.g., memory, storage system, etc.) storing code, or computer readable instructions, representative of the product to be produced. As noted, the code or computer readable instructions defining the product that can be used to physically generate the object, upon execution of the code or instructions by an additive manufacturing system. For example, the instructions may
20 include a precisely defined 3D model of the product and can be generated from any of a large variety of well-known CAD software systems such as AutoCAD®, TurboCAD®, DesignCAD 3D Max, etc. Alternatively, a model or prototype of the product may be scanned to determine the 3D information of the product. Accordingly, by controlling an additive manufacturing apparatus according to the computer
25 executable instructions, the additive manufacturing apparatus can be instructed to print out the product.

In light of the above, embodiments include methods of manufacture via additive manufacturing. This includes the steps of obtaining a design file representing the
30 product and instructing an additive manufacturing apparatus to manufacture the product according to the design file. The additive manufacturing apparatus may include a processor that is configured to automatically convert the design file into computer executable instructions for controlling the manufacture of the product. In

these embodiments, the design file itself can automatically cause the production of the product once input into the additive manufacturing apparatus. Accordingly, in this embodiment, the design file itself may be considered computer executable instructions that cause the additive manufacturing apparatus to manufacture the product.

- 5 Alternatively, the design file may be converted into instructions by an external computing system, with the resulting computer executable instructions being provided to the additive manufacturing apparatus.

Given the above, the design and manufacture of implementations of the subject matter
10 and the operations described in this specification can be realized using digital electronic circuitry, or in computer software, firmware, or hardware, including the structures disclosed in this specification and their structural equivalents, or in combinations of one or more of them. For instance, hardware may include processors, microprocessors, electronic circuitry, electronic components, integrated circuits, etc.
15 Implementations of the subject matter described in this specification can be realized using one or more computer programs, i.e., one or more modules of computer program instructions, encoded on computer storage medium for execution by, or to control the operation of, data processing apparatus. Alternatively or in addition, the program instructions can be encoded on an artificially generated propagated signal, e.g., a
20 machine-generated electrical, optical, or electromagnetic signal that is generated to encode information for transmission to suitable receiver apparatus for execution by a data processing apparatus. A computer storage medium can be, or be included in, a computer-readable storage device, a computer-readable storage substrate, a random or serial access memory array or device, or a combination of one or more of them.
25 Moreover, while a computer storage medium is not a propagated signal, a computer storage medium can be a source or destination of computer program instructions encoded in an artificially generated propagated signal. The computer storage medium can also be, or be included in, one or more separate physical components or media (e.g., multiple CDs, disks, or other storage devices).

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Although additive manufacturing technology is described herein as enabling fabrication of complex objects by building objects point-by-point, layer-by-layer, typically in a vertical direction, other methods of fabrication are possible and within the

scope of the present subject matter. For example, although the discussion herein refers to the addition of material to form successive layers, one skilled in the art will appreciate that the methods and structures disclosed herein may be practiced with any additive manufacturing technique or other manufacturing technology.

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In the foregoing detailed description, embodiments of the present disclosure in relation to apparatuses for dispensing and assaying biofluid samples are described with reference to the provided figures. The description of the various embodiments herein is not intended to call out or be limited only to specific or particular representations of the present disclosure, but merely to illustrate non-limiting examples of the present disclosure. The present disclosure serves to address at least one of the mentioned problems and issues associated with the prior art. Although only some embodiments of the present disclosure are disclosed herein, it will be apparent to a person having ordinary skill in the art in view of this disclosure that a variety of changes and/or modifications can be made to the disclosed embodiments without departing from the scope of the present disclosure. Therefore, the scope of the disclosure as well as the scope of the following claims is not limited to embodiments described herein.

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