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(54) **SINGLE-USE MICROFLUIDIC CARTRIDGE FOR DETECTION OF TARGET CHEMICAL PRESENCE IN HUMAN BREATH**

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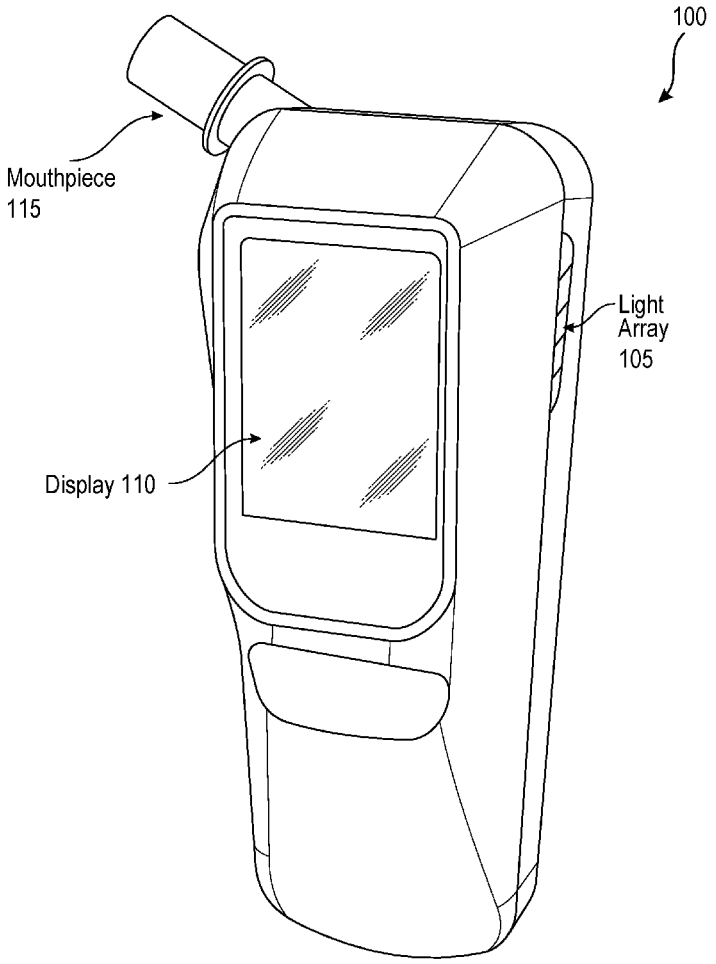
(57) **ABSTRACT**

The present disclosure describes a single-use microfluidic cartridge that is can be utilized with a portable and handheld breath collection and analysis device to detect a presence of a target chemical in human breath. The cartridge receives an air sample of human breath, processes it to extract the target chemical in solution, and reacts the solution with chemical reagent(s) to determine a concentration level of the target chemical present in the collected breath sample. Additionally, a portion of the collected sample can be contained in a separate reservoir of the cartridge of evidence preservation. The cartridge may further contain a cryptographic computing chip to store information regarding the sample processed within the cartridge.



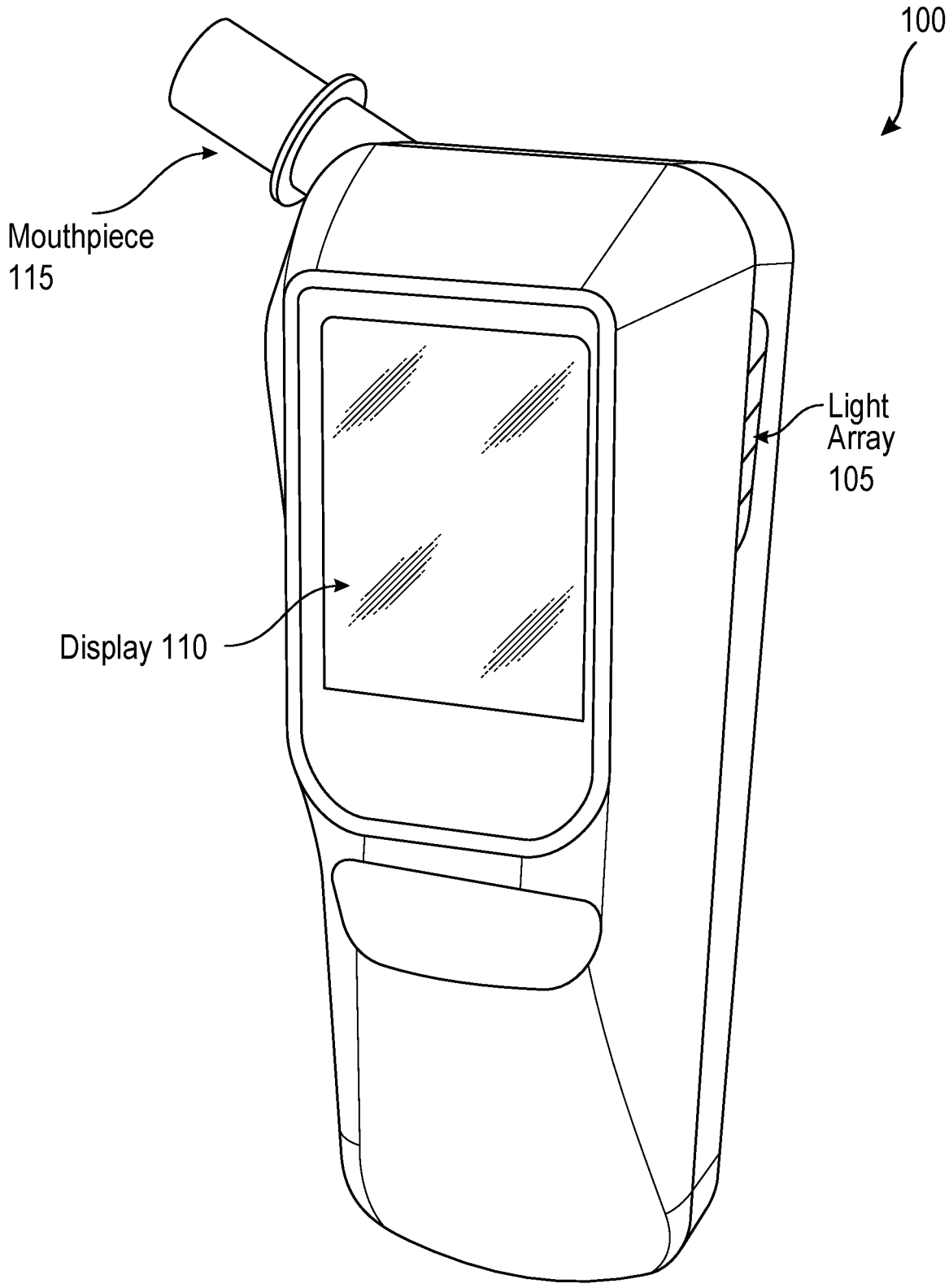


FIG. 1

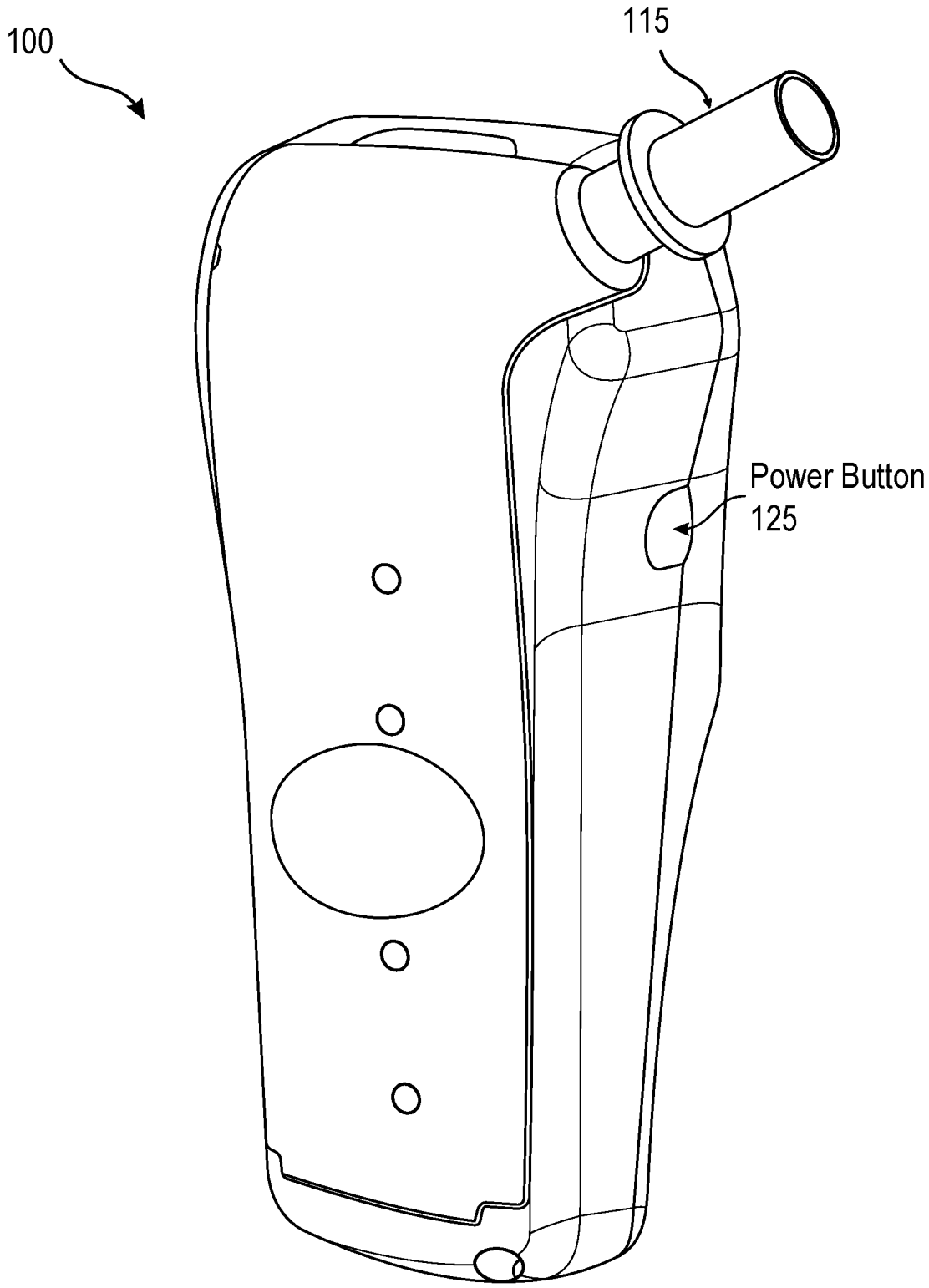


FIG. 2

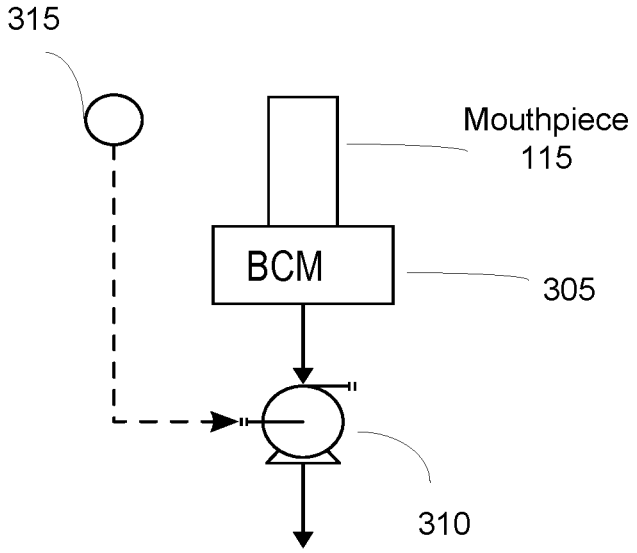

315
Mouthpiece
115
BCM
305
310

FIG. 3

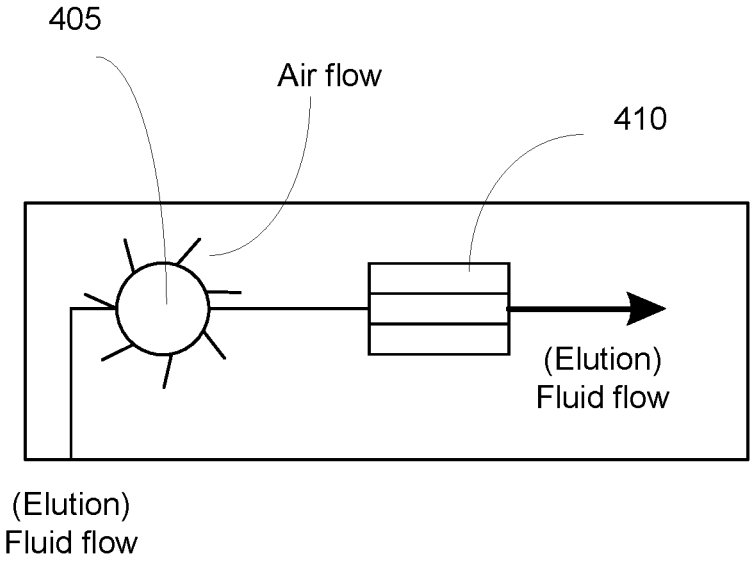

405
Air flow
410
(Elution)
Fluid flow
(Elution)
Fluid flow

FIG. 4

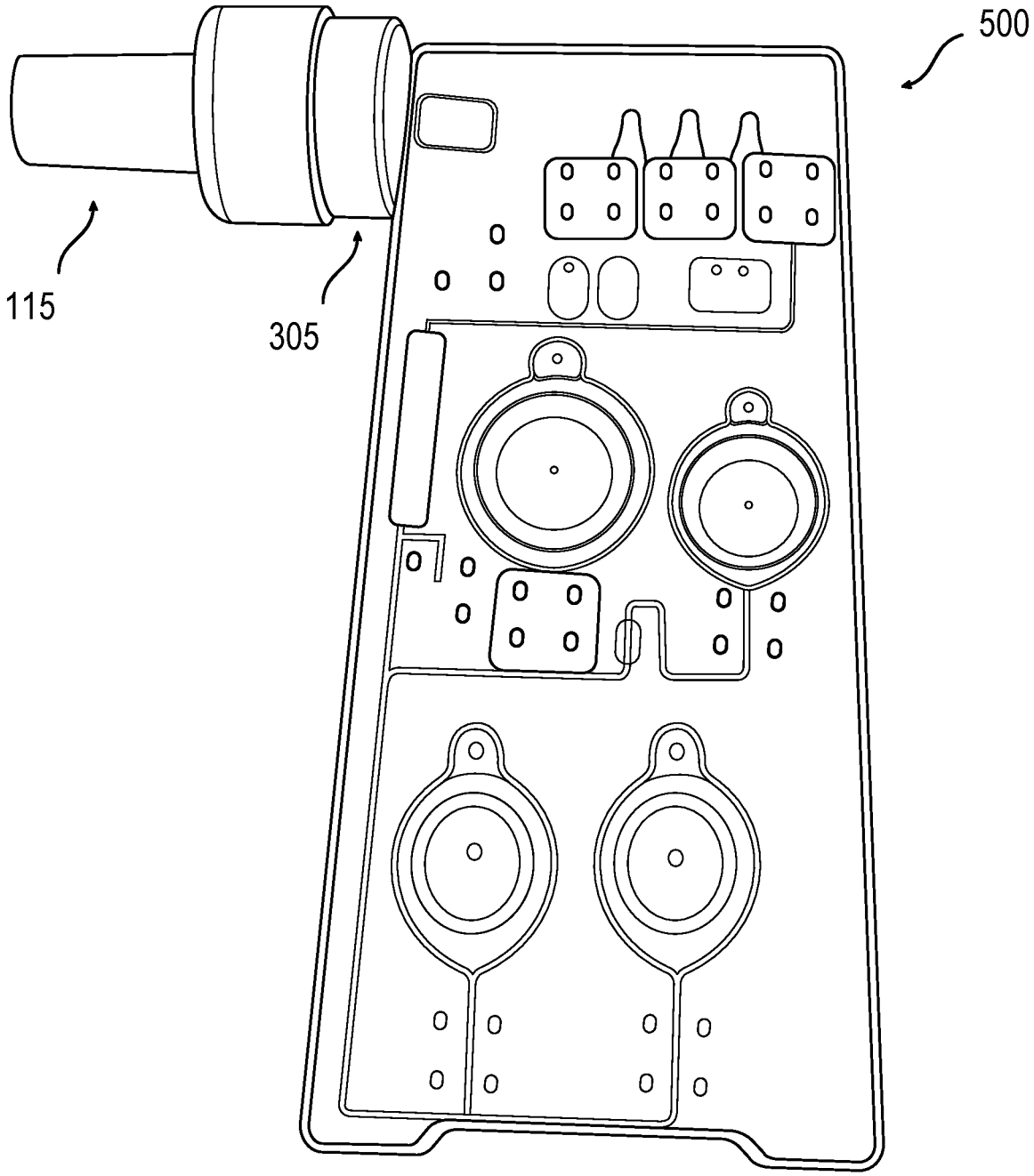


FIG. 5

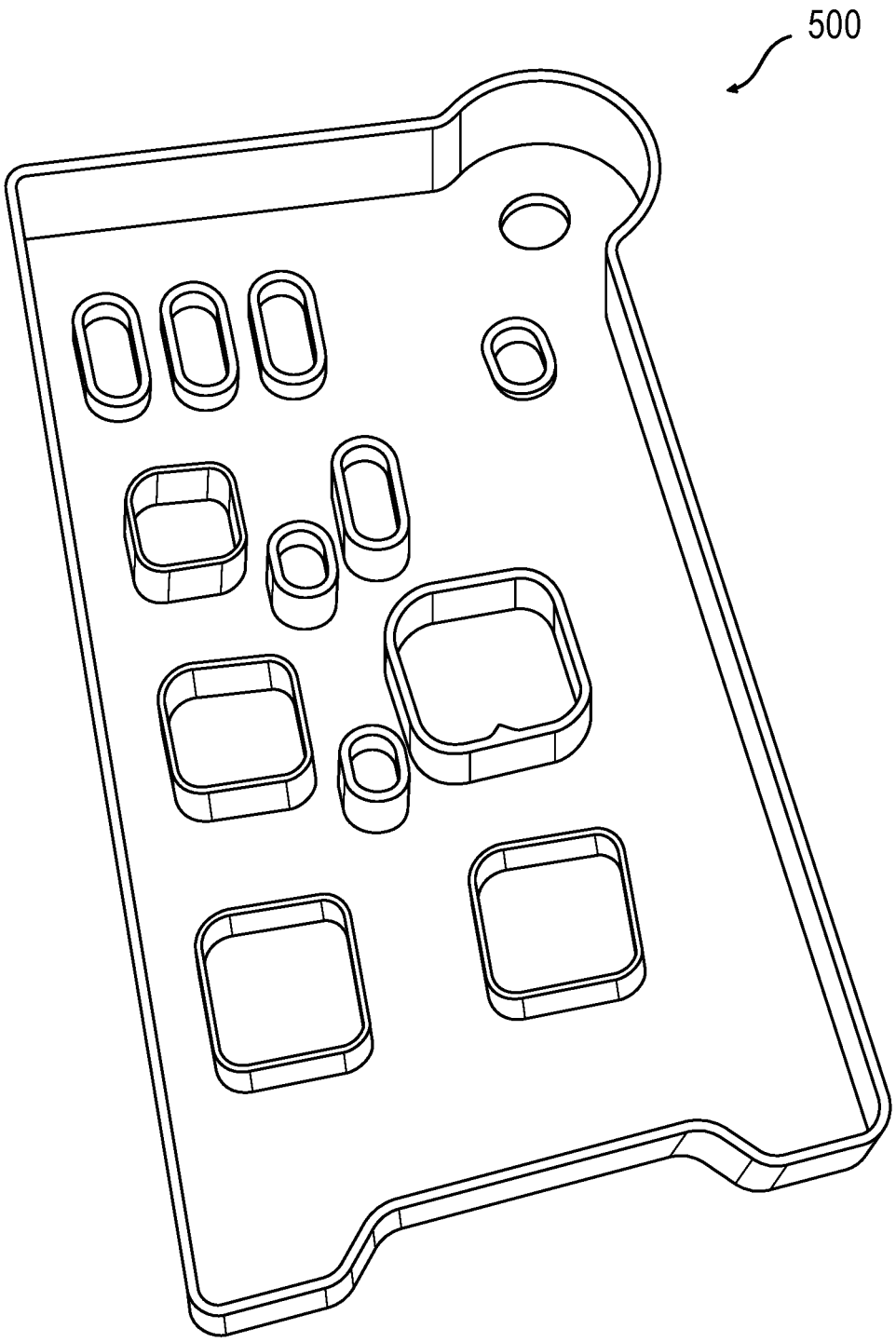


FIG. 6

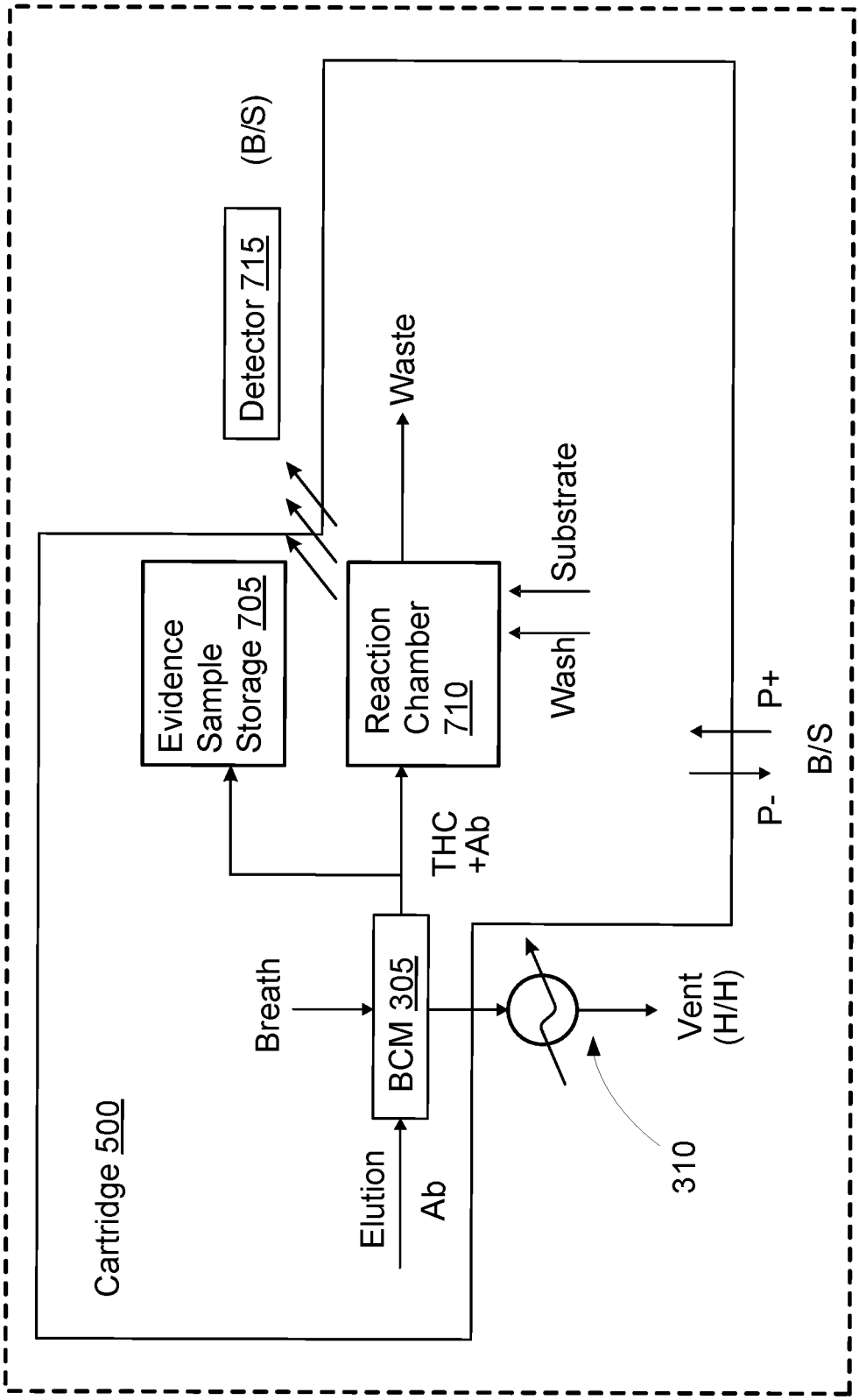

Cartridge 500
Elution
Ab
BCM 305
Breath
THC
+Ab
Evidence
Sample
Storage 705
Reaction
Chamber
710
Detector 715
(B/S)
Waste
Substrate
Wash
P+
P-
B/S
Vent
(H/H)
310

FIG. 7

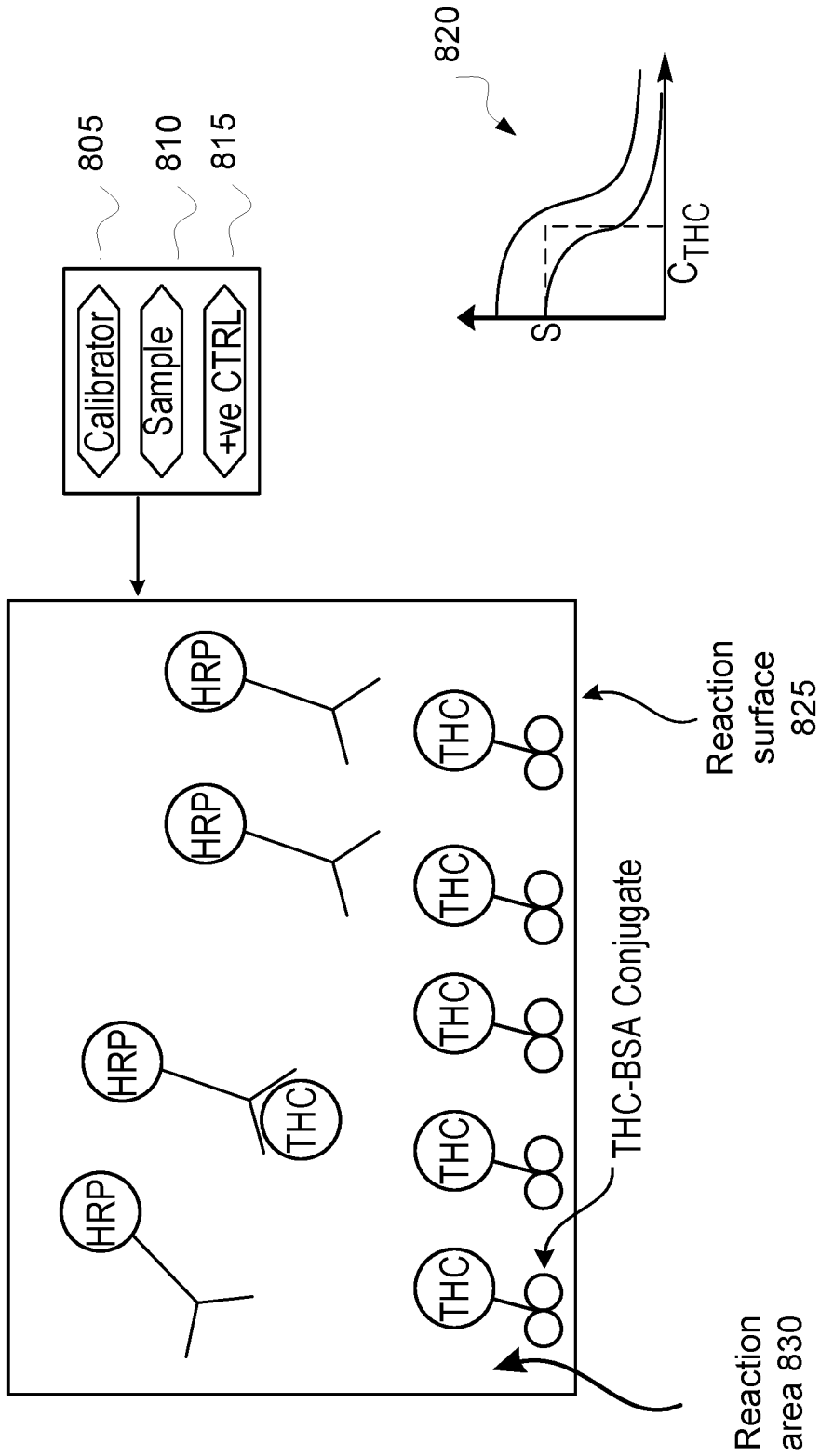

820
805
810
815
Calibrator
Sample
+ve CTRL
S
C_{THC}
HRP
THC
Reaction surface 825
THC-BSA Conjugate
Reaction area 830

FIG. 8

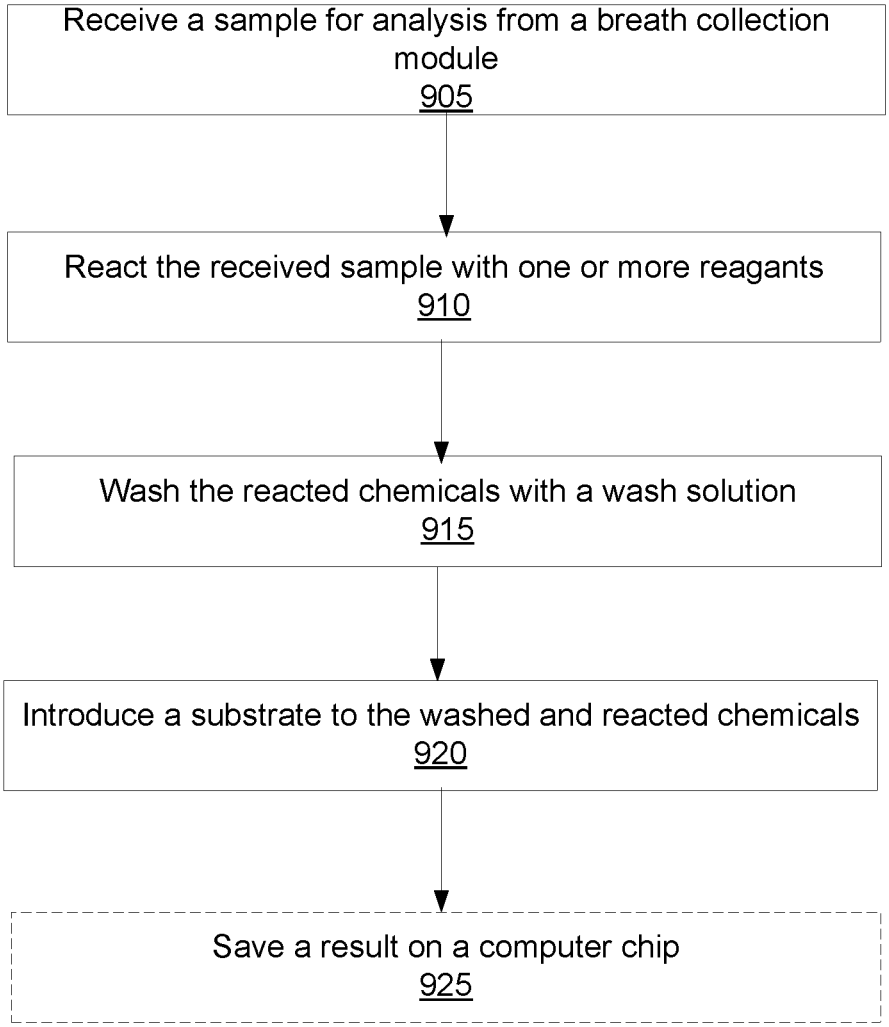

Receive a sample for analysis from a breath collection module
905
React the received sample with one or more reagants
910
Wash the reacted chemicals with a wash solution
915
Introduce a substrate to the washed and reacted chemicals
920
Save a result on a computer chip
925

FIG. 9

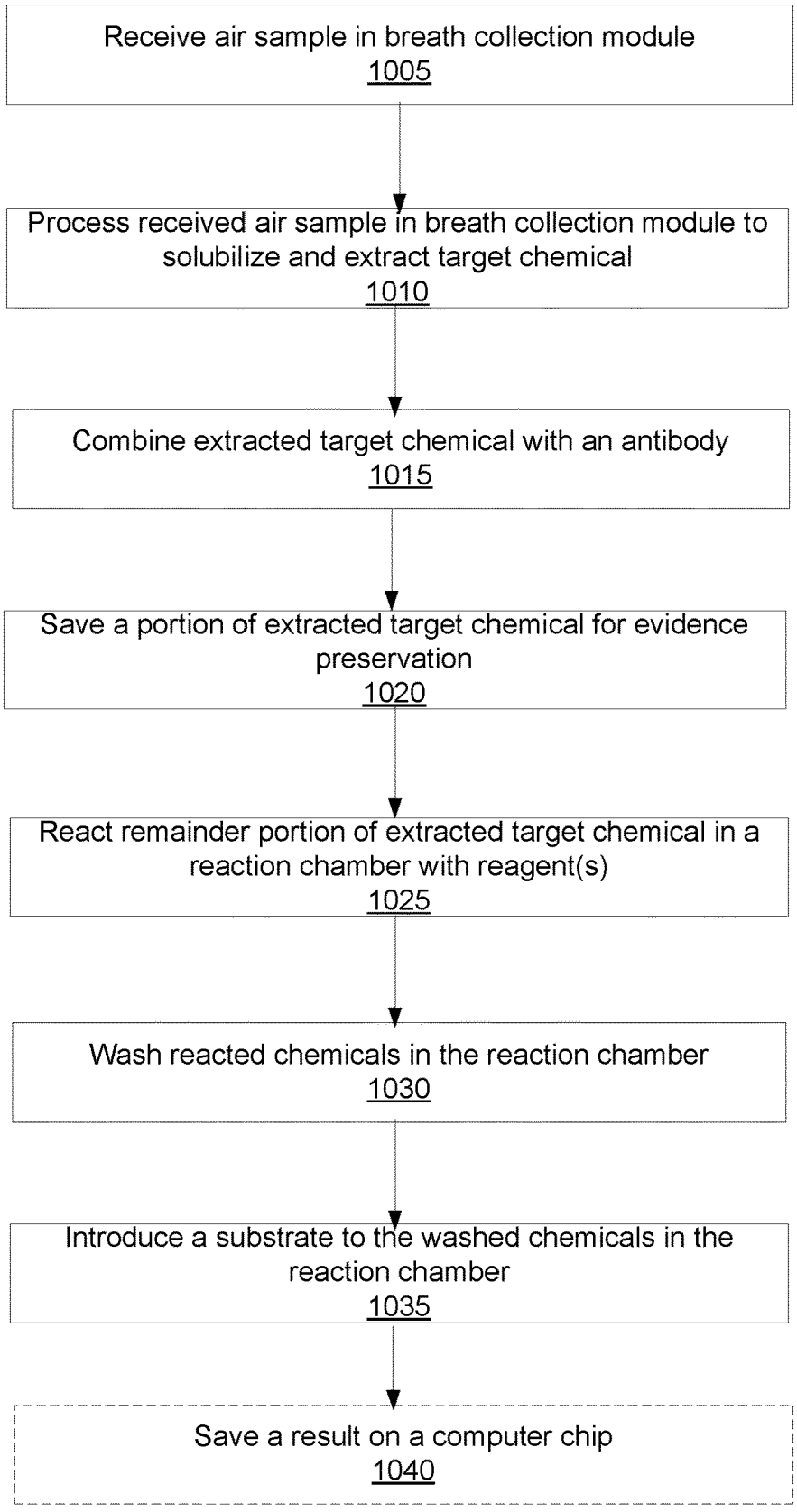

Receive air sample in breath collection module
1005
Process received air sample in breath collection module to solubilize and extract target chemical
1010
Combine extracted target chemical with an antibody
1015
Save a portion of extracted target chemical for evidence preservation
1020
React remainder portion of extracted target chemical in a reaction chamber with reagent(s)
1025
Wash reacted chemicals in the reaction chamber
1030
Introduce a substrate to the washed chemicals in the reaction chamber
1035
Save a result on a computer chip
1040

FIG. 10

SINGLE-USE MICROFLUIDIC CARTRIDGE FOR DETECTION OF TARGET CHEMICAL PRESENCE IN HUMAN BREATH

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims the priority benefit of U.S. Provisional Patent Application No. 62/799,675 filed on Jan. 31, 2019, which is incorporated by reference herein in its entirety.

FIELD OF THE INVENTION

[0002] The present disclosure relates to a cartridge within a portable and handheld breath collection and analysis device, for analysis of a chemical present in a human body.

BACKGROUND

[0003] Existing portable systems exist for measuring a concentration of ethanol present in a person's body, via their breath. However, such portable systems do not presently exist for measuring other substances accurately in a human body. The present disclosure is directed to a replaceable cartridge that can be utilized in a portable system for collecting and determining a measurement of such other substances in a human body via a breath collection and analysis device.

SUMMARY

[0004] This summary is provided to introduce a selection of concepts in a simplified form that are further described in the Detailed Description below. This summary is not intended to identify key features or essential features of the claimed subject matter, nor is it intended to be used as an aid in determining the scope of the claimed subject matter.

[0005] In one embodiment, the present disclosure is directed to a single-use microfluidic cartridge for detection of a target chemical present in human breath via a breath collection and analysis device, the cartridge comprising: a breath collection module configured to collect a desired volume of air from the human subject, and extract a target chemical from the collected air; an evidence sample storage chamber configured to preserve a sample of the extracted target chemical from the collected air for later analysis; and a multi-channel reaction chamber configured to process a competitive immunoassay to generate a signal representing a concentration amount of the target chemical present in the collected air from the human subject.

[0006] In another embodiment, the present disclosure is directed to a method for detection of a target chemical present in human breath via a single-use microfluidic cartridge, the method comprising: receiving a desired volume of air from a human subject in a breath collection module of the single-use microfluidic cartridge; processing the received air in the breath collection module to solubilize and extract the target chemical present in the received air from a surface upon which particles in the breath are collected and concentrated; combining the extracted target chemical with an antibody; saving a portion of the extracted target chemical for evidence preservation; reacting a remainder portion of the extracted target chemical in a multi-channel reaction chamber with one or more chemical reagents; washing the reacted chemicals in the multi-channel reaction chamber with a wash solution; introducing a substrate to the washed chemicals in the multi-channel reaction chamber, the substrate configured to emit a low level light from the single-use microfluidic cartridge, communicating with a detector device to determine a concentration level of the target chemical from the emitted low level light.

[0007] Other features, examples, and embodiments are described below.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] The accompanying drawings, where like reference numerals refer to identical or functionally similar elements throughout the separate views, together with the detailed description below, are incorporated in and form part of the specification, and serve to further illustrate embodiments of concepts that include the claimed disclosure, and explain various principles and advantages of those embodiments.

[0009] The methods and systems disclosed herein have been represented where appropriate by conventional symbols in the drawings, showing only those specific details that are pertinent to understanding the embodiments of the present disclosure so as not to obscure the disclosure with details that will be readily apparent to those of ordinary skill in the art having the benefit of the description herein.

[0010] FIG. **1** illustrates an exemplary front view of a portable breath collection and analysis device.

[0011] FIG. **2** illustrates an exemplary back view of a portable breath collection and analysis device.

[0012] FIG. **3** illustrates exemplary air flow from a mouthpiece via a pump system.

[0013] FIG. **4** illustrates a simplified top view of elution and air flow in a cartridge.

[0014] FIG. **5** depicts an exemplary front view of a single-use cartridge.

[0015] FIG. **6** depicts an exemplary back view of a single-use cartridge.

[0016] FIG. **7** is a simplified schematic of a single-use cartridge.

[0017] FIG. **8** illustrates exemplary reaction processes that occur on the single-use cartridge.

[0018] FIG. **9** is an exemplary flow chart of a process conducted within reaction chamber of the single-use cartridge.

[0019] FIG. **10** is an exemplary flow of a process conducted on the single-use cartridge.

DETAILED DESCRIPTION

[0020] In the following description, for purposes of explanation, numerous specific details are set forth in order to provide a thorough understanding of the disclosure. It will be apparent, however, to one skilled in the art, that the disclosure may be practiced without these specific details. In other instances, structures and devices are shown as block diagram form only in order to avoid obscuring the disclosure.

[0021] Reference throughout this specification to "one embodiment" or "an embodiment" means that a particular feature, structure, or characteristic described in connection with the embodiment is included in at least one embodiment of the present invention. Thus, the appearances of the phrases "in one embodiment" or "in an embodiment" or "according to one embodiment" (or other phrases having similar import) at various places throughout this specification are not necessarily all referring to the same embodi-

ment. Furthermore, the particular features, structures, or characteristics may be combined in any suitable manner in one or more embodiments. Furthermore, depending on the context of discussion herein, a singular term may include its plural forms and a plural term may include its singular form. Similarly, a hyphenated term (e.g., "on-demand") may be occasionally interchangeably used with its non-hyphenated version (e.g., "on demand"), a capitalized entry (e.g., "Device") may be interchangeably used with its non-capitalized version (e.g., "device"), a plural term may be indicated with or without an apostrophe (e.g., PE's or PEs), and an italicized term (e.g., "N+1") may be interchangeably used with its non-italicized version (e.g., "N+1"). Such occasional interchangeable uses shall not be considered inconsistent with each other.

[0022] The terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention. As used herein, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the terms "comprises" and/or "comprising," when used in this specification, specify the presence of stated features, integers, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, integers, steps, operations, elements, components, and/or groups thereof. It is further noted that various figures (including component diagrams) shown and discussed herein are for illustrative purpose only, and are not drawn to scale.

[0023] The present disclosure pertains to methods, systems, and apparatus for capturing human breath at a point of care, extracting certain chemical(s) from the captured breath, and measuring a concentration of the extracted chemicals. In one example, an amount of tetrahydrocannabinol (THC) level from a breath sample is determined by practicing embodiments of the present disclosure. While THC is discussed herein for simplicity, similar methods can be utilized to extract and measure a concentration of other chemicals in human breath as well, such as ethanol, other controlled substances, or airborne indicators of various disease states.

[0024] Embodiments of the present disclosure describe a proprietary microfluidic cartridge that is disposable, and used within a portable breath collection and analysis device. The cartridge is located within a portable handheld device and provides for mechanisms to capture and accurately measure an amount of a target chemical that is present in a person's breath.

[0025] In one example, the target chemical is THC. When THC is present in human breath, the bulk of it is contained within aerosol droplets. The present disclosure relates to mechanisms for capturing those aerosol droplets from human breath, such that a sufficient amount of THC can be captured from a human breath sample to accurately analyze. The THC is extracted from a physical surface of an impaction plate where it is collected and concentrated. The extracted THC is subjected to further analysis, such as to measure a concentration level. In addition to sample processing, the disposable cartridge also allows for processing on-board calibrators, positive controls, and negative controls. In addition, the disposable cartridge may contain a cryptographic computing chip with an RFID tag to attach personal information about the human subject's sample contained and analyzed within the cartridge.

[0026] FIG. **1** depicts an exemplary front view of a portable breath collection and analysis device **100** (also sometimes referred to herein as simply device **100**). In various embodiments, breath collection and analysis device **100** is a handheld device that can be used at a point of care in any indoor or outdoor location. Device **100** may be utilized in conjunction with a base station (not shown), to accurately determine an amount of a target chemical that is present in a human subject's breath at a given time.

[0027] In the exemplary figure of device **100**, there is display **110** that may or may not be a touchscreen. From this display **110**, an administrator utilizing device **100** to test a subject's breath can view information and results about the breath collection and sampling. As would be understood by persons of ordinary skill in the art, any information can be displayed on the display **110** for the administrator of device **100** and/or a subject whose breath is being tested.

[0028] Exemplary FIG. **1** also depicts a light array **105**. Light array **105** may be one or more lights of any kind (such as LED lights), to quickly indicate a status of breath collecting, analysis, or other items. As would be understood by persons of ordinary skill in the art, light array **105** may be located at other places on device **100**, and not solely in the location depicted in FIG. **1**.

[0029] Device **100** also contains a mouthpiece **115**, which may be a disposable tube that is placed into a subject's mouth while the subject breathes air into device **100**. In various embodiments, mouthpiece **115** may be constructed of PVC (polyvinyl chloride) or similar material. Mouthpiece **115** may be further connected to device **100**. In this way, mouthpiece **115** may be a removable and disposable component of device **100**.

[0030] FIG. **2** depicts an exemplary back view of breath collection and analysis device **100**. A power button **125** is depicted in the exemplary figure to turn device **100** on and off. In various embodiments, power button **125** may be located at other places on device **100**, rather than solely in the location depicted in exemplary FIG. **2**.

[0031] FIG. **3** depicts a simplified breath collection mechanism for device **100**. A mouthpiece **115** is placed into a subject's mouth. A breath collection module **305** captures air with aerosol droplets potentially containing the target chemical from the subject's breath, until a predetermined volume of air has been captured. A pump **310**, that is triggered by a pressure sensor **315**, may aid in drawing the subject's breath from mouthpiece **115** through breath collection module **305**. When pressure sensor **315** detects that a human subject is blowing air through mouthpiece **115**, it activates (suction) pump **310** to increase the flow rate of air into it and facilitate breath capture. When a subject starts to breathe through mouthpiece **115**, pressure sensor **315** detects a positive pressure at mouthpiece **115** and triggers the pump **310** to turn on. When the subject stops breathing, then pump **310** stops as well. Pump **310** may be connected via a TTL connection to other hardware components within device **100**.

[0032] In an exemplary embodiment, 18 liters of breath is desired to be captured within 2 minutes. For a typical human subject, this is approximately 3-10 breaths. In various embodiments, device **100** tracks an amount of volume of air collected with each breath of the subject, until the full desired volume is collected. Further, with each breath, pump **310** is activated and then turns off when the breath stops, as detected by pressure sensor **315**. That is, if a human subject

blows into mouthpiece **115** four times, pump **310** turns on and off with each breath (four times total), within the allotted time (2 minutes in this exemplary embodiment).

[0033] Further, device **100** can track an amount of volume of air collected via a timer. Pump **310** dictates a flow rate of air passing through breath collection module **305**. Thus, a flow rate of air passing through breath collection module **305** is fixed, regardless of how fast or slow a subject blows through mouthpiece **115**. Since the flow rate is dictated by pump **310**, and is a known value, an amount of time needed to collect a fixed volume of air (such as 18 liters) can be determined. Device **100** may count down the time for each breath, until the requisite amount of time has elapsed and the desired volume of air is captured. This may help determine depth of sample volume from the subject's respiratory tract to minimize a potential for spoofing the system.

[0034] As would be understood by persons of ordinary skill in the art, although 18 liters is discussed herein as the desired volume of air to be captured, the present disclosure is equally applicable to other amounts of desired volume of air capture.

[0035] In various embodiments, breath collection module **305** may also filter out saliva from the subject's breath. Breath collection module contains a plurality of internal components that are discussed in greater detail in co-pending U.S. patent application Ser. No. NNN filed on DDD.

[0036] After breath capture via breath collection module **305**, elution is used to extract the target chemical from the aerosol droplets in the captured breath. In analytical and organic chemistry, elution is the process of extracting one material from another by washing with a solvent.

[0037] The captured aerosol droplets are contacted with a fluid to solubilize the target chemical from the aerosol droplets into a solution. By minimizing the volume of solution used to extract the target chemical from the aerosol droplets, the concentration of the target chemical in the solution can be maximized. Further, by utilizing a circular geometry in the breath collection module **305** pieces, one can minimize the total volume of fluid present in the breath collection module **305**. This enables one to maximize the concentration of the target chemical extracted.

[0038] An elution buffer serves to remove the target chemical from an impactor surface in the breath collection module **305**, and is also utilized as a solvent for a reagent in an immunoassay utilized by a cartridge within device **100** to analyze the concentration of the target chemical present in the captured sample. Thus, the elution buffer is compatible to an antibody in the immunoassay utilized downstream in device **100**, but also has properties that extract the target chemical from the impactor surface.

[0039] FIG. **4** depicts a top down view of elution and air flow. After air passes through an impactor surface **405** of breath collection module **305** and the desired volume of air is captured, the elution fluid passes through the impactor surface **405** to capture the target chemical.

[0040] As depicted in FIG. **4**, aerosol droplets containing the target chemical are captured from an air flow by impactor surface **405** in breath collection module **305**, and the remainder of the air is deflected outwards. In some embodiments, a restrictor may be used in the breath collection module **305** to divert some air (such as up to 5% of air) to a separate path, such as a path to a blood alcohol concentration sensor, the pressure sensor **315**, and/or any other sensors. While air flow is being captured, no liquid flow is present. Once the desired volume of air has been captured (e.g., 18 liters), then the air ports may be blocked off via one or more valves, and elution fluid is passed through impactor surface **405** to extract the target chemical from the captured aerosol droplets. The elution liquid with the extracted target chemical is then sent downstream to a reaction chamber **410** within a cartridge inside device **100**, for analysis of target chemical concentration.

[0041] FIG. **5** depicts an exemplary front view of a single-use (disposable) cartridge **500** that is utilized within device **100** for analysis of the target chemical. Cartridge **500** is connected to mouthpiece **115**, and breath collection module **305**, which may also be single-use components for device **100**. Cartridge **500** contains electronic and chemical components for extraction and analysis of the target chemical in the captured breath sample from the subject.

[0042] FIG. **6** depicts an exemplary back view of single-use cartridge **500**.

[0043] FIG. **7** is a simplified schematic of a cartridge **500** that is used within device **100**. As discussed above, breath is captured by breath collection module **305**, facilitated by pump **310**. The excess air (after the aerosol droplets have been captured), is released through a vent in the handheld device **100**. Further, while not depicted in the figure, there may be filter(s) or one-way valve(s) present to prevent cross-contamination of samples from one cartridge to the next within device **100**.

[0044] After breath sample capture, an elution fluid with antibody-enzyme conjugate is passed through breath collection module **305**, as discussed above with reference to FIG. **4**. The solubilized target chemical plus the added antibodies are then directed to a reaction chamber **710** and evidence sample storage **705**.

[0045] The reaction chamber **710** is pre-coated with THC-BSA (Bovine Serum Albumin) conjugate. Within reaction chamber **710**, a process occurs whereby, the sample incubates for a period of time to allow the antibody to competitively bind to target analyte in sample as well as the antigen coated on the surface. The reaction chamber **710** is then washed to remove any unbound species. Subsequently, a substrate is introduced, which generates a signal proportional to the number of antibody-enzyme molecules bound to the reaction surface.

[0046] Turning to FIG. **8**, the reaction chamber **710** contains three separate and parallel reaction channels: a calibrator channel **805**, a sample channel **810**, and a positive control channel **815**. The assay is performed within reaction chamber **710** such that three separate signals are generated—one for each reaction channel. The final determination of concentration of target chemical is based on the ratio of the sample signal to the calibrator signal. As would be understood by persons of ordinary skill in the art, there may be fewer or additional reaction chambers than the three discussed herein, in other embodiments.

[0047] The fluid entering reaction chamber **710** has antibody mixed with the target chemical (THC in this example). This fluid enters the sample channel **810**. In the calibrator channel, the fluid is just the antibody, which may or may not be mixed with a solution. In the positive control channel **815**, there is a separate reservoir that contains a known amount of the target chemical. The positive control channel **815** and calibrator channel **805** are utilized to ensure that the

workflow of the assay in the sample channel **810** processed correctly, and that the reagents of cartridge **500** are functioning properly.

[0048] Calibrator channel **805** allows for the correction of any small deviations in the response of the chemical reagents present in cartridge **500**. It can act to compensate for small changes in environmental conditions as well (such as temperature), and/or small changes in the optical train from system to system or cartridge to cartridge. No target chemical is present in calibrator channel **805**, and thus it functions as a negative control.

[0049] In exemplary embodiments, reaction chamber **710** provides a competitive immunoassay. That is, the generated signal decreases with an increase in concentration of the target chemical, as depicted in graph **820**. For example, higher signal values indicate a lower concentration of THC, and vice versa.

[0050] Thus, since calibrator channel **805** has no target chemical, it should have a maximum signal value. This provides a baseline for normalization. While there may be some differences in reagent activity from cartridge to the next, calibrator channel **805** provides for the normalization of a signal within each cartridge, since the same reagent is used in all three reaction channels. Thus, the relative response of the reagent in all three channel is harmonized, and a target chemical concentration can be determined based on a relative response between the three reaction channels, rather than an absolute magnitude of a signal generated in any one particular reaction chamber. Thus, calibrator channel **805** creates a relative signal to a maximum signal possible.

[0051] Positive control chamber **815** contains the target chemical (THC), completely isolated from the sample. It is placed in a separate reservoir in the reaction chamber **710**. Since the concentration of the target chemical in the positive control sample is known, the expected response of the reagent and the expected signal generated by positive control chamber **815** is known. By checking the response generated from positive control chamber **815** against the expected response, it can be objectively determined if the sample processed correctly through the reaction chamber **710**. In this way, device **100** can provide a mechanism to verify its own accuracy of reaction chamber **710**.

[0052] The negative control from calibrator channel **805** determines what the generated signal from reaction chamber **710** would be if there was no THC in the sample. The positive control chamber **815** determines what the generated signal from the reaction chamber **710** would be if there was pure THC in the sample. A cutoff point is determined from graph **820** for comparison with the generated signal from sample chamber **810**.

[0053] In processing a sample, reaction area **830** of reaction chamber **710** undergoes a multi-step process. Fluid is introduced into reaction area **830** via all three reaction channels **805**, **810**, and **815**. Subsequently, the antibody is introduced into reaction area **830**. It competes with any THC present, whether that THC was introduced from the sample chamber **810** or the positive control chamber **815**. It then binds to an antigen that is on reaction surface **825** and forms a THC-BSA conjugate.

[0054] By utilizing this competing immunoassay process, if there are no free THC molecules, all of the antibodies bind to reaction surface **825** and a maximum signal is generated. If there is a high amount of THC, all of the antibodies are tied up with the free THC and there is nothing to bind to reaction surface **825**, yielding a low signal.

[0055] After the antibody introduction step, reaction area **830** is washed by sending a wash buffer solution through reaction area **830**. The wash buffer solution clears away any unbound species from reaction area **830**. In exemplary embodiments, the wash buffer solution may be introduced anywhere from 1-10 times.

[0056] After washing, a substrate is introduced into reaction area **830**. In exemplary embodiments, the substrate may be a small molecule such as luminol. Luminol in the presence of an oxidizing agent and an enzyme such as Horseradish Peroxidase (HRP) emits light.

[0057] During the reaction process, a catalyst for the reaction may be used within reaction area **830**. In one example, the catalyst is horseradish peroxidate enzyme (HRP). This enzyme catalyzes luminol and produces light. HRP enzyme has a high turnover rate and serves as an effective catalyst for reactions in reaction area **830**.

[0058] After introduction of the substrate, the amount of light emitted from reaction chamber **710** is in the order of 0.1-10 pW.

[0059] Returning to FIG. **7**, a detector **715** located in a base station is used to detect the light emitted from reaction chamber **710**. In an exemplary embodiment, detector **715** is a silicon photomultiplier for low light detection. The base station processes the received light signal and determines a concentration of THC that was present in the sample collected from the human subject's breath.

[0060] In exemplary embodiments, the detector **715** may be placed in physical proximity to reaction chamber **715**, when cartridge **500** is removed from device **100**. In other embodiments, cartridge **500** may have optical fibers with liquid light guides to assist with detection of light being emitted from reaction chamber **715**. This allows for positional flexibility as to where the detector is placed relative to cartridge **500**.

[0061] While not explicitly depicted in the figures, cartridge **500** may also have a cryptographic computing chip to store information on the single-use cartridge itself. The cryptographic computing chip ensures that cartridge **500** can only be utilized with an approved device **100**, base station, and/or detector **715**. Further, cryptographic computing chip may contain a read/write RFID tag to store information about the human subject whose sample is contained within cartridge **500**. For example, information regarding the human subject such as any one or more of a unique identifier number, name, age, address, phone number, etc. may be stored on the RFID tag of the cryptographic computing chip on cartridge **500**. In addition, objective information such as any one or more of date, time, location, identifier for person administering the test via device **100**, etc. may also be stored in the cryptographic computing chip. Further, device information and measurement(s) may also be stored on the cryptographic computing chip such as any one or more of breath collection workflow (e.g., breath volume collected, flow rate, number/duration of breaths collected by device **100**), assay workflow (e.g., reaction light levels of optical measurements from the reactions), system serial numbers, calibration dates, quantities of the one or more target chemicals, such as a THC level and/or BAC (Blood Alcohol Content) level.

[0062] As would be understood by persons of ordinary skill in the art, mechanisms other than an RFID tag may also

be used to store information on the cryptographic computing chip. Further, any type of information other than that enumerated here may be stored on the chip.

[0063] FIG. **7** also depicts an evidence sample storage **705** chamber in cartridge **500**. Because a sample is usually collected at a point of use away from a testing laboratory, the result from reaction chamber **710** is written into the cartridge, such as on the cryptographic computing chip of cartridge **500**. However, it is desirable to be able to corroborate this result in a laboratory at a later time using a reference method such as LC-MS.

[0064] When testing alcohol on a human subject's breath, there is a known behavior of how the concentration of alcohol in the breath changes over time. Thus, field testing can be used to generate one result, and later verified by testing the subject's breath again with more sophisticated equipment at a law enforcement facility. By measuring the concentration of alcohol in the subject's breath as detected by the more sophisticated equipment, the concentration of alcohol in the subject's breath at a time of a field test can be extrapolated using a known profile for alcohol kinetic behavior over time.

[0065] However, other chemicals, such as THC, do not have similar degradation profiles over time. In particular, THC levels in human breath degrade very quickly in time. Thus, a portion of sample collected from the subject via device **100** is physically preserved on single-use cartridge **500**. In this way, when cartridge **500** is removed from device **100**, the sample from evidence sample storage **705** can be independently tested using reference means (such as mass spectrometry) at a later time to verify a result generated on device **100** from a test conducted in a field location.

[0066] As shown in FIG. **7**, after THC is extracted from the sample collected in breath collection module **305**, a small part of the fluid is directed to evidence sample storage **705**. In exemplary embodiments, a valving means may be provided to influence the amount of fluid directed to evidence sample storage **705** compared to the amount of fluid directed to reaction chamber **710**.

[0067] Evidence sample storage **705** contains a filter with an absorbent material that absorbs the received sample. In a laboratory environment, the absorbent material containing the sample can be removed from cartridge **500**, the contents extracted from the absorbent material into a solvent such as methanol, and then fluid can be processed using known methods such as mass spectrometry. In this way, the absorbent material retains an amount of the original sample before it is processed by reaction chamber **710** of cartridge **500**, and preserves that sample for later testing.

[0068] THC is prone to oxidation and degradation of its molecules over time. A key driver of degradation is light exposure. To combat this, evidence sample storage **705** shields the sample within a compartment of cartridge **500** such that the sample is opaque on all sides.

[0069] FIG. **9** depicts an exemplary flow chart of a process conducted within the reaction chamber of cartridge **700**. It would be understood that there may be fewer or additional steps present than those depicted in the exemplary figure, according to various embodiments of the present disclosure.

[0070] In step **905** of the reaction process, a sample is received by the reaction chamber for analysis of a target chemical. The sample is received from a breath collection module. In step **910**, the received sample is reacted with one or more chemical reagents, as discussed herein. The reacted chemicals are then washed with a wash solution in step **915**. A substrate is introduced to the washed and reacted chemicals in step **920**. Optionally, a result of the reaction process is generated and saved on a cryptographic computing chip of the cartridge, in step **925**.

[0071] FIG. **10** depicts an exemplary flow of a process conducted by cartridge **500** for analysis of a human breath sample received from a human subject. In step **1005** an air sample is received from a human subject in a breath collection module of cartridge **500**. The received air sample is processed in the breath collection module to solubilize and extract a target chemical in step **1010**. The extracted target chemical is combined with an antibody substance in step **1015**. A portion of the extracted target chemical is saved for evidence preservation in an evidence sample storage compartment of the cartridge.

[0072] A remainder portion of the extracted target chemical is reacted in a reaction chamber with one or more chemical reagents in step **1025**. The reacted chemicals are then washed in the reaction chamber with a wash solution in step **1030**. A substrate is introduced to the washed chemicals in the reaction chamber in step **1035**. Optionally, a result of the process is generated and saved on a cryptographic computing chip of the cartridge, in step **1040**. Further, as discussed herein, a low level light may be generated by the reaction chamber of the cartridge, for detection by a detector device that is separate and apart from the cartridge.

[0073] The corresponding structures, materials, acts, and equivalents of all means or step plus function elements in the claims below are intended to include any structure, material, or act for performing the function in combination with other claimed elements as specifically claimed. The description of the present disclosure has been presented for purposes of illustration and description, but is not intended to be exhaustive or limited to the present technology in the form disclosed. Many modifications and variations will be apparent to those of ordinary skill in the art without departing from the scope and spirit of the present disclosure. Exemplary embodiments were chosen and described in order to best explain the principles of the present disclosure and its practical application, and to enable others of ordinary skill in the art to understand the present disclosure for various embodiments with various modifications as are suited to the particular use contemplated.

[0074] Aspects of the present disclosure are described above with reference to flowchart illustrations and/or block diagrams of methods, apparatus (systems) according to embodiments of the present disclosure.

[0075] The flowchart and block diagrams in the Figures illustrate the architecture, functionality, and operation of possible implementations of systems, methods and apparatus, according to various embodiments of the present disclosure.

[0076] Thus, systems and methods for a single-use microfluidic cartridge for detecting a presence of a target chemical in human breath are described herein. While various embodiments have been described, it should be understood that they have been presented by way of example only, and not limitation. The descriptions are not intended to limit the scope of the disclosure to the particular forms set forth herein. Thus, the breadth and scope of a preferred embodiment should not be limited by any of the above-described exemplary embodiments. It should be understood that the above description is illustrative and not restrictive. To the

contrary, the present descriptions are intended to cover such alternatives, modifications, and equivalents as may be included within the spirit and scope of the disclosure as defined by the appended claims and otherwise appreciated by one of ordinary skill in the art. The scope of the present disclosure should, therefore, be determined not with reference to the above description, but instead should be determined with reference to the appended claims along with their full scope of equivalents.

What is claimed is:

1. A single-use microfluidic cartridge for detection of a target chemical present in human breath via a breath collection and analysis device, the cartridge comprising:

a breath collection module configured to collect a desired volume of air from the human subject, and extract a target chemical from the collected air;

an evidence sample storage chamber configured to preserve a sample of the extracted target chemical from the collected air for later analysis; and

a multi-channel reaction chamber configured to process a competitive immunoassay to generate a signal representing a concentration amount of the target chemical present in the collected air from the human subject.

2. The cartridge of claim **1**, wherein the multi-channel reaction chamber comprises a calibrator channel, a sample channel, and a positive control channel.

3. The cartridge of claim **1**, wherein the multi-channel reaction chamber comprises a calibrator channel, the calibrator channel containing a fluid of antibodies.

4. The cartridge of claim **1**, wherein the multi-channel reaction chamber comprises a positive control channel, the positive control channel containing a fluid of a known concentration of the target chemical.

5. The cartridge of claim **1**, wherein the competitive immunoassay process comprises utilizing a reagent to bind the target chemical to a reaction surface of the multi-channel reaction chamber.

6. The cartridge of claim **1**, wherein the multi-channel reaction chamber is further configured to undergo a wash process and then a substrate process, after processing the competitive immunoassay.

7. The cartridge of claim **1**, wherein the multi-channel reaction chamber is further configured to emit a low level light, that can be captured by a detector device of a base station compatible with the breath collection and sampling device.

8. The cartridge of claim **1**, further comprising a cryptographic computing chip configured to be read by a computer, the cryptographic computing chip comprising at least one or more of identifying information about the human subject, information about the breath collection workflow, the assay workflow, and subsequent quantities of the target chemical.

9. The cartridge of claim **1**, further comprising a cryptographic computing chip configured to be read by a computer, the cryptographic computing chip comprising information to verify the cartridge to the breath collection and analysis device.

10. The cartridge of claim **1**, further comprising a cryptographic computing chip with an RFID tag.

11. The cartridge of claim **1**, wherein the breath collection module of the cartridge is connected to a mouthpiece of the breath collection and analysis device, the mouthpiece configured to be placed in the human subject mouth to receive air from the human subject.

12. The cartridge of claim **1**, wherein the target chemical is extracted in the breath collection module via an elution buffer solution configured to extract and solubilize the target chemical from aerosol droplets in the collected air.

13. The cartridge of claim **1**, wherein the desired volume of air collected from the human subject is 18 liters.

14. A method for detection of a target chemical present in human breath via a single-use microfluidic cartridge, the method comprising:

receiving a desired volume of air from a human subject in a breath collection module of the single-use microfluidic cartridge;

processing the received air in the breath collection module to solubilize and extract the target chemical present in the received air;

combining the extracted target chemical with an antibody;

saving a portion of the extracted target chemical for evidence preservation;

reacting a remainder portion of the extracted target chemical in a multi-channel reaction chamber with one or more chemical reagents;

washing the reacted chemicals in the multi-channel reaction chamber with a wash solution;

introducing a substrate to the washed chemicals in the multi-channel reaction chamber, the substrate configured to emit a low level light from the single-use microfluidic cartridge, communicating with a detector device to determine a concentration level of the target chemical from the emitted low level light.

15. The method of claim **14**, further comprising saving a result of analysis on a cryptographic computing chip present on the single-use microfluidic cartridge.

16. The method of claim **14**, further comprising saving identifying information for the human subject on a cryptographic computing chip present on the single-use microfluidic cartridge.

17. The method of claim **14**, further comprising saving identifying information for the human subject on an RFID tag of a cryptographic computing chip present on the single-use microfluidic cartridge.

18. The method of claim **14**, further comprising calibrating a result from the multi-channel reaction chamber based on a positive control channel of the reaction chamber and a calibrator channel of the multi-channel reaction chamber.

19. The method of claim **14**, wherein the target chemical is THC.

20. The method of claim **14**, wherein the reacting the remainder portion of the extracted target chemical in a multi-channel reaction chamber with one or more chemical reagents further comprises utilizing a competitive immunoassay process.

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