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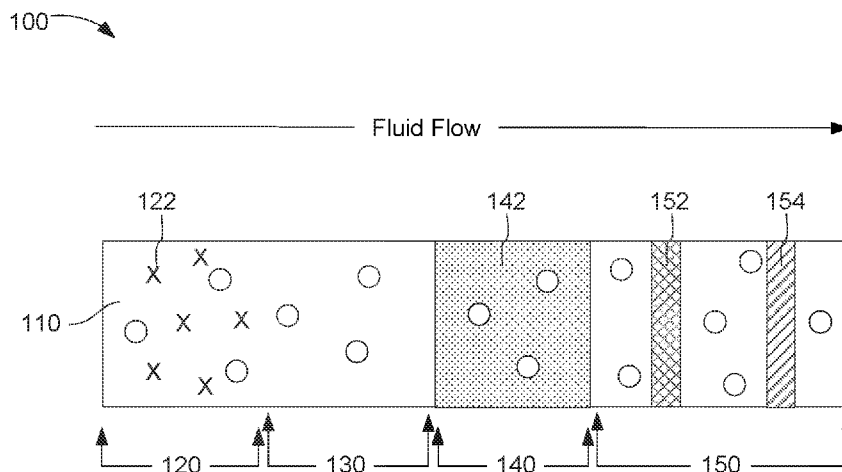


FIG. 1

(57) **Abstract:** The present disclosure relates to a self-wicking device. The device can include a fluid flow channel including a porous substrate for sequential fluid flow through multiple regions. The multiple regions can include a complexing region, a charge adjusting region, a concentrating region, and a detecting region. The complexing region can include a compound having a functional group to bind with an analyte in a sample to form an analyte complex. The charge adjusting region can provide charge modulation by modifying a charge of the analyte complex or providing a modified concentration of charged centers to interact with the analyte complex. The concentrating region can include an immobilized material having an affinity to the analyte complex following charge modulation. The detecting region can receive concentrated analyte from the concentrating region.



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SELF-WICKING DEVICES

BACKGROUND

[0001] Self-wicking devices are intended to detect the presence of a target
10 analyte in a sample fluid. These devices are simple and can be used typically
without specialized training by the user. Accordingly, self-wicking devices can be
widely used for medical diagnostic testing, environmental sample testing, and in
laboratories, to name a few.

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BRIEF DESCRIPTION OF THE DRAWINGS

[0002] FIG. 1 graphically illustrates an example self-wicking device in
accordance with the present disclosure;

[0003] FIG. 2 graphically illustrates an example self-wicking system in
20 accordance with the present disclosure; and

[0004] FIG. 3 graphically illustrates a method of concentrating and
detecting an analyte in a sample fluid in accordance with the present disclosure.

DETAILED DESCRIPTION

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[0005] Self-wicking devices can permit the detection of a target analyte in a
sample fluid. These devices can incorporate a porous substrate. The sample fluid
sequentially runs along the porous substrate via capillary flow. When a target
analyte is present in the sample fluid, the target analyte will interact with a
30 compound having a functional group that is capable of binding to the target
analyte. A testing region on the porous substrate can detect a complex of the

target analyte and the compound and a control region on the porous substrate can detect the compound. When a complex of the target analyte and the compound is detected in the testing region, an optical indicator will appear or will not appear, depending on the device type. When the compound is detected in the control region, an optical indicator will appear, such as a line. Self-wicking devices may be limited in use due to detection limits of these devices.

[0006] In accordance with an example of the present disclosure, a self-wicking device ("device") can include a fluid flow channel including a porous substrate for sequential fluid flow through multiple regions. The multiple regions of the porous substrate can include a complexing region including a compound that can have a functional group to bind with an analyte in a sample fluid to form an analyte complex; a charge adjusting region to provide charge modulation by modifying a charge of the analyte complex or providing a modified concentration of charged centers to interact with the analyte complex; a concentrating region that can include an immobilized material having an affinity to the analyte complex after the charge modulation; and a detecting region that can receive concentrated analyte from the concentrating region. In one example, modification of the charge of the analyte complex in the charge adjusting region can occur by a change in pH therein of from about 1 pH unit to about 3.5 pH units relative to a pH of fluid of the complexing region. In another example, a pH of the fluid in the complexing region can be about 6.5 to about 7.5, and a pH of the fluid in the charge adjusting region can be about 4 to about 6 or from about 8 to about 10. In yet another example, the charge adjusting region, the concentrating region, or a combination thereof includes charged centers including a divalent cation. In a further example, the divalent cation can be selected from a calcium ion, a magnesium ion, a barium ion, a strontium ion, or a combination thereof. In another example, the charge adjusting region and the concentrating region are at a common location on of the porous substrate. In one example, the device can further include a fluid input port to flow a sample fluid into the fluid flow channel and the fluid input port can be available to subsequently flow an elution fluid therethrough, or the device can

further include a separate elution fluid input port positioned to flow an elution fluid at or upstream of the concentrating region.

[0007] In another example, a self-wicking system ("system") can include a self-wicking device and a sample fluid containing the analyte to flow through the fluid flow channel. The self-wicking device can include a fluid flow channel including a porous substrate for sequential fluid flow through multiple regions. The multiple regions can include a complexing region including a compound that can have a functional group to bind with an analyte in a sample fluid to form an analyte complex; a charge adjusting region to provide charge modulation by modifying a charge the analyte complex or providing charged centers to interact with the analyte complex; a concentrating region that can include an immobilized material having an affinity with the analyte complex after the charge modulation; and a detecting region that can receive concentrated analyte from the concentrating region. In an example, modification of the charge of the analyte complex in the charge adjusting region can occur by a change in pH of the sample fluid therein of from about 1 pH unit to about 3.5 pH units relative to a pH of the sample fluid in the complexing region, or wherein the charge adjusting region, the concentrating region, or a combination thereof includes charged centers that can include a divalent cation. In another example, the system can further include an elution fluid to decouple the analyte complex from the immobilized material. In yet another example, a pH of fluid in the complexing region can be from about 6.5 to about 7.5, and a pH of fluid in the charge adjusting region can be from about 4 to about 6 and the elution fluid can include a tris base, a dibasic sodium phosphate, magnesium oxide, disodium hydrogen phosphate, arginine, sodium bicarbonate, ammonium bicarbonate, sodium carbonate, borate, glycine-NaOH, or a combination thereof; or can be from about 8 to about 10 and the elution fluid can include citric acid, tris-HCl, monobasic sodium phosphate, tartaric acid, succinic acid, acetic acid, phosphoric acid, glycerine-HCl, sodium acetate, or a combination thereof. In yet another example, the charge adjusting region, the concentrating region, or the combination thereof can include the divalent cation

and the elution fluid can include EDTA, EGTA, GLDA, trisodium α -DL-alanine diacetate, phytic acid, tetrasodium iminodisuccinate, or a combination thereof.

[0008] In another example, a method of concentrating and detecting an analyte in a sample ("method") is disclosed herein. The method can include
5 flowing a sample fluid along a fluid flow channel including a porous substrate, where relative to fluid flow, the fluid flow channel sequentially includes a complexing region, a charge adjusting region, a concentrating region, and a detecting region. The method can also include binding an analyte carried by the sample fluid to a compound having a function group to bind with the analyte in the
10 complexing region to form an analyte complex, and modulating a charge by modifying a charge of the analyte complex in the charge adjusting region or providing a modification of charged centers in the charge adjusting region or the concentrating region. The method can further include immobilizing the analyte complex in the concentrating region, releasing concentrated analyte from the
15 concentrating region, and detecting the concentrated analyte in the detecting region. In an example, modulating the charge occurs by modifying the charge of the analyte complex in the charge adjusting region by changing a pH of the sample fluid therein of from about 1 pH unit to about 3.5 pH units relative to a pH of fluid in the complexing region, or providing a divalent cation loaded in the
20 charge adjusting region. In another example, the releasing of the concentrated analyte can include passing an elution fluid through the concentrating region.

[0009] When discussing the self-wicking device, the self-wicking system, and the method of concentrating and detecting an analyte in a sample fluid herein, such discussions can be considered applicable to one another whether or
25 not they are explicitly discussed in the context of that example. Thus, for example, when discussing a complexing region in a self-wicking device, such disclosure is also relevant to and directly supported in the context of the self-wicking system, the method of concentrating and detecting an analyte in a sample, and *vice versa*. Furthermore, in accordance with the definitions and examples herein, FIG. 1 and
30 FIG. 2 depict various self-wicking devices and systems, respectively, and FIG. 3 depicts an example method. These various examples can include various

features, with several common features. Thus, the reference numerals used to refer to features depicted in FIGS. 1-2 may be the same throughout to avoid redundancy, even though the self-wicking devices and the self-wicking systems can have structural differences, as shown.

5 [0010] Terms used herein will be interpreted as the ordinary meaning in the relevant technical field unless specified otherwise. In some instances, there are terms defined more specifically throughout or included at the end of the present disclosure, and thus, these terms are supplemented as having a meaning described herein.

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Self-wicking Devices

[0011] A self-wicking device 100, as illustrated in FIG. 1, can include a fluid flow channel including a porous substrate 110 for sequential fluid flow through multiple regions. The multiple regions can include a complexing region 120 that can include a compound 122 having a functional group to bind with an analyte in a sample fluid to form an analyte complex, a charge adjusting region 130 configured to provide charge modulation by modifying a charge of the analyte complex or providing a modified concentration of charged centers to interact with the analyte complex, a concentrating region 140 that can include an immobilized material 142 with an affinity to the analyte complex after the charge modulation, and a detecting region 150 that can receive concentrated analyte from the concentrating region. In one example, the charge adjusting region and the concentrating region can overlap or be within the same physical area, but can provide both functions. The detecting region can include a testing strip 152 and a control strip 154 as shown in FIG. 1.

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[0012] The fluid flow channel can include a negative space that can be etched, molded, or engraved from a material of a housing and may surround the porous substrate of a self-wicking device. The fluid flow channel can have a channel size that can range from about 5 μm to about 15 mm in diameter. In yet other examples, the fluid flow channel can have a diameter that can range from about 5 μm to about 1,000 μm , from about 1 mm to about 15 mm, from about 100

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μm to about 500 μm, from about 500 μm to about 1,000 μm, or from about 5 mm to about 10 mm, etc. The fluid flow channel may include a pathway. The pathway may be a linear pathway, a curved path, a pathway with turns, a branched pathway, a serpentine pathway, or any other pathway configuration. In some examples, the pathway may be linear and/or branched. The porous substrate may be present in a portion of or throughout the entire length of the fluid flow channel.

[0013] The porous substrate may include a fibrous substrate that can allow a sample fluid to flow therethrough via capillary action. In some examples, the porous substrate can include nitrocellulose, cellulose, acetate cellulose, fiberglass, porous silica, polyester, surface modified polyester, hydrogel, or a combination thereof. In one example, the porous substrate can include a nitrocellulose pad, a cellulose pad, or a fiberglass pad. In another example, the porous substrate can include a nitrocellulose pad. Pores of the porous substrate can have an average pore size ranging from about 500 nm to about 10 μm, from about 1 μm to about 10 μm, from about 5 μm to about 10 μm, from about 500 nm to about 5 μm, or from about 2 μm to about 8 μm. A thickness of the porous substrate can range from about 0.1 mm to about 1 mm, from about 0.5 mm to about 1 mm, or from about 0.2 mm to about 0.8 mm. A length of the porous substrate can range from about 1 mm to about 10 mm, from about 5 mm to about 10 mm, from about 1 mm to about 5 mm, or from about 2 mm to about 8 mm. A width of the porous substrate can range from about 1 mm to about 20 mm, from about 5 mm to about 15 mm, or from about 8 mm to about 16 mm.

[0014] The porous substrate can include multiple regions that can be designed to interact with an analyte in a sample fluid. The porous substrate can include a complexing region, a charge adjusting region, a concentrating region, and a detecting region. The complexing region in further detail can be a hydrophilic region and can have a pH ranging from about 6.5 to about 7.5, from about 7 to about 7.5, or from about 6.5 to about 7. The complexing region can be impregnated with a compound having a functional group that can bind with an analyte in a sample fluid to form an analyte complex. The complexing region can

release the compound having the functional group to bind with the analyte in the sample upon application and movement of a sample fluid therethrough. The compound having a functional group to bind with an analyte in a sample may vary based on the analyte and the purpose of the self-wicking device. In some

5 examples, the compound having the functional group to bind with the analyte in the sample fluid can include a colloidal gold, a colored latex particle, a fluorescent latex particle, a paramagnetic latex particle, a cellulose nanobead, a florescent tag, or a combination thereof. The compound having the functional group to bind with the analyte can be a detection moiety that can be detected in a control strip of

10 the detecting region; thereby indicating that a sample fluid has passed through the self-wicking device.

[0015] The charge adjusting region can provide charge modulation. The charge modulation may include modifying a charge of the analyte. The charge modulation may include providing a modified concentration of charged centers to

15 interact with the analyte complex. In an example, adjusting the charge of the analyte complex can occur by adjusting a pH of the sample fluid that the analyte complex is in. Modification of the charge of the analyte complex in the charge adjusting region can occur by a change in pH of the sample fluid therein of from about 1 pH unit to about 3.5 pH units relative to a pH of the sample fluid in the

20 complexing region. A pH of the sample fluid in the complexing region can range from about 6.5 to about 7.5. In some examples, a pH of the sample fluid can be reduced to a pH ranging from about 4 to about 6, from about 4.5 to about 5.5, or from about 5 to about 6. In other examples, a pH of the sample fluid can be increased to a pH ranging from about 8 to about 10, from about 9 to about 10, or

25 from about 8.5 to about 9.5. In yet another example, providing charge modulation can occur by providing a modified concentration of charged centers. The charged centers can include a divalent cation. The divalent cation can be selected from a calcium ion, a magnesium ion, a barium ion, a strontium ion, or a combination thereof. In another example, the divalent cation can be selected from a calcium

30 ion, a magnesium, or a combination thereof. The divalent cation can be located in the charge adjusting region, the concentrating region, or a combination thereof.

[0016] Following charge modulation, the analyte complex may become temporarily trapped in the concentrating region. An immobilized material in the concentrating region can have an affinity with the analyte complex. As used herein, "affinity with" indicates that the immobilized material is capable of
5 attracting, interacting, binding, covalent bonding, ionic bonding, hydrogen bonding, slowing the movement of, attesting, or any combinations thereof of the analyte complex as it enters and flows through the concentrating region. Other components of the sample fluid will continue to pass therethrough. The immobilized material can include a ligand, gold, polymer, or a combination thereof
10 that can be responsive with the analyte complex.

[0017] The affinity between the immobilized material and the analyte complex can be reversed by further modulating a charge of the analyte complex. This can occur as a charge-modifying fluid flows through the concentrating region and a pH of the fluid returns to neutral or as the divalent ion is removed. The
15 charge-modifying fluid can include an elution fluid or additional sample fluid. The charge-modifying fluid may be added to the porous substrate of the self-wicking device at or upstream of the concentrating region. In one example, the charge adjusting region and the concentrating region can overlap or be within the same physical area, but can provide both functions.

[0018] The detecting region can be configured to receive concentrated analyte from the concentrating region. "Concentrated analyte" as used herein can refer to the analyte in any form and may include analyte complex, charge-modified analyte, analyte, or any other forms of analyte that are flowing through the detecting region. The detecting region can include a test strip and a
25 control strip. The detecting region may be a sandwich format detecting region or a competitive format detecting region. A sandwich format detecting region can generate a positive result by displaying an optical indicator, such as a colored line. A competitive format detecting region can generate a positive result by displaying the absence of an optical indicator.

[0019] In some examples, the self-wicking device may further include other components. For example, the device may include a fluid input port. The fluid

input port may be used to access the complexing region so that a sample fluid, an elution fluid, or a combination thereof may be applied through the fluid flow channel and onto the porous substrate. The self-wicking device may also include an elution fluid input port. The elution fluid input port may be positioned at or
5 upstream of the concentrating region. The elution fluid input port may also be used to add other charge-modifying fluids into the self-wicking device.

[0020] In some examples, the self-wicking device can further include a flow controlling agent. The flow controlling agent may be impregnated within the porous substrate and may include buffer salts, proteins, surfactants, and the like.
10 The flow controlling agent may increase or decrease a fluid flow rate of the sample fluid through the porous substrate.

[0021] In some examples, the self-wicking device may further include a housing. A housing can be a casing that the porous substrate may be disposed within. In some examples, the housing may further include a viewing window over
15 the detecting region. The viewing window may be an opening in the housing or may include an optically transparent material in the area of the detecting region to allow a user to view the results of a self-wicking test.

[0022] In some examples, the self-wicking device can further include a backing. The backing can support the porous substrate. In some examples, the
20 backing can include polyphenylene ether, polyester, polytetrafluoroethylene, glass, glass fiber, cellulose, nitrocellulose, or a combination thereof. The backing can be used to provide stability to the porous substrate.

Self-wicking Systems

25 [0023] Also presented herein is a self-wicking system 200. The system can include a self-wicking device 100 and a sample fluid 210. The self-wicking device can include a fluid flow channel including a porous substrate 110 for sequential fluid flow through multiple regions. The multiple regions can include a complexing region 120 that can include a compound 122 having a functional group to bind
30 with an analyte in a sample to form an analyte complex, a charge adjusting region 130 that can provide charge modulation by modifying a charge of the analyte

complex or by providing a modified concentration of charged centers to interact with the analyte complex, a concentrating region 140 that can include an immobilized material 142 having an affinity to the analyte complex after charge modulation, and a detecting region 150 that can receive concentrated analyte from the concentrating region. In one example, the charge adjusting region and the concentrating region can overlap or be within the same physical area, but can provide both functions. The sample fluid 210 can include the analyte 212 to flow through the fluid flow channel. The self-wicking device can be as described above.

10 [0024] The sample fluid may be a fluid that can include an analyte to be detected or can exclude the analyte to be detected by the self-wicking device. When the sample fluid includes the analyte, a positive result may be generated by the device. When the sample fluid excludes the analyte, a negative result may be generated by the device. The analyte in the sample fluid may be selected from amino acids, peptide strands, glycans, polypeptides, antibodies, proteins, or a combination thereof. In one example, the analyte can include a protein. The analyte may be at least ten residues long. A single strand of the analyte may have a weight average molecular weight ranging from about 1,500 Daltons to about 250 KD, about 5,000 Daltons to about 200 KD, or from about 50 KD to about 250 KD.

20 [0025] In some examples, the system can further include an elution fluid. The elution fluid can decouple the analyte complex from the immobilized material in the concentrating region. In some examples, the sample fluid with the analyte complex can have a pH of from about 4 to about 6 and the elution fluid can be selected from a tris base, a dibasic sodium phosphate, magnesium oxide, disodium hydrogen phosphate, arginine, sodium bicarbonate, ammonium bicarbonate, sodium carbonate, borate, glycine-NaOH, or a combination thereof. In another example, the sample fluid with the analyte complex can have a pH of from about 8 to about 10 and the elution fluid can be selected from citric acid, tris-HCl, monobasic sodium phosphate, tartaric acid, succinic acid, acetic acid, phosphoric acid, glycerine-HCl, sodium acetate, or a combination thereof. In a

further example, the charge adjusting region, the concentrating region, or a combination thereof can include a divalent cation, and the elution fluid can be selected from EDTA, EGTA, GLDA, trisodium α -DL-alanine diacetate, phytic acid, tetrasodium iminodisuccinate, or a combination thereof.

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Method of Concentrating and Detecting an Analyte in a Sample Fluid

[0026] Further presented herein is a method of concentrating and detecting an analyte in a fluid sample. The method 300 can include flowing 310 a sample fluid along a fluid flow channel including a porous substrate, where
10 relative to fluid flow, the fluid flow channel sequentially can include a complexing region, a charge adjusting region, a concentrating region, and a detecting region. A sample fluid can pass sequentially through the complexing region, the charge adjusting region, the concentrating region, and the detecting region. The method can further include binding 320 an analyte carried by the sample fluid to a
15 compound having a functional group to bind with the analyte in the complexing region to form an analyte complex; modulating 330 a charge by modifying a charge of the analyte complex in the charge adjusting region or by providing a modification of charged centers in the charge adjusting region; immobilizing 340 the analyte complex in the concentrating region; releasing 350 concentrated
20 analyte from the concentrating region; and detecting 360 the concentrated analyte in the detecting region.

[0027] In an example, modifying a charge of the analyte complex in the charge adjusting region can occur by modifying a pH of the sample fluid that the analyte complex is located in or by providing a divalent cation. Modifying the
25 charge by adjusting a pH can involve changing the pH of the sample fluid by from about 1 pH unit to about 3.5 pH units relative to a pH of the sample fluid in the complexing region. The pH modifying fluids and divalent cations can be as described above.

[0028] The releasing can include, in some examples, passing an elution
30 fluid through the concentrating region. The elution fluid may vary depending on how the charge modulation occurs and can be as described above.

[0029] The detecting can include visually inspecting the detecting region for the presence of an optical indicator. The optical indicator may be a colored dye in an example.

[0030] The method can concentrate an analyte when present in a sample
5 fluid in the concentrating region of the device, thereby eliminating a need for sample preparation and concentrating steps before applying a sample fluid to a porous substrate of a self-wicking device. Further, concentrating the analyte in the concentrating region can improve the results of the device by increasing a quantity of the concentrated analyte passing through the detecting region at a
10 time period thereby increasing an overall sensitivity of the device.

Definitions

[0031] As used in this specification and the appended claims, the singular forms "a," "an," and "the" include plural referents unless the content clearly
15 dictates otherwise.

[0032] As used herein, a plurality of items, structural elements, compositional elements, and/or materials may be presented in a common list for convenience. However, these lists should be construed as though individual members of the list are individually identified as a separate and unique member.
20 Thus, no individual member of such list should be construed as a *de facto* equivalent of any other member of the same list solely based on presentation in a common group without indications to the contrary.

[0033] Concentrations, dimensions, amounts, and other numerical data may be presented herein in a range format. A range format is used merely for
25 convenience and brevity and should be interpreted flexibly to include the numerical values explicitly recited as the limits of the range, and also to include all the individual numerical values or sub-ranges encompassed within that range as if individual numerical values and sub-ranges are explicitly recited. For example, a numeric range that ranges from about 10 to about 500 should be interpreted to
30 include the explicitly recited sub-range of about 10 to about 500 as well as sub-ranges thereof such as about 50 and about 300, as well as sub-ranges such

as from about 100 to about 400, from about 150 to about 450, from about 25 to about 250, etc.

[0034] The terms, descriptions, and figures used herein are set forth by way of illustration and are not meant as limitations. Many variations are possible within the disclosure, which is intended to be defined by the following claims -- and equivalents -- in which all terms are meant in the broadest reasonable sense unless otherwise indicated.

EXAMPLES

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[0035] The following illustrates examples of the present disclosure. However, the following are illustrative of the application of the principles of the present disclosure. Numerous modifications and alternative compositions, methods, and systems may be devised without departing from the spirit and scope of the present disclosure. The appended claims are intended to cover such modifications and arrangements.

Example 1 – Protein Concentration and Detection

[0036] A sample fluid is tested for the presence of a protein. The sample fluid is applied to a self-wicking device including a nitrocellulose porous substrate having a complexing region, a charge adjusting region, a concentrating region, and a detecting region thereon, as described above. The complexing region includes a colored latex particle capable of binding with the protein to form an analyte complex. A pH of the sample fluid including the analyte complex is reduced using monobasic sodium phosphate. The analyte complex binds to immobilized gold in the concentrating region of the device. A pH of the sample fluid is increased using dibasic sodium phosphate. Following an increase in the pH the analyte complex is released and passes to the detecting region, where a testing strip indicates the presence of the protein by showing a colored line.

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Example 2 – Antibody Concentration and Detection

[0037] A sample fluid is tested for the presence of an antibody. The sample fluid is applied to a self-wicking device including a nitrocellulose porous substrate having a complexing region, a charge adjusting region, a concentrating region, and a detecting region thereon, as described above. The complexing region includes a fluorescent latex particle capable of binding with the antibody to form an analyte complex. Divalent calcium ions in the charge adjusting region provide additional interaction centers allowing the analyte complex to further interact and concentrate. The analyte complex binds to immobilized gold in the concentrating region. EDTA is flowed through the self-wicking device and the analyte complex is released from the concentrating region. The analyte complex passes to the detecting region, where a testing strip indicates the presence of the antibody by showing a colored line.

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CLAIMS

What is Claimed Is:

- 5 1. A self-wicking device, comprising a fluid flow channel including a porous substrate for sequential fluid flow through multiple regions, including:
 a complexing region including a compound having a functional group to bind with an analyte in a sample fluid to form an analyte complex;
 a charge adjusting region to provide charge modulation by modifying a
10 charge of the analyte complex or to provide a modified concentration of charged centers to interact with the analyte complex;
 a concentrating region including an immobilized material having an affinity with the analyte complex after the charge modulation; and
 a detecting region to receive concentrated analyte from the concentrating
15 region.
2. The device of claim 1, wherein modification of the charge of the analyte complex in the charge adjusting region occurs by a change in pH of the sample fluid therein of from about 1 pH unit to about 3.5 pH units relative to a pH of the
20 sample fluid in the complexing region.
3. The device of claim 2, wherein a pH of the sample fluid in the complexing region is to be about 6.5 to about 7.5, and a pH of the sample fluid in the charge adjusting region is to be from about 4 to about 6 or from about 8 to
25 about 10.
4. The device of claim 1, wherein the charge adjusting region, the concentrating region, or a combination thereof includes charged centers including a divalent cation.
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5. The device of claim 4, wherein the divalent cation is selected from a calcium ion, a magnesium ion, a barium ion, a strontium ion, or a combination thereof.

5 6. The device of claim 1, wherein the charge adjusting region and the concentrating region are at common location of the porous substrate.

7. The device of claim 1, further comprising a fluid input port to flow a sample fluid into the fluid flow channel and

10 wherein the fluid input port is also available to subsequently flow an elution fluid therethrough, or

 wherein the device further includes a separate elution fluid input port positioned to flow an elution fluid at or upstream of the concentrating region.

15 8. A self-wicking system, comprising:

 a self-wicking device, comprising a fluid flow channel including a porous substrate for sequential fluid flow through multiple regions, including:

 a complexing region including a compound having a functional group to bind with an analyte in a sample fluid to form an analyte complex,

20 a charge adjusting region to provide charge modulation by modifying a charge of the analyte complex or providing a modified concentration of charged centers to interact with the analyte complex,

25 a concentrating region including an immobilized material having an affinity to the analyte complex after the charge modulation, and

 a detecting region to receive concentrated analyte from the concentrating region; and

30 a sample fluid containing the analyte to flow through the fluid flow channel.

9. The system of claim 8, wherein modification of the charge of the analyte complex in the charge adjusting region occurs by a change in pH of the sample fluid therein of from about 1 pH unit to about 3.5 pH units relative to a pH of the sample fluid in the complexing region, or wherein the charge adjusting region, the
5 concentrating region, or a combination thereof includes charged centers including a divalent cation.

10. The system of claim 8, further comprising an elution fluid to decouple the analyte complex from the immobilized material.

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11. The system of claim 9, wherein a pH of the sample fluid in the complexing region is to be about 6.5 to about 7.5, and a pH of the sample fluid in the charge adjusting region is:

from about 4 to about 6 and the elution fluid includes a tris base, a dibasic
15 sodium phosphate, magnesium oxide, disodium hydrogen phosphate, arginine, sodium bicarbonate, ammonium bicarbonate, sodium carbonate, borate, glycine-NaOH, or a combination thereof; or

from about 8 to about 10 and the elution fluid includes citric acid, tris-HCl, monobasic sodium phosphate, tartaric acid, succinic acid, acetic acid, phosphoric
20 acid, glycerine-HCl, sodium acetate, or a combination thereof.

12. The system of claim 9, wherein the charge adjusting region, the concentrating region, or a combination thereof includes the divalent cation, and wherein the elution fluid includes EDTA, EGTA, GLDA, trisodium α -DL-alanine diacetate, phytic acid, tetrasodium iminodisuccinate, or a combination thereof.
25

13. A method of concentrating and detecting an analyte in a sample fluid, comprising

flowing a sample fluid along a fluid flow channel including a porous
30 substrate, wherein relative to fluid flow, the fluid flow channel sequentially

includes a complexing region, a charge adjusting region, a concentrating region, and a detecting region;

binding an analyte carried by the sample fluid to a compound having a function group to bind with the analyte in the complexing region to form an analyte
5 complex;

modulating a charge by modifying a charge of the analyte complex in the charge adjusting region or providing a modification of charged centers in the charge adjusting region;

immobilizing the analyte complex in the concentrating region;
10 releasing concentrated analyte from the concentrating region; and
detecting the concentrated analyte in the detecting region.

14. The method of claim 13, wherein modulating a charge occurs by
modifying the charge of the analyte complex in the charge adjusting region
15 by changing a pH of the sample fluid therein of from about 1 pH unit to about 3.5
pH units relative to a pH of the sample fluid in the complexing, or
providing a divalent cation loaded in the charge adjusting region.

15. The method of claim 13, wherein the releasing of the concentrated
20 analyte includes passing an elution fluid through the concentrating region.

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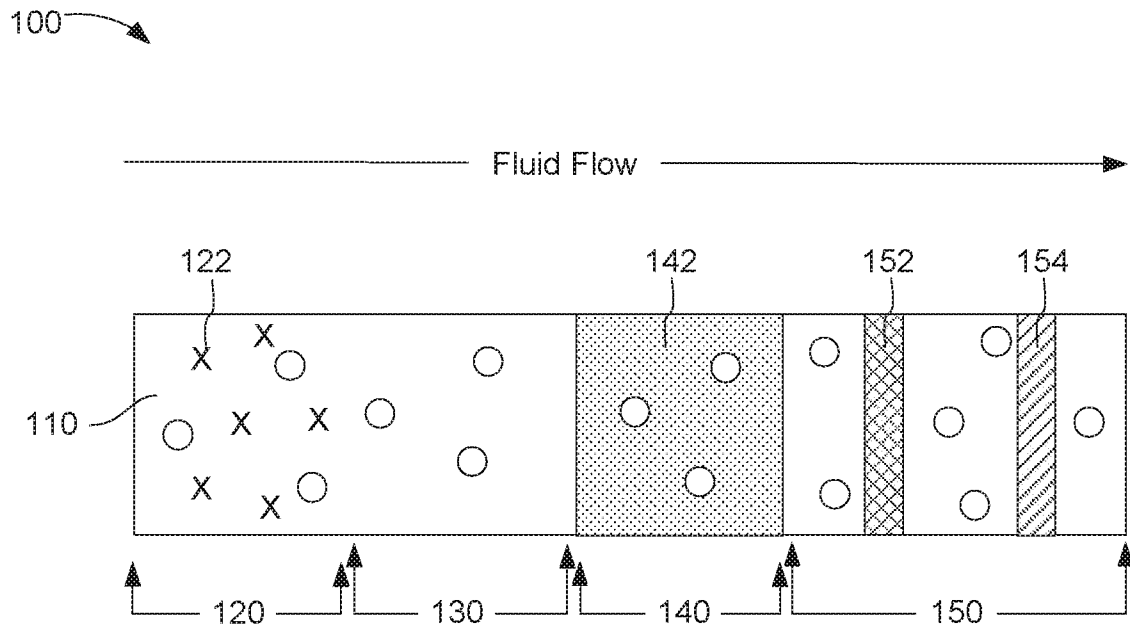


FIG. 1

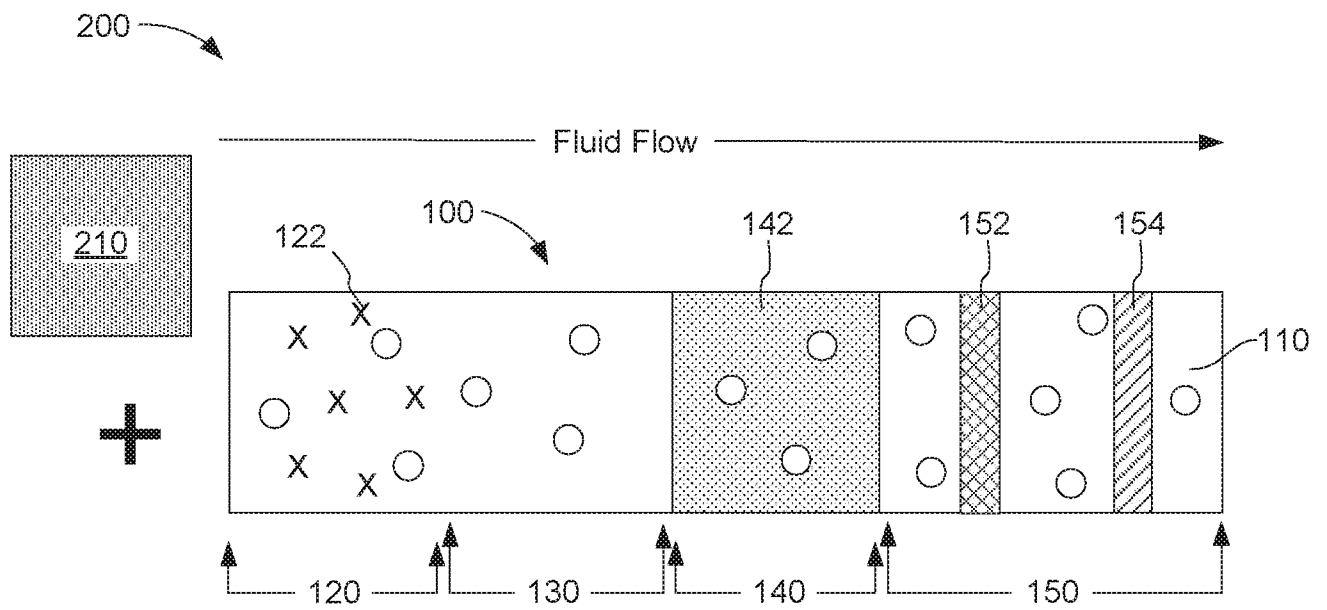


FIG. 2

2/2

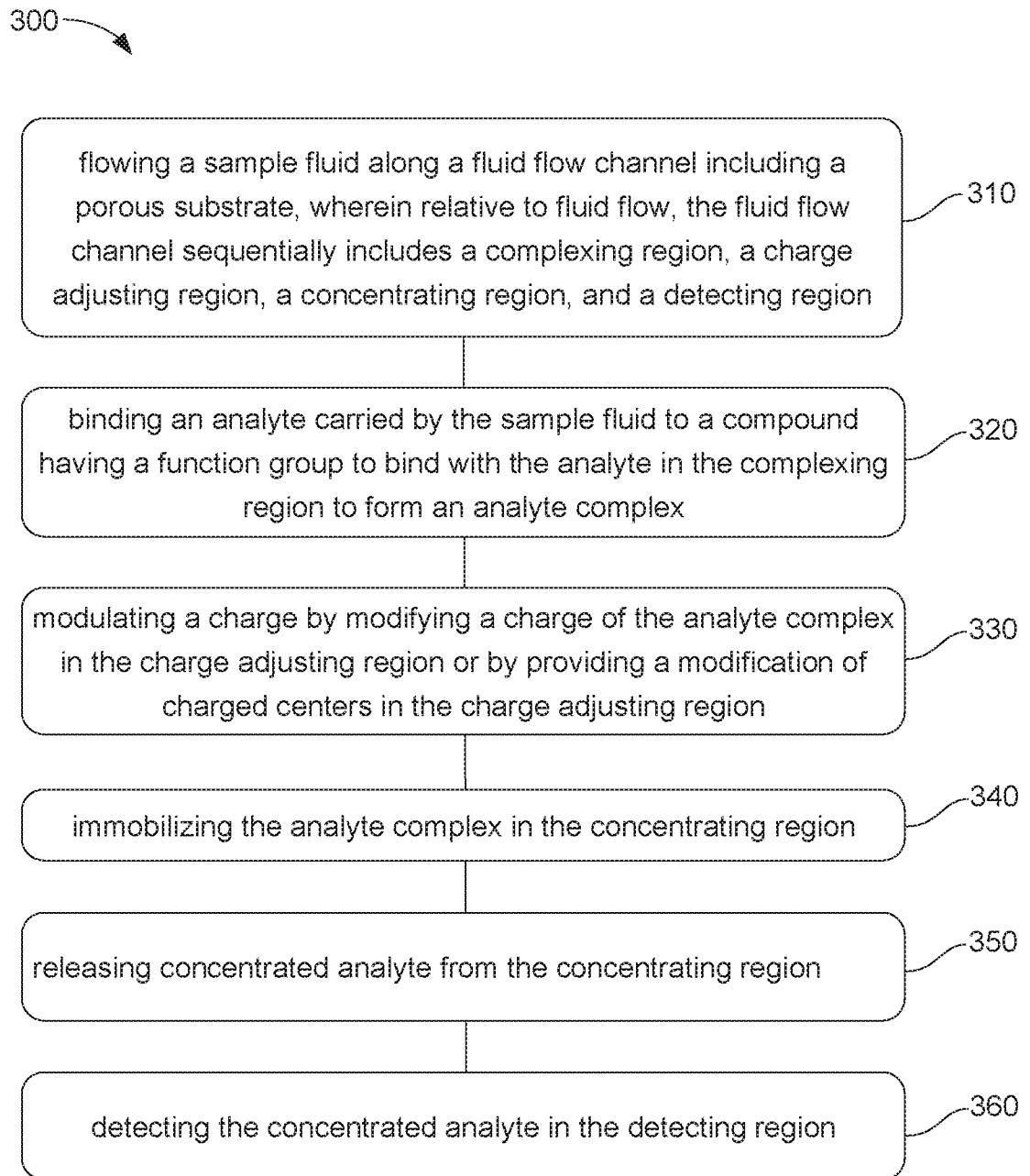


FIG. 3

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 2020/054917

A. CLASSIFICATION OF SUBJECT MATTER
G01N 30/92 (2006.01)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

G01N 30/90-30/95, 30/00, 33/00, 33/48-33/53

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PatSearch (RUPTO internal), USPTO, PAJ, Esp@cenet, Information Retrieval System of FIPS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 10267792 B2 (INTERNATIONAL BUSINESS MACHINES CORPORATION) 23.04.2019	1-15
A	US 8647888 B2 (HOLOGIC, INC) 11.02.2014	1-15
A	EP 2469269 B1 (ALERE SWITZERLAND GMBH) 30.03.2016	1-15
A	US 2006/0134796 A1 (3M INNOVATIVE PROPERTIES COMPANY) 22.06.2006	1-15

☐

Further documents are listed in the continuation of Box C.

☐

See patent family annex.

* Special categories of cited documents:

“**A**” document defining the general state of the art which is not considered to be of particular relevance

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“**T**” later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

“**X**” document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

“**Y**” document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

“**&**” document member of the same patent family

Date of the actual completion of the international search

09 June 2021 (09.06.2021)

Date of mailing of the international search report

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