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(54) **SAMPLE COLLECTION SYSTEM AND ELUENT DELIVERY ELEMENT FOR THE SAME**

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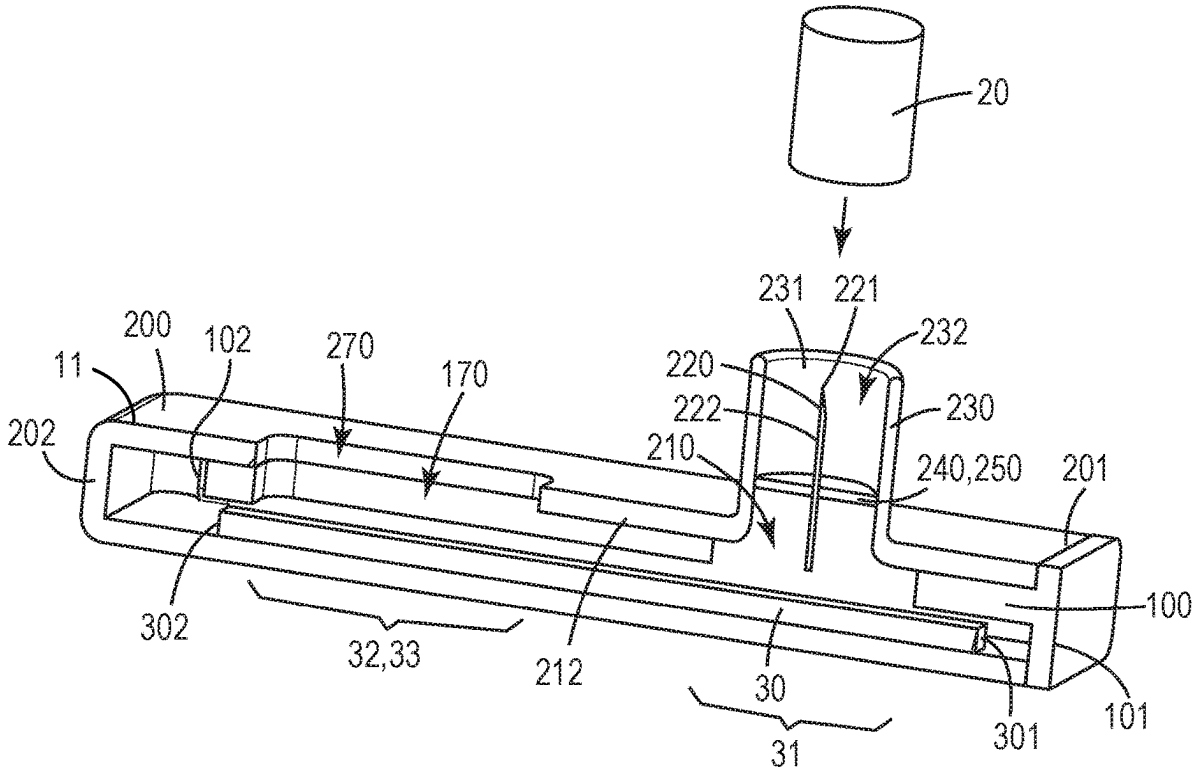
CPC ***B01L 3/5023*** (2013.01); ***A61B 5/097*** (2013.01); *B01L 2200/16* (2013.01); *B01L 2300/048* (2013.01); *B01L 2300/0672* (2013.01); *B01L 2300/0681* (2013.01); *B01L 2400/0406* (2013.01)

(57) **ABSTRACT**

According to an embodiment, a sample collection system includes a sample collection device and an eluent delivery element. The sample collection devices includes a housing including an airflow path extending from a proximal end including an air inlet to a distal end; a piercing element arranged within the airflow path; and a sample collector including porous sample collection media arranged to occlude the airflow path. The eluent delivery element includes a reservoir containing an eluent; and a membrane disposed at a coupling end of the reservoir and sealing the reservoir, the coupling end being constructed to couple with the proximal end of the airflow path such that the piercing element pierces the membrane.



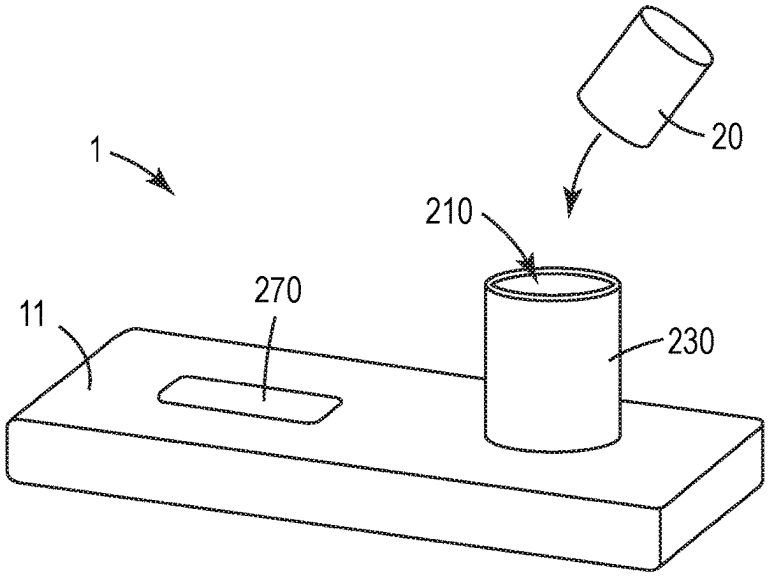

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Fig. 1A

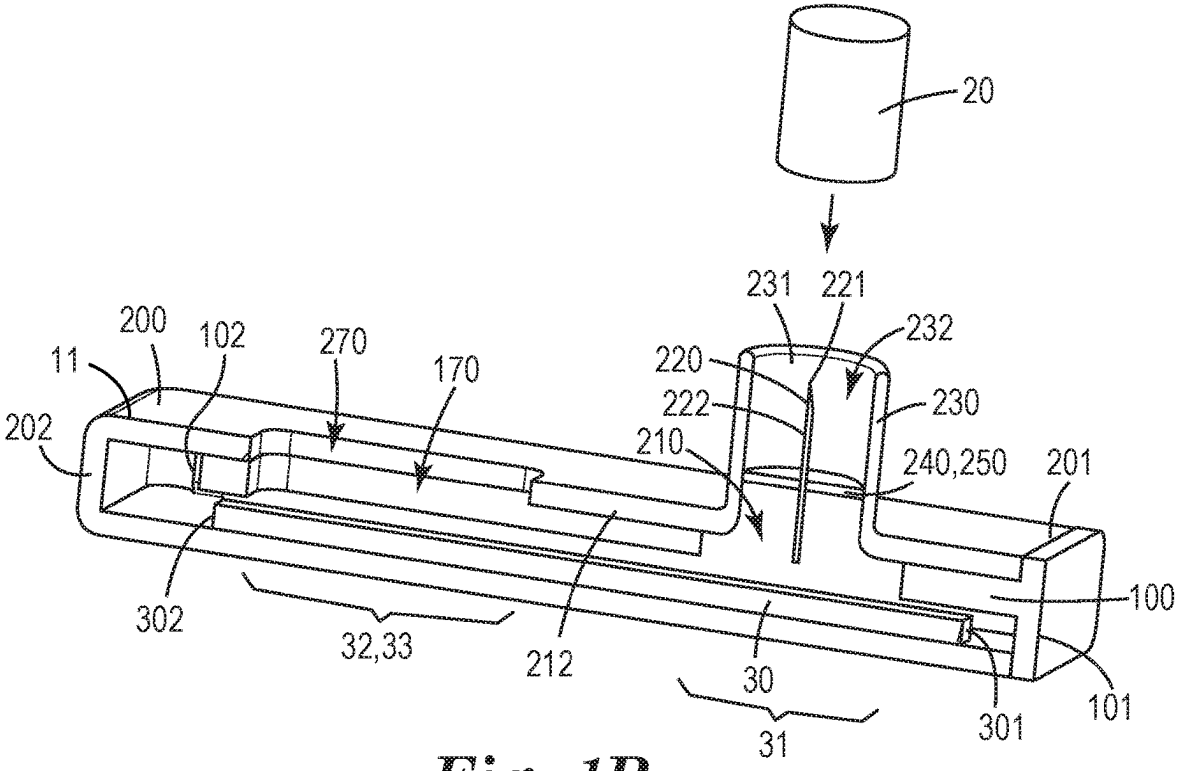
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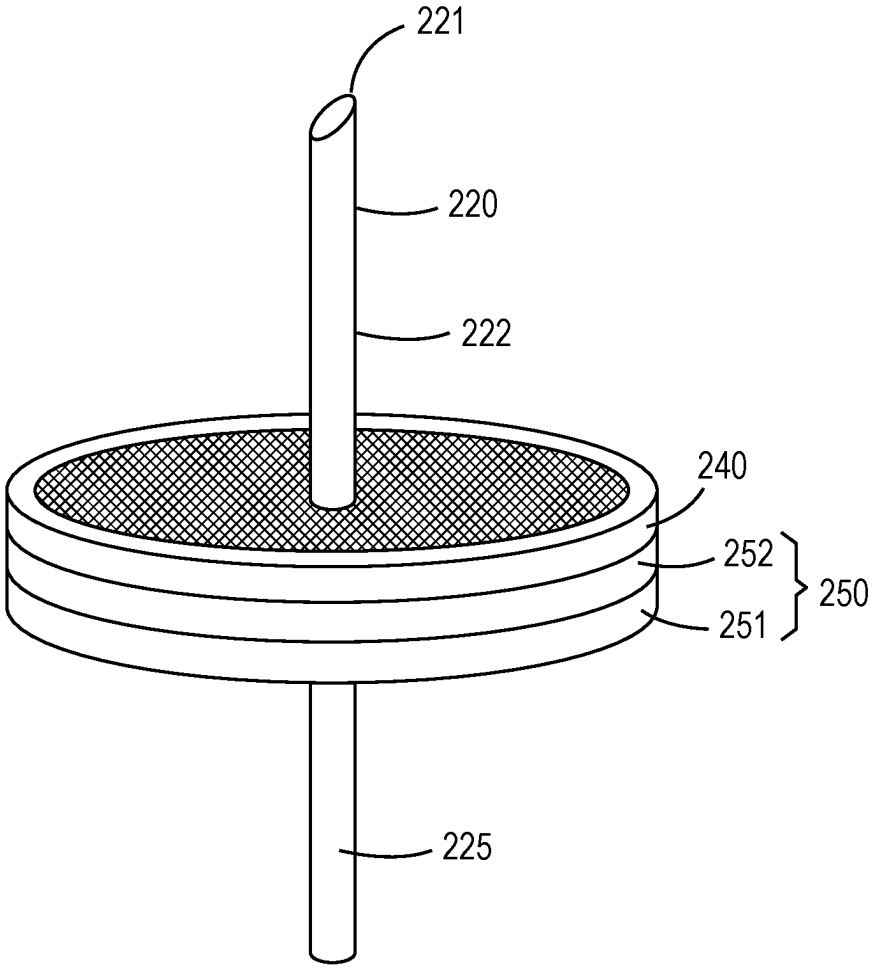
Fig. 1B



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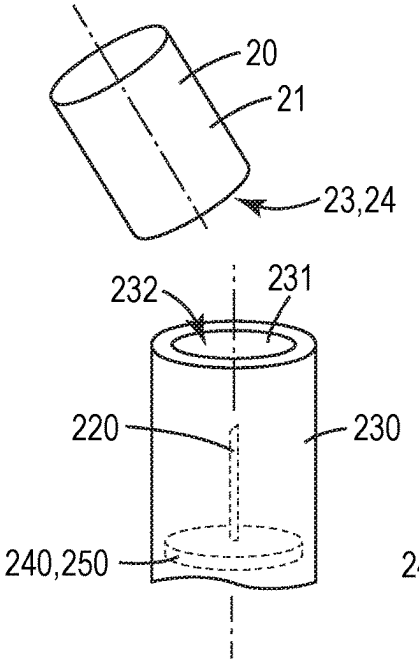

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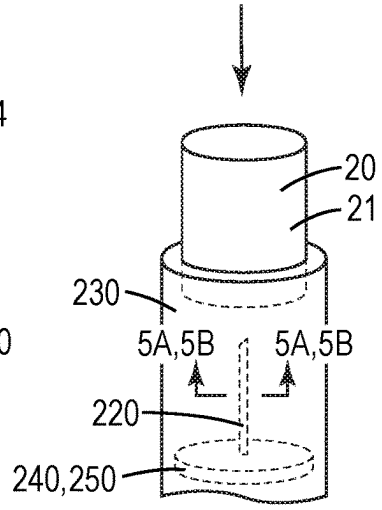

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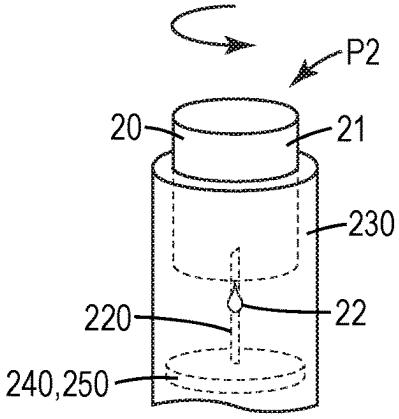
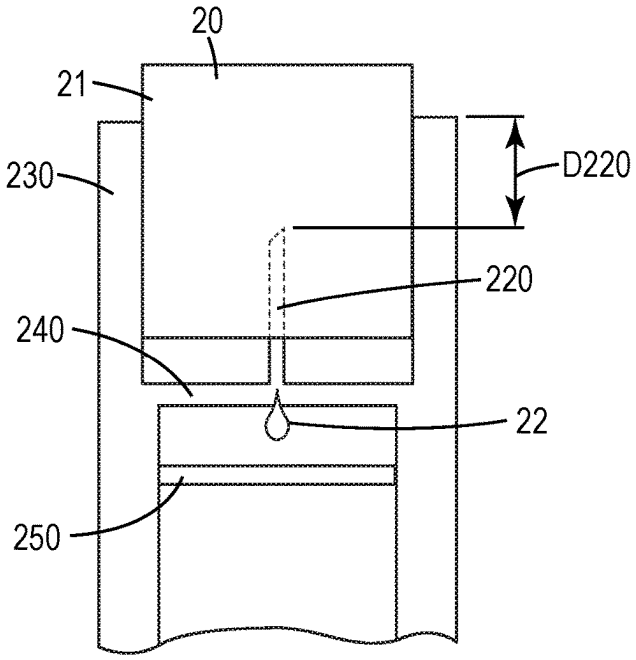


Fig. 3C



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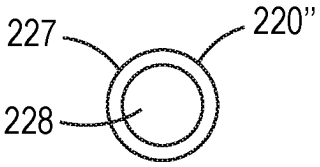
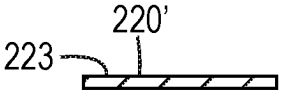


Fig. 5A



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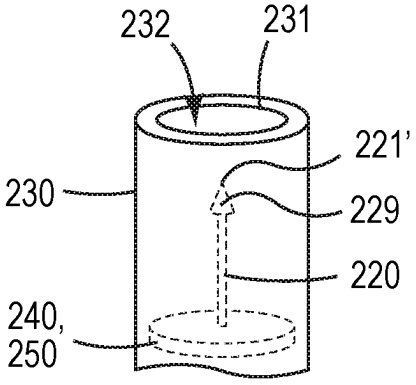

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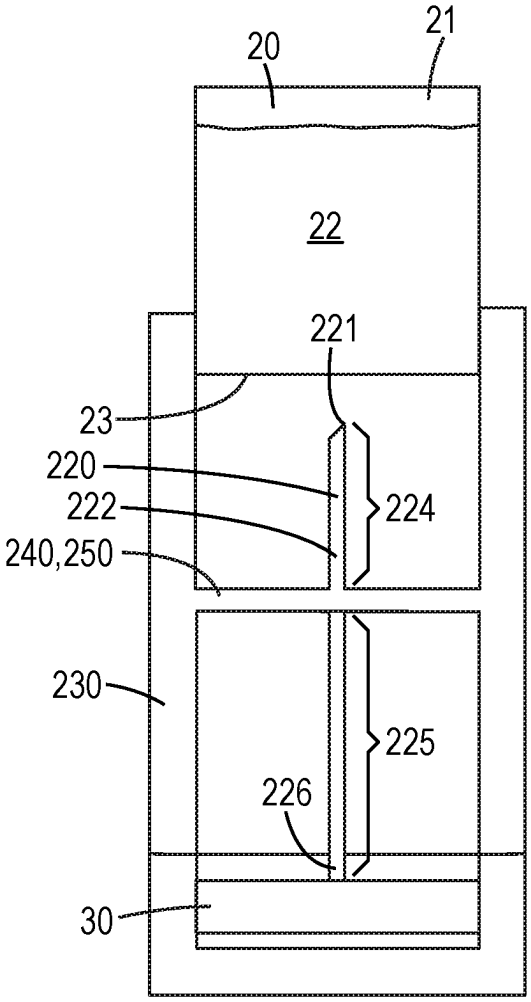
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Fig. 6

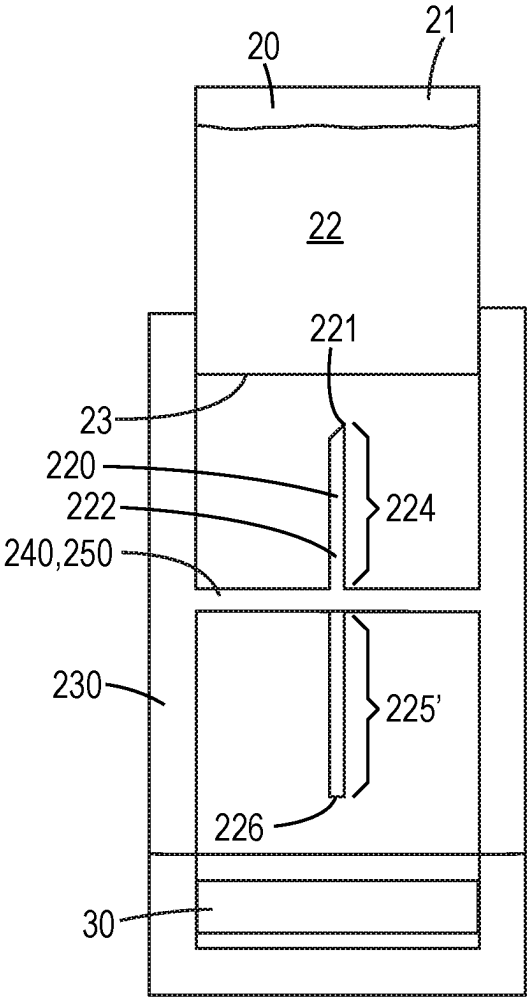
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Fig. 7

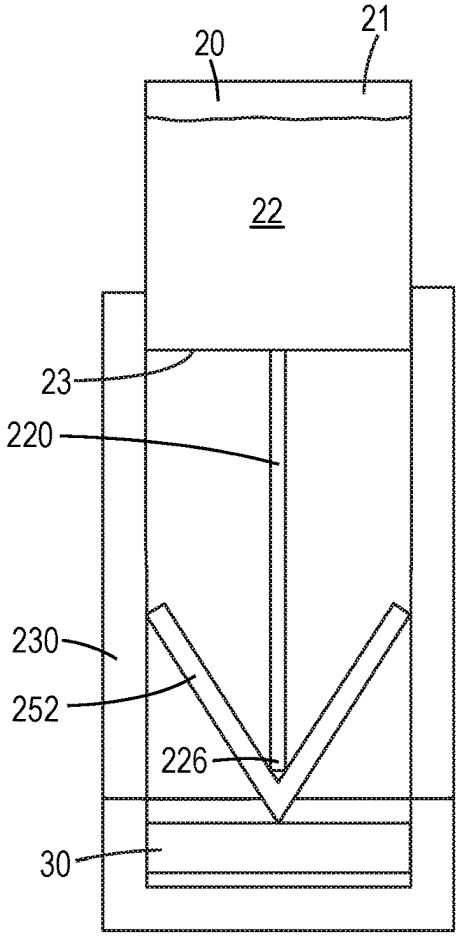
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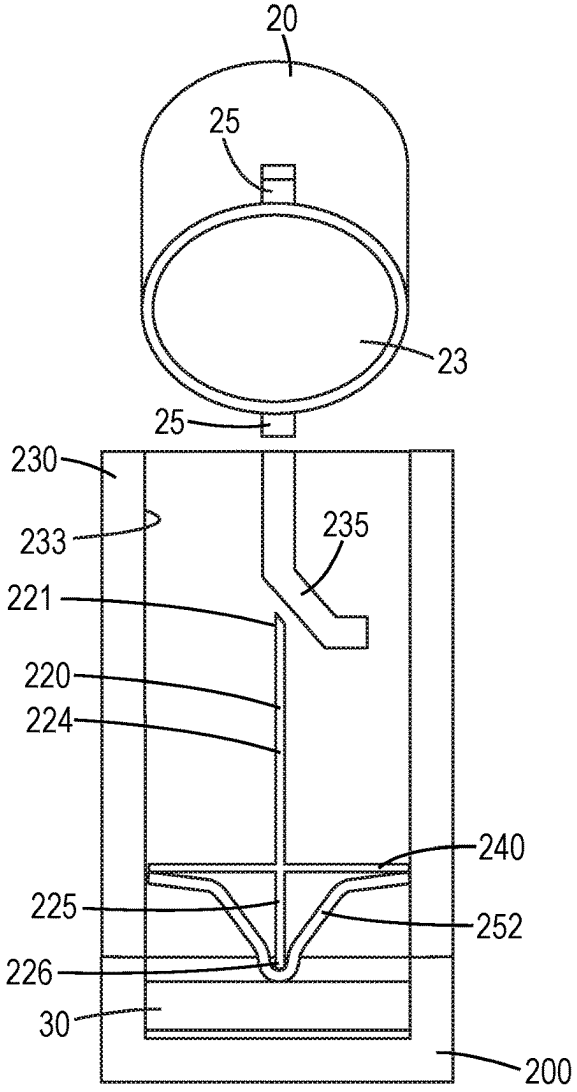
Fig. 8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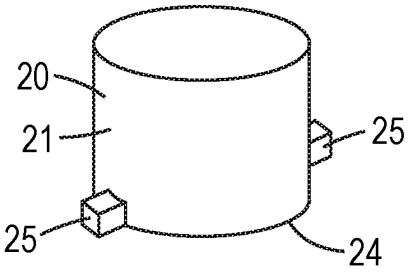

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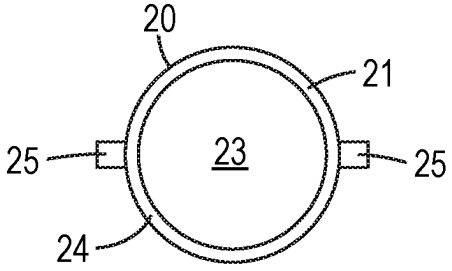

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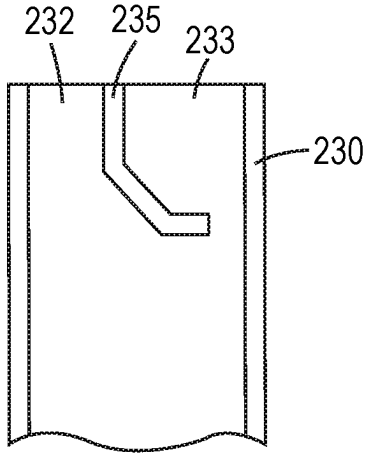

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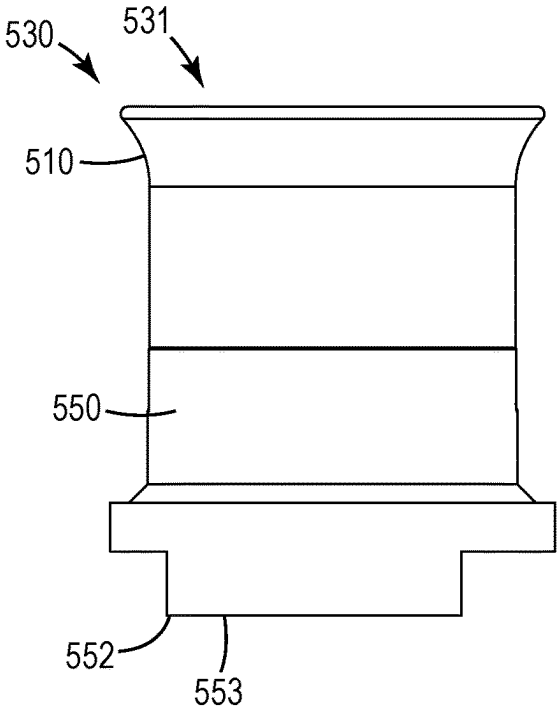

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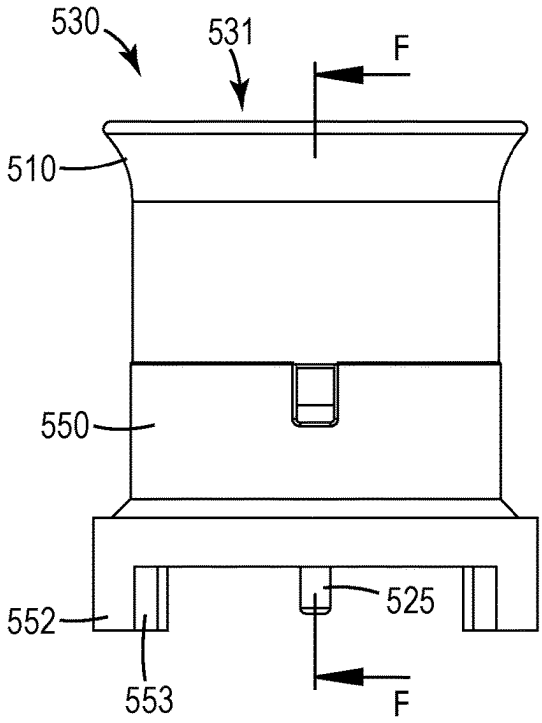

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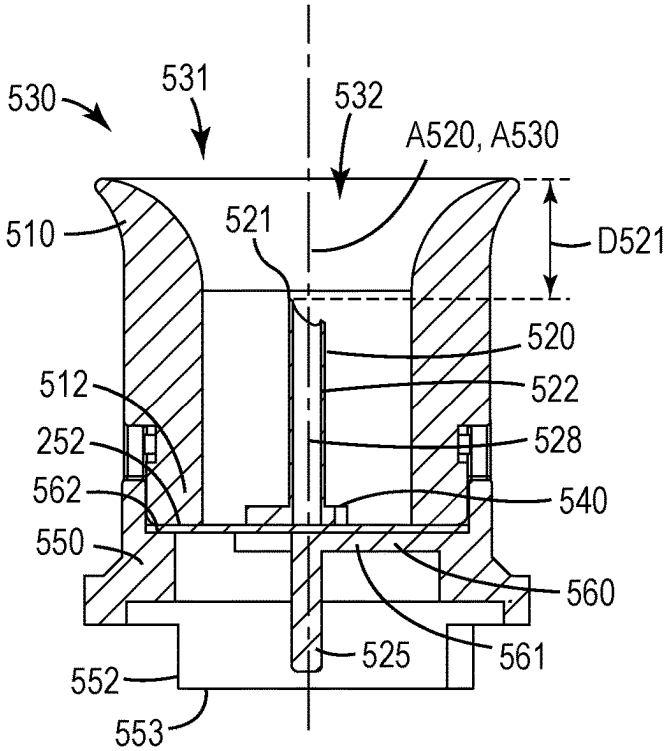

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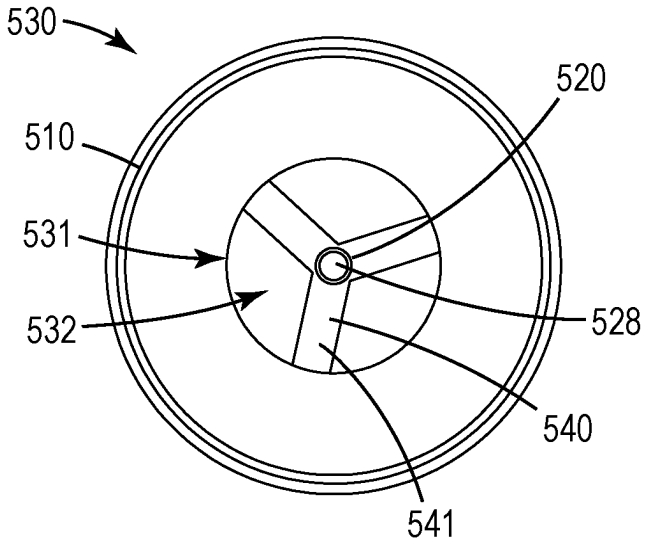

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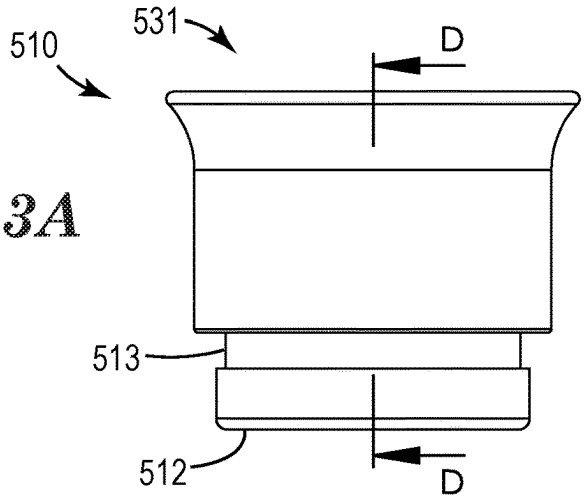

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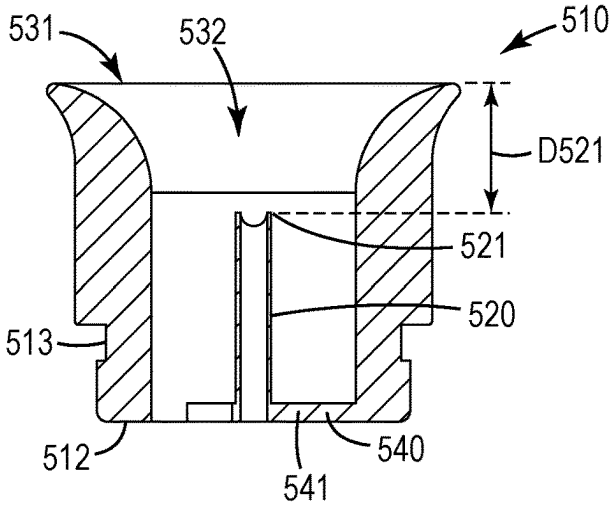

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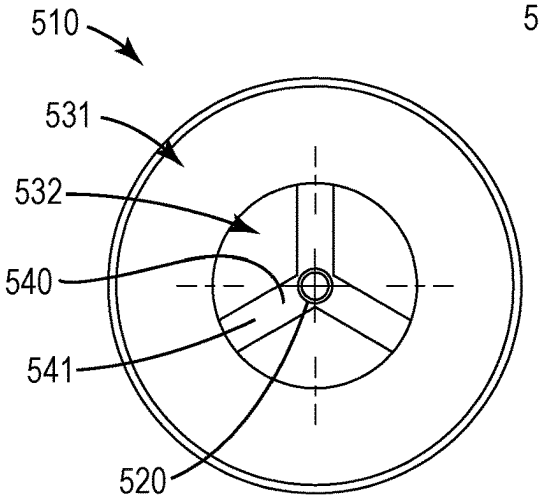

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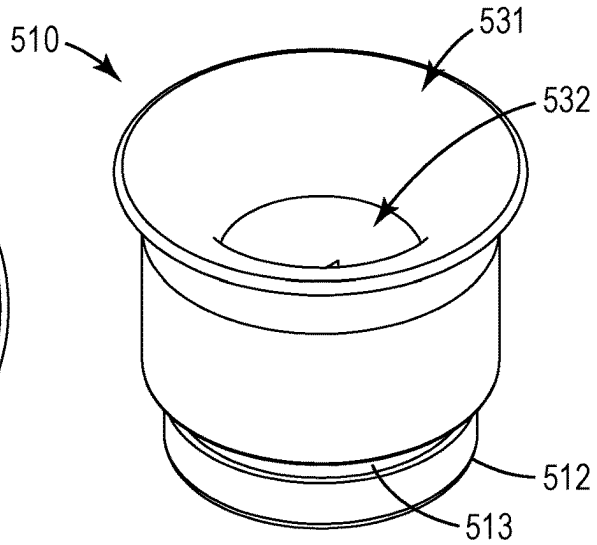

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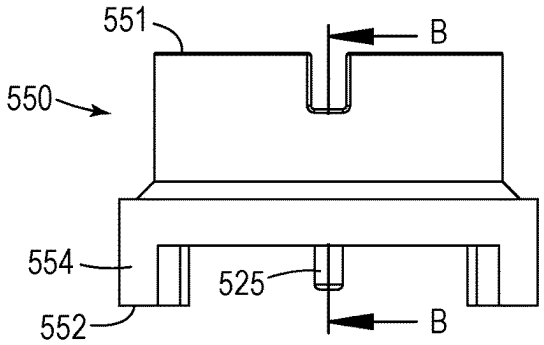
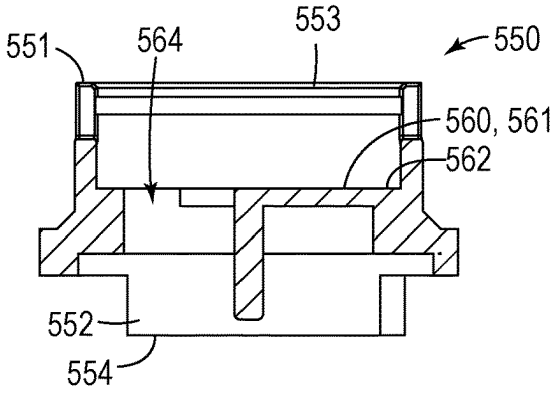


Fig. 14A



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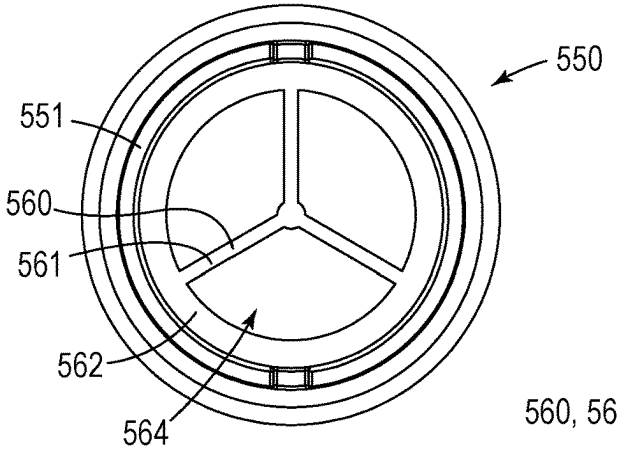

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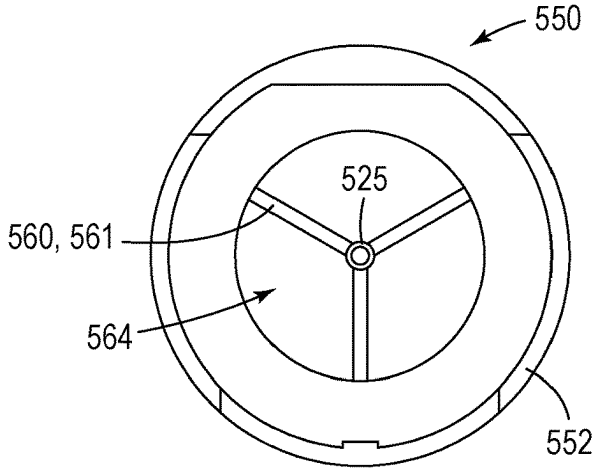

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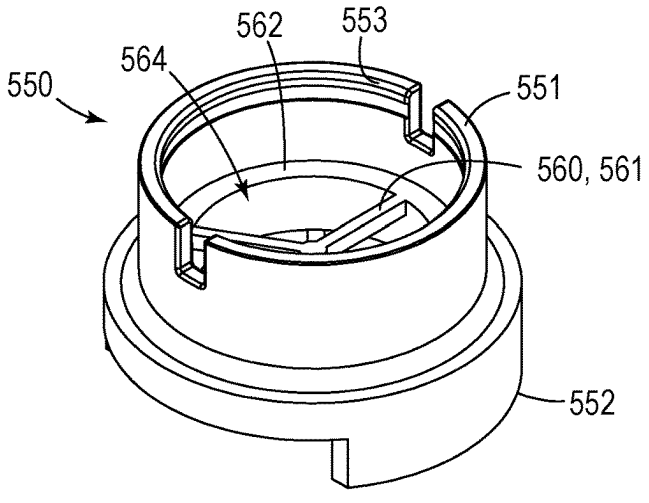

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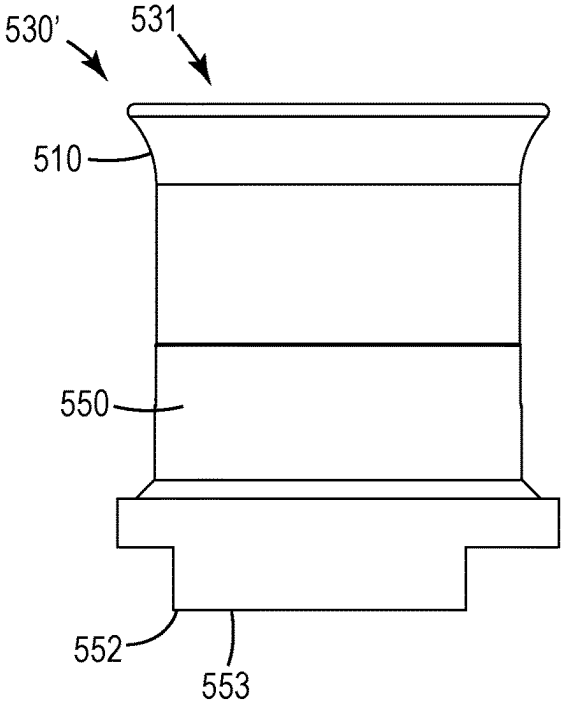
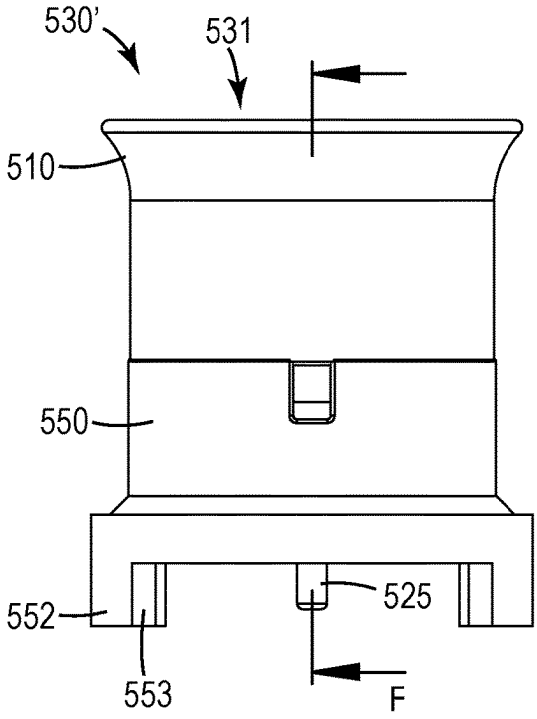


Fig. 15A



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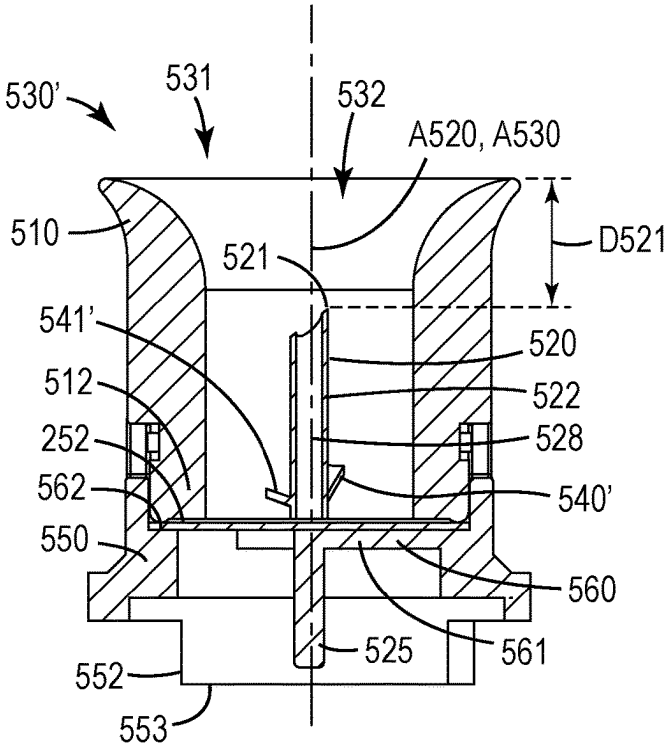

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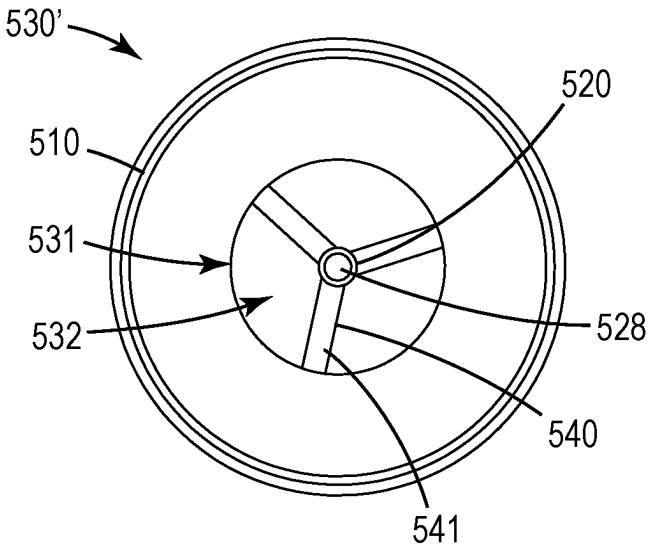

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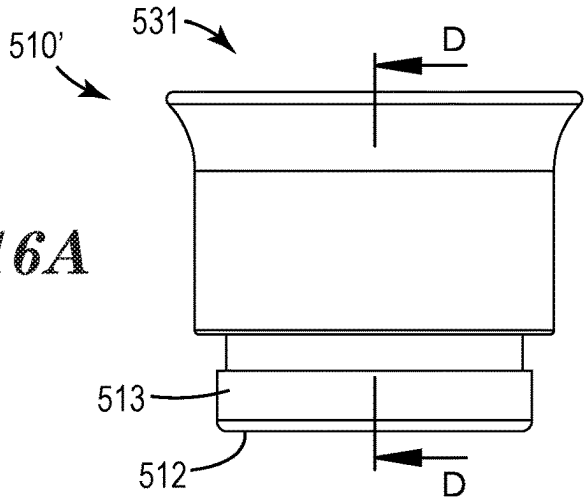

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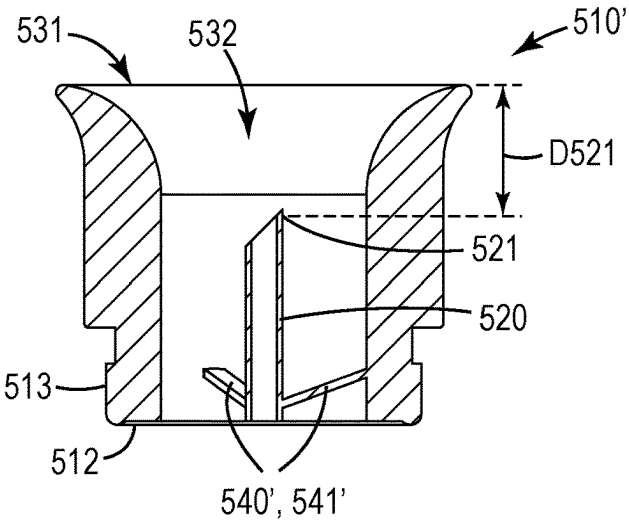

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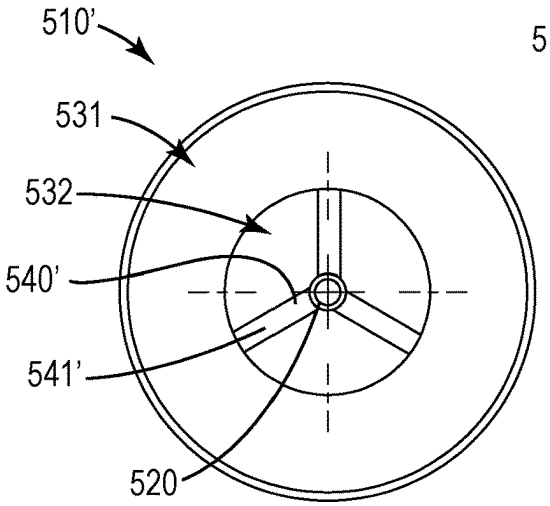

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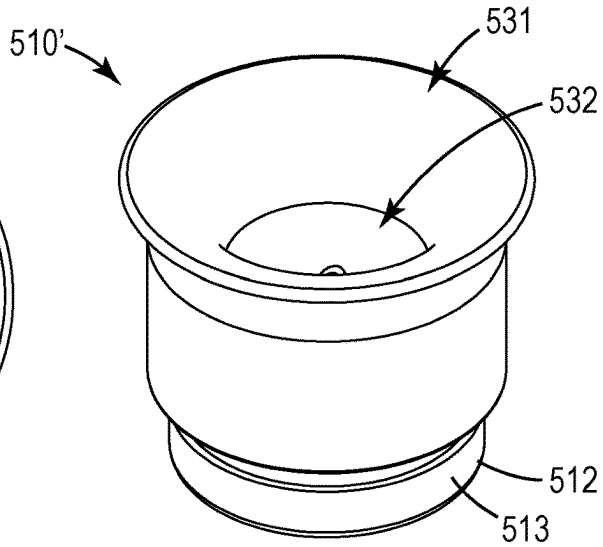

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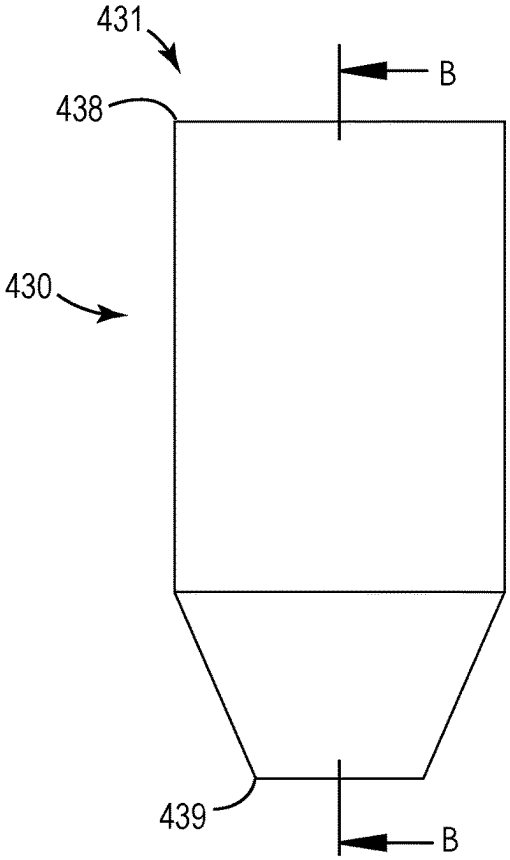

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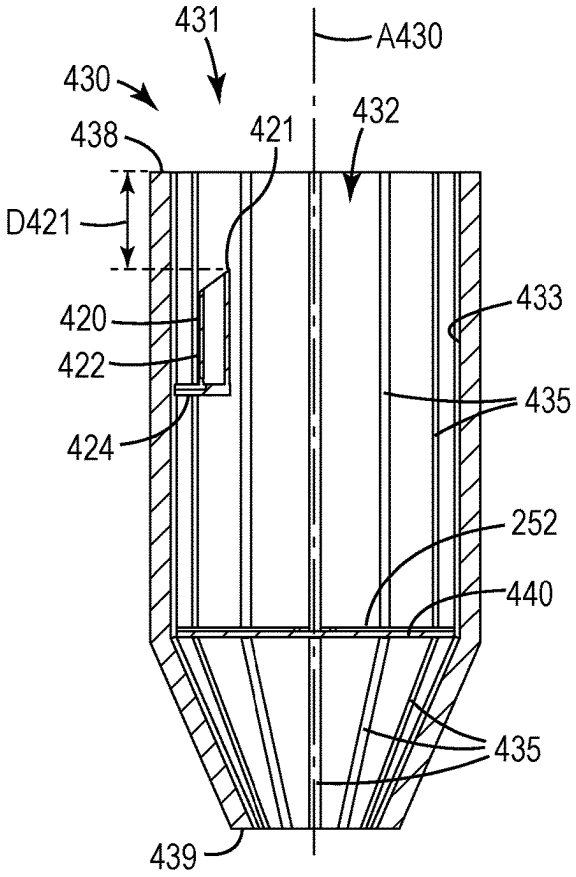

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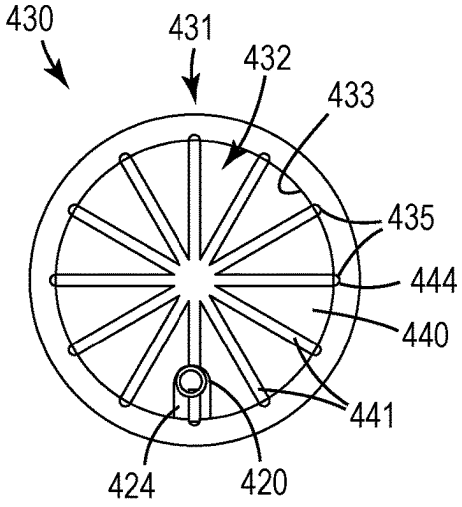

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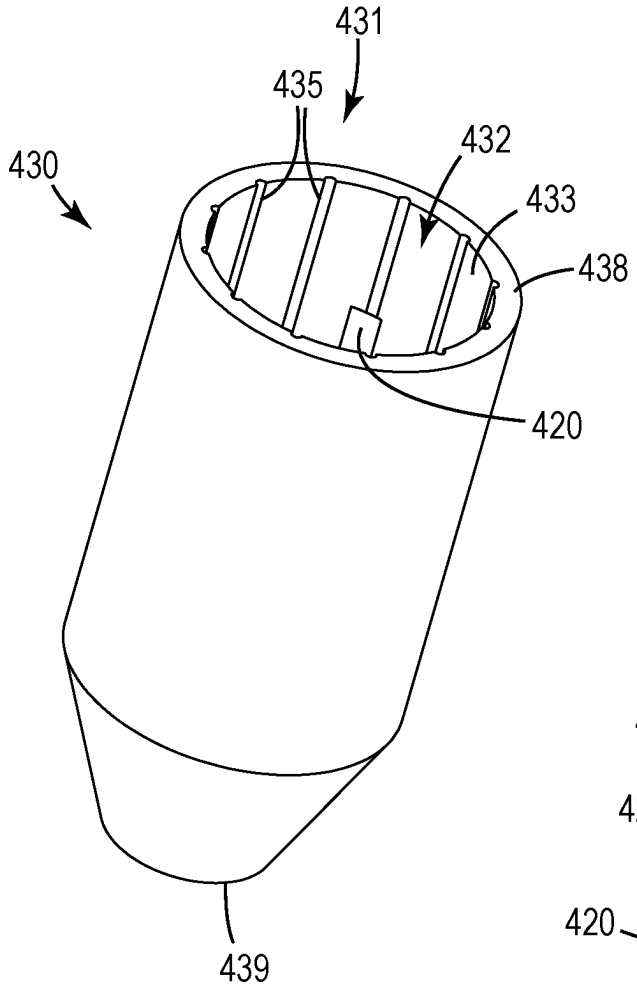

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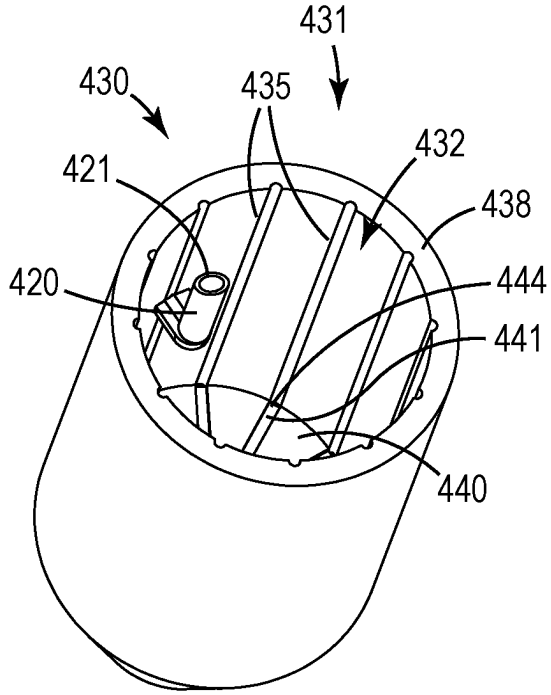

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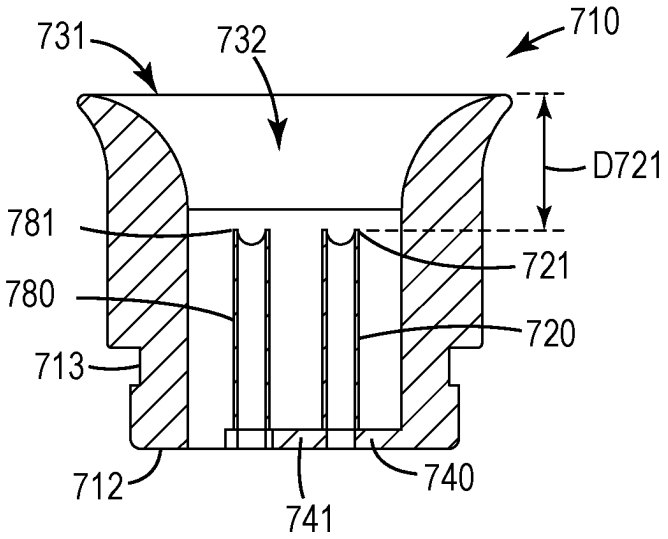

Fig. 18A

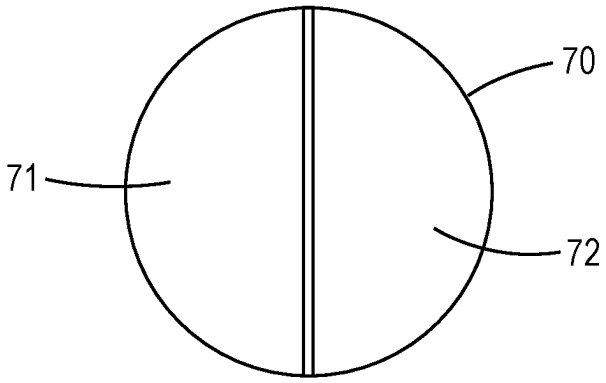

Fig. 18B

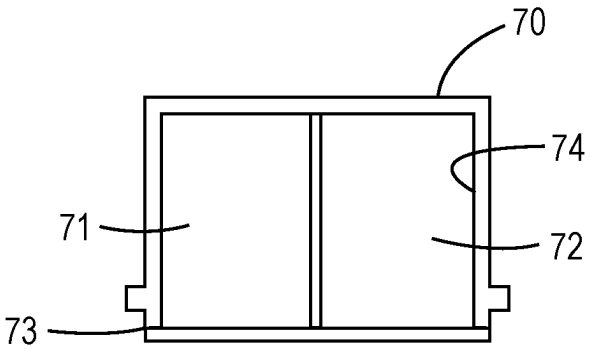

Fig. 18C

SAMPLE COLLECTION SYSTEM AND ELUENT DELIVERY ELEMENT FOR THE SAME

FIELD

[0001] The present disclosure relates to a sample collection device and system. The present disclosure relates to a bioaerosol collection device and system. The present disclosure further relates to an eluent delivery element for a sample collection device and system.

BACKGROUND

[0002] Diagnostic tests used to test for the presence of a virus or other pathogen in the airways, throat, or nasopharynx typically involve the insertion of a swab into the back of the nasal passage, the mid-turbinate area of the nasal passage, the anterior nares, or the throat to obtain a sample. The swab is then inserted into a container and analyzed or sent to a lab for processing. Other diagnostic tests involve collecting a saliva sample and then placing it in a container.

[0003] Recently, an unprecedented need for rapid viral testing has arisen due to the COVID-19 pandemic. Attempts to control the pandemic require a massive expansion of testing for SARS-CoV-2 virus in several different clinical and epidemiological contexts. Until recently, nasopharyngeal (NP) swabs were the United States Centers for Disease Control and Prevention's (CDC) preferred specimen type, as these specimens were thought to provide the most robust detection of patient infection. However, there are conflicting reports as to which of several specimen types bear the highest viral load.

[0004] Sensitivity is a complex issue, however, as detection in the upper airways (nasopharynx and oropharynx) is affected by multiple factors including duration of illness prior to testing, as well as the limit of detection (LoD) of the RT-PCR assay used. Availability of NP swabs and the resources to establish NP collection sites with specimen collection personnel have remained critical bottlenecks. To resolve these issues, healthcare systems have adopted multiple different strategies, including engaging industrial manufacturers to mass produce novel 3D-printed NP swabs, as well as evaluating different specimen types and alternative sample-collection strategies, such as saliva.

[0005] Assessment of nasal swabs and saliva is a rapidly growing area of interest, specifically because these specimen sample type involves a less invasive procedure than NP swabs. Accordingly, such samples can be self-collected by patients with a simple set of instructions, alleviating the need for highly trained medical personnel for specimen collection and reducing use of personal protective equipment (PPE) in short supply.

[0006] Many of the US Food and Drug Administration Emergency Use Authorization (FDA EUA) RT-PCR assays have approval for use of nasal swabs as a specimen type as well as saliva, but how well these samples perform compared to NP swabs remains unclear. To date, nasal-swab studies have shown conflicting results, with some researchers reporting similar test performance to NP swabs and others finding decreased sensitivity.

[0007] Currently available at-home viral tests (e.g., COVID-19 tests) involve a nasal swab and a test kit (for example, the Ellume™ test, the Abbot™ BinaxNOW™ test, and the Lucira™ All-in-One test kit). Tests that utilize nasal swab samples or saliva contend with contaminants that can interfere with the various diagnostic tests. As a result, these sample types require a purification step when using RT-PCR molecular testing.

[0008] The need exists for a simpler and cleaner sample collection system and easy elution of samples in a simple-to-use procedure. Further, a need exists for a sample collection system that can also capture and elute samples that have a low SARS-CoV-2 viral load but are still capable of transmitting the virus to others. There is also a need for a more precise system to reduce human error and provide more repeatable a reliable test results.

SUMMARY

[0009] There is a need for an inexpensive, simple to use, and reliable sample collection system that may be used by laypeople to obtain a sample for testing for the presence of a target virus, target pathogen, or other target analyte, in a collected sample. There is a need for an inexpensive, simple to use, and reliable eluent delivery element that may be used by laypeople to transfer a collected sample from a sample collection device to an assay. The sample collection system of the present disclosure includes a sample collection device for collecting a sample from exhalation airflow onto sample collection media and an eluent delivery element for eluting the sample onto an assay, such as a lateral flow assay, which may be used to analyze the sample.

[0010] It is desirable to provide a sample collection device and system that are easy to use. The device and system may advantageously be self-contained and optionally sterile. A self-contained (and optionally sterile) device and system may improve accuracy and reliability of pathogen testing due to the reduced contamination and background noise, unlike swabs and other test collection devices which may be contaminated upon use and/or during testing.

[0011] It is further desirable to provide a system which, after sample collection, provides for easy elution and transfer of the collected sample onto an assay for testing safely and without contamination. It is further desirable to provide a system that provides a metered dose of an eluent for easy elution and transfer of the collected sample onto an assay. A metered dose may improve accuracy of the analysis. According to embodiments disclosed herein, such systems are provided.

[0012] According to an embodiment, a sample collection system includes a sample collection device and an eluent delivery element. The sample collection devices includes a housing comprising an airflow path extending from a proximal end comprising an air inlet to a distal end; a piercing element arranged within the airflow path; and a sample collector comprising porous sample collection media arranged to occlude the airflow path. The eluent delivery element includes a reservoir containing an eluent; and a membrane disposed at a coupling end of the reservoir and sealing the reservoir, the coupling end being constructed to couple with the proximal end of the airflow path such that the piercing element pierces the membrane.

[0013] The sample collection system has an uncoupled position and a coupled position where the eluent delivery element is coupled with the sample collection device. The eluent delivery element is constructed to deliver eluent from the reservoir onto the porous sample collection media in the coupled position. The eluent delivery element may be con-

structed to deliver a metered dose of the eluent from the reservoir onto the porous sample collection media in the coupled position.

[0014] The sample collection system may further include a lateral flow assay. The lateral flow assay may be disposed adjacent the porous sample collection media.

[0015] The housing may include a mouthpiece defining the proximal end of the airflow path. The piercing element may be recessed in the mouthpiece.

[0016] The housing includes a support element in the airflow path and may further include a protrusion extending from the support element in a direction opposite of the piercing element. The protrusion may define a fluid flow guide extending distally from the sample collector. The fluid flow guide may be a distal section of the piercing element. The distal section may be in direct contact with a sample receiving area of the lateral flow assay. The protrusion may cause the porous sample collection media to be deformed into a cone shape. The protrusion may cause the porous sample collection media to come into direct contact with a sample receiving area of the assay.

[0017] The porous sample collection media may be made of a nonwoven material. The nonwoven material may include polylactic acid, polypropylene, or a combination thereof. The porous sample collection media may carry an electrostatic charge.

[0018] According to an embodiment, a kit includes a sample collection device, an eluent delivery element, and an assay. The sample collection device includes a housing comprising an airflow path having a length extending from a proximal end comprising an air inlet to a distal end; a sample collector comprising porous sample collection media arranged to occlude the airflow path; and a piercing element arranged within the airflow path and extending from the sample collector along the length of the airflow path. The eluent delivery element includes a reservoir containing an eluent; and a membrane disposed at a coupling end of the reservoir and sealing the reservoir, the coupling end being constructed to couple with the proximal end of the airflow path such that the piercing element pierces the membrane. The assay is arranged or arrangeable to receive a sample from the sample collection element.

[0019] According to an embodiment, a method of obtaining a sample using a sample collection system includes breathing into the proximal end of the airflow path to collect a sample on the porous sample collection media; coupling the coupling end of the eluent delivery element with the first end of the airflow path; and transferring a metered dose of the eluent from the reservoir onto the porous sample collection media to elute the collected sample from the porous sample collection media. The method may further include causing an eluate including the collected sample to be deposited onto the lateral flow assay.

BRIEF DESCRIPTION OF FIGURES

[0020] FIG. **1**A is a perspective view of a sample collection system according to an embodiment.

[0021] FIG. **1**B is a cut-off perspective view of the sample collection system of FIG. **1**A.

[0022] FIG. **2** is a schematic perspective view of a piercing element and sample collector of the system of FIG. **1**A according to an embodiment.

[0023] FIGS. **3**A-**3**C are schematics of the insertion of an eluent delivery element into the mouthpiece of the device of FIG. **1**A according to an embodiment.

[0024] FIG. **4** is a schematic cross-sectional view of the mouthpiece and an eluent delivery element of the system of FIG. **1**A in a coupled position according to an embodiment.

[0025] FIG. **5**A is a cross-sectional view of a hollow needle piercing element for the system of FIG. **1**A according to an embodiment.

[0026] FIG. **5**B is a cross-sectional view of a blade-shaped piercing element for the system of FIG. **1**A according to an embodiment.

[0027] FIG. **5**C is a schematic perspective view of an arrow-head-shaped piercing element and mouthpiece for the system of FIG. **1**A according to an embodiment.

[0028] FIG. **6** is a schematic cross-sectional side view of the system of FIG. **1**A with an alternative piercing element according to an embodiment.

[0029] FIG. **7** is a schematic cross-sectional side view of the system of FIG. **1**A with an alternative piercing element according to an embodiment.

[0030] FIG. **8** is a schematic cross-sectional side view of the system of FIG. **1**A with an alternative piercing element according to an embodiment.

[0031] FIG. **9** is a schematic cross-sectional view of a sample collection system with an alternative piercing element according to an embodiment.

[0032] FIG. **10**A is a schematic perspective view of an eluent delivery element of the system of FIG. **1**A according to an embodiment.

[0033] FIG. **10**B is a schematic bottom view of the eluent delivery element of FIG. **10**A according to an embodiment.

[0034] FIG. **11** is a schematic cross-sectional side view of a mouthpiece for the system of FIG. **1**A according to an embodiment.

[0035] FIG. **12**A is a side view of a mouthpiece for the system of FIG. **1**A according to an embodiment.

[0036] FIG. **12**B is another side view of the mouthpiece of FIG. **12**A.

[0037] FIG. **12**C is a cross-sectional side view of the mouthpiece of FIG. **12**A.

[0038] FIG. **12**D is a top view of the mouthpiece of FIG. **12**A.

[0039] FIG. **13**A is a side view of an inlet part of the mouthpiece of FIG. **12**A.

[0040] FIG. **13**B is a cross-sectional side view of the inlet part of FIG. **13**A.

[0041] FIG. **13**C is a top view of the inlet part of FIG. **13**A.

[0042] FIG. **13**D is a perspective view of the inlet part of FIG. **13**A.

[0043] FIG. **14**A is a side view of a base of the mouthpiece of FIG. **12**A.

[0044] FIG. **14**B is a cross-sectional side view of the base of FIG. **14**A.

[0045] FIG. **14**C top view of the base of FIG. **14**A.

[0046] FIG. **14**D is a bottom view of the base of FIG. **14**A.

[0047] FIG. **14**E is a perspective view of the base of FIG. **14**A.

[0048] FIG. **15**A is a side view of a mouthpiece for the system of FIG. **1**A according to an embodiment.

[0049] FIG. **15**B is another side view of the mouthpiece of FIG. **15**A.

[0050] FIG. **15**C is a cross-sectional side view of the mouthpiece of FIG. **15**A.

[0051] FIG. **15**D is a top view of the mouthpiece of FIG. **15**A.

[0052] FIG. **16**A is a side view of an inlet part of the mouthpiece of FIG. **15**A.

[0053] FIG. **16**B is a cross-sectional side view of the inlet part of FIG. **16**A.

[0054] FIG. **16**C is a top view of the inlet part of FIG. **16**A.

[0055] FIG. **16**D is a perspective view of the inlet part of FIG. **16**A.

[0056] FIG. **17**A is a side view of a mouthpiece for the system of FIG. **1**A according to an alternative embodiment.

[0057] FIG. **17**B is a cross-sectional side view of the mouthpiece of FIG. **17**A.

[0058] FIG. **17**C top view of the mouthpiece of FIG. **17**A.

[0059] FIG. **17**D is a perspective view of the mouthpiece of FIG. **17**A.

[0060] FIG. **17**E is another perspective view of the mouthpiece of FIG. **17**A.

[0061] FIG. **18**A is a cross-sectional side view of a mouthpiece for the system of FIG. **1**A according to an alternative embodiment.

[0062] FIG. **18**B is a cross-sectional top view of an eluent delivery element for use with the mouthpiece of FIG. **18**A.

[0063] FIG. **18**C is a cross-sectional side view of the eluent delivery element of FIG. **18**B.

DEFINITIONS

[0064] All scientific and technical terms used herein have meanings commonly used in the art unless otherwise specified. The definitions provided herein are to facilitate understanding of certain terms used frequently herein and are not meant to limit the scope of the present disclosure.

[0065] Unless otherwise indicated, the terms "polymer" and "polymeric material" include, but are not limited to, organic homopolymers, copolymers, such as for example, block, graft, random and alternating copolymers, terpolymers, etc., and blends and modifications thereof. Furthermore, unless otherwise specifically limited, the term "polymer" shall include all possible geometrical configurations of the material. These configurations include, but are not limited to, isotactic, syndiotactic, and atactic symmetries.

[0066] The terms "downstream" and "upstream" refer to a relative position based on a direction of exhalation airflow through the device. For example, the upstream-most element of the device is the inlet or mouthpiece element, and the downstream-most element of the device is the outlet or sample receiving area of the assay.

[0067] All headings provided herein are for the convenience of the reader and should not be used to limit the meaning of any text that follows the heading, unless so specified.

[0068] The term "i.e." is used here as an abbreviation for the Latin phrase id est, and means "that is," while "e.g." is used as an abbreviation for the Latin phrase exempli gratia and means "for example."

[0069] All scientific and technical terms used herein have meanings commonly used in the art unless otherwise specified. The definitions provided herein are to facilitate understanding of certain terms used frequently herein and are not meant to limit the scope of the present disclosure.

[0070] The term "about" is used here in conjunction with numeric values to include normal variations in measurements as expected by persons skilled in the art and is understood have the same meaning as "approximately" and to cover a typical margin of error, such as +5% of the stated value. Moreover, unless otherwise indicated, all numbers expressing quantities, and all terms expressing direction/orientation (e.g., vertical, horizontal, parallel, perpendicular, etc.) in the specification and claims are to be understood as being modified in all instances by the term "about."

[0071] Terms such as "a," "an," and "the" are not intended to refer to only a singular entity but include the general class of which a specific example may be used for illustration.

[0072] The terms "a," "an," and "the" are used interchangeably with the term "at least one." The phrases "at least one of" and "comprises at least one of" followed by a list refers to any one of the items in the list and any combination of two or more items in the list.

[0073] As used here, the term "or" is generally employed in its usual sense including "and/or" unless the content clearly dictates otherwise. The term "and/or" means one or all of the listed elements or a combination of any two or more of the listed elements.

[0074] The recitations of numerical ranges by endpoints include all numbers subsumed within that range (e.g., **1** to **5** includes 1, 1.5, 2, 2.75, 3, 3.80, 4, 5, etc. or 10 or less includes 10, 9.4, 7.6, 5, 4.3, 2.9, 1.62, 0.3, etc.). Where a range of values is "up to" or "at least" a particular value, that value is included within the range.

[0075] As used here, "have", "having", "include", "including", "comprise", "comprising" or the like are used in their open-ended sense, and generally mean "including, but not limited to." It will be understood that "consisting essentially of," "consisting of," and the like are subsumed in "comprising" and the like.

[0076] As used herein, "consisting essentially of," as it relates to a composition, product, method or the like, means that the components of the composition, product, method or the like are limited to the enumerated components and any other components that do not materially affect the basic and novel characteristic(s) of the composition, product, method or the like.

[0077] The term "substantially" as used here has the same meaning as "significantly," and can be understood to modify the term that follows by at least about 90%, at least about 95%, or at least about 98%. The term "not substantially" as used here has the same meaning as "not significantly," and can be understood to have the inverse meaning of "substantially," i.e., modifying the term that follows by not more than 10%, not more than 5%, or not more than 2%.

[0078] The words "preferred" and "preferably" refer to embodiments that may afford certain benefits, under certain circumstances. However, other embodiments may also be preferred, under the same or other circumstances. Furthermore, the recitation of one or more preferred embodiments does not imply that other embodiments are not useful and is not intended to exclude other embodiments from the scope of the disclosure, including the claims.

[0079] Any direction referred to here, such as "front," "back," "top," "bottom," "left," "right," "upper," "lower," and other directions and orientations are described herein for clarity in reference to the figures and are not to be limiting of an actual device or system or use of the device or system. Devices or systems as described herein may be used in a number of directions and orientations.

[0080] Any direction referred to here, such as "top," "bottom," "left," "right," "upper," "lower," and other directions and orientations are described herein for clarity in

reference to the figures and are not to be limiting of an actual device or system or use of the device or system. Devices or systems as described herein may be used in a number of directions and orientations.

DETAILED DESCRIPTION

[0081] The present disclosure relates to a sample collection device and system. The present disclosure relates to a bioaerosol sample collection device and system.

[0082] The sample collection device includes sample collector that includes porous sample collection media along an airflow path formed by the device housing. The porous sample collection media is constructed to capture viruses, pathogens, or other analytes, carried in an exhalation airflow. The porous sample collection media may be a nonwoven material capable of capturing pathogens, viruses, or other analytes. After loading a sample onto the porous sample collection media, the sample may be eluted from the sample collection media onto an assay. The sample may be analyzed for the presence of a pathogen or other analyte of interest. According to an embodiment, the sample may be eluted by passing a liquid (e.g., eluent) through the porous sample collection media to elute the sample, including pathogens, viruses, or other analytes, bound to the porous sample collection media, forming an eluate, and allowing the eluate to flow onto the assay. The eluate may then be analyzed using the assay.

[0083] According to an embodiment, the sample collection system includes a sample collection device and an eluent delivery element. The sample collection device includes a housing with an airflow path extending from a proximal end to a distal end. The proximal end forms an air inlet. The distal end may be at or adjacent a sample receiving area of the assay. A piercing element is arranged within the airflow path. The sample collection device further includes a sample collector that includes porous sample collection media arranged to occlude the airflow path. The eluent delivery element includes a reservoir containing an eluent and a membrane disposed at a coupling end of the reservoir to seal the reservoir. The coupling end is constructed to couple with the proximal end of the airflow path (e.g., the inlet end) such that the piercing element pierces the membrane and releases the eluent from the reservoir.

[0084] According to an embodiment, a user may exhale into the sample collection device and load the sample collector with a sample of the exhalation airflow to form a loaded porous sample collection media. The user may exhale through an air inlet in the sample collection device. The air inlet may be formed as a mouthpiece. Alternatively, the sample collection device may have a nose piece constructed for exhaling through the nose (e.g., through one or both nostrils). The user may exhale through an air inlet in the mouthpiece or the nose piece of the sample collection device. The housing is constructed so that by exhaling through the air inlet, the exhalation airflow passes through the porous sample collection media. The porous sample collection media is constructed to capture viruses, other pathogens, or other analytes, from the exhalation airflow. The user may then connect the eluent delivery element to the mouthpiece of the device to apply an eluent to the loaded porous sample collection media to elute the loaded sample onto an assay.

[0085] The sample collection system may include a lateral flow assay adjacent the porous sample collection media. In some embodiments, the porous sample collection media is in direct contact with the lateral flow assay. In other embodiments, the porous sample collection media is not in direct contact with the lateral flow assay.

[0086] The housing may include an inlet part or a mouthpiece defining the proximal end of the airflow path. The piercing element may be recessed in the inlet part or mouthpiece. The piercing element is constructed to pierce, puncture, score, cut, slit, or otherwise rupture the membrane of the eluent delivery reservoir and to create an opening in the membrane. These piercing functions are referred to here collectively as "piercing." The piercing element may remain inside the eluent delivery reservoir or may break off during or after piercing. Rotating the eluent delivery element as it is inserted in the airflow path may aid in the piercing of the membrane and may create an opening in the membrane that is larger than the size of the piercing element. The piercing element may further be constructed to act as a fluid guide. The piercing element may be constructed to draw fluid from the reservoir. The piercing element may be constructed to guide the flow of eluent onto the porous sample collection media and optionally onto a sample receiving area on the assay.

[0087] The piercing element may be recessed in the mouthpiece by any suitable distance that will allow the eluent delivery reservoir to be pierced yet reduces or minimizes the likelihood of a user inadvertently coming into contact with the piercing tip. A suitable recessed distance may be determined based on the particular dimensions of the mouthpiece and the eluent delivery element. The piercing element may be recessed, for example, by a distance of 4 mm or more, 5 mm or more, or 6 mm or more. The piercing element may be recessed by a distance of 10 mm or less, 9 mm or less, or 8 mm or less. In some embodiments, the piercing element is recessed by 4 mm to 10 mm or by 5 mm to 8 mm.

[0088] Referring now to FIGS. **1**A and **1**B, an exemplary embodiment of sample collection system **1** with a sample collection device **10** and eluent delivery element **20** is shown. The sample collection device **10** includes a housing **11** that houses the assay **30** (e.g., a lateral flow assay). A mouthpiece **230** extends from the housing **11**, forming an airflow path **210**. A sample collector **250** including porous sample collection media **252** occludes the airflow path **210**. The mouthpiece **230** is constructed to receive an eluent delivery element **20**. A piercing element **220** is disposed in the airflow path **210** and configured to pierce the eluent delivery element **20**.

[0089] The construction of the sample collection device **10** is not particularly limited, as long as the sample collection device **10** facilitates the sample collector **250**, airflow path **210**, piercing element **220**, eluent delivery element **20**, and assay **30**. The housing of a suitable sample collection device may be modified to include the mouthpiece **230**, **430**, **530**, **530'** with airflow path, sample collector, and piercing element of the present disclosure. Examples of such sample collection devices that may be modified include those described in U.S. Provisional Patent Application Nos. 63/200,058 (filed on Feb. 12, 2021), 63/202,140 (filed on May 28, 2021), 63/200,958 (filed on Apr. 6, 2021), 63/202,143 (filed on May 28, 2021), 63/201,983 (filed on May 21, 2021), 63/203,441 (filed on Jul. 22, 2021), and 63/203,442 (filed on Jul. 22, 2021).

[0090] The housing **11** of the sample collection device may be constructed from one or more pieces or parts. In some embodiments, as shown in FIGS. **1**A and **1**B, the housing **11** includes a first part **100** that carries the assay **30** (e.g., a lateral flow assay) and a second piece **200** that houses the first part **100** and assay **30** and provides or connects with the airflow path **210** and sample collector **250**. The mouthpiece **230** may be a separate piece coupled with the housing **11** or may be integrally formed with the housing **11**, as shown. The housing **11** may include a viewing window **270** that allows a user to view the result of the assay **30**.

[0091] The mouthpiece **230** may define the proximal end **211**, including the air inlet **231**, of the airflow path **210**. The mouthpiece **230** may include a support element **240** or support grid. The piercing element **220** element extends proximally (toward the air inlet **231**) from the support element **240** or support grid. The piercing element **220** may be recessed in the mouthpiece **230** by a distance D**220**. The piercing element **220** may be recessed by a sufficient distance to reduce or minimize the likelihood of a user inadvertently coming into contact with the piercing tip **221** of the piercing element **220**. The piercing element **220** is constructed to pierce, puncture, score, cut, slit, or otherwise rupture the membrane **23** of the eluent delivery element **20**. The piercing element **220** may further be constructed to act as a fluid guide. The piercing element **220** may be constructed to draw fluid from the reservoir **21**. The piercing element **220** may be constructed to guide the flow of eluent **22** onto the porous sample collection media **252** and optionally onto a sample receiving area **31** on the assay **30**.

[0092] FIG. **2** shows a schematic view of the piercing element **220**, support element **240** or support grid, and sample collector **250**. The piercing element **220** may have a shaft **222** that extends proximally from the support element **240** or support grid. The piercing element **220** may also extend distally (toward the assay **30**) from the support element **240** and include a distal section **225**. The support element **240** or support grid may serve multiple purposes, including supporting the piercing element **220** within the airflow path **210**, but optionally also supporting the porous sample collection media **252**. That is, the support element **240** or support grid may form part of the sample collector **250**. In some embodiments, the support element **240** or support grid may support either the porous sample collection media **252**, the piercing element **220**, or both the porous sample collection media **252** and the piercing element **220**. In some embodiments, the sample collector **250** includes a separate media support element **251**. The porous sample collection media **252** may be disposed adjacent the support element **240** or a media support element **251** (if provided), or be disposed between the support element **240** and the media support element **251**. In some embodiments, such as those shown in FIGS. **12**A-**16**D, the support element **240** may be provided in an inlet part **510** of the mouthpiece **530** and the media support element **251** may be provided in a base **550** of the mouthpiece **530**. The support element **240** or support grid may have any suitable construction. For example, the support element **240** or support grid may have a wheel-and-spoke design, a mesh, or any other suitable configuration. In some embodiments, the support element **240** or support grid may be tapered or angled toward the center of the airflow channel and toward the assay to facilitate fluid flow to the assay, as shown in FIGS. **15**C, **15**D, and **16**B.

[0093] According to an embodiment, a user may exhale into the mouthpiece **230** of the sample collection device **10** and load the porous sample collection media **252** of the sample collector **250** with a sample of the exhalation airflow. The user may exhale through the air inlet **231** of the mouthpiece **230**. The exhalation airflow passes along the airflow path **210** and through the porous sample collection media **252**.

[0094] After loading the sample collector **250** (e.g., the porous sample collection media **252**) with a sample, the user may connect the eluent delivery element **20** with the sample collection device **10** to apply the eluent **22** to the loaded media. The coupling of the eluent delivery element **20** with the sample collection device **10** is shown schematically in FIGS. **3**A-**3**C. The sample collection system **1** has an uncoupled position P**1** (FIG. **3**A) and a coupled position P**2** (FIG. **3**C). In the coupled position P**2**, the eluent delivery element is coupled with the mouthpiece **230** of the sample collection device **10** and delivers eluent from the reservoir onto the porous sample collection media **252**. The eluent delivery element **20** may be coupled with the sample collection device **10** by inserting the coupling end **24** of the eluent delivery element **20** into the air inlet **231** and the interior cavity **232** of the mouthpiece **230**. The eluent delivery element **20** may be pushed, twisted, or snapped into place. The sample collection system **1** may have an indicator configured to indicate whether the sample collection system is in the coupled position P**2**. The indicator may be, for example, an audible indicator (e.g., a "click" sound) or a visual indicator (e.g., corresponding aligning features on the eluent delivery element and the sample collection device). When the eluent delivery element **20** is in the coupled position P**2**, the longitudinal center axis A**20** of the eluent delivery element **20** may be coaxial with the longitudinal center axis A**230** of the mouthpiece **230**.

[0095] According to an embodiment, the eluent delivery element **20** is constructed to deliver a metered dose of the eluent **22** from the reservoir **21** onto the porous sample collection media **252** in the coupled position P**2**.

[0096] The sample collection system **1** may be constructed so that after the eluent delivery element **20** is inserted and pierced, the eluent delivery element **20** is partly retracted axially to facilitate eluent flow from the reservoir **21**. The eluent delivery element **20** may have a piercing position, e.g., the coupled position P**2**, and a fluid delivery position, where the fluid delivery position is axially proximal (along the longitudinal axis A**230** of the mouthpiece **230**) to the piercing position P**2**.

[0097] FIG. **4** shows a cross-sectional schematic of the eluent delivery element **20** in the coupled position P**2** with the mouthpiece **230**. In the coupled position P**2**, the piercing element **220** extends into the reservoir **21**.

[0098] The piercing element **220** may have any suitable shape. Various shapes are shown in FIGS. **5**A-**5**C. The piercing element **220** includes a tip **221** and a shaft **222**. In some embodiments, the piercing element **220** is shaped like a needle **227** or a blade **223**. A needle **227** shaped piercing element **220** may optionally have a hollow center **228**, as shown in the cross-section in FIG. **5**A. The piercing element **220** may have non-circular cross-sectional shape along its longitudinal center axis, such as the cross-sectional shape of the blade **223** shown in FIG. **5**B. The cross-sectional shape or size of the piercing element **220** may vary along the length of the piercing element. That is, the piercing element

220 may have a first cross-sectional shape and a second cross-sectional shape along the longitudinal center axis A220, where the second cross-sectional shape is different from the first cross-sectional shape. The piercing element 220 may have a first cross-sectional diameter and a second cross-sectional diameter along the longitudinal center axis, where the second cross-sectional diameter is different from the first cross-sectional diameter. For example, the cross-sectional shape or size or both may be different at the tip 221 of the piercing element 220 than along the shaft 222. An example of a piercing element 220 that has a tip 221' with a different cross-sectional shape and size than the shaft 222 is the piercing element 220' with an arrow-head shaped tip 229 shown in FIG. 5C. The arrow-head shaped tip 229 may have a largest cross-dimension at the base of the tip 229 that is greater than the cross-dimension of the shaft. Having a tip 221, 229 with a larger cross-dimension than the shaft 222 may help drain the reservoir even if the piercing element remains in the pierced opening of the membrane.

[0099] The mouthpiece 230 (and the airflow path 210) may define a longitudinal center axis A230. In some embodiments, the piercing element 220 extends parallel to the longitudinal center axis A230. In some embodiments, the piercing element 220 is not co-axial with the mouthpiece 230 and the airflow path 210. In some embodiments, the piercing element 220 is co-axial with the mouthpiece 230 and the airflow path 210.

[0100] The piercing element 220 may be constructed to act as a fluid guide and may include features that help draw fluid from the reservoir 21 or guide the flow of eluent 22 onto the porous sample collection media 252 and optionally onto a sample receiving area 31 on the assay 30. In some embodiments, the piercing element 220 is a hollow needle 227 having a hollow center 228 extending from an open first end to an opposing open second end. The piercing element 220 may have surface texture, surface treatment, or material configured to facilitate wicking or capillary flow. For example, the piercing element 220 may have surface texture, surface treatment, or material that helps to draw out fluid from the reservoir 21 or to flow the fluid toward the porous sample collection media 252 or both. Examples of materials that can facilitate wicking or capillary flow include porous materials, such as cellulosic materials, and hydrophilic materials, such as hydrophilic polymers. Examples of surface textures that can facilitate wicking or capillary flow include angled channels (e.g., channels having a V-shaped cross section), micro channels, capillary channels, and surface roughness. Examples of surface treatments that can facilitate flow of the eluent include corona treatment to render a surface easily wettable.

[0101] In some embodiments, the piercing element 220 includes a proximal section 224 (e.g., the section that functionally forms the piercing element 220) extending in a proximal direction from a support element 240 and a distal section 225 extending in a distal direction from the support element 240. Examples of such embodiments are shown in FIGS. 6 to 9.

[0102] The distal section 225 may be in direct contact with a sample receiving area 31 of the lateral flow assay 30, as shown in FIG. 6. That is, the distal end 226 contacts the sample receiving area 31 of the lateral flow assay 30. In some embodiments, as shown in FIG. 7, the distal section 225' is not in direct contact with the sample receiving area 31.

[0103] The distal section 225 (or the entire piercing element 220, including the proximal section 224 and the distal section 225) may have surface texture, surface treatment, or material configured to facilitate wicking or capillary flow. Examples of materials that can facilitate wicking or capillary flow include porous materials, such as cellulosic materials, and hydrophilic materials, such as hydrophilic polymers. Examples of surface textures that can facilitate wicking or capillary flow include angled channels (e.g., channels having a V-shaped cross section), micro channels, capillary channels, and surface roughness. Examples of surface treatments that can facilitate flow of the eluent include corona treatment to render a surface easily wettable.

[0104] In some embodiments, shown in FIGS. 8 and 9, the porous sample collection media 252 is disposed below the distal section 225 of the piercing element 220, which extends from the support grid or support element 240 toward the assay 30 and pushes or deforms the porous sample collection media 252 into a non-planar shape, such as a cone or a cup shape. The distal section 225 of the piercing element 220 may cause the porous sample collection media 252 to come into direct contact with a sample receiving area 31 of the assay 30.

[0105] The sample collection device 10 and the eluent delivery element 20 may be coupled by bayonet coupling, interference fit, snap fit, or threaded coupling. The eluent delivery element 20 may be constructed to be rotatably inserted into the airflow path 210 (e.g., into the mouthpiece 230). Rotating the eluent delivery element 20 as it is inserted in the airflow path 210 may aid in the piercing of the membrane 23 and may create an opening in the membrane 23 that is larger than the size of the piercing element 220.

[0106] According to an embodiment, the mouthpiece 230 and eluent delivery element 20 include coupling elements to guide the movement of the eluent delivery element 20 as it is received within the interior cavity 232 of the mouthpiece 230. The reservoir 21 may have a cylindrical body and the mouthpiece 230 may have a cylindrical interior cavity 232. The eluent delivery element 20 (e.g., the reservoir 21) is constructed to be at least partially received within the interior cavity 232. The eluent delivery element 20 may include one or more coupling elements 25 (e.g., alignment pins). For example, the eluent delivery element 20 may have two coupling elements 25 (e.g., alignment pins) formed by protrusions extending from opposite sides of the reservoir 21, as shown in FIGS. 10A and 10B. The interior wall 233 of the mouthpiece 230 may include corresponding receiving elements 235 (e.g., grooves), as shown in FIG. 11 constructed to receive the coupling elements 25 (e.g., alignment pins). The receiving elements 235 may be curved, as shown, to facilitate a bayonet fit, or may be straight (parallel to the longitudinal axis A230).

[0107] In some embodiments, the mouthpiece may be constructed of two or more parts to facilitate assembly of the mouthpiece and the insertion of the porous sample collection media. Examples of two-part mouthpieces are shown in FIGS. 12A-16D.

[0108] As shown in FIGS. 12A-12D, the mouthpiece 530 may include an inlet part 510 coupled with a base 550. The inlet part 510 defines an air inlet 531 and an opposing distal end 512. The distal end 512 of the inlet part 510 couples with the inlet receiving end 551 of the base 550. The distal end 552 of the base 550 couples with the housing 11 of the sample collection device such that the airflow path 532

aligns with the sample receiving area **31** of the assay **30**. Any suitable coupling mechanism (e.g., snap fit, bayonet, interference, treaded, or the like) may be used to couple the base **550** to the housing **11**, and the inlet part **510** to the base **550**.

[0109] The sample collection media **252** may be disposed between the inlet part **510** and the base **550**. The base **550** may form a ledge **562** and the distal end **512** of the inlet part **510** may abut the ledge **562**.

[0110] The sample collection media **252** may be disposed between the ledge **562** and the distal end **512** of the inlet part **510**. The base **550** and the inlet part **510** may fit together using a snap fit connection that pinches the edges of the sample collection media **252** between the ledge **562** and the distal end **512** of the inlet part **510**. For example, the snap fit connection may be formed, in part, by an undercut **553** on the base **550** and by a protrusion (not shown) on the inlet part **510**.

[0111] The inlet part **510** (which is shown in more detail in FIGS. **13**A-**13**D) may form a support grid **540**. The piercing element **520** may extend from and be supported by the support grid **540**. The piercing element **520** may have a longitudinal axis A**520** that extends along the longitudinal center axis A**530** of the mouthpiece **530**. Alternatively, the piercing element **520** may be positioned off-center relative to (not coaxial with) the inlet part **510**. The piercing element **520** may have any suitable shape. In some embodiments, such as shown in FIGS. **12**C, **12**D, **13**B, and **13**C, the piercing element **520** may be a hollow needle. The piercing element **520** may have a shaft **522** with a hollow center **528**. The piercing element may extend from the support grid **540** to a piercing tip **521**. The piercing tip **521** is recessed within the inlet part **510**. The piercing tip **521** is recessed by a distance D**521** from the inlet end of the mouthpiece **530**.

[0112] The support grid **540** may have any suitable shape. In the exemplary embodiment shown, the support grid **540** has a wheel-and-spoke configuration with a plurality of spokes **541** extending from the center of the support grid **540**. The support grid **540** defines opening **544** between the spokes **541**.

[0113] The base **550** (which is shown in more detail in FIGS. **14**A-**14**E) may include a second support grid **560**. A distal fluid guide **525** may optionally extend distally (toward the assay) from the second support grid **560**. The distal fluid guide **525** may extend along the longitudinal center axis A**530** of the mouthpiece **530**. The second support grid **560** may also act as a media support for the sample collection media **252**. The second support grid **560** may have any suitable shape. In the exemplary embodiment shown, the second support grid **560** has a wheel-and-spoke configuration with a plurality of spokes **561** extending from the center of the support grid **560**. The support grid **560** defines opening **564** between the spokes **561**.

[0114] The interior wall **533** of the mouthpiece **530** may include similar receiving elements **235** (e.g., grooves) as shown in FIG. **11** constructed to receive the coupling elements **25** of the eluent delivery element **20**.

[0115] In another embodiment, shown in FIGS. **15**A-**16**D, the support grid **540'** of the inlet part **510'** has spokes **541'** that are angled downward from the interior wall **533** toward the piercing element **520**. That is, the spokes **541'** may be set at a non-perpendicular angle relative to the longitudinal center axis A**520** of the piercing element **520**, where the end of the spoke **541'** attached to the piercing element **520** is lower (closer to the porous sample collection media **252**) than the opposing end. Angling the spokes **541'** toward the porous sample collection media **252** may help guide the eluent from the eluent delivery element **20** to the porous sample collection media **252**. The rest of the mouthpiece **530'** shown in FIGS. **15**A-**16**D may be the same or similar to the mouthpiece **530** shown in FIGS. **12**A-**14**E.

[0116] In some embodiments, the piercing element is not co-axial with the mouthpiece. An example of an alternative mouthpiece **430** for use with the sample collection system of FIGS. **1**A and **1**B is shown in FIGS. **17**A-**17**E. The mouthpiece **430** extends from an inlet end **438** to an outlet end **439** and defines an air inlet **431** at the inlet end **438**. The mouthpiece **430** includes a piercing element **420** that is attached to the interior wall **433** of the mouthpiece **430** by an extension **424**. The piercing element **420** includes a shaft **422** and a piercing tip **421**. The piercing tip **421** is recessed in the interior **432** of the mouthpiece **430** by a distance D**421** from the inlet end **438**. The extension **424** may position the piercing element **420** in the mouthpiece **430** such that a fluid guide element **20** can be inserted into the mouthpiece **430** and be pierced by the piercing element **420**. The piercing element **420** may have any suitable shape, such as the hollow needle shown.

[0117] The mouthpiece **430** may include a support grid or platform **440** for supporting the porous sample collection media **252**. The platform **440** may be substantially planar and perpendicular to the longitudinal center axis A**430** of the mouthpiece. The interior wall **433** of the mouthpiece **430** may include a plurality of grooves or channels **435** that may act as fluid guides. The plurality of channels **435** may extend parallel to the longitudinal axis A**430** of the mouthpiece **430**. The channels **435** may extend below the platform **440** into the conical lower portion of the mouthpiece **430**. The platform **440** may also include wicking channels **441** on the top side of the platform **440**. The wicking channels **441** may help guide the eluent from the center of the platform **440** (and sample collection media **252**) toward the interior wall **433**. The mouthpiece may include a plurality of openings **444** between the platform **440** and the interior wall **433** where the platform **440** meets the channels **435** (see FIG. **17**C).

[0118] When the mouthpiece **430** is used, after the eluent delivery element **20** is inserted into the inlet end **438** of the mouthpiece **430**, the piercing element **420** pierces the eluent delivery element **20** and eluent may flow from the pierced opening through or along the piercing element **20** and/or the channels **435**. The eluent may elute the collected sample from the sample collection media **252** and further be wicked along the wicking channels **441** of the platform **440**, through the openings **444**, and down the channels **435** below the platform **440**, toward the sample receiving area **31** of the assay.

[0119] The mouthpiece **430** may be coupled with the housing **11** of the sample collection device by any suitable mechanism, including by using a mechanical coupling (such as bayonet fit, snap fit, pressure fit, interference fit, threaded fit, or the like), an adhesive, or by welding.

[0120] In some embodiments, the eluent delivery element includes a second reservoir containing a fluid, and the mouthpiece includes two piercing elements for the two reservoirs. An example of an inlet part **710** of a mouthpiece with two piercing elements **720**, **780** is shown in FIG. **18**A. The first and second piercing elements **720**, **780** both extend proximally from the support element **740** to a first piercing

tip **721** and a second piercing tip **781**, respectively. The tips **721**, **781** of the first and second piercing elements **720**, **780** are recessed in the mouthpiece (inlet part) **710** by a distance D**721**, as described above. The first and second piercing elements **720**, **780** may be recessed by the same distance or by different distances, as long as both piercing elements **721**, **781** are recessed sufficiently to reduce or minimize the likelihood of a user inadvertently coming into contact with the tips **721**, **781** of the first and second piercing elements **720**, **780**. For example, the first and second piercing elements **720**, **780** may independently be recessed by 4 mm or more, 5 mm or more, or 6 mm or more. The first and second piercing elements **720**, **780** may independently be recessed by a distance of 10 mm or less, 9 mm or less, or 8 mm or less. The inlet part **710** may be otherwise similar to the inlet part **510** shown in FIGS. **13**A-**13**D, including an air inlet **731**, an airflow path **732**, and a distal end **712**. The support element **740** may have any suitable construction and may include spokes **741** or ribs with spaces formed between the spokes **741** or ribs for fluid flow. The inlet part **710** may be used with the base **550** shown in FIGS. **14**A-**14**E to form a mouthpiece. However, the two piercing elements **720**, **780** are not limited to the particular shape of the mouthpiece, inlet part **710**, or base **550** and can be provided with any mouthpiece or nose piece discussed herein.

[0121] The eluent delivery element **70** with two reservoirs **71**, **72** is shown in FIGS. **18**B and **18**C. The eluent delivery element **70** is otherwise similar to the eluent delivery element **20** shown, for example, in FIGS. **10**A and **10**B, including two coupling elements **75** (e.g., alignment pins) and a membrane **73**. The interior of the eluent delivery element **70** is divided by an interior wall **74** into a first reservoir **71** and a second reservoir **72**. The first and second reservoirs **71**, **72** each include a fluid. For example, the first reservoir **71** may include an eluent (e.g., a metered dose of an eluent) and the second reservoir **72** may include a solution with one or more reagents or other components. The one or more reagents or other components may, for example, participate in elution or transfer of the collected sample or in the reaction or analysis when the collected sample reaches the assay **30**. The second reservoir **72** may be sealed by the same membrane **73** as the first reservoir **71**, or may be sealed by a second membrane.

[0122] When the eluent delivery element **70** is received within the airflow path **732** of the mouthpiece (inlet part) **710**, the first and second piercing elements **720**, **780** pierce the first and second reservoirs **71**, **72**. The coupling elements **75** (e.g., alignment pins) may help guide the eluent delivery element **70** into place within the mouthpiece (inlet part) **710**. The interior wall of the mouthpiece (inlet part) **710** may include corresponding receiving elements, such as grooves or slots (not shown). The eluent delivery element **70** may be constructed to deliver the fluid from the second reservoir **72** simultaneously with the eluent from the first reservoir **71**. The eluent delivery element **70** may be constructed to deliver the fluid from the second reservoir **72** in succession with the eluent from the first reservoir **71**.

[0123] The housing may include a pre-filter or screen disposed in the airflow path in front (upstream) of the porous sample collection media. The screen may be constructed to catch larger particles (larger than viruses or pathogens) and prevent such particles from reaching the porous sample collection media. The exhalation airflow may passe through a thickness of the pre-filter or screen. The pre-filter or screen may at least partially occlude the air flow path. In some cases, the pre-filter or screen may have a major plane that is orthogonal to the direction of the exhalation airflow passing through the thickness of the pre-filter or screen. The pre-filter or screen may be a non-woven layer configured to filter out larger particles from the exhalation airflow passing through the pre-filter or screen. In some cases, the pre-filter or screen may be a non-woven layer that does not have an electrostatic charge. In some embodiments, the pre-filter or screen does not capture significant amounts of viral material, pathogen material, or other analyte material, and instead allows them to transmit through the pre-filter or screen. In some embodiments, the pre-filter or screen is made of or includes at least one of a plastic mesh, a woven net, a needle-tacked fibrous web, a knitted mesh, an extruded net, and/or a carded or spunbond coverstock. In some embodiments, the pre-filter or screen is part of the support grid or support element structure.

[0124] The porous sample collection media may be a nonwoven material capable of capturing pathogens, viruses, or other analytes from an exhalation airflow. According to an embodiment, the porous sample collection media is a nonwoven material carrying an electrostatic charge. The electrostatic charge may enable capturing pathogens, viruses, or other analytes from an exhalation airflow. In some cases, the porous sample collection media may be a hydrophobic nonwoven material. In other cases, the porous sample collection media may be a hydrophilic nonwoven material. The porous sample collection media may be a hydrophobic nonwoven material carrying an electrostatic charge configured to capture pathogens, viruses, or other analytes from an exhalation airflow. The porous sample collection media may be a hydrophilic nonwoven material carrying an electrostatic charge configured to capture pathogens, viruses, or other analytes from an exhalation airflow. The term "hydrophobic" refers to a material having a water contact angle of 90 degrees or greater, or from about 90 degrees to about 170 degrees, or from about 100 degrees to about 150 degrees. The term "hydrophilic" refers to a material having a water contact angle of less than 90 degrees. Water contact angle is measured using ASTM D5727-1997 Standard test method for surface wettability and absorbency of sheeted material using an automated contact angle tester.

[0125] The porous sample collection media may be formed of any suitable material that is capable of capturing viruses, pathogens, or other analytes from exhalation airflow and releasing the captured viruses, pathogens, or other analytes upon being contacted with an eluent, such as a saline solution. The porous sample collection media may be formed of polymeric material. The porous sample collection media may be formed of a polyolefin. Examples of suitable polyolefins include polypropylene, polylactic acid, and the like, and a combination thereof. In one embodiment the porous sample collection media is formed of polypropylene. In one embodiment the porous sample collection media is formed of polylactic acid. One illustrative porous sample collection media is commercially available from 3M Company (St. Paul MN, U.S.A.) under the trade designation FILTRETE Smart MPR 1900 Premium Allergen, Bacteria & Virus Air Filter Merv 13.

[0126] The porous sample collection media may have a thickness (orthogonal to the major plane) of 200 μm or greater or 250 μm or greater. The porous sample collection media may have a thickness of 750 μm or less or 1000 μm

or less. The porous sample collection media may have a thickness of in a range from 200 μm to 1000 μm, or from 250 μm to 750 μm. The porous sample collection media may have major plane surface area (of one side) of 1 cm^2 or greater or 2 cm^2 or greater. The porous sample collection media may have major plane surface area of 3 cm^2 or less or 4 cm^2 or less. The porous sample collection media may have major plane surface area in a range from 1 cm^2 to 4 cm^2, or 2 cm^2 to 3 cm^2.

[0127] In some embodiments, the porous sample collection media may be pleated. In some embodiments, the pleat frequency is between about 1 pleat per 0.6 cm of media and about 1 pleat per 2 mm of media. In some embodiments, the pleat height is between about 2 mm and about 4 mm. The specific pleating patterns or shape of the pleating features is a generally frustoconical, pleated shape and/or pattern, but any desired pattern and shape may be used.

[0128] According to an embodiment, the sample is eluted from the loaded sample collection media by dispensing a liquid (an eluent) onto the loaded sample collection media. The sample may be eluted by a metered dose of the liquid (eluent). The eluent may be an aqueous liquid. The eluent may be a buffer solution. The eluent may be an aqueous buffer solution. The eluent may be a saline solution. The eluent may include a surfactant. The eluent may have a contact angle of greater than 90 degrees when measured on the porous sample collection media. The eluent may be a saline solution including a surfactant. The eluent (e.g., a buffer or a saline solution) may include from 0.1 wt-% or more or 0.5 wt-% or more, and up to 1 wt-% or up to 2 wt-% of surfactant. When provided as a metered dose, the eluent may have a volume of 50 μL or greater, 100 μL or greater, 150 μL or greater, or 200 μL or greater. The metered dose may be 500 μL or less, 400 μL or less, 300 μL or less, or 250 μL or less. The metered dose may be from 50 μL to 500 μL, or from 100 μL to 400 μL. According to an embodiment, the reservoir of the eluent delivery element contains an eluent that may be an aqueous buffer solution or saline solution. According to an embodiment, the reservoir of the eluent delivery element contains a metered dose of the eluent. According to an embodiment, the reservoir of the eluent delivery element contains a volume of eluent that is greater than the metered dose.

[0129] The eluent may be applied onto the loaded porous sample collection media. The eluent may be wicked and/or guided by the piercing element. The eluent may travel through the surface and thickness of the loaded porous sample collection media and flow off of the porous sample collection media carrying any virus, pathogen, or other analyte, that was present on the loaded porous sample collection media. This loaded eluent (e.g., eluate) may flow onto the assay and be tested for the presence of a pathogen or other analyte of interest. The eluate may be guided by a fluid flow guide onto the assay.

[0130] The assay included in the sample collection system may be any suitable assay. In some embodiments, the assay is a lateral flow assay ("LFA") or a vertical flow assay ("VFA"). LFAs and VFAs are generally paper-based platforms for the detection and quantification of analytes in complex mixtures, including biological samples such as saliva, urine, etc. LFAs and VFAs are typically easy to use and can be used both by professionals in a health care setting or laboratory as well as by lay persons at home. Typically, a liquid sample is placed on the assay in a sample receiving region and is wicked by capillary flow along the device to a test region. LFAs and VFAs are typically based on antigens or antibodies that are immobilized in the test region and that selectively react with the analyte of interest. The result is typically displayed in less than 30 minutes, such as within 5 to 30 minutes. LFAs and VFAs can be tailored for the testing of a variety of viruses and other pathogens, as well as many other types of analytes. According to an embodiment, the assay used in the sample collection system of the present disclosure is constructed for the detection of a target virus, target pathogen, or other target analyte. According to an embodiment, the assay used in the sample collection system of the present disclosure is constructed for the detection of a target virus, target pathogen, or other target analyte, that may be present in the exhalation air flow of a subject.

[0131] The housing of the sample collection device may be formed of a rigid material, such as plastic or a paper-based material such as cardboard or cardstock. In some embodiments, the housing is made of plastic. In some embodiments, at least a portion of the housing is transparent. For example, the housing may include transparent material in an area of a result display of the assay. The housing may include a viewing window (either transparent material or an opening) in the area of the result display. In some cases, the entire housing may be made of a transparent material. In other embodiments, the material may be a soft material, such as a closed cell foam.

[0132] The sample collection system may be provided as a kit. The kit may include the sample collection device and eluent delivery element and an assay, as discussed above. The kit may include a sample collection device including a housing with an airflow path having a length extending from a proximal end comprising an air inlet to a distal end; a sample collector including porous sample collection media arranged to occlude the airflow path; and a piercing element arranged within the airflow path and extending from the sample collector along the length of the airflow path. The kit may further include an eluent delivery element including a reservoir containing an eluent; and a membrane disposed at a coupling end of the reservoir and sealing the reservoir, where the coupling end is constructed to couple with the proximal end of the airflow path such that the piercing element pierces the membrane. The kit may further include a lateral flow assay arranged or arrangeable to receive a sample from the sample collection element.

[0133] A method of obtaining a sample using a sample collection system includes breathing into the proximal end of the airflow path to collect a sample on the porous sample collection media. The exhalation airflow passes through the porous sample collection media, which is constructed to capture viruses, other pathogens, or other analytes, from the exhalation airflow. This results in the formation of a loaded media. The method further includes coupling the coupling end of the eluent delivery element with the first end of the airflow path. Coupling the eluent delivery element with the sample collection device causes the membrane of the eluent delivery element to be pierced, causing eluent to flow from the reservoir onto the loaded media. The method may include transferring a metered dose of the eluent onto the loaded media to elute the collected sample from the porous sample collection media. The eluent elutes the sample from the loaded media. The eluent containing the sample (the eluate) may further flow onto a lateral flow assay. to deposit the collected sample on the lateral flow assay.

[0134] The method may further include reading a test result from the lateral flow assay. The result may be read through a viewing window on the housing of the sample collection device.

[0135] The following is a list of illustrative embodiments according to the present disclosure.

[0136] Embodiment 1 is a sample collection system comprising: a sample collection device comprising: a housing comprising an airflow path extending from a proximal end comprising an air inlet to a distal end; a piercing element arranged within the airflow path; and a sample collector comprising porous sample collection media arranged to occlude the airflow path; and an eluent delivery element comprising: a reservoir containing an eluent; and a membrane disposed at a coupling end of the reservoir and sealing the reservoir, the coupling end being constructed to couple with the proximal end of the airflow path such that the piercing element pierces the membrane.

[0137] Embodiment 2 is the sample collection system of embodiment 1 further comprising a lateral flow assay adjacent the porous sample collection media.

[0138] Embodiment 3 is the sample collection system of embodiment 2, wherein the porous sample collection media is in direct contact with the lateral flow assay.

[0139] Embodiment 4 is the sample collection system of any one of embodiments 1 to 3, wherein the housing comprises a mouthpiece defining the proximal end of the airflow path.

[0140] Embodiment 5 is the sample collection system of embodiment 4, wherein the piercing element is recessed in the mouthpiece.

[0141] Embodiment 6 is the sample collection system of any one of embodiments 1 to 5, wherein the reservoir comprises a cylindrical body.

[0142] Embodiment 7 is the sample collection system of any one of embodiments 1 to 6, wherein the airflow path comprises a cylindrical interior cavity and wherein the coupling end of the eluent delivery element is constructed to be at least partially received within the airflow path.

[0143] Embodiment 8 is the sample collection system of any one of embodiments 1 to 7, wherein the eluent delivery element comprises a coupling element and wherein the airflow path defines an interior surface comprising a corresponding receiving element constructed to receive the coupling element.

[0144] Embodiment 9 is the sample collection system of any one of embodiments 1 to 8, wherein the sample collection device and eluent delivery element are coupled by bayonet coupling, interference fit, snap fit, or threaded coupling.

[0145] Embodiment 10 is the sample collection system of any one of embodiments 1 to 9, wherein the eluent delivery element is constructed to be rotatably inserted into the airflow path.

[0146] Embodiment 11 is the sample collection system of any one of embodiments 1 to 10, wherein the sample collector comprises a support grid and wherein the piercing element extends from the support grid.

[0147] Embodiment 12 is the sample collection system of any one of embodiments 1 to 11, wherein the piercing element comprises a needle.

[0148] Embodiment 13 is the sample collection system of any one of embodiments 1 to 12, wherein the piercing element comprises a blade.

[0149] Embodiment 14 is the sample collection system of any one of embodiments 1 to 13, wherein the airflow path comprises a longitudinal center axis and wherein the piercing element extends parallel to the longitudinal center axis.

[0150] Embodiment 15 is the sample collection system of any one of embodiments 1 to 14, wherein the piercing element is not co-axial with the airflow path.

[0151] Embodiment 16 is the sample collection system of any one of embodiments 1 to 15, wherein the piercing element has a longitudinal center axis and a cross-sectional shape along the longitudinal center axis that is non-circular, optionally wherein the cross-sectional shape is an arrowhead shape.

[0152] Embodiment 17 is the sample collection system of any one of embodiments 1 to 16, wherein the piercing element has a longitudinal center axis and a first cross-sectional shape and a second cross-sectional shape along the longitudinal center axis, wherein the second cross-sectional shape is different from the first cross-sectional shape.

[0153] Embodiment 18 is the sample collection system of any one of embodiments 1 to 17, wherein the piercing element has a longitudinal center axis and a first cross-sectional diameter and a second cross-sectional diameter along the longitudinal center axis, wherein the second cross-sectional diameter is different from the first cross-sectional diameter.

[0154] Embodiment 19 is the sample collection system of any one of embodiments 1 to 18, wherein the piercing element comprises a hollow center extending from an open first end to an opposing open second end.

[0155] Embodiment 20 is the sample collection system of any one of embodiments 1 to 19, wherein the piercing element comprises surface texture or material configured to facilitate wicking or capillary flow. Embodiment 21 is the sample collection system of any one of embodiments 2 to 20, wherein the piercing element comprises a distal section in direct contact with a sample receiving area of the lateral flow assay.

[0156] Embodiment 22 is the sample collection system of embodiment 21, wherein the distal section comprises surface texture or material configured to facilitate wicking or capillary flow.

[0157] Embodiment 23 is the sample collection system of any one of embodiments 1 to 22, wherein the sample collection system has an uncoupled position and a coupled position where the eluent delivery element is coupled with the sample collection device, and wherein the eluent delivery element is constructed to deliver eluent from the reservoir onto the porous sample collection media in the coupled position.

[0158] Embodiment 24 is the sample collection system of embodiment 23, wherein the eluent delivery element is constructed to deliver a metered dose of the eluent from the reservoir onto the porous sample collection media in the coupled position.

[0159] Embodiment 25 is the sample collection system of embodiment 23, wherein the sample collection system comprises an indicator configured to indicate whether the sample collection system is in the coupled position.

[0160] Embodiment 26 is the sample collection system of embodiment 25, wherein the indicator comprises an audible indicator or a visual indicator.

[0161] Embodiment 27 is the sample collection system of any one of embodiments 1 to 26, wherein the airflow path

comprises a longitudinal center axis, wherein the eluent delivery element has a piercing position and a fluid delivery position, and wherein the fluid delivery position is axially proximal to the piercing position.

[0162] Embodiment 28 is the sample collection system of any one of embodiments 1 to 27, wherein the housing comprises a support element in the airflow path and a protrusion extending from the support element in a direction opposite of the piercing element.

[0163] Embodiment 29 is the sample collection system of embodiment 28, wherein the protrusion causes the porous sample collection media to be deformed into a cone shape.

[0164] Embodiment 30 is the sample collection system of any one of embodiments 2 to 29, wherein the piercing element defines a fluid flow guide extending distally from the sample collector.

[0165] Embodiment 31 is the sample collection system of embodiment 30, wherein the fluid flow guide comprises a distal section in direct contact with a sample receiving area of the lateral flow assay.

[0166] Embodiment 32 is the sample collection system of embodiment 31, wherein the distal section comprises surface texture or material configured to facilitate wicking or capillary flow.

[0167] Embodiment 33 is the sample collection system of any one of embodiments 1 to 27, wherein the sample collection device comprises a mouthpiece defining an interior surface, and wherein the interior surface comprises wicking channels.

[0168] Embodiment 34 is the sample collection system of embodiment 33, wherein mouthpiece comprises a platform and wherein the porous sample collection media is disposed on the platform.

[0169] Embodiment 35 is the sample collection system of any one of embodiments 1 to 34, wherein the eluent delivery element comprises a second reservoir containing a fluid, wherein the second reservoir is sealed by a second membrane.

[0170] Embodiment 36 is the sample collection system of embodiment 35, wherein the piercing element comprises two prongs defining a first piercing tip and a second piercing tip.

[0171] Embodiment 37 is the sample collection system of embodiment 36, wherein the eluent delivery element is constructed to deliver the fluid from the second reservoir simultaneously with the eluent from the first reservoir.

[0172] Embodiment 38 is the sample collection system of any one of embodiments 1 to 37, wherein the porous sample collection media comprises nonwoven material.

[0173] Embodiment 39 is the sample collection system of embodiment 38, wherein the nonwoven material comprises polylactic acid, polypropylene, or a combination thereof.

[0174] Embodiment 40 is the sample collection system of embodiment 39, wherein the porous sample collection media carries an electrostatic charge.

[0175] Embodiment 41 is the sample collection system of any one of embodiments 1 to 40, wherein the eluent delivery element is constructed to deliver a metered dose of the eluent from the reservoir, and wherein the metered dose has a volume of 50 μL or greater, 100 μL or greater, 150 μL or greater, or 200 μL or greater. The metered dose may have a volume of 500 μL or less, 400 μL or less, 300 μL or less, or 250 μL or less. The metered dose may have a volume of 50 μL to 500 μL, or from 100 μL to 400 μL.

[0176] Embodiment 42 is the sample collection system of any one of embodiments 1 to 41, wherein the eluent comprises an aqueous liquid, and optionally a buffer solution or an aqueous buffer solution, optionally wherein the eluent comprises a saline solution, and further optionally wherein the eluent comprises a surfactant.

[0177] Embodiment 43 is the sample collection system of any one of embodiments 1 to 42, wherein the piercing element is recessed by a distance of 4 mm or more, 5 mm or more, or 6 mm or more. The piercing element may be recessed by a distance of 10 mm or less, 9 mm or less, or 8 mm or less. The piercing element may be recessed by 4 mm to 10 mm or by 5 mm to 8 mm.

[0178] Embodiment 44 is a kit comprising: a sample collection device comprising: a housing comprising an airflow path having a length extending from a proximal end comprising an air inlet to a distal end; a sample collector comprising porous sample collection media arranged to occlude the airflow path; and a piercing element arranged within the airflow path and extending from the sample collector along the length of the airflow path; an eluent delivery element comprising: a reservoir containing an eluent; and a membrane disposed at a coupling end of the reservoir and sealing the reservoir, the coupling end being constructed to couple with the proximal end of the airflow path such that the piercing element pierces the membrane; and an assay arranged or arrangeable to receive a sample from the sample collection element.

[0179] Embodiment 45 is a kit comprising the sample collection device of any one of embodiments 1 or 3-43, and the assay of embodiment 2 arranged or arrangeable to receive a sample from the sample collection element.

[0180] Embodiment 46 is a method of obtaining a sample using a sample collection system comprising:

[0181] a sample collection device comprising: a housing comprising an airflow path extending from a proximal end comprising an air inlet to a distal end; a piercing element arranged within the airflow path; and a sample collector comprising porous sample collection media arranged to occlude the airflow path; and

[0182] an eluent delivery element comprising: a reservoir containing an eluent; a membrane disposed at a coupling end of the eluent delivery element and sealing the reservoir, the coupling end being constructed to couple with the proximal end of the airflow path such that the piercing element pierces the membrane,

[0183] the method comprising: breathing into the proximal end of the airflow path to collect a sample on the porous sample collection media; coupling the coupling end of the eluent delivery element with the proximal end of the airflow path; and transferring a metered dose of the eluent from the reservoir onto the porous sample collection media to elute the collected sample from the porous sample collection media.

[0184] Embodiment 47 is the method of embodiment 46, wherein the sample collection system comprises a lateral flow assay, and wherein eluting the collected sample causes an eluate comprising the collected sample to be deposited onto the lateral flow assay.

[0185] All references and publications cited herein are expressly incorporated herein by reference in their entirety into this disclosure, except to the extent they may directly contradict this disclosure. Although specific embodiments have been illustrated and described herein, it will be appre-

ciated by those of ordinary skill in the art that a variety of alternate and/or equivalent implementations can be substituted for the specific embodiments shown and described without departing from the scope of the present disclosure. It should be understood that this disclosure is not intended to be unduly limited by the illustrative embodiments and examples set forth herein and that such examples and embodiments are presented by way of example only with the scope of the disclosure intended to be limited only by the claims set forth here.

1. A sample collection system comprising:
- a sample collection device comprising:
  - a housing comprising an airflow path extending from a proximal end comprising an air inlet to a distal end;
  - a piercing element arranged within the airflow path; and
  - a sample collector comprising porous sample collection media arranged to occlude the airflow path; and
- an eluent delivery element comprising:
  - a reservoir containing an eluent; and
  - a membrane disposed at a coupling end of the reservoir and sealing the reservoir,
  - the coupling end being constructed to couple with the proximal end of the airflow path and be at least partially received within the airflow path such that the piercing element pierces the membrane.

2. The sample collection system of claim **1** further comprising a lateral flow assay adjacent the porous sample collection media.

3. The sample collection system of claim **2**, wherein the porous sample collection media is in direct contact with the lateral flow assay.

4. The sample collection system of claim **1**, wherein the housing comprises a mouthpiece defining the proximal end of the airflow path and wherein the piercing element is recessed in the mouthpiece.

5-13. (canceled)

14. The sample collection system of claim **1**, wherein the airflow path comprises a longitudinal center axis and wherein the piercing element extends parallel to the longitudinal center axis.

15-18. (canceled)

19. The sample collection system of claim **1**, wherein the piercing element comprises a hollow center extending from an open first end to an opposing open second end.

20. The sample collection system of claim **1**, wherein the piercing element comprises surface texture or material configured to facilitate wicking or capillary flow.

21. The sample collection system of claim **2**, wherein the piercing element comprises a distal section in direct contact with a sample receiving area of the lateral flow assay.

22. The sample collection system of claim **21**, wherein the distal section comprises surface texture or material configured to facilitate wicking or capillary flow.

23. The sample collection system of claim **1**, wherein the sample collection system has an uncoupled position and a coupled position where the eluent delivery element is coupled with the sample collection device, and wherein the eluent delivery element is constructed to deliver a metered dose of eluent from the reservoir onto the porous sample collection media in the coupled position.

24-27. (canceled)

28. The sample collection system of claim **1**, wherein the housing comprises a support element in the airflow path and a protrusion extending from the support element in a direction opposite of the piercing element and wherein the protrusion causes the porous sample collection media to be deformed into a cone shape.

29. (canceled)

30. The sample collection system of claim **2**, wherein the piercing element defines a fluid flow guide extending distally from the sample collector.

31. The sample collection system of claim **30**, wherein the fluid flow guide comprises a distal section in direct contact with a sample receiving area of the lateral flow assay.

32. (canceled)

33. The sample collection system of claim **1**, wherein the sample collection device comprises a mouthpiece defining an interior surface, and wherein the interior surface comprises wicking channels.

34. (canceled)

35. The sample collection system of claim **1**, wherein the eluent delivery element comprises a second reservoir containing a fluid, wherein the second reservoir is sealed by a second membrane.

36. (canceled)

37. (canceled)

38. The sample collection system of claim **1**, wherein the porous sample collection media comprises nonwoven material.

39. The sample collection system of claim **38**, wherein the nonwoven material comprises polylactic acid, polypropylene, or a combination thereof.

40. The sample collection system of claim **39**, wherein the porous sample collection media carries an electrostatic charge.

41. A kit comprising:
- a sample collection device comprising:
  - a housing comprising an airflow path having a length extending from a proximal end comprising an air inlet to a distal end;
  - a sample collector comprising porous sample collection media arranged to occlude the airflow path; and
  - a piercing element arranged within the airflow path and extending from the sample collector along the length of the airflow path;
- an eluent delivery element comprising:
  - a reservoir containing an eluent; and
  - a membrane disposed at a coupling end of the reservoir and sealing the reservoir,
  - the coupling end being constructed to couple with the proximal end of the airflow path such that the piercing element pierces the membrane; and
- an assay arranged or arrangeable to receive a sample from the sample collection element.

42. A method of obtaining a sample using a sample collection system comprising:
- a sample collection device comprising:
  - a housing comprising an airflow path extending from a proximal end comprising an air inlet to a distal end;
  - a piercing element arranged within the airflow path; and
  - a sample collector comprising porous sample collection media arranged to occlude the airflow path; and
- an eluent delivery element comprising:
  - a reservoir containing an eluent;
  - a membrane disposed at a coupling end of the eluent delivery element and sealing the reservoir,

the coupling end being constructed to couple with the proximal end of the airflow path such that the piercing element pierces the membrane,

the method comprising:

breathing into the proximal end of the airflow path to collect a sample on the porous sample collection media;

coupling the coupling end of the eluent delivery element with the proximal end of the airflow path; and

transferring a metered dose of the eluent from the reservoir onto the porous sample collection media to elute the collected sample from the porous sample collection media.

43. (canceled)

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