

1

## SYSTEMS AND METHODS FOR DETECTION AND QUANTIFICATION OF ANALYTES

### CROSS-REFERENCE TO RELATED PATENT APPLICATIONS

This application is a continuation of International Application No. PCT/US2014/023821, filed Mar. 11, 2014, which claims priority under 35 U.S.C. §119(e) to U.S. Provisional Application No. 61/776,254, filed Mar. 11, 2013, the content of each of which is hereby incorporated by reference in its entirety.

### FIELD OF THE INVENTION

The present technology relates generally to the field of molecule detection. In particular, the technology relates to microfluidic devices, systems, and methods for detecting the presence, absence and/or quantity of one or more particular analytes within a collected sample.

### BACKGROUND

Conventional technologies for identifying the presence, absence and/or quantity of nucleic acids, proteins, and/or other molecules of interest within a sample often require expensive laboratory equipment and the expertise of highly-trained medical professionals. Consequently, such analyses are typically performed within laboratories or medical facilities. Such molecule detection can be important, for example, to detect the presence of pathogens, disease, contamination, overdoses, and poisonings within a person or other animal or within the environment. Unfortunately, today, individuals may face long waits before the proper tests can be performed and before the results can be generated and analyzed. Due to the long waits and the inconvenience of traveling to a laboratory or medical facility, illnesses and contaminations often spread and may cause substantial harm before the presence of said illness or contamination is even identified.

### SUMMARY

There is a significant need for improved molecule detection and quantification technologies. There is a need for devices that can detect molecules of interest in less time and with less technical expertise than the conventional devices used today. There is a need for molecule detection technologies that can be utilized by consumers in non-clinical settings, for example, in schools, places of employment, and in the home. There is also a need for molecule detection technologies that can be used by consumers upon entering a pharmacy or healthcare facility, and which can generate results quickly so that results are available by the time the consumer talks with a pharmacist or healthcare practitioner. There is also a need for consumer-targeted molecule detection devices configured to minimize biohazard risks. Various embodiments disclosed herein may fulfill one or more of these needs.

One aspect of the disclosure is directed to a system for detecting molecules. In various embodiments, the system includes a cartridge device, a reader device removably coupled to the cartridge device, and a sample collection device. In some embodiments, the cartridge device includes: a cartridge housing having internal barriers defining a plurality of reservoirs, an analysis channel, and an input tunnel; and a circuit board coupled to or disposed within the cartridge housing, the circuit board forming a wall of the analysis channel and having a plurality of sensors disposed within a

2

portion of the analysis channel. In some embodiments, the reader device includes: a magnet aligned with the sensor; a circuit electrically coupled to the sensor; and a processor having memory with instructions stored thereon. In such embodiments, the reader device also includes a reader housing in which the magnet, circuit, and processor are located, the reader housing defining a dock which receives at least a portion of the sample analysis cartridge. In some embodiments, the sample collection device is sized to fit at least partially within the input tunnel. Additionally, in some embodiments, the molecule detection system also includes a sonication component electrically coupled to the circuit and aligned with a first of the plurality of reservoirs. The sonication component may form a component of the cartridge device or the reader device and can be comprised partially or wholly of a piezoelectric transducer.

Another aspect of the disclosure is directed to a sample analysis cartridge. In some embodiments, the cartridge includes a housing and a circuit board disposed on, under, or within the housing. In some embodiments, the housing has internal barriers defining a plurality of reservoirs, an analysis channel, and an input tunnel. The plurality of reservoirs includes a first reservoir at least partially filled with a first liquid volume comprising sample preparation reagents and another reservoir at least partially filled with a liquid volume comprising a chemical substrate. In some embodiments, the plurality of reservoirs additionally includes a reservoir at least partially filled with a liquid volume comprising a wash solution. In certain embodiments, the input tunnel extends from an aperture at a surface of the housing to the first reservoir and each of the plurality of reservoirs is, at least at times, in fluid communication with the analysis channel. In certain embodiments, the circuit board includes a plurality of sensors aligned with a portion of the analysis channel.

In some such embodiments, the sample preparation reagents include a plurality of magnetic particles having surface-bound affinity molecules, a plurality of detector agents, and a plurality of agents to facilitate access to the target analyte and binding between the target analyte and the surface-bound affinity molecules and the detector agents. In other embodiments, the cartridge also includes a membrane disposed between the input tunnel and the first reservoir. The membrane of some such embodiments dry-stores a plurality of competitive binding agents, each competitive binding agent including a pre-bound target analyte bound to a signaling agent. Additionally, in such embodiments, the sample preparation reagents in the first reservoir include a plurality of magnetic particles having surface-bound affinity molecules and a plurality of agents to facilitate access to the target analyte and to facilitate binding of the surface-bound affinity molecules to the target analyte or the competitive binding agent. In various embodiments, the plurality of magnetic particles may include magnetic particles of two or more sizes, each size having a different surface-bound affinity molecule such that each size binds to a different target analyte.

In some embodiments of a sample analysis cartridge, the cartridge includes a plurality of valves corresponding with the plurality of reservoirs with one valve positioned at each intersection between one of the plurality of reservoirs and the analysis channel. In some such embodiments, each of the plurality of valves is phase-changeable upon the application of heat, and the circuit board includes a plurality of vias aligned with (e.g., disposed directly above or below) the plurality of valves; such vias are physically coupled to a heating element. In some embodiments, the sample analysis cartridge further includes an absorbant material disposed at a downstream end of the analysis channel.