

prises a fluorescent dye in fluid communication with the nucleic acid amplification reagents, which fluoresces when the target nucleic acid is amplified. The dyes can be introduced concurrently with the nucleic acid amplification reagents or separately into fluid communication with the nucleic acid amplification reagents after the amplification, for example, from one of the reagent cartridges (see Example 3, FIG. 10).

The dyes can be any colorimetric dyes or fluorescent dye identifiable by a skilled person. For example, in some embodiments, the colorimetric dye can be hydroxynaphthol blue (HNB). HNB denotes target amplification to the unaided eye via a color shift that stems from changes in the concentration of Mg^{2+} in solution: free Mg^{2+} in the reaction solution binds to pyrophosphate that is generated as deoxynucleotide triphosphates are added to growing amplification product, forming magnesium pyrophosphate. In other embodiments, the colorimetric dye can be picogreen, which is a fluorescent intercalating dye.

In other embodiments, the detection element comprises a lateral flow dipstick (LFD).

According to another aspect of the disclosure, apparatus for diagnosing a condition in an individual is described. The condition is associated to presence of a target nucleic acid in the individual, which is produced by certain pathogens.

The term "condition" as used herein indicates a physical status of the body of an individual (as a whole or as one or more of its parts), that does not conform to a standard physical status associated to a state of complete physical, mental and social well-being for the individual. Conditions herein described include but are not limited disorders and diseases wherein the term "disorder" indicates a condition of the living individual that is associated to a functional abnormality of the body or of any of its parts, and the term "disease" indicates a condition of the living individual that impairs normal functioning of the body or of any of its parts and is typically manifested by distinguishing signs and symptoms.

The term "individual" as used herein in the context of diagnosing a condition includes a single biological organism, including but not limited to, animals and in particular higher animals and in particular vertebrates such as mammals and in particular human beings.

The term "pathogen" as used herein indicates a biological agent that may cause an infection or infectious disease in a host. The term "infection" as used herein indicates presence and/or colonization of an infecting species of pathogen in a host organism. During infection, the pathogen seeks to use the host's resources to survive and reproduce, often resulting in one or more infectious diseases. The term "infectious disease" as used herein indicates clinically evident illness that may have characteristic medical signs and/or symptoms, resulting from infection, presence and growth of an infecting species of pathogen in a host organism. In some cases, an infectious disease may be asymptomatic for much or all or their course, known as the latency period. A pathogen can be naturally occurring microbe or microorganism, including a virus, bacterium, prion, fungus or parasites or be produced by deliberate human agency.

In some embodiments, the pathogen can be, for example, viruses, bacteria, fungi, and combinations thereof.

In some embodiments, the condition is an infectious disease. In particular, in some embodiments, the infectious disease can be, for example, foot and mouth disease, flu, swine flu, avian flu, MRSA, anthrax, STDs, AIDS, CT/NG, HPV, HCV, C. Diff, Strep A, Influenza and combinations thereof.

According to another aspect of the disclosure, methods for detecting a target nucleic acid in a sample are described. In

some embodiments, the method comprises sealing the sample within a containment vessel, transferring the sample to a nucleic acid binding element position in the containment vessel, purifying nucleic acid from the sample in the containment vessel, amplifying the target nucleic acid in the containment vessel, detecting amplification of the target nucleic acid in the containment vessel, and detecting the target nucleic acid. FIG. 4A shows a procedural flow chart illustrating the steps 4A.1-4A.6 according to these embodiments.

In some embodiments, the method further comprises collecting the sample before the sealing. In particular, in some embodiments, collecting the sample further comprises collecting a bodily sample, such as conducting a nasal swab, collecting a blood sample, collecting a saliva sample, collecting a nasal mucus sample, collecting a urine sample, collecting a buccal cell sample, or collecting a fecal sample.

In some embodiments, collecting the sample further comprises collecting the sample with a sample collection element. In particular, in some embodiments, sealing the sample within a containment vessel comprises removably coupling the sample collection element to the containment vessel.

In some embodiments, the sample collection element comprises a lumen, and transferring the sample is performed by lavaging the sample through the lumen of the sample collection element when the sample collection element is removably coupled to the containment vessel.

In some embodiments, purifying and amplifying nucleic acid further comprises introducing a plurality of reagents suitable for nucleic acid purification and amplification into fluid communication with the nucleic acid binding element. In particular, in some embodiments, the introducing is performed through introducing the plurality of reagents from a plurality of reagent cartridges. In some embodiments, the plurality of reagent cartridges may be connected directly to the containment vessel.

Additionally, in those embodiments where the sample collection element comprises a lumen, the plurality of reagent cartridges may be coupled to the sample collection element and connected with the lumen. In these embodiments, the plurality of reagents can be delivered from the reagent cartridges through the lumen into the containment vessel for placement in fluid communication with the nucleic acid binding element located in the containment vessel.

In some embodiments, the purification further comprises collecting a waste into a waste collection unit which is connected to the containment vessel.

In some embodiments, the nucleic acid amplification reagents are sequestered within separate polymer shells. The polymer shells are comprised within the containment vessel and are configured to melt and release the nucleic acid amplification reagents into fluid communication with the nucleic acid binding element upon heating the polymer shells. In some embodiments, the polymer shells can be polycaprolactone (PCL) shells.

In some embodiments, amplifying the target nucleic acid further comprises heating the nucleic acid binding element in fluid communication with nucleic acid amplification reagents. In particular, in some embodiments, the heating further comprises isothermally heating the nucleic acid binding element in fluid communication with the nucleic acid amplification reagents to a temperature in the range of 60° C. to 65° C. for a duration of up to one hour.

In some embodiments, the heating is performed by using a disposable heater.

In some embodiments, the heating is performed by heating via an exothermic chemical reaction identifiable by a skilled