

[0053] FIG. 1 illustrates a representation of the integrated single-use DNA amplification device and its interaction with an instrument, in accordance with an exemplary embodiment of the present invention.

[0054] FIG. 2 illustrates a top view of the integrated single-use DNA amplification device, in accordance with an exemplary embodiment of the present invention.

[0055] FIGS. 3 (a)-(b) illustrate different perspectives of the integrated single-use DNA amplification device and its interaction with an instrument, in accordance with an exemplary embodiment of the present invention.

[0056] FIGS. 4 (a)-(b) illustrate the ingress and egress valves with flexible diaphragm seals and with pylon seals, respectively, in accordance with an exemplary embodiment of the present invention.

[0057] FIGS. 5 (a)-(b) illustrates the DNA swab device for collection of a buccal swab sample mating with a single-use DNA amplification device by a screw-in means, in accordance with an exemplary embodiment of the present invention.

[0058] FIGS. 6 (a)-(b) illustrates the DNA swab for collection of a buccal swab sample mating with a single-use DNA amplification device by a latch means, in accordance with an exemplary embodiment of the present invention.

[0059] FIGS. 7 (a)-(d) illustrates the silicon chip forming a wall of the amplification chamber where the exterior surface has a heating circuit and a temperature sensing circuit, in accordance with an exemplary embodiment of the present invention. FIG. 7(a) illustrates an extra rib support and a fan cooling means. FIG. 7(b) illustrates the details of FIG. 7(a) wherein a cooling fan and an associated heat sink on the heater chip is used. FIG. 7(c) illustrates a cross-sectional view of the silicon chip. FIG. 7(d) illustrates the interaction and connections from the amplification device to the silicon chip.

[0060] FIG. 8 illustrates the integrated single-use DNA amplification device interaction with an instrument, in accordance with an exemplary embodiment of the present invention.

[0061] FIG. 9 illustrates a heating cycle profile versus time applied to the amplification device and the temperature response of the temperature sensor, in accordance with an exemplary embodiment of the present invention.

[0062] FIG. 10 illustrates gel electrophoresis of amplicons for target gene 1 (in example 1) after 22, 24, 26, 28, 30 and 35 PCR amplification cycles in the amplification device, in accordance with an exemplary embodiment of the present invention.

[0063] FIG. 11 illustrates a typical chronoamperometry output for PCR with target gene 1 after 22, 24, 26, 28, 30 and 35 PCR amplification cycles in the amplification device, in accordance with an exemplary embodiment of the present invention.

[0064] FIG. 12 illustrates the cross section of a single-use DNA amplification device with respect to the clipping means of attaching the silicon heater to the amplification chamber, in accordance with an exemplary embodiment of the present invention.

[0065] FIG. 13 illustrates the cross section of a single-use DNA amplification device with respect to a staking means of attachment, in accordance with an exemplary embodiment of the present invention.

[0066] FIG. 14 illustrates a preferred reaction sequence for PCR amplification, in accordance with an exemplary embodiment of the present invention.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0067] According to an exemplary embodiment of the present invention, the nucleic acid amplification cartridge 10 of FIG. 2 is designed to be single-use and low-cost. Furthermore, it is also disposable in a manner that retains used reagents and patient biological samples safely within the device. The device is capable of producing an amplicon in a manner that is convenient, and can even be used at a point-of-care location outside of a laboratory. The cartridge device comprises a housing that includes an amplification chamber 11 with an ingress 12 with a reversible seal 13, an egress 14 with a reversible seal 15, and also a sealable sample entry orifice 16. The amplification cartridge 10 includes a wall 17 that forms a portion of the chamber 11 that is made of a thermally conductive material, preferably silicon or the like. Alternatively, the wall 17 can be made of alumina, quartz, gallium arsenide, a thermally conductive plastic, and the like. The wall 17 includes an interior surface 18 and an exterior surface 19 (see FIG. 7(c)), and on the exterior surface 19 there is a heating circuit 20 (see FIG. 7(c)) and a temperature sensor 21. These components are optionally directly fabricated onto the wall surface, such as, for example, by well-known microfabrication techniques where metals are patterned on a silicon wafer surface, by screen printing of a conductive ink, or other like techniques. Where a wafer is used, it can be diced into individual chips and used to form the wall by assembly and adhesion with a second plastic component 22 to form the amplification chamber 11. The sample entry orifice 16 permits a sample of nucleic acid to be introduced into the chamber 11 for amplification.

[0068] In one exemplary embodiment, the ingress 12 is connected to a conduit 23 that terminates in a pneumatic pump 24. In another alternative exemplary embodiment, the conduit 23 can also be connected to a fluid pouch 25. As it is usually necessary to remove amplicon from the amplification chamber 11 after the amplification reaction, the egress 14 is connected to a second conduit 26 that permits egress of the amplicon from the chamber 11. These conduits are preferably microfluidic channels formed in one or more injection molded plastic components. Where two or more components are used, they can be assembled together with a double-sided adhesive layer 37 (see FIGS. 7(a)-(b)), by sonic welding, or the like. The plastic materials are selected to have insignificant reactivity and interference with amplification reagents. The conduits 23, 26 and chamber 11 preferably have a low wet retention, i.e., fluids do not stick to the respective surfaces. Various methods can be used to achieve such an objective, including, for example, judicious materials selection, e.g., plastic and the surface treatments, including hydrophobic coatings such as acetals, polycarbonates, thermal plastics, and surface treatments such as corona treatment.

[0069] Regarding the pump 24, it is preferably formed as a flexible diaphragm 28 (see FIGS. 1, 3(a)-(b)) capable of engaging and being actuated by a plunger 29 on an instrument 30 (see FIGS. 1, 3(a)-(b), respectively) with which the device mates. In one exemplary embodiment, a void 31 (see FIGS. 3(a)-(b)) in a plastic housing is covered and sealed in