

polymerase. The amplification chamber can be capable of a temperature increase ramp rate in the range of about 10 to about 50 degrees centigrade per second. The amplification chamber can be capable of a temperature decrease ramp rate in the range of about 4 to about 50 degrees centigrade per second.

[0046] According to the first aspect, the amplification chamber can comprise an optical window. The amplification device can be capable of engaging and being operated by an instrument. For example, the instrument can comprise a fan capable of cooling the amplification chamber. Alternatively, the instrument can comprise a heat-sink capable of contacting and cooling the amplification chamber. The second surface of the first wall can comprise a Peltier circuit or the like with a first and second connecting pad for contacting an external circuit. The first reversible seal can comprise a flexible diaphragm or the like. Such a flexible diaphragm can be capable of actuation into a closed position by an applied force and an open position by the absence of the applied force. The flexible diaphragm can be capable of actuation into a closed position by an applied force provided by an engaged instrument with a pin mating with the flexible diaphragm. The second reversible seal can comprise a flexible diaphragm or the like. Such a flexible diaphragm can be capable of actuation into a closed position by an applied force and an open position by the absence of the applied force. The flexible diaphragm can be capable of actuation into a closed position by an applied force provided by an engaged instrument with a pin mating with the flexible diaphragm.

[0047] According to the first aspect, the second conduit can comprise a mating feature for engaging a device for detection of the amplicon. The ingress and the egress can be at substantially opposite corners or ends of the amplification chamber. The first conduit can comprise a chip insert with a fluid detection sensor. A portion of the chip can be coated with a nucleic acid amplification reagent. The nucleic acid amplification reagent can comprise at least one of a buffer, a dye, one or more primers, dNTPs and a polymerase. The first conduit can be coated with a nucleic acid amplification reagent comprising at least one of a buffer, a dye, one or more primers, dNTPs and a polymerase. The first surface can comprise an interior surface, and the second surface can comprise an exterior surface.

[0048] According to a second aspect of the present invention, a combination includes a single-use nucleic acid amplification device for producing an amplicon and an instrument for engaging and operating the amplification device. The amplification device includes a housing, and an amplification chamber. The amplification chamber includes an ingress with a first reversible seal, an egress with a second reversible seal, a sealable sample entry orifice, and a first wall forming a portion of the amplification chamber. The first wall comprises a thermally conductive material and includes a first surface and an second surface. The second surface includes a heating circuit and a temperature sensor. The sample entry orifice permits a sample of nucleic acid to enter the amplification chamber. The ingress is connected to a first conduit along with a pump and a reservoir. The egress is connected to a second conduit permitting egress of the amplicon from the amplification chamber. The instrument includes a recess for receiving and engaging the amplification device. The instrument includes electrical connectors for contacting the

heating circuit and the temperature sensor, and mechanical connectors for engaging the ingress seal, the egress seal, the pump and the reservoir.

[0049] According to the second aspect, the instrument can comprise a fan for directing an air stream at the thermally conductive material of the second surface of the first wall. Alternatively, the instrument can comprise a heat sink for making contact with the thermally conductive material of the second surface of the first wall. The electrical connectors can be capable of contacting a Peltier circuit on the thermally conductive material of the second surface of the first wall. The electrical connectors can be capable of contacting a fluid detection sensor in the amplification device. The instrument can be portable and battery powered. The first surface can comprise an interior surface, and the second surface can comprise an exterior surface. The pump can comprise a pneumatic pump or other like device or mechanism. The reservoir can comprise a fluid pouch or other like means for storing fluid.

[0050] According to a third aspect of the present invention, a method of nucleic acid amplification for producing an amplicon in a single-use device includes the steps of: a.) introducing a nucleic acid sample into an amplification chamber through a sample entry orifice; b.) sealing the orifice; c.) transferring a fluid from a reservoir through a reversibly sealable ingress to the amplification chamber; d.) sealing the ingress and an egress of the amplification chamber; e.) mixing the fluid with the sample to form a mixture comprising nucleic acid, a buffer, a polymerase and one or more primers; f.) cycling the temperature of the amplification chamber between first and second temperatures for a predetermined time and for a predetermined number of cycles to form an amplicon; g.) opening the ingress and egress of the chamber; and h.) applying a pneumatic force to the ingress to move the amplicon from the chamber through the egress. According to an exemplary embodiment of the third aspect, the reservoir can comprise, for example, a fluid pouch or the like.

[0051] According to a fourth aspect of the present invention, a method of nucleic acid amplification for producing an amplicon in a single-use device includes the steps of: a.) introducing a nucleic acid sample into an amplification chamber through a sample entry orifice; b.) sealing the orifice; c.) transferring a fluid from a reservoir through a reversibly sealable ingress to the amplification chamber; d.) sealing the ingress and an egress of the chamber; e.) mixing the fluid with the sample to form a mixture comprising nucleic acid, a buffer, a polymerase and one or more primers; f.) increasing the temperature of the chamber to an isothermal amplification temperature for a predetermined time to form an amplicon; g.) opening the ingress and the egress of the amplification chamber; and h.) applying a pneumatic force to the ingress to move the amplicon from the chamber through the egress. According to an exemplary embodiment of the fourth aspect, the reservoir can comprise, for example, a fluid pouch or the like.

BRIEF DESCRIPTION OF THE DRAWINGS

[0052] Other objects and advantages of the present invention will become apparent to those skilled in the art upon reading the following detailed description of preferred embodiments, in conjunction with the accompanying drawings, wherein like reference numerals have been used to designate like elements, and wherein: