

amplicons of the negative control polynucleotide; and/or contacting the neutralized polynucleotide sample or a PCR amplicon thereof and the negative control polynucleotide or a PCR amplicon thereof with at least one probe that is selective for a polynucleotide sequence.

[0204] In various embodiments, a method of using the apparatus and cartridge described herein can further include one or more of the following steps: determining the presence of a polynucleotide sequence in the biological sample, the polynucleotide sequence corresponding to the probe, if the probe is detected in the neutralized polynucleotide sample or a PCR amplicon thereof; determining that the sample was contaminated if the probe is detected in the negative control polynucleotide or a PCR amplicon thereof; and/or in some embodiments, wherein the PCR reagent mixture further comprises a positive control plasmid and a plasmid probe selective for at least a portion of the plasmid, the method further including determining that a PCR amplification has occurred if the plasmid probe is detected.

Kit

[0205] In various embodiments, the microfluidic cartridge as described herein can be provided in the form of a kit, wherein the kit can include a microfluidic cartridge, and a liquid transfer member (such as a syringe or a pipette). In various embodiments, the kit can further include instructions to employ the liquid transfer member to transfer a sample containing extracted nucleic acid from a sample container via a sample inlet to the microfluidic network on the microfluidic cartridge. In some embodiments, the microfluidic cartridge and the liquid transfer member can be sealed in a pouch with an inert gas.

[0206] Typically when transferring a sample from liquid dispenser, such as a pipette tip, to an inlet on the microfluidic cartridge, a volume of air is simultaneously introduced into the microfluidic network, the volume of air being between about 0.5 mL and about 5 mL. Presence of air in the microfluidic network, however, is not essential to operation of the cartridge described herein.

[0207] In various embodiments, the kit can further include at least one computer-readable label on the cartridge. The label can include, for example, a bar code, a radio frequency tag or one or more computer-readable characters. When used in conjunction with a similar computer-readable label on a sample container, such as a vial or a pouch, matching of diagnostic results with sample is thereby facilitated.

[0208] In some embodiments, a sample identifier of the apparatus described elsewhere herein is employed to read a label on the microfluidic cartridge and/or a label on the biological sample.

Heater Unit

[0209] An exemplary heater unit **2020** is shown in FIG. 26. The unit is configured to deliver localized heat to various selected regions of a cartridge received in a receiving bay **2014**. Heater unit **2020** is configured to be disposed within a diagnostic apparatus during operation, as further described herein, and in certain embodiments is removable from that apparatus, for example to facilitate cleaning, or to permit reconfiguration of the heater circuitry. In various embodiments, heater unit **2020** can be specific to particular designs of microfluidic networks and microfluidic substrate layouts.

[0210] Shown in FIG. 26 is a heater unit having a recessed surface **2044** that provides a platform for supporting a microfluidic cartridge when in receiving bay **2014**. In one embodiment, the cartridge rests directly on surface **2044**. Surface **2044** is shown as recessed, in FIG. 2, but need not be so and, for example, may be raised or may be flush with the surrounding area of the heater unit. Surface **2044** is typically a layer of material that overlies a heater chip or board, or a heater substrate, that contains heater micro-circuitry configured to selectively and specifically heat regions of a microfluidic substrate, such as in a cartridge, in the receiving bay **2014**.

[0211] Area **2044** is configured to accept a microfluidic cartridge in a single orientation. Therefore area **2044** can be equipped with a registration member such as a mechanical key that prevents a user from placing a cartridge into receiving bay **2014** in the wrong configuration. Shown in FIG. 26 as an exemplary mechanical key **2045** is a diagonally cutout corner of area **2044** into which a complementarily cutoff corner of a microfluidic cartridge fits. Other registration members are consistent with the heater unit described herein, for example, a feature engineered on one or more edges of a cartridge including but not limited to: several, such as two or more, cut-out corners, one or more notches cut into one or more edges of the cartridge; or one or more protrusions fabricated into one or more edges of the cartridge. Alternative registration members include one or more lugs or bumps engineered into an underside of a cartridge, complementary to one or more recessed sockets or holes in surface **2044** (not shown in the embodiment of FIG. 26). Alternative registration members include one or more recessed sockets or holes engineered into an underside of a cartridge, complementary to one or more lugs or bumps on surface **2044**. In general, the pattern of features is such that the cartridge possesses at least one element of asymmetry so that it can only be inserted in a single orientation into the receiving bay.

[0212] Also shown in FIG. 26 is a hand-grasp **2042** that facilitates removal and insertion of the heater unit into an apparatus by a user. Cutaway **2048** permits a user to easily remove a cartridge from receiving bay **2014** after a processing run where, e.g., a user's thumb or finger when grabbing the top of the cartridge, is afforded comfort space by cutaway **2048**. Both cutaways **2042** and **2048** are shown as semicircular recesses in the embodiment of FIG. 26, but it would be understood that they are not so limited in shape. Thus, rectangular, square, triangular, half-oval, contoured, and other shaped recesses are also consistent with a heater unit as described herein.

[0213] In the embodiment of FIG. 26, which is designed to be compatible with an exemplary apparatus as further described herein, the front of the heater unit is at the left of the figure. At the rear of heater unit **2020** is an electrical connection **2050**, such as an RS-232 connection, that permits electrical signals to be directed to heaters located at specific regions of area **2044** during sample processing and analysis, as further described herein. Thus, underneath area **2044** and not shown in FIG. 2 can be an array of heat sources, such as resistive heaters, that are configured to align with specified locations of a microfluidic cartridge properly inserted into the receiving bay. Surface **2044** is able to be cleaned periodically, for example with common cleaning agents (e.g., a 10% bleach solution), to ensure that any liquid spills that may occur during sample handling do not cause any short circuiting. Such cleaning can be carried out frequently when the