

result could optionally be communicated wirelessly to a central medical records database for the particular patient, provided that wireless communication means were built into instrument **8**. The microfluidic cartridge assembly **300** (which contains the infectious sample) may then be ejected from instrument **8**, and disposed into an approved bio-hazardous waste container.

[0124] The present invention thus provides for a single use disposable cartridge assembly **300** formed of the sample carrier **200** and microfluidic cartridge **7**, which integrates the functions of sample preparation, nucleic acid extraction, amplification of target sequences, and detection of a target sequence. The disposable device works in conjunction with a control platform comprising portable instrument (reader) **8** and its reagent pack which provides the chemistry protocol to the disposable device in a pre-programmed manner thus avoiding the need for specialist involvement, and which stores and displays the results of the assay.

[0125] Thus, preferred embodiments of the present invention provide a portable or point of care bio-safe system for rapidly, reliably, and accurately detecting the target nucleic acid sequences of a range of infectious diseases, which is substantially as accurate as current PCR and RT-PCR based tests but which does not require expensive equipment, clinical laboratories, or skilled personnel to perform such tests. Furthermore, in embodiments where the system of the present invention is made portable, rapid in-field testing of particular infectious diseases may be performed.

[0126] Further, the United States Food and Drug Administration (FDA) in 1988 introduced guidelines for diagnostic systems that meet the requirements of the Clinical Laboratory Improvement Amendments (CLIA), which covers approximately 175,000 laboratory entities. CLIA defines a laboratory as any facility which performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health. Many clinicians' offices accordingly can now function as clinical laboratories by gaining CLIA waiver status. However to obtain CLIA waiver status, a diagnostic system must meet particular requirements of accuracy, sensitivity, quality control, and ease of use. Preferred embodiments of the present invention may thus provide for such waiver status.

[0127] It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

What is claimed is:

1. A biosafe system for assaying a target nucleic acid in a biosample, the system comprising:

- a) A two-piece sample carrier comprising a swab for collecting a sample to be tested, said swab with capture end and extended neck topped by a threaded cap with locking means, and a body with compartment for accepting said swab, and further comprising a threaded upper lip and lower tubular nose with axial orifice, said orifice with inner seal;
- b) A disposable microfluidic cartridge with external surfaces, with internal works, and with docking means for receiving said two-piece sample carrier, the microfluidic cartridge further comprising a bridging manifold with first fluidic channel in fluidic connection with a sample

receiving receptacle, a means for sealingly accepting the tubular nose of said sample carrier in said sample receiving receptacle, a means for fluidically joining said first fluidic channel to said sample carrier, valve means for introducing and withdrawing lysis reagent to and from said compartment, a means for extracting a target nucleic acid from a sample lysate, a means for eluting a target nucleic acid, an amplification chamber and stirrer means for amplifying a nucleic acid in a sample eluate, a lightpath through said chamber for detecting an amplification product by optical detection means; and,

- c) A control platform instrument with microprocessing means for sealedly engaging and controlling said internal works of said microfluidic cartridge, said means for sealingly engaging and controlling comprising at least one ported external hydraulic interface on said microfluidic cartridge, and detection means for reading and displaying an assay result; and further,
- d) Wherein said means for sealingly accepting the tubular nose of said sample carrier in said sample receiving receptacle, said means for fluidically joining said first fluidic channel to said sample carrier, and said means for sealedly engaging and controlling said internal works are configured to isolate said nasal swab, internal works of said microfluidic cartridge, external surfaces, and instrument, from forward and reverse contamination.

2. A biosafe system of claim **1** wherein said means for sealingly accepting the tubular nose of said sample carrier in said sample receiving receptacle comprises a compression seal formed between said tubular nose with orifice and said sample receiving receptacle in said bridging manifold, said compression seal further comprising a snap-lock mechanism formed of a mating undercut locking ring in said sample receiving receptacle and an oversized barbed lip on said tubular nose with axial orifice, such that insertion of the barbed lip through said locking ring irreversibly secures said compression seal.

3. A biosafe system of claim **1** wherein said means for fluidically joining said first fluidic channel to said sample carrier comprises a snap-lock mechanism formed of a mating female locking ring in said sample receiving receptacle and an oversized barbed lip on said tubular nose, and further comprises a sharp mounted in said sample receiving receptacle of said bridging manifold and extending into said axial orifice of said tubular nose, whereby said sharp pierces said inner seal and forms a patent fluid path between said first fluidic channel of said sample receiving manifold and said sample body compartment containing said nasal swab as said sample carrier is pressed into said sample receiving receptacle of said bridging manifold, said press fit assembly further aided by docking means.

4. A biosafe system of claim **1**, wherein said stirring means comprises a stirring motor with magnet on said control platform instrument and a stir bar with arms with ferromagnetic elements at the tips of said arms in said amplification chamber.

5. A biosafe system of claim **4**, wherein said stir bar is transparent except at the tips of said arms.

6. A biosafe system of claim **1**, wherein said optical detection means comprises an LED/photodiode pair straddling said optical window over said amplification chamber.

7. A biosafe system of claim **6**, wherein said optical detection means further comprises an interference filter.