

CLAIMS

1. An integrated diagnostic cartridge, comprising:
 - a loading module having a fill chamber within the cartridge having a volume sufficient to hold a sample, a fluid inlet in fluid communication with the fill chamber, a fluid outlet in fluid communication with fill chamber;
 - a lysis module;
 - a purification module; and
 - a reaction module;wherein the loading module is in fluidic communication with the lysis module and the purification module is in fluidic communication with the reaction module;
 - further wherein the loading module, the lysis module, the purification module and the reaction module are arranged for use while the cartridge is in a vertical orientation; and
 - further wherein when the cartridge is in a horizontal sample loading orientation the fluid inlet accesses the fill chamber via an upper surface of the cartridge and when the cartridge is in a vertical sample processing orientation the fluid inlet is positioned adjacent to an upper portion of the fill chamber and the fluid outlet is arranged for the sample to flow out of a lower portion of the fill chamber.
2. The integrated diagnostic cartridge of claim 1 further comprising one or more fluid filling conduits arranged to flow into an upper portion of a vertically oriented chamber within a fluidic card of the integrated diagnostics cartridge and one or more fluid outlet conduits arranged to flow out of a lower portion of the vertically oriented chamber within the fluidic card of the integrated diagnostics cartridge.
3. The integrated diagnostic cartridge of claim 2, wherein the vertically oriented chamber further comprises a filter assembly in fluid communication with a fluid outlet conduit of the vertically oriented chamber.

4. The integrated diagnostic cartridge of claim 1, wherein the lysis module comprises a mixing assembly having a vertically oriented lysis chamber containing a lysis agent and a non-magnetized stir bar.
5. The integrated diagnostic cartridge of claim 4, wherein the non-magnetized stir bar is made from a metal having a magnetic permeability to be responsive to a rotating magnetic field induced between a drive magnetic element and a driven magnetic element of a magnetic drive system.
6. The integrated diagnostic cartridge according to claim 4, wherein the non-magnetized stir bar is coated with an impermeable material to prevent corrosion by a chemical lysis buffer in the vertically oriented lysis chamber.
7. The integrated diagnostic cartridge of claim 4 wherein, when in use within a diagnostic instrument, the non-magnetized stir bar is disposed between a driving magnet system and a driven magnet system of a magnetic mixing assembly in the diagnostic instrument, wherein the driving magnet system is configured to rotate the non-magnetized stir bar within the vertically oriented lysis chamber at least 1000 rpm.
8. The integrated diagnostic cartridge of claim 4, further comprising a fluid inlet to the vertically oriented lysis chamber and a fluid outlet to lysis chamber wherein the vertically oriented lysis chamber is isolated from the other modules on the cartridge by a first frangible seal in fluid communication with the fluid inlet to the vertically oriented lysis chamber and a second frangible seal in fluid communication with the fluid outlet to the vertically oriented lysis chamber.
9. The integrated diagnostic cartridge according to claim 1 further comprising a fluidic card and a cover.
10. The integrated diagnostic cartridge of claim 9, wherein the fluidic card further comprises a first film adhered to a surface of at least a portion of the fluidic card, wherein the first film forms one surface of one or more chambers, compartments, or fluid conduits of the loading module, the lysis module, the purification module and the reaction module.

11. The integrated diagnostic cartridge of claim 9 further comprising an interference feature on the cover, wherein the interference feature is sized and positioned to interact with one of an upper rail or a lower rail of a loading apparatus of a diagnostic instrument.
12. The integrated diagnostic cartridge according to claim 11, wherein a thickness of the fluidic card is selected for sliding arrangement within an upper rail and a lower rail of a loading apparatus of the diagnostic instrument.
13. The integrated diagnostic cartridge of claim 11 further comprising a cartridge front face and a cartridge rear face forming an upper spacing and a lower spacing wherein each of the upper spacing and the lower spacing is sized and positioned to engage with the upper rail and lower rail of the diagnostic instrument.
14. The integrated diagnostic cartridge of claim 15 further comprising an interference feature within the upper spacing or the lower spacing positioned to ensure the cartridge engages with the upper rail and the lower rail in a desired orientation.
15. The integrated diagnostic cartridge of claim 9 wherein a total sample process volume of the integrated diagnostic cartridge is related to a thickness of the cartridge corresponding to a spacing between the one or more chambers, compartments, or fluid conduits of the loading module, the lysis module, the purification module and the reaction module formed in the fluidic card and the first film.
16. The integrated diagnostic cartridge of claim 15, wherein a diagnostic instrument is adapted and configured to accommodate a variation of the thickness of the cartridge by increasing a width of a loading slot of the diagnostic instrument to accommodate the increased thickness of the cartridge or a displacement range of a cartridge clamping system of the diagnostic instrument is adapted to accommodate the increased thickness of the cartridge.
17. The integrated diagnostic cartridge of claim 1 further comprising a plurality of frangible seal chambers in fluid communication with at least one or more of the loading module, the lysis module, the purification module or the reaction module.

18. The integrated diagnostic cartridge of claim 1, the integrated diagnostic cartridge further comprising a machine-readable code adapted and configured to identify the cartridge to a diagnostic instrument or an image of a patient identification marking.

19. The integrated diagnostic cartridge according to claim 1, the purification module further comprising: a rotary valve comprising:

- a. a stator comprising a stator face and a plurality of passages, each passage comprising a port at the stator face;
- b. a rotor operably connected to the stator and comprising a rotational axis, a rotor valving face, and a flow channel having an inlet and an outlet at the rotor valving face, wherein the flow channel comprises a porous solid support; and
- c. a retention element biasing the stator and the rotor together at a rotor-stator interface to form a fluid tight seal.

20. The integrated diagnostic cartridge of claim 19, wherein the rotary valve further comprises a gasket between the stator face and the rotor valving face, and wherein the stator comprises a displaceable spacer for preventing the gasket from sealing against at least one of the rotor and stator, and wherein, when the spacer is displaced the gasket seals the rotor and stator together in a fluid-tight manner.

21. The integrated diagnostic cartridge of claim 20, wherein, when the cartridge is positioned within a diagnostic instrument, engagement with a valve drive assembly of the diagnostic instrument displaces the spacer and seals the rotor and stator together in a fluid-tight manner.

22. The integrated diagnostic cartridge of claim 19, the purification module further comprising: a waste collection element, a wash buffer reservoir and an elution buffer reservoir.

23. The integrated diagnostic cartridge of claim 19 further comprising a pneumatic interface in fluidic communication with at least the purification module.

24. An integrated diagnostic cartridge, comprising:
a loading module;

a lysis module;

a purification module comprising a rotary valve comprising:

- a. a stator comprising a stator face and a plurality of passages, each passage comprising a port at the stator face;
- b. a rotor operably connected to the stator and comprising a rotational axis, a rotor valving face, and a flow channel having an inlet and an outlet at the rotor valving face, wherein the flow channel comprises a porous solid support; and
- c. a retention element biasing the stator and the rotor together at a rotor-stator interface to form a fluid tight seal; and

a reaction module comprising a plurality of individual assay chambers, wherein at least one surface in each one of the plurality of individual assay chambers is provided by a plug comprising:

a body with a bottom surface;

a central opening in the body; and

a dried reagent on the bottom surface, wherein the body is formed from a material transmissive to excitation wavelengths and emission wavelengths in at least one of a red spectrum, a blue spectrum and a green spectrum,

further wherein the loading module is in fluidic communication with the lysis module and the purification module is in fluidic communication with the reaction module; and

wherein the loading module, the lysis module, the purification module and the reaction module are arranged for use while the cartridge is in a vertical orientation.

25. The integrated diagnostic cartridge of claim 24, wherein the bottom surface of the plug body comprises a cavity in the bottom surface with the dried reagent within the cavity, and wherein the plug has a plug thickness between a central opening bottom and the plug body bottom, and further wherein a depth of the cavity is less than 90% of the plug thickness, is less than 70% of the plug thickness or is less than 50% of the plug thickness.

26. The integrated diagnostic cartridge of claim 24, wherein the plug has a polished or smooth finish facilitating the transmissivity of the excitation wavelengths and the emission wavelengths.
27. The integrated diagnostic cartridge according to claim 24, wherein the dried reagent is selected from the group consisting of nucleic acid synthesis reagents, nucleic acids, nucleotides, nucleobases, nucleosides, monomers, detection reagents, catalysts or combinations thereof.
28. The integrated diagnostic cartridge according to claim 24, wherein the body of the plug protrudes into the monolithic substrate of the assay chamber at a depth such that the assay chamber volume can be readily changed by altering the depth at which the body of the plug protrudes into the monolithic substrate of the assay chamber.
29. The integrated diagnostic cartridge according to claim 24 further comprising at least one fluid inlet conduit to each one of the plurality of individual assay chambers of the reaction module wherein each one of the at least one fluid inlet conduits further comprises a heat staked region.
30. The integrated diagnostic cartridge according to claim 29 wherein a heat stake in the heat staked region fluidically isolates the reaction module from the loading module, the lysis module, and the purification module.