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Claims

- 10 1. A self-contained microfluidic system for use in conducting an assay on a liquid sample, the microfluidic system comprising:
- 15 a sample input port for receiving the liquid sample, the sample input port connected to at least one microfluidic channel, wherein each/said microfluidic channel(s) comprises one or more reagents deposited therein for use in conducting the assay and a detection zone for use in detecting any analyte which may be present in a sample or analyte reaction product thereof; and
- 20 each/said microfluidic channel(s) is further fluidly connected to a compressible, gas-filled chamber downstream from each/said detection zone, and
- wherein the system is formed from three layers, which are sandwiched together to define each/said microfluidic channel(s) and said gas filled chamber, and wherein compressing or decompressing said chamber causes gas to be expelled from or drawn into the chamber, which in turn causes movement of the liquid sample within said/each microfluidic channel.
- 25 2. The microfluidic system according to claim 1, wherein following reaction of the liquid sample with said one or more reagents deposited within said/each microfluidic channel, gas expelled from the chamber serves to remove liquid from the detection zone within said/each microfluidic channel, in order that any analyte

or analyte reaction product within said/each detection zone can be detected in a substantially liquid free environment.

- 5 3. The microfluidic system according to claims 1 or 2, comprising a plurality of microfluidic channels, wherein each of said plurality of microfluidic channels is in fluid communication with the sample input port, optionally wherein a single microfluidic channel splits into said plurality of channels.
- 10 4. The microfluidic system according to claim 3 wherein each of said plurality of microfluidic channels is connected to a respective gas filled chamber, and/or two or more microfluidic channels are connected to a gas filled chamber.
- 15 5. The microfluidic system according to any preceding claim wherein the sample port is connected to a first end of said/each microfluidic channel(s) and a second end of said/each microfluidic channel(s) is connected to one or more of said gas filled chambers.
- 20 6. The microfluidic system according to any preceding claim further comprising one or more sink features designed to receive fluid waste and/or excess liquid sample.
7. The microfluidic system according to any preceding claim, wherein the top and bottom layers are planar and optionally of uniform thickness.
- 25 8. The microfluidic system according to claim 7 wherein the top and bottom layers are formed from the same material.
9. The microfluidic system according to either of claims 7 or 8 wherein the system is formed from a web or roll-to-roll process
- 30 10. The microfluidic system according to any of claims 7 - 9 wherein the planar substrates are sealed together by application of heat and/or the use of adhesive.

11. The microfluidic system according to claim 10 wherein the planar substrates are sealed together using an adhesive which is resilient and facilitates with the compressibility of each/said chamber.
- 5 12. The microfluidic system according to any preceding claim wherein said/each microfluidic channel(s) in the system comprises one or more fluid stop features, which are designed to prevent the sample and/or other fluids from passing through said stop feature(s) by virtue of capillary action alone.
- 10 13. The microfluidic system according to any preceding claim comprising a one-way valve which is designed only to allow gas to exit the system upon a liquid sample being introduced into the system by capillary action, whilst not permitting fluid from being introduced into the system via the valve.
- 15 14. The microfluidic system according to claim 13, wherein the valve is positioned adjacent to a stop feature which has been designed to prevent further transport of the sample within the microfluidic channel by capillary action alone.
- 20 15. The microfluidic system according to claim 14 wherein the valve is located within a microfluidic channel of smaller dimension than said/each microfluidic channel and which is in fluid communication with one of said microfluidic channels.
- 25 16. The microfluidic system according to any preceding claim comprising one or more electrode features in contact with said/each channel(s) for use in measuring or detecting liquid present in said/each channel(s).
- 30 17. The microfluidic system according to any preceding claim further comprising an analyte binding agent deposited within said channel(s), wherein optionally the analyte binding agent is bound to a surface of said channel(s).
18. The microfluidic system according to claim 17 wherein the binding agent is attached to a magnetic or paramagnetic particle.

19. The microfluidic system according to claims 17 or 18 wherein the binding agent or magnetic/paramagnetic particle are deposited within said/each microfluidic channel(s) of the system, such that upon the sample being applied to the system and being drawn into said/each channel(s), the binding agents or magnetic/paramagnetic particles are suspended by the liquid sample.
20. The microfluidic system according to any of claims 17 – 19 wherein the binding agent or magnetic/paramagnetic particles are deposited within an area of said/each microfluidic channel(s) defined by features at either end of the area of deposition designed to limit movement of the magnetic/paramagnetic particles when initially deposited in said/each channel.
21. The microfluidic system according to either of claims 19 or 20 wherein the magnetic/paramagnetic particles are deposited on an inner surface of said/each channel which is opposite to the external surface of the system to which a magnet or magnetic force is brought into close proximity.
22. The microfluidic system according to any preceding claim wherein the system further comprises one or more additional reagents deposited within said/each microfluidic channels(s), which additional reagents facilitate detection of analyte present in the sample.
23. The microfluidic system according to claim 22 wherein said one or more additional reagents includes a label which has been adapted to specifically bind to an analyte to be detected for facilitating analyte detection.
24. The microfluidic system according to claims 22 or 23 wherein analyte is bound to the analyte binding agent in a first area of said/each microfluidic channel(s), before being transported to a further area or areas of said/each microfluidic channel(s), in which said one or more further reagents and/or label is deposited, by way of gas being drawn back into said/each gas filled chamber.

25. The microfluidic system according to any preceding claim wherein said system is capable of carrying out a plurality (such as 2, 3, 4, 5, 6, 7, 8, 9, 10 or more) of the same and/or different assays on a single sample.
- 5 26. The microfluidic system according to any preceding claim wherein the volume of the sample applied to the system is less than 100 μ l, 50 μ l, such as less than 40 μ l, 30 μ l, or 20 μ l.
- 10 27. A kit comprising a microfluidic system according to any preceding claim, together with a sample collection device.
- 15 28. The kit according to claim 27 wherein the sample collection device is adapted to be inserted into to sample input port of the system and thereafter provide a seal to the input port.
- 20 29. The kit according to claim 28 for use in conducting a nucleic acid detection assay.
- 25 30. A reader device for use with a microfluidic system of any of claims 1 – 26, or kit according to claims 27 - 29, the reader device comprising:
force control means for controlling compression or decompression of a gas filled chamber of the microfluidic system; and detection means for enabling detection of a desired analyte within a liquid sample introduced into the microfluidic cartridge, or analyte reaction product thereof;
- 30 31. The reader device according to claim 30, wherein the piezoelectric bender is in the form of a strip, bar, rod or the like comprising a first immobilised end and a second non-immobilised end, wherein the second non-immobilised end is free to bend away from the gas filled chamber, upon suitable electrical signalling.

- 5 32. The reader device according to claim 31 further comprising a foot which is capable of engaging with an external surface of the gas filled chamber, wherein a top surface of the foot is in contact with the piezobender and wherein the foot is capable, through action of the bender, of effecting the compression or decompression of the gas filled chamber.
- 10 33. The reader device according to any of claims 30 – 32 wherein the piezobender is initially biased, or causes the associated foot, into contact with the external surface of the gas filled chamber.
- 15 34. The reader device according to claims 30 - 33 further comprising detection means for enabling detection of a desired analyte or analyte reaction product present within a liquid sample introduced into the microfluidic system.
- 20 35. The reader device according to claims 30 – 33 further comprising a receiving port, optional adapted for receiving different sized systems, each differently sized system designed to carry out a defined number of assays.
- 25 36. The reader device according to claim 35 wherein the receiving port is so adapted to ensure correct insertion and identification of each differently sized system.
- 30 37. The reader device according to claims 30 – 36 further comprising a permanent magnet to be brought into close proximity to, or electromagnet which is designed to apply a magnetic field to, a system according to claims 18 – 26 which has been introduced into the reader, in order to concentrate and hold the magnetic/paramagnetic particles in the detection zone of said/each microfluidic channel of the system.
38. The reader device according to any of claims 30 – 37 wherein said piezobender or foot is designed to contact only a portion of the total external surface of gas filled chamber.

39. The reader device according to claim 38 wherein each piezobender or foot is sized to contact between 10 and 50% of the external surface of each chamber.
- 5 40. The reader device according to any of claims 30 – 39 wherein the piezobender is designed to be bent and relaxed using electrical circuitry present in the reader and connected to the piezobender.
- 10 41. The reader device according to claim 40 wherein the electrical circuitry is capable of causing the bending of the piezobender at a variable rate such that gas within the system can be drawn into and/or expelled from said/each gas filled chamber at different rates.
- 15 42. The reader device according to claims 30 - 41 wherein the detection means is an optical detection device, such as a fluorimeter or spectrophotometer.
- 20 43. The reader device according to any of claims 30 – 43 further comprising heating and/or cooling means to allow assays to be conducted at a particular temperature, or plurality of temperatures.
- 25 44. An assay system comprising a self-contained microfluidic system and an associated reader device, wherein:
the self-contained microfluidic system comprises:
a sample input port for receiving a liquid sample to be assayed, the sample input port connected to at least one microfluidic channel, wherein each/said microfluidic channel(s) comprises one or more reagents deposited therein for use in conducting an assay and a detection zone for use in detecting any analyte which may be present in a sample or analyte reaction product; and
each/said microfluidic channel(s) is in fluid communication with a compressible, gas-filled chamber downstream from each/said detection zone,
30 wherein the microfluidic system is formed from three layers, which are sandwiched together in order to define each/said microfluidic channel(s) and said

gas filled chamber, and wherein compressing or decompressing said chamber causes gas to be expelled from or drawn into the chamber, which in turn causes movement of the liquid sample within said/each microfluidic channel; and

5 a reader device for use with the microfluidic system, the reader device comprising:

force control means for controlling compression or decompression of the gas filled chamber of the microfluidic system; and detection means for enabling detection of a desired analyte within a liquid sample introduced into the microfluidic cartridge, or analyte reaction product thereof;

10 wherein the force control means comprises a piezoelectric bending actuator which is designed to directly or indirectly compress or decompress the gas filled chamber through displacement of the actuator.

45. A method of conducting an assay on a liquid sample, the method comprising:

15 a) providing a microfluidic system as described herein to a reader device as described herein;

b) compressing a/said gas filled chamber(s) of the microfluidic system, so as to expel gas from said/each gas filled chamber(s);

20 c) introducing a liquid sample to the microfluidic system and allowing the sample to be drawn into said/each microfluidic channel(s) by capillary action, and/or partially decompressing said/each gas filled chamber(s) such that gas is drawn into said/each chamber(s) thereby causing the liquid sample to be drawn into said/each microfluidic channel(s);

d) allowing one or more reagent(s) to react with any analyte present in the liquid sample;

25 e) optionally partially further partially decompressing said/each gas filled chamber(s) of the microfluidic system, such that the liquid sample is drawn further along said/each microfluidic channel(s) towards said/each gas filled chamber(s) and optionally contacting the liquid sample with an analyte binding agent and/or one or more further reagent(s);

- f) optionally capturing any analyte or analyte reaction product and compressing said/each gas filled chamber(s), such that gas expelled from said/each chamber(s) causes the liquid sample and uncaptured material to be pushed away from any captured analyte or analyte reaction product; and
- 5 g) detecting any analyte or analyte reaction product, or captured analyte or analyte reaction product.
46. The method according to claim 45 wherein step e) is carried out as a single or multiple steps, whereby the sample is drawn to a further or a number of successive locations respectively within said/each microfluidic channel
10 corresponding to the number of times a decrease in force is carried out.
47. The method according to claims 45 or 46 wherein the analyte/analyte binding agent complexes or analyte reaction product/analyte binding agent complexes to be formed comprise magnetic or paramagnetic particles.
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48. The method according to claim 47 wherein the magnetic particles which are employed to form the complexes are initially deposited on an internal surface of said microfluidic channel(s) which is opposite to the external surface of the system to which a magnet is brought into close contact, or a magnetic force
20 applied, in order that the magnetic particles are drawn laterally through said microfluidic channel(s).
49. The method according to claims 45 -48 wherein the step e) is carried out as a single or multiple steps, whereby the sample is drawn to a further or a number of successive locations respectively within said/each microfluidic channel
25 corresponding to the number of times a decrease in force is carried out.
50. The method according to any of claims 45– 49 wherein the volume of gas which is expelled from the/said chamber(s) causing liquid to be expelled from at least a portion of the/said microfluidic channel(s) where the analyte/analyte binding agent complexes are captured, is sufficient to cause the liquid to be removed
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from the detection zone or portion thereof, but not further along the microfluidic channel(s).

51. A self-contained disposable microfluidic system for use in conducting a plurality of distinct assays, the microfluidic cartridge comprising:
a sample input port for introducing a liquid sample into the microfluidic cartridge;
multiple microfluidic channels; each of said microfluidic channels being adapted to receive a portion of the liquid sample and being capable of conducting one or more assays on said portion of sample using one or more reagents which are present within each of said microfluidic channels prior to liquid sample introduction; and
wherein fluid movement within each microfluidic channel is independently controllable by compression and/or decompression of two or more gas filled chambers of the microfluidic system, which chambers are each in fluid communication with one or more of said microfluidic channels.
52. The self-contained disposable microfluidic system according to claim 51 for use in a method according to any of claims 45 – 50.
53. The self-contained disposable microfluidic system according to claim 51 further comprising the features as defined in claims 1 – 26.
54. The self-contained disposable microfluidic system according to any of claims 51 – 53 which is capable of carrying out at least two, three, four, five or more of the following types of assays: immunoassay, nucleic acid assay, receptor-based assay, cytometric assay, colorimetric assay, enzymatic assay, electrophoretic assay, electrochemical assay, spectroscopic assay, chromatographic assay, microscopic assay, topographic assay, calorimetric assay, turbidmetric assay, agglutination assay, viscometric assay, coagulation assay, clotting time assay, protein synthesis assay, histological assay, culture assay, or osmolarity assay.

55. The self-contained disposable microfluidic system according to any of claims 50 -
53 which is capable of conducting a panel of separate assays which are
designed to test for a heart condition, pregnancy, kidney condition, neurological
condition, an adrenal gland condition, a liver condition, diabetes, pathogens or
5 drugs of abuse.
56. The self-contained disposable microfluidic system according to claim 55 for use
in detecting a heart condition and wherein the panel of separate assays is for
detecting one or more of the following: lipid levels, apolipoprotein; homocysteine;
10 C-reactive protein (CRP) troponin, BNP; and/or Cardiac enzymes.
57. The self-contained disposable microfluidic system according to claim 55 for use
in detecting an adrenal condition, and wherein the panel of separate assays is for
detecting one or more of aldosterone, cortisol, 18-hydroxcortisol, and/or DHEA-S.
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58. The self-contained disposable microfluidic system according to claim 55 for use
in detecting a liver condition and wherein the panel of separate assays is for
detecting a level of one or more liver enzymes, bilirubin, albumin, prothrombin
and/or the presence of a virus or viruses.
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59. The self-contained disposable microfluidic system according to claim 55 for use
in detecting subjects at risk of developing diabetes or confirming subjects with
diabetes and wherein the panel of separate assays is for detecting one or more
of: lipid levels, complete blood count, fasting glucose levels, haemoglobin A1c
25 and/or albumin.
60. The self-contained disposable microfluidic system according to claim 55 for use
in detecting drugs of abuse, wherein the panel of assays is for detecting one or
more of: Amphetamines; Barbiturates; Buprenorphine; Benzodiazepines;
30 Cocaine; Ecstasy; Methamphetamines; Heroin (Opiates/Morphine); Methadone;
Tricyclic Antidepressants; and/or Cannabis.

61. A multiplex assay platform for use in conducting multiple panels of assays, the multiplex assay platform comprising a plurality of microfluidic systems according to any of claims 50 - 60, each system being capable of conducting a defined panel of assays on a sample and a reader constructed to be capable of receiving and verifying each of said plurality of microfluidic systems, whereby the reader is configurable for detecting and/or determining levels of a panel of analytes which may be present in the sample.
62. A multiplex assay platform for use in conducting multiple panels of assays according to claim 61 for use with a reader device according to any of claims 30 - 43.
63. A valve system for use in accordance with an assay system according to any of claims 1 - 26, the valve system comprising:
- a vent or slit opening in a top or bottom surface of an assay system according to the present invention; and
- a microfluidic channel of smaller dimension to the/said microfluidic channel of the assay system, which microfluidic channel of smaller dimension is in fluid communication with the vent or slit opening and the/said microfluidic channel of the assay system.
64. The valve system according to claim 63, wherein the valve system is positioned so as to be adjacent to a capillary stop of the/said microfluidic channel, such that upon the sample being introduced to the assay system, the sample fills by capillary action to the capillary stop and a portion of the sample also at least partially fills the microchannel of smaller dimension.
65. The valve system according to claim 64 wherein the portion of the sample at least partially filling the microchannel of smaller dimension acts as a barrier to further fluid transport along the microchannel of smaller dimension and fluid export through the vent or slit.