ASSAY DEVICE AND READER

FIELD OF THE INVENTION

[0001] The present invention relates to a microfluidic based assay system, comprising a disposable assay cartridge and associated reading device, as well as the individual components themselves. The present invention also relates to methods of conducting assays, using the cartridge and device of the invention, as well as kits for conducting assays.

BACKGROUND TO THE INVENTION

[0002] The in vitro diagnostics (IVD) market is highly competitive and there is a constant need within the IVD market to develop fast, low volume, precise and cheap IVD tests. This is coupled with the fact there is a strong market desire to develop capillary finger stick blood tests with reduced user complexity to allow total market penetration (e.g. point of care, doctors surgery, home etc). This capillary finger stick IVD testing model has proved hugely successful for diabetes testing developing into a $3.5 billion market (ref: Medical Device Today). The desire and ability to evolve immunoassay IVD towards capillary finger stick blood testing has been hampered by technology developments, however this remains a golden aim of many diagnostic companies as it allows reduced complexity and greater placement of products in existing or untapped market.

[0003] It is amongst the objects of the present invention to provide a cheap and reliable assay system for carrying out IVD tests.

[0004] It is amongst the objects of the present invention to provide an assay cartridge design platform and reader which may be easily and cheaply fabricated, as well as being able to be configured to carry out a specified assay or assays.

[0005] It is amongst the objects of the present invention to provide an assay cartridge which may easily be adapted to carry out a variety of different specified assays.

[0006] It is amongst the objects of the present invention to provide an assay system comprising a reader which may preferably be used or easily adapted to perform a variety of different assays.

SUMMARY OF THE INVENTION

[0007] In a first aspect the present invention provides a microfluidic assay cartridge for use in detecting an analyte in a sample of fluid, the cartridge comprising:

[0008] a substrate comprising one or more microfluidic channels disposed therein and comprising a binding agent disposed within said channel(s) for binding any of said analyte within the sample;

[0009] a sample port for introducing said fluid sample into the cartridge;

[0010] at least one fluid input port for allowing one or more fluids to be introduced to the cartridge from an associated reader device and transported through the microfluidic channel(s); and

[0011] a fluid outlet sink for removing fluid from said channel(s).

[0012] The cartridge may further comprise a detection area where any bound analyte may be detected. The detection area maybe contained within the sample channel, which is directly adjacent or downstream from the sample port.

[0013] The cartridge design of the present invention may easily be adapted to carry out a number of different assays and hence can be considered as an assay platform for a variety of assays. The cartridge and channel(s) disposed therein may be formed in any manner of ways known to the skilled addresses, which may include photolithography, wet chemical etching, laser ablation, injection moulding, embossing and printing techniques. However, in a preferred embodiment, the cartridge and the channels and other features disposed therein, are formed by a sandwich of three separate substrates—a top, middle and bottom substrate.

[0014] The cartridge can be formed of any suitable material, such as polycarbonate, polyester, polystyrene, PMMA, etc. and the/each substrate may be formed of a single or plurality of material(s). In the embodiment comprising three substrates, the middle substrate comprises a pattern cut through the substrate, corresponding to certain features of the cartridge, such as the channel(s), fluid reservoir/reservoirs port, sink area and the like. By applying and sandwiching (such as by heat sealing, gluing, stapling and the like) appropriately cut top and bottom substrates, to sandwich the middle substrate between the top and bottom substrates, a cartridge can be provided in which channels and other features are disposed. Openings or features in the top and/or bottom substrate may be designed to co-locate with features in a reader device (as will be discussed hereinafter), which may facilitate with correct location of the cartridge in the reader and also importantly allow for a fluid, such as a wash buffer, to be introduced from a fluid reservoir/reservoirs in the reader to the cartridge or sample to be applied or air to be vented from the cartridge. The fluid/wash buffer or gas can be introduced into the cartridge by way of suitable means such as a pump/pumps means in the reader and the fluid transport means can therefore control fluid transport within the cartridge itself. Thus once a sample has been introduced into the cartridge such as by way of capillary action, further fluid transport within and throughout the cartridge is controlled/facilitated by way of means provided in the reader device. It will be appreciated that the fluid introduced into the cartridge by way of the fluid input port may be a liquid and/or a gas, such as air.

[0015] As identified, in use, the sample is applied to the cartridge through a sample introduction port such as by way of capillary action or other means. In a preferred embodiment the sample introduction port is an aperture in a side or face of the cartridge. Desirably the cartridge is in the form of a generally thin planar device comprising top and bottom faces and four edges. In this arrangement, the sample introduction port may be formed in one of the edges of the cartridge, so that a user need only contact the sample with the aperture formed in the edge, in order to enable sample uptake into the cartridge. In use the user contacts the fluid sample with the port/aperture and, in certain embodiments, due to the dimensions of said channel(s) within the cartridge, fluid is drawn into the cartridge by capillary action. The dimensions of the sample port/aperture may be smaller than the dimensions of the channel(s).

[0016] When fluid is being transported through the cartridge, fluid is not expelled through the sample port as there are no surfaces to wet. However, because the sink offers a large void area which can be wetted the preferential fluidic path is into the sink.

[0017] Said fluid input port(s) of the cartridge is/are adapted to co-locate with a feature in the reader, so that a fluid, such as a wash buffer or gas, such as air, contained in a reservoir/reservoirs within the reader, can be introduced into the cartridge. Typically the inlet port is simply an aperture or