

holding step by an applied magnetic field) and where other deposited dry reagents (30, 32) may be resuspended in buffer (for example, the same buffer as the wash buffer) which is then pumped into the sample channels (14, 16), to allow binding events to occur in a very controlled manner. Or as previously described, the washed magnetic particle—analyte complex which is contained within the clean buffer matrix may be transported upstream, past stop feature (20) to the location in the strip where the label is dried down in the disposable test cartridge. At this point the magnetic particle—analyte complex can bind to the label followed by an additional wash step and measurement of the label. (In both of these examples only the magnetic bead-analyte binding reaction occurs in the blood, all the other reaction and/or binding steps occur in a very controlled buffer environment).

[0093] However, the magnetic field may also be “relaxed” (see FIG. 9) by moving the magnet away from the cartridge and thereby reducing the magnetic attraction in this manner the magnetic particles (18) may still be held by the magnetic field, albeit less strongly and a more diffuse band (84) of particles may form. Moving the magnet (80) back towards the cartridge again will serve to concentrate the particles (18) once more.

[0094] In summary, this means that any reagents and/or labels never contact the “dirty” blood matrix, and all reactions/binding (other than the initial analyte capture step) is very controlled in a buffered, optionally heated environment to maximise detection efficiency and prevent/minimise non specific binding and interfering products to be removed (maximising the repeatability/precision of the measurement). This allows the present system to use reagents that would not have normally chosen because they were “problematic” in plasma/blood. In addition it also means all the detection measurements, such as fluorescent measurements also occur in a “clean” buffer environment meaning sample quenching/interference (as expected in blood or plasma) is reduced/removed allowing very sensitive reproducible measurements to be made. This allows a much greater choice of detection labels e.g. fluorophores, because quenching of excitation or emission light is minimised.

[0095] It should be appreciated that the foregoing description, with reference to FIG. 1, has been made in relation to a two channel cartridge, but the present invention also relates to single channel as well as multi-channel e.g. 6, 7, 8 etc cartridges. Each channel may carry out the same reaction for reproducibility/accuracy purposes, or may be designed to carry out different assays—in this way each cartridge may be capable of carrying out a “multiplex” reaction.

[0096] FIG. 10 shows a similar cartridge (10) to that shown in FIG. 1, but additionally shows fill electrodes (23) which may detect correct filling of the sample by the cartridge (10). Further electrodes (24) are provided to enable a hematocrit value to be obtained from the blood sample.

[0097] A further embodiment of a cartridge (11) in accordance with the present invention, is shown in FIG. 11. In this preferred embodiment 6 channels are fed by a single sample inlet port instead of the two channels being fed by the single sample inlet port. The 6 channel strip design is an expanded version of the 2 channel strip shown in FIG. 1 whereby additional channels have been added which all share the same sink (90). This allows a more effective use of strip footprint and allows increased multiplexing capacity.

[0098] Ultimately a measurement is made (e.g. fluorescent) by a reader using optical or other detection means, suitable for

the label to be detected. For example, if the label is a fluorescent label the detection means may be able to perform and detect the excitation and emission of the chosen fluorophores: a schematic view of a hand held reader in accordance with the present invention is shown in FIGS. 12-15. This embodiment of the reader (MST Pro Meter V1) is the specific embodiment that was used to perform the experiments as described in the Experimental section. In addition all experimental results were obtained using the 6 channel strip design (as shown in FIG. 26). The reader (100) comprises a platform (106) for receiving and holding a cartridge (10) of the present invention and a sealing head (105) the actuation of which can be controlled by solenoids (108) for the purpose of producing a sealed system whereby the instrument can pump either a gas, such as air or a fluid such as a wash buffer into the strip in a controlled manner. Additionally the reader comprises a fluid reservoir/reservoirs cartridge (111) for holding fluid or gas for subsequent delivery to the cartridge (10). The reservoir/reservoirs cartridge may contain a separate chamber for each test channel contained on the strip such that the fluid/air actuation and control for each test channel is driven directly from what is effectively a separate pump source. Alternatively the reservoir/reservoirs cartridge may comprise of one chamber which is then split into multiple outlets such that the fluid/air actuation and control for each test channel is driven from a common pump source. The fluid or gas is delivered by way of an actuator (113) acting on the reservoir/reservoirs cartridge. There is also provided suitable optical detection means (107) and electrical circuitry (112) and an associated computer chip or chip(s) and software for controlling the reader and conducting the assay. In addition because the described system has the flexibility to perform many wash and reagent delivery steps many assay formats can be configured using the current system.

[0099] A magnet holder (103) and associated magnet which may be orientated at 45 degrees, (104) can be controlled through the use of a motor (110) in order to bring the magnet in contact or close proximity to the test strip, for the purpose of influencing magnetic or paramagnetic particles contained within the test strip. In order to perform the assay measurement (e.g. fluorescent) the optical reading head (107) can be moved along the measurement or detection zones (222) of each of the multiple test channels in the test cartridge controlled by a motor (109). Thus the optical reading head can be utilized to perform multiple measurements across one disposable test cartridge. The plot shown in FIG. 25 shows the results of an example read of the optical reading head across a test channel in the test cartridge. (using the reader design MST Pro Meter V1). From the results it can be seen that the instrument can make multiple measurements across the width of the test channel allowing the peak fluorescence signal to be identified and transformed into a result through the use of an algorithm and displayed to the user through the LCD (101). In addition the instrument could interpret the shape associated with the measurements taken across the test channel and use this as an on board control, for example if the read response gives the shape of a steady decay or steady increase instead of a parabolic response then it could be used to determine an erroneous or non uniform result.

[0100] It will be appreciated that the reader is required to very accurately control the fluid/gas delivery of for example, the buffer wash to the disposable cartridge. The cartridge may involve a number of separate sample channels, and a number of wash steps may be required for each channel, with each