

[0133] In the cartridge design shown in FIG. 1, two identical channels are shown; however, measurements do not require this, therefore one channel in the cartridge may be employed, and this could allow a sub 1 μ L immunoassay measurement.

[0134] In comparison to the 2 channel strip design, the channels within the 6 channel strip design (shown in FIG. 11) are joined. In the 2 channel strip the two channels are separate entities that are not joined. The 6 channel strip design can have joined channels (as can the 2 channel strip design) because the system is a sealed system. In FIG. 11, electrodes are shown that could be used for electrochemical measurements (219) that could be situated in one or more of the sample channels. Electrodes are also shown that could be used for electrochemical and/or detection of sample fluid as well as acting as fluidic stop features (220, 221). FIG. 11 also shows 2 alternative strip design features that would lend the strip to be filled with the test sample being presented to either the end of the strip (217) or the top of the strip (218). Each test channel within the test cartridge can have one or more wash ports (206, 208, 200, 202).

[0135] The strip wash ports (200, 202) are closed (sealed by the reader). After a certain amount of time, (e.g. 5 minutes), the reader can position a magnet in contact with the test strip, or in close proximity to it, which will result in the magnetic beads being accumulated into a tight band which will be held in position during the primary wash step. The syringe pump cartridge can then be actuated in order to perform a wash step using liquid or gas, either one channel at a time, for example using valves to control the opening and closing off of each channel. (e.g., the first port (206) in isolation). Or all channels at the same time whereby each port (206 and 202) is open to the syringe pump cartridge through the absence of a valve system, or a valve system where all associated valves are open. The preferred embodiment is the case where no valves are present, neither in the reader nor the disposable test cartridge. When the blood is washed out by buffer or gas (e.g. air) being introduced through the first port (206) the blood is pushed over a fluidic stop feature (221) into the sink (210). The previously described magnetic particle accumulation, relaxation processes by permanent or electromagnets etc remains exactly the same. In the case where the syringe pump cartridge has washed the test cartridge test channels with gas for a one step assay, at this point the final fluorescent measurement for each channel can be made in the detection/measurement area (222). Note that in this case the measurement is that of an accumulated magnetic bead band—fluorophore complex in air. In the case of a multiple step assay, the reader is required to perform additional tasks as stated below.

[0136] The blood is not pushed into the other channels (212, 213, 214, 215, 216) as the ports (200, 202) are either sealed or under positive pressure/force due to the syringe pump cartridge acting on these ports at the same time. (In this case no valves are required neither in the reader nor the disposable test cartridge). Therefore the only place for the displaced blood to go is into the sink (210). Each channel has at least one fluid input port(s), therefore as the first port is open (e.g. 206) and being used as a port to dispense fluid into the cartridge, additional ports (e.g. 208) located up channel can be closed preventing any fluid being dispensed up the channel. The blood is therefore washed from the channel and into the sink.

[0137] A secondary delivery of label can be performed or alternatively the magnetic particle analyte complex can be transferred up the channel to the zone where the label is deposited. (211, 212, 213, 214, 215, 216). Note that printed features on the strip design can be used to contain these reagents in a pre defined area. This concept could also be applied to the primary reagents deposited in the test sample channel (223). This secondary delivery of label process can again be performed individually in a channel by channel process, or be performed on all channels at once. When multiple ports are used for a channel, this process relies on the ports (200, 202, 206, 208) being opened and closed (only one port is open per channel at a time). In the case of a single port associated with each channel, this is not necessary. In the case of the delivery of the label the first strip wash port (206) used for the wash step would be closed, and the second port located up channel would then be opened and used to dispense fluid to rehydrate and deliver the label to the magnetic particle-analyte complex or remove air (resulting in a transferral event). The transferral event is possible because the strip is a sealed system, and instead of pumping fluid into the strip, air is sucked from the strip by the “pump” resulting in the magnetic particle-analyte complex in buffer being sucked along the channel to the deposited label. This process would then be repeated for the remaining channels (212, 213, 214, 215, 216).

[0138] In the case where there is only one port associated with each test channel (FIG. 26, 224), the air volume present in the area (225) between the test sample and the port can be used to displace the sample from the sample channel area (filled from the sample entry port (226)). Thus in the case of the syringe pump cartridge containing fluid, only one port is required to perform a 2 step assay, as the primary wash is performed using air that is already present in the test cartridge test channel, allowing the subsequent fluid pumped from the cartridge to rehydrate the secondary reagents (deposited in region identified by point 227) and present them to the magnetic particle complex present in the sample channel area of the test channel. It is possible to perform a 1 step assay with an air wash with only 1 port (224) associated with each channel, this is the cartridge design (MST Pro Strip V1, FIG. 26) associated with the experimental section.

[0139] As discussed previously the present platform allows multiple analytes to be measured within each channel. Multiplexing can be performed easily in one channel by depositing magnetic particles with different binding agents against the analytes to be measured. This could be achieved by making individual preparations of antibody functionalised magnetic particles and then combining them and depositing them into the sample channel. In comparison a single preparation could be made whereby a mixed antibody population (against all the analytes that are going to be measured) are coupled to a magnetic particle population resulting in magnetic particles having a number of different antibodies coupled thereto. In both embodiments, fluorescent latex particles/fluorophores preparations could be made conferring the required antibody specificity against the analytes to be measured allowing a classical immunoassay “sandwich” complex to be made (immunoassays employing fluorescent measurements in blood and plasma could not perform these measurements as magnetic particles specific to different analytes could not be spatially distributed as previously described). Further amplification steps could still be performed if needed; and the reagents could be further tuned to allow this. There is an extensive range of fluorophores available with different excitation and