

[0053] The detectable labels may be used alone, or in conjunction with a microparticle or bead, such as a metal oxide, polysaccharide or latex particle. Many types of latex and other particles are known in the art.

[0054] The reader comprises suitable means for transporting fluid from the fluid reservoir/reservoirs into and throughout the cartridge. The reader may also be configured to enable air, such as filtered air, to be transported into the said microfluidic channel(s) of the cartridge. The reader comprises appropriate tubing, valves and/or seals, as necessary, to enable fluid in the reservoir/reservoirs and/or air to be introduced into the cartridge. The means may be a pump/pumps and the pump may pump fluid/gas in one-direction, or may be able to pump fluid/gas back and forth. A preferred pump is a stepper motor linear actuator, piezoelectric pump, osmosis pump, peristaltic pump or piston pump. Fluid/gas delivery to the sample cartridge may be controlled by a microfluidic control assembly, which may control delivery of one or more fluids/gases to the sample cartridge, to one or more input apertures in the cartridge and at suitable time points.

[0055] The reader may include other features, such as a heating device to allow assays to be conducted at a particular temperature, as well as appropriate electrical circuitry and software to allow the reader to be programmed to carry out one or more different assays.

[0056] The platform system of the present invention, comprising cartridge and reader provides a number of distinct advantages:

[0057] 1. Reduced Sample Volume: capillary introduction of a fluid, such as a finger stick blood sample, reduces the complexity for the user and allows the tests to be performed in any environment (e.g. ambulance, point of care, doctor's surgery, battle field etc), and similar to glucose testing, allowing products to be placed anywhere.

[0058] 2. Performance, Sensitivity and Precision: The ability to perform multiple step assays will increase sensitivity, precision and reproducibility of assays, a major requirement of any IVD test. This will become more and more important as the FDA continues its reduction of the allowable total error for product launches of new IVD tests (entry into existing and new product markets will become harder).

[0059] 3. Room Temperature Stability: Many existing IVD tests require refrigerated storage and shipping, this requirement adds significant cost to the product and also restricts the usage and distribution of the product. The initial "dry" nature of the sample cartridges aids in their stability and shelf-life.

[0060] 4. Low material costs and a simple manufacturing process allow for low costs of goods (COGs), allowing substantial and increased profits to be generated by the sales of IVD strips. This is especially needed in the immunoassay and molecular IVD market where the conventional tests tend to be of high complexity driving both the strip material costs and overall assay cost higher.

DETAILED DESCRIPTION OF THE INVENTION

[0061] The present invention will now be further described by way of example and with reference to the figures which show:

[0062] FIG. 1 shows a schematic representation of a sample cartridge in accordance with the present invention;

[0063] FIG. 2 is a schematic representation of how a cartridge of the present invention may be formed;

[0064] FIG. 3 is a photograph of a portion of a cartridge according to the present invention showing various features;

[0065] FIGS. 4 and 5 show blood entering and filling the portion of the cartridge shown in FIG. 3;

[0066] FIGS. 6, 7 and 8 are photographs of a detailed portion of a cartridge of the present invention showing magnetic particles being captured by a magnet and being retained following washing away of a blood sample;

[0067] FIG. 9 is a photograph of a detailed portion of a cartridge of the present invention showing magnetic particles being held more diffusely following partial removal of a magnet;

[0068] FIGS. 10 and 11 are schematic representations of further embodiments of a sample cartridge in accordance with the present invention;

[0069] FIG. 12 is a schematic of a reader device in accordance with the present invention;

[0070] FIG. 13 is a schematic of the internal mechanisms associated with a reader device in accordance with the present invention

[0071] FIG. 14 is a schematic representation of a fluid management system found within a reader device of the present invention;

[0072] FIG. 15 shows a schematic representation of a fluid reservoir/reservoirs system and how this may be used within a reader of the present invention.

[0073] FIG. 16 shows graphed experimental results of a total PSA washed wet assay with the assay cartridges measured in the MST Pro Meter V1 in accordance with the current invention;

[0074] FIG. 17 shows graphed experimental results showing the correlation between the Total PSA washed wet assays measured in strips in the MST Pro meter and the Victor V reference instrument;

[0075] FIG. 18 shows graphed experimental results showing the correlation between the Total PSA washed wet assays measured in strips in the MST Pro meter and the Victor V reference instrument;

[0076] FIG. 19 shows graphed experimental results showing the total PSA wet assay performed in the MST Pro Meter and Strip, the meter using a air wash step to expel unbound label from the channel;

[0077] FIG. 20 shows graphed experimental results showing the total PSA wet assay performed in the MST Pro Meter and Strip, does not use a wash step and measures the fluorescence intensity of the fluorophore after the magnetic particle-PSA-fluorescent latex complex are accumulated by the magnet;

[0078] FIG. 21 shows graphed experimental results showing the total PSA washed wet assay performed with the MST Pro Meter V1 and Strip. For the data, the MST Pro Meter V1 uses a fluid wash to expel the sample (containing unbound label) from the strip channels into the sink;

[0079] FIG. 22 shows graphed experimental results of a total PSA dry assay performed with reagents dried in the MST Pro Strip V1 and the assay performed on MST Pro Meter V1 in accordance with the current invention; 1

[0080] FIG. 23 shows graphed experimental results of a total PSA half dried 2 step assay performed with reagents dried in the MST Pro Strip V1 and the assay performed on the MST Pro Meter V1. In this case the fluorescent latex was deposited in the test cartridge in dry format.