

air from the syringe pump cartridge to displace the sample fluid from the channel, and hence remove the unbound latex from the detection area (222, 241) and displace it into the sink (236). The optical reader head then carries out a measurement of the remaining fluorescent signal (from the specific sandwich binding complexes of paramagnetic particles-PSA-fluorescent particles) which remain in air by scanning across the detection areas of each channel (see FIG. 23 for a description of these results).

[0233] Results for Assay 4:

[0234] FIG. 23 shows a Total PSA two step assay performed in the MST Pro Meter and Strip. The meter uses an air wash step to expel unbound label from the channel. Fluorescent latex label was deposited in the strip. The summary results are shown in FIG. 23. The fluorescent latex label was deposited in the strip and the sample containing PSA and paramagnetic particles was added to the strip. The meter performed an air wash and optically measured the concentration of captured fluorescent latex label. Systematic dose response curves are observed and demonstrate that two or three step assays can be formatted on the MST Pro Platform and that fluorescent latex label could be deposited in one strip and used to perform two step assays.

Assay 5: 2 Step Half Dry Assay (Dried Paramagnetic Particles) with Wash and Measurement Carried Out in 'MST Pro Meter V1' Reader

[0235] Reagents are deposited and dried within a 'MST pro strip V1' cartridge as follows:

[0236] 10  $\mu$ l 0.5% functionalized paramagnetic particles (with biotinylated 1H12 bound)

[0237] 10  $\mu$ l PBS, pH 7.2

[0238] 10  $\mu$ l 25 mg/ml trehalose in PBS, pH 7.2

[0239] 10  $\mu$ l 300 mg/ml BSA in PBS, pH 7.2

[0240] 10  $\mu$ l 0.1% tween-20 in PBS, pH 7.2

[0241] The above reagents are combined and 1  $\mu$ l of this deposition mix added per channel of a 'MST pro strip V1' cartridge (as shown in FIG. 26). Reagents are deposited at position (223, 242) in each channel (however it is not vital that these reagents are kept distinct from the detection area as no label (fluorescent latex) is being deposited). For deposition, the cartridge is half assembled, with only the bottom and middle layer of cartridge bonded together. The reagents are pipetted into the reagent deposition zone of the half assembled test sample channel (see FIG. 26, with reagent deposition zone indicated on the cartridge as point 223, 242). These are dried in an oven at 33 deg C. for 10 min. The top layer of the cartridge is then bonded to the half assembled cartridge to produce a fully assembled three layer cartridge (see FIG. 2 for an example of how the three layers come together to form an assembled cartridge, for a different cartridge design) with dried reagents. FIG. 26 (240) indicates the shape of the double sided adhesive material which is cut away to form channels and sink structures when bonded between two layers of laminate material. The cartridge is then stored in a sealed foil pouch containing desiccant until use.

[0242] In this 2 step assay, the first binding step (functionalized latex 1 with PSA) is carried out in a wet format, before the second binding step (functionalized latex 1-PSA with functionalized paramagnetic particles) occurs using dried

functionalized paramagnetic particles within the 'MST pro strip V1' cartridge as follows:

[0243] Step1

[0244] The following reagents are combined:

[0245] 2  $\mu$ l 0.25% functionalized latex 1 (with bound biotinylated 5A6)

[0246] 6  $\mu$ l 30 mg/ml BSA in PBS, pH 7.2

[0247] 2  $\mu$ l PSA (diluted in 60 mg/ml BSA in PBS, pH 7.2)

[0248] This first step binding reaction is incubated for 5 min at room temperature before 8  $\mu$ l is added to the cartridge (as shown in FIG. 26) containing dried functionalized paramagnetic particles to fill the test sample channels. The 8  $\mu$ l sample is applied to sample inlet port (226) and it fills the channels up to the fluidic stop features (229, 228, 239) 5 min binding incubation occurs before the reader brings a permanent magnet to the cartridge where it acts to collect the paramagnetic particles and anything bound to them into the detection area (222, 241). The sealing head of the reader then makes a fluid tight seal with input ports of channels 1,2,3,4, 5,6 (224, 231, 232, 233, 234, 235 respectively). Whilst the paramagnetic complexes are maintained in place by the magnet, the reader carries out a wash step by expelling air from the syringe pump cartridge to displace the sample fluid from the channel, and hence remove the unbound latex from the detection area (222, 241) and displace it into the sink (236). The optical reader head then carries out a measurement of the remaining fluorescent signal (from the specific sandwich binding complexes of paramagnetic particles-PSA-fluorescent particles) which remain in air by scanning across the detection areas of each channel (222, 241) (see FIG. 24 for a description of these results).

[0249] Results for Assay 5:

[0250] FIG. 24 shows a Total PSA two step assay performed in the MST Pro Meter and Strip, the meter using air wash step to expel unbound label from the channel. Paramagnetic particle capture phase was deposited in the strip. The meter uses an air wash step to expel unbound label from the channel. The paramagnetic particles were deposited in the strip and PSA sample/latex label was added to the strip. The meter performed an air wash and optically measured the concentration of captured fluorescent latex label. A systematic dose response curve is shown for the two step assays and demonstrate that two or three step assays can be formatted on the MST Pro Platform and that paramagnetic particles could be deposited in one strip and used to perform two step assays. These results, together with those of Assay 4 (FIG. 23) show how it would be possible to dry latex and paramagnetic particles within the same cartridge and perform a fully dry 2 step assay.

What is claimed is:

1.-44. (canceled)

45. An assay system for conducting an assay on a fluid sample, the assay system comprising:

- a) a microfluidic cartridge 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 the binding agent within the cartridge comprising magnetic properties;
- a sample port for introducing said fluid sample into the cartridge;
- at least one input port for allowing fluid transport within the cartridge an associated reader device and transported through the microfluidic channel(s); and