

accurate measurements using the MST Pro Meter and Strip (Platform) in very small sample volumes. The sample channel is 1 μL however the volume measured in the MST pro strip V1 by the optical block is only approximately 0.2 μL .

Assay 2: 1 Step Wet Assay with Wash and Measurement Carried Out in 'MST Pro Meter V1' Reader

[0200] Assay reagents are combined in the following volumes and concentrations into an eppendorf tube:

[0201] 0.5% functionalized paramagnetic particles (with bound b1H12): 1 μL

[0202] 30 mg/ml BSA, 0.05% tween all in PBS, pH 7.2: 6 μL

[0203] 0.25% functionalized latex 1 (with biotinylated 5A6 bound): 1 μL

[0204] PSA (diluted in 60 mg/ml BSA in PBS, pH 7.2): 2 μL

[0205] All reagents are mixed and then used to fill the channels of a 'MST pro strip V1' cartridge (see FIG. 26 for description of cartridge used) via sample inlet port (226) where it fills the channels up to the fluidic stop features (229, 228, 237). This cartridge is inserted into a 'MST pro meter V1' reader (see FIG. 12 for a description of the reader used) via connector (230), where a 5 min incubation occurs. The reader then 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 optical reader head then carries out a measurement of the fluorescent signal by scanning across the detection areas of each channel (222, 241). This measurement includes the fluorescent latex specifically bound to the paramagnetic particles via PSA and also any unbound fluorescent latex which is found within the detection area (see FIG. 20 for description of these results). The sealing head of the reader 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 either a) wash buffer (0.1% tween-20 in PBS, pH 7.2) or b) air from the syringe pump cartridge (as shown in FIG. 15, bottom image of 6 chamber syringe cartridge) via the input ports (231, 232, 233, 234, 235, 224) to displace the sample fluid from the channel, and hence remove the unbound latex from the detection area, where it is displaced into the sink (236). The optical reader head then carries out a measurement of the remaining fluorescent signal from the binding complexes within the matrix of the wash substance (fluid or air) by scanning across the detection areas of each channel (222, 241) (see FIG. 19 for a description of these results using the air wash and FIG. 21 for results using the wash buffer wash).

[0206] Results for Assay 2:

[0207] FIG. 20 shows a 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 paramagnetic particle-PSA-fluorescent latex complex are accumulated by the magnet. A highly effective integrated onboard control is summarised in FIG. 20. Before an air or fluid wash is performed by the meter the paramagnetic particle-PSA-fluorescent latex particle complexes are accumulated by the magnet. At this point the meter can perform an optical read of the channels and quantify the concentration of fluorescent latex label as shown in FIG. 20. Interestingly the fluorescent response ADC counts is related to PSA concentration, i.e. a dose response without a wash step, which could be used as a independent homogenous assay. The meter then

performs the wash step and measures the concentration of the paramagnetic particle-PSA-fluorescent latex complexes. The assay fluorescent signal should always be lower after the wash step (air or fluid) as the unbound fluorescent label is removed from the channel.

[0208] FIG. 19 shows Total PSA wet assay performed in the MST Pro Meter and Strip, the meter using an air wash step to expel unbound label from the channel. Total PSA washed wet assays were performed with the MST Pro Meter V1 and Strip. The MST Pro Meter V1 uses an air wash to expel the sample (containing unbound label) from the strip channels in the sink. The results are summarised in FIG. 19, the assay dose response curve clearly demonstrates a rapid, sensitive, accurate and quantitative assay response for Total PSA. The 5 minute test time would be a significant improvement on current rapid POC PSA tests, as would the improvements in sensitivity/accuracy and the quantitative nature of the assay demonstrated. Interestingly the data clearly demonstrates a "air wash" is a very effective method to remove unbound fluorescent label from the channel and that accurate sensitive measurements of the fluorescent labels bound to the paramagnetic particles via analyte (PSA) can be performed in a non liquid environment. This allows simple but highly functional assays to be formatted on the MST Pro Platform.

[0209] FIG. 21 shows an example data dose response curve for Total PSA wet assay performed in the MST Pro Meter and Strip, where the meter uses a fluid wash step to expel unbound label from the channel. The fluid wash is highly effective demonstrating a sensitive, accurate rapid PSA test. In comparison to the air wash methodology the paramagnetic particle-PSA-fluorescent latex label complexes are optically measured in the fluid environment. The fluid buffer wash could contain components that could enhance the fluorescent signal further (for example, chelating agents, fluorescent dye release agents etc).

Assay 3: 1 Step Dry Assay with Wash and Measurement Carried Out in 'MST Pro Meter V1' Reader

[0210] Reagents are deposited and dried within a 'MST pro strip V1' cartridge as follows:

[0211] 8 μL 0.5% functionalized paramagnetic particles (with bound biotinylated 1H12)

[0212] 8 μL 25 mg/ml trehalose in PBS, pH 7.2

[0213] 8 μL 300 mg/ml BSA in PBS, pH 7.2

[0214] 8 μL 0.1% tween-20 in PBS, pH 7.2

[0215] 8 μL 0.25% functionalized latex 2 (with 5A6 bound via SPDP)

[0216] The above reagents are combined and 1 μL of this 1 step 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 and not allowed to enter the detection area (222, 241) (this is achieved by use of a hydrophobic pen line to define the reagent deposition area on a single surface of the laminate cartridge, which is sufficient to prevent reagent spread but not strong enough to prevent sample filling of the fully assembled cartridge by capillary force). 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