

used to move reactants through microscale, or larger, channels in the fluidic chip. The structure of the flow path, as shown from top to bottom in FIGS. 4a and 4b, will generally be designed to effectively convey the fluid sample through the fluidic chip 26: In various embodiments, the sample inlet ports 41 will be generally dimensioned to permit efficient introduction of the fluid sample into the one or more fluidic channels 42 which subsequently flows across the pads 43, 45 and 46, and down to the channel vents 47 where fluid flow eventually terminates. In such embodiments, the fluid sample flow characteristics may be regulated by appropriate setting of the relative dimensions, porosity and surface chemistry of each of the pads 43, 45 and 46, of the channels 42 and of the channel vents 47.

[0066] The fluid sample moving along a channel 42 first comes into contact with a reagent pad 43. The reagent pad 43 is located upstream of the sensor pad 45, separated by a diffusion zone 44. The reagent pad 43 contains a specific quantity of dried target-linker-label conjugates, which has been specifically synthesised for the target analyte, along with quantities of other substances necessary to facilitate the assay. When more than one channel is used to detect different analytes, each reagent pad may contain a conjugate which has been specifically synthesised for each target analyte. In certain embodiments, the fluorescent labels may be functionalised derivatives of the Alexa Fluor (e.g. AlexaFluor 647), BODIPY, Dylight Fluor (e.g. Dylight 649), Cascade Blue, Oregon Green, Lucifer Yellow and Texas Red series of commercially available dyes, or other fluorescent dyes including, but not restricted to, coumarin, fluorescein, rhodamine, eosin, erythrosine and other visible-emitting dyes. It will be appreciated that any of a wide variety of fluorescence conjugation techniques could be used as understood by those skilled in the art.

[0067] In various embodiments, when the fluid sample moving along a channel 42 comes into contact with a reagent pad 43, the fluid flows about each pad thereby facilitating the rapid dissolution of conjugates and other substances necessary to facilitate the assay into the fluid (eg. in less than 3 sec). The fluid then flows along the section of the channel 42 referred to as the diffusion zone 44, subsequently presenting a substantially regular concentration/flow profile of conjugate/fluid sample solution to each of the downstream sensor pads 45. The diffusion zones are important at ensuring that there is uniform and comprehensive dissolving of the conjugate into the sample fluid. The sensor pad 45 comprises an analyte-specific receptor material, (eg. an antibody, antigen, or MIP) immobilised on a carrier material. In various embodiments, a procedural control receptor (eg. a broad spectrum antibody or MIP, and/or antigen,) is positioned downstream from the analyte-specific receptor MIP. The procedural control may be included to ensure that (i) sample fluid has flowed past the analyte-specific receptor, (ii) the right conditions are present for binding of the target analytes and the analyte-specific receptors and/or (iii) the signal reader component of the apparatus 12 is functioning correctly. In one embodiment, when the fluid sample with dissolved conjugates arrives at each sensor pad 45, target analyte molecules in the fluid compete with their respective conjugate molecules for binding by the analyte-specific receptor sites of the MIP material. Target analytes and conjugates bind to the analyte-specific receptor sites and the procedural control receptor sites before flowing onwards. Remaining unbound conjugates are washed away through a second diffusion zone 44 towards the absor-

bent pad 46. Fluid flow terminates at a location downstream of the absorbent pad 46 where a channel vent 47 provides a capillary stop. One advantage of this approach is that the total fluid flow time, i.e., total assay time, measured is typically is about 30 sec, a value that represents a significant enhancement of assay speed when compared with the usual time durations of traditional flow immunoassays. Another advantage of employing reagent 43, sensor 45 and absorbent 46 pads that are introduced into the one or more channels 42 at appropriate locations in a discontinuous, non-contiguous manner, is that, in comparison with a traditional flow immunoassay, the quantity of porous materials employed within the fluid flow path, and, hence, the effective surface area in contact with the fluid sample during flow, can be much smaller. As a result, the levels of unwanted non-specific adsorption of target analytes onto the available pad and channel surfaces is expected to be significantly less pronounced. In various embodiments, this is a factor by which the system 10 facilitates the reliable detection of the presence of target analytes such as, e.g., drugs of abuse, given the low detection thresholds associated with such substances (typically less than 10 to 100 ng/ml).

[0068] In various embodiments, the reader 13 comprises a socket to receive the cartridge 11, a light delivery arm to direct excitation radiation through the cartridge inspection window 34 onto the sensor pad locations 45 in the fluidic chip 26, and a sensing arm to collect and detect fluorescence radiation from each of the sensor locations 45 in parallel, via the inspection window 34. In various embodiments, the analysis system is used with an apparatus 12 the mother instrument 12 which incorporates electronic circuitry with associated software to process the detected signal parameters to generate an immediate reading. In various embodiments, this reading may be of sufficient accuracy for initial screening at the scene, such as at a road checkpoint.

[0069] While the use of fluorescence detection is used as an exemplary detection means herein, it is to be understood that any detection means may be used. In particular, it will be appreciated that directly or indirectly detectable labels can be involved. For example, without limitation, besides fluorescent labels, other labels that can be read optically include gold or silver nanoparticles, which may be detected by light scattering, colorimetric means, etc These examples are in no way exhaustive, but simply illustrate a few of the labelling strategies that can be applied in various embodiments of the current invention.

[0070] With the cartridge 11 inserted into the reader 13, the module is closed to form a lightproof seal. In various embodiments, the module 13 directs an excitation beam of a specific wavelength at each of the sensor pad locations 45 within the one or more channels 42 of the fluidic chip 26 in order to excite the fluorescent dyes in the conjugates that have been bound at each sensor pad 45 during the assay. In various embodiments, the presence of target analyte within the fluid sample prevents binding of the fluorescent conjugates to the antibodies, antigens or molecularly imprinted polymers, According to such embodiments, the concentration of the target analyte is inversely related to the intensity of the fluorescence signal measured at the sensor pad 45. The resulting fluorescence signal arising at each sensor pad location 45 may then be measured and, for example, compared with previously measured and stored calibration data using an algorithm to produce an output electrical signal. In various embodiments, this signal is passed on to the apparatus 12