ANALYSIS SYSTEM

[0001] The present invention relates to analyses of fluid samples to detect the presence of target analytes.

[0002] WO2006017175 describes an apparatus for drugs of abuse screening, including a lateral flow immunoassay, and two types of test are carried out in the one housing.

[0003] The invention is directed towards providing improved screening in terms of consistency and repeatability of results, and/or extent of multiplexing of different tests, and/or ability to cater for impurities in sample fluids.

STATEMENTS OF INVENTION

[0004] According to the invention, there is provided an analysis system comprising:

[0005] a sampling cartridge comprising a housing having an inlet for receiving a fluid sample, a sensor, and a guide extending between the inlet and the sensor for guiding sample into contact with the sensor; and

[0006] an optical detection reader for optically inspecting the sensor;

[0007] wherein the cartridge housing comprises an inspection window; and the reader comprises a socket to receive at least part of the cartridge, and an optical system for inspecting the sensor through the window, and

[0008] wherein the cartridge guide comprises at least one microfluidic channel for flow of sample from the inlet into contact with the sensor.

[0009] In one embodiment, the cartridge guide comprises a plurality of channels, and the channels are preferably separate, without possibility of sample cross-over. The sensor may comprise discrete sensor elements in the at least one channel, and it may include an antibody, an antigen, or molecular imprinted polymer on a substrate.

[0010] Preferably, each channel has a cross-sectional area in the range of about 0.3 mm^2 to about 5 mm^2, and most preferably in the range of about 1 mm^2 to about 2 mm^2. In one embodiment, at least one channel comprises a reagent pad upstream of the sensor, and preferably at least one channel has a free space diffusion zone between the reagent pad and the sensor, the free space being sufficient for comprehensive dissolution of reagent into the sample fluid before reaching the sensor.

[0011] In one embodiment, at least one channel comprises an absorbent pad downstream of the sensor, and preferably at least one channel has an opening at the end of the channel to act as a vent to assist sample fluid flow, and preferably at least one channel has a free space diffusion zone between the sensor and the absorbent pad. In one embodiment, the sensor and each pad are on a strip adhered to a base of the at least one channel.

[0012] In one embodiment, there is a gap above the sensor in the channel, the gap being wide enough to permit flow above the sensor of a small quantity of sample fluid, sufficient to contribute to capillary flow along the channel, and preferably the gap is in the range of 0.05 mm and 0.5 mm.

[0013] In one embodiment, the inlet comprises a swab pressing means. Preferably, the pressing means comprises a hinged handle, wherein the handle forms a cover or lid for the housing, closure of the handle causing an inserted swab to be pressed. In one embodiment, the inlet has an opening configured to receive a swab and allow manual pressing of the swab head. In one embodiment, the inlet comprises a membrane over an inlet volume to allow injection of sample by a syringe. In one embodiment, the inlet comprises an extraction chamber in fluid communication with a draining chamber, fluid travelling from the extraction chamber to the draining chamber in a first direction, and the draining chamber is in fluid communication with at least one channel.

[0014] In one embodiment, the draining chamber comprises a top reservoir and a bottom reservoir, the fluid flowing from the top reservoir into the bottom reservoir in the first direction; and an interface between the top and the bottom reservoir configured to direct the flow of the fluid along the first direction. In one embodiment, the top and the bottom reservoirs have a substantially similar width in a second direction perpendicular to the first direction, and the bottom reservoir has a width in a third direction perpendicular to the first direction and the second direction, and the top reservoir has a width in the third direction larger than that of the bottom reservoir; and the interface between the top and the bottom reservoirs is configured to direct the flow of the fluid along the first direction and the second direction inside the bottom reservoir.

[0015] In one embodiment, there is a plurality of channels and the cartridge comprises a distribution chamber configured for spreading sample fluid flow from the bottom reservoir in the second direction and in the third direction into the channels. Preferably, the interface between the top reservoir and the bottom reservoir is configured to separate or eliminate a bubble in sample fluid above the interface from sample fluid flowing in the first direction across the interface into the bottom reservoir. In one embodiment, the top reservoir has a large volume to assist bubble removal. In one embodiment, there is a narrow interface between the extraction chamber and the top reservoir, thus blocking impurity particles. In one embodiment, the interface is in the form of an elongate slot extending in said second direction. In one embodiment, an intersection of the distribution chamber and the channels is configured with dimensions and shape determining the size of impurity particles blocked from passing from the distribution chamber to the channels.

[0016] In one embodiment, the bottom reservoir and the distribution chamber each have a small dimension in the third direction, said dimension being in the range of 0.25 mm to 2.0 mm.

[0017] In one embodiment, a reagent pad located in at least one channel upstream of the sensor has a porosity determining the size of impurity particles withheld from moving towards the sensor in addition to being optimised for conjugate release.

[0018] In one embodiment, the at least one channel is in a substrate sandwiched between cartridge housing parts. In one embodiment, the cartridge housing has placement features corresponding to and engaging placement features on the substrate, in order to facilitate positioning of said substrate with respect to the inlet. In one embodiment, the substrate has alignment features protruding outside of the cartridge housing and being configured for engagement with corresponding engagement features of the optical detection reader, thereby providing registration between the sensor and the optical detection reader. Preferably, an optical detection reader alignment feature comprises a biased latch member configured for retaining the substrate in position despite mechanical shock. In one embodiment, the cartridge housing has guiding rails that facilitate its insertion into the optical detection reader.