

[0044] FIG. 48 shows a cartridge suitable for use with the rack of FIG. 47, in accordance with an embodiment.

[0045] FIG. 49 shows the tilt rack of FIG. 47 filled with cartridges of FIG. 48, in accordance with an embodiment.

[0046] FIG. 50 shows the results from the HIV antigen and antibody combination assay.

[0047] It is noted that, for purposes of illustrative clarity, certain elements in the drawings may not be drawn to scale.

DETAILED DESCRIPTION

[0048] The present instrumentalities advance the art by providing a simple diagnostic system that solves many of the problems in the field. The system is capable of delivering a panel of serologic assay results rapidly using a small volume of samples including, but not limited to, whole blood, serum, or plasma.

[0049] In one embodiment, the system may contain a device such as a cartridge and a reader instrument capable of reading and processing data obtained from the cartridge. In another embodiment, the disclosed device and system may yield results from multiple fluorescence assays using a single sample. The device (e.g., cartridge) may contain one or more capture molecules such as antigens or antibodies. The device may further contain a fluidic channel to allow for the flow and contact between the sample and the capture molecules. After a sample is loaded onto the device, the analyte(s) in the sample may make contact with the capture molecules. Detection molecules that bind to the analyte(s) may be added to the device to generate signals, which are detected and/or quantified by the reader instrument. In one aspect, the sample may be a fluidic sample from a human, an animal or otherwise obtained from the environment or from an industrial process. In another aspect, the system and method disclosed herein may be employed to deliver a panel of serologic assay results rapidly using a single drop of blood, serum, or plasma sample from a human or an animal. For purpose of this disclosure, a protein may be natural, synthetic or recombinant. The sample suitable for the purpose of the present disclosure may be whole blood sample, serum or plasma.

[0050] It is also disclosed here a method for analyzing a sample having one or more analytes, the method may include: (a) adding the sample or a portion thereof to the device as described herein; (b) allowing the sample to incubate with the plurality of capture molecules on the first surface; (c) adding a detection reagent (such as an antibody) to said device, wherein the detection reagent has been labeled with an excitable tag; and (d) allowing the detection reagent to incubate with the first surface. In another aspect, the method may further include (e) providing light from a light source to illuminate the refractive volume of the device, wherein the light is coupled to the planar waveguide via the refractive volume. In another aspect, the method may further include (f) detecting light signal emitted by the excitable tag. The detection reagent may be, for example, an anti-human IgG antibody or an anti-human IgM antibody. An advantageous feature of the disclosed device is that only a small amount of the sample is required for each assay. For instance, about 30 microliters or less of blood sample is sufficient to ensure full contact between the sample and all reaction sites of the device.

[0051] In another embodiment, a method is disclosed for analyzing a sample having one or more analytes, wherein the method may include the steps of: (a) adding the sample or a portion thereof to a detection reagent and allowing the detec-

tion reagent to bind to target analyte(s) if present; then (b) allowing the sample-detection reagent mixture incubate with the plurality of capture molecules on the first surface. Optionally, (c) applying a wash may be used to remove unbound material from the first surface. In another aspect, the method may further include (d) providing light from a light source to illuminate the refractive volume of the device, wherein the light is coupled to the planar waveguide via the refractive volume. In another aspect, the method may further include (e) detecting light signal emitted by the excitable tag. The detection reagent may be, for example, a fluorescently labeled recombinant antigen, peptide, protein, antibody, or aptamer.

[0052] In another embodiment, a device is disclosed for analyzing a sample having one or more analytes. The device may be in the form of a slide, a cartridge or other forms of solid support. The device may contain a planar waveguide, and a refractive volume. The planar waveguide and the refractive volume may be integrated into one single piece, with the refractive volume being configured for optically coupling light provided by a light source into the planar waveguide. In an embodiment, the refractive volume includes a lens. The planar waveguide may be made of a plastic material that is optically transparent and, additionally, exhibits low autofluorescence. Examples of such optically transparent plastic material include, but are not limited to, cyclic olefin polymer, cyclic olefin copolymer, polyolefin, polystyrene, acrylic, polymethylmethacrylate, polycarbonate, and combinations thereof.

[0053] In another aspect, the planar waveguide may have at least two surfaces, a first surface and a second surface, wherein the second surface is opposite from the first surface. The plurality of capture molecules may be immobilized to the first surface of the planar waveguide. The device may have an inlet port for addition of sample onto the device, and an outlet port for letting out the sample. The device and the planar waveguide may be configured such that, after the sample is loaded onto the device through the inlet port, the first surface is in contact with the sample.

[0054] In another embodiment, the device has a channel to allow the sample to flow therein and to be in contact with the reaction sites and the control sites. The device may further contain a configuration for allowing the sample to be in contact with all reaction sites and control sites.

[0055] In another aspect, at least a portion of the first surface may be modified to improve attachment of the capture molecules to the first surface. In another aspect, the modification may provide means for covalently attaching capture molecules to the first surface; exemplary attachment chemistries include, but are not limited to organosilane or polymer formulations providing epoxy groups, aldehyde groups, amine groups, thiol groups, thiol-reactive groups, or succinimidyl esters. In another aspect, the modification may provide a means for immobilizing capture molecules via hydrophobic interactions; exemplary attachment chemistries include self-assembled monolayers with long chain hydrocarbons. In another aspect, the modification may provide means for immobilization of capture molecules via ionic interactions; exemplary attachment chemistries include polycationic polymers, such as poly-L-lysine. In another aspect, the modification may provide means for immobilization of capture molecules via hydrogen bonding or van der Waals interactions. In another aspect, the modification may provide means for immobilization of capture molecules via ligand binding interactions; an exemplary ligand binding system is avidin-biotin.