

[0075] FIG. 33 is an exploded assembly drawing illustrating the laminar assemblage for a two-piece, extraction assay cartridge in accordance with the schematic diagram given in FIG. 32.

[0076] FIG. 34 depicts a cutaway exploded view of one preferred design for a cartridge reader.

[0077] FIGS. 35(a)-(b) show one embodiment of a cap for a cartridge sample chamber.

[0078] FIG. 36 shows a 3-point cradle design for holding ampoules in a cartridge.

[0079] FIGS. 37(a)-(b) show a schematic representation of a fluidic design for one embodiment of a cartridge.

[0080] FIGS. 38(a)-(e) show one embodiment of a liquid collection chamber.

[0081] FIG. 39 shows one configuration of fluidic junctions in the fluidics of a cartridge.

[0082] FIG. 40 shows a hydrodynamic resistance matched fluid flow path.

[0083] FIG. 41(a) is a color contour plot showing the effect of channel dimensions on hydrodynamic resistance. FIG. 41(b) is a black and white version of the color plot depicted in FIG. 41(a).

[0084] FIG. 42 shows one embodiment of an ampoule breaking mechanism for rupturing glass ampoules in a cartridge.

[0085] FIGS. 43(a)-(g) show cutaway views of one embodiment of a cartridge reader design with a cartridge tray in the fully extended and fully retracted positions (color FIGS. 43(a) and (b), respectively). FIGS. 43(c)-(e) show schematic representations of the mechanisms for inserting and properly positioning the cartridge tray within this reader design. FIGS. 43(f) and (g) are black and white depictions of FIGS. 43(a) and (b).

[0086] FIGS. 44(a)-(d) show top views of one embodiment of a cartridge tray for holding a cartridge in a cartridge reader. Views are provided showing (a) a cartridge partially inserted in the tray and (b) a cartridge fully seated in the tray. FIGS. 44(c) and (d) are black and white depictions of FIGS. 44(a) and (b).

[0087] FIGS. 45 (a)-(b) show one embodiment of a mechanism for supporting a photodiode within a cartridge reader and for aligning the photodiode with array elements or electrodes within the cartridge.

[0088] FIGS. 46(a)-(g) show a schematic representation of the operation of the photodiode alignment mechanism of FIG. 45.

[0089] FIGS. 47(a)-(c) illustrate one embodiment of a sample chamber that includes a sample overflow chamber and a sample volume indicator window.

DETAILED DESCRIPTION

[0090] The invention, as well as additional objects, features and advantages thereof, will be understood more fully from the following detailed description of certain preferred embodiments. Where the terms “measure” or “measurement” are used herein, they are understood to encompass quantitative and qualitative measurement, and encompasses measurements carried out for a variety of purposes including, but not limited to, detecting the presence of a thing or property, measuring the amount of a thing or property, and/or identifying a thing or property in a sample. Unless otherwise defined herein, scientific and technical terms used in connection with the present invention shall have the meanings that are commonly understood by those of ordinary skill in the art. Fur-

ther, unless otherwise required by context, singular terms shall include pluralities and plural terms shall include the singular. The articles “a” and “an” are used herein to refer to one or to more than one (i.e., to at least one) of the grammatical object of the article. By way of example, “an element” means one element or more than one element.

[0091] The present invention includes apparatuses, electrodes, electrode arrays, systems, system components, kits, reagents and methods for performing one or more assays on a sample. The invention includes assay modules (e.g., assay cartridges, assay plates, etc.) having one or more assay cells (e.g., wells, compartments, chambers, conduits, flow cells, etc.) that may comprise one or more assay domains (e.g., discrete locations on a assay cell surface where an assay reaction occurs and/or where an assay dependent signal, such as an electrochemical or preferably an electrode induced luminescence signal is induced) for carrying out a plurality of assay measurements.

[0092] In certain preferred embodiments, assay domains are supported on assay electrodes (preferably, an array of assay electrodes, most preferably a one dimensional array of assay electrodes) so as to permit the conduct of assays based on electrochemical or electrode induced luminescence measurements. The assay domains are, optionally, defined by a dielectric layer deposited on the electrodes. The assay modules, preferably, have one or more attributes that make them suitable for use in “point of care” clinical measurements, e.g., small size, low cost, disposability, multiplexed detection, ease of use, etc. The methods and apparatuses of the invention, allow these benefits to be achieved while maintaining the performance of traditional batch processing instruments of the type typically used in the central clinical lab.

[0093] The assay module may comprise the necessary electronic components and/or active mechanical components for carrying out an assay measurement, e.g., one or more sources of electrical energy, ammeters, potentiometers, light detectors, temperature monitors or controllers, pumps, valves, etc. Preferably, some or all of the electronic and/or active mechanical components are arranged within a separate assay module reader. The reader would also have the appropriate electrical, fluidic and/or optical connections to the assay module for carrying out an assay on the assay module. Using such an arrangement, the assay module can be designed to be low cost and disposable while the reader (which holds the more expensive and complex components) is reusable. A preferred assay procedure using an assay module and assay reader would comprise inserting the cartridge in the reader, making the appropriate electrical, fluidic and/or optical connections to the cartridge (making use of electrical, fluidic and/or optical connectors on the cartridge and reader), and conducting an assay in the cartridge. The sample is preferably introduced into the cartridge prior to inserting the cartridge in the reader. The assay may also involve adding one or more assay reagents to the cartridge; preferably, one or more assay reagents are stored in the cartridge in a dry and/or wet form.

[0094] The invention also includes methods of preparing the assay modules including methods for preparing electrode arrays and forming assay domains on these electrode arrays. The invention also includes methods for washing assay domains to remove unbound reagents without allowing these reagents to interact with other surfaces in the assay module.

[0095] One preferred embodiment of the invention comprises an assay cartridge comprising one or more assay flow cells. The assay flow cell comprises a chamber having a fluid