ASSAY CARTRIDGES AND METHODS OF USING THE SAME

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims priority to U.S. Provisional Application No. 60/436,569, filed Dec. 26, 2002, which is incorporated herein by reference.

FIELD OF THE INVENTION

[0002] This application relates to apparatuses, systems, kits and methods for conducting chemical, biochemical and/or biological assays on a sample. These apparatuses include assay cartridges and cartridge readers for conducting these assays. The application also describes electrode arrays for use in assays, methods of preparing and using these electrode arrays and diagnostic devices comprising the arrays. These electrode arrays may be incorporated into the cartridges and apparatuses of the invention.

BACKGROUND OF THE INVENTION

[0003] Clinical measurements have been traditionally carried out in central clinical labs using large clinical analyzers that can handle large numbers of samples in batch mode. These laboratories are staffed by trained personnel that are capable of maintaining and running these complex analyzers. There is a growing desire to move clinical measurements from the central lab to the "point of care", e.g., the emergency room, hospital bedside, physicians office, home, etc. Point of care measurements allow a care provider or patient to quickly make decisions based on diagnostic information, as opposed to having to wait hours or days to receive laboratory results from a clinical lab. The difficulty in developing point of care diagnostic systems has been making them small enough and easy enough to use so that they can be used by unskilled operators in decentralized clinical settings, but at the same time maintaining the low cost, diverse assay menu, and/or high performance of tests carried out on traditional clinical analyzers in central laboratories.

SUMMARY OF THE INVENTION

[0004] The invention relates in part to assay modules, preferably assay cartridges. An assay module of the invention incorporates one or more fluidic components such as compartments, wells, chambers, fluidic conduits, fluid ports/vents, valves, and the like and/or one or more detection components such as electrodes, electrode contacts, sensors (e.g. electrochemical sensors, fluid sensors, mass sensors, optical sensors, capacitive sensors, impedance sensors, optical waveguides, etc.), detection windows (e.g. windows configured to allow optical measurements on samples in the cartridge such as measurements of absorbance, light scattering, light refraction, light reflection, fluorescence, phosphorescence, chemiluminescence, electrochemiluminescence, etc.), and the like. A module may also comprise reagents for carrying out an assay such as binding reagents, detectable labels, sample processing reagents, wash solutions, buffers, etc. The reagents may be present in liquid form, solid form and/or immobilized on the surface of solid phase supports present in the cartridge. In certain embodiments of the invention, the modules include all the components necessary for carrying out an assay. In other embodiments, the invention also includes a module reader adapted to receive the module and carry out certain operations on the module such as controlling fluid movement, supplying power, conducting physical measurements on the cartridge, and the like.

[0005] The invention also relates, in part, to a method of performing a plurality of assays wherein an assay dependent signal is measured using a plurality of electrodes. Preferably, at least one of the electrodes is used as a working electrode for measuring an assay dependent signal and, subsequently, as a counter electrode for measuring a different assay dependent signal at a different electrode. In one preferred embodiment, at least two of the electrodes are used as a working electrode and, subsequently, as a counter electrode. Most preferably, the method uses at least a dedicated counter electrode, a dedicated working electrode and two or more additional electrodes, each of which is used as a working electrode for measuring an assay dependent signal and, subsequently, as a counter electrode for measuring a different assay dependent signal at a different electrode.

[0006] In another preferred embodiment, a method of performing a plurality of biochemical assays using a plurality of electrodes is disclosed. The method comprises the steps of applying electrical energy between first and second electrodes, measuring an assay dependent signal at the second electrode, applying electrical energy between the second electrode and a third electrode and measuring an assay dependent signal at the third electrode. The measured assay dependent signal is, preferably, selected from electrical current, electrical potential and/or electrode-induced luminescence. The second and third electrodes can each have an assay reagent immobilized thereon. Furthermore, each electrode can have a different assay reagent immobilized thereon where each assay reagent can be specific for a different analyte of interest.

[0007] In one embodiment, the plurality of electrodes can be arranged within a flow cell. In a preferred embodiment, the flow cell can have a flow cell path along which the electrodes may be arranged. The electrodes can be arranged along the path, sequentially. Moreover, the electrodes can be arranged such that the first electrode is adjacent the second electrode and the second electrode is adjacent the third electrode. The electrodes can be arranged within a single detection chamber. Additionally, the electrodes may comprise printed carbon ink. Further, the assay reagents may be immobilized on the electrode surface within an assay domain defined by a dielectric layer on the electrodes.

[0008] In yet another embodiment, the electrodes may have electrical leads for supplying electrical energy to the electrodes. The electrical leads may comprise exposed surfaces that at least partially define an inlet conduit in fluid communication with the flow cell. The method may then include the further step of applying an inlet conduit interrogation potential between the exposed surfaces of the electrical leads to determine the presence or composition of fluid in the inlet conduit. Preferably the interrogation potential would be of insufficient magnitude to induce electrochemiluminescence.

[0009] According to another aspect of the invention, an apparatus for performing a plurality of biochemical assays is disclosed. The apparatus may comprise a plurality of electrodes comprising at least one dedicated working electrode, at least one dual-role electrode and at least one dedicated