LAMINATED ASSAY DEVICES

BACKGROUND OF THE INVENTION

[0001] Various analytical procedures and devices are commonly employed in assays to determine the presence and/or absence of analytes in a test sample. For instance, immunoassays utilize mechanisms of the immune systems, wherein antibodies are produced in response to the presence of antigens that are pathogenic or foreign to the organisms. These antibodies and antigens, i.e., immunoreactants, are capable of binding with one another, thereby causing a highly specific reaction mechanism that may be used to determine the presence or concentration of that particular antigen in a biological sample. There are several well-known techniques for detecting the presence of an analyte.

[0002] One such technique is described in WO 01/38873 to Zhang. Zhang describes flow-through electrochemical biosensors designed to detect the presence of an analyte. **FIG. 2** of Zhang, for instance, illustrates a sensor assembly **5** that includes an absorbent pad **18**, a wicking mesh **22**, and a conjugate pad **20** that overlay an application area **14**' and a detection area **16**'. The wicking mesh **22** functions as a carrier to deliver the fluid sample through capillary action to the detection area **16**' where the analyte will become immobilized on the electrode surface. In Example 4 of Zhang, various materials of different pore sizes (ranging from 0.63 to 100 microns) were tested to determine the time for a buffer solution to flow **4** centimeters along the membrane. The times ranged from 40 seconds to 3 minutes, 45 seconds. Zhang indicates that any of the membranes tested could be used to provide a rapid test.

[0003] Unfortunately, conventional flow-through electrochemical biosensors, such as described above, possess various problems. For instance, traditional flow-through assay devices require a large sample volume because of the presence of a large sampling pad, wicking pad, and porous membrane. Moreover, the contact of the sample with the working electrode surface is not always sufficient because a large portion of the sample does not flow through the electrode surface, rather it flows through the membrane itself and bypasses the working electrode. Furthermore, the positioning of two or more electrodes close to each other poses a challenge for the surface treatment of the working electrode. In particular, such biosensors often exhibit substantial background interference due to contamination of the counter/reference electrode(s) resulting from surface treatment of the working electrode. As such, a need still exits for an improved flow-through, electrochemical assay device.

SUMMARY OF THE INVENTION

[0004] In accordance with one embodiment of the present invention, an assay device is disclosed for detecting the presence or quantity of an analyte residing in a test sample. The assay device comprises a first substrate defining a first surface on which is disposed a detection working electrode. The assay device further comprises a second substrate defining a second surface on which is disposed an auxiliary electrode (e.g., counter electrode, reference electrode, or combinations thereof). The first substrate and the second substrate are at least partially laminated together so that the first surface faces the second surface, wherein the detection working electrode is capable of generating a measurable detection current that is proportional to the amount of the analyte within the test sample.

[0005] In accordance with another embodiment of the present invention, an assay device for detecting the presence or quantity of an analyte residing in a test sample is disclosed. The assay device comprises a first substrate defining a first surface on which is disposed a detection working electrode treated with an affinity reagent. The assay device further comprises a second substrate defining a second surface on which is disposed a counter electrode, a reference electrode, or combinations thereof. The first substrate and the second substrate are at least partially laminated together so that the first surface faces the second surface, wherein the detection working electrode is capable of generating a measurable detection current that is proportional to the amount of the analyte within the test sample.

[0006] In accordance with still another embodiment of the present invention, a method for forming an assay device is disclosed. The method comprises treating a detection working electrode disposed on a first surface of a first substrate with an affinity reagent. Thereafter, the first substrate is at least partially laminated to a second substrate. The second substrate defines a second surface on which is disposed an auxiliary electrode, wherein the first surface of the first substrate faces the second surface of the second substrate.

[0007] In accordance with yet another embodiment of the present invention, a method for detecting the presence or quantity of an analyte residing in a test sample is disclosed. The method comprises treating a detection working electrode disposed on a first surface of a first substrate with an affinity reagent. Thereafter, the first substrate is at least partially laminated to a second substrate, the second substrate defining a second surface on which is disposed an auxiliary electrode. The first surface of the first substrate faces the second surface of the second substrate. A test sample is allowed to contact the detection working electrode. A potential difference is applied between the detection working electrode and the auxiliary electrode to generate a detection current. In some embodiments, the method may further comprise applying a potential difference between a calibration working electrode disposed on the first surface of the first substrate and the auxiliary electrode to generate a calibration current. The calibration current may be used to calibrate the detection current.

[0008] Other features and aspects of the present invention are discussed in greater detail below.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] A full and enabling disclosure of the present invention, including the best mode thereof, directed to one of ordinary skill in the art, is set forth more particularly in the remainder of the specification, which makes reference to the appended figures in which:

[0010] **FIG. 1** is a schematic illustration of a substrate containing working electrodes for use in one embodiment of an assay device of the present invention;

[0011] **FIG. 2** is a schematic illustration of a substrate containing auxiliary electrodes for use in one embodiment of an assay device of the present invention;

[0012] **FIG. 3** is a schematic illustration of one embodiment for forming an assay device from the substrates of **FIGS. 1 and 2**;