ELECTROCHEMICAL-BASED ANALYTICAL TEST STRIP WITH HYDROPHILICITY ENHANCED METAL ELECTRODES

BACKGROUND OF INVENTION

[0001] 1. Field of the Invention

[0002] This invention relates, in general, to analytical devices and, in particular, to electrochemical-based analytical test strips and associated methods.

[0003] 2. Description of the Related Art

[0004] The determination (e.g., detection and/or concentration measurement) of an analyte in a fluid sample is of particular interest in the medical field. For example, it can be desirable to determine glucose, cholesterol, acetaminophen and/or HbA1c concentrations in a sample of a bodily fluid such as urine, blood or interstitial fluid. Such determinations can be achieved using analytical test strips, based on, for example, photometric or electrochemical techniques, along with an associated meter. For example, the OneTouch® Ultra® whole blood testing kit, available from LifeScan, Inc., Milpitas, USA, employs an electrochemical-based analytical test strip for the determination of blood glucose concentration in a whole blood sample.

[0005] Typical electrochemical-based analytical test strips employ a plurality of electrodes (e.g., a working electrode and a reference electrode) and an enzymatic reagent to facilitate an electrochemical reaction with an analyte of interest and, thereby, determine the concentration of the analyte. For example, an electrochemical-based analytical test strip for the determination of glucose concentration in a blood sample can employ an enzymatic reagent that includes the enzyme glucose oxidase and the mediator ferricyanide. Further details of conventional electrochemical-based analytical test strips are included in U.S. Pat. No. 5,708,247, which is hereby incorporated in full by reference.

BRIEF DESCRIPTION OF DRAWINGS

[0006] A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[0007] **FIG. 1** is a simplified exploded perspective view of an electrochemical-based analytical test strip according to an exemplary embodiment of the present invention;

[0008] **FIG. 2** is a simplified plan view of the patterned conductive layer of the electrochemical-based analytical test strip of **FIG. 1**;

[0009] **FIG. 3** is a simplified plan view of a portion of the electrically-insulating substrate, conductive layer and insulating layer of the electrochemical-based analytical test strip of **FIG. 1**;

[0010] **FIGS. 4A and 4B** are simplified depictions of a chemical sequence for treating a gold metal electrode surface and the resulting gold electrode surface with hydrophilicity-enhancing moieties thereon, respectively.

[0011] **FIG. 5** is a bar chart depicting the water contact angle for a clean gold substrate surface, a clean polyester substrate surface, a clean gold substrate surface treated with MESNA and a clean polyester substrate surface treated with MESNA;

[0012] **FIG. 6** is a bar chart depicting the water contact angle for a clean gold substrate surface, a clean gold substrate surface treated with MESNA and a clean gold substrate surface treated with MESNA after storage for two weeks;

[0013] **FIG. 7** is an artist's rendition of a photographic image of a portion of a comparison electrochemical-based analytical test strip with gold electrodes in the absence of hydrophilicity-enhancing moieties on the upper surface of the gold electrodes;

[0014] **FIG. 8** is a chart of current response versus YSI determined glucose concentration for a comparison electrochemical-based analytical test strip with gold metal electrodes in the absence of hydrophilicity-enhancing moieties on the upper surface of the gold electrodes;

[0015] **FIG. 9** is an artist's rendition of a photographic image of a portion of an electrochemical-based analytical test strip with gold metal electrodes according to an exemplary embodiment of the present invention that includes hydrophilicity-enhancing moieties on the upper surface of gold metal electrodes;

[0016] **FIG. 10** is a chart of current response versus YSI determined glucose concentration for an electrochemical-based analytical test strip with gold metal electrodes according to an exemplary embodiment of the present invention that includes hydrophilicity-enhancing moieties on the upper surface of the gold metal electrodes; and

[0017] **FIG. 11** is a flow chart of a process for manufacturing a portion of an electrochemical-based analytical test strip according to an exemplary embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0018] An embodiment of an electrochemical-based analytical test strip according to the present invention includes an electrically-insulating substrate and at least one metal electrode (e.g., a gold metal electrode) disposed on a surface of the electrically-insulating substrate. In addition, the metal electrode has an upper surface with hydrophilicity-enhancing chemical moieties thereon and an enzymatic reagent layer disposed on the upper surface. Details, characteristics and benefits of such an electrochemical-based analytical test strip are described with respect to the further embodiments discussed below.

[0019] **FIG. 1** is a simplified exploded perspective view of an electrochemical-based analytical test strip **10** according to the present invention. Electrochemical-based analytical test strip **10** includes an electrically-insulating substrate **12**, a patterned conductor layer **14**, an insulation layer **16** (with electrode exposure window **17** extending therethrough), an enzymatic reagent layer **18**, a patterned adhesive layer **20**, a hydrophilic layer **22** and a top film **24**. As will be described in more detail below with respect to **FIGS. 2, 3, 4**A and **4**B, patterned conductor layer **14** includes three electrodes and at least a portion of each of these electrodes has an upper surface with hydrophilicity-enhancing moieties (depicted in **FIG. 4B**) thereon.