

[0036] A is an area of the electrode at which a reaction occurs (also referred to as the active surface area of the electrode);

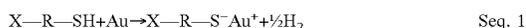
[0037] and

[0038] J is the flux of a species of interest to the electrode.

[0039] Based on equation 1 above, a reliable and accurate determination (e.g., quantification) of an analyte concentration in a fluid sample requires knowledge of the area of the working electrode at which the reaction occurs. It has been determined that the sensing area of an electrode in an electrochemical-based analytical test strip is dependent on the uniformity and adherence of an enzymatic reagent layer to the electrode throughout manufacturing and during use. In addition, it has been determined that employing a metal electrode with hydrophilicity-enhancing moieties thereon improves the uniformity and adherence of enzymatic reagent layers and, thus, the reproducibility and accuracy of results obtained with electrochemical-based analytical test strips that employ such metal electrodes.

[0040] FIGS. 4A and 4B are simplified depictions of a chemical sequence for treating a gold metal electrode surface 40 and the resulting gold metal electrode surface with hydrophilicity-enhancing moieties 42 thereon, respectively. FIG. 4A depicts the manner in which gold metal surface 40 is exposed to a hydrophilicity-enhancing composition 44 to produce hydrophilicity-enhancing moiety 42 and liberate hydrogen.

[0041] The reaction that occurs between a gold metal electrode surface and the thiol (—SH) group of hydrophilicity-enhancing composition 44 is described by a general reaction sequence of the form:



[0042] where:

[0043] X is either a polar side group, a positively charged side group, or negatively charged side group;

[0044] R is a carbon chain from, for example, C₁ to C₅;

[0045] SH is a thiol group;

[0046] Au represents atomic gold;

[0047] and

[0048] X—R—S⁻Au⁺ represents a gold metal electrode surface with a hydrophilicity-enhancing moiety thereon.

[0049] In sequence 1 above, R can be beneficially limited to the range of C₁ to C₅ to provide a hydrophilicity-enhancing composition that is soluble, yet avoids the formation of self-assembled monolayers on the gold metal electrode surface. Self-assembled monolayers of hydrophilicity-enhancing moieties need not necessarily be avoided, but their formation is difficult to control, often slow and can require an electrode surface that is “atomically” clean. The manufacturing of such self-assembled monolayers is, therefore, more difficult than the non-self-assembled disposition of hydrophilicity-enhancing moieties that occurs spontaneously by dip coating an electrode surface with a MENSNA solution as described elsewhere in this disclosure.

[0050] Furthermore, the thiol group (also referred to as a “tail” group) enables a conjugation between the gold metal electrode surface and the hydrophilicity-enhancing composition to occur. In addition, the polar, positively charged or negatively charged side group “X” (also referred to as a “head” group) provides for a hydrophilic interaction with an enzymatic reagent layer, thereby improving the uniformity and adherence of the enzymatic reagent layer to the metal electrode upper surface. Examples of suitable head groups include, but are not limited to, the following groups: NH₂ (amine) group, COOH (carboxy) group, and SO₂OH (sulphonate) group.

[0051] As noted above, the length of the “R” group (also referred to as a “spacer chain”) is a factor in determining whether or not the hydrophilicity-enhancing moieties are disposed on the electrode surface as a self-assembled monolayer.

[0052] Although FIGS. 4A and 4B and sequence 1 are illustrated for the circumstance of a gold metal electrode surface, once apprised of the present disclosure one of ordinary skill in the art will recognize that other metal electrode surfaces can also be beneficially treated to dispose hydrophilicity-enhancing moieties thereon.

[0053] Enzymatic reagents are formulated such that they readily mix with common fluid samples (such as a whole blood or other bodily fluid sample) and, therefore, typically consist of components that are readily soluble in aqueous solutions. It has been determined that such components have an affinity for hydrophilic or at least amphiphilic surfaces.

[0054] A variety of metal electrode surfaces are naturally hydrophobic. In other words, such metal electrode surfaces tend to repel water, aqueous solutions, and solutions with significant hydrophilic component content (such as enzymatic reagents). However, it has been determined that such metal electrode surfaces can be rendered more hydrophilic (i.e., be hydrophilically-enhanced) by treating the metal electrode surfaces with a hydrophilicity-enhancing composition that disposes hydrophilicity-enhancing moieties on the metal electrode surface.

[0055] Examples of hydrophilicity-enhancing compositions are compositions that contain 2-mercaptoethanesulphonic acid (MESNA), 3-mercaptopropanesulphonic acid, 2,3-dimercaptopropanesulphonic acid and its homologues, bis-(2-sulphoethyl)disulphide, bis-(3-sulphopropyl)disulphide and homologues; mercaptosuccinic acid, cysteine, cysteamine, and cystine. When such hydrophilicity-enhancing compositions include a compound with a sulphonate moiety (e.g., MESNA) or a compound with an amino moiety (e.g., cysteamine), the adhesion of an enzymatic reagent layer to the upper surface of a metal electrode is particularly enhanced.

[0056] FIG. 5 is a bar chart depicting the water contact angle for clean gold substrate surface (A), a clean polyester substrate surface (B), a clean gold substrate surface treated with MESNA (C) and a clean polyester substrate surface treated with MESNA (D). FIG. 6 is a bar chart depicting the water contact angle for a clean gold substrate surface (A, as in FIG. 5), a clean gold substrate surface treated with MESNA (C, as in FIG. 5) and a clean gold substrate surface treated with MESNA after storage for two weeks (E). The MESNA treatment reflected in FIGS. 5 and 6 was a 5 minute exposure to a MESNA composition consisting of 4 g/L of MESNA in water.