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[54] **ELECTROCHEMICAL ENZYME ASSAY**

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This patent is subject to a terminal disclaimer.

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Related U.S. Application Data

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[58] **Field of Search** 435/7.6, 18, 23, 435/24, 817, 287.2, 287.7, 287.9; 204/403

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[57] **ABSTRACT**

A diagnostic kit, method, and apparatus for electrochemically determining the presence or concentration of an analyte in a sample. A mixture is formed which includes the sample, an enzyme acceptor polypeptide, an enzyme donor polypeptide, and a labeled substrate. The enzyme donor polypeptide is capable of combining with the enzyme acceptor polypeptide to form an active enzyme complex. The formation of such the active enzyme complex is responsive to the presence or concentration of the analyte in the fluid sample. The active enzyme hydrolyzes the labeled substrate, resulting in the generation of an electroactive label, which can then be oxidized at the surface of an electrode. A current resulting from the oxidation of the electroactive compound can be measured and correlated to the concentration of the analyte in the sample.

31 Claims, 5 Drawing Sheets