TEST STRIPS FOR DETECTING THE PRESENCE OF A REDUCED COFACTOR IN A SAMPLE AND METHOD FOR USING THE SAME

FIELD OF THE INVENTION

The field of this invention is analyte measurement

BACKGROUND OF THE INVENTION

Analyte measurement in physiological fluids, e.g., blood or blood derived products, is of ever increasing importance to today's society. Analyte detection assays find use in a variety of applications, including clinical laboratory testing, home testing, etc., where the results of such testing play a prominent role in diagnosis and management in a variety of disease conditions. Analytes of interest include alcohol, formaldehyde, glucose, glutamic acid, glycerol, beta-hydroxybutyrate, L-lactate, leucine, malic acid, pyruvic acid, steroids, etc. In response to this growing importance of analyte measurement, a variety of analyte measurement protocols and devices for both clinical and home use have been developed. Many of the protocols and devices that have been developed to date employ a signal producing system to identify the presence of the analyte of interest in a physiological sample, such as blood.

While a variety of such signal producing systems have been developed to date for use in the measurement of a wide variety of different analytes, there continues to be a need for the further development of such systems.

Relevant Literature

Patent documents of interest include: EP 0 908 453 A1; WO 94/01578 and WO

SUMMARY OF THE INVENTION

Test strips and methods for their use in the detection of an analyte in a sample are provided. The subject test strips are characterized by at least including a water soluble tetrazolium salt on a surface of a positively charged substrate. In many embodiments, the water soluble tetrazolium salt is present as part of an analyte oxidizing signal producing system, which system includes one or more of the following additional components: an analyte oxidizing enzyme, e.g., an analyte dehydrogenase or an analyte oxidase; an electron transfer agent; and an enzyme cofactor. Also provided are systems and kits incorporating the subject test strips. The subject test strips, systems and kits find use in the measurement of a wide variety of analytes in a sample, such as a physiological sample, e.g., blood or a fraction thereof, or ISF (interstitial fluid).

BRIEF DESCRIPTION OF THE FIGURES

FIG. 1 provides the results of a 400 mg/dl Glucose Test conducted on positively charged and non-charged membranes, using water soluble tetrazolium as indicator according to the subject invention.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

Test strips and methods for their use in the measurement of an analyte in a sample are provided. The subject test strips are characterized by at least including a water soluble tetrazolium salt on a surface of a positively charged substrate. In many embodiments, the water soluble tetrazolium salt is present as part of an analyte oxidizing signal producing system, which system includes one or more of the following additional components: an analyte oxidizing enzyme, e.g., an analyte dehydrogenase or an analyte oxidase; an electron transfer agent; and an enzyme cofactor. Also provided are systems and kits incorporating the subject test strips. The subject test strips, systems and kits find use in the detection of a wide variety of analytes in a sample, such as a physiological sample, e.g., blood or a fraction thereof, or ISF (interstitial fluid).

Before the subject invention is described further, it is to be understood that the invention is not limited to the particular embodiments of the invention described below, as variations of the particular embodiments may be made and still fall within the scope of the appended claims. It is also to be understood that the terminology employed is for the purpose of describing particular embodiments, and is not intended to be limiting. Instead, the scope of the present invention will be established by the appended claims.

In this specification and the appended claims, singular references include the plural, unless the context clearly dictates otherwise. Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood to one of ordinary skill in the art to which this invention belongs.

COMPOSITIONS

As summarized above, the subject invention provides compositions for use in detecting a wide variety of analytes in a sample. The compositions include a positively charged substrate and water soluble tetrazolium salt present on the surface of the substrate, typically as a member of an analyte oxidizing signal producing system. The subject compositions are typically present as dry compositions, such as are found in reagent test strips. In particular, the invention provides strips for assaying for a particular analyte in whole blood or a derivative fraction thereof, e.g., glucose, alcohol, glycated proteins, etc. In the broadest sense, the reagent test strips include a positively charged substrate and an analyte oxidizing signal producing system present on a surface of the substrate, which system includes a water soluble tetrazolium salt.

The above elements of the subject compositions are now further described in greater detail.

Positively Charged Substrate

A feature of the subject compositions is the presence of a positively charged substrate. By positively charged substrate is meant a substrate that displays one or more, usually a large plurality of, positive charges, e.g., as found on positively charged groups or moieties, on at least one of its surfaces. The substrate may be fabricated from a single material or may be a composite of two or more different materials, where these different materials may be blended, layered, or otherwise arranged to provide for the desired positively charged surface.

In addition, the positively charged substrate may be bibulous or non-bibulous. By bibulous is meant a material that exhibits preferential retention of one or more components as would occur, for example, in materials capable of absorbing or "imbibing" one or more components, as occurs in chromatographic separations. Examples of bibulous materials include, but are not limited to: untreated forms of paper, nitrocellulose and the like which result in chromatographic separation of components contained in liquids which are passed therethrough.

Alternatively, the positively charged substrate may be non-bibulous. Non-bibulous positively charged substrate