NEAR REAL TIME BIOSENSOR FOR THE FACTOR V LEIDEN DIAGNOSIS (04031)

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Technology description

Extremely short assay time (approximately ten minutes);
There are currently no real time diagnostic tools or sensors for Factor V Leiden.
Detection and diagnosis of disease is usually a necessary prerequisite to treatment and/or curing of the disease. With many inherited diseases, definitive diagnosis must often occur at a molecular level, and typically includes DNA testing, which can be impractical and expensive owing to the complex and time-consuming procedure inherent to DNA testing. This is especially true of diseases caused by single point mutations, where the historical difficulty in obtaining purified monoclonal antibodies leaves DNA testing as the only viable method of diagnosing disease. While this is true of most diseases caused by single point mutations, one exemplary disease is a clotting disorder associated with a single point mutation of the gene encoding Factor V, where the mutated gene is known as Factor V Leiden.
To maintain a normal physiological system, it is crucial for blood to travel in an unobstructed manner through the vascular system. When injury occurs to the body, hemostasis assists in clot formation to prevent the loss of blood, while conversely, an anti-coagulant system ensures that the clot is localized at the site of damage rather than inside blood vessels. Naturally, disturbances in the hemostatic system result in diminished ability to dissolve clots in blood vessels, which can cause traumatic thromboembolitic results. Thromboembolism may cause a variety of dangerous conditions within the body, such as deep vein thrombosis, lung embolism, stroke, and heart attack as normal blood flow from the heart to the body organs is blocked.
The most well-recognized inherited thrombophilic conditions include a resistance to the anti-coagulant Activated Protein C, as well as deficiencies of anti-coagulants, such as Protein C, Protein S, and Antithrombin III deficiencies. For example, Factor V is a blood coagulant that is inhibited by Activated Protein C. The single point mutation to Factor V that results in Factor V Leiden (FVL) causes a resistance to Activated Protein C, thereby preventing the inhibition by Activated Protein C of the clotting activity associated with Factor V.
FVL is the most common hereditary blood coagulation disorder in the Unites States. It is present in 5% of the Caucasian population and 1.2% of the African American Polulation. FVL increases the risk of venous thrombosis approximately 3-8 fold for heterozygous and 30-140 folds for homozygous individuals.
Annually, as many as 600,000 hospitalizations and approximately 50,000 deaths are caused by

pulmonary embolism alone. It has been estimated that death from pulmonary embolism results within 30 minutes on onset. Despite the widespread belief that FVL is responsible for a significant number of these hospitalizations and fatalities, clinicians do not routinely screen for FVL. This failure to screen may result, in part, from the lack of widely accepted detection methods.

Presently, most accurate FVL detection methods require DNA analysis, which are impractical for routine screening. Consequently, FVL is usually screened with a clotting assay that is not sufficiently specific for, FVL. Conventional methods are not able to distinguish between FVL and other types of blood disorders, such as deficiencies in Protein C or Antithrombin. In fact, because FVL results in a resistance to Activated Protein C, FVL and Protein C deficiency may be indistinguishable with current assay protocols.

In view of the large population of affected individuals, early screening of FVL could make affected individuals aware of their high risk for thromboembolic complications and encourage them to take preventive actions. This may help to avoid the enormous after-care expenses incurred by victims - including physical debilitation and also emotional stress.

Researchers in the Chemical Engineering Department of the University of Louisville have developed a sensor and method to quantify both normal Factor V and Factor V Leiden in blood plasma by using fiber-optic immunosensors. Quantification can be performed in approximately ten minutes using this method and the immunosensor can also provide information as to the status and progression of the disease.

Advantages

Early diagnosis of Factor V Leiden disorders.

The process may be applied to other single point mutation diseases

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