

FORENSICS & DIAGNOSTIC SOLUTIONS LICENSING OPPORTUNITIES

Method and apparatus for determining hemocompatibility

Invention Summary

An assay for detecting conformational changes in adsorbed fibrinogen as a measurement of material hemocompatibility.

Background

In the field of medical devices, many devices are designed to come into direct contact with patient blood. Such devices may include externals ones such as catheters and stents, as well as external devices such as oxygenators and apheresis units. Devices in contact with human blood may trigger certain biological responses, such as inflammation or coagulation of the blood. Such coagulation of the blood may be mediated by certain blood proteins, such as fibrinogen.

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Modifications in the conformation of adsorbed fibrinogen may lead to the exposure of certain internal epitopes. Exposure of such epitopes may result in platelet adhesion or thrombosis. Therefore, a sensitive and robust test for detecting conformation changes of fibrinogen adsorbed on material surfaces may be beneficial for the screening and development of novel biomaterials.

The currently available analytical technologies for assessing the conformation of adsorbed fibrinogen are complicated, expensive, time-intensive, and of limited sensitivity. As such, these techniques are unsuitable for high-throughput biomaterial screening.

Technology

This Cytiva invention provides techniques for screening materials for hemocompatibility. These techniques take advantage of conformational changes that may occur in fibrinogen when this protein is adsorbed on certain materials. Adsorption of fibrinogen onto a material with a corresponding conformational change may prevent cleavage of fibrinogen by thrombin. When thrombin cleavage is prevented or reduced, the cleavage products of fibrinogen, such as fibrinopeptide A or fibrinopeptide B, are also reduced. Accordingly, the products of thrombin cleavage of fibrinogen may be assessed to determine the hemocompatibility of a material.

The techniques provide an advantage over previous techniques for evaluating materials by measuring fibrinogen conformational changes upon adsorption as a marker for hemocompatibility. While fibrinogen adsorption onto a material may influence the formation of fibrin on the surface of the material, which may ultimately influence platelet adhesion and coagulation, fibrinogen adsorption alone may not be directly related to platelet adhesion.

Figure 1 below illustrates the process for performing the hemocompatibility screening according to the present techniques

Figure 2 below is a representative standard curve for fibrinopeptide A (FPA);

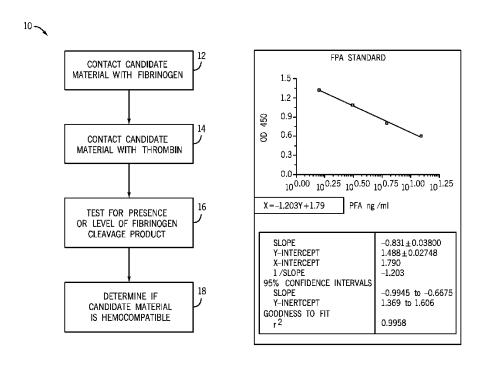


FIG. 1 FIG. 2