



New Licensing Opportunity

Assay for rapid detection of human APC using a monoclonal antibody (MAB)

Field of Technology: Diagnostic for cardiovascular disorders (Thrombosis & Sepsis)

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Background: Worldwide, more than a million people die from thrombosis every year. Almost 1400 people die per day from Septic shock. Individuals with high propensity towards thrombotic disorders and Sepsis show reduced levels of Protein-C and Activated Protein-C (APC) in blood. Recent studies suggest that APC is an effective treatment for Septic shock. Hence, a quick and accurate evaluation of blood APC levels in critically ill patients is highly important. Accurately measuring APC levels can also help identify individuals with higher propensity to thrombosis.

Several clinical reports have stated that Protein-C supplementation can substantially improve the clinical outcome of Sepsis treatment. However, in some cases, Protein-C supplementation appears to increase APC production to a variable extent. In addition, some patients with severe sepsis have much lower APC levels than would be anticipated based on other clinical evaluations. This indicates malfunctioning of Protein-C activation mechanism. In such cases, use of APC to treat the patients is very important. Ability to measure circulating APC in situations that demand a quick decision whether to

use APC or Protein-C, or to continue APC treatment in previously treated patients, greatly help the treatment of Sepsis.

Disadvantages of Traditional Approach: Currently, there are 2 approaches to measuring APC levels.

1) Thrombin in combination with Thrombomodulin (TM), and aided by Endothelial Cell Protein-C Receptor (EPCR), activates Protein-C to form APC. Hence, first approach attempts to analyze APC levels by measuring TM and EPCR expressed in endothelium (to determine the efficiency of TM and EPCR activity). Disadvantage is that it is impossible to determine the efficiency of TM and EPCR activity without removing blood vessels.

2) The 2nd approach measures APC levels in circulation by using antibodies directed against Protein-C that cross-react with APC. The disadvantages of this approach are the low specificity of antibodies used, and the extensive time (3 to 4 weeks) required to develop the assay.

Advantages of OMRF's Invention: Quick and highly accurate. The MAB fragment used in this invention has high specificity towards APC. It can detect APC in plasma within one hour, making clinical detection of APC practical.

Stage of Development: Proof of concept studies completed. Technology is ready for rigorous testing and development.



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