

innovations

from the University of Vermont

TITLE: HIGHLY SENSITIVE IMMUNOASSAYS AND ANTIBODIES FOR DETECTION OF BLOOD FACTOR VIII

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DESCRIPTION: The invention provides highly sensitive immunoassays and antibodies capable of accurate detection of FVIII concentration in the plasma of normal human subjects and those with hemophilia. This assay detects FVIII concentrations significantly below 1% normal physiological concentration which is important for management of hemophilia and in FVIII replacement therapy. Levels of detection exhibited by particular embodiments greatly exceed those of previously described assays. This assay works between 1-4000 pM (0.001-4 nM, 3 orders of magnitude range). The enhanced sensitivity of the assays is contributed in part by using a combination of two antibodies that can bind human FVIII protein in plasma with high affinity and selectivity following treatment with an agent that causes the FVIII to dissociate from FVIII-binding molecules to which it is bound, such as Von Willebrand factor (vWF).

ADVANTAGES: Sensitivity of the assay is contributed in part by the very high binding affinity of a preferred capture antibody, and by ability of the anti-FVIII antibodies used in the assay to bind to FVIII protein under conditions in which the protein is dissociated from FVIII-binding molecules such as von Willebrand factor after treatment with a reducing agent. Using this method, the concentration of FVIII protein detectable in the sample is between about 0.001 nM and 1000 nM. This assay is not only useful for quantifying FVIII in healthy individuals and hemophilia patients, it can also be used to quantify FVIII in FVIII concentrates. FVIII assay is useful to quantify FVIII in patients with anti-coagulant antibodies (anti-phospholipid antibodies such as Lupus where APTT cannot be used).

PATENT STATUS: Patent pending

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