

METHOD FOR MANUFACTURING A TISSUE FACTOR-BASED PROTHROMBIN TIME REAGENT

ABSTRACT OF THE DISCLOSURE

A method for manufacturing a tissue factor-based prothrombin-time reagent includes combining predetermined quantities of tissue factor (TF), phospholipid and detergent-containing buffer to create a TF/phospholipid mixture. In this combining step, the quantity of TF is predetermined based upon its measured TF activity. Next, the detergent is removed from the TF/phospholipid mixture to produce an essentially detergent-free TF/phospholipid mixture that is useful as a tissue factor-based PT reagent. The method can include the use of hydrophobic resin that has been prescreened based on phospholipid recovery to accomplish the removal of the detergent.

Figure 1