



# Quantitative determination of activated coagulation factor XI as an impurity in therapeutic immunoglobulins from Chinese blood fractionation companies

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**ABSTRACT.** Residual activated coagulation factor XI (FXIa) has been suggested to play an important role in thromboembolic events associated with the use of intravenous immunoglobulin (IVIG) lots. This study investigated the predominant plasma proteases in 42 IVIG lots from 4 Chinese manufacturers. In one-stage clotting assays, the procoagulant activities of factors II, VII, IX, X, XI, and XII were quantified. Non-activated partial thromboplastin time and a modified thrombin generation test served as global and FXIa-specific clotting assays, respectively. We found that coagulation factor clotting activities of the 42 IVIG lots were below the detection limit of the assays, except for the products of manufacturer B (lots of 2010), in which 0.030 to 0.032 IU/mL FXI:C were detected. The peak time of thrombin using a thrombin generation test was greater than 35 min, the relevant amount of FXIa was below 0.37 nM, and non-activated partial thromboplastin time was greater than 200 s. Consequently, the 42 IVIG lots showed non-significant

procoagulant potential. Further study is required to determine whether a program for FXIa determination in IVIG products should be launched in China.

**Key words:** Activated coagulation factor XI; Thromboembolic events; Intravenous immunoglobulin; Thrombin generation test