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Titel des Beitrags: Clinical multicenter evaluation of a new FXa-based Antithrombin assay.

Abstract: The determination of functional Antithrombin is a central part of thrombophilia screening. In this multicenter study, a new FXa-based method (INNOVANCE® Antithrombin) was evaluated on four different analyzers. The INNOVANCE Antithrombin method was evaluated by precision and reference interval studies and by comparing the new method with established methods through parallel measurement of samples from 249 patients and 151 apparently healthy individuals. The INNOVANCE Antithrombin assay demonstrated on all analyzers repeatability coefficients of variation (CVs) <= 3.2% and within-device and between-run CVs <= 6.9%. The reference intervals of all analyzers are comparable with 2.5th percentiles between 80% and 85% of normal. The INNOVANCE Antithrombin and the FIIa-based Berichrom® AT III (A) methods demonstrated good concordance with correlation coefficients of r = 0.908 or higher. The INNOVANCE Antithrombin method demonstrated furthermore an excellent comparability with the STA® Antithrombin III assay and an acceptable comparability with the Coamatic® LR Antithrombin assay. The patients with congenital deficiency (n = 31) were identified with all assays except for the patients carrying the P41L heparin-binding site mutation, which was only identified with the INNOVANCE Antithrombin and the STA Antithrombin III methods.
INNOVANCE Antithrombin assay has high sensitivity for Antithrombin deficiencies and is reliable, precise and suitable for routine clinical use.