Validation of PKA Kinetic Assay and Screening of Korea Intravenous Plasma Derivatives

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To validate the kinetic assay for prekallikrein activator, a potential vasodilator, comparison of the methods and co-laboratory test is performed. For the reproducible and sensitive assay, prekallikrein, a substrate of prekallikrein activator, was carefully purified on a DEAE ion-exchange chromatography and the potency was validated. In the comparison of other methods, the coefficient variation between end-point and kinetic assay using 9 lots of human albumin preparations was within ±6.6% and the mean recovery of kinetic assay was 101.9%, but the commercial assay showed 82.1% due to the different composition of assay buffers between the methods. As a further validation study for the assay reliability, the co-laboratory test was performed between 4 laboratories and the mean standard deviation was determined as ±1.7 IU/mL and the co-relation factor was 0.9914 when applied to 7 lots of human albumin preparations. As an inter-assay, mean coefficient variation between experimenters at each laboratory is below ±4.1%. With reliable kinetic assay, prekallikrein activator contents of the blood products are investigated. In the intravenous immunoglobulin preparations (32 lots), all test result showed non-detectable prekallikrein activator content and in the human serum albumin (171 lots), the average prekallikrein activator contents was 5.8 IU/mL. There was no significant variation of prekallikrein activator content in blood products relating to plasma sources and manufacturing sites so far. This assay was now applied to the lot release test to improve the quality control of related blood products since June, 2002 in Korea.

Key word: PKA, Hypotension, Blood Products, Co-laboratory, Validation