Abstract It is well known that most immunoassay systems are highly precise but are poor in compatibility of their determinations. Thus, it is difficult to compare the determinations among different systems, posing problems when a patient is transferred to different hospitals or when a laboratory intends to change the system currently used. In the study, we tried to approach how to assure inter-immunoassay compatibility among four different systems through determination of the exchanged calibrators. First, determinations of total protein and albumin, and electrophoretic fractionation demonstrated marked differences among calibrators in their protein constituent. Some calibrators were prepared with human sera, but others were with inorganic or non-human albumin-based solution. Regression analysis of calibrators between the indicated concentrations by manufacturers and those actually determined by the different immunoassay systems revealed that; most slopes were closed to 1.0 for α—fetoprotein and prostate—specific antigen, but widely dissociated from 0.28 to 4.71 for CA19–9. In evaluation of clinical serum samples, determinations by one immunoassay system were compared with those converted based on a linear regression equation that was obtained by determination of the exchanged calibrators. However, this procedure could not improve compatibility, and positive effects of conversion varied by immunoassay systems combined, and also by test parameters.

With these, we concluded that simple conversion of determinations by using the exchanged calibrators and a statistical linear regression could not provide us with the expected compatibility. Thus, standardization of target molecules or probes, and of calibrator constituent were urgent issue to assure inter-immunoassay compatibility.

Key words: Compatibility of determination (測定値互換性), determination of exchanged calibrators (キャリブレータ相互測定), constituent of calibrator (キャリブレータ組成), immunoassay (免疫測定), standardization (標準化)