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Study for the development of *in vitro* method determining the potency of anti-tetanus human immunoglobulin

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Anti-tetanus human immunoglobulin (hTIG) is biologics which is prepared by plasma fractionation and is administered for the prophylaxis or treatment of tetanus. For this purpose, it is essential to measure the accurate potency of hTIG. Currently, the potency of hTIG for quality control is tested by *in vivo* toxin neutralization assay. However, *in vivo* method is time-consuming, relatively expensive, and raises ethical issues regarding the use of live mammals. The aim of this study is to establish *in vitro* potency method based on enzyme-linked immunosorbent assay (ELISA). We developed *in vitro* method and compared with 2 commercial EIA kits. There was no significant difference between developed and commercial kits when statistically analyzing their precision and accuracy. The method validation study was conducted on developed EIA kit according to ICH guideline. All validation parameters including accuracy, precision, specificity, linearity and range satisfied the defined specification. Correlation study between currently used *in vivo* method and *in vitro* method couldn't show the correlativity because of the insufficient experiments, but importantly there was no statistical distinction of potencies obtained by *in vitro* and *in vivo* methods (p=0.2423). Finally, *in vitro* potency of national standard hTIG candidate was tested collaboratively in 3 laboratories. The candidate hTIG standard material was assigned a potency of 37.15 international units (IU) per vial by the international standard hTIG (NIBSC, TE-3). In conclusion, we developed a reliable EIA kit for *in vitro* hTIG potency assay. However, further study is needed to confirm that the developed *in vitro* assay can be used as an official quality control test.

Biography

Yong Seok Kang has completed his Ph.D. from Gwang ju Institute of Science and Technology. He is currently the scientific officer of blood product team, National Lot Release Center of South Korea.

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