S03-4 Development of bioanalytical methods for therapeutic mAbs

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In recent years, as the use of therapeutic mAbs has progressed, the necessity of bioanalysis for proper use in clinical examination, development of new drugs and biosimilars has been increased. For these purposes, ELISA methods are mainly performed. Although ELISA methods permit high-sensitivity and high-throughput analysis, some potential exists for cross-reactivity of capture antibodies and low accuracy. Therefore, specific and highly reliable bioanalytical methods complementing conventional ELISA methods have been desired. We developed a simple, accurate bioanalytical methods for therapeutic mAbs which combines affinity purification and high-temperature reversed-phase LC with native fluorescence detection. Furthermore, we succeeded in acquiring anti-idiotype DNA aptamer that specifically recognizes the complementary determining region of bevacizumab as new molecular recognition molecule replacing capture antibodies. Our developed anti-bevacizumab DNA aptamer is not only with high affinity (K_d = 12 nM) for bevacizumab but also low-cost, chemically stable, and easy to modify compared to anti-monoclonal antibodies. In this symposium, we also introduce two kinds of bioanalytical methods those using this aptamer. Our methods are inexpensive and versatile, and these have sufficient sensitivity and good quantitativity to perform bioanalysis in various area such as drug development and clinical examination.