Thrombin generation assay for IVIG product, 11/13

Haemtech Biopharma Services announced the successful validation of a thrombin generation assay for an intravenous immunoglobulin drug. The assay was validated in 2012 to support the use of TGA as a release assay for Biotest Pharmaceuticals' FDA biologics license application for BIVIGAM, an immune globulin intravenous (human), 10 percent liquid product. The validated TGA assay was designed and performed on the Calibrated Automated Thrombogram platform from Diagnostica Stago.

TGA is a universal test capable of assessing a research subject's global hemostatic balance in the case of hemorrhage or thrombosis. The CAT method is both specific and sensitive, thus giving increased relevance to hemostatic testing in academic research centers, pharmaceutical companies, and contract research organizations.

Using this specific and effective method, coagulation factor XIa-like procoagulant activity can be measured in IVIG and other plasma-derived therapeutics. In this way, the thrombogenic potential of these drugs can be measured, enabling manufacturers to increase the safety of their drug product and satisfy regulatory requirements for product submission.

***Haemtech Biopharma Services**, 802-878-1777*