Assay Evaluation Project BAY94-9027

BAY 94-9027 is a Site-Specifically PEGylated B-Domain-Deleted Recombinant FVIII which has demonstrated safety and efficacy in more than 5 years of clinical studies.

Because BAY 94-9027 is a modified molecule, there is the potential for differences in performance when it is measured with certain coagulation assays established for standard FVIII products. To support medical laboratories in their need for BAY 94-9027 assay performance information, Bayer has entered into a partnership with North American Specialized Coagulation Laboratory Association (NASCOLA) and External quality Control for Assays and Tests (ECAT) to develop BAY 94-9027 quality control samples for proficiency evaluation and further data collection on assay performance within the coagulation testing community.

The Evaluation Sample Sets contain BAY 94-9027 active pharmaceutical ingredient (API) spiked into FVIII depleted human plasma at 5 different target concentrations from 0.05 IU/mL to 1.5 IU/mL. The individual BAY 94-9027 QC sample vials are lyophilised for reconstitution with 2 mL of water prior to potency testing. Laboratories are requested to measure these samples in multiple dilutions with either one-stage clotting assay and/or a chromogenic assay according to their regular laboratory protocol. Results and detailed information about the methodology used are returned to ECAT using a standard report form. Laboratories will receive a report after evaluation of their results.

Laboratories interested in participation in this project can obtain one Evaluation Set free of charge. You can order an Evaluation Set at the ECAT website:
http://www.ecat.nl/information/assay-project-bay94-9027