Measuring Factor Activity in Patients Infused with Modified FVIII and FIX Products

Factor VIII Product	Modification	One-stage assay			Chromogenic Assay
		Actin FSL	Pathromtin SL	STA-aPTT	
		Soy Phosphatides; Ellagic acid activator	Vegetable PL; Silica activator	Cephalin; Silica activator	
Eloctate® Antihemophilic Factor, Fc Fusion Protein[1]	Immunoglobulin Fc fragment	Performed as for unmodified	Performed as for unmodified	Performed as for unmodified	Overall 20-30% higher activity with CS but significant inter-laboratory variation
Adynovate® Antihemophilic Factor, PEGylated[2]	20 kDa polyethylene glycol	Performed as for unmodified	Performed as for unmodified	Performed as for unmodified	Intra- and inter-assay variability higher with CS than OS
Factor IX Product					Note no FDA licensed FIX chromogenic assay yet
Alprolix® Coagulation Factor IX, Fc Fusion Protein[3, 4]	Immunoglobulin Fc fragment	Performed as for unmodified	**Less than unmodified (25-50%)**	**Less than unmodified (25-50%)**	Performed as for unmodified
Idelvion® Coagulation Factor IX, Albumin Fusion Protein[4,5]	Albumin tag	**Less than unmodified (~50%)***	Performed as for unmodified	Performed as for unmodified	Not reported

*Reported with Actin FS, and we have seen with Actin FSL

References:

1. Sommer JM, et al. Comparative field study evaluating the activity of recombinant factor VIII Fc fusion protein in plasma samples at clinical haemostasis laboratories. Haemophilia;2014:294-300.
2. Turecek, et al, ISTH-SSC, May 25-28, 2016
3. Sommer JM, et al, Comparative field study: impact of laboratory assay variability on the assessment of recombinant factor IX FC fusion protein (rFIXFc) activity. Thromb Haemost. 2014;112:932-940.
4. Kitchen S. World Federation of Haemophilia, Orlando, FL, July 2016.
5. St. Ledger et al, World Federation of Haemophilia, Orlando, FL, July 2016.

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