

Clarification of the Accuracy Study Plan 1/3

Aim of study:

To show the accuracy of the turoctocog alfa pegol (N8-GP) Chromogenic assay by using the (b) (4) method One-stage clotting assay

Clarification of the Accuracy Study Plan 2/3

Parameter	Description
Assays	Chromogenic and One-stage clotting*
Samples	N8-GP drug product placebo + N8-GP reference material (b) (4) (same matrix)
(b) (4)	(b) (4)
(b) (4) potency	(b) (4)
Study design, both assays	(b) (4)
Acceptance criteria for recovery	(b) (4)

(b) (4)

2 pages determined to be not releasable: (b)(4)