MEMO

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To: Dr. Bidwell


Tests on Clinical Trial batch 9D 999

Here are the results of the additional tests for potential thromogenicity performed on a range of samples from the batch 9D 999:

1. Tests performed on samples of the final unheparinised pool prior to distribution and freeze-drying.

   TGt50 6 minutes
   FDA, thrombin/fibrinogen time > 6 hours
   NAPTT
     1/10 257 seconds
     1/100 277 seconds
     Mean control 285 seconds

2. Tests performed on a sample from a bottle reconstituted as for clinical use (containing 4 u/ml heparin).

   (a) NAPTT (heparin not neutralised) 1/10 > 420 seconds
      1/100 256 seconds
      Mean control 275 seconds

   (b) NAPTT (heparin neutralised with protamine sulphate) 1/10 365 seconds
      1/100 386 seconds
      Mean control 399 seconds

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