

# Evaluation of Factor VIII Values in Cryoprecipitated AHF Products after Implementation of Chromogenic Factor VIII Testing

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Session # Online

**Background** Factor VIII (FVIII) activity is evaluated to demonstrate consistency of the collection and freezing processes for both Cryoprecipitated AHF for transfusion and Plasma Frozen Within 24 Hours of Phlebotomy (RPF < 24hours) for fractionation. A large regional donor testing facility that was using a clotting method for FVIII/Fibrinogen quality control testing implemented a chromogenic method and the new WHO FVIII Standard in 2006. A comparison of overall average FVIII values for component production facilities for clotting and chromogenic methods was performed.

**Methods** Overall average Factor VIII values for an 18 month period (July 2004 – December 2005) using the clotting method were calculated and compared to an 18 month period (July 2006 – December 2007) using the chromogenic method and the new standard. The acceptable average for Cryoprecipitated AHF in the U.S. is 80% activity. The acceptable average for RPF < 24 hours, according to the European Pharmacopeia, is  $\geq 0.7$  IU/ $\mu$ L. Results for Cryoprecipitated AHF product testing only were used, as RPF < 24hours products were not routinely tested for FVIII during the 18 month period for the clotting method.

**Results** The overall average FVIII result for July 2004 through December 2005, exclusively using a clotting method, was 207 % activity or 2.1 IU/ $\mu$ L. The overall average FVIII result for July 2006 through December 2007, exclusively using a chromogenic method, was 166% activity or 1.7 IU/ $\mu$ L. This represents a decrease of 41% activity or 0.4 IU/ $\mu$ L due to the combined change of the methodology and new WHO standard.

**Conclusion** Use of the chromogenic method and WHO standard resulted in lower overall FVIII values for component production facilities producing Cryoprecipitated AHF products. The primary cause for the decrease appears to be use of the new WHO standard since the majority of the component production facilities involved had no significant process changes to their product preparation methods in the timeframes used for this comparison

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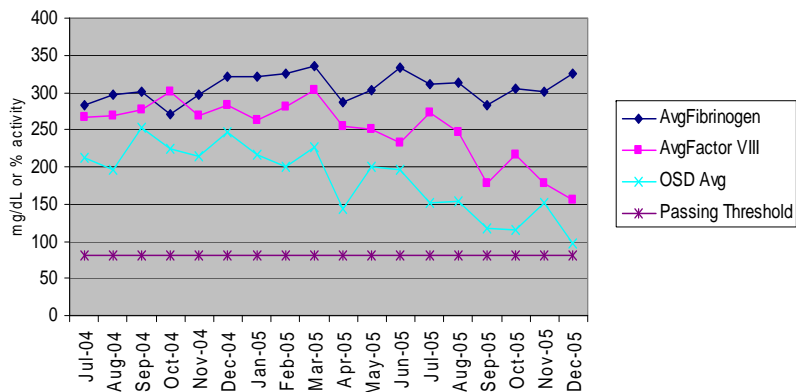
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BSI and OSD Average FVIII and Fib Jul '04-Dec '05



BSI and OSD Average FVIII and Fib Jul 06-Dec 07

