2.02 Laboratory issues

CALIBRATION OF HUMAN COAGULATION FACTOR VIII IN NOVEL QUALITY CONTROL MATERIALS: A COLLABORATIVE STUDY

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Background and Aims. Participation in Proficiency Testing Schemes (PTS) enables laboratories to continuously monitor their analytical performance, demonstrate their technical competence and the validity of their quality system, identify any issues and implement appropriate corrective actions. It is considered essential for laboratories involved in haemophilia A diagnosis to prove accuracy and precision of the final outcomes and ensure patients' safety. In this study, two candidate preparations of pooled fresh frozen human plasma were characterized and calibrated to provide Quality Control Materials (QCMs) for assessing Human Coagulation Factor VIII (FVIII) assays, with the aim of proposing a proficiency study for haemophilia centres. Selection of appropriate QCMs is one of the critical factors that must be carefully evaluated when organizing an interlaboratory comparison.

Materials and Methods. Fresh frozen plasma units were involved in the production of QMCs. All starting materials were characterized for serological and molecular markers of viral infection, haemagglutinins, and factor VIII. The final preparations were calibrated in a collaborative study, organized by the National Centre for the Control and Evaluation of Medicines of the Istituto Superiore di Sanità (ISS). This study involved 21 laboratories, which performed one-stage clotting assays (OSCAs) and chromogenic substrate assays (CSAs) to estimate FVIII activity. Prior to sending samples to haemophilia centres, homogeneity and stability of the obtained materials were studied.

Results. The collaborative study enabled the assignment of FVIII potency to the two candidate preparations and the evaluation of consistency between chromogenic and one-stage clotting assay results. The results of homogeneity and stability experiments showed that preparations did not undergo any significant changes when stored at - 20°C and used within 24 hours of thawing.

Conclusions. The final materials could be used to establish a proficiency testing scheme for assessing the performance and reliability of coagulation laboratories in FVIII testing.