INTERNAL VALIDATION OF THE POWERPLEX® FUSION SYSTEM KIT

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To offer services using new technology as a regular service, laboratories that perform paternity tests, and that are accredited under ISO 17025, must carry out internal validations to verify that the methods are reliable and robust.

The Genes SAS Laboratory performed an internal validation of the PowerPlex® Fusion System STRs amplification kit (Promega CO) in the Applied Biosystems® 3500 Genetic Analyzer. This kit is a 24-locus multiplex, that contains 13 autosomal STR loci included in the core of the CODIS (U.S.A.), as well as the 12 markers from the European Standard Set (ESS). The kit also includes the sex-determining Amelogenin locus and the Y-STR DYS391. It uses 5-colours and is regularly used in human identification applications.

This study was made following the recommendations of the European Network of Forensic Science Institutes (ENFSI) and the Revised Validation Guidelines of the Scientific Working Group on DNA Analysis Methods (SWGDAM). The analyzed validation allowed to determine the analytical threshold, DNA control samples, a proficiency test, relations between quality and the final reaction volume, reproducibility, precision, accuracy, and concordance. The results of this internal validation showed that the PowerPlex® Fusion System produces accurate and reproducible STR profiles.