Beyond the Validation: Finding the Balance of QA Requirements and Understanding the Data Prior to Implementation into Casework

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Information from suppliers, scientific journal articles or affiliated organisations can provide information that guide the validation for a new chemistry for any step in the DNA profiling process. Typically, a developmental validation has been completed by the supplier and an internal validation or performance check is completed by each individual laboratory.

SWGDAM[1] outline validation requirements for individual laboratories which include concordance, reproducibility, accuracy and precision, sensitivity and stochastic effects and mixture studies. The details of these requirements are informative but balancing of sample numbers versus robust results to establish conclusions and subsequent guidelines is more tricky.

Focusing on three pieces of work, the validation of quantitation kits, STR amplification kits (both autosomal STRs and Y STRs) and Genetic Analysers, I will describe the lessons learnt from validation studies at the Institute of Environmental Science and Research Ltd (ESR). The goal being an understanding of the performance of each kit or instrument including its limitations when used on casework like samples.

For example as sensitivities of extraction and amplification methods have improved, quantitation kits with lower limits of detection have been developed. We examined the alignment of quantitation values and profiling results in samples and controls at the extreme lower limits of detection of the system.

Understanding the reproducibility of data from amplification kits and how this may affect the interpretation of DNA results for casework samples containing varying numbers of contributors is explored as well as demonstrating whether a Y STR specific multiplex gives results from female DNA. Also are the different sensitivities of each Genetic Analyzer used in a laboratory sufficient to warrant repeated validation on each instrument with all amplification kits or not?

This presentation explores these variables in more detail and aims to answer the question of how to ensure fit for purpose validation or performance checks are undertaken prior to implementation in a laboratory.

1. Scientific Working Group on DNA analysis methods. Validation Guidelines for DNA analysis methods. (https://www.swgdam.org/publications)