

Criminalistics Section – 2007

B104 A Streamlined Approach to Validating New Forensic DNA Technologies

Ralph Jocham, BS, Gloria Lam, MBA, Sharada Vijaychander, MS, Jacquelyn Benfield, BS*, Karen Cormier, BS, and Ravi Gupta, MS, Applied Biosystems, 850 Lincoln Centre Drive, Foster City, CA 94404

After attending this presentation, attendees will have learned how the application of a novel software package specifically designed for Forensic DNA laboratories will improve the speed and ease of validation and implementing a new technology.

This presentation will impact the forensic community and/or humanity by demonstrating a software solution that will enable laboratories to effectively and efficiently implement new technologies while meeting SWGDAM/DAB recommendations.

As the demand for processing DNA evidence has continued to grow, so has the development of new technologies for DNA analysis. These factors can make it difficult for a crime laboratory to strike a balance between successful case workload management and the evaluation and implementation of new technologies. Laboratory accreditation and Forensic DNA Analyst education require careful assessment and thorough validation studies. Validation studies provide objective evidence help to ensure the generation of robust, reliable, and reproducible data and in turn, confidence in the DNA results.

There is a variety of challenges the Forensic DNA laboratory faces when implementing a new methodology. A common challenge identified by laboratories is a lack of resources available for validation. Laboratories also point to the existence of diverse opinions with respect to validation protocols, sample numbers, and definition of appropriate and effective experiments as notable challenges. These variables have been shown to contribute to extensive validation studies that include unnecessary or excessive tests without the benefit of additional confidence. In addition, data management and analysis are cumbersome processes that are often manual operations or utilize a series of limited tools which analysts have developed on their own.

In order to streamline the validation process as well as meet SWGDAM/DAB recommendations, a software solution was developed by the Human Identity group at Applied Biosystems to include the following unique features:

- · Easy to use software program with a simple graphical user interface requiring minimal training.
- Experimental design tools and recommendations that assist laboratories in establishing Forensic DNA-specific validation protocols.
- Integration of all portions of validation and workflow processes including; Automated generation of worksheet and applicable set- up files for quantitation, dilution, normalization, mixture prepa- ration, amplification, capillary electrophoresis and genotyping.
- Validation-specific data analysis and graphing tools that help identify optimal operating parameters and performance character- istics required to establish standard operating procedures and interpretation guidelines.
- Project and documentation management that will enable a labo- ratory to track the progress of the validation and effectively maintain all validation-associated information for accreditation and/or auditing purposes.

Validation, STR Validation, Data Analysis