

A NEW MODEL OF VALIDATION SUPPORT SERVES LABORATORY NEEDS AND THE EXPEDITED IMPLEMENTATION OF NEW METHODOLOGIES

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In June 2009, the North Louisiana Criminalistics Laboratory (NLCL) purchased guided validation services from QIAGEN, Inc. The employment of QIAGEN to offer validation support is new to the forensic community. The services consisted of a two day on-site visit where a validation set of samples was generated in-house, but guided by QIAGEN, Inc., and tailored to the forensic needs of our laboratory. In two days more than 250 DNA samples on three QIAGEN instruments were extracted and purified using the Investigator Kit chemistry. The resultant validation sample set generated satisfied all requirements as mandated by the July 1, 2009 revision of the FBI Quality Assurance Standards (QAS) and ISO/IEC 17025, and included sensitivity and stochastic studies, reproducibility and precision, known and non-probative, mixture studies, and contamination assessment.

The practices employed in our laboratory describe the time efficient and cost effective use of NIJ funds to purchase and validate two instruments, the QIAGEN BioRobot EZ1 Advanced XL and the Applied Biosystems 3130 XL. Additionally, our practices explain how the in-house generated validation DNA sample set was subsequently used to validate two multiplex PCR analysis kits: Promega's PowerPlex 16 HS and Applied Biosystems AmpFISTR SEfiler Plus. The time and cost efficient methods, observations, and results generated using the in-house generated validation DNA sample set for each instrument and chemistry will be presented. Additionally, the sensitivity and stochastic effects observed from the two multiplex PCR kits will be discussed, and the results of the two multiplex PCR kits will be compared to the forensic casework method currently used by the NLCL, the PowerPlex 16 System. The resulting work demonstrated (1) the value of validation test kits to expedite extensive validation; (2) the design and implementation of the validation according to the relevance of the customer's needs; (3) the compliance with the FBI's Quality Assurance Guidelines, July 2009 revision; and (4) the compliance with the- ISO/IEC 17025:2005(E) document.