VALIDATION OF THE DNAscan™ RAPID DNA ANALYSIS™ SYSTEM: PRESENTATION OF DATA

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Introduction: The DNAscan Rapid DNA Analysis System, when fully integrated into the law enforcement environment, will increase the speed of DNA processing, minimize crime lab backlogs, and help lower the cost of law enforcement by providing a biometric link between a criminal activity and an individual being held in custody. The aim of this presentation is to proffer for the first time the experimental plan and results obtained to date of system's performance verification testing and developmental validation.

Materials and methods: The performance verification testing and developmental validation studies were designed and conducted to evaluate the "swab in to profile out" system as a whole, and the expert system software as an individual component. Challenging samples such as those demonstrating off-ladder alleles and triallelic patterns were incorporated into the set of test samples. The developmental validation studies were performed in partnership with several laboratories across the world. The FBI's Quality Assurance Guidelines for validation were followed and the primary studies included sensitivity, reproducibility, contamination, and precision.

Results and discussion: The results of the performance verification testing and developmental validation will be presented. Data from fresh and dried buccal swabs, blood swabs, and purified DNA samples will be presented. Additionally, results of ongoing reagent stability studies will be presented to demonstrate long-term, room temperature stability of the BioChipSet™ Cassette, which houses all reagents needed for the DNA processing. The presentation of the results will provide the forensic community the necessary information to make a data-driven decision about robustness and reliability of the DNAscan system for implementation in the crime laboratory and law enforcement environment.