Developmental Validation of the DNAscan™ Rapid DNA Analysis™ Instrument and Expert System: Reference sample processing for upload to the National DNA Index System

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The comprehensive developmental validation was performed to objectively demonstrate the reliability, reproducibility and robustness of the DNAscan Rapid DNA Analysis System across a number of laboratories and buccal sample variations. The goal of this extensive study was to obtain, document, analyze, and assess if the data generated by the DNAscan and its internal Expert System can reliably genotype reference samples in a manner compliant with the FBI's Quality Assurance Standards (QAS) and the NDIS Operational Procedures. The practical knowledge and subject matter expertise of accredited, NDIS-participating laboratories was sought and integrated into the design and execution of the experiments.

A general overview of the system and integrated expert system will be provided. The DNAscan System consists of an instrument, sample collection kit, single-use disposable BioChipSet Cassette using PowerPlex® 16 chemistry, and integrated Expert System for automated data analysis. Additionally, the developmental validation approach, sample collection procedure, and overall study design will be presented.

The developmental validation of a fully integrated Rapid DNA Analysis System with Expert System and subsequent formal NDIS approval will allow forensic laboratories to utilize the technology for direct upload of reference samples to NDIS, a milestone in the responsible adoption of Rapid DNA Analysis. This critical first step will enable forensic laboratories to design effective and fundamentally sound Rapid DNA programs throughout their states. The implementation of responsible Rapid DNA programs has the potential to dramatically improve societal safety by revolutionizing the speed and manner in which suspects are identified, enrolled in the CODIS database, and searched against unsolved criminal cases.