

RAPID DNA ANALYSIS IN THE ANDE SYSTEM: FULLY INTEGRATED, FULLY AUTOMATED GENERATION OF STR PROFILES FROM BUCCAL SWABS

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The Rapid DNA Analysis system currently in development at NetBio is a modular platform that will allow customization to provide a wide range of nucleic acid analyses. In this presentation, we summarize our success in generating DNA profiles from buccal swabs without human intervention. Independent modules have been developed for DNA purification, DNA quantitation, highly multiplexed amplification, SNP generation, DNA sequencing, electrophoretic separation and detection, post-reaction cleanup, and related control and analytical software. Based on the DNA purification, multiplexed amplification, separation and detection, and software modules, NetBio is completing development of a fully integrated system for STR analysis from buccal swab samples. The system consists of a fully automated instrument and a single accompanying consumable that can be used by non-technical personnel in laboratory, office, or field-based settings while dramatically reducing the time to perform STR analysis.

NetBio's Field-Deployable Accelerated Nuclear DNA Equipment ("ANDE") is operated by inserting five buccal swab samples into a biochipset, placing the biochipset into the instrument, and pressing the start button. The instrument provides all the subsystems required for the completion of STR analyses, including the power, thermal cycling, pneumatic, optical, ruggedization, process control, and computer subsystems. The instrument interfaces to the biochipset using a number of features, including a pneumatic manifold (to allow fluids to be driven), thermal features (to maintain appropriate temperatures during PCR and electrophoresis), optical paths (to allow excitation and detection of separated STR fragments), and electrical connections (to allow electrophoresis). The instrument and biochipset are based in part on microfluidic technology and have several critical features:

- The biochipset contains all reagents on-board, factory pre-loaded. The user neither loads the instrument nor the biochipset with reagents. Several reagents are lyophilized (e.g. amplification reaction mix) and others are in liquid form (e.g. purification reagents). The biochipset is closed: each buccal sample is processed through its own sealed processing path and samples and reagents do not have any contact with the instrument itself.
- The biochipset is a single part; the operator has nothing to connect. It is a single-use part made of disposable plastic. No washing or opening of the disposable piece is required, eliminating the possibility of run-to-run contamination.
- The instrument is ruggedized to MIL STD 810F for shock and vibration. This allows it to be moved within the laboratory or transported for use outside of the forensic laboratory without the need to recalibrate the system.
- The instrument contains an on-board computer and touch screen monitor for interfacing with the operator. Profiles are available approximately one hour following swab introduction, and the instrument's connectivity (e.g. wireless, USB, Ethernet) can be configured based on user requirements. Also based on user requirements, the system includes a sample tracking database, expert system for conversion of electrophoretic traces to CODIS/NDIS compatible profiles, internal database to store instrument-generated profiles, capability for comparing instrument-generated profiles with profiles provided from external database, and GPS-derived tagging of data products with location and time data.

Data characterizing individual processing modules and the fully-integrated system will be presented.