



B121 GendSite™ Integrated System for Automated STR Analysis

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The goal of this presentation is to describe the features of a fully integrated plastic STR DNA profiling prototype device designed to perform automated DNA extraction, DNA quantification, PCR amplification, capillary electrophoresis, and “expert system” data analysis.

This presentation will impact the forensic community by describing a device that eliminates manual handling of samples for DNA STR analysis. Additional advantages of the GendSite™ system include reduced chance of contamination, low reagent consumption, accelerated DNA extraction and PCR reaction times, excellent detection sensitivity and high-resolution separation.

In 2003, the FBI advertised through a Broad Agency Announcement the requirement for a disposable, single-use device that would be able to perform the complete STR analysis of human DNA following procedures similar to those used in the FBI Laboratory. The DNA had to be obtained from both sperm and epithelial cells (i.e., by differential extraction from mixtures) and the extract needed to be quantified, so the amount of DNA used for the STR analysis would be known. The device had to be capable of using the commercial STR kits with five-color detection. The separation of the PCR products had to be by the capillary electrophoresis method and the raw data had to be converted into alleles of the various STR loci. An expert system was required to make the analysis completely automatic and results had to be in a format compatible with the CODIS-interface. The contract was awarded to the Center for Applied NanoBioscience at Arizona State University (ASU).

The ASU team has developed the GendSite™ system that comprises a fully automated microfluidic system for rapid sample preparation and STR typing of sexual assault samples. This system has been fully developed, prototyped and tested in-house, generating data from mixtures of different ratios of sperm and epithelial cells. The system uses commercially available reagent kits for magnetic bead DNA capture, DNA quantification, and STR-typing. A key feature of the instrument platform is the use of disposable plastic cartridges that can perform the entire work-flow starting with the differential extraction of DNA from sperm and epithelial cells to the transfer to a chip-based 5-color CE-detection. The entire process from sample elution to obtaining the STR-profile takes approximately four hours.

To allow large volume and cost effective fabrication of the disposable STR-typing plastic cartridges, scalable manufacturing processing using injection molding and cold bonding were developed for the full assembly of the microfluidic devices. The feasibility of performing an automated STR-typing process on such integrated all-polymer microfluidic system was demonstrated, establishing the possibility of building a reliable low to medium throughput, sample-to-profile system.

Other instrumental features of the GendSite™ system include the following: (i) differential cell extraction module, (ii) chip-based capillary electrophoresis detection for high resolution separation, (iii) PCR thermal cycler using plastic chips compatible for RT-PCR interface, (iv) computer-controlled power supplies, (v) microfluidic device for sample preparation using microbeads assays, and (vi) STR typing software that includes data acquisition, sizing of alleles for the 13 CODIS-STR loci relative to an internal size standard, quality scoring with identification of problematic data, and compliant interface with CODIS compatible data format and CODIS-interface for upload to the National DNA Index System. The GendSite™ software platform comprise a LabView based customized user-interface, a data analysis module that can interface with most commercially available expert systems, in particular the FSS-i³. This configuration will allow data conversion into the CODIS software to create a Local DNA Index System (LDIS).

The prototype has been tested with model systems and proof-of-concept has been demonstrated. The technology is ready to be transferred for evaluation by forensic laboratories. However, the system has not been tested with casework samples containing typical forensic background materials. A systematic validation study is the next step before the system can be deployed by the forensic community.

STR, Microfluidics, Automation